

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: February 27, 2014

FINDINGS DATE: March 6, 2014

PROJECT ANALYST: Julie Halatek

INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: L-10182-13 / Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Rocky Mount / Add 11 dialysis stations for a total of 41 dialysis stations upon completion of this project and Project I.D. #L-10177-13 / Nash County

L-10211-13 / Total Renal Care, Inc. d/b/a Nash County Dialysis / Develop a new 12-station kidney disease treatment center in Nash County / Nash County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C - BMA Rocky Mount

C - Nash County Dialysis

The 2013 State Medical Facilities Plan (2013 SMFP) and the July 2013 Semiannual Dialysis Report (July 2013 SDR) provide a county need methodology for determining the need for new dialysis stations. According to Section 2(E) of the dialysis station county need methodology, found on page 380 of the 2013 SMFP:

“If a county’s December 31, 2013 projected station deficit is 10 or greater and the July SDR shows that utilization of each dialysis facility in the county is 80 percent or greater, the December 31, 2013 county station need determination is the same as the December 31, 2013 projected station deficit. If a county’s December 31, 2013 projected station deficit is less than 10 or if the utilization of any dialysis facility in

the county is less than 80 percent, the county's December 31, 2013 station need determination is zero."

The county need methodology results in a need determination for 19 dialysis stations in Nash County.

Two applications were received by the Certificate of Need Section (CON Section) for development of the 19 dialysis stations. The two applicants applied for a total of 23 dialysis stations. Pursuant to the need determination in the July 2013 SDR, 19 dialysis stations is the maximum number of dialysis stations that may be approved in this review.

BMA Rocky Mount – Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Rocky Mount (BMA Rocky Mount) proposes to add 11 stations to its existing facility for a total of 41 stations upon completion of this project and Project I.D. #L-10177-13 (relocate 12 stations to a new facility in Nash County). The July 2013 SDR identifies a need determination for no more than 19 dialysis stations in Nash County. The applicant proposes to develop no more than 11 new dialysis stations in Nash County. Therefore, the application is conforming to the need determination in the July 2013 SDR.

Nash County Dialysis – Total Renal Care, Inc. d/b/a Nash County Dialysis (Nash County Dialysis) proposes to develop a new 12-station dialysis facility in Rocky Mount, Nash County. The July 2013 SDR identifies a need determination for no more than 19 dialysis stations in Nash County. The applicant proposes to develop no more than 12 new dialysis stations in Nash County. Therefore, the application is conforming to the need determination in the July 2013 SDR.

There is one policy in the 2013 SMFP applicable to both applications. Policy GEN-3: Basic Principles 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."

BMA Rocky Mount

Promote Safety and Quality

In Section II.1, page 25, the applicant states:

“...BMA’s 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. ...”

In Section II.3, pages 34-36, the applicant describes the methods used to ensure and maintain quality of care, which include the following:

- Facility Programs
 - Quality Improvement Program
 - Staff Orientation and Training
 - In-Service Education

- Corporate programs
 - Technical Audits
 - Continuous Quality Improvement

- External Surveys - DFS Certification Surveys
- Core Indicators of Quality
- Single Use Dialyzers

BMA Rocky Mount adequately demonstrates that the proposal will promote safety and quality.

Promote Equitable Access

In Section II.1, pages 26-27, the applicant states:

“BMA has removed the economic barriers with regard to access to treatment. The overwhelming majority of dialysis treatments are covered by Medicare/Medicaid; in fact, within this application, BMA is projecting that 84.2% of the In-center dialysis treatments will be covered by Medicare or Medicaid; an additional 3.7% are expected to be covered by VA. Thus, 87.9% of the In-center revenue is derived from government payors. ...”

10A NCAC 2202 (b)(8) requires a commitment by BMA ‘to admit and provide services to patients who have [sic] 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.’ BMA provides such assurances within Section VI of this application.

...

BMA is also keenly sensitive to the second element of ‘equitable access’ - time and distance barriers. At this time, Nash County has two operational dialysis facilities and one proposal for a new facility under CON review (FMC South Rocky Mount,

Project ID # L-10177-13). As the dialysis patient population of Nash County continues to increase, the need for dialysis stations will continue to increase. BMA will apply to develop new dialysis facilities when needed. ...

Over the years, BMA has sought to develop new facilities and new dialysis stations in an effort to make dialysis convenient to the patient. This application to add 11 dialysis stations to BMA Rocky Mount is another example of BMA efforts to meet the needs of the ESRD patient population of Nash County.”

In Section VI.1(a), page 54, the applicant states:

“...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. ...

BMA of North Carolina has historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. ...

The facility will conform to the North Carolina State Building Code, the National Fire Protection Association 101 Life Safety Code, the Americans with Disabilities Act, ANSI Standards for Handicapped Access, and any other applicable requirement of federal, state, and local bodies.”

In Section VI.2, page 57, the applicant states:

“The design of the facility is such that handicapped persons will have easy access to the facility; the facility will comply with ADA requirements. It was constructed in compliance with applicable sections of North Carolina State Building Code, Vol. #1-General Construction, which lists minimum requirements for the handicapped applicable to institutional and residential structures. In addition, wheelchairs are always available for transporting patients who are unable to stand or walk.”

In Section VI.7, page 58, the applicant states:

“The BMA admission policy states that ‘patients shall be accepted for treatment at BMA when such treatment is deemed indicated and appropriate according to the clinical judgment of the patients’ attending physician. No arbitrary criteria with respect to the patient’s age or magnitude of complicating medical problems are established.’

BMA also has an AIDS policy that states ‘a diagnosis of AIDS or HIV-positive status (absent other contraindications) is not acceptable reason to refuse referral of a patient. Established referral patterns should be followed without regard to AIDS status of patients.’

Please see Exhibit 9 for a copy of policy/procedure.”

BMA Rocky Mount adequately demonstrates that medically underserved groups will have equitable access to the proposed services.

Maximize Healthcare Value

In Section II.1, page 27, the applicant states:

“BMA is not projecting a capital expenditure for this project. BMA is not seeking State or Federal monies to develop the CON application or the additional dialysis stations at the facility; BMA is not seeking charitable contributions. Rather, BMA, through its parent company, FMC is taking on the burden to complete this addition of stations in an effort to bring dialysis treatment close to the patient homes.”

BMA Rocky Mount adequately demonstrates that the proposed project will maximize healthcare value.

BMA Rocky Mount adequately demonstrates that projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served.

The application is consistent with Policy GEN-3 and is therefore conforming to this criterion.

Nash County Dialysis

Promote Safety and Quality

In Section II.3, pages 25-27, the applicant states:

“DaVita HealthCare Partners Inc., operating at [sic] Total Renal Care, Inc. d/b/a Nash County Dialysis 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.

Our Quality Management Program includes the following Quality Programs:

- *Quality Improvement Methodology - utilizing outcome-driven, patient centered management programs to measure, monitor and manage outcomes.*

- *Computerized Information System - integrating clinical and laboratory information for comprehensive outcomes tracking and reporting.*
- *Teammate and Patient Education Program - ensuring continuous updates and training to ensure high quality patient care.*
- *Quality Assessment Audit Program - systematically utilizing a comprehensive detailed assessment tool to assure the highest quality standards in every facility.*
- *Quality Management Team - experienced clinical facilitators for implementing and maintaining ongoing quality improvement programs.*
- *Quality Biomedical Team - experienced specialists in all aspects of Biomedical requirements (i.e., water treatment, disinfection and machine maintenance).*

DaVita's Quality Management Team works closely with each facility's Quality Improvement team to:

- *Improve patient outcomes*
- *Provide patient and teammate training*
- *Develop Quality Improvement Programs*
- *Facilitate the Quality Improvement Process*
- *Continuously improve care delivered*
- *Assure facilities meet high quality standards*

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. ...

Our goal is to have each facility serve as a quality improvement laboratory, where successful outcomes can be disseminated throughout DaVita.

...

Nash County Dialysis will be attended by Dr. Will Bynum and other admitting Nephrologists who directly oversee the quality of care of the dialysis facility. In addition, Dr. Bynum will serve as Medical Director and will provide the overall medical supervision of the dialysis unit. The facility administrator is the day to day manager of the facility and maintains the company's Quality Management Program that monitors the overall care of the patients. The Quality Management Program is reviewed by the Quality Assurance Committee consisting of the Nephrologists, Unit Administrator, clinical teammates, social worker and the dietitian. This Quality Assurance Program will address Nash County Dialysis as a whole, then compares each sister unit to the whole and to industry standards. The Committee then makes recommendations to improve quality. Continuous Quality Improvement teams address facility issues with the goal of improving patient care and patient outcomes."

Nash County Dialysis adequately demonstrates that the proposed project will promote safety and quality.

Promote Equitable Access

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

“Nash County 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.

Nash County 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.

