

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: February 27, 2011

PROJECT ANALYST: Tanya S. Rupp

CON CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: M-8743-11 / Total Renal Care of North Carolina, LLC d/b/a Spring Lake Dialysis / Develop a new eleven-station dialysis facility on Buffalo Lakes Road / Harnett County

M-8752-11 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anderson Creek / Develop a new eleven-station dialysis facility on Highway 87 / Harnett 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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Both Applicants

The 2011 State Medical Facilities Plan (2011 SMFP) and the July 2011 Semiannual Dialysis Report (SDR) provide a county need methodology for determining the need for additional dialysis stations and facilities. According to Section 2(E) of the dialysis station county need methodology, found on page 333 of the 2011 SMFP, *“If a county’s December 31, 2010 projected station deficit is ten or greater and the July SDR shows that utilization of each dialysis facility in the county is 80 percent or greater, the December 31, 2011 county station need determination is the same as the December 31, 2010 projected station deficit. ...”* The county need methodology for 2011 results in a need determination for 11 dialysis stations in Harnett County. Two applications were received by the Certificate of Need Section for development of the 11 dialysis stations. Each applicant proposed the development of a new 11-station dialysis facility in southwestern Harnett County. The two applicants collectively applied for a total of 22 dialysis stations. Pursuant to the need determination in the 2011 SMFP and the

July 2011 SDR, 11 dialysis stations is the limit on the number of dialysis stations that may be approved in this review. A competitive review of these applications began on October 1, 2011. Following is a brief description of the two proposals submitted in this review:

- **M-8743-11 Total Renal Care of North Carolina, LLC d/b/a Spring Lake Dialysis** proposes to develop a new 11-station dialysis facility in southwest Harnett County, in response to the county need methodology. In Section I.8, pages 2 - 3 of the application, the applicant states the facility will offer in-center hemodialysis and training in peritoneal dialysis on eleven dialysis stations, including one isolation station.
- **M-8752-11 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anderson Creek** proposes to develop a new 11-station dialysis facility in southwest Harnett County, in response to the county need methodology. In Section I.8, page 2 of the application, the applicant states the facility will offer in-center hemodialysis, peritoneal dialysis, and training in home hemo-dialysis on eleven dialysis stations, including one isolation station and one station dedicated to home training.

There is one policy in the 2011 SMFP applicable to the review of two of the applications submitted for review. Policy Gen-3, on page 40 of the 2011 SMFP 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.”*

Both applications propose dialysis stations in Harnett County in response to a need determination in the 2011 SMFP.

### **M-8743-11 Total Renal Care of North Carolina, LLC d/b/a Spring Lake Dialysis:**

#### Promote Safety and Quality

In Section II.3, page 37, the applicant states:

*“DaVita Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita’s Quality Management Program is facilitated by a dedicated clinical team of Registered Nurses who make up our Clinical Support Services and Biomedical Quality Management Coordinators working under the direction of our Director of Clinical Support Services and Area*

*Biomedical Administrator. These efforts receive the full support and guidance of the clinical executive leadership team of DaVita. Combined, this group brings hundreds of years of ESRD experience to the program. The program exemplifies DaVita's total commitment to enhancing the quality of patient care through its willingness to devote the necessary resources to achieve our clinical goals...."*

In addition, in Section II.3, page 38, the applicant states:

*DaVita has a quality improvement program, IMPACT (Incident Management of Patients Actions Centered on Treatment), with focus care in the first 90 days to improve key indicators and to address the elevated risk of mortality for patients new to dialysis. IMPACTing the key indicators of Access, Anemia, Adequacy, Albumin, Fluid control and Mineral Bone Disorders in an effort to reduce mortality and morbidity [sic]. Critical components include the Intake Process, Patient Education, Management Tools and Reporting Mechanisms. Each DaVita facility, region and division receives a monthly IMPACT scorecard which provides an overall grade and score by individual indicator as compared to the DaVita Village (Company) as a whole."*

In addition, in Exhibit 26 the applicant provides a copy of *DaVita, Inc. Health and Safety, Policy and Procedure Manual* that describes DaVita's policies with regard to safety in the dialysis facility. In Exhibit 4, the applicant provides a copy of publications and articles about DaVita and its approach to safety and quality in clinical outcomes. Therefore, the applicant adequately demonstrates the methods by which it proposes to promote safety and quality in the provision of dialysis services in Harnett County.

#### Document Plans for Access to Healthcare by Underserved

In Section VI.1, page 60, the applicant states,

*"Spring Lake Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. We will serve patients without regard to race, sex, age, or handicap. We serve patients regardless of ethnic or socioeconomic situation.*

*Spring Lake Dialysis will make every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. The facility will provide dialysis six days per week with two patient shifts per day to accommodate patient need.*

*Spring Lake Dialysis will not require payment upon admission to its services; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons."*

The applicant adequately documented its plans for providing access to health care by the underserved groups.

### Maximize Healthcare Value

In Section III.9, on page 51, the applicant states,

- *“This application calls for the development of a new, state of the art facility that will require the purchase of hundreds of items that will include dialysis machines, chairs and TVs. The parent corporation, DaVita, operates over 1,400 dialysis facilities nationwide. The corporation has a centralized purchasing department that negotiates national contracts with numerous vendors in order to secure the best product available at the best price. We will be purchasing the equipment for this project under this procedure.*
- *Spring Lake Dialysis will purchase all of the products utilized in the facility, from office supplies to drugs to clinical supplies, under a national contract in order to secure the best products at the best price.*
- *Spring Lake Dialysis will utilize the reuse process that contains costs and the amount of dialyzer waste generated by the facility. The dialyzers are purchased under a national contract in order to get the best quality dialyzer for the best price.*
- *Spring Lake Dialysis will install an electronic patient charting system that reduces the need for paper in the facility. Much of the other documentation in the facility will also be done on computer which reduces the need for paper.*
- *Spring Lake Dialysis Bio-Medical Technician assigned to the facility will conduct preventative maintenance on the dialysis machines on a monthly, quarterly, and semi-annual schedule that reduces the need for repair maintenance and parts. This will extend the life of the dialysis machines.”*

The applicant adequately documents its plans for providing access to services for patients with limited financial resources. Furthermore, the applicant adequately demonstrates that projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served, because the applicant’s projection of need is based upon supported and reliable assumptions of the patients proposed to be served by the dialysis facility. See Criterion (3) for additional discussion. Consequently, the application is consistent with Policy Gen-3, is consistent with the need determination and therefore is conforming to this criterion.

### **M-8752-11 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anderson Creek:**

#### Promote Safety and Quality

In Section II.3, pages 26 – 27, the applicant states:

*“BMA is a high quality health care provider. The Table at II.3 D provides a comparison of quality indicators for the FMC Anderson Creek facility. In addition, BMA parent company, Fresenius Medical Care, encourages all BMA facilities to attain the FMC UltraCare® certification. This is not a one time test, but rather is an ongoing*

*process aimed at encouraging all staff, vendors, physicians, and even patients to be a part of the quality care program. Facilities are evaluated annually for UltraCare certification.”*

The applicant refers to a table at Section II.3D; however, there is no table as referenced. Nevertheless, in Section II.3D, the applicant describes how FMC adheres to CMS standards of quality referred to as “*Core Quality Initiatives.*” The applicant states FMC has established goals for its facilities that are “*more stringent than the national averages for [quality indicators].*”

In addition, in Section II.2, page 27, the applicant describes the *UltraCare* certification values to which BMA strives to adhere:

*“[The UltraCare] Mission Statement is: Through UltraCare, improving the quality of life of every patient, every treatment.*

*All of the nearly 40,000 FMCNA employees share the company’s UltraCare commitment of delivering excellent care to patients through innovative programs, the latest technology, continuous quality improvement and a focus on superior customer service. UltraCare is delivered by highly trained staff and demonstrated through dedication, leadership and compassion, by every team member, every day.*

*There are six underlying elements of UltraCare.’*

- ◆ *Clinical Leadership*
- ◆ *Continuous Quality Improvement*
- ◆ *Superior Customer Service Team Approach to Care*
- ◆ *Innovative Technology*
- ◆ *Patient-Centered Care*

*... all employees engaged in patient care must achieve annual re-certification related to their UltraCare training. New employees participate in specialized Destination UltraCare training to ensure the mission is pervasive throughout our corporate culture.*

...

*Our Vision is to ensure UltraCare is recognized as the leading renal therapy, to be widely acknowledged as the leader in clinical quality and service innovation, and to attract and develop the best patient care team and managerial talent in renal care.”*

The applicant provides additional information with regard to its commitment to providing quality care that will ensure the safety of patients and staff members in Section II.3, pages 34 – 36.

In addition, in Exhibit 13 the applicant provides a copy of *FMCNA Dialysis Services CQI* that describes BMA’s policies with regard to quality of care and safety in the dialysis facility. In Exhibit 9, the applicant provides a copy of FMC’s *Airborne Pathogen Exposure Control Plan* which outlines guidelines to ensure the safety of patients and employees. Therefore, the applicant adequately demonstrates the methods by which it proposes to promote safety and quality in the provision of dialysis services in Harnett County.

Document Plans for Access to Healthcare by Underserved

In Section VI.1, page 56, the applicant states,

*“...BMA currently operates 81 facilities in 40 North Carolina Counties.... 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 applicant provides a table on page 56 that it states *“is the patient population at FMC Anderson Creek.”* The applicant also states:

*“It is clear that FMC Anderson Creek 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.”*

Since the application is for the development of a new dialysis facility and FMC Anderson Creek is not yet constructed, the project analyst concludes that the statements provided by the applicant are projections based upon the historical experience of other BMA facilities in Harnett County. See the following table, from page 56:

FACILITY	MEDICAID/ LOW INCOME	ELDERLY (65+)	MEDICARE	WOMEN	RACIAL MINORITIES
FMC Anderson Creek	48.80%	19.50%	80.50%	48.80%	68.30%

The applicant adequately documented its plans for providing access to health care by the underserved groups.

Maximize Healthcare Value

In Section II.1, on page 28, the applicant states,

*“...BMA, through its parent company, FMC is taking on the financial burden to complete this transfer of stations in an effort to bring dialysis treatment closer to the patient homes. BMA notes that the overwhelming majority of dialysis treatments are reimbursed through Medicare, Medicaid, or other government payor sources. For example, within this application, BMA projects that 83.3% of the treatments are covered by Medicare and Medicaid, and an additional 8.4% are covered by VA. The*

*point here is that government payors are working from a fixed payment schedule, often at significantly lower reimbursement rates than the posted charges. As a consequence BMA must work diligently to control costs of delivery for dialysis. BMA does.”*

The project analyst concludes that the applicant’s reference to the “*transfer of stations*” is a typographical error, since this application is for the development of a new dialysis facility pursuant to a need determination in the 2011 SMFP and the July, 2011 SDR.

Additionally, in Section XI.6(d), pages 82 – 83, the applicant documents the methods that will be used by the proposed facility to maintain energy efficient operations and contain utility costs in building design and operation.

The applicant adequately documents its plans for providing access to services for patients with limited financial resources. Furthermore, the applicant adequately demonstrates that projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served, because the applicant’s projection of need is based upon supported and reliable assumptions of the patients proposed to be served by the dialysis facility. See Criterion (3) for additional discussion. Consequently, the application is consistent with Policy Gen-3, is consistent with the need determination and therefore 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.

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Both Applicants

There are currently two dialysis facilities operating in Harnett County, both of which are operated by Fresenius Medical Care of North Carolina, Inc. d/b/a Bio-Medical Applications of North Carolina, Inc. The Dunn Kidney Center is located on Tilghman Drive in Dunn, and FMS Dialysis Services of Lillington is on South Main Street in Lillington. A third dialysis facility, FMC Angier, has been approved for development on Fish Drive in Angier. The July 2011 Semiannual Dialysis Report (SDR) in *Table A: Inventory of Dialysis Stations and Calculation of Utilization Rates* indicates that, as of December 31, 2010, there were 136 in-center dialysis patients in the two operational Harnett County facilities dialyzing on 40 dialysis stations. *Table B: ESRD Dialysis Station Need Determination by Planning Area*, in the July 2011 SDR projects that, as of December 31, 2011, there will be 199 Harnett County residents in need of in-center dialysis treatments and a total of 51 dialysis stations. This means utilization in the County would be 98%, with 3.9 patients per station [199 patients / 51 stations = 3.90 patients per station.  $199 / (51 \times 4) = 0.975$ ]. The 2011 State Medical

Facilities Plan (2011 SMFP) and the July 2011 SDR have thus identified a need for 11 additional dialysis stations in Harnett County, which would result in 80% utilization, with 3.2 patients per station [199 patients / 62 stations = 3.21 patients per station.  $199 / (62 \times 4) = 0.802$ ]. 3.2 patients per station is considered to be the number of patients which would ensure the provision of quality dialysis care, according to the July 2011 SDR.

