

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DATE: November 14, 2014
PROJECT ANALYST: Celia C. Inman
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: J-10342-14/ Bio-Medical Applications of North Carolina, Inc. d/b/a Zebulon Kidney Center (BMA Zebulon) / Add 5 dialysis stations for a total of 28 stations upon completion of this project and Project ID #K-10099-13 (relocate 7 stations to Franklin County / Wake County)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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.

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Bio-Medical Applications of North Carolina, Inc. d/b/a Zebulon Kidney Center, also referred to as BMA Zebulon, proposes to add five dialysis stations for a total of 28 certified dialysis stations upon completion of this project and Project I.D.# K-10099-13. BMA Zebulon is an existing 30-station dialysis facility in Wake County, located at 465 Stratford Drive, Zebulon. Project I.D. #K-10099-13 proposes to relocate seven of BMA Zebulon's stations to Franklin County. Upon the relocation of seven stations, BMA Zebulon will have 23 stations before the addition of the five stations proposed in this application, which brings the total number of dialysis stations at BMA Zebulon to 28, as stated above.

Project I.D.#K-10099-13, Bio-Medical Applications of North Carolina, Inc.'s application to develop FMC Tar River, a 10-station dialysis facility in Franklin County by relocating seven stations from BMA Zebulon and three stations from FMC Eastern Wake, was conditionally approved in August 2013 and appealed by Total Renal Care of

North Carolina. The Administrative Law Judge upheld the Agency decision in June 2014. The case is currently in the North Carolina Court of Appeals. The applicant states that this application was submitted under the assumption that the contested case hearing will have a favorable outcome for BMA and the seven stations will be relocated to FMC Tar River in Franklin County.

At the time of the review of this application, the contested case has still not been resolved. The review of this application is being conducted under the same assumption under which the applicant filed the application: namely, seven stations will be relocated from BMA Zebulon to FMC Tar River, leaving 23 stations at BMA Zebulon. Therefore, the decision in this review is conditional upon the Agency's decision regarding Project I.D. #K-10099-13 being upheld, as stated in Condition 2 of Criterion (4).

Need Determination

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 12 dialysis stations in Wake County; therefore, based on the county need methodology, there is no need for additional stations in Wake County. However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for Zebulon Kidney Center (BMA Zebulon), in the July 2014 SDR is 82.5% and 3.30 patients per station. This utilization rate was calculated based on 99 in-center dialysis patients and 30 certified dialysis stations. ($99 \text{ patients} / 30 \text{ stations} = 3.30 \text{ patients per station} / 4 = 0.825$).

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

OCTOBER 1 REVIEW-JULY 2014 SDR

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/13		82.50%
Certified Stations		30
Pending Stations		0
Total Existing and Pending Stations		30
In-Center Patients as of 12/31/13 (SDR2)		99
In-Center Patients as of 6/30/13 (SDR1)		93
Step	Description	
(i)	Difference (SDR2 - SDR1)	6
	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/13	0.1290
(ii)	Divide the result of Step (i) by 12	0.0108
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/12 until 12/31/13)	0.1290
(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	111.77
(v)	Divide the result of Step (iv) by 3.2 patients per station	34.93
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations] to determine the number of stations needed	4.93

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 4.93 (rounded to 5) stations, up to a maximum of 10. 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 five new stations and, therefore, is conforming with the facility need determination for dialysis stations.

Policies

Policy GEN-3: BASIC PRINICIPLES, page 38 of the 2014 SMFP, 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.”

The applicant addresses Policy GEN-3 beginning on page 18 of the application.

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section I, pages 4-8, Section II, pages 18-19, Section V, pages 38-42, 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 II, pages 19-20, Section III, pages 31-35, Section V, pages 38-42, Section VI, page 43, 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 II, pages 20-21, Section III, pages 31-35, Section V, page 42, 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.

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES is not applicable to this review because the applicant is not proposing a capital expenditure greater than \$2 million.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the July 2014 SDR and Policy GEN-3.

Therefore, the application is conforming to this criterion subject to Condition 2 in Criterion (4).

- (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.

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The applicant proposes to add five dialysis stations to the existing Zebulon dialysis facility for a total of 28 dialysis stations upon completion of this project and Project I.D. #K-10099-13 (relocate seven stations to Franklin County).

