ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: August 27, 2013

PROJECT ANALYST: Michael J. McKillip
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: K-10099-13 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Tar River / Develop a new 10-station dialysis facility in Louisburg by relocating 7 stations from BMA Zebulon and 3 stations from FMC Eastern Wake / Franklin 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.

C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Tar River filed a Category D application on March 15, 2013 for the review cycle beginning April 1, 2013. The applicant proposes to develop a new 10-station dialysis facility in Louisburg (Franklin County) by relocating 7 stations from BMA Zebulon and 3 stations from FMC Eastern Wake, both of which are located in Wake County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. *Table B: ESRD Dialysis Station Need Determination by Planning Area* in the January, 2013 Semi-Annual Dialysis Report (SDR) projects a 10-station deficit in Franklin County. The January 2013 SDR is part of the 2013 State Medical Facilities Plan (SMFP) and is published by the State Health Coordinating Council and the Medical Facilities Planning Branch, Department of Health and Human Services. However, because the utilization of the dialysis stations in the only existing dialysis facility in Franklin County is less than 80%, the county need determination is zero. The county and facility need methodologies in the January 2013 SDR and the 2013 SMFP are not applicable to this review.

However, Policy ESRD-2: Relocation of Dialysis Stations is applicable to this review. The policy states:

> *"Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:*
>
> 1. *demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
>
> 2. *demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report."*

The applicant proposes to relocate ten existing dialysis stations from Wake County to Franklin County. Therefore, the dialysis station inventory in Wake County would decrease by ten stations and the dialysis station inventory in Franklin County would increase by ten stations. Wake and Franklin Counties are contiguous to each other.

At the time the application was submitted and when the review began, the January 2013 SDR was the most recent SDR. Table B in the January 2013 SDR shows a 19-station surplus in Wake County. In addition, Table B in the January 2013 SDR shows a 10-station deficit in Franklin County, the county into which the applicant proposes to relocate the stations. The applicant adequately demonstrates that the proposal will not result in a deficit in the number of dialysis stations in Wake County, the county that would be losing stations as a result of the proposed project. Furthermore, the applicant adequately demonstrates that the proposal will not result in a surplus of dialysis stations in Franklin County, the county that would gain stations as a result of the proposed project, because the applicant proposes to relocate ten dialysis stations into a county which the January 2013 SDR has identified as having a deficit of ten dialysis stations. Therefore, the application is conforming to Policy ESRD-2, and 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

Currently, there is one dialysis facility in Franklin County, Dialysis Care of Franklin County, which is a 23-station facility operated by DaVita, Inc., and is located in Louisburg. The

January 2013 SDR shows that Dialysis Care of Franklin County was operating at 75% utilization, with 69 in-center patients dialyzing on 23 stations [69 / 23 = 3.00; 3.00 / 4 = 75%].

In this application, BMA proposes to establish a new 10-station dialysis facility, FMC Tar River, in Louisburg, Franklin County, by relocating seven existing dialysis stations from the BMA Zebulon facility in Wake County, and three existing dialysis stations from the FMC Eastern Wake facility, also in Wake County. In Section II.1, page 15, the applicant projects that 35 existing dialysis patients will initially transfer to the new facility in Louisburg, including 25 existing in-center BMA patients who are residents of Franklin County, 6 existing in-center BMA patients who are residents of Vance, Wake and Nash counties, and 4 existing home dialysis patients who are residents of Wake and Nash counties. The applicant does not propose to add new dialysis stations to an existing facility or to establish new dialysis stations.

Population to be Served

In Section III.7, page 70, the applicant provides a table showing the projected patient origin for the patients to be served at the proposed facility, as shown in the table below:

FMC TAR RIVER	OPERATING YEAR 1 CY2015		OPERATING YEAR 2 CY2016		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Franklin	28.7	2.0	28.9	4.0	75.4%	76.7%
Vance	3.0	0.0	3.0	0.0	7.4%	7.0%
Wake	1.0	2.0	1.0	2.0	7.4%	7.0%
Nash	2.0	2.0	2.0	2.0	9.8%	9.3%
Total	34.7	6.0	34.9	8.0	100%	100%

The applicant adequately identifies the population to be served.

Demonstration of Need

The applicant proposes to relocate ten existing, certified dialysis stations from existing facilities in Wake County to develop a new facility in Franklin County, in which the applicant projects the stations will be utilized at 85% of capacity by the end of the first year of operation, with 34 patients dialyzing on 10 in-center dialysis stations.

In Section III.3, page 59, the applicant states,

> *"BMA proposes to relocate 10 dialysis stations to develop the FMC Tar River facility. Within this application, BMA has projected to be serving 34 patients at the end of the first year of operations for this facility; this equates to an 85% utilization rate or 3.4 patients per station. … This is an application to transfer a total of 10 dialysis stations from two BMA facilities; the facility is projected to be serving 3.2 patients per station at the end of the first operating year. BMA has included 35 letters of support from dialysis patients, each indicating that a BMA*

facility in Louisburg would be more convenient. … BMA projections are based upon transfers of patients from other BMA facilities in counties contiguous to Franklin County."

On pages 86-87, the applicant states,

"CON Section approval of this application will necessarily result in a new in-center dialysis facility to serve the ESRD patient population of Franklin County and surrounding areas. Therefore a new competitive element will be introduced. At the present time the only provider of in-center dialysis services within the County is the DaVita facility. However, BMA has long been a provider of care for the ESRD patients of Franklin County. Consider the January 2013 SDR. Table B of the SDR indicates that there were 117 dialysis patients residing in Franklin County as of June 30, 2012. Table B further indicates that there were 14 home dialysis patients in the County. Thus, there were 103 in-center dialysis patients in the County. However, Table A indicates that the DaVita facility was providing care to only 69 in-center patients as of June 30, 2012. Thus at June 30, 2012 there were 34 in-center patients, 33% of the in-center patient population, leaving the county for dialysis treatment. BMA was providing treatment for the overwhelming majority of those patients. BMA has included many patient letters of support from patients who reside in Franklin County. Thus, while development of "bricks and mortar" may be construed as the introduction of a competitive force within the County, BMA suggests that the competition between providers has been ongoing for many years.