**M-8743-11, Spring Lake Dialysis** - proposes to develop a new 11-station dialysis facility in Harnett County, in response to the county need methodology. The applicant projects that 100% of its patients will reside in Harnett County, and that the facility will dialyze 36 in-center patients on 11 dialysis stations at the end of project year one, which is 3.3 patients per station, or a utilization rate of 81.8% [36 patients / 11 stations = 3.27 patients per station. 36 patients / (11 x 4) = 0.818].

Population to be Served

In Section III.7, page 42 of the application, the applicant states 100% of its patients are projected to reside in Harnett County. See the following table:

COUNTY	OPERATING YEAR 1 2013 - 2014		OPERATING YEAR 2 2014 - 2015		COUNTY PATIENTS AS PERCENT OF TOTAL	
	IN-CTR. PTS.	HOME PTS.	IN-CTR. PTS.	HOME PTS.	YEAR 1	YEAR 2
Harnett	36	8	41	10	100%	100%
Total	36	08	41	10	100%	100%

\*Source: Application page 42

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section III.7, pages 42 – 50, the applicant presents the assumptions and methodology used to project utilization in the proposed dialysis facility in the first two operating years. On page 42, the applicant states:

*“TRC assumes that a significant number of Harnett County in-center ESRD dialysis patients who are leaving Harnett County three times a week to receive their dialysis treatments at facilities outside of Harnett County.*

*TRC assumes that ESRD patients residing in Harnett County will want to dialyze at a dialysis facility in Harnett County. Since a significant number of ESRD patients who live there are apparently leaving the county to obtain their dialysis treatments elsewhere, if those patients have a choice of a facility that is closer and with greater flexibility and availability of shift times that would come with the new facility, many of them will find it more convenient to transfer to a facility within Harnett County.*

*The patient population in Harnett County will be projected forward using the current Five Year Average Annual Change Rate of 13.1% as published in the July 2011 SDR.*

*TRC assumes that the percentage of patients dialyzing on home therapies on June 30, 2013 will be the same as the percentage published in the July 2011 SDR. The July 2011 SDR indicates that as of December 31, 2010, 11.6% of the dialysis patients in Harnett County were home dialysis patients.”*

On page 43, the applicant describes the location and patient population of the two existing BMA Harnett County dialysis facilities. Likewise, the applicant reiterates that the new BMA facility, FMC Angier, is projected to begin dialyzing patients on 10 new stations by June of 2013.

The applicant then presents a three-step methodology for projecting utilization at the proposed Spring Lake Dialysis facility. The applicant first projects the dialysis patient population for the entire county and then, taking into account the existing and approved BMA dialysis facilities, projects how much of that dialysis patient population will be served by the Spring Lake Dialysis Center. On page 43, the applicant states:

**“Step 1: Calculating the Future Number of In-Center Patients**

*The first step in TRC’s methodology is to project the total number of Harnett County patients who will be receiving in-center hemodialysis when the Spring Lake facility opens. To do this TRC begins with the ESRD patient population of 199 total dialysis patients in Harnett County as of December 31, 2010.*

*First TRC projects this census forward for one year, using the Five Year Average Annual Change Rate of 13.1% as published in the July 2011 SDR. This is the projected patient census as of December 31, 2011.*

$$199 \times 0.131 = 26.069 + 199 = 225.069 \text{ or } 225.1$$

*TRC again projects that census forward for one year, using the Five Year Average Annual Change Rate of 13.1% as published in the July 2011 SDR. This is the projected patient census for December 31, 2012.*

$$225.1 \times 0.131 = 29.4881 + 225.1 = 254.5881 \text{ or } 254.6$$

*TRC then projects this census forward for one half year, using the Five Year Average Annual Change Rate of 13.1% as published in the July 2010 SDR. This is the projected patient census for June 30, 2013. This is day before the projected certification date for the project.*

$$254.6 \times 0.0655 = 16.6763 + 254.6 = 271.2763 \text{ or } 271.3.^1$$

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<sup>1</sup> On page 44, the applicant states it rounds up or down as appropriate in its actual need calculations; the percentage points included thus far are for demonstration purposes.

Thus, the applicant projects that as of June 30, 2012, there will be 271.3 dialysis patients residing in Harnett County.

On page 44, the applicant reduces the projected number of in-center patients by the number of patients projected to utilize home dialysis treatments, based on the number of home patients reported in the July 2011 SDR. According to the July 2011 SDR, that percentage of patients in Harnett County is 11.6%. Therefore, the applicant subtracts approximately 31 patients from the projected 271 patients, to arrive at the projected number of in-center dialysis patients projected to reside in Harnett County as of June 2013. See the following calculations:

$$\begin{aligned} & \text{"}271.3 \times 0.116 = 31.4708 \text{ or } 31.5 \\ & 271.3 - 31.5 = 239.8\text{"} \end{aligned}$$

Based on those numbers, the applicant concludes there will be 239.8 in-center dialysis patients residing in Harnett County as of June 30, 2013.

In Step 2, which begins on page 44, the applicant projects growth in each of the two existing and operational Harnett County dialysis facilities (BMA Dunn and FMS of Lillington). According to the July 2011 SDR, there were 136 patients dialyzing at one of the two Harnett County dialysis facilities.<sup>2</sup> Utilizing the Harnett County Average Annual Change Rate (AACR) of 13.1%, the applicant first projects growth in the BMA Dunn facility as follows:

*"To project the future population of the Dunn facility, TRC begins with the reported patient population of the Fresenius Medical Care Dunn Kidney Center as of December 31, 2010. TRC assumes that the 87 in-center patients are residents of Harnett County.*

...

*TRC projects this census forward for one year, using the Five Year Average Annual Change Rate of 13.1% as published in the July 2011 SDR that was used to project the total in-center population. This is the projected Dunn Kidney Center in-center patient census for December 31, 2011.*

$$87 \times 0.131 = 11.397 + 87 = 98.397 \text{ or } 98.4$$

*TRC projects this census forward for one year, using the Five Year Average Annual Change Rate 13.1% as published in the July 2011 SDR. This is the projected Dunn Kidney Center in-center patient census for December 31, 2012,*

$$98.4 \times 0.131 = 12.8904 + 98.4 = 111.2904 \text{ or } 111.3$$

*TRC projects this census forward for one half year, using the Five Year Average Annual Change Rate 13.1 as published in the July 2011 SDR. This is the projected Dunn Kidney*

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<sup>2</sup> See Table A: Inventory of Dialysis Stations and Calculation of Utilization Rates in the July 2011 SDR.

*Center in-center patient census for June 30, 2013, the projected opening date of TRC 'S facility:*

$$111.3 \times 0.0655 = 7.29015 + 111.3 = 118.59015 \text{ or } 118.6$$

*This total of 188 patients also exceeds the capacity of the facility operating two shifts per day, six days a week, but TRC is allowing for the possibility that some of these patients may choose to transfer to the proposed Angier facility once it opens.”*

The applicant states that “188” patients exceeds the capacity of the BMA Dunn facility; however, the project analyst concludes that this is a typographical error. However, a projection of 118.6 patients does exceed the capacity of the BMA Dunn facility, since it would result in dialyzing 4.74 patients per week per station on two shifts, or a 119% utilization rate. Thus it is reasonable for the applicant to assume that some of the BMA patients that would have resulted in a “surplus” in the BMA Dunn facility would transfer to the proposed Angier facility once it opens.

The applicant performs the same analysis and projection calculation for the FMS of Lillington facility on pages 45 – 46. The patient population of the Lillington facility as reported in the July 2011 SDR was 49 as of December 31, 2010; and the AACR is 13.1%. The project analyst performed the same calculations:

- ◆  $49 \times 0.131 = 6.419 + 49 = 55.419$  (as of December 31, 2011)
- ◆  $55.419 \times 0.131 = 7.2599 + 55.419 = 62.6789$  (as of December 31, 2012)
- ◆  $62.678 \times 0.0655 = 4.105 + 66.783$  (as of June 30, 2013).

Thus the applicant projects, based on the number of patients currently dialyzing at the FMS of Lillington facility and the Harnett County AACR, there will be 67 patients at FMS of Lillington in June of 2013. The applicant draws a similar conclusion about the projection of patients in 2013 exceeding the capacity of the current facility. The FMS of Lillington facility has 15 certified dialysis stations. [66.8, or 67 patients dialyzing on 15 dialysis stations results in 4.47 patients per station per week, or a 116.7% utilization rate.] On page 46, the applicant states it assumes that some of those “surplus” patients would transfer to the proposed BMA Angier facility once it is open. Combined, the two existing dialysis facilities in Harnett County are projected to have a total of 185.38 in-center patients who will need dialysis by June 30, 2013.

On page 46, the applicant subtracts the number of in-center dialysis patients projected at the two existing dialysis facilities in Harnett County from the total number of dialysis patients projected in Step 1 of the applicant’s methodology. This calculation results in 54.4 in-center dialysis patients whom the applicant states are “*additional in-center patients not included within the patient populations calculated for these two facilities.*” [239.8 Harnett County in-center dialysis patients – 185.4 dialysis patients projected at the two BMA facilities = 54.4 patients not projected to be served by any facility.]

The third step in the applicant's methodology is presented on pages 46 - 47. The applicant utilizes information contained in the BMA application submitted to the CON Section in 2010 for the proposed Angier facility.<sup>3</sup> In that application, BMA projected to serve 22.7 Harnett County patients in the Angier facility as of June 30, 2013. The applicant states:

*“Subtracting the projected population of 22.7 Harnett County patients at the Angier facility at the end of the first operating year on June 30, 2013, from the figure 54.4 derived above, the result is 31.7 Harnett County patients on the projected opening date of the Spring Lake facility who would not be receiving dialysis at any of the three Harnett County facilities.”*

In addition, the applicant states that there are eight patients who could potentially be added back into the 31.7 patients projected to need dialysis but not at a particular facility in June 2013. On page 46, the applicant states:

*“...it should be also noted that the patient letters in the Angier CON application include four (4) who are receiving dialysis at the Dunn facility and four (4) who are receiving dialysis at the Lillington facility. Thus, these 8 patients already are receiving dialysis within Harnett County and they would be included within the group of 118 projected patients at Dunn and 66.8 projected patients at Lillington which were accounted for in TRC's growth projections for those two facilities. Therefore, these 8 patients need not be logically subtracted from the total of 54.4 in-center patients who would not be served by one of the existing facilities in Harnett County. Therefore, if anything, the figure 31.7 patients who are prospective transfers to the Spring Lake facility is a very conservative number.”*

Thus, the applicant projects that, as of June 30, 2013, there will be 31.7 in-center dialysis patients in Harnett County who will need dialysis and who are not included within the patient population projections for any of the three BMA facilities (two existing and one approved). The applicant concludes that it is reasonable to assume that those 31.7 Harnett County in-center dialysis patients who are not projected to be served by an existing or proposed facility could be served by the proposed TRC Spring Lake facility.

On page 46 the applicant states,

*“Based on these calculations and considerations, TRC has arrived at a projected patient population of 31.7 in-center dialysis patients who will not be served by any facility within Harnett County on the date when the Spring Lake facility opens on July 1, 2013. Therefore, these in-center patients could be reasonably served by a TRC facility without affecting the reasonable growth of existing facilities in Harnett County. Based on the information available, it is reasonable to project that at least that many patients will transfer to the Spring Lake facility when it opens on June 30, 2013.”*

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<sup>3</sup> See Project ID #M-8596-10.

In addition, on pages 47 – 49, the applicant presents a ZIP code analysis of the areas of Harnett County identified by the Southeastern Kidney Council (SEKC) as ZIP codes in which patients who receive dialysis services reside. On page 47 the applicant provides a table to illustrate those ZIP codes in which patients who receive in-center dialysis treatments reside. The applicant reported three separate dates represented in the SEKC report. To that, the project analyst added two dates included on later SEKC reports:

COUNTY	ZIP CODE	TOWN	12/31/10	03/31/11	06/30/11	10/04/11	01/09/12
Harnett	27332	Sanford	17	17	20	18	18
Harnett	27501	Angier	12	11	12	15	16
Harnett	27506	Buies Creek	1	1	1	1	--
Harnett	27521	Coats	8	7	6	7	7
Harnett	27546	Lillington	28	30	26	23	22
Harnett	28323	Bunnlevel	6	6	5	6	7
Harnett	28326	Cameron	9	11	10	10	12
Harnett	28334	Dunn	47	49	49	47	45
Harnett	28335	Dunn	2	2	3	3	3
Harnett	28339	Erwin	15	16	16	15	17
Harnett	28368	Olivia	4	3	3	2	2
Harnett	28390	Spring Lake	22	26	27	28	31

\*Source: Application page 47, Southeastern Kidney Council, *Zip Code of Residence for Patients Currently Dialyzing in Network 6 Units*.