Population to be Served

In Section IV.1, page 36, the applicant states the number of patients served at BMA Zebulon, as of June 30, 2014 as follows:

County	# Patients Dialyzing at Home	# Patients Dialyzing In-Center
Wake	0	78
Franklin	0	3
Johnston	0	11
Nash	0	3
Vance	0	2
Wilson	0	2
Total	0	99

The applicant proposes to add five dialysis stations to the existing Zebulon dialysis facility for a total of 28 certified dialysis stations upon the completion of this project and Project I.D. #K-10099-13 (relocate seven stations from BMA Zebulon). In Section II, page 12 and Section III.7, page 31, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, December 31, 2016, as summarized in the table below:

**Projected Dialysis Patient Origin
 January 2017 – December 2018**

COUNTY	IN-CENTER PATIENTS		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	Year 1	Year 2	Year 1	Year 2
Wake	89.8	93.5	84.9%	85.4%
Johnston	11.0	11.0	10.4%	10.0%
Nash	3.0	3.0	2.8%	2.7%
Wilson	2.0	2.0	1.9%	1.8%
Total	105.8	109.5	100.0%	100.0%

Analysis of Need

As discussed in Criterion (1), based on the facility need methodology for adding dialysis stations, the potential number of stations needed is five stations. The applicant proposes to add five stations.

In Section II, pages 12-13, and Section III.7, pages 31-32, the applicant provides the assumptions and methodology it uses to determine the need for additional stations and to project BMA Zebulon’s proposed patient utilization.

The assumptions and methodology are summarized below:

- The applicant assumes that the Wake County patient population at its Zebulon facility will increase at a rate commensurate with the Wake County Five Year Average Annual Change Rate (AACR) of 4.1%, as published in the July 2014 SDR.
- The applicant assumes the Franklin County patients currently dialyzing at BMA Zebulon will transfer to the FMC Tar River facility proposed for development in Project I.D. #K-10099-13. The State’s conditional approval of that application is still involved in appeal. The applicant states:

“BMA notes that the FMC Tar River decision has been appealed by DaVita and is currently before the NC Court of appeals. Appeals to the NC COA have no statutory time limits. BMA assumes a favorable decision by the COA, by the end of 2015. Absent further appeal to the NC Supreme Court, BMA assumes that the FMC Tar River project will be constructed and certified by December 31, 2016. As a matter of continuity, BMA will assume the Franklin County patients to transfer their care to FMC Tar River.”

- BMA Zebulon currently serves patients from Vance County. The applicant assumes these patients will be closer to the FMC Tar River facility and will

dialyze in Franklin County rather than in Zebulon. Thus the applicant does not include patients from Vance County in its projections.

The applicant makes note that should patients from Franklin or Vance counties choose to continue to dialyze at BMA Zebulon, the additional treatments would only increase the projected revenues of the facility. The applicant states that BMA will not deny treatment to any patient who has been properly referred to the facility.

- The applicant is currently serving 16 in-center patients residing in Nash, Wilson and Johnston counties and assumes these patients will continue dialysis at the BMA Zebulon facility. The applicant does not project any increase in this segment of the patient population.
- The project is projected to be complete on December 31, 2016, with Operating Years 1 and 2 being from January 1, 2017 through December 31, 2017 and January 1, 2018 through December 31, 2018, respectively.

Projected Utilization

The following table demonstrates the applicant's calculations used to arrive at the projected patient census for Operating Years One and Two. The projection assumes the favorable outcome on the contested case hearing on Project I.D. #K-10099-13 (relocate seven dialysis stations from BMA Zebulon to FMC Tar River in Franklin County).

BMA Zebulon	In-Center Patients
The applicant begins with Wake County patients dialyzing at the Zebulon facility as of June 30, 2014	78
The applicant uses the Wake County Five Year AACR to project the census forward for 6 months to December 31, 2014.	$[78 \times (.041 / 12 \times 6)] + 78 = 79.6$
The applicant projects this patient population forward for 1 year to December 31, 2015.	$(79.6 \times .041) + 79.6 = 82.9$
The applicant projects this patient population forward for 1 year to December 31, 2016.	$(82.9 \times .041) + 82.9 = 86.3$
The applicant adds the 16 patients from outside Wake County for the projected ending census December 31, 2016.	$86.3 + 16 = 102.3$
The applicant projects the December 31, 2016 Wake County patient population forward for 1 year to December 31, 2017.	$(86.3 \times .041) + 86.3 = 89.8$
The applicant adds the 16 patients from outside Wake County for the projected ending census for Operating Year 1, December 31, 2017.	$89.8 + 16 = 105.8$
The applicant projects the December 31, 2017 Wake County patient population forward for 1 year to December 31, 2018.	$(89.8 \times .041) + 89.8 = 93.5$
The applicant adds the 16 patients from outside Wake County for the projected ending census for Operating Year 2, December 31, 2018.	$93.5 + 16 = 109.5$

