

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 26, 2018

Findings Date: April 26, 2018

Project Analyst: Tanya S. Rupp

Assistant Chief: Lisa Pittman

Project ID #: M-11448-18

Facility: Fresenius Medical Care of Lillington

FID #: 050131

County: Harnett

Applicant: Fresenius Medical Care of Lillington, LLC

Project: Relocate two dialysis stations from Carolina Dialysis - Sanford to FMC Lillington for a total of 16 dialysis stations at FMC Lillington and 34 stations at Carolina Dialysis-Sanford 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

Fresenius Medical Care of Lillington, LLC (the applicant) is a joint venture between Bio-Medical Applications of North Carolina, Inc. and Carolina Dialysis, LLC. The applicant proposes to relocate two dialysis stations from Carolina Dialysis-Sanford (CDS) in Lee County to Fresenius Medical Care Lillington (FMC Lillington), a dialysis facility in Harnett County, for a total of 16 certified dialysis stations at FMC Lillington and 34 certified dialysis stations at CDS upon project completion.

Need Determination

The 2018 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2018 Semiannual Dialysis Report (SDR), the county need methodology shows

there is no county need determination for Harnett County. An applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology if the facility's utilization rate as reported in the latest SDR is at least 3.2 patients per station per week. However, neither of the two need determination methodologies in the 2018 SMFP apply to this proposal.

Policies

There are two policies in the 2018 SMFP which are applicable to this review: Policy ESRD-2: Relocation of Dialysis Stations and Policy GEN-3, Basic Principles.

Policy ESRD-2, on page 27 of the 2018 SMFP states:

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

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

The applicant addresses *Policy ESRD-2* as follows:

Facility Losing Stations is Serving Residents of the Contiguous County: In Section D, page 20, the applicant provides a table to illustrate the in-center patient census of CDS in Lee County, as shown below:

Carolina Dialysis-Sanford Patient Census as of December 31, 2017

COUNTY	IN-CENTER PTS.	HOME HEMODIALYSIS PTS.	PERITONEAL DIALYSIS PTS.
Lee	98	3	8
Chatham	4	0	1
Cumberland	0	0	5
Harnett	11	1	6
Hoke	1	0	0
Moore	3	0	1
Total	117	4	21

The applicant shows that CDS currently serves Harnett County residents at its Lee County facility.

Proposal Will Not Result in Deficit or Increase in Deficit: In Section B, page 7, the applicant states that Harnett County, the county that will receive stations, currently has a deficit of 11 dialysis stations, per the January 2018 SDR. The relocation of two dialysis stations from CDS in Lee County will reduce that deficit by two stations, resulting in a deficit of nine dialysis stations following project completion. Therefore, the relocation of stations as proposed in this application will not result in a deficit of dialysis stations or an increase in the existing deficit of dialysis stations in Lee County.

Proposal Will Not Result in Surplus or Increase in Surplus: In Section B, page 7, the applicant states Harnett County, the county to which the stations will relocate, currently has a surplus of 12 dialysis stations per the January 2018 SDR. The relocation of two dialysis stations from CDS in Lee County will reduce that surplus by two stations, resulting in a surplus of ten stations following project completion. Therefore, the relocation of stations as proposed in this application will not result in a surplus of dialysis stations or an increase in the existing surplus of dialysis stations in Harnett County.

The application is conforming to Policy ESRD-2.

Policy GEN-3: Basic Principles. Policy GEN-3, on page 33, states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

The applicant addresses *Policy GEN-3* as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), page 8, Section O, pages 56 - 60, and Exhibit O-1. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 9, Section C, page 15, Section L, pages 48 - 51, and Exhibit L-1. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c) and (d), page 10 and Section N, page 54. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (2) Repealed effective January 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 two dialysis stations from Carolina Dialysis-Sanford in Lee County to FMC Lillington in Harnett County for a total of 16 certified dialysis stations at FMC Lillington and 34 certified dialysis stations at CDS upon project completion.

