

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 9, 2018

Findings Date: February 9, 2018

Project Analyst: Bernetta Thorne-Williams

Assistant Chief: Lisa Pittman

Project ID #: J-11402-17

Facility: Zebulon Kidney Center

FID #: 970505

County: Wake

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

Project: Add 2 dialysis stations for a total of 30 dialysis stations upon completion of this project

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Department 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 Zebulon Kidney Center, whose parent company is Fresenius Medical Care Holdings, Inc., proposes to add 2 dialysis stations to the existing facility for a total of 30 certified dialysis stations following project completion.

Need Determination

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the

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July 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 12 dialysis stations in Wake County. This surplus is projected to be reduced by four stations as BMA was approved in Project I.D. # J-11372-17 to relocate four dialysis stations from FMC New Hope, located in Wake County, to Fresenius Kidney Care Selma (FMC Selma) to help develop a new ten station facility in Johnston County. Therefore, Wake County would still have a surplus of eight dialysis stations. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. 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 Zebulon Kidney Center in the July 2017 SDR is 3.7500 patients per station per week, or 93.75% ($3.7500 / 4$ patients per station = 0.9375). This utilization rate was calculated based on 105 in-center dialysis patients and 28 certified dialysis stations (105 patients / 28 stations = 3.75 patients per station per week).

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table:

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/16		93.8%
Certified Stations		28
Pending Stations		0
Total Existing and Pending Stations		28
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR2)		105
In-Center Patients as of 6/30/16 (Jan 2017 SDR) (SDR1)		98
Step	Description	Result
	Difference (SDR2 - SDR1)	7
(i)	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.1429
(ii)	Divide the result of Step (i) by 12	0.0119
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.1429
(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	120.0000
(v)	Divide the result of Step (iv) by 3.2 patients per station	37.5000
	and subtract the number of certified and pending stations to determine the number of stations needed	9.5000

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is ten stations (rounded up). 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 two new stations, therefore, the applicant is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2017 SMFP which is applicable to this review. *POLICY GEN-3: BASIC PRINCIPLES* on page 33 of the 2017 SMFP is applicable to this review because the facility need methodology is applicable to this review. 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.”

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4, page 8, and Section O, page 55. 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, page 9, Section C, page 15, Section L, pages 47-48, 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, page 10, Section N, page 53, and referenced exhibits. The information provided

by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported because:

- The applicant relies on existing policies, historical data, and verifiable sources to provide future projections and demonstrate conformity with Policy GEN-3.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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 add 2 dialysis stations to the existing facility for a total of 30 certified dialysis stations at Zebulon Kidney Center following project completion.

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94*

remaining counties is a separate dialysis station planning area.” Thus, the service area is Wake County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 17, the applicant provides a table showing the historical patient origin for in-center (IC) patients served by Zebulon Kidney Center, as shown below:

Zebulon Kidney Center Dialysis Patients as of 6/30/2017	
COUNTY	IC PATIENTS
Wake	60
Edgecombe	1
Franklin	12
Johnson	17
Nash	8
Wilson	9
Total	99

In Section C.1, page 13, the applicant provides the projected patient origin for Zebulon Kidney Center for the first two years of operation following project completion, as follows:

	ZEBULON KIDNEY CENTER			
	OPERATING YEAR 1 CY2019	OPERATING YEAR 2 CY2020	COUNTY PATIENTS AS A PERCENT OF TOTAL IN-CENTER	
	IN-CENTER	IN-CENTER	YEAR 1	YEAR 2
Wake	68.8	72.6	63.8%	65.1%
Edgecombe	1.0	1.0	0.9%	0.9%
Franklin	12.0	12.0	11.1%	10.7%
Johnston	17.0	17.0	15.8%	15.2%
Nash	8.0	8.0	7.4%	7.2%
Wilson	1.0	1.0	0.9%	0.9%
TOTAL	108.0	112.0	100.0%	100.0%

The applicant provides the assumptions and methodology for the projections above on pages 13-14. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

The applicant proposes to add two dialysis stations to the existing Zebulon Kidney Center for a total of 30 certified dialysis upon project completion. In Section B.2, page 6, the applicant states the application is filed pursuant to the facility need methodology in the 2017 SMFP utilizing data from the July 2017 SDR. In Section C.1, pages 13-14, the applicant provides the

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assumptions used to demonstrate the need for the project. The facility's patients who reside in Wake County are projected to increase at a rate commensurate with the Five-Year Average Annual Change Rate for Wake County, which is 5.6%. The applicant does not project growth of its patients residing in other counties; those existing patients were added to the projected Wake County patients at appropriate points in the methodology.