Nash County 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.”

In Section VI.2, page 48, the applicant states:

“Nash County Dialysis will satisfy all state requirements and local building codes to allow equal access for handicapped patients. Many of our patients will be severely physically handicapped. The facility will ensure access by these individuals by providing wheelchair ramps, handicapped bathrooms, wheelchair scales and ADA compliant doors at the facility. Additionally, our teammates will be trained to assist handicapped persons into and out of their dialysis treatment stations.”

In Section VI.7, page 49, the applicant states:

*“Nash County Dialysis will have an open policy and accept all patients including those with hepatitis and/or AIDS. This facility will have an established isolation area for the treatment of any patient with hepatitis and will accept patients with AIDS. See **Exhibit 25** for a copy of the Interpretive Guidelines, Tag Number V266 and the DaVita Hemodialysis Policies, Procedures and Guidelines referencing Hepatitis Surveillance, Vaccination and Infection Control Measures. Total Renal Care, Inc. complies with all federal and state requirements pertaining to isolation of patients with communicable diseases.”* (emphasis in original)

In Section VI.1(c), page 46, the applicant projects that that 91.9 percent of its patients will have some or all of their services paid for by Medicare or Medicaid. On pages 45-46, the applicant also provides the basis for these projections as follows:

“TRC currently does not have any facilities in Nash County from which to draw this information. Therefore we have based our payor mix on the average percentages of patients who are currently dialyzing at Wilson Dialysis Center. Wilson Dialysis Center is a DaVita owned facility in Wilson County, which is contiguous to Nash

County. The pertinent demographics of Wilson County, while not identical to Nash County, are similar. ...”

Nash County Dialysis adequately demonstrates that the proposed project will promote equitable access to the proposed services.

Maximize Healthcare Value

In Section III.9, pages 35-36, the applicant states:

“Nash County Dialysis will promote cost-effective approaches in the facility in the following ways:

- *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 HealthCare Partners, operates over 1,900 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.*
- *Nash County 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.*
- *Nash County Dialysis will be a facility that utilizes single-use dialyzers. The dialyzers will be purchased under a national contract in order to get the best quality dialyzer for the best price.*
- *Nash County 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.*
- *Nash County 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.*
- *Nash County Dialysis will have an inventory control plan that ensures enough supplies are available without having an inordinate amount of supplies on hand. Supply orders will be done in a timely manner to ensure that the facility does not run out of supplies, thus avoiding emergency ordering, which is costly.”*

Nash County Dialysis adequately demonstrates that the proposed project will maximize healthcare value.

Nash County Dialysis adequately demonstrates that projected volumes for the proposed services incorporate basic principles in meeting the needs of patients to be served.

The application is consistent with Policy GEN-3 and is therefore conforming to this criterion.

Summary

Both applications are conforming to the need determination in the July 2013 SDR for 19 dialysis stations in Nash County. However, the limit on the number of dialysis stations that may be approved in this review is 19. Collectively, the two applicants propose a total of 23 dialysis stations. Therefore, even if both applications are conforming or conditionally conforming to all statutory and regulatory review criteria, both applications cannot be approved as proposed. See the Conclusion following the Comparative Analysis for the decision.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C - BMA Rocky Mount
C - Nash County Dialysis

There are currently two dialysis facilities located in Nash County. FMC of Spring Hope is currently certified for 10 stations and is approved to add 3 stations (Project I.D. #L-8796-12). BMA Rocky Mount is currently certified for 42 stations. There is a third facility approved—FMC South Rocky Mount—which will be certified for 12 stations (Project I.D. #L-10177-13). Those 12 stations are being relocated from BMA Rocky Mount, which will leave BMA Rocky Mount with 30 certified stations when Project I.D. #L-10177-13 is complete, if no further stations are approved. See the following table:

Nash County Dialysis Facilities			
Dialysis Facility	Certified Stations 12/31/12	% Utilization	Patients Per Station
FMC Spring Hope*	10	82.50%	3.3
BMA Rocky Mount**	42	91.07%	3.6

Source: July 2013 SDR, Table A.

*FMC Spring Hope is approved to develop three additional stations (Project I.D. #L-8796-12) for a total of 13 stations upon project completion.

**BMA is approved to relocate 12 stations to a new facility (FMC South Rocky Mount) (Project I.D. #L-10177-13).

Table B: ESRD Dialysis Station Need Determinations by Planning Area in the July 2013 SDR indicates that, as of December 31, 2012, there were 259 total patients from Nash County. Pursuant to the need determination in the 2013 SMFP and the July 2013 SDR, there is a need for 19 additional dialysis stations in Nash County.

BMA Rocky Mount proposes to add 11 stations at its existing facility in response to the need determination. The applicant was previously approved in Project I.D. #L-10177-13 to relocate 12 stations and the home training program to a new facility in south Rocky Mount. In Section II, page 13, the applicant states that it plans to maintain a small home training presence at the existing BMA Rocky Mount facility.

Population to be Served

In Section III.7, page 42, the applicant provides projected patient origin for the first two years of operation following completion of the proposed project, as illustrated in the following table:

BMA Rocky Mount - Projected Patient Origin						
County	Year One: 2015		Year Two: 2016		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis Patients	In- Center Patients	Home Dialysis Patients	Year 1	Year 2
Nash	73.5	0.0	73.1	2.0	55.5%	56.0%
Edgecombe	32.0	0.0	32.0	0.0	24.1%	23.9%
Halifax	25.0	0.0	25.0	0.0	18.9%	18.6%
Wilson	1.0	0.0	1.0	0.0	0.8%	0.7%
Warren	1.0	0.0	1.0	0.0	0.8%	0.7%
TOTAL	132.5	0.0	132.1	2.0	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve.

Need Analysis

The assumptions and methodology used to project in-center utilization are provided in Section II.1, pages 14-16 and pages 19-22, and Section III.7, pages 40-43. The applicant states on pages 14-16:

“Assumptions:

1. *This project is scheduled for completion December 31, 2014.
Operating Year 1: January 1, 2015 through December 31, 2015.
Operating Year 2: January 1, 2016 through December 31, 2016.*
2. *The July 2013 SDR reports that BMA Rocky Mount was operating at 91.07% utilization with a census of 153 patients dialyzing on 42 certified dialysis stations as of December 31, 2012.*
3. *BMA does **not** assume that the patient population of Nash County will grow at the Nash County Five Year Average Annual Change Rate as published in the July 2013 SDR (9.6%). Rather, BMA will use a much more conservative growth rate of 2.1%.*

The growth rate as published within the SDR is suspect. The DHSR Medical Facilities Planning Section has developed this SDR using provider self reported information. This was the first time the SDR was prepared in such a manner.

BMA, like all other providers in North Carolina has participated in the Self Reporting process. Unfortunately, the BMA Rocky Mount and BMA East Rocky Mount facilities erred in preparation of the self reported data. Rather than provide the county of residence for all patients, the facilities actually reported all patients as residing in the County of the dialysis facility. Consequently, while the information in Table A of the SDR is correct, the information in Table B contains errors.

BMA has brought the errors to the attention of the Division of Health Service Regulation and all other dialysis providers currently operating in North Carolina. A copy of the information provided to DHSR is included in Exhibit 32 of this application.

4. *In CON Project ID # L-10177-13, BMA projected that 26 dialysis patients from BMA Rocky Mount, who reside in Nash County would transfer their care to the new FMC South Rocky Mount. Within this application, BMA will maintain those projected transfers.*
5. *As of June 30, 3013 [sic], BMA Rocky Mount was serving a total of 59 in-center dialysis patients, and 18 home patients, from counties other than Nash. The next table identifies the county of residence for the patient population of BMA Rocky Mount as of June 30, 2013.*

<i>BMA Rocky Mount</i>	<i>June 30, 2013</i>		
	<i>In-Center</i>	<i>PD</i>	<i>HH</i>
<i>Nash</i>	95	12	5
<i>Edgecombe</i>	32	10	0
<i>Halifax</i>	25	8	0
<i>Wilson</i>	1	0	0
<i>Warren</i>	1	0	0
<i>TOTAL</i>	154	30	5

6. *BMA assumes that the patient population of BMA Rocky Mount but residing in other Counties is dialyzing at BMA Rocky Mount as a function of patient choice. BMA will not project any increase within this segment of the BMA Rocky Mount patient population. Each of the other Counties identified has at least one existing dialysis facility. In the interest of providing a most conservative approach to projections of future patient populations to be served, BMA does not project additional growth of the patient population from other Counties. BMA does assume that these patients will continue to dialyze at BMA Rocky Mount as a function of patient choice.*
7. *As noted above, BMA will utilize a growth factor of 2.1%. The basis for this growth factor is included within the information provided at Exhibit 32, Tab F.*

BMA has calculated a Five Year Average Annual Change Rate for Nash County using the more correct data from the BMA Rocky Mount and BMA East Rocky Mount facilities. The corrected information is included in Exhibit 32, Tab B. BMA incorporated this information into the Patient Origin Report as provided by DHSR Medical Facilities Planning Section and included at Exhibit 32, Tab C. The resultant corrected information is included at Exhibit 32, Tab D.