At the end of Operating Year One, BMA Zebulon is projecting a patient census of 105 patients for a utilization rate of 93.75% or 3.75 (105 patients / 28 stations = 3.75) patients per station. At the end of operating Year Two, BMA Zebulon is projected to have an in-center patient census of 109 patients for a utilization rate of 97% or 3.89 (109 patients / 28 stations = 3.89) patients per station.

Projected patient in-center utilization at the end of Year One is 3.75 in-center patients per station per week which satisfies the 3.2 in-center patients per station required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and supported assumptions regarding continued growth.

Thus, assuming the completion of the relocation of the seven dialysis stations from BMA Zebulon to FMC Tar River (Project I.D. #K-10099-13), the applicant adequately identifies the population to be served and adequately demonstrates the need that population has for the proposed services.

Access

In Section VI.1(a), page 43, the applicant states:

“It is clear that BMA provides service to historically underserved populations. It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

On page 43, the applicant states that the patient population of BMA Zebulon is comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
BMA Zebulon	43.4%	50.5%	69.7%	30.3%	79.8%

Note: The Medicare percentage represents the percentage of patients receiving some type of Medicare benefit, not the percentage of facility treatment reimbursement. The above percentages are not meant to total to 100% of facility utilization.

On pages 44 and 59, the applicant projects that 92.52% of its patients will be covered by some form of Medicare or Medicaid. The applicant adequately demonstrates 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.

Conclusion

In summary, assuming the completion of the relocation of seven dialysis stations from BMA Zebulon to FMC Tar River (Project I.D. #K-10099-13), the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed project based on reasonable and supported utilization projections and assumptions and demonstrates the extent to which all residents of the area, and in particular, underserved groups, are likely to have access to the services. Therefore, the application is conforming to this criterion, subject to Condition 2 of Criterion (4).

- (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.

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In Section III.9, pages 33-35, the applicant discusses the alternatives considered prior to the submission of its application, which include:

- 1) Maintain the status quo – the applicant states that not applying would not resolve the growing ESRD patient population in Wake County.
- 2) Relocate dialysis stations from another BMA Wake County facility – the applicant states that the BMA dialysis facilities in Wake County have been developed in order to provide for localized delivery of care to the county patient population in a way which minimizes patient need to travel for care. The applicant provides data that it says indicates that the utilization at the other BMA Wake County facilities is sufficient to support the number of stations at each facility.
- 3) Expansion of another facility in Wake County – BMA is simultaneously filing to add dialysis stations at BMA Zebulon, FMC Eastern Wake, FMC Central Raleigh and BMA Fuquay-Varina. The applicant states that each facility is in a different part of Wake County and serving a different segment of the Wake County ESRD patient population.

The applicant states that the chosen alternative to apply to expand the existing Zebulon facility by adding five stations is the most effective and least costly alternative for meeting the needs of the patients projected to receive treatment at the BMA Zebulon facility.

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative based on the on the continued growth of BMA Zebulon's patient population. See the discussion regarding need in Criterion (3) which is incorporated herein by reference.

Furthermore, the application is conforming or conditionally 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 its proposal is the least costly or most effective alternative to meet the identified need. 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.**
 - 2. The certificate of need for Project I.D. #J-10342-14 shall not be issued until the certificate of need is issued for Project I.D. #K-10099-13.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Zebulon Kidney Center shall develop and operate no more than five additional dialysis stations for a total of no more than 28 certified dialysis stations at the completion of this project and Project I.D. #K-10099-13, which shall include any home hemodialysis training or isolation 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 Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

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In Section VIII.5, page 52, the applicant states, *“BMA does not project to incur capital costs for this project. Please refer to Exhibit 24 for letter of commitment from Mark Fawcett, Vice President and Assistant Treasurer, Fresenius Medical Care Holdings, Inc.”*

The letter in Exhibit 24 from Fresenius Medical Care’s Vice President states:

“BMA is submitting a Certificate of Need Application to add five dialysis stations to its Zebulon Kidney Center dialysis facility in Wake County. The five stations are intended to replace five of the stations approved for relocation to the proposed FMC Tar River facility in Franklin County in CON Project ID # K-10099-13. This project does not require any capital expenditure on behalf of BMA.”