Operating Year 1 (OY1) = Calendar Year (CY) 2019
OY2 = CY2020

Projected Utilization

In Section C, page 14, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

Begin with Wake County patients dialyzing at Zebulon Kidney Center as of June 30, 2017.	60
The applicant projects Wake County patient population forward for six months using one half of the Five-Year Average Annual Change Rate for Wake County 2.8 ($5.6/2 = 2.8$).	$60 \times 1.028 = 61.68$
Project the Wake County patient population forward for one year to December 31, 2018.	$(61.68 \times 1.056) = 65.1$
The applicant adds the 39 patients from other counties	$65.1 + 39 = 104.1$
Project the Wake County patient population forward one year to December 31, 2019.	$(65.13 \times 1.056) = 68.8$
OY1: Add 39 patients from outside Wake County. This is the projected census for OY 1.	$68.8 + 39 = 107.8$
Project the Wake County patient population forward one year to December 31, 2020.	$(68.8 \times 1.056) = 72.7$
OY2: Add 39 patients from outside Wake County. This is the projected census for OY 2.	$72.7 + 39 = 111.7$

Thus, the applicant projects that Zebulon Kidney Center will serve a total of 108 in-center patients at the end of OY1 for a utilization rate of 82.7% or 3.3 patients per station per week ($108 \text{ patients} / 30 \text{ stations} = 3.6 / 4 = 0.9$ or 90%). The projected utilization of 3.6 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization for the in-center patients is based on reasonable and adequately supported assumptions regarding continued growth.

Home Hemodialysis and Peritoneal Dialysis

On page 13 of the application, the applicant states Zebulon Kidney Center does not currently provide home hemodialysis (HH) or peritoneal dialysis (PD) training nor does the applicant propose adding a home training program in the proposed application. On page 13, the applicant states that those patients who desire HH and PD training will be referred the Wake Dialysis Clinic facility. On page 37, the applicant states patients will be referred to BMA Raleigh Clinic Home training program. In Exhibit I.1, the applicant provides a copy of a home training agreement with BMA's home training center program. The agreement does not clarify the name of the training program, however, Zebulon Kidney Center does have an agreement in place for home training.

Access

In Section L.1(a), pages 47-48, the applicant states that each of BMA's 109 facilities in 48 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons regardless of their ability to pay. In Section L.7, page 51, the applicant provides the historical payor mix calendar year (CY) 2016 for Zebulon Kidney Center, as illustrated below.

Payment Source	Percent of Total Patients
Self Pay/ Indigent/ Charity	0.0%
Medicare	61.0%
Medicaid	12.0%
Commercial Insurance	3.0%
Medicare / Commercial	20.0%
Misc. (VA)	5.0%
Total	100.0%

As illustrated in the table above, in CY2016 93.0% of all Zebulon Kidney Center patients were Medicare or Medicaid recipients. On page 48, the applicant projects that 90.25% of its patients in project year (PY) 2 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

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses historical data that is clearly cited and is reasonable to use to make the assumptions used by the applicant with regard to identifying the population to be served

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and with regard to demonstrating the need the population projected to be served has for the proposed services.

- The applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need the population projected to be served has for the proposed services.
- The applicant uses historical data to project future access to the services it provides for all residents, including underserved groups.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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

BMA does not propose the reduction or elimination of a service in the proposed application, but rather the addition of two dialysis stations pursuant to the facility need methodology in the 2017 SMFP. Therefore, Criterion (3a) is not applicable to this review.

- (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, page 21, the applicant discusses the alternatives considered prior to submitting this application, which include:

- Maintain the status quo - The applicant states that maintaining the status quo is not an effective alternative because of the number of people currently dialyzing at Zebulon Kidney Center. The applicant states that utilization at Zebulon Kidney Center will be greater than 80% by the end of OY1. (see page 14). Therefore, this alternative was rejected.

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- Apply for Fewer Stations - Applying for fewer than two stations would not resolve the growing need for additional in-center dialysis stations at Zebulon Kidney Center. Even with the addition of two in-center dialysis stations, the facility is projected to exceed 80% utilization by the end of operating year one. Applying for a single station would have been unproductive. Therefore, this alternative was rejected.
- Apply for More Stations - Application of the facility need methodology indicated a need for an additional ten stations based on the continued growing need for dialysis services at Zebulon Kidney Center. However, the physical plant capacity is limited to 30 in-center stations, thus, the facility could not apply for more than two stations and remain at the same location. Therefore, this alternative was rejected.

Thus, after considering the above alternatives, the applicant states that its proposal to add two stations to Zebulon Kidney Center is the most efficient or cost effective alternative.

