ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: May 27, 2016
Findings Date: May 27, 2016

Project Analyst: Tanya S. Rupp
Team Leader: Lisa Pittman

Project ID #: M-11135-16
Facility: Dunn Kidney Center
FID #: 944644
County: Harnett
Applicant(s): Bio-Medical Applications of North Carolina, Inc. d/b/a Dunn Kidney Center
Project: Add four dialysis stations to existing facility for a total of 35 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NC

The applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a Dunn Kidney Center proposes to add four dialysis stations to the existing facility for a total of 35 certified dialysis stations upon completion of the project.

Need Determination

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for Harnett County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the

utilization rate reported for Dunn Kidney Center in the January 2016 SDR is 3.5 patients per station. This utilization rate was calculated based on 108 in-center dialysis patients and 31 certified dialysis stations as of June 30, 2015 (108 patients / 31 stations = 3.48 patients per station). Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/15		87.10%
Certified Stations		31
Pending Stations		0
Total Existing and Pending Stations		**31**
In-Center Patients as of 6/30/15 (SDR2)		108
In-Center Patients as of 12/31/14 (SDR1)		98
Step	**Description**	**Result**
(i)	Difference (SDR2 - SDR1)	10
	Multiply the difference by 2 for the projected net in-center change	20
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/14	0.2041
(ii)	Divide the result of step (i) by 12	0.0170
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/15 until 12/31/15)	0.1020
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	119.0204
(v)	Divide the result of step (iv) by 3.2 patients per station	37.1939
	and subtract the number of certified and pending stations to determine the number of stations needed	**6**

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is six stations. Step (C) of the facility need methodology states *"The facility may apply to expand to meet the need established …, up to a maximum of ten stations."* The applicant proposes to add four new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2016 SMFP which is applicable to this review: Policy GEN-3: Basic Principles. Policy GEN-3 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), pages 11 - 12, Section O, pages 59 - 65, and referenced exhibits. 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 13, Section L, pages 51 - 55, and referenced exhibits. 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), pages 13 - 14, and Section N, page 57. However, the applicant does not adequately demonstrate that the proposed project is the least costly or most effective alternative or that the project will not result in the unnecessary duplication of existing health service capabilities or facilities. See Criteria (4) and (6), which are incorporated herein by reference. Based on these facts, the applicant does not adequately demonstrate that the proposal will maximize healthcare value.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the January 2016 SDR. However, the applicant does not adequately demonstrate that the proposal will incorporate the basic principles of GEN-3. Therefore, the application is not 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 add four dialysis stations for a total of 35 certified dialysis stations upon completion of the project.

Population to be Served

On page 369, the 2016 SMFP defines the service area for dialysis stations 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 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 23, the applicant provides the historical in-center and home dialysis patient origin for Dunn Kidney Center as of December 31, 2015, as illustrated in the following table:

Historical Patient Origin Dunn Kidney Center as of December 31, 2015

COUNTY OF RESIDENCE	# IN-CENTER PATIENTS	% OF TOTAL	# HH PATIENTS	% OF TOTAL	# PD PATIENTS	% OF TOTAL
Harnett	75	75.0%	6	54.5%	0	-
Cumberland	7	7.0%	1	9.0%	0	-
Johnston	4	4.0%	2	18.2%	0	-
Sampson	14	14.0%	2	18.2%	1	100.0%
Total	**100**	**100.0%**	**11**	**100.0%**	**1**	**100.0%**

Numbers may not foot due to rounding

In Section C.1, page 17, the applicant provides the projected patient origin for Dunn Kidney Center for the first two years of operation following completion of the project as follows:

COUNTY	OPERATING YEAR 1 (CY 2018)			OPERATING YEAR 2 (CY 2019)			COUNTY PATIENTS AS % OF TOTAL	
	IN-CTR.	HH	PD	IN-CTR.	HH	PD	OY 1	OY 2
Harnett	83.7	6.9	3.2	87.0	7.3	4.3	72.9%	73.0%
Cumberland	8.1	1.0	0.0	9.0	1.0	0.0	7.1%	7.1%
Johnston	4.6	2.0	0.0	5.0	2.0	0.0	5.2%	5.1%
Sampson	16.2	2.0	1.0	17.0	2.0	1.0	14.9%	14.8%
Total	**112.6**	**11.9**	**4.2**	**118.0**	**12.3**	**5.3**	**100.0%**	**100.0%**

The applicant provides the assumptions and methodology used to project patient origin on pages 17 - 20. The applicant adequately identifies the population to be served.