The data in the table shows that the number of in-center dialysis patients who reside in those ZIP codes within Harnett County has increased overall since December 31, 2010.

Additionally, on page 47, the applicant states:

*“There are at least three communities that are located in southwestern Harnett County that have no Harnett County dialysis facility anywhere near where they live. These communities are Spring Lake, Olivia and Cameron. These three communities had 35 in-center patients as of December 31, 2010, 40 in-center patients as of March 31, 2011 and 40 in-center patients as of June 30, 2011.”*

The applicant specifically identifies the ZIP codes as: 28326 (Cameron), 28368 (Olivia), and 28390 (Spring Lake). According to a Harnett County map, those ZIP codes are in the southwestern area of Harnett County. The BMA Dunn facility is on the eastern edge of Harnett County (ZIP code 28334); and the FMS of Lillington facility (ZIP code 27546) is roughly in the center of the county. The approved FMC Angier facility is located in Angier (ZIP code 27501), in the far northeastern portion of the county.

On pages 48 – 49, the applicant projects that the Spring Lake facility will include 70% of those dialysis patients projected by the SEKC report as residing in the three ZIP codes identified by the applicant (Cameron, Olivia and Spring Lake). Specifically, the applicant states:

*“Spring Lake Dialysis projects that it’s [sic] population will include at least 70% of the in-center patients identified in the Zip Code of Residence for Patients Currently*

*Dialyzing in Network 6 Units ... who live in the three closest zip codes: 28326 (Cameron — 9 patients), 28368 (Olivia — 4 patients) and 28390 (Spring Lake — 22 patients). 70% of the patients in these three zip codes would amount to 24.5 patients as of January 3, 2011, which is also only about 76% of the 31.7 in-center patients identified above as not being served by any of the three facilities in the county when Spring Lake Dialysis opens.*

*Based on it's [sic] proximity to the zip codes identified above, the omission of any of these zip codes from the patient transfer letters submitted in the Angier CON application, as well as the greater flexibility and availability of shift times, TRC projects that in-center patients will transfer to Spring Lake Dialysis when it opens.*

*We expect that many patients will learn of the new facility and will apply for admission through their Nephrologist while the facility is under construction. These patients will make up the waiting list and will be the first patients to be admitted to the facility after certification.*

*TRC projects that the patient population forward to calculate the expected patient populations for the end of Operating Years 1 and 2.*

*TRC begins with the projected patient population of 24 patients as noted above. This is the projected census as of December 31, 2010.”*

Thus the applicant proposes to serve approximately two-thirds of the Harnett County in-center dialysis patient population projected as of June 30, 2013, who are not projected to be served through growth calculations in the existing and approved Harnett County facilities.

On pages 48 – 49, the applicant projects future utilization beginning with the initial 24 patients, based on the AACR for Harnett County, to the end of the second project year (June 30, 2015). Those calculations follow:

- ◆ 24 patients x 1.131 = 27.1 (December 31, 2011)
- ◆ 27.1 x 1.131 = 30.7 (December 31, 2012)
- ◆ 30.7 x 1.0655 = 32.7 (June 30, 2013)
- ◆ 32.7 x 1.131 = 36.9 (June 30, 2014)
- ◆ 36.9 x 1.131 = 41.7 (June 30, 2015)

On page 49, the applicant states Project Year one is July 1, 2013 – June 30, 2014; and Project Year 2 is July 1, 2014 – June 30, 2015. The project analyst notes that the application contained an error which does not adversely affect the applicant's assumptions and methodology. On page 49, the applicant performed the same calculations as the project analyst did above; however, it calculated 32.4 patients as of June 30, 2013 rather than 32.7 patients. Thus, subsequent calculations by the applicant are likewise in error, but likewise do not affect the assumptions and methodology. Therefore, the applicants projections shows it projects to serve 36 in-center dialysis patients on 11 stations at the end of Operating Year 1, which is a utilization rate of 82% [36 patients / 11 stations = 3.27. 36 / (11 x 4) = 0.818].

Likewise, by the end of Operating Year 2, the applicant projects to 41 patients on 11 stations, which is a utilization rate of 93% [ $41 / 11 = 3.73$ .  $41 / (11 \times 4) = 0.932$ ].

The project analyst consulted the latest SEKC report, which provides data current as of January 9, 2012. The data shows that the dialysis patient population residing in the three ZIP codes projected to be served by the applicant had grown to 45 patients, thus already above what the applicant projects to serve by the end of PY 2015.

The applicant's analysis with regard to projection of total Harnett County ESRD patients through the first two Operating Years of the proposed project is reasonable, since it subtracts both the home dialysis patients in the county as well as the future dialysis patient population projected to be served by existing and approved ESRD facilities. In addition, the applicant's calculation of the patient population not projected to be served by any provider is likewise reasonable, because it utilizes the Harnett County AACR and utilization information from the July 2011 SDR for the existing Harnett County ESRD facilities. Exhibit 15 provides letters from physicians who indicate support for the proposed facility and willingness to refer patients for dialysis treatment.

The applicant's assumptions regarding the number of dialysis patients it projects to serve at the proposed Spring Lake facility are reasonable for the following reasons:

1. The applicant projects the entire dialysis patient population of Harnett County, using the AACR from the July 2011 SDR,
2. The applicant notes the percentage of dialysis patients on home therapies as reported by the SDR and adjusts the projected dialysis patient population to determine the number of in-center dialysis patients in the County,
3. The applicant then subtracts those in-center patients projected to be served by the existing and approved dialysis facilities in the County,
4. Using the SEKC report the applicant performs a ZIP code analysis of the areas in Harnett County in which dialysis patients reside,
5. The applicant narrows the ZIP code analysis to the three ZIP codes located closest to the proposed facility,
6. The applicant verifies that those three ZIP codes are not included in the ZIP codes identified in the recently approved FMC Angier application's proposed service area,
7. The applicant does not project to capture 100% of the dialysis patient population within those three ZIP codes,
8. The most recent SEKC report indicates that the in-center dialysis patient population residing in the three ZIP codes identified by the applicant has grown to more patients than the applicant projected by the end of the second project year, or June 30, 2015.

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need for the new eleven-station dialysis facility in Harnett County. Consequently, the application is conforming to this criterion.

**Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anderson Creek** proposes to develop a new 11-station dialysis facility in Harnett County, in response to the county

need methodology. The applicant projects that 76.6% of its patients will reside in Harnett County and 21.3% of its patients will reside in Cumberland County in the first operating year. The applicant projects that the facility will dialyze 36 in-center patients on 11 dialysis stations at the end of project year one, which is 3.3 patients per station, or a utilization rate of 81.8% [36 patients / 11 stations = 3.27 patients per station. 36 patients / (11 x 4) = 0.818].

Population to be Served

In Section III.7, page 45, the applicant provides the following table to illustrate the residence of the patient population it projects to serve:

FMC ANDERSON CREEK	OPERATING YEAR 1			OPERATING YEAR 2			COUNTY PATIENTS AS % OF TOTAL	
	IN-CTR. PTS.	HOME HEMO	PD	IN-CTR. PTS.	HOME HEMO	PD	YEAR 1	YEAR 2
Harnett	27.4	2.0	2.0	29.0	4.3	4.3	76.6%	78.7%
Cumberland	9.0	0.0	0.0	9.0	0.0	0.0	23.4%	21.3%
Total	36.4	2.0	2.0	38.0	4.3	4.3	100.0%	100.0%

\*Source: Application page 45

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section III.7, pages 40 - 45, the applicant provides the assumptions and methodology it used to calculate its projections. Specifically, on page 40, the applicant states:

*“This is an application to develop an 11 station dialysis facility. In order to be conforming to .2203 (a) BMA must prove 3.2 patients per station, or 35.2, rounded to 36 patients.*

*BMA proposes to complete development of this project by June 30, 2013. Thus, Operating Year 1 is the period from July 1, 2013 through June 20, 2014. Operating Year 2 is the period from July 1, 2014 through June 30, 2015.”*

On page 40, the applicant states it assumes the patient population in Harnett County will grow 13.1%, according to the AACR published in the July 2011 SDR. The applicant continues to describe its assumptions by acknowledging that BMA currently operates two facilities in central and northeastern Harnett County, and has been approved to develop a new facility in eastern Harnett County.

With regard to the proposed facility, on pages 40 – 41, the applicant states:

*c. “BMA has contacted the patients residing in southern Harnett County through their respective dialysis facility. BMA has explained that a new facility maybe developed in closer proximity to the patient residence. BMA has asked for and received letters of support from patients of the area. Exhibit 22 includes 35 patient letters of support for*

*this project. BMA has mapped the residence location of patients from southern Harnett County. These patients are dialyzing in a BMA facility or in the Carolina Dialysis-Sanford facility. As the map indicates, there are a large number of patients residing in the southwest portion of Harnett County. It is for this reason that BMA has selected the Anderson Creek area for development.*

- d. BMA does propose to establish a home dialysis program at FMC Anderson Creek. As with other BMA proposals to develop new home dialysis training programs, BMA necessarily offers conservative projections of home patients. BMA will not restrict patients from choosing home dialysis. Rather, for the purposes of the CON Application, BMA offers conservative and reasonable projections of patients to be served. BMA does expect the home patient population will increase. BMA also assumes that initial growth of the home patient population will exceed recent Harnett County experience. This will be a result of the additional services becoming available within the County.”*

On page 42, the applicant states:

*“Based upon patient letters of support, BMA proposes that the new facility would open with a census of 35 patients. Of these 35 patients, nine are actually Cumberland County residents who believe that the proposed facility would be a more convenient location for their dialysis as opposed to their current dialysis facility. These patients all reside in the Spring Lake area of Cumberland County. Travel from Spring Lake to one of the facilities in Fayetteville involves transiting Fort Bragg. The transition across Fort Bragg involves heavy traffic. It will be much easier for these patients to reach the FMC Anderson Creek facility.”*

Below is a table provided by the applicant on page 43 that illustrates the ZIP codes of those patients who signed letters of support:

ZIP CODE	CUMBERLAND COUNTY	HARNETT COUNTY
27306	0	1
27332	0	1
27333	0	1
27546	0	1
27564	0	2
28326	0	5
28390*	9	11
No ZIP given	0	4
Total	9	26

\*ZIP Code 28390 exists both in Cumberland and Harnett Counties.

On pages 42 – 43, the applicant projects growth of the patients at the proposed facility based on the Harnett County AACR of 13.1%, as reported in the July 2011 SDR. The applicant states that it will begin operation with 35 patients: 26 from Harnett County and nine from Cumberland County. On page 43, the applicant states it will not project growth of the Cumberland County patients who are projected to dialyze at FMC Anderson Creek; instead, the applicant projects growth only of the Harnett County residents.