Exhibit 4 contains the consolidated financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ending December 31, 2013 and 2012, which document cash and cash equivalents of \$275,719,000 and total equity of more than \$7 million.

Thus, the applicant adequately demonstrates the availability of adequate funds to develop the project.

Based on information provided by the applicant in Section X.1, page 55, the dialysis facility’s projected allowable charges per treatment for each payment source are as follows:

SOURCE OF PAYMENT	ALLOWABLE CHARGE PER TREATMENT
Private Pay	\$1,425.00
Commercial Insurance	\$1,425.00
Medicare	\$239.00
Medicaid	\$140.23
Medicare/Medicaid	\$239.00
Medicare/Commercial	\$239.00
State Kidney Program	\$100.00
VA	\$231.12
Other: Self/Indigent	\$1,425.00

On page 56, the applicant states:

“In November 2013, Medicare announced further cuts to reimbursement for dialysis treatment. These cuts amount to a 12% reduction in revenues and will be phased in over several years. The following table demonstrates the projected Medicare reimbursement by calendar year. BMA will use these rates within in the application and its projections of revenues.”

Table X.1-2
Anticipated Medicare Reimbursement by Year

YEAR	MEDICARE RATE
2014	\$239.02
2015	\$239.02
2016	\$229.46
2017	\$220.28
2018	\$211.47
2019	\$211.47

In Sections X.2-X.4, pages 57-63, the applicant reports projected revenues and expenses as follows:

	OPERATING YEAR 1 1/1/17-12/31/17	OPERATING YEAR 2 1/1/18-12/31/18
Total Net Revenue	\$4,450,231	\$4,481,221
Total Operating Costs	\$3,968,681	\$4,033,783
Net Profit	\$481,550	\$447,438

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. See Section X.3, page 58 for the applicant’s assumptions on number of treatments (3 treatments/week, 52 weeks/year, and 6.5% missed treatments)

for in-center patients. The applicant's projections of treatments and revenues are reasonable based on the number of in-center patients projected for the first two operating years. See Criterion (3) for further discussion on the applicant's assumptions for projections which is incorporated herein by reference.

In Section VII.1, page 48, the applicant provides projected staffing and salaries. The financials in Sections X.4-5, pages 62-63, provide operating costs adequate to cover projected staffing.

In summary, assuming the completion of the relocation of seven dialysis stations from BMA Zebulon to FMC Tar River (Project I.D. #K-10099-13), the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the proposed project. The applicant also adequately demonstrates that the financial feasibility of the project is based on reasonable projections of revenues and operating costs, including the proposed staffing. Therefore, the application is conforming to this criterion, subject to Condition 2 of Criterion (4).

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

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The following table identifies the existing and approved kidney disease treatment centers located in Wake County as reported in the July 2014 SDR.

WAKE COUNTY DIALYSIS CENTERS		
FACILITY	LOCATION	UTILIZATION
BMA of Fuquay Varina Kidney Center	Fuquay-Varina	86.84%
BMA of Raleigh Dialysis	Raleigh	84.88%
Cary Kidney Center	Cary	97.50%
FMC Apex	Apex	75.00%
FMC Central Raleigh	Raleigh	93.33%
FMC Eastern Wake	Rolesville	94.64%
FMC Millbrook	Raleigh	91.18%
FMC New Hope Dialysis	Raleigh	59.03%
FMC Northern Wake (new site)	Raleigh	0.00%
Southwest Wake County Dialysis	Raleigh	87.90%
Wake Dialysis Clinic	Raleigh	81.50%
Wake Forest Dialysis Center	Raleigh	98.33%
Zebulon Kidney Center (BMA Zebulon)	Zebulon	82.50%

As shown in the table above, of the thirteen Wake County dialysis facilities, the only existing facility operating at less than 60% of capacity as of December 2013, was FMC New Hope Dialysis, operating at 59.03% of capacity. FMC Northern Wake is a new site.

The applicant proposes to add five dialysis stations to its existing Wake County BMA Zebulon facility for a total of 28 certified dialysis stations upon completion of this

project and Project I.D. #K-10099-13. The applicant adequately demonstrates the need for five additional stations based on the number of in-center patients it proposes to serve. See the discussion on need in Criterion (3) which is incorporated herein by reference.

In summary, assuming the completion of the relocation of seven dialysis stations from BMA Zebulon to FMC Tar River (Project I.D. #K-10099-13), the applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion subject to Condition 2 of Criterion (4).