Patient Origin

On page 365, the 2018 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 Harnett County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 16, the applicant provides the historical in-center patient origin for FMC Lillington as of December 31, 2017, summarized in the following table:

**FMC Lillington
Historical Patient Origin 12/31/17**

COUNTY OF RESIDENCE	# IN-CTR PTS
Harnett	47
Total	47

In Section C.1, page 13, the applicant projects patient origin for FMC Lillington for operating year one (OY1), Calendar Year (CY) 2019, and OY 2, CY 2020, following project completion, as follows:

FMC Lillington Projected Patient Origin				
COUNTY	OY 1 (CY 2019)	OY 2 (CY 2020)	COUNTY PATIENTS AS % OF TOTAL	
			OY 1	OY 2
Harnett	56.5	60.7	100.0%	100.0%
Total	56	60	100.0%	100.0%

The applicant provides the assumptions and methodologies used to project in-center patient origin in Section C.1, pages 13 - 14. The applicant adequately identifies the population to be served.

Analysis of Need

In Section B.4, page 8, the applicant states the application is not filed pursuant to the facility need or county need methodology in the 2018 SMFP; rather, it is an application to relocate existing dialysis stations pursuant to Policy EDRD-2. In Section C.1, pages 13 - 14, the applicant provides the following assumptions to project in-center patients:

1. The current patient census at FMC Lillington is 47 in-center patients as of December 31, 2017.
2. Although the Five Year Average Annual Change Rate (AACR) for Harnett County published in the January 2018 Semi-annual Dialysis Report (SDR) is 15.2%, the applicant will use a growth rate of 7.5% to project patient growth. The applicant states the anticipated AACR in the July 2018 SDR will be approximately 10%; therefore, it will use the lower growth rate for a more conservative estimate.
3. The applicant includes letters from two patients currently dialyzing at CDS in Lee County, each of whom is a resident of Harnett County, and each of whom indicates an intent to transfer dialysis care to FMC Lillington following relocation of the stations as proposed in this application.
4. Operating Year (OY) one is calendar year (CY) 2019, and OY two is CY 2020.

Projected Utilization of In-Center Patients

In Section C.1, page 13, the applicant provides the methodology used to project in-center patient utilization, as illustrated in the following table:

Begin with December 31, 2017 facility census	47
Project Harnett County patient population forward 12 months to December 31, 2018, using applicant's growth rate	$47 \times 1.075 = 50.5$
Add two patients dialyzing at CDS who signed letters to transfer care to FMC Lillington. This is the beginning census for the facility	$50.5 + 2 = 52.5$
Project patient population forward one year to December 31, 2019. This is end of OY 1.	$52.5 \times 1.075 = 56.5$
Project patient population forward one year to December 31, 2019. This is end of OY 2.	$56.5 \times 1.075 = 60.7$

On page 13, the applicant projects to serve 56 in-center dialysis patients on 16 stations at the end of OY 1, and 60 in-center dialysis patients on 16 stations at the end of OY 2, which is 3.5 patients per station per week at the end of OY 1, and 3.75 patients per station per week at the end of OY 2.

Therefore, the applicant's projected utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

In summary, the applicant adequately identifies the patient origin and adequately demonstrates the need for two additional dialysis stations at FMC Lillington.

Access

In Section C.3, page 15, the applicant states that Fresenius related facilities have a long history of serving the underserved population in the state and that each facility serves "*low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.*" The applicant further states that it will continue to provide access to low income and medically underinsured persons. In Section L.7, page 52, the applicant states that 84.8% of FMC Lillington's patients were Medicare or Medicaid recipients in CY 2017. In Section L.1, page 48, the applicant projects the same percentage at FMC Lillington in OY 2.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.

- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.

The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

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

C

The applicant proposes to relocate two dialysis stations from CDS to FMC Lillington, for a total of 16 certified dialysis stations at FMC Lillington and 34 certified dialysis stations at CDS upon project completion.