On page 43 the applicant provides a table to illustrate projected dialysis patient population growth in the proposed facility beginning June 30, 2013, the opening date for the facility, with a beginning census of 26 patients. See the following table:

<i>BMA begins with the Harnett County patients supporting this project. These patients are projected to transfer to the new center upon opening, June 30, 2013.</i>	26
<i>BMA projects this population forward for 12 months to June 30, 2014 at the Harnett County Five Year Average Annual Change Rate</i>	$(26 \times 13.1) + 26 = 29.4$
<i>At this point, BMA will subtract 2 patients who are projected to change to home dialysis during the year.</i>	$29.4 - 2 = 27.4$
<i>BMA adds the 9 patients from Cumberland County. This is the projected in-center census for the end of Operating Year 1</i>	$27.4 + 9 = 36.4$
<i>BMA projects the Harnett County patient population forward for one year to June 30, 2015</i>	$(27.4 \times 13.1) + 27.4 = 31.0$
<i>At this point, BMA will subtract 2 patients who are projected to change to home dialysis during the year.</i>	$31.0 - 2 = 29.0$
<i>BMA adds the 9 patients from Cumberland County. This is the projected in-center census for the end of Operating Year 2.</i>	$29.0 + 9 = 38$

On page 44 the applicant describes the assumptions used to consider home hemo-dialysis patients. The applicant states,

*“BMA expects that the home patients will be equally divided between home peritoneal dialysis and home hemo dialysis. BMA projections for home hemo-dialysis necessarily consider a myriad of issues surrounding home hemo-dialysis. For example, training is not as routine as in-center dialysis, not every patient who begins home hemo-dialysis training will complete the training and ultimately dialyze at home, not every patient has necessary resources for home hemo-dialysis, etc.*

*Traditional Home hemo-dialysis training can not be scheduled in similar manner as in-center treatment, i.e., two patients per day. During the patient training, the dialysis patient also receives a dialysis treatment. In addition to a dialysis treatment, the RN responsible for training is teaching the patient (and home partner) about dialysis concepts, the equipment and procedure. Due to the many issues involved, the patient training day may extend far beyond the normal four hour dialysis treatment. As a consequence, BMA is not able to schedule multiple patients in the same training room on the same day.*

*In addition to “traditional” home hemo-dialysis, BMA has recently been allowed to train dialysis patients for use on the “NxStage” home hemo-dialysis equipment. Dialysis using NxStage is indeed hemo-dialysis; however, rather than the traditional three weekly dialysis treatments normally provided to hemo-dialysis patients, NxStage is actually performed more frequently, possibly on a daily basis, and for shorter periods of time. Thus, while a patient on traditional hemo dialysis would be expected to receive 12 hours of treatment per week (three, four hour treatments are average), the patient using the NxStage equipment would likely receive five (or more) treatments averaging 2.5 hours, for a total of approximately 12.5 hours. The NxStage training regimen could, in theory, accommodate two patients per day on one station, but does require five days of training each week during the training; however, patient education is also a key part of the process and thus two patients per day is not feasible.*

*At present, training averages five weeks for each patient who completes the training. Based upon an average of five weeks to train, a traditional home hemo-dialysis training room can reasonably plan to train ten patients per year. Annual capacity is an issue for consideration, but is not the overall concern. In addition to the annual capacity, one must also consider that not every patient who begins training will complete the training and perform dialysis at home. Many patients find that while the concept of home hemo - dialysis offers greater flexibility, the process in and of itself may not be compatible with the patient lifestyle, or, the patient may not be comfortable with the process, or the patient may lose availability of the partner (patients should not dialyze while alone).*

*It has been FMC (parent to BMA) experience that the home hemo-dialysis patient population is growing nationwide and significantly within North Carolina. After careful consideration of the above, and the size of the ESRD patient population as a whole, BMA plans to utilize one dialysis station as dedicated home hemo-dialysis training station.”*

The applicant states it will subtract two patients from the projected patient population in Operating Year One, and assume they will be home-trained. In Operating Year Two, the applicant subtracts four patients for home-training. Therefore, the applicant proposes to serve 36 in-center patients on 11 stations at the end of Operating Year One; and 38 in-center patients on 11 stations at the end of Operating Year Two. The applicant states that the company’s experience shows the number of home-trained dialysis patients is increasing both nationally and within North Carolina. Thus, the applicant’s projection to serve two home patients in the first year and two additional home patients in the second year is reasonable and supported.

10A NCAC 14C §.2203(a) requires that an applicant proposing a new dialysis facility be able 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, 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.” In this application, the applicant projects to serve 3.3 patients per station per week based on 36 in-center patients in the first Operating Year, or an 82% utilization rate [36 patients / 11 stations = 3.27. 36 patients / (11 x 4) = 0.818]. Likewise, in the second Operating Year, the applicant projects to serve 3.4 patients per station per week based on 38 in-center patients, or an 86% utilization rate [38 / 11 = 3.45. 38 / (11x4) = 0.864]. Thus, the applicant’s projections satisfy the requirements of 10A NCAC 14C §.2203(a).

In Exhibit 22 the applicant provides 35 letters from patients which it states provide the basis for a beginning patient census of 35 (the applicant subtracts 9 proposed Cumberland County residents from this total to arrive at the 26 patients discussed above). The applicant provides a table on page 15, in Section II of the application to illustrate the diversity of ZIP codes in the proposed service area defined by the applicant and reported on patient letters. The applicant’s table follows:

ZIP CODE	CUMBERLAND COUNTY	HARNETT COUNTY
27306		1
27332		1
27333		1
27546		1
27564		2
28326		5
28390	9	11
No Zip specified		4
<b>Total</b>	<b>9</b>	<b>26</b>

\*Source: Application Section II, page 15

The project analyst researched county ZIP codes and tallied the patient letters. The analyst’s findings are summarized in the following table:

ZIP CODE	TOWN	CUMBERLAND COUNTY	HARNETT COUNTY
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27306	Mt. Gilead	1*	
27332	Sanford	--	1
27333	Analyst could not find 27333 on any maps; 27330 is central Lee County		
27546^	Lillington	--	1
27564^	ZIP Codes as given do not exist		1
25764^			1
28326	Cameron	--	5
28390	Spring Lake	9	11
No Zip specified			4
<b>Total</b>		<b>9</b>	<b>25</b>

\*Every map search conducted indicated 27306 is in Cumberland County  
 ^The analyst assumes all these ZIP codes are intended to be 27546; the other two ZIP codes given do not exist

The data verified by the analyst shows inconsistencies with regard to the ZIP code information presented by the applicant; particularly with regard to 27333, 27564, and 25764. The inconsistencies with regard to patient residence ZIP codes as presented by the applicant are not adverse to the application: the number of letters signed is consistent with the number of letters reported by the applicant, and 91%, or 32 of the letters have ZIP codes that can be verified. Therefore, the applicant presents 35 patient letters which show support for the proposed FMC Anderson Creek facility.

In summary, the applicant adequately identified the population it proposes to serve, and adequately demonstrated the need the population would have for the proposed dialysis services. Therefore, the application is conforming to this criterion.

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

NA  
 Both Applicants

- (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.

C  
 Spring Lake Dialysis

NC  
 FMC Anderson Creek

**Spring Lake Dialysis** - The applicant proposes the development of a new 11-station dialysis facility in the Spring Lake area of Harnett County. The applicant states in Section III.9 that it considered several alternatives before proposing this project. Therefore the application, as conditioned, is conforming to all other applicable statutory review criteria, and to Criteria and Standards for End Stage Renal Disease Services 10A NCAC 14C Section .2200. Therefore, the applicant adequately demonstrates that its proposal is an effective alternative. Consequently, the application is conforming to this criterion, subject to the conditions in the conclusion section of these findings.

**FMC Anderson Creek** - The applicant proposes the development of a new 11-station dialysis facility in the Spring Lake area of Harnett County. The applicant states in Section III.9 that it considered several alternatives before proposing this project. Therefore the application is conforming to all other applicable statutory review criteria. However, the application is not conforming to the Criteria and Standards for End Stage Renal Disease Services 10A NCAC 14C Section .2200; specifically 10A NCAC 14C Section .2202(b)(2). Therefore, the applicant did not adequately demonstrate that its proposal is an effective alternative. Consequently, the application is not conforming to this criterion.

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

## C

### Both Applicants

**Total Renal Care of North Carolina, LLC d/b/a Spring Lake Dialysis** - states in Section VIII.1, page 69, that the total capital cost of the project will be \$1,407,618, including \$880,000 in construction costs, \$145,200 for dialysis machines, \$95,000 for RO water treatment, \$161,265 in other equipment and furniture, \$70,000 in architect/engineering fees, and \$56,153 in miscellaneous project costs, including dialysis chairs, chair side computers, and televisions. In Section IX, page 72, the applicant projects start-up costs of \$142,060 and initial operating expenses in the amount of \$846,273, for a total working capital of \$988,333. In Section VIII.2, page 69, the applicant states that 100% of the capital cost of the project will be financed with the cash reserves of DaVita, Inc., the parent company of Total Renal Care of North Carolina, LLC. The applicant states in Section IX.4, page 73, that the total working capital will likewise be financed with the cash reserves of DaVita, Inc.

Exhibit 20 contains a September 12, 2011 letter signed by James K. Hilger, Chief Accounting Officer, DaVita, which states,

*“I am the Chief Accounting Officer of DaVita, Inc., the parent and 100% owner of Total Renal Care, Inc. I also serve as the Chief Accounting Officer of Total Renal Care Inc., which owns 85% of Total Renal Care of North Carolina, LLC (‘TRC’).*

*We are submitting a Certificate of Need Application to develop a [sic] eleven-station End Stage Renal Disease hemodialysis facility in south Harnett County. The project*

*calls for a capital expenditure of \$1,407,618, start-up expenses of \$142,060 and a working capital requirement of \$846,273.*

*DaVita and Total Renal Care of North Carolina, LLC have committed cash reserves in the amount of \$2,395,951 for this project. We will ensure that these funds are made available for the development and operation of this project. As Chief Accounting Officer of Total Renal Care of North Carolina, LLC, I can also confirm that we will provide all of the funds that we receive from DaVita for this project to Total Renal Care of North Carolina, LLC for the development of this project.”*

In Exhibit 21, the applicant provides the audited consolidated Balance Sheets for DaVita, Inc. which confirm that, as of December 31, 2009, DaVita, Inc. had total assets in the amount of \$7,558,236,000, including \$539,549,000 in cash and cash equivalents. The balance sheets also show that DaVita, Inc. had net assets (total current assets less total current liabilities) of \$1,255,580,000 as of December 31, 2009.

In Section X of the application, on pages 54 and 57, the applicant projects costs and net revenue for the first two operating years of the proposed project. See the following table:

PROJECTED EXPENSES AND NET REVENUE	OP. YEAR 1	OP. YEAR 2
Projected Operating Costs	\$1,692,545	\$2,125,673
Net Patient Revenue	\$1,604,942	\$2,242,054

In the ProFormas in Section X of the application, the applicant projects that revenue will exceed expenses in the second operating year of the project. The rates in Section X.1 of the application are consistent with the standard Medicare/ Medicaid rates.

In summary, the applicant adequately demonstrated the availability of funds for the total capital costs of the project and adequately demonstrated the long-term financial feasibility of the proposal. Further, the applicant adequately demonstrated that the projections of costs and charges are based upon reasonable projections of the population to be served. See Criteria (3), (4), and (7) for discussion of reasonableness. Consequently, the application is conforming to this criterion.

**Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anderson Creek** – states in Section VIII.1, page 64, that the total capital cost of the project will be \$1,046,061, including \$772,394 in construction costs, \$50,120 for RO water treatment equipment, \$86,496 in other equipment and furniture, \$58,591 in architect/engineering fees, and \$78,460 in generator connection costs and contingency fees. In Section IX, pages 68 - 69, the applicant projects start-up costs of \$61,717 and initial operating expenses in the amount of \$1,019,830, for a total working capital of \$1,081,547. In Section VIII.2, page 65, the applicant states that 100% of the capital cost of the project will be financed with the cash reserves of Fresenius Medical Care North America, the parent company of Bio-Medical Applications of North Carolina, Inc. The applicant states in Section IX.4, page 70, that the total working capital

will likewise be financed with the cash reserves of Bio-Medical Applications of North Carolina, Inc.

Exhibit 24 contains a September 15, 2011 letter signed by the Vice President of Fresenius Medical Care Holdings, Inc., which states,

*“This is to inform you that Fresenius Medical Care Holdings, Inc. is the parent company of National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc.*

*BMA proposes to develop a new 11 station dialysis facility in the Anderson Creek area of Harnett County, pursuant to the need identified in the July 2011 SDR. The project calls [sic] the following capital expenditures on behalf of BMA.*

*Capital Expenditure* *\$1,046,061*

*As Vice President, I am authorized and do hereby authorize the development of this 11 station dialysis facility, Fresenius Medical Care of Anderson Creek, for capital costs of \$1,0046,061. 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 consolidated Balance Sheets for Fresenius Medical Care Holdings, Inc. and Subsidiaries (“**FMCH**”) for years ending December 31, 2009 and 2010. The balance sheets confirm that, as of December 31, 2010, FMCH had total assets in the amount of \$2,753,682,000, including \$163,292,000 in cash and cash equivalents. The balance sheets also show that FMCH had net assets (total current assets less total current liabilities) of \$569,121,000 as of December 31, 2010.

In Section X of the application, on pages 72 and 77, the applicant projects costs and net revenue for the first two operating years of the proposed project. See the following table:

<b>PROJECTED EXPENSES AND NET REVENUE</b>	<b>OP. YEAR 1</b>	<b>OP. YEAR 2</b>
Projected Operating Costs	\$1,529,745	\$1,717,220
Net Patient Revenue	\$1,592,403	\$1,788,902

In the ProFormas in Section X of the application, the applicant projects that revenue will exceed expenses in both operating years of the project. The rates in Section X.1 of the application are consistent with the standard Medicare/ Medicaid rates.

In the ProFormas in Section X of the application, the applicant projects that revenue will exceed expenses in the second operating year of the project. The rates in Section X.1 of the application are consistent with the standard Medicare/ Medicaid rates. In summary, the applicant adequately demonstrated the availability of funds for the total capital costs of the project and adequately demonstrated the long-term financial feasibility of the proposal.