Analysis of Need

In Section B.2, page 9, the applicant states the application is filed pursuant to the facility need methodology in the 2016 SMFP utilizing data from the January 2016 SDR. The applicant proposes to add four dialysis stations to Dunn Kidney Center for a total of 35 stations upon project completion. The applicant used the following assumptions, from Section C.1, pages 17 - 20:

In-Center Assumptions

- The applicant states the Dunn Kidney Center census has *"been increasing at a rate greater than the Harnett County Five Year Average Annual Change Rate, which is only 1.4%."* The applicant chose a 5% growth rate for the patient census, which is lower than the facility's most recent six-month growth rate [10.2% from December 2014 to June 2015).
- The applicant projects one in-center patient each year will transfer his or her care to home hemo-dialysis, and assumes that patient will be a Harnett County resident.
- The applicant projects project completion by December 31, 2017; therefore Operating Year One will be calendar year 2018 and Operating Year 2 will be calendar year 2019.

Projected In-Center Utilization

The applicant's methodology for in-center utilization is illustrated in the following table:

The applicant begins with the facility census as of 12/31/15	100
Project the census forward one year to 12/31/16 using the applicant's 5% growth rate	100 x 1.05 = 105
Subtract one patient projected to change to home hemodialysis	105 – 1 = 104
The applicant projects this census forward one year to 12/31/17 using 5% growth rate	104 x 1.05 = 109.2
Subtract one patient projected to change to home hemodialysis	109.2 – 1 = 108.2
The applicant projects this census forward one year to 12/31/18 using 5% growth rate	108.2 x 1.05 = 113.6
Subtract one patient projected to change to home hemodialysis (this is operating year 1)	113.6 – 1 = 112.6
The applicant projects this census forward one year to 12/31/19 using 5% growth rate	112.6 x 1.05 = 118.2
Subtract one patient projected to change to home hemodialysis (this is operating year 2)	118.2 – 1 = 117.2

The applicant projects to serve 113 in-center patients on 35 stations or 3.2 patients per station per week (113 / 35 = 3.2) by the end of Operating Year 1 and 117 in-center patients or 3.3 patients per station per week (117 / 35 = 3.3) by the end of Operating Year 2 for the proposed 35-station facility. This 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).

The January 2016 SDR reports a 1.4% Five Year Average Annual Change Rate (AACR) for Harnett County; however, in its assumptions, the applicant states the Dunn Kidney Center patient census has actually been increasing at a rate greater than the Harnett County AACR. Based on data reported in the SDR, during the period from December 31, 2014 to June 30, 2015, the in-center patient census at Dunn Kidney Center increased from 98 to 108 patients, which is a semi-annual growth rate of 10 percent. Based on the most recent SDRs, the facility's growth rate was 18.9% from June 30, 2014 to June 30, 2015. See the following table illustrating the facility's growth, based on the most recent SDRs:

Dunn Kidney Center Utilization

SDR	# STATIONS	# PATIENTS	GROWTH RATE	ANNUAL GROWTH RATE 1/1/15 – 1/1/16
January 2015	31	91	--	
July 2015	31	98	7.7%	
January 2016	31	108	10.2%	18.9%

In this application, the applicant assumes a projected annual growth rate of 5 percent for the in-center patient and home patient census at Dunn Kidney Center, which is higher than the Harnett County Five Year AACR of 1.4 percent but lower than the applicant's recent historical experience. Therefore, projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Home Dialysis Assumptions

- The applicant states on page 19 that Dunn Kidney Center had 11 peritoneal dialysis (PD) patients and one home hemodialysis (HH) patient as of December 31, 2015.
- The applicant will use the same 5% growth rate to project future HH patients at the facility.
- The applicant will add one HH patient each year, as reflected in the in-center growth projections.