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 its most effective alternative to meet the identified need.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a Zebulon Kidney Center shall materially comply with all representations made in the certificate of need application as conditioned.**
- 2. Pursuant to the facility need determination in the July 2017 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than 2 additional dialysis stations for a total of no more than 30 certified stations at Zebulon Kidney Center upon project completion which shall include any home hemodialysis training or isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Zebulon Kidney Center shall install plumbing and electrical wiring through the walls for no more than two**

additional dialysis stations, which shall include any isolation or home hemodialysis training stations.

4. Bio-Medical Applications of North Carolina, Inc. d/b/a Zebulon Kidney Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add 2 dialysis stations to the existing facility for a total of 30 certified dialysis stations at Zebulon Kidney Center following project completion.

Capital and Working Capital Costs

In Section F, pages 23 and 26, the applicant projects no capital or working capital cost associated with the proposed project.

Financial Feasibility

The applicant provided 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.

	Operating Year 1 CY2019	Operating Year 2 CY2020
Total Treatments	15,561	16,153
Total Gross Revenues (Charges)	\$62,057,268	\$64,418,164
Total Net Revenue	\$4,251,536	\$4,413,281
Total Operating Expenses (Costs)	\$4,138,062	\$4,263,090
Net Income	\$113,474	\$150,191

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 applicant adequately demonstrates sufficient funds for the capital and operating needs of the proposal (should they arise) and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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 add 2 dialysis stations to the existing facility for a total of 30 certified dialysis stations at Zebulon Kidney Center following project completion.

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Wake County. Facilities may serve residents of counties not included in their service area.

According to the July 2017 SDR, there are currently 17 dialysis facilities in Wake County, as illustrated below.

WAKE COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of DECEMBER 31, 2016				
Dialysis Facility/Owner	Certified Stations 12/31/16	# In-center Patients	Percent Utilization	Patients per Station
BMA of Fuquay-Varina	28	79	70.54%	2.8214
BMA of Raleigh Dialysis	50	173	86.50%	3.4600
Cary Kidney Center (BMA)	28	81	72.32%	2.8929
FMC Apex (BMA)	20	53	66.25%	2.6500
FMC Central Raleigh (BMA)	19	64	84.21%	3.3684
FMC Eastern Wake (BMA)	17	53	77.94%	3.1176
FMC Millbrook (BMA)	17	62	91.18%	3.6471
FMC Morrisville (BMA)	10*	0	0	0
FMC New Hope (BMA)**	36	119	82.64%	3.3056
FMC Northern Wake (BMA)	16	25	39.06%	1.5625
FMC Rock Quarry (BMA)	10*	0	0	0
FMC White Oak (BMA)	12*	0	0	0
Oak City Dialysis (DaVita)	10*	0	0	0
Southwest Wake County (BMA)	30	117	97.50%	3.9000
Wake Dialysis Clinic (BMA)	50	214	107.00%	4.2800
Wake Forest Dialysis (DaVita)	20	77	96.25%	3.8500
Zebulon Kidney Center (BMA)	28	105	93.75%	3.7500
Totals	359	1,222	85.1%	3.4039

Source: July 2017 SDR.

*New stations approved but not certified as of 6/9/2017

**Proposed relocation of four stations to FKC Selma (see Project I.D. # J-11372-17)

As shown in the table above, four facilities are under development. Three will be operated by BMA and one will be operated by DaVita. The applicant operates 12 of the 13 operational facilities in Wake County. Of BMA's operational facilities utilization ranged from 107% at Wake Dialysis Clinic to 39.06% at FMC Northern Wake where utilization has increased to 60.9% as of June 30, 2017. DaVita's only operational facility in Wake County, Wake Forest Dialysis, operated at 96.2% utilization. For Wake County, as a whole, utilization was 85.01% as of December 31, 2016.

According to Table D in the July 2017 SDR, there is a surplus of 12 dialysis station in Wake County. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if its utilization rate, as reported in the most recent SDR, is at least 3.2

patients per station per week, or 80%. According to the July 2017 SDR, Zebulon Kidney Center had a utilization rate of 93.75% or 3.75 patients per station per week. This utilization rate was calculated based on 105 in-center dialysis patients and 28 certified dialysis stations (105 patients / 28 stations = 3.75 patients per station per week).

The applicant adequately demonstrates its proposal would not result in an unnecessary duplication of existing or approved dialysis services in Wake County based on the following analysis:

- The applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need for the proposed services.
- The applicant provides adequate documentation that the proposed services will not result in the unnecessary duplication of existing or approved health service capabilities or facilities.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

In Section H, page 34, the applicant provides current and projected staffing in full time equivalents (FTEs) for Zebulon Kidney Center. The applicant does not project a change in its FTE staff, as illustrated below.