Indeed, BMA has been providing dialysis treatment to a significant portion of the Franklin County ESRD patient population as is noted within this application. Further, the physicians of Capital Nephrology are likewise providing medical coverage for patients from Franklin County. In fact, the physicians for Capital Nephrology Associates report that at the present time they are providing care for a large number of Stage 3, 4, and 5 Chronic Kidney Disease patients from Franklin County. Thus, while approval of this application will allow introduction of a new dialysis provider into the county, the reality is that approval of this application will not significantly alter the competitive climate of Franklin County. BMA is already serving dialysis patients from Franklin County.

This proposal does increase the number of dialysis stations within Franklin County; and will completely resolve the 10 station deficit reported in the January 2013 SDR. BMA does not anticipate that this proposal will have any effect upon dialysis facilities in Franklin County. BMA projections of patients to be served by the facility are a function of the existing patient population served by BMA coupled with growth of that population. BMA has not asserted that it would capture 100% of new dialysis patients in Franklin County. Rather, BMA projections of future patient populations also anticipate that the patient population of the DaVita clinic would increase at the same rate proposed by BMA."

Projected Utilization

In Section III.7, pages 70-72, the applicant presents the assumptions and detailed methodology used to project utilization at FMC Tar River. The applicant states:

1. *"BMA is serving a significant number of Franklin County dialysis patients at its facilities in Warren and Wake Counties.*

2. *BMA assumes that the patient population of FMC Tar River will be comprised of patients from Franklin, Vance, Wake and Nash Counties.*

3. *BMA assumes that the patient population of Franklin County will grow at a rate commensurate with the Franklin County Five Year Average Annual Change Rate as published in the January 2013 SDR. That rate is 7.7%.*

4. *BMA also assumes after the facility is certified, that four home dialysis patients residing in Wake and Nash Counties will transfer their care to the new facility. These patients reside in northern Wake County or western Nash County and are not near the home dialysis programs of facilities within those counties. The Louisburg location will be more convenient for these patients. Two patients are PD* [peritoneal dialysis] *patients and two are HH* [home hemodialysis] *patients.*

5. *Further, as the ESRD home population of Franklin County and new FMC Tar River facility increases, some patients will change their dialysis modality and begin home dialysis with FMC Tar River. BMA projects two patients per year in Operating Years 1 and 2 to change modality. BMA projects one patient each year will choose PD and one patient will choose HH. Thus, two in-center patients will be subtracted from the projected in-center census of Franklin County patients in Operating Years 1 and 2. This is not to say that BMA will restrict patient admissions to the home program, but rather that BMA will utilize extremely conservative projections for the purposes of this application.*

6. *BMA is **NOT** projecting that patients currently served by the DaVita dialysis facility in Louisburg will transfer their care. In addition, BMA projects that some of the future home patients from Franklin County will choose FMC Tar River as their dialysis provider. (BMA will not prohibit any patient from changing providers; the only requirement is proper referral from a physician with admitting privileges at the facility).* [Emphasis in original]

7. *BMA is suggesting that patients currently served by BMA and residing in Franklin County, or in Vance, Wake and Nash Counties, will transfer care to the facility.*

8. *The January 2013 SDR reports that the DaVita facility in Louisburg was underutilized on June 30, 2011 with a reported 79.35%* [sic] *utilization rate.*

9. *In his letter of support, Dr. Fred Jones, Medical Director for the proposed FMC Tar River facility, and President of the Capital Nephrology Associates, has indicated that he and his associates would extend their practice footprint into Franklin County by seeking admitting privileges at the Franklin Regional Medical Center in Louisburg. The significance of this is that Dr. Jones and his associates are already serving a significant portion of the Franklin County ESRD patient population.*

10. *This proposal by BMA is consistent with Policy ESRD 2. ESRD 2 says in part, 'Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties* ***currently served*** *by the facility.' [Emphasis added] Both of the facilities contributing dialysis stations to this proposal are currently serving at least one patient from Franklin County.* [Emphasis in original]

    Further, the relocation of these stations will not create a surplus of stations in Franklin County, nor will the relocations create a deficit in the counties losing stations. See discussion specific to Policy ESRD 2.

11. *This project is scheduled for completion and certification of stations at December 31, 2014.*
    Operating Year 1 is January 1 through December 31, 2015
    Operating Year 2 is January 1 through December 31, 2015 [sic]*."*

In Section III.7, page 73, the applicant projects that 31 in-center patients will initially transfer their treatment to the proposed Franklin County facility when it becomes operational in January 2015, including 25 Franklin County in-center dialysis patients and 6 in-center patients from other counties who have expressed their intention to transfer to the proposed facility. The applicant also projects that four home dialysis patients will transfer to the proposed Franklin County facility.

In Exhibit 22, the applicant provides 35 letters signed by current BMA patients as evidence of those patients' willingness to transfer their care to FMC Tar River when the facility is certified. Each letter includes the patient's signature, the name of the dialysis facility in which the patient currently receives treatment, and the county and ZIP code of the patient's residence. The project analyst prepared the following table to illustrate the information contained in the patient letters:

RESIDENCE ZIP CODE	CITY/TOWN	CURRENT DIALYSIS FACILITY/COUNTY	# LETTERS SIGNED
27597	Zebulon	BMA Zebulon / Wake	2
		Raleigh Dialysis / Wake	2
27544	Kittrell	Oxford Dialysis / Granville	1

		Neuse River Dialysis / Granville	2
27557	Middlesex	BMA Zebulon / Wake	2
27596	Youngsville	FMC Eastern Wake / Wake	2
		Wake Dialysis / Wake	1
		Raleigh Dialysis / Wake	1
27882	Spring Hope	BMA Zebulon / Wake	2
		Raleigh Dialysis / Wake	2
27587	Wake Forest	BMA Zebulon / Wake	1
		FMC Eastern Wake / Wake	1
27549	Louisburg	FMC Eastern Wake / Wake	4
		Wake Dialysis / Wake	1
		Oxford Dialysis / Granville	1
27525	Franklinton	FMC Eastern Wake / Wake	3
		Wake Dialysis / Wake	1
		Oxford Dialysis / Granville	1
		Neuse River Dialysis / Granville	2
27508	Bunn	BMA Zebulon / Wake	2
		FMC Eastern Wake / Wake	1
Total Letters			**35**

Thus, the applicant provides evidence that supports 35 existing in-center and home dialysis patients who are residents of Franklin, Vance, Wake, and Nash counties will consider transferring to the Franklin County facility when it becomes operational.