8. *BMA assumes that in Operating Year 2 of this project, two of the Nash County in-center patients will change modality to home peritoneal dialysis.” (emphasis in original)*

The applicant states on pages 41-43:

“Methodology:

The next table represents BMA calculations of future patient population at BMA Rocky Mount.

<i>BMA begins with the 95 Nash County in-center dialysis patients served as of June 30, 2013.</i>	<i>95 In-center patients</i>
<i>BMA projects this patient population forward for 6 months to December 31, 2013 using a growth rate of one half of 2.1%.</i>	<i>[95 X (.021 / 12 X 6)] + 95 = 96.0</i>
<i>BMA projects this in-center patient population forward for 12 months to December 31, 2014. This is the projected certification date of this project.</i>	<i>(96 X .021) + 96 = 98.0</i>
<i>BMA subtracts the 26 Nash County residents projected to transfer to the new FMC South Rocky Mount.</i>	<i>98.0 – 26 = 72</i>
<i>BMA adds the 59 in-center patients from other counties. This is the projected beginning census for this project.</i>	<i>72.0 + 59 = 131</i>
<i>BMA projects the Nash County in-center patient population forward for 12 months to December 31, 2015.</i>	<i>(72.0 X .021) + 72.0 = 73.5</i>
<i>BMA adds the 59 in-center patients from other counties. This is the projected ending census for Operating Year 1.</i>	<i>73.5 + 59 = 132.5</i>
<i>BMA projects the Nash County in-center patient population forward for 12 months to December 31, 2016.*</i>	<i>(73.5 X .021) + 73.5 = 75.1</i>
<i>BMA subtracts two patients projected to change to modality to home peritoneal dialysis.</i>	<i>75.1 – 2 = 73.1</i>
<i>BMA adds the 59 in-center patients from other counties. This is the projected ending census for Operating Year 2.</i>	<i>73.1 + 59 = 132.1</i>

*The applicant made a rounding error which does not alter the projected utilization. In projecting the Nash County in-center population forward for 12 months to December 31, 2016, the applicant shows an in-center patient population calculation of 75.1. The calculation, done out with more than one decimal place, is $(73.5 \times .021) + 73.5 = 75.0435$. While the calculation methods are correct, rounding is incorrect; the projected number of Nash County in-center patients for the end of Operating Year Two is still 73 patients.

Summary:

Based on the above, BMA projects to serve the following number of patients by modality and county of residence for Operating Years One and Two:

BMA Rocky Mount	Operating Year 1		Operating Year 2		County patients as a percent of TOTAL	
	In-Center	PD	In-Center	PD	Year 1	Year 2
Nash	73.5		73.1	2	55.5%	56.0%
Edgecombe	32.		32		24.1%	23.9%
Halifax	25		25		18.9%	18.6%
Wilson	1		1		0.8%	0.7%
Warren	1		1		0.8%	0.7%
TOTAL	132.5	0.0	132.1	2.0	100.0%	100.0%

BMA also recognizes that Craig Smith, CON Section Chief, has previously indicated that patients are not partial patients, but rather are whole. In the following utilization calculations BMA has rounded down to the whole number. Utilization at BMA Nations Ford [sic] is expected to be:

Operating Year 1

*132 patients dialyzing on 41 stations = 3.22 patients per station
132 (4 X 41) = .805, or 80.5%*

Operating Year 2

*132 patients dialyzing on 41 stations = 3.22 patients per station
132 (4 X 41) = .805, or 80.5%” (emphasis in original)*

Projected utilization is based on reasonable, credible, and supported assumptions. Specifically, continued growth at the facility is adequately supported by the historic growth. Furthermore, the applicant makes adjustments for the patients expected to transfer to the new facility in south Rocky Mount. Therefore, the applicant adequately demonstrates the need for the proposed stations.

In summary, the applicant adequately identified the population to be served and demonstrated the need this population has for the addition of 11 dialysis stations to the existing BMA Rocky Mount facility. Therefore, the application is conforming to this criterion.

Nash County Dialysis proposes to develop a new 12-station facility offering in-center dialysis and training for home hemodialysis and home peritoneal dialysis. An unrelated developer will purchase the property and build a shell building. Nash County Dialysis will lease the building. Nash County Dialysis will then up-fit the shell building, hire and train employees, purchase dialysis machines, and purchase the equipment needed to operate the facility.

Population to be Served

In Section III.7, page 29, the applicant provides projected patient origin for the first two years of operation following completion of the proposed project, as illustrated in the following table:

Nash County Dialysis - Projected Patient Origin						
County	Year One: 2015/2016		Year Two: 2016/2017		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis Patients	In-Center Patients	Home Dialysis Patients	Year 1	Year 2
Nash	33	8	37	9	87.2%	88.5%
Wilson	6	0	6	0	12.8%	11.5%
TOTAL	39	8	43	9	100.0%	100.0%

The applicant adequately identified the population proposed to be served.

Need Analysis

The assumptions and methodology used to project in-center utilization are provided in Section II.1, pages 13-17, and Section III.7, pages 30-34. The applicant states on pages 13-14:

*“The July 2013 SDR Table B indicates that there were 259 patients living in Nash County as of December 31, 2012 including 43 home patients. Of the 216 in-center patients, 186 were receiving dialysis from a Nash County facility and the other 30 were receiving dialysis from a facility outside Nash County. See the table below excerpted from the 12/31/2012 Patient Origin Data chart (**Exhibit 11**).*

Provider Number	Facility Name	Facility County	Home Patients	In-Center	County Total
34-2517	Rocky Mount Kidney Center (BMA)	Nash	33	153	186
34-2644	FMC of Spring Hope	Nash	0	33	33
34-2589	Zebulon Kidney Center (BMA)	Wake	0	14	14
34-2507	Wilson Dialysis (DaVita)	Wilson	6	5	11
34-2637	Forest Hills Dialysis (DaVita)	Wilson	0	5	5
34-2577	Dialysis Care of Edgecombe County (DaVita)	Edgecombe	0	3	3
34-2512	BMA of Raleigh Dialysis	Wake	2	0	2
34-2596	FMC Dialysis Services East Carolina University	Pitt	1	1	2
34-2571	Dialysis Care Franklin County (DaVita)	Franklin	0	2	2
34-2502	Greenville Dialysis Center (FMC)	Pitt	1	0	1
	Nash Totals		43	216	259

Total Renal Care, Inc. uses the following assumptions in projecting a future census for the Nash County ESRD dialysis patient population.

- *TRC assumes that a significant number of Nash County in-center ESRD dialysis patients are leaving Nash County three times a week to receive their dialysis treatments at facilities outside Nash County.*
- *TRC assumes that all ESRD patients prefer to dialyze at a facility that is convenient and close to their place of residence. Specifically, ESRD patients residing in Nash County will want to dialyze at a dialysis facility in Nash County. Since a significant number of ESRD patients who live in Nash County are apparently leaving the county to obtain their dialysis treatments elsewhere, if those patients have a choice of a facility that is closer and has*

greater flexibility and availability of shift times such as the new facility would provide, many of them will find it more convenient to transfer to a facility within Nash County. Additionally some patients residing in contiguous counties such as Wilson and Edgecombe may find a facility in Rocky Mount more convenient than a facility in their own county and may desire to transfer to the new facility.

- *The patient population in Nash County will be projected forward using the current Five Year Average Annual Change Rate of 9.6% as published in the July 2013 SDR.*
- *TRC assumes that the percentage of patients dialyzing on home therapies on June 30, 2015 will be the same as the percentage published in the July 2013 SDR. The July 2013 [SDR] indicates that as of December 31, 2012, 16.6% of the dialysis patients in Nash County were home dialysis patients.*
- *A new facility should project its growth by taking into account patient proximity to its location, and also allowing for the continued growth of existing dialysis facilities in the County by focusing its projections on patients served by sister facilities of the proponent of the application in other nearby counties. This approach builds the new facility’s growth projections upon the existing referral patterns that have brought patients to its sister facilities.*
- *Letters of support from patients indicating a willingness to consider transferring to a new facility are strong evidence of patient support and commitment.” (emphasis in original)*

The applicant states, regarding the methodology used to determine utilization, on pages 31-32:

“Calculating the Future Number of In-Center Patients

*The excerpt from the Patient Origin Data chart above shows that as of 12/31/2012, TRC provided in-center dialysis to 15 residents of Nash County at facilities outside of the County. As demonstrated by the patient support letters in **Exhibit 12**, as of September 1, 2013, that number had grown to at least 25 patients.*

<i>Facility</i>	<i>Nash County in-center patients as of 12/31/2012 based on Patient Origin Data</i>	<i>Nash County in-center patients as of 09/1/2013 based on Support Letters</i>
<i>Wilson Dialysis in Wilson County</i>	5	8
<i>Forest Hills Dialysis in Wilson County</i>	5	7
<i>Dialysis Care of Edgecombe County</i>	3	10
<i>Dialysis Care Franklin County</i>	2	
TOTAL	15	25

In addition to these patients, as of September 1, 2013 Dr. Bynum, a nephrologist, also provided in-center dialysis to 1 Nash County dialysis patient who did not identify where she was currently receiving her dialysis, but indicated that she would consider transferring to the new Nash County Dialysis when it is open. There are

also 6 dialysis patients who reside in Wilson County who indicated their willingness to consider transferring to the new facility since it would be more convenient for them than their current facility. See patient letters in **Exhibit 12**.