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

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The following table illustrates the projected staffing for BMA Zebulon, as provided by the applicant in Section VII.1, page 48.

Position	Total FTE Positions
RN	4.00
Patient Care Technician	12.00
Clinical Manager	1.00
Administrator (Area Manager)	0.15
Dietician	0.75
Social Worker	0.75
Medical Records	1.00
Chief Tech	0.15
Equipment Technician	0.75
In-Service Technician	0.34
Clerical	1.00
Total	21.89

As shown in the above table, the applicant proposes to employ a total of 21.89 full-time equivalent (FTE) positions to staff the Zebulon facility upon completion of the proposed project. In Section VII.4, page 49, the applicant states, “*BMA anticipates no difficulties in filling staff positions.*”

The following table shows the projected number of direct care staff for each shift offered at BMA Zebulon after the relocation of seven stations to FMC Tar River and the addition of the five stations which are the subject of this review (30 stations – 7 + 5 = 28 stations).

Radiology, or Raleigh Access Center. All BMA staff are trained to respond to emergencies and there is a fully stocked crash cart available on-site. If needed, patients will be transported by ambulance to the hospital for further acute care. Spectra will provide laboratory services (Exhibit 15). Self care training, including hemodialysis, peritoneal dialysis, CAPD and CCPD will be provided by BMA Raleigh (Exhibit 20). The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health 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

NA

- (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

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

NA

- (11) Repealed effective July 1, 1987.

- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of

providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

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In Section VI.1(a), page 43, the applicant states that Fresenius Medical Care Holdings, Inc., parent company to BMA, currently operates 102 dialysis facilities in 42 North Carolina counties (including affiliations with RRI facilities). The applicant further states, *“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.”* The patient population of the Zebulon facility is comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
BMA Zebulon	43.4%	50.5%	69.7%	30.3%	79.8%

Note: The Medicare percentage represents patients receiving some type of Medicare benefit. This is not to say 69.7% of the treatment reimbursement is from Medicare.

On pages 43, the applicant further states:

“BMA notes that the historical performance as reported here represents the payor mix for BMA Zebulon as of June 30, 2014. The historical performance is not a guarantee of future performance as the payor source does change as new patients are admitted. Commercial insurance for patients generally covers the patient for a period of 30 months from the beginning of treatment; thereafter, Medicare provides coverage for the patient. The commercial insurance population is therefore constantly changing.”

In Section VI.1(b), page 44, the applicant reports that 92.52% of the patients who were receiving treatments at BMA Zebulon as of June 30, 2014, had some or all of their services paid for by Medicare or Medicaid in the past year. The following table illustrates the historical and projected payment source for the facility.

BMA ZEBULON PAYOR MIX

SOURCE OF PAYMENT	% OF TOTAL
Commercial Insurance	2.40%
Medicare	71.69%
Medicaid	8.02%
VA	5.04%
Medicare/Commercial	12.81%
Other (Self/Indigent)	0.05%
Total	100.00%

Totals may not sum due to rounding.

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Wake, Johnston, Nash and Wilson counties and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Wake County	9.8%	3.3%	18.4%
Johnston County	17.5%	6.7%	20.0%
Nash County	19.6%	8.7%	19.7%
Wilson County	21.9%	9.0%	21.9%
Statewide	16.5%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/31/2013, page 99.*)¹

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. However, a direct

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender do not include information on the number of elderly, minorities or women utilizing health services.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides national statistics for FY 2011:

*"The December 31, 2011 prevalent population included 430,273 patients on dialysis"*² (p. 216)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were white, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p.218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states:

"In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant." (p. 216).

The *2013 USRDS Annual Data Report* (p. 332) provides 2011 ESRD spending by payor, as follows:

ESRD Spending by Payor		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
Total	\$49.2	100.0%

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

² www.usrds.org/adr.aspx

Number and Percent of Dialysis Patients by Age, Race, and Gender 2013		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
Gender		
Female	6,845	44.5%
Male	8,544	55.5%
Race		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.³

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.1(f), page 45, 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

³<http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

In Section VI.6 (a), page 46, the applicant states, “*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.*”

The application is conforming to this criterion.

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

C

In Section VI.1(d), page 45, the applicant states:

“BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.” [emphasis in original]

On page 44, the applicant reports that it expects 92.52% of the dialysis patients who received treatments at BMA Zebulon to have all or some of their services paid for by Medicare or Medicaid as indicated below.