In Section D.1, pages 20 - 21, the applicant explains why it believes the needs of the population presently utilizing the dialysis services at CDS will be adequately met following completion of the project. The applicant states that, as of December 31, 2017, there were 117 in-center patients dialyzing on 36 stations, which is 3.25 patients per station per week [$117 / 36 = 3.25$]. See the following table from page 20:

CAROLINA DIALYSIS SANFORD – PATIENT RESIDENCE COUNTIES	PATIENT CENSUS AS OF DECEMBER 31, 2017		
	IN-CENTER	HOME HD	PERITONEAL DIALYSIS
Lee	98	3	8
Chatham	4	0	1
Cumberland	0	0	5
Harnett	11	1	6
Hoke	1	0	0
Moore	3	0	1
Total	117	4	21

On page 20, the applicant provides a table to show projected utilization of the remaining stations at CDS:

Begin with Lee County patient census as of December 31, 2017	98
Project census forward 12 months to December 31, 2018, using the Five Year AACR for Lee County in the January 2018 SDR	$98 \times 1.013 = 99.3$
Add 19 in-center patients from other counties	$99.3 + 19 = 118.3$
Projected Census for December 31, 2018	118

Thus, on December 31, 2018, the applicant projects that CDS will dialyze 118 patients on 34 in-center stations, which is a utilization rate of 3.5 patients per station per week.

Projected utilization is reasonable and adequately supported.

In Section D.2, page 21, the applicant states the proposed relocation of stations will not have any effect on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed dialysis care at CDS.

Conclusion

The Agency reviewed the:

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

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

- The needs of the population currently using the dialysis services at CDS will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

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

CA

In Section E.1, pages 22 - 23, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo
- Relocate stations from FMC Angier
- Relocate stations from BMA Dunn
- Relocate stations from other facilities in contiguous counties

On page 23, the applicant states that its proposal is the most effective alternative because relocating stations from Lee County will reduce the surplus of dialysis station in that county and will reduce the deficit of dialysis stations in Harnett County. In addition, the selected proposal will allow for the relocation of stations without any capital cost, since the space for the stations already exists at FMC Lillington.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Fresenius Medical Care of Lillington, LLC shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Policy ESRD-2, Fresenius Medical Care of Lillington shall relocate two dialysis stations from Carolina Dialysis Sanford to FMC Lillington for a total of no more than 16 stations at FMC Lillington upon project completion.**
 - 3. Fresenius Medical Care of Lillington, LLC shall install plumbing and electrical wiring through the walls for no more than two dialysis stations which shall include any isolation stations.**
 - 4. Upon completion of this project, Fresenius Medical Care of Lillington, LLC shall take the necessary steps to decertify two dialysis stations at Carolina Dialysis Sanford for a total of no more than 34 dialysis stations at Carolina Dialysis Sanford upon project completion.**
 - 5. Fresenius Medical Care of Lillington, LLC 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 the 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

Fresenius Medical Care of Lillington, LLC proposes to relocate two dialysis stations from CDS in Lee County to FMC Lillington in Harnett County, for a total of 16 certified dialysis stations at FMC Lillington and 34 certified dialysis stations at CDS upon project completion.

Capital and Working Capital Costs

In Section F.1, page 24, the applicant states that there will be no capital cost for the project. In Sections F.10 - F.12, pages 26 - 27, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project since FMC Lillington is an existing facility.

Financial Feasibility

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

	OY 1 (CY 2019)	OY 2 (CY 2020)
Total In-Center Treatments	8,002	8,595
Total Gross Revenues (Charges)	\$31,911,976	\$34,276,860
Deductions from Gross Revenues	\$28,793,603	\$30,927,396
Total Net Revenue	\$3,118,373	\$3,349,464
Average Net Revenue per Treatment	\$389.69	\$389.69
Total Operating Expenses (Costs)	\$2,090,140	\$2,192,515
Average Operating Expense per Treatment	\$261.22	\$255.09
Net Income	\$1,028,233	\$1,156,949

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

Fresenius Medical Care of Lillington, LLC proposes to relocate two dialysis stations from CDS to FMC Lillington, for a total of 16 certified dialysis stations at FMC Lillington and 34 certified dialysis stations at CDS upon project completion.