Projected Home Hemodialysis Utilization

The applicant's methodology for HH patients is illustrated in the following table, again assuming Operating Year 1 is CY 2018 and Operating Year 2 is CY 2019:

The applicant begins with the facility HH census as of 12/31/15	1
Project the census forward one year to 12/31/16 using the applicant's 5% growth rate, and adds one patient projected to change dialysis modality	(1 x 1.05) + 1 = 2.1
Project the census forward one year to 12/31/17 using the applicant's 5% growth rate, and adds one patient projected to change dialysis modality	(2.1 x 1.05) + 1= 3.2
Project the census forward one year to 12/31/18 using the applicant's 5% growth rate, and adds one patient projected to change dialysis modality (OY 1)	(3.2 x 1.05) + 1 = 4.3
Project the census forward one year to 12/31/19 using the applicant's 5% growth rate, and adds one patient projected to change dialysis modality (OY 2)	(4.3 x 1.05) + 1 = 5.5

Projected Home Peritoneal Dialysis Utilization

The applicant's methodology for PD patients is illustrated in the following table. The applicant's calculations are not accurate; the accurate calculations are shown in brackets:

The applicant begins with the facility PD census as of 12/31/15	11
Project the census forward one year to 12/31/16 using the applicant's 5% growth rate, and adds one patient projected to change dialysis modality	(1 x .05) + 1 = 11.6 [11 x 1.05 = 11.6]
Project the census forward one year to 12/31/17 using the applicant's 5% growth rate, and adds one patient projected to change dialysis modality	(11.6 x .05) + 11.6 = 13.1 [11.6 x 1.05 = 12.2]
Project the census forward one year to 12/31/18 using the applicant's 5% growth rate, and adds one patient projected to change dialysis modality (OY 1)	(13.1 x .05) + 13.1 = 13.8 [12.2 x 1.05 = 12.8]
Project the census forward one year to 12/31/19 using the applicant's 5% growth rate, and adds one patient projected to change dialysis modality (OY 2)	(13.8 x .05) + 13.8 = 14.5 [12.6 x 1.05 = 13.4]

Since there are no minimum performance standards for either type of home dialysis, the applicant's projections of HH and PD patients to be served at Dunn Kidney Center following completion of the proposed project are reasonable.

Access

In Section L.1(a), pages 51 - 52, the applicant states that each of BMA's 104 facilities in 42 North Carolina Counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. On page 52, the applicant projects 84.7% of its in-center patients will be Medicare or Medicaid recipients. 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 the population has for four additional in-center stations at Dunn Kidney Center, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. 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.

NA

(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.

NC

In Section E.1, page 26, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative due to the lack of capacity at the facility to meet the need of patients choosing to dialyze at the Dunn Kidney Center facility.
- Apply for Fewer Stations – The applicant states it rejected this alternative because fewer stations would not effectively meet the projected utilization for Dunn Kidney Center.
- Apply for More than Four Stations – The applicant states it did not apply for more than four stations because the physical plant will not accommodate more than four additional stations.

The applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

However, the applicant failed to consider relocating stations from one of its other Harnett County facilities as an alternative to this proposal. Currently, the applicant operates all four dialysis facilities in Harnett County. The most recent utilization of those facilities is shown in the following table:

Harnett County Dialysis Facilities' Utilization as of June 30, 2015

FACILITY	# STATIONS	# PATIENTS	% UTILIZATION
Dunn Kidney Center	31	108	87.10%
FMC Anderson Creek	11	25	56.82%
FMC Angier	10	28	70.00%
Fresenius Medical Care of Lillington	17	34	50.00%
Harnett County Totals	**69**	**195**	**70.65%**

*Source: January 2016 SDR

Neither FMC Angier nor FMC Anderson Creek have a sufficient number of stations to relocate any stations. However, FMC Lillington has 17 in-center stations, with current utilization of 50% [34 / 17 = 2.0; 2.0 / 4 = 0.50]. In fact, the utilization of the 17 existing stations at FMC Lillington decreased from 64.71% in June 30, 2014 (January 2015 SDR). The applicant could relocate four stations from FMC Lillington, leaving that facility with 13 in-center stations and room for additional patient growth. The applicant does not provide sufficient information to adequately document that the chosen alternative is the least costly or most effective alternative to meet the need for four additional stations at Dunn Kidney Center.

Furthermore, the application is not conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (6) and (18a), which are incorporated herein by reference. An application that cannot be approved is not an effective alternative.

In summary, the applicant did not adequately demonstrate that the proposal is the least costly or most effective alternative to meet the identified need. Consequently, the application is not conforming to this criterion.

(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

In Section F.1, page 28, the applicant states that it projects $17,800 in capital costs to develop this project. In Sections F.10 - F.12, pages 31 - 32, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project, since the facility is currently operational.