In Section III.8, page 73, the applicant provides a chart which projects utilization growth at the proposed Franklin County facility based on a starting census of 25 Franklin County in-center dialysis patients, and using the Franklin County 7.7% Five Year Average Annual Change Rate (AACR) as published in the January 2013 SDR. The projections also include six in-center patients who are residents of Vance, Wake and Nash counties, but who have expressed an interest in transferring to the proposed Franklin County facility. See the following table, from page 73:

BMA begins with the 25 Franklin County in-center dialysis patients currently served, as of March 15, 2013. This is the application filing date.	25 in-center patients
BMA projects this patient population forward for 9 months to December 31, 2013 using a growth rate of 7.7% as discussed.	[25 (0.077/12 X 9)] + 25 = 26.4
BMA projects this patient population forward for 12	(26.4 X 0.077) + 26.4 =

months to December 31, 2014 using the growth rate of 7.7%.	28.5
BMA adds the six patients from other counties who have expressed a desire for dialysis care and treatment by BMA in Louisburg. This is the projected beginning census for this project.	28.5 + 6 = 34.5
BMA projects the Franklin County patient population forward for 12 months to December 31, 2015. This is the end of Operating Year 1.	(28.5 X 0.077) + 28.5 = 30.7
BMA adds the six patients from other counties who have expressed a desire for dialysis care and treatment by BMA in Louisburg.	30.7 + 6 = 36.7
BMA subtracts two Franklin County patients who are projected to change modality to home dialysis. This is the projected Operating Year 1 ending census for the in-center program.	36.7 – 2 = 34.7
BMA projects the Franklin County patient population forward for 12 months to December 31, 2016. This is the end of Operating Year 2.	(28.7 x 0.077) + 28.7 = 30.9
BMA adds the six patients from other counties who have expressed a desire for dialysis care and treatment by BMA in Louisburg.	30.9 + 6 = 36.9
BMA subtracts two Franklin County patients who are projected to change modality to home dialysis. This is the projected Operating Year 2 ending census for the in-center program.	36.9 – 2 = 34.9

The Performance Standards for dialysis facilities, as promulgated in 10A NCAC 14C .2203(a), requires an applicant to "*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....*" In this application, the applicant adequately demonstrates that it will serve a total of 34 in-center patients on 10 stations at the end of the first operating year, which is 3.4 patients per station per week, or a utilization rate of 85% of capacity. Therefore, the applicant demonstrated that the proposed Franklin County facility would meet the minimum performance standard requirements in the Rule.

Access

The applicant projects 91.1% of its patients will be covered by Medicare and Medicaid. The applicant demonstrates adequate access for the medically underserved to its services.

In summary, the applicant adequately identified the population to be served, adequately demonstrated the need the population projected to be served has for the proposed project, and demonstrated all residents of the service area, and, in particular, underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the

effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to establish a new dialysis facility in Louisburg by transferring existing dialysis stations from two different facilities located in a contiguous county. In Section III.3, page 57, the applicant states:

> *"This proposal is designed to make more effective use of existing certified dialysis stations. As noted in the Policy ESRD-2 discussion (Section II of this application), there is currently a surplus of dialysis stations in Wake County and a deficit of stations in Franklin County. BMA proposes to mitigate the Franklin County deficit by transferring surplus stations to Franklin County. This action will not create a station deficit within Wake County, nor will it create a station surplus in Franklin County. The transferring facilities, BMA Zebulon and FMC Eastern Wake are* ***currently serving*** *patients from Franklin County."* [Emphasis in original].

In Section III.3 (d), page 65, the applicant states:

> *"To the extent that this could be considered a reduction of service at BMA Zebulon or FMC Eastern Wake, BMA notes that he projected utilization at these facilities is not negatively impacted and no patients will be denied treatment as a result of this transfer. … BMA Zebulon and FMC Eastern Wake will continue to have capacity to accept dialysis patients. BMA will apply for additional stations at these facilities using the Facility Need Methodology as each demonstrates need for additional stations."*

In Section III.3(c), pages 59-63, the applicant describes the impact of the proposed transfer of stations from BMA Zebulon and FMC Eastern Wake. In Section III.3(c), pages 59-61, the applicant describes the impact of the proposed transfer of stations from the BMA Zebulon facility as follows:

> *"<u>BMA Zebulon</u>*
>
> *BMA Zebulon is currently certified for 30 dialysis stations. According to the January 2013 SDR, the facility was operating at 72.5% utilization with 87 patients as of June 30, 2012. As of December 31, 2012 the facility had 90 patients.*
>
> *Transferring seven stations from BMA Zebulon to FMC Tar River will result in the facility having 23 stations. In this application, BMA projects that nine dialysis patients will transfer from BMA Zebulon to the FMC Tar River facility upon completion of the project and certification of the stations at FMC Tar River. The following table identifies the county of residence for the patients at BMA Zebulon as of December 32,* [sic] *2012:*

BMA ZEBULON	***DECEMBER 31, 2012 IN- CENTER***
Wake	*62*
*Franklin**	*7*
Johnston	*4*
Wilson	*2*
Nash	*14*
Vance	*1*
Total	***90***

**Note: Within Section II in response to Rule 10A NCAC 14C 2202 (a)(7) BMA reports only six Franklin County patients have signed letters of support for the project. The difference here is that the letters of support were obtained after December 31, 2012. It is probable that the one patient difference is a function of patient relocation, changing dialysis facilities, or possible expiring. However, the difference is a function of timing, not a typographical error or other oversight by BMA.*

The applicant proposes to relocate seven existing dialysis stations from BMA Zebulon, along with nine existing patients who are residents of Franklin, Wake and Nash counties, to the proposed dialysis facility in Franklin County.