Thus, based on the patient support letters included in **Exhibit 12**, TRC begins its projections with 26 Nash County patients (25 from DaVita facilities and 1 whose current facility is unknown) and 6 Wilson County patients as of September 1, 2013.

First, TRC projects the Nash County patient census forward for four months (to December 31, 2013), using the Five Year Average Annual Change Rate of 9.6% as published in the July 2013 SDR. This is the projected patient census as of December 31, 2013.

- $26 \times 1.032 = 26.8$

TRC then projects that Nash County patient census forward for one full year, using the Five Year Average Annual Change Rate of 9.6% to derive the projected patient census as of December 31, 2014.

- $26.8 \times 1.096 = 29.4$

In-Center Patients at Certification

TRC again projects the Nash County patient census forward, this time for 6 months, using the Five Year Average Annual Change Rate of 9.6% as published in the July 2013 SDR. This is the projected Nash County patient census for June 30, 2015, the day before the projected certification date for the project.

- $29.4 \times 1.048 = 30.8$

In addition there are 6 Wilson County patients who have indicated by support letters that they would consider transferring to the new facility. We have not applied the Nash County Five Year Average Annual Change Rate to these patients since Wilson County's change rate would be different from Nash County's. We have simply added those patients to the Nash County census.

- $30.8 + 6 = 36.8$

Based on these calculations, on July 1, 2015, the projected certification date for the project, TRC is projecting that it will have 30 Nash County in-center patients and 6 Wilson County in-center patients for a total of 36 in-center patients.

In-Center Patients at the End of Operating Years One and Two

To calculate the in-center patients at the end of operating years one and two, TRC again applies the Nash County Five Year Average Annual Change Rate of 9.6% to the starting census of Nash County patients and then adds the 6 Wilson County in-

center patients to that total. This results in an in-center census of 39 patients at the end of Operating Year 1 and 43 patients at the end of Operating Year 2.

- *30.8 X 1.096 = 33.8 Nash County in-center patients plus 6 Wilson County in-center patients for a total of 39.8 or 39 in-center patients as of June 30, 2016, the end of Operating Year 1.*
- *33.8 X 1.096 = 37.0 Nash County in-center patients plus 6 Wilson County in-center patients for a total of 43.0 or 43 in-center patients as of June 30, 2017, the end of Operating Year 2.” (emphasis in original)*

Projected utilization is based on reasonable, credible, and supported assumptions. Specifically, the applicant documents that as many as 32 in-center patients would be interested in transferring to the proposed facility. Continued growth of this population is also adequately supported by the five year average annual change rate as published by the Agency in the July 2013 SDR. Therefore, the applicant adequately demonstrates the need for the proposed 12-station facility.

In summary, the applicant adequately identified the population to be served and demonstrated the need this population has for the development of a new 12-station dialysis facility. 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 Applications

- (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 - BMA Rocky Mount
C - Nash County Dialysis

BMA Rocky Mount – In Section III.9, pages 44-45, the applicant describes the alternatives it considered prior to the submission of its application:

“BMA of North Carolina has considered several alternatives to this project. ...

- (a) *BMA considered not applying to develop these 11 stations. However, as noted within the application BMA is serving a significant number of dialysis patients who reside in Rocky Mount, Nash and other counties in the area. BMA expects this patient population to continue to increase based upon the patient relationship with BMA facilities and the participation of nephrology*

physicians from Boice-Willis. BMA projections of patient population to be served certainly warrant 11 additional stations at the facility.

- (b) *BMA could have chosen to develop a new facility pursuant to the County Need Determination, and could have applied for up to 19 dialysis stations. In fact, BMA has applied in August 2013 to develop the new FMC South Rocky Mount.*

...

BMA does not believe that another part of the county would be suitable for development of a new facility or 10 or more stations.

...

Development of new stations at BMA Rocky Mount was the most suitable alternative.

- (c) *BMA could have applied by way of the County Need Determination to add some stations to its proposed FMC South Rocky Mount. However, within the application to develop FMC South Rocky Mount, BMA proved the need for 12 stations at that location. It is not likely that the proposed FMC South Rocky Mount facility could support additional stations and remain compliant with 10A NCAC 14C. 2203(a). Thus, BMA has made the decision to site stations at the BMA Rocky Mount facility. Development of new stations at BMA Rocky Mount was the most suitable alternative.*

- (d) *BMA could have used the Nash County Five Year Average Annual Change Rate as published in the July 2013 SDR. BMA has noted its disagreement with the SDR as published. ... BMA has offered an application which is based on credible information and offers a conservative approach to projections of need.”*

Furthermore, the application is conforming with all other applicable statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative.

The applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion.

Nash County Dialysis – In Section III.9, pages 34-35, the applicant describes the alternatives it considered prior to the submission of its application:

“One alternative considered was to do nothing on our part. We determined that while this may be the least costly; however, it is not the most effective alternative for the large number [of] dialysis patients we are serving who live in Scotland [sic] County who travel outside their county for dialysis treatments.

The other alternative is to do the right thing and bring additional dialysis services and a new provider to the patients who live in Nash County. It was determined that the facility would be located in Rocky Mount. Most of the patient [sic] who signed letters indicated that they live in or near Rocky Mount. The proposed site for the dialysis facility is near major highways that run north and south and east and west, providing easy access for patients.

...

Total Renal Care will up-fit the shell building and turn it into a modern, state-of-the-art dialysis facility that will serve the needs of the ESRD dialysis patients living in Nash County, but dialyzing outside of the county. It will also be available to new dialysis patients who are diagnosed with End Stage Renal Disease and find themselves in need for dialysis treatments. Having a second provider in the county offers the Nephrologists and patients an alternative.”

Furthermore, the application is conforming with all other applicable statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative.

The applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the need. Therefore, the application is 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 - BMA Rocky Mount
C - Nash County Dialysis

BMA Rocky Mount – In Section VIII.1, page 62, the applicant states that this is an existing facility and no renovations are necessary to accommodate the 11 stations. All equipment is to be leased, not purchased. As a result, the applicant projects no capital costs. In Section IX, page 66, the applicant states that because this is an existing facility, there will be no start-up costs or initial operating expenses as a result of this project.

In Section X.1, page 67, the applicant provides the following information regarding the facility’s allowable charge per treatment by payor source:

BMA Rocky Mount Allowable Charge per Treatment by Payment Source		
	In-Center	Home PD
Commercial Insurance*	\$1,375.00	\$1,375.00
Medicare	\$234.00	\$234.00
Medicaid	\$137.29	\$137.29
VA	\$146.79	\$147.85
Private Pay	\$1,375.00	\$1,375.00

*The applicant notes that commercial charges listed do not reflect actual reimbursement rates. The applicant states that it is industry standard for providers to have contractual relationships with various providers that results in less reimbursement than the stated charge.

In Section X, pages 68 and 74, the applicant projects revenues and operating costs for the first two operating years of the proposed project, as shown in the table below.

BMA Rocky Mount			
	Current Operating Year	Year 1	Year 2
Gross Revenue	\$12,355,720	\$8,256,342	\$8,506,168
Contractual Adjustments	\$2,962,347	\$1,776,899	\$1,844,268
Net Revenue	\$9,393,372	\$6,479,443	\$6,661,899
Total Operating Costs	\$7,009,864	\$5,372,268	\$5,511,318
Net Profit	\$2,383,508	\$1,107,175	\$1,150,581

As shown in the table above, the applicant projects that revenues will exceed operating costs in each of the first two years of operation following completion of this project. Revenues and operating costs are based on reasonable, credible and supported assumptions, including the projected number of treatments, charges, reimbursement rates, contractual adjustments and salaries.