On page 365, the 2018 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 Harnett County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, there are four dialysis facilities in Harnett County, all of which are operated by the applicant or a related entity. Information on all of these dialysis facilities, from Table B of the January 2018 SDR, is provided below:

**Harnett County Dialysis Facilities
 Certified Stations and Utilization as of June 30, 2017**

DIALYSIS FACILITY	LOCATION	# OF CERTIFIED STATIONS	# PATIENTS	UTILIZATION
Dunn Kidney Center	Dunn	35	96	68.57%
FMC Anderson Creek	Cameron	11	39	88.64%
FMC Angier	Angier	10	29	72.50%
FMC Lillington	Lillington	17	44	64.71%

Source: January 2018 SDR, Table B.

According to Table D in the January 2018 SDR, there is a surplus of 12 dialysis stations in Lee County, and a deficit of 11 dialysis stations in Harnett County. The applicant proposes to relocate two dialysis stations from Lee County to Harnett County, which will decrease the surplus in Lee County and also decrease the deficit in Harnett County. The applicant does not propose to establish a new facility. In Section G, page 32, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Harnett County. The applicant states:

“...there are four End Stage Renal Disease Treatment facilities within Harnett County. The January 2018 SDR reports that Harnett County has an 11 station deficit. The relocation of two stations to FMC Lillington will reduce the deficit to nine

stations. To the extent that there is a deficit of stations in the county, then there is not a duplication of dialysis stations within the service area.”

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

- The proposal decreases the surplus of dialysis stations in Lee County and decreases the deficit of dialysis stations in Harnett County.
- The applicant adequately demonstrates that the proposed relocation of dialysis stations is needed at FMC Lillington.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

In Section H.1, page 33, the applicant provides the current staffing for the facility, and states the staffing is not projected to change as a result of this proposal. The applicant states the facility currently staffs 12.05 full time equivalent (FTE) positions. In addition, the applicant provides projected direct care staff in OY 2 in Section H.7, page 35.

The assumptions and methodology used to project staffing are provided in Section H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H, page 34, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 37, the applicant identifies the current medical director. In Exhibit i-5, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the facility.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

In Section I.1, page 36, the applicant includes a list of providers of the necessary ancillary and support services.

FMC LILLINGTON ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
In-center dialysis/maintenance	FMC Lillington
Self-care training (in-center)	Refer to BMA Dunn
Home training	
HH	--
PD	Refer to BMA Dunn
Accessible follow-up program	--
Psychological counseling	Harnett County Mental Health
Isolation – hepatitis	FMC Lillington
Nutritional counseling	FMC Lillington
Social Work services	FMC Lillington
Acute dialysis in an acute care setting	WakeMed Central Carolina
Emergency care	FMC Lillington/911/hospital
Blood bank services	Central Harnett Hospital
Diagnostic and evaluation services	Central Harnett Hospital
X-ray services	Central Harnett Hospital
Laboratory services	Spectra Labs
Pediatric nephrology	UNC
Vascular surgery	Raleigh Access Center, Triangle Vascular Association, Pinehurst Surgical, Sandhills Surgical, Rex Vascular Specialists
Transplantation services	Duke UMC, UNC Hospitals
Vocational rehabilitation & counseling	Vocational Rehabilitation of Harnett County
Transportation	Harnett County Transportation Services

In Section I.2, page 37, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1, I-

2, I-3 and I-4. In addition, on page 38, the applicant provides a list of nephrologists who have agreed to provide medical coverage at the facility and who have expressed support for the project.