In Section III.3, the applicant projects utilization at BMA Zebulon based on a starting census of 62 Wake County in-center dialysis patients, and using the Wake County 4.2% Five Year Average Annual Change Rate (AACR) as published in the January 2013 SDR. The projections also include 21 in-center patients who are residents of Johnston, Wilson, Nash and Vance counties. See the following table, from page 61 of the application:

BMA begins with the in-center patient population residing in Wake County as of December 31, 2012	62
BMA projects growth of this patient population for one year to December 31, 2013	(62 x 0.042) + 62 = 64.6
BMA projects growth of this patient population for one year to December 31, 2014. This is the projected certification date of this project.	(64.6 X .042) + 64.6 = 67.3
BMA subtracts the one Wake County patient projected to transfer to FMC Tar River.	67.3 – 1 = 66.3
BMA adds the 21 patients from Johnston, Wilson, Nash, and Vance Counties. BMA did not include the patients from Franklin County.	66.3 + 21 = 87.3

BMA subtracts the two patients from Nash County projected to transfer to FMC Tar River.	87.3 – 2 = 85.3

Thus, the applicant projects BMA Zebulon will operate at 92.4% of capacity, with 85 in-center patients dialyzing on 23 stations as of December 31, 2014, which is the projected certification date of the proposed FMC Tar River facility. Therefore, the applicant demonstrates that the needs of the population presently served at the BMA Zebulon facility will continue to be adequately met.

In Section III.3(c), pages 61-63, the applicant describes the impact of the proposed transfer of stations from the FMC Eastern Wake facility as follows:

> *"FMC Eastern Wake*
>
> *FMC Eastern Wake is currently certified for 14 dialysis stations. According to the January 2013 SDR, the facility was operating at 82.14% utilization with 46 patients as of June 30, 2012. As* [of] *December 31, 2012 the facility had 41 patients dialyzing on 14 stations.*
>
> *In this application, BMA projects that 11 Franklin County patient* [sic] *will transfer from FMC Eastern Wake to the FMC Tar River facility upon completion of the project and certification of the stations at FMC Tar River. The following table identifies the county of residence for the patients at FMC Eastern Wake as of December 31, 2012:*

FMC EASTERN WAKE	***DECEMBER 31, 2012 IN- CENTER***
Wake	*33*
*Franklin**	*7*
Johnston	*1*
Total	***41***

> **Note: Within Section II in response to Rule 10A NCAC 14C 2202 (a)(7) BMA reports only* [sic] *11 Franklin County patients have signed letters of support for the project. The difference here is that the letters of support were obtained after December 31, 2012. It is probable that the patient difference is a function of patient admissions to FMC Eastern Wake. However, the difference is a function of timing, not a typographical error or other oversight by BMA.*
>
> *In addressing the needs of patients continuing to dialyze at FMC Eastern Wake subsequent to the transfer of three stations to FMC Tar River, BMA will project growth of the FMC Eastern Wake patient population to the projected date of project completion and certification of the new FMC Tar River facility: December 31, 2014. BMA assumes that the Wake County patients will continue to dialyze at FMC Eastern Wake. BMA will project 11 patients from Franklin County to transfer from FMC Eastern Wake to the new facility upon completion of the project. BMA will assume*

that the one patient from Johnston County will continue to dialyze at the FMC Eastern Wake as a function of patient choice."

The applicant proposes to relocate three existing dialysis stations from FMC Eastern Wake, along with 11 existing patients who are residents of Franklin County, to the proposed dialysis facility in Franklin County. Note: As of December 31, 2012, FMC Eastern Wake was serving 7 Franklin County residents. By the time this application was prepared, that number had increased to 11 Franklin County residents.

In Section III.3, the applicant projects utilization at FMC Eastern Wake based on a starting census of 33 Wake County in-center dialysis patients, and using the Wake County 4.2% Five Year Average Annual Change Rate (AACR) as published in the January 2013 SDR. The projections also include one in-center patient who is a resident of Johnston County. See the following table, from page 62 of the application:

BMA begins with the in-center patient population residing in Wake County as of December 31, 2012	33
BMA projects growth of this patient population for one year to December 31, 2013.	(33 X .042) + 33 = 34.4
BMA projects growth of this patient population for one year to December 31, 2014. This is the projected certification date of this project.	(34.4 X .042)) + 34.4 = 35.8
BMA adds the one Johnston County patient. The patients from Franklin County are assumed to transfer.	35.8 + 1 = 36.8

Thus, the applicant projects FMC Eastern Wake will operate at 84.1% of capacity, with 37 in-center patients dialyzing on 11 stations as of December 31, 2014, the projected certification date of the proposed FMC Tar River facility. Therefore, the applicant demonstrates that the needs of the population presently served at the FMC Eastern Wake facility will continue to be adequately met.

The applicant proposes to develop a new 10-station dialysis facility in Louisburg in Franklin County by relocating existing stations from two dialysis facilities in Wake County. The applicant adequately demonstrates that the two facilities from which dialysis stations would be transferred would have sufficient capacity following the transfer of stations to the proposed Franklin County facility. Thus, the applicant adequately demonstrates that the needs of the population presently served will be met adequately by the proposed relocation of dialysis stations. Therefore, the application is conforming to this criterion.

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

CA

In Section III.9, pages 74-75, the applicant discusses the alternatives it considered prior to submitting this application, which include

a) not developing the proposed facility at all, which was rejected because the applicant states it currently serves Franklin County residents and projects the population to increase.
b) selecting a different location within Franklin County to develop the facility. This proposal was rejected because the applicant states Louisburg is the *"most logical"* choice, given the current residence of existing patients.

With regard to location, in Section III.3(d), page 63, the applicant states,

> *"As BMA has evaluated its existing patient population of Franklin County dialysis patients BMA has sought to find a point most common to all patients and in close proximity to the Franklin Regional Medical Center. By locating close to the hospital, BMA will enable patients to combine their dialysis treatment with other medical appointments."*

After considering those alternatives, the applicant states the alternative represented in the application is the most 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 its proposal is the least costly or most effective alternative to meet the 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 FMC Tar River shall materially comply with all representations made in the certificate of need application.**

2. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Tar River shall relocate no more than 10 dialysis stations to FMC Tar River, which shall include any isolation or home hemodialysis stations.**

3. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Tar River shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations which shall include any isolation or home hemodialysis stations.**

4. **Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify seven dialysis stations at BMA Zebulon for a total of no more than 23 dialysis stations at BMA Zebulon.**

5. **Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify three dialysis stations at FMC Eastern Wake for a total of no more than 11 dialysis stations at FMC Eastern Wake.**

6. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Tar River 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.