According to the Centers for Medicare & Medicaid Services (CMS), the End-Stage Renal Disease Prospective Payment System (ESRD PPS) base rate for CY 2012 was \$234.81.¹ The applicant appears to use the CY 2012 ESRD PPS reimbursement rates in its pro formas. In Section X.1, pages 67-68, the applicant does not reduce the Medicare reimbursement rate by 20 percent. While Medicare will routinely pay for 80 percent of Medicare-approved dialysis treatments, the patient is responsible for the remaining 20 percent. Thus, the total revenue for each Medicare patient would be 100 percent of the maximum allowable charge: Medicare would pay 80 percent and the patient would pay 20 percent. Moreover, in Section X.2, page 68, the applicant provides a table with a line item labeled “*Other Deductions from Revenue (Total Contractual Allowances)*” and deducts more than 20 percent of the gross patient service revenue as contractual allowances. In Section X.4, pages 73-74, the applicant provides a table showing actual and estimated annual operating expenses. The applicant includes a line item for bad debt and charity expenses in its annual operating expenses. Between contractual adjustments and bad debt/charity items, the applicant reduces its gross revenue for the current operating year, Operating Year One, and Operating Year Two by 28.5 percent, 26.2 percent, and 26.4 percent, respectively.

In Section X.4, page 76, the applicant discusses the impact of a potential cut in Medicare reimbursement rates due to the implementation of the American Taxpayer Relief Act of 2012. The applicant states that Medicare reimbursement rates may be cut as much as 9 percent. The applicant states that if the Medicare reimbursement rate were cut 9 percent, the facility would have less profit but would also have less tax liability. A proposed rule was published in the Federal Register on July 8, 2013 proposing a Medicare ESRD PPS base rate of \$216.95 (which would have been a cut of 12 percent from the CY 2013 Medicare ESRD PPS base rate). However, the final rule, published in the Federal Register and effective on December 10, 2013, fixed the CY 2014 Medicare ESRD PPS base rate at \$239.02. The applicant, in its alternate pro formas, demonstrates that even if the Medicare reimbursement rate were as low as \$213, the

¹ “End-Stage Renal Disease Prospective Payment System,” Payment System Fact Sheet Series, ICN 905143, December 2012.

facility will still generate revenues exceeding expenses during the first two operating years of the project.

The applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming with this criterion.

Nash County Dialysis – In Section VIII.1, page 55, the applicant states the capital cost is projected to be \$1,589,227. In Section IX.3, page 59, the applicant states that the total working capital needed will be \$979,174 (\$150,088 in start-up expenses and \$829,086 in initial operating expenses.)

In Section VIII.2-3, pages 56-57, and Section IX.4, pages 59-60, and Exhibit 29, the applicant states it will fund the capital and working capital needs of the proposed project from the cash reserves of DaVita HealthCare Partners, Inc., the parent company of Total Renal Care, Inc. Exhibit 29 contains a letter, dated September 12, 2013, from the Chief Accounting Officer of DaVita HealthCare Partners, Inc., which states:

“I am the Chief Accounting Officer of DaVita HealthCare Partners, Inc. (“DaVita”), which is the parent company and 100% owner of Total Renal Care, Inc. (“Total Renal Care”). I also serve as the Chief Accounting Officer of Total Renal Care, which will be applying for a certificate of need to develop a new End Stage Renal Disease hemodialysis facility in Rocky Mount in Nash County, which is projected to open in the third quarter of 2015. DaVita, through Total Renal Care has committed cash reserves in the total amount of \$2,668,401 for the capital costs, start up costs and the working capital needed for this new facility. Our company is absolutely committed to the development and operation of this new facility, and we will ensure that these funds are made available.”

In Exhibit 30, page F-6, the applicant provides audited financial statements for DaVita HealthCare Partners, Inc. (DaVita) which document that DaVita had \$533,748,000 in cash and cash equivalents as of December 31, 2012. The applicant adequately demonstrated the availability of sufficient funds for the capital and working capital needs of the project.

In Section X.1, page 61, the applicant provides the following information regarding the facility’s allowable charge per treatment by payor source:

Nash County Dialysis Allowable Charge per Treatment by Payment Source	
	In-Center
Commercial	\$1,442.00
Medicare	\$192.28
Medicaid	\$143.00
Medicare/Medicaid	\$240.36
Medicare/Commercial	\$240.36
VA	\$193.00

*The applicant notes that for the Medicare only charges, it applied the Medicare ESRD PPS base rate for CY 2013—\$240.36—minus 20 percent when there is no secondary payor—to get the charge of \$192.28.

According to the Centers for Medicare & Medicaid Services (CMS), the End-Stage Renal Disease Prospective Payment System (ESRD PPS) base rate for CY 2013 was \$240.36.² As noted above, the applicant reduces its ESRD PPS base rate by 20 percent to account for patient responsibility. In Section X.2, page 61, and Section X.4, page 64, the applicant documents that bad debt and charity expenses were deducted from revenues.

In Section X, pages 61 and 64, the applicant projects the revenues and operating costs for the first two operating years of the proposed project, as shown in the table below.

Nash County Dialysis		
	Year 1	Year 2
Net Revenue	\$1,928,798	\$2,121,721
Total Operating Costs	\$1,797,870	\$1,923,139
Net Profit	\$130,928	\$198,582

As shown in the table above, the applicant projects that revenues will exceed operating costs in each of the first two years of operation following completion of this project. Revenues and operating costs are based on reasonable, credible and supported assumptions, including the projected number of treatments, charges, reimbursement rates and salaries.

The applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming with 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 - BMA Rocky Mount
C - Nash County Dialysis

There are currently two dialysis facilities located in Nash County. FMC of Spring Hope is currently certified for 10 stations and is approved to add 3 stations (Project I.D. #L-8796-12). BMA Rocky Mount is currently certified for 42 stations. There is a third facility approved—FMC South Rocky Mount—which will be certified for 12 stations (Project I.D. #L-10177-13). Those 12 stations are being relocated from BMA Rocky Mount, which will leave BMA Rocky Mount with 30 certified stations when Project I.D. #L-10177-13 is complete, if no further stations are approved. See the following table:

² “End-Stage Renal Disease Prospective Payment System,” Payment System Fact Sheet Series, ICN 905143, December 2012.

Nash County Dialysis Facilities			
Dialysis Facility	Certified Stations 12/31/12	% Utilization	Patients Per Station
FMC Spring Hope*	10	82.50%	3.3
BMA Rocky Mount**	42	91.07%	3.6

Source: July 2013 SDR, Table A.

*FMC Spring Hope is approved to develop three additional stations (Project I.D. #L-8796-12) for a total of 13 stations upon project completion.

**BMA is approved to relocate 12 stations to a new facility (FMC South Rocky Mount) (Project I.D. #L-10177-13).

BMA Rocky Mount – The 2013 SMFP and the July 2013 SDR indicate a need for 19 additional dialysis stations in Nash County. BMA Rocky Mount proposes to add 11 certified stations to its existing facility in Rocky Mount, in Nash County. The applicant adequately demonstrates the need to add 11 stations to the existing facility. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. Therefore, the applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

Nash County Dialysis – The 2013 SMFP and the July 2013 SDR indicate a need for 19 additional dialysis stations in Nash County. Nash County Dialysis proposes to develop a new 12-station dialysis facility in Rocky Mount, in Nash County. The applicant adequately demonstrates the need to develop a new 12-station dialysis facility. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. Therefore, the applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

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

C - BMA Rocky Mount
C - Nash County Dialysis

BMA Rocky Mount – In Section VII.1, page 59, the applicant projects the following staffing during the first two operating years:

Position	Total FTEs Years 1 and 2
RN	7.00
Technician	15.00
Clinical Manager	1.00
Admin. (Dir. of Ops.)	0.20
Dietician	1.30
Social Worker	1.30
Home Training Nurse	1.00
Chief Tech	0.40
Equipment Tech	1.70
In-Service	0.33
Clerical	2.00
Total	31.23

As shown in the above table, the applicant proposes a total of 31.23 FTE positions, which is also the current staffing level. BMA Rocky Mount is currently certified for 42 certified dialysis stations. The applicant has been approved to relocate 12 stations to a new facility in south Rocky Mount. In this application, the applicant proposes to add 11 stations for a total of 41 certified dialysis stations upon project completion. The applicant reasonably projects the same staffing levels for the proposed 41 certified dialysis stations as the current staffing for the 42 existing certified dialysis stations.