BMA ZEBULON PAYOR MIX

SOURCE OF PAYMENT	% OF TOTAL
Commercial Insurance	2.40%
Medicare	71.69%
Medicaid	8.02%
VA	5.04%
Medicare/Commercial	12.81%
Other (Self/Indigent)	0.05%
Total	100.00%

Totals may not sum due to rounding.

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5, page 46, the applicant states that:

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. BMA Zebulon will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.

Patients cannot self-refer for dialysis and dialysis treatment does require orders from an attending physician with staff privileges at the facility. Transient patients are accepted upon proper coordination of care with the patient’s regular nephrologist and a physician with staff privileges at the facility.”

The applicant adequately demonstrates that it provides a range of means by which a person can access the proposed 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 V.3, pages 39-40, the applicant states:

“Exhibit 19 contains a letter to Wake Technical Community College encouraging the school to include the BMA Zebulon facility in their clinical rotations for nursing students.

...

All health related education and training programs are welcomed to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment. This experience enhances the clinical experience of the students enrolled in these programs enabling them to learn about the disease, prognosis and treatment for the patient with end stage renal disease.”

Exhibit 19 contains a copy of a letter from Fresenius Medical Care to the Department of Nursing at Wake Technical Community College inviting the college to include BMA Zebulon (Zebulon Kidney Center) in the clinical rotation for its nursing students. The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with 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 five dialysis stations to its existing Wake County BMA Zebulon facility for a total of 28 certified dialysis stations upon completion of this project and Project I.D. #K-10099-13. According to the July 2014 SDR, Wake County has 13 dialysis centers, as shown below:

WAKE COUNTY DIALYSIS CENTERS		
FACILITY	LOCATION	UTILIZATION
BMA of Fuquay Varina Kidney Center	Fuquay-Varina	86.84%
BMA of Raleigh Dialysis	Raleigh	84.88%
Cary Kidney Center	Cary	97.50%
FMC Apex	Apex	75.00%
FMC Central Raleigh	Raleigh	93.33%
FMC Eastern Wake	Rolesville	94.64%
FMC Millbrook	Raleigh	91.18%
FMC New Hope Dialysis	Raleigh	59.03%
FMC Northern Wake (new site)	Raleigh	0.00%
Southwest Wake County Dialysis	Raleigh	87.90%
Wake Dialysis Clinic	Raleigh	81.50%
Wake Forest Dialysis Center	Raleigh	98.33%
Zebulon Kidney Center (BMA Zebulon)	Zebulon	82.50%

In Section V.7, page 42, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states it does not expect this proposal to have an effect on competition in Wake County. The applicant states that the patients to be served at BMA Zebulon are existing dialysis patients and future patients residing in Wake County. The applicant further states that DaVita operates a dialysis facility in Wake Forest, 18 miles from the Zebulon facility, making it unlikely that they serve the same patients. The applicant also states that the strength of its relationship with Capital Nephrology and Wake Nephrology, the two predominant nephrology practices in Wake County adds value to BMA Zebulon. The applicant further states:

“BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 97% of the In-center patients will be relying upon government payors. The facility must capitalize upon every opportunity for efficiency.

BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients.

...

This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients’ lives.”

The information provided above by the applicant is reasonable and credible and adequately demonstrates that the addition of five stations to the existing facility will have a positive impact on cost-effectiveness, quality and access to the proposed dialysis services because:

- The applicant adequately demonstrates the need to add five certified dialysis stations to the existing 23-station (30 stations less the seven stations to be relocated to Franklin County per Project I.D. #K-10099-13) for a total of 28 stations at the BMA Zebulon facility. See the discussion regarding need in Criterion (3) which is incorporated herein by reference.
- The applicant adequately demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to patients in Wake County. See the discussion regarding cost effectiveness in Criterion (4) which is incorporated herein by reference.
- The applicant adequately demonstrates it has provided and will continue to provide quality services. See the discussion regarding quality in Criterion (1) which is incorporated herein by reference.
- The applicant demonstrates it will provide adequate access to medically underserved populations. See the discussion regarding access in Criterion (13a) which is incorporated herein by reference.

Therefore, the application is conforming to this criterion subject to Condition 2 of Criterion (4).

- (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

Zebulon Kidney Center, also referred to as BMA Zebulon, currently provides dialysis services. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the BMA Zebulon facility operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of the decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183(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.