C

In Section VIII.1, page 97, the applicant projects that the total capital cost will be $1,518,384, including $999,436 in construction costs, $164,050 for water treatment equipment, $156,010 for additional equipment, and $198,888 in architect and engineering fees and contingencies. In Section VIII.5, page 99, the applicant states Fresenius Medical Care Holdings, Inc., parent company of BMA, will finance the project with accumulated reserves. In Section IX.3, page 104, the applicant states there will be $100,406 in start-up expenses. In Section IX.2, page 103, the applicant states there will be $1,123,090 in initial operating expenses, for a total working capital requirement of $1,223,496. In Exhibit 24, the applicant provides a March 15, 2012 letter from the Vice President of Fresenius Medical Care Holdings, Inc., which states:

> *"This is to inform you that Fresenius Medical Care Holding, Inc. is the parent company of National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc.*
>
> *BMA proposes to develop a new 10 station dialysis facility in Louisburg, Franklin County by transferring 10 existing and certified dialysis stations from Wake County into Franklin County. The project calls the following capital expenditures on behalf of BMA.*
>
> | | |
> |---|---|
> | *Capital Expenditure* | *$1,518,384* |
> | *Start-up Expenses* | *$ 100,406* |
> | *Working Capital (first eight months operations)* | *$1,123,090* |
> | *Total Required* | *$2,741,880* |
>
> *As Vice President, I am authorized and do hereby authorize the development of this 10 station dialysis facility, Fresenius Medical Care Tar River, for capital costs of $1,518,384 and $1,223,496 in startup and working capital. Further, I am authorized and do hereby authorize and commit all necessary cash and cash reserves for the start up and working capital which may be needed for this project."*

In Exhibit 10, the applicant provides the audited financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ended December 31, 2010 and 2011. As of December 31, 2011, Fresenius Medical Care Holdings, Inc. and Subsidiaries had cash and cash equivalents totaling $204,142,000 with $13,864,530,000 in total assets and $7,881,326,000 in net assets (total assets less total liabilities). The applicant adequately demonstrated the availability of funds for the capital and working capital needs of the project.

In Section X.1, page 105, the applicant provides projected allowable charges per treatment for each payment source as follows:

FMC Tar River	
Source of Payment	In-Center Charge Per treatment
Commercial Insurance	$1,375.00
Medicare	$234.00
Medicaid	$137.29
VA	$147.85
Private Pay	$1,375.00

The Medicare/Medicaid rates in Section X.1 of the application are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.

The applicant projects net revenue in Section X.2 of the application and operating expenses in Section X.4 of the application, pages 106-110, as illustrated in the table below.

FMC TAR RIVER	**CY2015 PY1**	**CY2016 PY 2**
Net Revenue	$1,838,249	$2,009,543
Operating Expenses	$1,746,081	$1,862,150
Profit (Loss)	**$92,168**	**$147,393**

The applicant projects that revenue will exceed operating expenses in each of the first two operating years. Operating costs and revenues are based on reasonable assumptions including projected utilization. See Sections X.2 and X.4, pages 106-110, for the assumptions. See Criterion (3) for discussion regarding utilization assumptions which is incorporated hereby as if set forth fully herein. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of operating costs and revenues.

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

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

C

The applicant proposes to develop a new 10-station dialysis facility in Louisburg by relocating 10 existing stations from two BMA facilities in Wake County. On page 29, the applicant states,

> *BMA is **NOT** projecting that patients currently served by the DaVita dialysis facility in Louisburg will transfer their care. In addition, BMA projects that some of the future home patients from Franklin County will choose FMC Tar River as their dialysis provider. (BMA will not prohibit any patient from changing providers; the only requirement is proper referral from a physician with admitting privileges at the facility).* [Emphasis in original]

On pages 86-87, the applicant states,

> *"CON Section approval of this application will necessarily result in a new in-center dialysis facility to serve the ESRD patient population of Franklin County and surrounding areas. Therefore a new competitive element will be introduced. At the present time the only provider of in-center dialysis services within the County is the DaVita facility. However, BMA has long been a provider of care for the ESRD patients of Franklin County. Consider the January 2013 SDR. Table B of the SDR indicates that there were 117 dialysis patients residing in Franklin County as of June 30, 2012. Table B further indicates that there were 14 home dialysis patients in the County. Thus, there were 103 in-center dialysis patients in the County. However, Table A indicates that the DaVita facility was providing care to only 69 in-center patients as of June 30, 2012. Thus at June 30, 2012 there were 34 in-center patients, 33% of the in-center patient population, leaving the county for dialysis treatment. BMA was providing treatment for the overwhelming majority of those patients. BMA has included many patient letters of support from patients who reside in Franklin County. Thus, while development of "bricks and mortar" may be construed as the introduction of a competitive force within the County, BMA suggests that the competition between providers has been ongoing for many years.*
>
> *Indeed, BMA has been providing dialysis treatment to a significant portion of the Franklin County ESRD patient population as is noted within this application. Further, the physicians of Capital Nephrology are likewise providing medical coverage for patients from Franklin County. In fact, the physicians for Capital Nephrology Associates report that at the present time they are providing care for a large number of Stage 3, 4, and 5 Chronic Kidney Disease patients from Franklin County. Thus, while approval of this application will allow introduction of a new dialysis provider into the county, the reality is that approval of this application will not significantly alter the competitive climate of Franklin County. BMA is already serving dialysis patients from Franklin County.*

This proposal does increase the number of dialysis stations within Franklin County; and will completely resolve the 10 station deficit reported in the January 2013 SDR. BMA does not anticipate that this proposal will have any effect upon dialysis facilities in Franklin County. BMA projections of patients to be served by the facility are a function of the existing patient population served by BMA coupled with growth of that population. BMA has not asserted that it would capture 100% of new dialysis patients in Franklin County. Rather, BMA projections of future patient populations also anticipate that the patient population of the DaVita clinic would increase at the same rate proposed by BMA."