The following table shows hours of operation as proposed by the applicant in Section VII.10, on page 61:

Weekly Hours of Operation				
Day	Morning	Afternoon	Evening	Total
Monday	6	5	0	11
Tuesday	6	5	0	11
Wednesday	6	5	0	11
Thursday	6	5	0	11
Friday	6	5	0	11
Saturday	6	5	0	11
Sunday	0	0	0	0
Total	36	30	0	66
Total Hours Operation per Year (weekly hours x 52):				3,432

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.1, page 59, and VII.10, page 61:

	# FTEs	Hrs/Yr/FTE	Total FTE Hours (annual)	Total Hrs of Operation (annual)	FTE Hrs/Hrs of Operation
RN	7.0	2,080	14,560	3,432	4.2
Techs	15.0	2,080	31,200	3,432	9.1
Total	22.0	2,080	45,760	3,432	13.3

Based on the proposed operating hours for the facility, it will be open 3,432 hours a year. In Section VII.1, page 59, the applicant projects 22.0 total Patient Care Technician and

Registered Nurse FTEs. Assuming one FTE works 2,080 hours annually, 22.0 FTEs would work a total of 45,760 hours annually, which is sufficient to cover the 3,432 hours of operation. The applicant proposes more than sufficient direct care staff to provide the proposed services.

In addition, the proposed facility projects to serve 132 in-center patients in Operating Year One on 41 stations in 2 shifts, per day, Monday through Saturday. The following table illustrates the maximum number of in-center patients per shift.

Time/Shift	M/W/F Patients	T/TH/SA Patients
Morning (41 stations)	41	41
Afternoon (41 stations)	41	41

As shown in the table above, the 41-station facility would be able to dialyze up to a maximum of 164 in-center patients on 41 dialysis stations, assuming one patient per station per shift and two shifts per day, Monday through Saturday. The applicant states it projects to serve 132 in-center patients in Operating Year Two on 41 stations.

In Section V.4(c), page 51, the applicant states that Michael Holland, MD has agreed to serve as Medical Director for the facility. Exhibit 21 contains a letter from Michael Holland, MD, which states: *“I am writing to wholeheartedly endorse the Certificate of Need application by Bio-Medical Applications of North Carolina, Inc., to add 11dialysis [sic] stations at the BMA Rocky Mounty [sic] dialysis. I am pleased to continue serving as Medical Director for BMA Rocky Mount.”*

The information regarding staffing provided in Section VII is reasonable and credible and supports a finding of conformity with this criterion.

Nash County Dialysis – In Section VII.1, page 51, the applicant projects the following staffing during the first two operating years:

Position	Total FTEs Years 1 and 2
RN	1.5
RN HT	0.7
Patient Care Technician	4.5
Bio-Med Tech	0.3
Admin	1.0
Dietician	0.4
Social Worker	0.4
Unit Secretary	1.0
Total	9.8

As shown in the above table, the applicant proposes a total of 9.8 full-time equivalent (FTE) positions. In Section VII.4, page 53, the applicant states that it does not anticipate having any difficulty staffing the proposed facility.

The following table shows hours of operation as proposed by the applicant in Section VII.10, on page 54:

Weekly Hours of Operation				
Day	Morning	Afternoon	Evening	Total
Monday	4	6	0	10
Tuesday	4	6	0	10
Wednesday	4	6	0	10
Thursday	4	6	0	10
Friday	4	6	0	10
Saturday	4	6	0	10
Sunday	0	0	0	0
Total	24	36	0	60
Total Hours Operation per Year (weekly hours x 52):				3,120

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 54:

	# FTEs	Hrs/Yr/FTE	Total FTE Hours (annual)	Total Hrs of Operation (annual)	FTE Hrs/Hrs of Operation
RN	1.5	2,080	3,120	3,120	1.0
Techs	4.5	2,080	9,360	3,120	3.0
Total	6.0	2,080	12,480	3,120	4.0

Based on the proposed operating hours for the facility, it will be open 3,120 hours a year. In Section VII, page 51, the applicant projects 6.0 total Patient Care Technician and Registered Nurse FTEs. Assuming one FTE works 2,080 hours annually, 6.0 FTEs would work a total of 12,480 hours annually, which is sufficient to cover the 3,120 hours of operation. The applicant proposes more than sufficient direct care staff to provide the proposed services.

In addition, the proposed facility projects to serve 39 in-center patients in Operating Year One on 12 stations in 2 shifts, per day, Monday through Saturday. The following table illustrates the maximum number of in-center patients per shift.

Time/Shift	M/W/F Patients	T/TH/SA Patients
Morning (12 stations)	12	12
Afternoon (12 stations)	12	12

As shown in the table above, the proposed 12-station facility would be able to dialyze up to a maximum of 48 in-center patients on 12 dialysis stations, assuming one patient per station per shift and two shifts per day, Monday through Saturday. The applicant states it projects to serve 43 in-center patients in Operating Year Two on 12 stations.

In Section V.4(c), page 41, the applicant states that Will Bynum, MD has agreed to serve as Medical Director of the facility. Exhibit 21 contains a letter from Will Bynum, MD stating that has agreed to serve as Medical Director of the proposed facility and that he has a nephrology practice in Nash County. The letter in Exhibit 21 states:

“As a practicing Nephrologist in Nash County, I support the efforts of Total Renal Care to expand their service into Nash County. I have agreed to serve as Medical Director for the facility. I will refer End State Renal Disease patients to Nash County Dialysis.”

The information regarding staffing provided in Section VII is reasonable and credible and supports a finding of conformity with 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 - BMA Rocky Mount
C - Nash County Dialysis

BMA Rocky Mount – In Section II.1, pages 23-24, and Sections V.1-2, pages 48-50, the applicant lists the providers of the necessary ancillary and support services, and provides documentation in Exhibits 16, 17, 18, 20, and 21. Exhibit 16 contains a copy of the existing Hospital Affiliation Agreement between BMA Rocky Mount and Nash General Hospital. Exhibit 17 contains a copy of the existing Transplant Agreement between BMA Rocky Mount and East Carolina University School of Medicine/Pitt County Memorial Hospital. The information provided in Section V and the referenced exhibits is reasonable and credible and supports a finding of conformity with this criterion.

Nash County Dialysis – In Section II.1, pages 22-24, and Sections V.1-2, pages 39-40, the applicant lists the providers of the necessary ancillary and support services. In Exhibits 7, 8, 15, 16, 17, 19, 20, and 21, the applicant documents how the project will be coordinated with the existing health care system. Exhibit 7 contains a copy of a letter dated September 10, 2013, from the Chief Operating Officer of Nash Hospitals, Inc., which states: *“This letter is to inform CON that Nash Hospitals, Inc. will enter into a Patient Transfer Agreement with Total Renal Care, Inc. when they are issued the Certificate of Need.”* Exhibit 7 also contains a copy of a letter dated August 26, 2013, from the President and Chief Executive Officer of Wilson Medical Center, which states: *“Our hospital will enter into a Patient Transfer Agreement with Total Renal Care, Inc. when they are issued the Certificate of Need.”* Exhibit 8 contains a copy of a letter dated September 13, 2013, from the President of Vidant Medical Center, which states: *“Our hospital will enter into a Transplant Agreement with Total Renal Care, Inc. when the Certificate of Need is awarded.”* Exhibit 8 also contains a copy of a letter dated September 3, 2013, from the Assistant Vice President of Carolinas Medical Center, which states: *“Our hospital will enter into a Transplant Agreement with Total Renal Care, Inc. when the Certificate of Need is awarded.”* The information provided in Section V and the referenced exhibits is reasonable and credible and supports a finding of conformity with this criterion.

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

NA - Both Applications

- (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 - Both Applications

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

NA - BMA Rocky Mount
C - Nash County Dialysis

Nash County Dialysis proposes to have an unrelated developer construct a 7,400 square foot building on Lot #8 of Winstead Park, on Winstead Avenue and English Road, in Rocky Mount. In Section XI.5(d), page 70, the applicant states, “*The facility will be constructed with energy-efficient glass, mechanically operated patient access doors and energy-efficient cooling and heating.*” In Section XI.6(g), pages 71-72, 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 demonstrates 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, which is incorporated hereby as if set forth fully herein. 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 - BMA Rocky Mount
NA - Nash County Dialysis

BMA Rocky Mount – In Section VI.1(a), page 54, the applicant states:

“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.

BMA of North Carolina has historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. For example, Medicare represented 84.8% of North Carolina dialysis treatments in BMA facilities in FY 2012. Medicaid treatments represented an additional 4.5% of treatments in BMA facilities in FY 2012, [sic] Low income and medically underinsured persons will continue to have access to all services provided by BMA.”

The following table illustrates the current payor mix for BMA Rocky Mount, as provided by the applicant in Section VI.1(b), pages 54-55:

BMA Rocky Mount Payor Mix as of June 30, 2013			
Payor Source	In-Center	HH	PD
Private Pay	0.0%	0.00%	0.00%
Commercial Insurance	12.2%	29.05%	29.05%
Medicare	81.4%	65.34%	65.34%
Medicaid	2.8%	2.59%	2.59%
Medicare/Medicaid	0.0%	0.00%	0.00%
Medicare/Commercial	0.0%	0.00%	0.00%
State Kidney Program	0.0%	0.00%	0.00%
VA	3.7%	3.02%	3.02%
Other: Self/Indigent	0.0%	0.00%	0.00%
Total	100.0%	100.00%	100.00%

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

	Total # of Medicaid Eligibles as % of Total Population* as of June 2010	Total # of Medicaid Eligibles Age 21 and older as % of Total Population* as of June 2010	% Uninsured 2008-2009 (Estimate by Cecil G. Sheps Center)*
Nash County	20%	8.7%	19.7%
Statewide	17%	6.7%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by BMA Rocky Mount. In fact, in 2011 only 5.8 percent of all newly-diagnosed ESRD patients (incident ESRD patients) in North Carolina's Network 6 were under the age of 35.