Availability of Funds

In Section F.2, page 29, the applicant states it will finance the capital costs with accumulated reserves. Exhibit F-1 contains a letter dated March 15, 2016 from the Senior Vice President & Treasurer for Fresenius Medical Care Holdings, Inc. (FMCH), the parent company for the applicant, which states the applicant has adequate funds for the proposed project. Exhibit F-2 contains the Consolidated Financial Statements for FMCH which indicates that it had $195,280,000 in cash and cash equivalents as of December 31, 2014, and total assets of $18 billion. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

In Section R, the applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statement (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.

	CY2018	CY2019
Total Net Revenue	$8,317,019	$8,868,928
Total Operating Expenses	$6,187,977	$6,528,777
Net Income	$2,129,042	$2,340,151

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section 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 that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

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

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

NC

The applicant proposes to add four dialysis station to the existing Dunn Kidney Center facility for a total of 35 stations upon project completion.

On page 369, the 2016 SMFP defines the service area for dialysis stations 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 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.

The applicant is eligible to apply for additional stations in Dunn Kidney Center based on application of the facility need methodology, because the utilization rate reported in the January 2016 SDR was 87%, or 3.48 patients per station.

According to Table A in the January 2016 SDR, there are four existing dialysis facilities in Harnett County, all of which are operated by the applicant. The most recent utilization of those facilities is shown in the following table:

BMA Harnett County Dialysis Facilities' Utilization as of June 30, 2015

FACILITY	# STATIONS	# PATIENTS	% UTILIZATION
Dunn Kidney Center	31	108	87.10%
FMC Anderson Creek	11	25	56.82%
FMC Angier	10	28	70.00%
Fresenius Medical Care of Lillington	17	34	50.00%
Harnett County Totals	**69**	**195**	**70.65%**

*Source: January 2016 SDR

FMC Anderson Creek opened in 2015 and has 11 stations. FMC Angier has ten stations, which is the minimum number of stations for a dialysis facility. FMC Lillington has 17 in-center stations, with current utilization of 50% [34 / 17 = 2.0; 2.0 / 4 = 0.50]. In fact, the utilization of the 17 existing stations at FMC Lillington decreased from 64.71% in June 30, 2014 (January 2015 SDR).

The applicant could relocate four stations from FMC Lillington, leaving that facility with 13 in-center stations and room for additional patient growth.

The applicant does not discuss why it choose not to relocate four of the existing certified stations from FMC Lillington to address the facility at Dunn Kidney Center. The January 2016 SDR reports a surplus of two dialysis stations in Harnett County, and a Five Year AACR of 1.4%. Approval of the application's proposal would increase the surplus of dialysis stations in Harnett County to six. Relocating four stations from FMC Lillington would eliminate the surplus. The applicant does not adequately demonstrate that the proposal would not result in the unnecessary duplication of existing or approved certified dialysis stations in Harnett County. Consequently, the application is not conforming to this criterion.

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

C

In Section H.1, page 39, the applicant provides the current staffing for the facility, which includes 22.95 full-time equivalent (FTE) employees, and the proposed staffing for the facility following completion of the project, which adds two FTEs, for a total of 24.95 FTEs after the addition of the four stations. In Section H.3, page 40, the applicant describes its experience and process for recruiting and retaining staff, and states that it does not anticipate difficulties in hiring the required staff for this project. Exhibit I-6 contains a copy of a letter from Samsher Sonawane, M.D., confirming his commitment to continue to serve as the Medical Director for the facility. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section I.1, page 42, the applicant includes a list of providers of the necessary ancillary and support services, which includes but is not limited to Betsy Johnson Hospital, Spectra Labs, and UNC Hospital. Exhibit I-6 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant adequately demonstrates that the necessary ancillary and support services will continue to be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

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

NA

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

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

C

In Section L, page 55, the applicant reports that 84.7% of the in-center patients who received treatments at Dunn Kidney Center had some or all of their services paid for by Medicare or Medicaid in the past year. The tables below shows the historical (CY2015) payment sources for each dialysis modality:

Dunn Kidney Center Historical Payor Mix CY 2015

PAYMENT SOURCE	IN-CENTER	PD	HH
Private Pay	4.9%	--	--
Commercial Insurance	8.8%	27.47%	--
Medicare	73.0%	61.49%	100.0%
Medicaid	6.1%	2.44%	--
VA	1.7%	--	--
Medicare/Commercial Insurance	5.6%	8.61%	--
Total	**100.0%**	**100.0%**	**100.0%**

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

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

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).[1]

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

[1] *See* http://www.esrdnetweork6.org/utils/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf.