POSITION	CURRENT # FTEs	PROJECTED # FTEs
Registered Nurse	5.00	5.00
Technician (PCT))	14.00	14.00
Dietitian	1.00	1.00
Dietician	1.00	1.00
Social Worker	1.00	1.00
Clinical Manager	1.00	1.00
Admin.	0.20	0.20
In-Service	0.20	0.20
Clerical	1.00	1.00
Chief Tech	0.20	0.20
Equipment Tech	1.00	1.00
Total	24.60	24.60

In Section H, page 36, the applicant provides the projected direct care staff hours for Zebulon Kidney Center in OY2. In Section I, page 38, the applicant identifies Dr. Daniel Koenig as the Medical Director of the facility. Exhibit I.5, of the application contains a signed letter from Dr. Koenig of North Carolina Nephrology, PA stating his willingness to continue to serve as the Medical Director. In Section H, page 35, the applicant describes the methods used to recruit and fill vacant or new positions.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant documents the availability of adequate health manpower and management personnel for the provision of the proposed dialysis services.
- The applicant documents support from the current and continuing Medical Director of Zebulon Kidney Center.
- The applicant documents the availability of other resources, including methods of recruitment and documentation of staff training, necessary for the provision of the proposed dialysis services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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, page 37, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I.5 contains a letter from the medical director of the facility expressing his support and willingness to continue serving in that role. The applicant discusses coordination with the existing health care system on pages 39-40. Exhibits I.2 through I.4, respectively, contain copies of agreements for Spectra Laboratories services, Wake Medical Center transfer agreement, and The University of North Carolina Hospitals for transplant services.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant documents the availability of necessary ancillary and support services for the provision of the proposed dialysis services.
- The applicant documents ongoing coordination with the existing health care system.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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 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

The proposed application is for the addition of two new dialysis stations at Zebulon Kidney Center. The applicant does not propose any new construction or renovation at Zebulon Kidney Center. 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 of the application, the applicant provides the information required for this criterion. The following table illustrates the actual payor mix for Zebulon Kidney Center during CY 2016.

Payment Source	Percent of Total Patients
Self Pay/ Indigent/ Charity	0.00%
Medicare	61.00%
Medicaid	12.00%
Commercial Insurance	3.00%
Medicare / Commercial	20.00%
Misc. (VA)	5.00%
Total	100.0%

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
Wake	12%	52%	58%	17%	7%	14%
Franklin	16%	50%	36%	16%	11%	14%
Johnston	13%	51%	31%	13%	10%	14%
Nash	18%	52%	50%	18%	11%	12%
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 SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28¹. 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). However, a direct comparison to the applicant's current payor mix would be of little value because the population data by age, race, or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The information in the application, including any exhibits, is reasonable and adequately supported because: the applicant's historical payor mix is adequate documentation of the extent to which medically underserved populations utilize the applicant's existing services.

The application is conforming to this criterion based on a review of the:

- Information in the application, including any exhibits.
 - Information which was publicly available during the review and used by the Agency.
- (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

¹http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L.3, page 50, 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 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 accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

In Section L.6, page 50, the applicant states that there have been no patient civil rights complaints filed against any BMA North Carolina facilities in the past five years.

The application is conforming to this criterion based on a review of the:

- Information in the application, including any exhibits.
 - Information which was publicly available during the review and used by the Agency.
- (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 of the application, the applicant provides the information required by this criterion. The following table illustrates the projected payor mix during the second full fiscal year.

Projected Payor Mix OY2

Payment Source	Percent of Total Patients
Self Pay/ Indigent/ Charity	1.90%
Medicare	57.16%
Medicaid	14.20%
Commercial Insurance	3.12%
Medicare / Commercial	18.89%
Misc. (VA)	4.72%
Total	100.00%

On page 48, the applicant states that the payor mix projections are based on historical performance at the facility.

The applicant is conforming to this criterion based on a review of the:

- Information in the application, including any exhibits.
 - Information which was publicly available during the review and used by the Agency.
- (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 50, the applicant states:

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. Zebulon Kidney Center has an open policy, which means that any Nephrologist may apply to admit patient to the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms. ... Transient patients are accepted upon proper coordination of care with the patient’s regular nephrologist and a physician with staff privileges at the facility.”