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 45.9 percent for those age 20 and younger and 30.6 percent 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.

The Centers for Medicare & Medicaid Services (CMS) website states:

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

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

total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9) populations.”³

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report (page 225), provides these national statistics for FY 2010: “*On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy.*” Of the 376,000 ESRD patients, 38.23 percent were African American, 55.38 percent were white, 55.65 percent were male, and 44.65 percent were 65 and older. The report further states:

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

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

ESRD Spending by Payor		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

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

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender demonstrating the following:

³ www.cms.gov/medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf

Number and Percent of Dialysis Patients by Age, Race and Gender		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%
Other	219	2.3%

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

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

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

C - BMA Rocky Mount
C - Nash County Dialysis

BMA Rocky Mount – Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.1(f), page 56, the applicant states: “*BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations.*” In Section VI.6(a), page 58, the applicant states: “*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.*” Therefore, the application is conforming to this criterion.

Nash County Dialysis – Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.1(f), page 47, the applicant states: “*Nash County Dialysis will have no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993.*” In Section VI.6(a), page 49, the applicant states: “*There have been no civil*

rights equal access complaints filed within the last five years against any facility operated by Total Renal Care, Inc. or by any facility in North Carolina owned by DaVita HealthCare Partners, Inc.” Therefore, the application is conforming to this criterion.

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

C - BMA Rocky Mount
C - Nash County Dialysis

BMA Rocky Mount – In Section VI.1(c), page 55, the applicant provides the following projected payor mix during the second year of operation:

Payor	In-Center	HH	PD
Private Pay	0.0%	0.00%	0.00%
Commercial Insurance	12.2%	29.05%	29.05%
Medicare	81.4%	65.34%	65.34%
Medicaid	2.8%	2.59%	2.59%
Medicare/Medicaid	0.0%	0.00%	0.00%
Medicare/Commercial	0.0%	0.00%	0.00%
State Kidney Program	0.0%	0.00%	0.00%
VA	3.7%	3.02%	3.02%
Other: Self/Indigent	0.0%	0.00%	0.00%
Total	100.0%	100.00%	100.00%

The applicant projects 84.2 percent of its in-center patients will have some or all of their care paid for by Medicare or Medicaid (81.4 percent Medicare plus 2.8 percent Medicaid). The applicant projects 67.93 percent of its home hemodialysis and peritoneal dialysis patients will have some or all of their care paid for by Medicare or Medicaid (65.34 percent Medicare plus 2.59 percent Medicaid). In Section VI.1(a), page 54, the applicant states:

“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.

BMA of North Carolina has historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. For example, Medicare represented 84.8% of North Carolina dialysis treatments in BMA facilities in FY 2012. Medicaid treatments represented an additional 4.5% of treatments in BMA facilities in FY 2012, [sic] Low income and medically underinsured persons will continue to have access to all services provided by BMA.”

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

Nash County Dialysis – In Section VI.1(c), page 46, the applicant projects the following payor mix during the second year of operation:

Payor Source	Percent Utilization by Payor Source
Private Pay	0.0%
Medicare	19.7%
Medicaid	5.4%
Medicare/Medicaid	35.5%
Commercial Insurance	5.4%
VA	2.7%
Indigent	0.0%
Medicare/Commercial	31.3%
TOTAL	100.0%

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

“Nash County 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.

...

Nash County 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.”

In Section VI.1(c), pages 45-46, the applicant states:

“TRC currently does not have any facilities in Nash County from which to draw this information. Therefore we have based our payor mix on the average percentages of patients who are currently dialyzing at Wilson Dialysis Center. Wilson Dialysis Center is a DaVita owned facility in Wilson County, which is contiguous to Nash County. The pertinent demographics of Wilson County, while not identical to Nash County, are similar. Moreover, there are several dialysis patients in Wilson County who dialyze in Wilson County at a TRC facility, who are expected to transfer to the new TRC facility in Nash County, so it is reasonable to use the payor mix from Wilson Dialysis Center as a basis for the payor mix for the Nash County facility.”

Wilson County is contiguous to Nash County. U.S. Census Bureau data show substantial similarities in the economic status of the two counties. The poverty level

in Wilson County is similar to that of Nash County. The families living below the poverty level is 22.8 percent in Wilson County and 17.6 percent in Nash County. The per capita income is \$20,671 in Wilson County and \$23,364 in Nash County. Further, as of July 2009, the population of Wilson County was 81,234 and the population of Nash County was 95,840. As of June 2010, the total Medicaid eligible population was 17,804 in Wilson County and 18,756 in Nash County. Thus it is reasonable to assume that these two contiguous counties are comparable in economic status. Furthermore, Wilson County is where almost all of the patients projected to transfer to the proposed facility currently receive their dialysis treatments.

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

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

C - BMA Rocky Mount
C - Nash County Dialysis

BMA Rocky Mount – In Section VI.5, pages 57-58, the applicant describes the range of means by which patients will have access to the proposed services. The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity with this criterion.

Nash County Dialysis – In Section VI.5, pages 48-49, the applicant describes the range of means by which patients will have access to the proposed services. The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity with 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 - BMA Rocky Mount
C - Nash County Dialysis

BMA Rocky Mount – In Section V.3, pages 50-51, the applicant provides information about how its proposed health services will accommodate the needs of health professional training programs in the area. On page 50, the applicant states: *“Exhibit 19 contains a letter from Anita Harris, FMC Director of Operations, to Wilson Community College inviting the school to include BMA Rocky Mount Center as a clinical rotation site for the Health Occupations students. This type of agreement is typical for all BMA facilities.”* The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion.

Nash County Dialysis – In Section V.3, page 41, the applicant provides information about how its proposed health services will accommodate the needs of health professional training programs in the area. The applicant states: “See **Exhibit 19** for a copy of the letters sent by *Dodie Robinson, Regional Operations Director, to the President of Nash Community College and the Career Technical Coordinator at Nash Central High School.*” The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion.

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

C - BMA Rocky Mount
C - Nash County Dialysis

There are currently two dialysis facilities located in Nash County. FMC of Spring Hope is currently certified for 10 stations and is approved to add 3 stations (Project I.D. #L-8796-12). BMA Rocky Mount is currently certified for 42 stations. There is a third facility approved—FMC South Rocky Mount—which will be certified for 12 stations (Project I.D. #L-10177-13). Those 12 stations are being relocated from BMA Rocky Mount, which will leave BMA Rocky Mount with 30 certified stations when Project I.D. #L-10177-13 is complete, if no further stations are approved. See the following table:

Nash County Dialysis Facilities			
Dialysis Facility	Certified Stations 12/31/12	% Utilization	Patients Per Station
FMC Spring Hope*	10	82.50%	3.3
BMA Rocky Mount**	42	91.07%	3.6

Source: July 2013 SDR, Table A.

*FMC Spring Hope is approved to develop three additional stations (Project I.D. #L-8796-12) for a total of 13 stations upon project completion.

**BMA is approved to relocate 12 stations to a new facility (FMC South Rocky Mount) (Project I.D. #L-10177-13).

BMA Rocky Mount – In Section V.7, pages 52-53, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

“BMA has been providing dialysis treatment to the overwhelming majority of the Nash County ESRD patient population as is noted within this application. Further, the

physicians of Boice-Willis are likewise providing medical coverage for patients from Nash County. This facility will have added value stemming from the strength of our relationship with the nephrology physicians at Boice-Willis. The practice brings together a team of highly qualified nephrologists to serve the ESRD patient needs of the area.”

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

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to add 11 dialysis stations to BMA Rocky Mount and that it is a cost-effective alternative;
- The applicant adequately demonstrates that it will continue to provide quality services; and
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations.

The application is conforming to this criterion.

Nash County Dialysis – In Section V.7, pages 42-44, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

“DaVita HealthCare Partners Inc. and Total Renal Care, Inc. do not expect that this proposal will have any adverse effect on competition within Nash County. In fact, because at this time there is only one provider of dialysis services in Nash County, the addition of a second provider should enhance competition.”

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

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to develop a new 12-station facility in Nash County and that it is a cost-effective alternative;
- The applicant adequately demonstrates that it will provide quality services; and
- The applicant demonstrates that it will provide adequate access to medically underserved populations.