Further, the applicant adequately demonstrated that the projections of costs and charges are based upon reasonable projections of the population to be served. See Criteria (3), (4), and (7) for discussion of reasonableness. Consequently, 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

Both Applicants

**Total Renal Care of North Carolina, LLC d/b/a Spring Lake Dialysis** – The 2011 SMFP and the July 2011 SDR provide a county need methodology for determining the need for additional dialysis stations facilities. The county need methodology for 2011 results in a need determination for 11 dialysis stations in Harnett County. Spring Lake Dialysis proposes to develop a new eleven-station dialysis facility along Buffalo Lakes Road in southwestern Harnett County. See discussion in Criterion (1) for conformity to the 11-station need determination identified by the 2011 SMFP need methodology and the July 2011 Semiannual Dialysis Report. In Section III the applicant’s proposal demonstrated the need to develop an 11-station dialysis facility in southwestern Harnett County. See Criterion (3) for discussion regarding the applicant’s methodology and its demonstration of need. The applicant demonstrated that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities, and therefore the application is conforming to this criterion.

**Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anderson Creek** – The 2011 SMFP and the July 2011 SDR provide a county need methodology for determining the need for additional dialysis stations facilities. The county need methodology for 2011 results in a need determination for 11 dialysis stations in Harnett County. Fresenius Medical Care of North Carolina, Inc. proposes to develop a new eleven-station dialysis facility along Highway 87 in southwestern Harnett County. See discussion in Criterion (1) for conformity to the 11-station need determination identified by the 2011 SMFP need methodology and the July 2011 Semiannual Dialysis Report. In Section III the applicant’s proposal demonstrated the need to develop an 11-station dialysis facility in southwestern Harnett County. See Criterion (3) for discussion regarding the applicant’s methodology and its demonstration of need. The applicant demonstrated that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities, and therefore the application is conforming to this criterion.

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

Both Applicants

**Total Renal Care of North Carolina, LLC d/b/a Spring Lake Dialysis** - In Section V.4(c), page 56, the applicant states that Dr. Dinesh Chandra has agreed to serve as Medical Director for the Spring Lake Dialysis facility. Exhibit 14 contains a September 12, 2011 letter from Dr. Chandra confirming her intent to serve in that role. Exhibit 14 also contains a copy of DaVita's Medical Director Agreement – Summary Sheet. In addition, in Exhibit 15 the applicant provides letters from other nephrologists and physicians in the area which state the physicians currently refer patients to Dr. Chandra and will continue to do so once the proposed facility is operational.

In Section VII, page 64, the applicant projects the following staffing for the proposed facility:

POSITION	TOTAL FTE'S YEAR 2
RN	1.5
RN HT	0.5
Pt. Care Technician	4.5
Bio-Med Tech	0.3
Medical Director	Contract Position
Admin	1.0
Dietician	0.3
Social Worker	0.3
Unit Secretary	1.0
Other - Reuse	0.5
TOTAL	9.9

As shown in the above table, TRC proposes a total of 9.9 FTE positions, 7.5 of which will be direct care positions. In Section VII.4, page 66, the applicant states that it does not anticipate having any difficulty staffing the proposed facility. In Section VII.8, also on page 66, the applicant states Dr. Chandra and Dr. Shah, who will both serve Spring Lake Dialysis, have admitting privileges at Cape Fear Valley Medical Center.

The following table shows hours of operation as proposed by the applicant in Section VII, on page 67:

WEEKLY HOURS OF OPERATION				
DAY	MORNING	AFTERNOON	EVENING	TOTAL
Monday	5	5	0	10
Tuesday	5	5	0	10
Wednesday	5	5	0	10
Thursday	5	5	0	10
Friday	5	5	0	10
Saturday	5	5	0	10
Sunday	5	5	0	10
Total	35	35	0	70
Total Hours Operation per Year (weekly hours x 52)				3,640

The following table shows the number of FTE direct care staff positions the applicant proposes based on the number of hours the facility will operate, as reported by the applicant in Section VII.10, page 67:

	# FTES	Hrs/Yr/FTE	TOTAL FTE HOURS (ANNUAL)	TOTAL HRS. OF OPERATION (ANNUAL) <sup>*</sup>	FTE HRS./HRS OF OPERATION
RNs	2.0	2,080	4,160	3,640	1.14
Techs	4.8	2,080	9,984	3,640	2.74
Total	6.8	2,080	14,144	3,640	3.90

Based on the operating hours and direct care staffing, the applicant has 3,640 hours to cover. The applicant proposed more hours than are necessary; thus, the applicant proposes sufficient staffing. In Section VII, page 45, the applicant projects 7.5 total direct care FTEs. Assuming one FTE works 2,080 hours annually, the project analyst calculated actual total direct care FTE hours projected in staffing for the proposed facility. For example, 2.0 RNs x 2,080 annual hours = 4,160, and 3,640 FTE hours are needed. Therefore, the applicant proposes more than sufficient staffing to cover direct care staff FTE positions.

In addition, at the end of the first operating year, the Spring Lake Dialysis facility projects to serve 37 in-center patients on 11 stations in two shifts on Monday, Wednesday and Friday, and two shifts on Tuesday, Thursday, and Saturday. See the following chart, prepared by the project analyst:

TIME/SHIFT	M/W/F PATIENTS	T/TH/SA PATIENTS
Morning (11 stations)	11	11
Afternoon (11 Stations)	11	11

The table illustrates that the Spring Lake Dialysis facility will be able to dialyze up to a maximum of 44 in-center patients in Operating Year One on 11 dialysis stations, assuming one patient per station per patient shift, which is sufficient to accommodate the 37 in-center patients it projects to serve. In the Second Project Year, the applicant projects to serve 42 in-center patients on 11 stations. Likewise, the applicant has sufficient capacity to accommodate the 42 in-center patients it projects to serve in the second Operating Year.

In summary, the applicant adequately demonstrates the availability of resources, including health manpower and management personnel, for the level of dialysis services proposed. Consequently, the application is conforming to this criterion.

**Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anderson Creek** – In Section V.4(c), page 51, the applicant states that Dr. Michael Casey has agreed to serve as Medical Director for the FMC Anderson Creek facility. Exhibit 21 contains a September 15, 2011 letter from Dr. Casey confirming his intent to serve in that role. Dr. Casey’s letter indicates that he is part of a Nephrology practice that currently serves dialysis patients in the Harnett County area, and that those physicians will continue their referrals and service once the proposed facility is operational.

In Section VII, page 60, the applicant projects the following staffing for the proposed facility in the first year of operation:

POSITION	TOTAL FTE'S YEAR 1
RN	1.50
Technician	3.50
Clinical Manager	1.00
Medical Director	Contract Position
Admin. (FMC Area Mgr.)	0.10
Dietician	0.25
Social Worker	0.25
Home Training Nurse	0.20
Chief Technician	0.10
Equipment Technician	0.30
In-Service	0.10
Clerical	0.75
<b>TOTAL</b>	<b>8.05</b>

As shown in the above table, FMC proposes a total of 8.05 FTE positions in the first year of operation, 5.1 of which will be direct care positions. In Section VII.4, page 62, the applicant states that it does not anticipate having any difficulty staffing the proposed facility. In Section VII.8, on page 63, the applicant lists 19 other dialysis facilities, and states the physicians associated with those facilities have admitting privileges at several area hospitals.

The following table shows hours of operation for the first operating year, as proposed by the applicant in Section VII.10, on page 63:

WEEKLY HOURS OF OPERATION			
DAY	MORNING	AFTERNOON	TOTAL
Monday	5	5	10
Tuesday	5	5	10
Wednesday	5	5	10
Thursday	5	5	10
Friday	5	5	10
Saturday	5	5	10
Sunday	5	5	10
Total	35	35	70
Total Hours Operation per Year (weekly hours x 52)			3,640

In Section VII.1, pages 60 – 61, the applicant states it will add a third shift in the third quarter of the second operating year. The applicant states:

*“BMA has projected that the FMC Anderson Creek facility would end Operating Year 2 with 38 patients. BMA has planned that the 11 station facility would have nine dialysis stations on the in-center treatment floor, one station dedicated to isolation/separation and one station dedicated to home hemo-dialysis training and support. Dialysis patients could utilize the isolation/separation station until such time as a patient positive for*

*hepatitis B begins treatment. CDC guidelines require isolation/separation for these patients.*

*Operating from the position that BMA can not predict when a patient will begin to require isolation/separation, BMA assumes that in a practical sense, this facility will have only nine dialysis stations available for routine use. Nine dialysis stations can effectively provide treatment for 36 patients on traditional shift schedules. Traditional shift schedules are Monday-Wednesday-Friday, morning and afternoon, and similarly, Tuesday-Thursday-Saturday, morning and afternoon*

*Thus at the point the facility receives its 37<sup>th</sup> patient, BMA must plan to operate a third dialysis shift. BMA assumes this will occur in the third quarter of Operating year 2[.] BMA has planned to add 0.5 FTE RN and 0.5 Patient Care Technician in the second quarter of Operating Year 2. These two staff positions will be hired for the 3<sup>rd</sup> shift operations, which would be expected to begin in Q3 of the Second Operating Year. These two staff positions would be more than sufficient staffing for the one or possibly two patients who might utilize the third shift in the second half of the Second Operating Year.”*

The applicant provides a table on page 61 that illustrates the addition of the FTE positions described above. However, the project analyst notes that there are inconsistencies within the table. For example, the applicant states it will add “0.5 FTE RN and 0.5 Patient Care Technician in the second quarter of Operating Year 2.” The table follows:

POSITION	FTE POSITIONS TO BE ADDED	TOTAL FTE POSITIONS	TOTAL POSITIONS TO BE FILLED
RN	0.75	2.00	0.50
Tech	0.75	4.25	0.50

\*Source: Application page 61; information in table reflects proposed staffing additions when a third shift is added in the beginning of the third quarter of the second operating year.

The applicant indicates in the second column that it proposes to add 0.75 FTE positions; however, in the narrative on page 61 and in the last column of the table on page 61, the applicant states it proposes to add 0.5 FTE positions. Furthermore, the calculations in the third column of the table above (Total FTE Positions) indicates addition of 0.5 FTE RNs and 0.75 FTE Techs. The project analyst concludes, based on the narrative information contained in the application on pages 61 and 63, that the applicant’s use of 0.75 is a typographical error. Therefore, all remaining analysis assumes the addition of 0.5 FTE RNs and 0.5 FTE Techs at the beginning of the third quarter of the second project year.

The hours of operation beginning with the third quarter of the second operating year, as reported by the applicant on pages 60 and 63, are shown in the following table:

<b>WEEKLY HOURS OF OPERATION, BEGINNING OF THIRD QUARTER, SECOND PROJECT YEAR</b>
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DAY	MORNING	AFTERNOON	EVENING	TOTAL
Monday	5	5	2	12
Tuesday	5	5	0	10
Wednesday	5	5	2	12
Thursday	5	5	0	10
Friday	5	5	2	12
Saturday	5	5	0	10
Sunday	5	5	0	10
Total	35	35	0	76
Total Hours Operation per Year (weekly hours x 52)				3,952

The following table shows the number of FTE direct care staff positions the applicant proposes based on the number of hours the facility will operate, as reported by the applicant in Section VII.10, page 63:

	# FTEs	Hrs/Yr/FTE	TOTAL FTE HOURS (ANNUAL)	TOTAL HRS. OF OPERATION (ANNUAL) <sup>1</sup>	FTE HRS./HRS OF OPERATION
RNs	2.0	2,080	4,160	3,952	1.05
Techs	4.0	2,080	8,320	3,952	2.11
Total	6.0	2,080	12,480	3,952	3.16

Based on the operating hours proposed at the beginning of the third quarter of the second project year and direct care staffing, the applicant has 3,952 hours to cover. The applicant proposed more hours than are necessary; thus, the applicant proposes sufficient staffing. In Section VII.10, page 63, the applicant projects 6.0 total direct care FTEs. Assuming one FTE works 2,080 hours annually, the project analyst calculated actual total direct care FTE hours projected in staffing for the proposed facility. For example, 2.0 RNs x 2,080 annual hours = 4,160, and 3,952 FTE hours are needed. Therefore, the applicant proposes more than sufficient staffing to cover direct care staff FTE positions.

In addition, at the end of the second operating year, FMC Anderson Creek projects to serve 38 in-center patients on 11 stations in three shifts on Monday, Wednesday and Friday, and two shifts on Tuesday, Thursday, and Saturday. See the following chart, prepared by the project analyst:

TIME/SHIFT	M/W/F PATIENTS	T/TH/SA PATIENTS
Morning (11 stations)	11	11
Afternoon (11 Stations)	11	11
Evening*	11	-

\*As stated above, the third shift will be added at the beginning of the third quarter of the second operating year.