There is currently one dialysis facility located in Louisburg, Dialysis Care of Franklin County, which is operated by DaVita. The DaVita facility is located less than one mile from the proposed FMC Tar River location. The following table shows the utilization of DaVita's Franklin County facility based on data reported in the Semi-Annual Dialysis Reports from July 2009 to January 2013.

DATE OF SDR	# PATIENTS	# STATIONS	% UTILIZATION
January 2009	73	23	79%
July 2009	75	23	81%
January 2010	76	23	82%
July 2010	70	23	76%
January 2011	70	23	76%
July 2011	71	23	77%
January 2012	73	23	79%
July 2012	70	23	76%
January 2013	69	23	75%
Average Utilization January 2009 to January 2013			**78%**

The data shows that the existing facility in Louisburg has operated at an average utilization rate of 78 percent over the past three and a half years, and has operated above 80% utilization during two of the last nine SDR reporting periods. There are no other providers of dialysis services in Franklin County.

In this application, the applicant demonstrates that it will serve a total of 34 in-center patients on 10 stations at the end of both the first and second operating years, which is 3.4 patients per station per week, or a utilization rate of 85% of capacity. Also, the applicant's utilization projections are based entirely on patients currently served at existing BMA facilities in other counties who have expressed their intention to transfer to the proposed Franklin County facility.

Consequently, the applicant adequately demonstrates the proposed project would not result in the unnecessary duplication of existing or approved dialysis services or facilities in Franklin County. Therefore, the application is conforming with 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 VII.1, page 93, the applicant projects the number of FTE positions following completion of the proposed project, as illustrated in the table below.

POSITION	PROJECTED # OF FTES
RN	2.50
Tech	4.25
Clinical Manager	1.00
Medical Director	Contract Position
Administration	0.15
Dietitian	0.25
Social Worker	0.25
Home Training Nurse	0.75
Medical Records	0.50
Chief Tech	0.10
Equipment Tech	0.35
In-Service	0.15
Clerical	0.50
Total	**10.75**

In Section V.4(c), page 83, the applicant states Dr. Fred Jones will be the Medical Director for FMC Tar River. In Exhibit 21, the applicant provides a March 15, 2013 letter signed by Dr. Jones that confirms his commitment to serve as Medical Director. In Exhibit 23, the applicant provides a copy of Dr. Jones's curriculum vitae, which confirms he is board-certified in internal medicine and nephrology. In Section VII.4, page 94, the applicant states it anticipates no difficulty in hiring the necessary staff for the FMC Tar River dialysis facility, and describes the experience it has in recruiting and hiring staff necessary to operate dialysis facilities. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section V.1, page 79, the applicant lists the providers of the necessary ancillary and support services to be provided for the proposed facility. Exhibits 16-22 contain documents which demonstrate the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information in Section V.1

and Exhibits 16-22 is reasonable and credible and supports a finding of conformity with this criterion.

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

NA

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

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

NA

(11) Repealed effective July 1, 1987.

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

C

In Section XI.6(h), page 118 of the application, the applicant states an unrelated developer will construct 8,000 square feet of shell space for the proposed dialysis facility in Louisburg which the applicant will upfit and lease. In Section XI.6(d), pages 116-117 of the application, the applicant states that applicable energy saving features and water treatment equipment will be incorporated into the construction plans in the following ways:

- HVAC system operating efficiency will equal *"industry standards for high seasonal efficiency."*

- Facility will use energy efficient exit signs, external insulation wrap for hot water heaters, water flow restrictors at sink faucets, and other methods of energy conservation.
- Water treatment system will allow for a percentage of the concentrate water to be re-circulated into the supply feed water, thus lowering water discharge quantity; and will use three-phase electric motors, which use less amperage.

Costs and charges are described by the applicant in Section X of the application, pages 105-111. See discussion in Criterion (5) regarding costs and charges which is incorporated hereby as if set forth fully herein.

The applicant adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

(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 VI.1(a), page 88, the applicant states:

"BMA has a long history of providing dialysis services to the underserved populations of North Carolina. … 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 FMC Tar River facility is expected to be similar to the facilities contributing stations to the project, and will likely be comprised of the following:

Facility	*Medicaid/ Low Income*	*Elderly (65+)*	*Medicare*	*Women*	*Racial Minorities*
FMC Tar River	*27.5%*	*47.0%*	*83.5%*	*44.0%*	*73.5%*

…It is clear that FMC Tar River projects to provide 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."

In Section VI.1(b), page 89, the applicant provides a table which combines the historical payer mix for the two Wake County BMA facilities, BMA Zebulon and FMC Eastern Wake, that are contributing stations to the proposed facility, which is summarized below:

Historical Payer Source for Wake County BMA Facilities

PAYER SOURCE	IN-CENTER
Commercial Insurance	5.2%
Medicare	85.0%
Medicaid	6.1%
VA	3.1%
Other: Self/Indigent	0.6%
Total	100.0%

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 Franklin, Nash, Vance and Wake counties, and statewide.

	June 2010 Total # of Medicaid Eligibles as % of Total Population *	**June 2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population ***	**CY 2009 % Uninsured (Estimate by Cecil G. Sheps Center)***
Franklin County	18%	7.4%	19.7%
Nash County	20%	8.7%	19.7%
Vance County	30%	13.4%	22.8%
Wake County	10%	3.3%	18.4%
Statewide	17%	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 BMA's Wake County facilities that will be contributing stations to the proposed Franklin County facility. In fact, only 5.8% of all newly-diagnosed ESRD patients (incident ESRD patients) in North Carolina's Network 6 were under the age of 35.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race and gender. However, a direct comparison to the applicant's current payer mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. About 25% of the Medicare-covered patients had employer group health plans as primary insurance, with Medicare as the secondary payer. Also, the CMS website states:

"Although the ESRD population is less than 1% of the entire U.S. population it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings. …

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9) populations."

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report (page 225) provides these national statistics for FY 2010:

"On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy."

Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

"Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. …Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively."

The report provides 2010 ESRD spending, by payer as follows:

ESRD Spending by Payer		
Payor	**Spending in Billions**	**% of Total Spending**
Medicare Paid	$29.6	62.32%

Medicare Patient Obligation	$4.7	9.89%
Medicare HMO	$3.4	7.16%
Non-Medicare	$9.8	20.63%

Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 340.