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

Conclusion

The Agency reviewed the application and supporting exhibits. Based on that review, the Agency concludes that the application is conforming to this criterion.

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

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

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective January 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

The applicant does not propose to construct any new space nor renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

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

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.7, page 52, the applicant provides the historical payor mix during CY 2017 at FMC Lillington, as shown in the table below.

PAYOR CATEGORY	% OF TOTAL
Self Pay/Indigent/Charity	0.43%
Medicare	71.32%
Medicaid	8.23%
Commercial Insurance	7.34%
Medicare/Commercial	5.25%
Miscellaneous (Incl. VA)	7.44%
Total	100.00%

Numbers 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
Harnett	12%	51%	38%	18%	10%	13%
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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 50, the applicant states:

"Fresenius related facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The

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

facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status.”

In Section L, page 51, the applicant states that during the last five years no patient civil rights access complaints have been filed against any Fresenius related facilities located in North Carolina.

The Agency reviewed the application and supporting exhibits. Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section L, page 48, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

PAYOR CATEGORY	% OF TOTAL
Self Pay/Indigent/Charity	0.43%
Medicare	71.32%
Medicaid	8.23%
Commercial Insurance	7.34%
Medicare/Commercial	5.25%
Miscellaneous (Incl. VA)	7.44%
Total	100.00%

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.43% of total services will be provided to self-pay/charity patients, 76.57% to Medicare patients and 8.23% to Medicaid patients.

On pages 48 - 49, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reason:

- the applicant states the projected payor mix is based on the historical experience of FMC Lillington's recent patient census.

The Agency reviewed the application and supporting exhibits. Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section L, page 50, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the application and supporting exhibits. Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section M, page 53, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

The Agency reviewed the application and supporting exhibits. Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective January 1, 1987.
- (16) Repealed effective January 1, 1987.
- (17) Repealed effective January 1, 1987.
- (18) Repealed effective January 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

Fresenius Medical Care of Lillington, LLC proposes to relocate two dialysis stations from Carolina Dialysis-Sanford in Lee County to FMC Lillington in Harnett County for a total of 16 certified dialysis stations at FMC Lillington and 34 certified dialysis stations at CDS upon project completion.

On page 365, the 2018 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 Harnett County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, there are four dialysis facilities in Harnett County, all of which are operated by the applicant or a related entity. Information on all of these dialysis facilities, from Table B of the January 2018 SDR, is provided below:

**Harnett County Dialysis Facilities
Certified Stations and Utilization as of June 30, 2017**

DIALYSIS FACILITY	LOCATION	# OF CERTIFIED STATIONS	# PATIENTS	UTILIZATION
Dunn Kidney Center	Dunn	35	96	68.57%
FMC Anderson Creek	Cameron	11	39	88.64%
FMC Angier	Angier	10	29	72.50%
FMC Lillington	Lillington	17	44	64.71%

Source: January 2018 SDR, Table B.

In Section N, page 54, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 54, the applicant states it anticipates the proposal will have no effect on competition in the service area, since Fresenius is the only provider of dialysis services in Harnett County.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

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

Conclusion

The Agency reviewed the application and supporting exhibits. Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

In Section O.3, page 59, the applicant states there are more than 100 Fresenius related dialysis facilities located in North Carolina.

In Section O.3, pages 59 - 60, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities. On page 60, the applicant states that all of the problems have been corrected and the facility is back in full compliance with CMS Guidelines. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in one of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all Fresenius facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- The applicant is proposing to relocate existing dialysis stations to an existing facility, FMC Lillington. Therefore, this performance standard is not applicable to this review.
- .2203(b) An applicant proposing to increase the number of dialysis stations in an existing End*

Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section C.1, page 13, the applicant projects to serve 56 in-center patients on 16 in-center stations by the end of OY1, which is 3.50 patients per station per week [$56 / 16 = 3.50$]. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 13 - 14, 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.