The table illustrates that FMC Anderson Creek will be able to dialyze up to a maximum of 44 in-center patients by the end of Operating Year One on 11 dialysis stations, assuming one patient per station per patient shift, which is sufficient to accommodate the 36 in-center patients it projects to serve. In the Second Project Year, the applicant projects to serve 38 in-

center patients on 11 stations, adding a third shift on Monday-Wednesday-Friday at the beginning of the third quarter. Likewise, the applicant has sufficient capacity to accommodate the 38 in-center patients it projects to serve in the second Operating Year.

In summary, the applicant adequately demonstrates the availability of resources, including health manpower and management personnel, for the level of dialysis services proposed. Consequently, 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

#### Both Applicants

**Total Renal Care of North Carolina, LLC d/b/a Spring Lake Dialysis** – states in Section V.1 and referenced Exhibits that FirstHealth Moore Regional Hospital and Cape Fear Valley Medical Center will provide ancillary and support services to the dialysis facility, including diagnostic and emergency services, blood bank services and acute dialysis in an acute care setting. In Exhibit 12 the applicant provides a copy of a laboratory services agreement that exists between DaVita, Inc. and DVA Laboratory Services for the provision of laboratory services to the proposed facility. In Section V.1, page 54, the applicant states transportation will be provided by the Department of Social Services and other agencies. In Exhibit 15, the applicant provides a copy of a September 13, 2011 letter from Ralph L. Thurman, Transit Services Manager for Harnett County Area Rural Transit System that indicates support for the proposed facility. 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 care system. Therefore, the application is conforming to this criterion.

**Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anderson Creek** – states in Section V.1 and referenced Exhibits that Wake Med Raleigh, Cape Fear Valley Fayetteville, Harnett County Hospital, and Central Carolina Hospital Sanford will provide ancillary and support services to the dialysis facility, including diagnostic and emergency services, blood bank services and acute dialysis in an acute care setting. In Exhibit 18 the applicant provides a copy of a laboratory services agreement that exists between Fresenius Medical Care Holdings, Inc. and Spectra Laboratory Services, Inc. for the provision of laboratory services to the proposed facility. In Section V.1, page 48, the applicant states transportation will be provided by Harnett Area Regional Transportation. 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 care system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health

service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

Both Applicants

**Total Renal Care of North Carolina, LLC d/b/a Spring Lake Dialysis** – The applicant proposes to construct a new facility on parcel of land identified as Parcel #0395750008,<sup>4</sup> located on Buffalo Lakes Road in Southwest Harnett County, near the intersection of NC Highway 87 and NC Hwy 24. The Parcel has a Lee County ZIP code, but is located in Harnett County, as verified by the Harnett County Tax Administration Office. In Section XI.5(h), page 86 of the application, the applicant provides a table to illustrate the projected 6,882 square feet of new construction for the proposed dialysis facility. In Section XI.5(d) and XI.5(e), pages 83 - 84 of the application, the applicant states that applicable energy saving features and water treatment equipment will be incorporated into the construction plans, to comply with Federal regulations. Additionally, in Section XI.6(g), pages 84 – 85, the applicant states the

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<sup>4</sup> The project analyst consulted the Harnett County Tax Administration office and discovered that the parcel ID number given by the applicant was missing one digit; the Tax office supplied the correct Parcel ID Number as indicated in these findings.

facility will be constructed in compliance with all laws and regulations pertaining to fire and safety equipment, and other health and safety requirements. The applicant adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative, and that the construction costs will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges. Therefore, the application is conforming to this criterion.

**Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anderson Creek** – The applicant proposes to construct a new facility on an undeveloped site at Highway 87, in southwestern Harnett County. The applicant states in Section I.7, page 2, that the ZIP code identified with the property is a Lee County ZIP code, but the proposed site is located in Harnett County. In Section XI.5, page 84 of the application, the applicant provides a table to illustrate the projected 6,200 square feet of new construction for the proposed dialysis facility. In Section XI.5(d) and XI.5(e), pages 82 - 83 of the application, the applicant states that applicable energy saving features and water treatment equipment will be incorporated into the construction plans, to comply with Federal regulations. Additionally, in Section XI.6(g), pages 83 – 84, the applicant states the facility will be constructed in compliance with all laws and regulations pertaining to fire and safety equipment, and other health and safety requirements. The applicant adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative, and that the construction costs will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges. 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  
Both Applicants

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 as of June, 2010. The data in the table was obtained on February 23, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

COUNTY	TOTAL #	TOTAL #	% UNINSURED
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	<b>MEDICAID ELIGIBLES AS % OF TOTAL POPULATION</b>	<b>MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION</b>	<b>CY 2008 - 09 (ESTIMATE BY CECIL G. SHEPS CENTER)</b>
Harnett	17.0%	6.2%	20.3%
Statewide	17.0%	6.7%	19.7%

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 Total Renal Care of North Carolina, Inc. or Bio-Medical Applications of North Carolina, Inc.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.9% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

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 or gender. However, a direct comparison to the applicants' current payor 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.

**Total Renal Care of North Carolina, LLC d/b/a Spring Lake Dialysis** – The applicant provides a table in Section VI.1(c) on page 60 that shows 88.9% of dialysis services were provided to Medicare and/or Medicaid patients in the Dialysis Care of Moore County facility, which is a dialysis facility located in Moore County, contiguous to and southwest of Harnett County. See the following table, from page 60:

<b>SOURCE OF PAYMENT</b>	<b>PERCENT</b>
Medicare	11.8%
Medicaid	0.7%
Medicare/Medicaid	25.5%
Medicare/Commercial	50.9%

VA	2.6%
Commercial Insurance	7.8%
Indigent	0.7%
<b>Total</b>	<b>100.0%</b>

The applicant demonstrated its facilities provide adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

**Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anderson Creek** – The applicant provides a table in Section VI.1(c) on page 57 that shows 83.3% of dialysis services were provided to Medicare and/or Medicaid patients in other BMA dialysis facilities in Harnett County. The applicant states that the projections of percentages of dialysis services to be provided to Medicare and/or Medicaid patients “are a function of BMA historical performance in Harnett county and other similar counties.”

See the following table, from page 57:

SOURCE OF PAYMENT	PERCENT
Medicare	74.5%
Medicaid	8.8%
Medicare/Medicaid	0.0%
Medicare/Commercial	0.0%
VA	8.4%
Commercial Insurance	8.2%
Indigent	0.0%
<b>Total</b>	<b>100.0%</b>

The applicant demonstrated its facilities provide 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**  
 Both Applicants

**Total Renal Care of North Carolina, LLC d/b/a Spring Lake Dialysis** – states in Section VI.6, page 63 that “There have been no civil rights equal access complaints filed within the last five years against any facility operated by Total Renal Care of North Carolina, LLC or by any facility in North Carolina owned by DaVita, Inc.”

**Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anderson Creek** – states in Section VI.6, page 59 that “There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.”

- (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**  
 Both Applicants

**Total Renal Care of North Carolina, LLC d/b/a Spring Lake Dialysis** – In Section VI.1(c), page 60, the applicant projects that 88.9% of its patients who will be served at the proposed facility will have all or some of their services paid for by Medicare or Medicaid. The applicant provides a table to show the projected percentage mix, which is based on the historical payor mix at one of the applicant’s Moore County facilities. See the following table:

SOURCE OF PAYMENT	PERCENT
Medicare	11.8%
Medicaid	0.7%
Medicare/Medicaid	25.5%
Medicare/Commercial	50.9%
VA	2.6%
Commercial Insurance	7.8%
Indigent	0.7%
<b>Total</b>	<b>100.0%</b>

In Section VI.1, page 60, the applicant states “*Spring Lake Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. We will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.*” In addition, the applicant states Spring Lake Dialysis will not require payment upon admission for dialysis services, thus making dialysis services available to all persons.

The applicant demonstrated the facility will provide adequate access to medically underserved populations. Therefore, the application is conforming to this criterion

**Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anderson Creek** – In Section VI.1(c), page 57, the applicant projects that 83.3% of its patients who will be served at the proposed facility will have all or some of their services paid for by Medicare or Medicaid. The applicant provides a table to show the projected percentage payor mix, which is based on the historical payor mix at similar BMA Harnett County facilities. See the following table:

SOURCE OF PAYMENT	PERCENT
Medicare	74.5%
Medicaid	8.8%
Medicare/Medicaid	0.0%
Medicare/Commercial	0.0%
VA	8.4%

Commercial Insurance	8.2%
Indigent	0.0%
<b>Total</b>	<b>100.0%</b>

In Section VI.1, page 60, the applicant states *“It is BMA policy to provide all services 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 addition, on page 57, 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 rates for such services.”* [emphasis in original]

The applicant demonstrated the facility will provide adequate access to medically underserved populations. 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  
Both Applicants

**Total Renal Care of North Carolina, LLC d/b/a Spring Lake Dialysis** – In Section VI.5(a), pages 61 - 62 of the application, the applicant states that patients with End Stage Renal Disease will have access to the facility through referrals by a Nephrologist who will have privileges at Spring Lake Dialysis. The applicant states most of these referrals come from primary care physicians, other specialty physicians, or other Nephrologists within the service area or from just outside the service area. In Exhibit 7 the applicant provides three letters dated in September 2011 which indicate that Cape Fear Valley Medical Center, FirstHealth of the Carolinas, and Harnett Health System will each enter into a transfer agreement with Spring Lake Dialysis when appropriate. The application is conforming to this criterion.

**Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anderson Creek** – In Section VI.5(a), page 58 of the application, the applicant states that patients with End Stage Renal Disease will have access to the facility through referrals by any Nephrologist who will have privileges at FMC Anderson Creek. The applicant also states other referrals will come from other physicians or nephrologists in the area. In Exhibit 16 the applicant provides a copy of an existing transfer agreement between Wake Med Raleigh and Fresenius Medical Care, Inc. 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  
Both Applicants

**Total Renal Care of North Carolina, LLC d/b/a Spring Lake Dialysis** – In Section V.3 of the application, page 56, the applicant states

*“Spring Lake Dialysis will employ registered nurses, patient care technicians, a social worker and dietician. The local community colleges are engaged in the training of nursing students and Certified Nursing Assistant students. Spring Lake Dialysis will be offered as a clinical learning site for nursing and CNA students at Central Carolina Community College and Fayetteville Technical Community College. Relationships will also be sought with the Overhills High School in Spring Lake in Harnett County.”*

In Exhibit 13, the applicant provides copies of letters from DaVita to the community colleges and high school listed above, offering Spring Lake Dialysis as a clinical rotation site when the new stations are certified. The application is conforming to this criterion.

**Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anderson Creek** - In Section V.3 of the application, page 50, the applicant states nursing students from Fayetteville Technical Community College will be provided opportunities to be included as a training site. In Exhibit 19, the applicant provides a September 6, 2011 letter signed by FMC Director of Operations to Fayetteville Technical Community College offering the proposed dialysis facility as a clinical training site. The application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
  
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C  
Both Applicants

**Total Renal Care of North Carolina, LLC d/b/a Spring Lake Dialysis** – See Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the proposal would have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- ◆ The applicant adequately demonstrates that the proposal is needed and that it is a cost-effective alternative to meet the demonstrated need [see Criteria (1), (3), (4) (5) and (12) for additional discussion];
- ◆ The applicant has and will continue to provide quality dialysis services [see Criteria (7), (8) and (20) for additional discussion];
- ◆ The applicant has and will continue to provide adequate access to medically underserved populations [see Criterion (13) for additional discussion].

Therefore, the application is conforming to this criterion.

**Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anderson Creek** - See Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the proposal would have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- ◆ The applicant adequately demonstrates that the proposal is needed and that it is a cost-effective alternative to meet the demonstrated need [see Criteria (1), (3), (4) (5) and (12) for additional discussion];
- ◆ The applicant has and will continue to provide quality dialysis services [see Criteria (7), (8) and (20) for additional discussion];
- ◆ The applicant has and will continue to provide adequate access to medically underserved populations [see Criterion (13) for additional discussion].

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  
Both Applicants

**Spring Lake Dialysis** – The applicant currently does not currently operate any dialysis facilities in Harnett County, but operates three facilities in contiguous Moore County, to the southwest. Additionally, the applicant operates two facilities in Hoke County, the northeastern tip of which touches Harnett County. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, those TRC facilities located in counties contiguous to or touching Harnett County have operated in compliance with all Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

**FMC Anderson Creek** - The applicant currently provides dialysis services at two facilities in Harnett County (Dunn Kidney Center in Dunn, and FMS Dialysis Services in Lillington), and has been approved for a third facility in Angier. Further, the applicant operates dialysis facilities in Wake, Johnston, Cumberland and Sampson Counties. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, BMA facilities in Harnett and surrounding counties have operated in compliance with all Medicare Conditions of Participation within the 18 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  
Spring Lake Dialysis

NC  
FMC Anderson Creek

**Spring Lake Dialysis's** application utilized an outdated version of Criteria and Standards for End Stage Renal Disease; however, the information necessary to respond to the Criteria and Standards is contained within the application as presented. Therefore, Spring Lake Dialysis's application is conforming to all the applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C Section .2200, as indicated below.