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender, as shown below:

Number and Percent of Dialysis Patients by Age, Race and Gender		
	# of ESRD Patients	**% of Dialysis Population**
Ages		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%

Other	219	2.3%

Source: Southeastern Kidney Council (SKC) Network 6.
Includes North Carolina, South Carolina and Georgia

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services and 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), pages 90-91, 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 VI.6(a), page 92, 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(c), page 89, the applicant states:

"Projections of future in-center reimbursement [are] *a function of historical performance of the facilities contributing stations to this project. The facilities contributing stations to the project are operating in Wake County."*

FMC Tar River Projected Patient Payer Source

PAYER SOURCE	IN-CENTER DIALYSIS	HOME HEMODIALYSIS	HOME PERITONEAL DIALYSIS
Commercial Insurance	5.2%	87.0%	24.9%
Medicare	85.0%	10.0%	70.7%

Medicaid	6.1%	0.7%	1.1%
VA	3.1%	2.3%	2.2%
Other: Self/Indigent	0.6%	0.0%	1.1%
Total	100.0%	100.0%	100.0%

As shown in the table above, the applicant projects that 91.1% of in-center patients will be Medicare or Medicare/Medicaid beneficiaries. The applicant demonstrates that medically underserved populations would 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(a), page 91, the applicant states:

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

The applicant adequately demonstrated that it will provide a range of means by which a person can access 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, page 82, the applicant states, *"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."* Exhibit 19 contains a copy of a letter from the Director of Operations for Fresenius Medical Care to the Department Head of the Nursing Program for Wake Technical Community College offering FMC Tar River as a clinical training site. The information provided in Section V.1 is reasonable and credible and supports a finding of conformity to this criterion.

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

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

C

The applicant proposes to develop a new 10-station dialysis facility in Louisburg (Franklin County) by transferring existing stations from two BMA facilities in Wake County. There is currently only one dialysis facility in Franklin County, Dialysis Care of Franklin County. That 23-station facility is operated by Davita, and is located in Louisburg.

In Section V.7, the applicant discusses the impact of the proposed project on competition as it relates to promoting cost-effectiveness, quality and access. The applicant estimates its 2012 Franklin County market share as 33 percent, and states that BMA already actively and effectively competes for dialysis patients in Franklin County. Further, the applicant states projected utilization for the proposed dialysis facility relies entirely on the assumption that only existing BMA patients will transfer to the FMC Tar River facility. As such, the applicant argues that the proposal will enable BMA to continue to effectively compete for Franklin County dialysis patients, but will not significantly change the "*competitive climate*" in Franklin County, nor will it significantly impact the utilization of the existing Franklin County dialysis facility, which is operated by DaVita. On pages 86-87, the applicant states,

> *"CON Section approval of this application will necessarily result in a new in-center dialysis facility to serve the ESRD patient population of Franklin County and surrounding areas. Therefore a new competitive element will be introduced. At the present time the only provider of in-center dialysis services within the County is the DaVita facility. However, BMA has long been a provider of care for the ESRD patients of Franklin County. Consider the January 2013 SDR. Table B of the SDR indicates that there were 117 dialysis patients residing in Franklin County as of June 30, 2012. Table B further indicates that there were 14 home dialysis patients in the County. Thus, there were 103 in-center dialysis patients in the County. However, Table A indicates that the DaVita facility was providing care to only 69 in-center patients as of June 30, 2012. Thus at June 30, 2012 there were 34 in-center patients, 33% of the in-center patient population, leaving the county for dialysis treatment. BMA was providing treatment for the overwhelming majority of those patients. BMA has included many patient letters of support from patients who reside in Franklin County. Thus, while development of "bricks and mortar" may be construed as the introduction of a competitive force within the County, BMA suggests that the competition between providers has been ongoing for many years.*

Indeed, BMA has been providing dialysis treatment to a significant portion of the Franklin County ESRD patient population as is noted within this application. Further, the physicians of Capital Nephrology are likewise providing medical coverage for patients from Franklin County. In fact, the physicians for Capital Nephrology Associates report that at the present time they are providing care for a large number of Stage 3, 4, and 5 Chronic Kidney Disease patients from Franklin County. Thus, while approval of this application will allow introduction of a new dialysis provider into the county, the reality is that approval of this application will not significantly alter the competitive climate of Franklin County. BMA is already serving dialysis patients from Franklin County.

This proposal does increase the number of dialysis stations within Franklin County; and will completely resolve the 10 station deficit reported in the January 2013 SDR. BMA does not anticipate that this proposal will have any effect upon dialysis facilities in Franklin County. BMA projections of patients to be served by the facility are a function of the existing patient population served by BMA coupled with growth of that population. BMA has not asserted that it would capture 100% of new dialysis patients in Franklin County. Rather, BMA projections of future patient populations also anticipate that the patient population of the DaVita clinic would increase at the same rate proposed by BMA.

This facility will have the added value stemming from the strength of our relationship with the nephrology physicians at Capital Nephrology. The practice brings together a team of eight highly qualified nephrologists to serve the ESRD patient needs of the area.

BMA facilities are compelled to operate at maximum 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 86.4% of the in-center patients will be relying upon either Medicare or Medicaid. 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. BMA has eliminated the re-use concept in its facilities and provides every patient a new dialyzer at each treatment. Every effort is made to (a) ensure that the applicant thoroughly plans for success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This facility will be no different. … This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives."

Note: The applicant states on page 87 that *"86.4% of in-center patients will be relying upon either Medicare or Medicaid."* However, that percentage is actually 91.1% (85.0% + 6.1% = 91.1%] (See page 89).

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to dialysis services in Franklin County. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need to relocate ten dialysis stations from Wake County to Franklin County, and that it is a cost-effective alternative to meet that need;

- The applicant adequately demonstrated it will continue to provide quality services; and

- The applicant adequately demonstrated it will continue to provide adequate access to medically underserved populations.