CA

The Criteria and Standards for End Stage Renal Disease Services, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C Section .2200, subject to Condition 2 in Criterion (4). The specific findings are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

.2202 INFORMATION REQUIRED OF APPLICANT

- (a) *An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:*

- (1) *Utilization rates;*

- C- In Section II.1, page 10, the applicant states that the utilization rate is reported in the July 2014 SDR. The July 2014 SDR shows a utilization rate of 82.5% for Zebulon Kidney Center. The rate was calculated based on 99 in-center dialysis patients and 30 certified dialysis stations as of December 31, 2013 (99 patients / 30 stations = 3.3 patients per station; 3.3 patients per station / 4.00 patients per station = 0.825). In Section II, page 12, the applicant projects 105 dialysis

patients on 28 stations (30 stations - 7 relocated in Project I.D. #K-10099-13 + 5 = 28) for a utilization rate of 94% ($105 / 28 = 3.75 / 4 = 0.9375$) in year 1 and 109 dialysis patients on 28 stations for a utilization rate of 97% ($109 / 28 = 3.89 / 4 = 0.9732$) in year 2.

(2) *Mortality rates;*

-C- In Section II, page 10, the applicant reports the 2011, 2012 and 2013 facility mortality rates as 6.7%, 10.2% and 8.6%, respectively.

(3) *The number of patients that are home trained and the number of patients on home dialysis;*

-NA- In Section II, page 10, the applicant states, “BMA Zebulon is not certified to offer home training. Patients who are candidates for home dialysis are referred to the BMA Raleigh facility.”

(4) *The number of transplants performed or referred;*

-C- In Section II, page 10, the applicant provides information showing BMA Zebulon referred 21 patients for transplant in 2012 and 11 patients in 2013; 0 transplants were performed in 2012, and 3 transplants were performed in 2013.

(5) *The number of patients currently on the transplant waiting list;*

-C- In Section II, page 10, the applicant states, “BMA Zebulon has six patients on the transplant waiting list.”

(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

-C- In Section II, page 10, the applicant states that there were 130 hospital admissions in 2013, 32 (24.6%) of which were dialysis related and 98 (75.4%) non-dialysis related.

(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*

-C- In Section II, page 11, the applicant provides information that shows there were no patients dialyzing at BMA Zebulon with Hepatitis B Conversions during 2012 and 2013 and no current patients with infectious disease (Hepatitis B).

(b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*

- (1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*

-NA- This is not an application for a new facility.

- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
 - (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
 - (B) *composition of the assessment/evaluation team at the transplant center,*
 - (C) *method for periodic re-evaluation,*
 - (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
 - (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- This is not an application for a new facility.

- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- This is not an application for a new or replacement facility.

- (4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- See Exhibit 12, in which the applicant provides copies of written policies and procedures, including back up procedures in the event of a power outage.

- (5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-NA- This is not an application for a new facility.

- (6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- In Section II, page 12, the applicant states:

“BMA will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations. BMA staffing consistently meets CMS and State guidelines for dialysis staffing. Fire safety equipment, the physical environment, water supply and other relevant health and safety equipment will be appropriately installed and maintained at BMA Zebulon.”

In Section XI.6(g), page 68, the applicant states, *“BMA of North Carolina provides and will continue to provide services in conformity with applicable laws and regulations pertaining to staffing, fire safety and equipment, physical environment and other relevant health and safety requirements. Information detailing conformity can be found in Sections II and VII and exhibits referenced therein. Additionally, this applicant has confirmed its commitment to provide services in conformity with the law on the Certification page provided in the front of the application.”*

- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- The applicant provides the following projected patient origin for the first two operating years on page 12 of the application, as shown below.

**Projected Dialysis Patient Origin
 January 2017 – December 2018**

COUNTY	IN-CENTER PATIENTS		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	Year 1	Year 2	Year 1	Year 2
Wake	89.8	93.5	84.9%	85.4%
Johnston	11.0	11.0	10.4%	10.0%
Nash	3.0	3.0	2.8%	2.7%
Wilson	2.0	2.0	1.9%	1.8%
Total	105.8	109.5	100.0%	100.0%

The applicant’s assumptions and methodology are provided on pages 12-14.

- (8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- The applicant is not proposing a new facility.

- (9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*

-C- In Section II, page 14, the applicant states,

“BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

.2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- The applicant proposes to add stations to an existing facility.