**FMC Anderson Creek's** application is not conforming to all the applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C Section .2200, as indicated 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;*
  - (2) *Mortality rates;*
  - (3) *The number of patients that are home trained and the number of patients on home dialysis;*

- (4) *The number of transplants performed or referred;*
- (5) *The number of patients currently on the transplant waiting list;*
- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus 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.*

**-NA- Both Applicants**

(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.*

**-C- Spring Lake Dialysis** – In Exhibit 7 of the application, the applicant provides three letters dated in September 2011 which indicate Cape Fear Valley Medical Center, FirstHealth of the Carolinas, and Harnett Health System will each enter an agreement with Spring Lake Dialysis to provide the following services:

- ◆ Acute Dialysis
- ◆ Emergency Room Care
- ◆ Diagnostic Evaluation Services
- ◆ X-Ray Services
- ◆ Special, Immunological and Routine Laboratory Services
- ◆ Blood Banking Services
- ◆ Surgical Services including Vascular Surgery

The application is conforming to this rule.

**-NC- FMC Anderson Creek** – The applicant refers to a “hospital affiliation” agreement in Exhibit 16; however, Exhibit 16 provides a copy of a transfer agreement between Wake Med Raleigh Hospital and the proposed FMC Anderson Creek. Furthermore, the proposed agreement provided does not specify the relationship with the dialysis facility and describe the services that the hospital will provide to patients of the dialysis facility, as required by this rule; instead, it outlines the methods by which a patient may be transferred. The application is not conforming to this rule.

- (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- **Spring Lake Dialysis** – In Exhibit 8, the applicant provides an September 6, 2011 letter signed by the Assistant Vice President at Carolinas Medical Center which states the hospital will enter into a transplant agreement with Spring Lake Dialysis in the event a certificate of need is issued. Additionally, the agreement commits that the hospital will provide the information required by this rule. Therefore, the application is conforming to this rule.

-C- **FMC Anderson Creek** – in Section II, page 11, the applicant states “*BMA has requested to formalize a transplant agreement with Duke UMC. A copy of correspondence is included in exhibit 17.*” However, Exhibit 17 contains a copy of an email correspondence from David Wells, FMC Area Director of Operations directed to a person named Lorie at UNC. There is also a copy of a signed September 15, 2011 letter from Mr. Wells to Lorie requesting a transplant agreement between UNC and FMC Anderson Creek if the application is approved. Therefore, the application is conforming to this rule.

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

-C- **Spring Lake Dialysis** – In Section XI.5(e), page 84 of the application, the applicant states the facility will have power and water available at the proposed location, and that the facility will comply with 42 CFR §405.2100. In Exhibit 10, the applicant provides a copy of the DaVita policy regarding water supply in dialysis facilities. The application is conforming to this rule.

-C- **FMC Anderson Creek** – In Section XI.6(g) and (f), page 83, the applicant states the facility will have power and water available at the proposed location, and that the facility will comply with 42 CFR §405.2100. In Exhibit 11, the applicant provides a copy of BMA policy regarding quality standards in its dialysis facilities. In Exhibit 30, the applicant provides documentation of the availability of power to the proposed site for the facility. In Exhibit 31, the applicant provides documentation that the proposed site for the facility has electrical and water/sewer available. The application is conforming to this rule.

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

-C- **Spring Lake Dialysis** - In Exhibit 9, the applicant provides a copy of a September 9, 2011 letter requesting that Spring Lake Dialysis be included in the

back up service that currently provides service to DaVita dialysis facilities in Moore County. In the same exhibit, the applicant also provides a copy of a DaVita policy regarding actions to be taken in the event of a power outage.

- C- **FMC Anderson Creek** – In Exhibit 12 the applicant provides copies of written policies and procedures for back-up for electrical service 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.*
- C- **Spring Lake Dialysis** – In Section II, pages 10 – 11, the applicant states two parcels of land are identified for the project. In Section XI.1, pages 80 - 82, the applicant describes the location of both the primary and secondary sites proposed for the facility. In Exhibit 23 the applicant provides a September 14, 2011 letter from TRC in which TRC commits to pursue acquisition of the site as required by this rule.
  - C- **FMC Anderson Creek** – In Section XI.2, pages 79 - 80, the applicant describes its intent to pursue a lease of each proposed site for the facility. In Exhibit 30, the applicant provides a copy of an August 31, 2011 letter from Wellons Realty, Inc. which confirms the availability of the proposed sites. In Exhibit 29, the applicant provides a copy of a July 9, 2007 letter signed by Health Property Services, Inc. which indicates that business is authorized to negotiate purchases and leases of properties for FMC.
- (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- **Spring Lake Dialysis** – In Sections VII.3, page 65 and XI.6(g), pages 84 - 85, the applicant provides documentation that services will be provided in conformity with applicable laws and regulations concerning staffing, fire safety, physical environment, and health and safety requirements.
  - C- **FMC Anderson Creek** – In Section II, page 12, the applicant states it will provide services in conformity with all applicable laws and regulations as required by this rule. In Sections VII.3, page 62, and XI.6(g), pages 83 - 84, the applicant states the dialysis center will operate in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.
- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- **Spring Lake Dialysis** –The information regarding patient origin and all of the assumptions provided by the applicant is found in Section II, pages 11 – 18, and

in Section III, pages 42 - 49 of the application. All patients are projected to reside in Harnett County.

- C- **FMC Anderson Creek** – The information regarding patient origin provided by the applicant is found in Section III.1, pages 12 - 17, and in Section III.7, pages 40 - 45 of the application. The patients are projected to reside in both Harnett and Cumberland Counties.

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

- C- **Spring Lake Dialysis** – In Section II.7, page 19 the applicant states that all of the patients projected to dialyze at Spring Lake Dialysis will reside within 30 miles of the proposed facility.

- C- **FMC Anderson Creek** – In Section III.8 page 17, the applicant states that 100% of the patients projected to dialyze at FMC Anderson Creek will reside within 30 miles of the proposed 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- **Spring Lake Dialysis** – The applicant states in Section II, page 19 of the application that Spring Lake Dialysis “...will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

- C- **FMC Anderson Creek** – The applicant states in Section II, page 18 that the proposed facility “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.*

- C- **Spring Lake Dialysis** – The applicant proposes to develop a new eleven-station dialysis facility and to serve 37 patients on 11 stations at the end of the first year of operation, which calculates to 3.4 patients per station. Thus, the requirement of 3.2 patients per station is satisfied. Consequently, the applicant is conforming to this rule. See Criterion (3) for discussion.

- C- **FMC Anderson Creek** – The applicant proposes to develop a new eleven-station dialysis facility and to serve 36 patients on 11 stations at the end of the first year of operation, which calculates to 3.3 patients per station. Thus, the

requirement of 3.2 patients per station is satisfied. Consequently, the applicant is conforming to this rule. See Criterion (3) for discussion.

(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- **Spring Lake Dialysis** – This is a new facility.

-NA- **FMC Anderson Creek** – This is a new facility.

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

-C- **Spring Lake Dialysis** - The applicant provides documentation of its assumptions in Section II.1, pages 19 – 26, and in Section III.7, pages 42 - 49 of the application. See Criterion (3) for discussion.

-C- **FMC Anderson Creek** – The applicant provides documentation of its assumptions in Sections II.1, pages 19 - 23, and in Section III.7, pages 40 - 45 of the application. However, those assumptions were found to be unsupported and thus unreliable. See Criterion (3) for discussion.

#### **.2204 SCOPE OF SERVICES**

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

(1) *diagnostic and evaluation services;*

-C- Spring Lake Dialysis - See Application Section V.1 and Exhibit 7.

-C- FMC Anderson Creek – See Application Section II, page 24, and Section V.1 page 48.

(2) *maintenance dialysis;*

-C- **Spring Lake Dialysis** – See Application Section V.1.

-C- **FMC Anderson Creek** - See Application Section II page 24, and Section V.1 page 48.

(3) *accessible self-care training;*

-C- **Spring Lake Dialysis** – In Application Section II, page 35, the applicant states “*Spring Lake Dialysis will provide self-care training to any patients admitted to the facility who requires or requests self-care training.*”

-C- **FMC Anderson Creek** - The applicant states that self-care training will be provided by the applicant at the FMC Anderson Creek facility. See Application Sections II page 24, and V.1, page 48.

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

-C- **Spring Lake Dialysis** - See Section V.1, page 54 of the application and Exhibit 11. The applicant states the Spring Lake facility will not provide home training

at the facility but will provide those resources to patients who require home training.

-C- **FMC Anderson Creek** – The applicant states BMA will develop these services at the FMC Anderson Creek facility. See Section II page 24 of the application.

(5) *x-ray services;*

-C- **Spring Lake Dialysis** – See Section V.1, page 54 of the application and Exhibit 7.

-C- **FMC Anderson Creek** – See Section II, page 24 and Section V.1, page 48 of the application.

(6) *laboratory services;*

-C- **Spring Lake Dialysis** – See Section V.1, page 54 and Exhibit 12 of the application.

-C- **FMC Anderson Creek** - See Section II, page 24, Section V.1, page 48, and Exhibit 18 of the application.

(7) *blood bank services;*

-C- **Spring Lake Dialysis** - See Section V.1, page 54 of the application, and Exhibit 7.

-C- **FMC Anderson Creek** – See Application Section II, page 24 and Section V.1, page 48.

(8) *emergency care;*

-C- **Spring Lake Dialysis** – See Section V.1, page 54, and Exhibit 7 of the application.

-C- **FMC Anderson Creek** - See Section II, page 24 and Section V.1, page 48 of the application.

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

-C- **Spring Lake Dialysis** See Section V.1, page 54, and Exhibit 7 of the application.

-C- **FMC Anderson Creek** – See Section II, page 24 and Section V.1, page 48 of the application.

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

-C- **Spring Lake Dialysis** - See Section V.1, page 54 and Exhibit 7 of the application.

-C- **FMC Anderson Creek** – See Section II, page 24 and Section V.1, page 48 of the application.

(11) *transplantation services;*

-C- **Spring Lake Dialysis** – See Section V.1, page 54 and Exhibit 8.

-C- **FMC Anderson Creek** - See Section II, page 25, Section V.1, page 48, and Exhibit 18 of the application. Note that the Exhibit contains a letter to UNC Medical Center, not Duke UMC, as stated by the applicant on page 25.

- (12) *vocational rehabilitation counseling and services; and*
- C- **Spring Lake Dialysis** - See Section V.1, page 54, and Exhibit 15 of the application.
  - C- **FMC Anderson Creek** – See Section II, page 25 and Section V.1, page 48 of the application.
- (13) *transportation.*
- C- **Spring Lake Dialysis** - See Section V.1, page 54, and Exhibit 15 of the application.
  - C- **FMC Anderson Creek** - See Section II, page 25 and Section V.1, page 48 of the application.

**.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- **Spring Lake Dialysis** – The applicant refers to Section VII.1, VII.2, and VII.3, pages 64 - 66 of the application. In Section VII.2, page 65, the applicant states all staffing will comply with the requirements in 42 C.F.R. §405.2100.
  - C- **FMC Anderson Creek** - The applicant states in Section II that staffing at the facility will be provide sufficient staffing. See also Section VII.1, pages 60 -61 of the application and Criterion (7) for discussion.
- (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- **Spring Lake Dialysis** – See Section VII.5, page 66 of the application. In addition, Exhibit 19 provides a copy of DaVita, Inc.’s “*Hemodialysis Policies, Procedures & Guidelines*” regarding training for “*New patient care provider teammates.*”
  - C- **FMC Anderson Creek** - See Section II, page 25 of the application. In addition, Exhibit 14 provides a copy of the Fresenius Medical Care Training Manual; and Exhibit 17 provides copies of additional training materials for nurses and technicians.

## COMPARATIVE ANALYSIS OF THE COMPETING APPLICATIONS

Pursuant to N.C.G.S. 131E-183(a)(1) and the need determination in the July 2011 SDR, no more than 11 new dialysis stations may be approved in this review for Harnett County. Because both applications in this review together propose the development of more than 11 dialysis stations, both applications cannot be approved, since it would result in the approval of dialysis stations in excess of the need determination in the 2011 SMFP.