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

C

In Section L.3(e), page 53, the applicant states:

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

In Section L.6, page 54, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section L.1(b), page 52, the applicant projects that 84.7% of the in-center patients who will receive treatments at Dunn Kidney Center in the second operating year (FY 2019) will have some or all of their services paid for by Medicare or Medicaid. The applicant states this projection is based on treatment volumes at that facility. The table below shows the projected OY 2 payment source for each dialysis modality:

Dunn Kidney Center Projected Payor Mix CY 2019

PAYMENT SOURCE	IN-CENTER	PD	HH
Private Pay	4.9%	--	--
Commercial Insurance	8.8%	27.5%	--
Medicare	73.0%	61.5%	100.0%
Medicaid	6.1%	2.4%	--
VA	1.7%	--	--
Medicare/Commercial Insurance	5.6%	8.6%	--
Total	**100.0%**	**100.0%**	**100.0%**

The applicant's projected payment sources are consistent with the applicant's historical payment sources as reported in Section L.7, page 55. The applicant demonstrates that medically underserved groups will continue to have adequate access to the dialysis services proposed at Dunn Kidney Center. 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 54, the applicant describes the range of means by which a person will have access to the dialysis services at Dunn Kidney Center, including referrals from nephrologists, other physicians, or hospital emergency rooms. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section M.1, page 56, the applicant states that it has communicated with local student nursing programs to offer the facility as a clinical training site for nursing students. Exhibit M-1 contains a copy of correspondence to Wake Tech Community College documenting the offer of the facility as clinical training site. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

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

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

NC

The applicant proposes to add four dialysis station to the existing Dunn Kidney Center facility for a total of 35 stations upon project completion.

On page 369, the 2016 SMFP defines the service area for dialysis stations 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 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.

The applicant is eligible to apply for additional stations in Dunn Kidney Center based on application of the facility need methodology, because the utilization rate reported in the January 2016 SDR was 87%, or 3.48 patients per station.
In Section N, page 57, the applicant states this proposal will have no effect on the competition in Harnett County. See also Sections C, F, G, H, L and P where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

According to Table A in the January 2016 SDR, there are four existing dialysis facilities in Harnett County, all of which are operated by the applicant. The most recent utilization of those facilities is shown in the following table:

BMA Harnett County Dialysis Facilities' Utilization as of June 30, 2015

FACILITY	# STATIONS	# PATIENTS	% UTILIZATION
Dunn Kidney Center	31	108	87.10%
FMC Anderson Creek	11	25	56.82%
FMC Angier	10	28	70.00%
Fresenius Medical Care of Lillington	17	34	50.00%
Harnett County Totals	**69**	**195**	**70.65%**

*Source: January 2016 SDR

Neither FMC Anderson Creek nor FMC Angier have a sufficient number of stations to relocate any stations. FMC Lillington has 17 in-center stations, with current utilization of 50% [34 / 17 = 2.0; 2.0 / 4 = 0.50]. In fact, the utilization of the 17 existing stations at FMC Lillington decreased from 64.71% in June 30, 2014 (January 2015 SDR). Therefore, the applicant could relocate four stations from FMC Lillington, leaving that facility with 13 in-center stations and room for additional patient growth.

The applicant does not discuss why it choose not to relocate four of the existing certified stations from FMC Lillington to address the facility need at Dunn Kidney Center. The January 2016 SDR reports a surplus of two dialysis stations in Harnett County, and a Five Year AACR of 1.4%. Approval of the application's proposal would increase the surplus of dialysis stations in Harnett County to six. Relocating four stations from FMC Lillington would eliminate the surplus.

The applicant did not adequately demonstrate that the proposed project is the least costly or most effective alternative to meet the identified need. The discussion regarding alternatives found in Criterion (4) is incorporated herein by reference. Moreover, the applicant did not adequately demonstrate that the proposal to develop four new certified dialysis stations in Harnett County would not result in an unnecessary duplication. The discussion regarding duplication found in Criterion (6) is incorporated herein by reference. Therefore, the application is not 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.

In Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. In Section O.3, pages 63 - 65, the applicant identifies two of its North Carolina facilities, BMA Lumberton and BMA East Charlotte, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. On page 65, the applicant states both facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

The application is conforming to 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-

(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- The applicant proposes to increase the number of in-center stations at Dunn Kidney Center pursuant to the facility need methodology. In Section P.1, page 66

and Section C.1, pages 17 – 19, the applicant projects the facility will dialyze 112 in-center patients on 35 stations in the first operating year, which is 3.2 patients per station.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section C.1, pages 17 – 19.