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

-C- In Section II, page 12, the applicant projects serving 105 dialysis patients on 28 (30 – 7 + 5) stations for a utilization of 94% or 3.75 ($105 / 28 = 3.75 / 4 = 0.9375$) patients per station per week at the end of the first operating year, based on the methodology and assumptions found in Section II, pages 12-14 and in Section III of the application.

.2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

- (1) *diagnostic and evaluation services;*

-C- Section II, page 15 and the table in Section V.1, page 38 state patients will be referred to Wake Medical Center or Rex Healthcare for diagnostic and evaluation services.

(2) *maintenance dialysis;*

-C- Section II, page 16 and the table in Section V.1, page 38, state the applicant will provide in-center maintenance dialysis.

(3) *accessible self-care training;*

-C- In Section II, page 16, the applicant states, "*Patients who are candidates for self-care are referred to the BMA Raleigh home training department.*" The table in Section V.1, page 38, shows patients will receive in-center hemodialysis, intermittent peritoneal dialysis, CAPD and CCPD at BMA Raleigh.

(4) *accessible follow-up program for support of patients dialyzing at home;*

-C- In Section II, page 16, the applicant states, "*Patients who are candidates for home dialysis are referred to the BMA Raleigh facility home training department.*" The applicant addresses accessible follow-up program for support of patients dialyzing at home in Section V, Question 2(d), page 39, stating,

"Currently, patients who desire to perform home dialysis will be trained and referred to the BMA Raleigh facility home training program. Patients who are candidates for home dialysis are referred by their attending nephrologists to facility BMA Raleigh Home Training Clinic. The applicant will provide back-up hemodialysis treatments to any home patient in need of temporary hemodialysis.

Services offered to home patients include home visitation, assistance with problems that patients have with catheters; diagnosis of infections and assistance with placing orders of needed supplies. Social work and dietary assessments are provided for those patients on an ongoing basis. Patients are given EPO at the facility or taught to administer it to themselves at home. Laboratory testing of blood samples may be provided by the facility as prescribed by the physician."

(5) *x-ray services;*

-C- Section II, page 16 and the table in Section V.1, page 38, state patients will be referred to Wake Medical Center for x-ray services.

(6) *laboratory services;*

-C- Section II, page 16 and the table in Section V.1, page 38, state the facility provides on-site laboratory services through contract with Spectra Labs. Exhibit 15 contains a laboratory services agreement.

(7) *blood bank services;*

-C- Section II, page 16 and the table in Section V.1, page 38, state patients will be referred to Wake Medical Center for blood bank services.

(8) *emergency care;*

-C- Section II, page 16 and the table in Section V.1, page 38, state emergency care is provided on site from the trained staff and fully stocked crash cart. Emergency services will be summoned via phone call to 911 in the event transport by ambulance to a hospital is required.

(9) *acute dialysis in an acute care setting;*

-C- Section II, page 16 and the table in Section V.1, page 38, state patients will be referred to Wake Medical Center for acute dialysis in an acute care setting.

(10) *vascular surgery for dialysis treatment patients;*

-C- Section II, page 16 and the table in Section V.1, page 38, state dialysis patients will be referred to Rex Vascular, Wake Med Radiology or Raleigh Access Center for vascular surgery.

(11) *transplantation services;*

-C- In Section II, page 16, the applicant states, "*BMA Zebulon has a transplant agreement with UNC. A copy of an executed transplant agreement is included in Exhibit 26.*"

(12) *vocational rehabilitation counseling and services; and*

-C- Section II, page 17 and the table in Section V.1, page 38, state patients will be referred to Wake Rehabilitation for vocational counseling and services.

(13) *transportation.*

-C- Section II, page 17 and the table in Section V.1, page 38, state transportation services for patients are provided by Wake Coordinated Transportation or Johnston County Area Transit System (JCATS).

.2205 STAFFING AND STAFF TRAINING

(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.*

-C- In Section VII.1, page 48, the applicant provides the proposed staffing for BMA Zebulon. On page 49, the applicant states, “*BMA Zebulon will comply with all staffing requirements as stated in 42 C.F.R. Section 494 (formerly 405.2100).*” See additional staffing details in Section 1.13, pages 4-8 and Section II.2. A, pages 22-23.

(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*

-C- In Section VII.5, page 49, the applicant refers to Exhibit 9 for an outline of the training program and Exhibit 10 for an outline of continuing education programs. The applicant also states that each new employee will be required to successfully complete a 10-week training program, including training in the clinical aspects of their job, facility and corporate policies and procedures, safety precautions, OSHA regulations, and CPR.