- ◆ The application submitted by Total Renal Care of North Carolina, LLC d/b/a Spring Lake Dialysis Center was found conforming to all statutory and regulatory review criteria.
- ◆ The application submitted by Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anderson Creek was found conforming to all statutory review criteria, but was found non-conforming under regulatory review criteria; specifically 10A NCAC 14C § .2202(b)(2).

However, after considering the information in each application and reviewing each application individually against all applicable review criteria, the project analyst also conducted a comparative analysis of the two proposals.

### SMFP Principles

Basic Principle 12 regarding the Availability of Dialysis Care as contained in Chapter 14, page 348 of the 2011 State Medical Facilities Plan states:

*“The North Carolina State Health Coordinating Council encourages applicants for dialysis stations to provide or arrange for:*

- a. Home training and backup for patients suitable for home dialysis in the ESRD dialysis facility or in a facility that is a reasonable distance from the patient’s residence;*
- b. ESRD dialysis service availability at times that do not interfere with ESRD patients’ work schedules;*
- c. Services in rural, remote areas.”*

#### a) Home Training

**Spring Lake Dialysis** – In Section V.2(d), page 55 the applicant states Spring Lake Dialysis will provide home training in peritoneal dialysis services. In addition, the applicant states home hemo dialysis training will be provided by Dialysis Care of Moore County, which is approximately 30 miles west of the Spring Lake Dialysis facility.

**FMC Anderson Creek** – In Section V.2(d), page 50 the applicant states the FMC Anderson Creek Dialysis facility will provide a home training program to its patients in need of home training. The applicant states the home training program will be supported by larger BMA Wake home training clinics.

The Southeastern Kidney Council (SEKC) publishes quarterly reports which identify residence ZIP codes of dialysis patients, by type of dialysis, by county within Network 6,

which includes North Carolina. See the following table, prepared by the project analyst, which shows those numbers for the last four reports published by the SEKC:

DATE OF REPORT	IN-CTR	HHD	HPD	“OTHER”
04/04/2011	179	0	19	
07/13/2011	178	1		1
10/04/2011	175	1	17	
01/09/2012	180	0	19	

The data shows that the actual number of dialysis patients receiving home hemo-dialysis is small. Therefore, although it appears that home hemodialysis training offered in the dialysis facility as opposed to a remote location is a better alternative; when considered in conjunction with the actual number of home hemodialysis patients reside in Harnett County, it is not an issue.

Therefore, with respect to home peritoneal dialysis training, both applicants are equally effective alternatives, since both propose to offer home training in each proposed facility.

b) Hours of Availability

**Spring Lake Dialysis** – In Section VII.10, page 67, the applicant states dialysis services will be available from 6:00 AM to 4:00 PM, Monday through Saturday. Spring Lake Dialysis does not propose a third shift.

**FMC Anderson Creek** – In Section VII.10, page 63, the applicant states dialysis services will be available from 7:00 AM to 5:00 PM, Monday through Saturday. The applicant will also operate a third shift that runs from 5:00 PM to 10:00 PM on Monday, Wednesday and Friday, beginning in the third quarter of the second operating year.

With respect to hours of availability, **Spring Lake Dialysis** is the less effective alternative, since that facility does not propose a third dialysis shift. **FMC Anderson Creek** is the most effective alternative, since it offers two shifts six days per week, in addition to a third shift that would run three days per week in the third quarter of the second operating year.

c) Services in rural, remote areas

Harnett County is rural but is not a remote area. Both applicants propose construction of a new dialysis facility in an area of Harnett County that is currently not served by a dialysis facility. Therefore, with regard to services in a rural area, both applicants are equally effective alternatives.

**Facility Location**

Both facilities propose a location that is adjacent to or very close to the intersection of North Carolina Highway 87 and North Carolina Highway 24 in the Southwestern portion of Harnett County. The only other existing dialysis facilities in Harnett County are in Lillington and Dunn, in the Central and Eastern portion of the county. Another dialysis

facility has been approved to be located in Angier, in Northern Harnett County. The dialysis facilities in Cumberland County to the South are located on the other side of Fort Bragg and are not easily accessible to residents of South or Southwestern Harnett County, since patients coming from the southern area of Harnett County would have to travel around the military base instead of directly through it. Another dialysis facility is located west of the proposed facilities' location, in Lee County, and there are three dialysis facilities in Moore County, to the Southwest. Both applicants propose a location that is approximately 6 miles north of the Cumberland County border and approximately ten miles from the Moore County and Lee County borders. **Spring Lake Dialysis** proposes a location that is located slightly west and north of the intersection of North Carolina Highways 87 and 24, on Buffalo Lake Road. **FMC Anderson Creek** proposes a location that is located slightly south and east of the intersection of North Carolina Highways 87 and 24, in a medical park. Each facility proposes a location near two North Carolina Highways that bisect the southwestern portion of Harnett County. Additionally, each applicant proposes a location that is situated between North Carolina Highway 210 to the southeast, which runs from the southwestern portion of the county to the northeastern portion of the county; and North Carolina Highway 27 to the northwest, which runs from the southwestern portion of the county to the northwestern portion of the county. Therefore, both applicants are equally effective alternatives..

### **Access by Underserved Groups**

**Spring Lake Dialysis** – In Section VI.1, page 60, the applicant states that 88.9% of its patients will have some or all of their services covered by Medicare or Medicaid.

**FMC Anderson Creek** – In Section VI.1, page 56, the applicant states that 83.3% of its patients will have some or all of their services covered by Medicare or Medicaid. The application submitted by **Spring Lake Dialysis** proposes the highest percentage of patients to have some or all of their services paid for by Medicare or Medicaid. Therefore, the proposal submitted by **Spring Lake Dialysis** is the more effective alternative with regard to access by underserved groups.

### **Service to Harnett County Residents**

According to the July 2011 SDR, BMA currently serves 87 in-center dialysis patients at the Dunn Kidney Center and 49 in-center dialysis patients at the FMS Lillington Dialysis Center. BMA's proposed facility, FMC Angier, projects to serve 22 in-center patients by June 30, 2013. The nephrologists currently serving and proposing to serve those patients will continue to do so. Although TRC does not have an established facility in Harnett County, it has dialysis facilities in Cumberland and Hoke Counties; and has established relationships with nephrologists in those counties (see Exhibit 14 and Exhibit 15). These physicians would continue to follow their dialysis patients in a TRC facility if one were to open in southwest Harnett County. Therefore, with regard to current service to Harnett County patients, BMA is the more effective alternative, since it currently serves Harnett County residents in Harnett County facilities.

### **Access to Alternative Providers**

Currently, BMA operates two dialysis facilities in Harnett County and has been approved to operate a third dialysis facility in the county. BMA is the only provider of dialysis services in the county. BMA operates five dialysis facilities in Cumberland County, 19 dialysis facilities in Wake County, and one dialysis facility in Lee County, all of which are contiguous to Harnett County. TRC operates three dialysis facilities in Moore County, which is contiguous to Harnett County. Therefore, with regard to providing dialysis patients access to an alternative provider, the proposal submitted by **Spring Lake Dialysis** is the more effective alternative.

**Operating Costs and Revenues**

In Section X of the application, each applicant projects costs and revenue for the first two operating years of the proposed project, which results in the following operating costs and revenue per treatment, as demonstrated in the tables below.

**Operating Costs**

<b>SPRING LAKE DIALYSIS</b>	<b>PY1</b>	<b>PY2</b>
Projected Operating Costs	\$1,692,545	\$2,125,673
# Dialysis Treatments	5,304	7,410
Average Cost per Treatment	\$319.11	\$286.86

<b>FMC ANDERSON CREEK</b>	<b>PY1</b>	<b>PY2</b>
Projected Operating Costs	\$1,529,745	\$1,717,220
# Dialysis Treatments	5,460	5,772
Average Cost per Treatment	\$280.17	\$297.51

The Operating Costs in Year Two projected by **Spring Lake Dialysis** are the lowest, and the Operating Costs projected by **FMC Anderson Creek** are the highest. Therefore, with regard to operating costs in Operating Year Two, the application submitted by **Spring Lake Dialysis** is the more effective alternative.

**Net Revenue**

<b>SPRING LAKE DIALYSIS</b>	<b>PY1</b>	<b>PY2</b>
Projected Net Revenue	\$1,604,942	\$2,242,054
# Dialysis Treatments	5,304	7,410
Average Revenue per Treatment	\$302.59	\$302.57

<b>FMC ANDERSON CREEK</b>	<b>PY1</b>	<b>PY2</b>
Projected Net Revenue	\$1,529,403	\$1,788,902
# Dialysis Treatments	5,460	5,772
Average Revenue per Treatment	\$280.11	\$309.93

The Net Revenue per treatment in Operating Year Two projected by **Spring Lake Dialysis** is the lowest; and the net Revenue per treatment in Operating Year Two projected by **FMC Anderson Creek** is the highest. Therefore, with regard to revenue per treatment, the application submitted by **Spring Lake Dialysis** is the more effective alternative.

## **Staffing**

### **Direct Care Staff Salaries**

The following table summarizes the staff salary information for the registered nurse and dialysis technician positions for the first year of operation for each of the applications, as reported in the table in Section VII.1 of the applications.

<b>POSITION</b>	<b>SPRING LAKE DIALYSIS</b>	<b>FMC ANDERSON CREEK</b>
RN	\$52,000	\$54,080
Technician	\$26,000	\$27,560
Administrator	\$72,000	\$84,053

**FMC Anderson Creek** projects higher registered nurse salaries, Technician salaries, and Practice Administrator salaries than **Spring Lake Dialysis**. Therefore, with regard to direct care staff salaries, **FMC Anderson Creek** proposes the more effective alternative because that applicant offers the highest salaries.

### **Availability of Staff**

Both applications projected sufficient shifts and sufficient number of FTE staff positions to accommodate the in-center patients projected in the second year of operation, and both have budgeted sufficient staff salaries. See Criteria (4) and (7) in each application.

## **Conformity with Review Criteria**

N.C. General Statute Section 131E-183 states that the Agency shall review all applications utilizing the statutory and regulatory review 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. The application submitted by Total Renal Care of North Carolina, Inc. was found conforming to all applicable statutory and regulatory review criteria. The application submitted by Bio-Medical Applications of North Carolina, Inc. was found non-conforming to regulatory review criterion 10A NCAC 14C §2202(b)(1). Therefore, with respect to conformity to all statutory and regulatory review criteria, the application submitted by Total Renal Care of North Carolina, Inc. is the better alternative.

## **CONCLUSION**

N.C. General Statute Section 131E-183(a)(1) states that the need determination in the SMFP is a determinative limit on the number of dialysis stations that can be approved by the CON Section. Both Bio-Medical Applications of North Carolina, Inc. and Total Renal Care of North Carolina, Inc. submitted applications for 11 dialysis stations, and therefore the review is competitive. The CON Section determined the application submitted by Total Renal Care of North Carolina, Inc. is the most effective alternative proposed in this review for 11 dialysis stations in Harnett County, for the following reasons:

1. The application submitted by Total Renal Care of North Carolina, Inc. proposes to serve a greater percentage of Medicare and Medicaid recipients;
2. The application submitted by Total Renal Care of North Carolina, Inc. offers a proposal to alternative dialysis providers in Harnett County
3. The application submitted by Total Renal Care of North Carolina, Inc. proposes lower Operating Costs in Year Two;
4. The application submitted by Total Renal Care of North Carolina, Inc. proposes lower Net Revenue per treatment in Year Two;
5. The application submitted by Total Renal Care of North Carolina, Inc. is conforming to all statutory and regulatory review criteria.

Both applications are equally effective in their proposals with regard to home training, provision of services in rural/remote areas, proposed location, and availability of sufficient staff to cover the proposed dialysis shifts. Although the application submitted by Bio-Medical Applications of North Carolina, Inc. proposes more hours of availability, proposes higher staff salaries, and currently serves Harnett County residents, it is less effective than the application proposed by Total Renal Care of North Carolina, Inc.

Therefore, the application submitted by Total Renal Care of North Carolina, Inc. is approved, subject to the following conditions:

- 1. Total Renal Care of North Carolina, Inc. d/b/a Spring Lake Dialysis shall materially comply with all representations made in the certificate of need application.**
- 2. Total Renal Care of North Carolina, Inc. d/b/a Spring Lake Dialysis shall develop and be certified for no more than 11 dialysis stations upon completion of this project, which shall include any home hemodialysis or isolation stations.**
- 3. Total Renal Care of North Carolina, Inc. d/b/a Spring Lake Dialysis shall install plumbing and electrical wiring through the walls for no more than 11 dialysis stations, which shall include any home hemodialysis or isolation stations.**
- 4. Total Renal Care of North Carolina, Inc. d/b/a Spring Lake Dialysis 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.**

Consequently, the proposal submitted by Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anderson Creek to establish a new 11-station dialysis facility in Harnett County is disapproved.