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

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

C

The applicant proposes to relocate stations from two of its Wake County facilities, BMA Zebulon and FMC Eastern Wake, to a new facility in Franklin County. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, those Wake County facilities have operated in compliance with all Medicare Conditions of Participation within the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

The 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, which are discussed below:

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) Utilization rates;
-C- See Section II.1, page 12, and Exhibit 2 (copy of the January 2013 SDR, Tables A and B), the applicant provides the utilization rates for BMA Zebulon and FMC Eastern Wake.

.2202(a)(2) Mortality rates;
-C- In Section IV.2, page 76, the applicant reports 2010, 2011 and 2012 facility mortality rates for BMA Zebulon and FMC Eastern Wake.

.2202(a)(3) The number of patients that are home trained and the number of patients on Home dialysis;
-NA- In Section IV.3, page 77, the applicant states that neither BMA Zebulon nor FMC Eastern Wake have a home dialysis program or any home-trained patients.

.2202(a)(4) The number of transplants performed or referred;
-C- In Section IV.4, page 77, the applicant reported that BMA Zebulon referred 27 patients for transplant evaluation in 2012, and no patients received transplants in 2012. FMC Eastern Wake referred 4 patients for transplant evaluation in 2012, and no patients received transplants in 2012.

.2202(a)(5) The number of patients currently on the transplant waiting list;
-C- In Section IV.5, page 77, the applicant states that BMA Zebulon has 8 patients on the transplant waiting list, and that FMC Eastern Wake has no patients on the transplant waiting list.

.2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;
-C- In Section IV.6, page 77, for BMA Zebulon, the applicant reports a total of 135 hospital admissions in 2012; 73% were non-dialysis related and 27% were dialysis-related. For FMC Eastern Wake, the applicant reports a total of 27 hospital admissions in 2012; 100% were non-dialysis related.

.2202(a)(7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.
-C- In Section IV.7, page 78, the applicant reports that in 2012 there were no patients

with an infectious disease, and no patients converted to infectious status in 2012 at either BMA Zebulon or FMC Eastern Wake.

(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:

.2202(b)(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

-C- Exhibit 16 contains a copy of an *"Affiliation Agreement"* between the applicant and WakeMed that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility.

.2202(b)(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.

-C- Exhibit 17 contains a copy of a *"Transplant Center Evaluation Services Agreement"* between the applicant and Duke University Medical Center that includes the information required by this rule.

.2202(b)(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.

-C- In Section II.1, page 14, the applicant states power and water are available at the proposed site. Exhibit 30 contains a copy of a letter from the Town Administrator for the Town of Louisburg that states water and power are available to the proposed site.

.2202(b)(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.

-C- Exhibit 12 contains a copy of written policies and procedures for back up for electrical service in the event of a power outage.

.2202(b)(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.*

-C- In Section II.1, pages 14-15, the applicant states, *"A copy of an e-mail exchange to Jim Swann is included in the site information to confirm that the sites remain available. … BMA neither owns nor controls either of the sites but has included information on two sites which are available for acquisition."* Exhibit 30 contains copies of correspondence between the applicant and real estate broker confirming the two sites are available.

.2202(b)(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- See Sections II.1, page 15; VII.2, page 94 and XI.6(g), page 117.

.2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- In Section II.1, page 16, FMC Tar River provided projected patient origin, which the applicant states is based on the patient origin of its existing patients who have expressed an interest in transferring to the proposed facility.

.2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-C- In Section II.1, page 23, the applicant states, *"BMA reasonably expects that 100% of the patient population of this facility resides well within 30 miles of the facility. Thirty miles from Louisburg covers the entirety of Franklin County."*

.2202(b)(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 for such services.*

-C- In Section II.1, page 23, 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."*

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.

-C- In Section II.1, pages 24-32, the applicant demonstrates that it will serve a total of 34 in-center patients on 10 stations at the end of the first operating year, which is 3.4 patients per station per week, or a utilization rate of 85%. Therefore, the applicant demonstrated that the proposed Franklin County facility would meet the minimum performance standard requirements in this rule.

.*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.*

-NA- The applicant is not 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.

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

-C- In Section II.1, pages 24-32, the applicant provides the assumptions and methodology used to project utilization of the facility.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

.2204(1) *Diagnostic and evaluation services;*

-C- Provided by Franklin Regional Medical Center or WakeMed. See Section V.1, page 79.

.*2204(2)* *Maintenance dialysis;*

-C- Provided by the applicant. See Section V.1, page 79.

.*2204(3)* *Accessible self-care training;*

-C- Provided by the applicant. See Section V.1, page 79.

.*2204(4)* *Accessible follow-up program for support of patients dialyzing at home;*

-C- Provided by the applicant and through BMA Raleigh. See Section V.1, page 79 and V.2(d), page 81.

.*2204(5)* *X-ray services;*

-C- Provided by Franklin Regional Medical Center or WakeMed. See Section V.1, page 79.

.*2204(6)* *Laboratory services;*
-C- Provided by Sprectra Laboratories. See Section V.1, page 79, and Exhibit 18.

.*2204(7)* *Blood bank services;*
-C- Provided by Franklin Regional Medical Center or Rex Hospital. See Section V.1, page 79.

.*2204(8)* *Emergency care;*
-C- Provided by local hospital (Franklin Regional Medical Center). See Section V.1, page 79.

.*2204(9)* *Acute dialysis in an acute care setting;*
-C- Provided by WakeMed. See Section V.1, page 79.

.*2204(10)* *Vascular surgery for dialysis treatment patients*
-C- Provided by Premier Surgical, Carolina Vascular, Duke Vascular, or Millenium Vascular. See Section V.1, page 79.

.*2204(11)* *Transplantation services;*
-C- Provided by Duke University Hospital. See Section V.1, page 79.

.*2204(12)* *Vocational rehabilitation counseling and services; and,*
-C- Provided by Vocational Rehabilitation of Louisburg. See Section V.1, page 79.

.*2204(13)* *Transportation*
-C- Provided by KARTS. See Section V.1, page 79.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

.*2205(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 93, the applicant provides the proposed staffing. In Section VII.2, page 94, the applicant states the proposed facility will comply with all staffing requirements set forth in the Federal code. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for additional discussion which is incorporated hereby as if set forth fully herein.

.*2205(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- See Section II.1, pages 41-42, Section VII.3, page 94, and Exhibits 14 and 15.