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

Zebulon Kidney Center

J-11402-17

Page 21

In Section M, page 52, the applicant states that Zebulon Kidney Center offered the facility as a site for clinical rotations for Wake Technical Community College's nursing students. Exhibit M.I contains a copy of a letter from Fresenius Kidney Care to Wake Technical Community College documenting the offer.

Therefore, the applicant adequately demonstrates 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.

C

The applicant proposes to add 2 dialysis stations to the existing facility for a total of 30 certified dialysis stations at Zebulon Kidney Center following project completion.

On page 373, the 2017 SMFP defines the service area for dialysis stations as "*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*" Thus, the service area is Wake County. Facilities may serve residents of counties not included in their service area.

According to the July 2017 SDR, there are currently 17 dialysis facilities in Wake County, as illustrated below.

WAKE COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of DECEMBER 31, 2016				
Dialysis Facility/Owner	Certified Stations 12/31/16	# In-center Patients	Percent Utilization	Patients per Station
BMA of Fuquay-Varina	28	79	70.54%	2.8214
BMA of Raleigh Dialysis	50	173	86.50%	3.4600
Cary Kidney Center (BMA)	28	81	72.32%	2.8929
FMC Apex (BMA)	20	53	66.25%	2.6500
FMC Central Raleigh (BMA)	19	64	84.21%	3.3684
FMC Eastern Wake (BMA)	17	53	77.94%	3.1176
FMC Millbrook (BMA)	17	62	91.18%	3.6471
FMC Morrisville (BMA)	10*	0	0	0
FMC New Hope (BMA)**	36	119	82.64%	3.3056
FMC Northern Wake (BMA)	16	25	39.06%	1.5625
FMC Rock Quarry (BMA)	10*	0	0	0
FMC White Oak (BMA)	12*	0	0	0
Oak City Dialysis (DaVita)	10*	0	0	0
Southwest Wake County (BMA)	30	117	97.50%	3.9000
Wake Dialysis Clinic (BMA)	50	214	107.00%	4.2800
Wake Forest Dialysis (DaVita)	20	77	96.25%	3.8500
Zebulon Kidney Center (BMA)	28	105	93.75%	3.7500
Totals	359	1,222	85.1%	3.4039

Source: July 2017 SDR.

*New stations approved but not certified as of 6/9/2017

**Proposed relocation of four stations to FKC Selma (see Project I.D. # J-11372-17)

As shown in the table above, four facilities are under development. Three will be operated by BMA and one will be operated by DaVita. The applicant operates 12 of the 13 operational facilities in Wake County. Of BMA's operational facilities utilization ranged from 107% at Wake Dialysis Clinic to 39.06% at FMC Northern Wake where utilization has increased to 60.9% as of June 30, 2017. DaVita's only operational facility in Wake County, Wake Forest Dialysis operated at 96.2% utilization. For Wake County, as a whole, utilization was 85.01% as of December 31, 2016.

In Section N, 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. The applicant states:

“BMA does not expect this proposal to have effect on the competitive climate in Wake County. BMA does not project to serve dialysis patients currently being served by another provider. The projected patient population for the facility begins with patients currently served by BMA, and growth of that patient population consistent with the Wake County five year average annual change rate of 5.6% as published within the July 2017 SDR.”

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 90% of the patients at Zebulon Kidney Center will have their services covered by Medicare or Medicaid.

Conclusion

The application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost effective alternative.
- The applicant adequately demonstrates that Zebulon Kidney Center will continue to provide quality dialysis services.
- The applicant adequately demonstrates that Zebulon Kidney Center will continue to provide access to medically underserved populations.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

(19) Repealed effective July 1, 1987

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section B.4, pages 8-11 and Section O, the applicant discusses the methods it uses to insure and maintain quality. In Section A.11, page 4, the applicant states that Bio-Medical Applications of North Carolina, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. On page 15, the applicant states, Fresenius operates 109 facilities in 48 North Carolina counties. In Section O, pages 58-59 and referenced Exhibits, the applicant identifies the two kidney disease

treatment centers located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation during the 18 month look-back period. Those two facilities had immediate jeopardy citations: RAI West College-Warsaw and BMA East Rocky Mount. Both facilities are back in compliance with the Medicare conditions of participation. 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 applicant provided sufficient evidence that quality care has been provided in the past.

(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 Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as 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- Zebulon Kidney Center Unit an existing facility.

.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, pages 13-14, the applicant demonstrates that Zebulon Kidney Center will serve a total of 108 in-center patients at the end of OY1 for a utilization rate of 90% or 3.6 patients per station per week (108 patients / 30 stations = 3.6 / 4 = 0.9 or 90%). The discussion regarding analysis of need 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 analysis of need found in Criterion (3) is incorporated herein by reference.