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 - BMA Rocky Mount
NA - Nash County Dialysis

BMA Rocky Mount – According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, BMA Rocky Mount operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

Nash County Dialysis does not have an existing facility in Nash County.

- (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 - BMA Rocky Mount
C - Nash County Dialysis

BMA Rocky Mount's application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as promulgated in 10A NCAC 14C .2200. See discussion below.

Nash County Dialysis's application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as promulgated in 10A NCAC 14C .2200. See discussion below.

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

.2202 INFORMATION REQUIRED OF APPLICANT

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

- C- **BMA Rocky Mount** – See Section II, page 11, which indicates the facility had a 91.07 percent utilization rate as of December 31, 2012.
- NA- **Nash County Dialysis** – The applicant proposes a new facility.
- (2) *Mortality rates;*
- C- **BMA Rocky Mount** – See Section IV.2, page 46, where the applicant reports 2010, 2011 and 2012 facility mortality rates of 18.7 percent, 19.4 percent and 23.0 percent, respectively.
- NA- **Nash County Dialysis** – The applicant proposes a new facility.
- (3) *The number of patients that are home trained and the number of patients on home dialysis;*
- C- **BMA Rocky Mount** – In Section IV.3, page 46, the applicant states that BMA Rocky Mount had 35 patients that were home trained in 2013.
- NA- **Nash County Dialysis** – The applicant proposes a new facility.
- (4) *The number of transplants performed or referred;*
- C- **BMA Rocky Mount** – In Section IV.4, page 46, the applicant states BMA Rocky Mount referred 18 patients for transplant evaluation in 2012. BMA Rocky Mount had seven patients receive a transplant in 2012.
- NA- **Nash County Dialysis** – The applicant proposes a new facility.
- (5) *The number of patients currently on the transplant waiting list;*
- C- **BMA Rocky Mount** – In Section VI.5, page 46, the applicant states that BMA Rocky Mount has 22 patients on the transplant waiting list.
- NA- **Nash County Dialysis** – The applicant proposes a new facility.
- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- **BMA Rocky Mount** – In Section IV.6, pages 46-47, the applicant reports a total of 289 hospital admissions in 2012; 201 were non-dialysis related and 88 were dialysis-related.
- NA- **Nash County Dialysis** – The applicant proposes a new facility.
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*

-C- **BMA Rocky Mount** – In Section IV.7, page 47, the applicant reports that in 2012 there was one patient with an infectious disease, and no patients converted to infectious status in 2012.

-NA- **Nash County Dialysis** – The applicant proposes a new facility.

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

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

-NA- **BMA Rocky Mount** – The applicant does not propose a new facility.

-C- **Nash County Dialysis** – Exhibit 7 contains a letter dated September 10, 2013, signed by the Chief Operating Officer, Nash Hospitals, Inc., stating that the hospital will enter into a Patient Transfer Agreement with the applicant when a certificate of need is issued. The letter describes the services that the hospital will provide to patients of the dialysis facility. Exhibit 7 also contains a letter dated August 26, 2013, signed by the President & CEO, Wilson Medical Center, stating that the hospital will enter into a Patient Transfer Agreement with the applicant when a certificate of need is issued. This letter also describes the services that the hospital will provide to patients of the dialysis facility. In Section II.1, page 11, the applicant also states, “*Nash County Dialysis will seek out other area hospitals to establish patient transfer agreements once the Certificate of Need has been awarded.*”

(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) *composition of the assessment/evaluation team at the transplant center,*
- (C) *method for periodic re-evaluation,*
- (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
- (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*

- NA- **BMA Rocky Mount** – The applicant does not propose a new facility.

- C- **Nash County Dialysis** – Exhibit 8 contains a letter dated September 13, 2013, signed by the President of Vidant Medical Center, stating that the hospital will enter into a Transplant Agreement with the applicant when a certificate of need is issued. The letter includes the requirements listed in subsection 2(a)-(e) of this rule. Exhibit 8 also contains a letter dated September 3, 2013, signed by the Assistant Vice President of Carolinas Medical Center, stating that the hospital will enter into a Transplant Agreement with the applicant when a certificate of need is issued. This letter also includes the requirements listed in subsection 2(a)-(e) of this rule. In Section II.1, page 11, the applicant also states, “*Nash County Dialysis will seek out other area transplant centers to establish transplant agreements once the Certificate of Need has been awarded.*”

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

- NA- **BMA Rocky Mount** – The applicant does not propose a new or replacement facility.

- C- **Nash County Dialysis** – Exhibit 9 contains a copy of an email response, sent September 5, 2013, from the Utilities Communication Coordinator for the Town of Rocky Mount, stating that electric and natural gas services are available at the primary site. In Section XI.5(e), page 71, the applicant states, “*The facility will be located in an area that is supplied by potable city water. **Exhibit 10** of the application describes the procedures that will be in place so that the facility will comply with 42 C.F.R. Section 405.2100. The facility will modify the existing water by providing for dechlorination, softening, reverse osmosis water systems combined with pyrogen filters for bacteria removal.*” (emphasis in original) Exhibit 10 also contains a copy of an email response sent September 5, 2013, from an Engineering Technician for the Town of Rocky Mount, documenting the availability of water and sewer at the primary site.

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

- C- **BMA Rocky Mount** – Exhibit 12 contains copies of written policies and procedures for back-up electrical services in the event of a power outage.

- C- **Nash County Dialysis** – In Section XI.5(f), page 71, the applicant states, “*The site will be served by standing power service. The facility will provide in its procedures for temporary power outages that sometimes occur during a treatment shift. This is done by resetting the machines, all which have a provision contained in their construction for hand rotation. This is considered adequate for temporary power outages. **Exhibit 9** contains a copy of the policies and procedures for temporary power outages.*” (emphasis in original) Exhibit 9 also documents a written request, dated September 9, 2013, from Nash

County Dialysis to the Regional Operations Director for DaVita, Inc., requesting to add Nash County Dialysis to the network of facilities that provide back-up to other facilities when there are emergencies. The letter requests Dialysis Care of Edgecombe County as the primary back-up and Wilson Dialysis Center and Forest Hills Dialysis Center as secondary back-ups.

- (5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- NA- **BMA Rocky Mount** – The applicant does not propose a new facility.
- C- **Nash County Dialysis** – In Sections XI.2 and XI.3, pages 67-39, the applicant describes the location of both the primary and secondary sites located at Winstead Park, at Winstead Avenue and English Road, Rocky Mount (different lots of the same business park). The applicant states in Section XI.1, page 67, “Attached as **Exhibit 32** [sic] is a copy of a letter from R. Gregg Hill, Manager of Hill/Gray Seven, LLC, indicating his intent to negotiate the purchase of property and construct a shell building. Once the shell building is constructed, Total Renal Care, Inc. will up-fit the shell building. This exhibit also has a copy of the DaVita Minimum Base Building Improvements and the DaVita Inc. Standard Lease Agreement.” Exhibit 33 (the correct exhibit) also contains a written commitment from the applicant to pursue acquiring the sites and documentation that the primary and secondary sites are available for acquisition.
- (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- **BMA Rocky Mount** – In Section XI.6(g), page 80, the applicant states, “BMA of North Carolina provides and will continue to provide services in conformity with applicable laws and regulations pertaining to staffing, fire safety and equipment, physical environment and other relevant health and safety requirements.” In Sections VII.1 & VII.2, pages 59-60, the applicant indicates staffing will meet or exceed minimum requirements. See Exhibit 11 for documentation regarding the water supply. Exhibit 9 contains a copy of the HIV/HBV Policy and Procedure. Exhibits 14 and 15 contain copies of FMC’s Training Program and Continuing Education Outline.
- C- **Nash County Dialysis** – In Sections XI.5(e) and XI.5(g), pages 71-72, the applicant states the dialysis center will operate in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, and other relevant health and safety requirements. In Sections

VII.1 & VII.2, pages 51-52, the applicant indicates staffing will meet or exceed minimum requirements. See Exhibit 10 for documentation regarding the water supply. Exhibit 25 contains a copy of the Isolation Policies and Procedures. Exhibit 36 contains a copy of the Safety Training Outline and Exhibit 37 contains a copy of a sample of an in-service training calendar like the one that will be used at the facility.

- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- **BMA Rocky Mount** – In Section III.7, pages 38-43, BMA Rocky Mount provided projected patient origin based on historical experience for the first two years of operation following completion of the project.
- C- **Nash County Dialysis** – The information regarding patient origin and all of the assumptions and methodology is found in Section III.7, pages 29-34.
- (8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- **BMA Rocky Mount** – The applicant does not propose a new facility.
- C- **Nash County Dialysis** – In Section III.8, page 30, the applicant states that all patients are projected to live within a 30-mile radius of the proposed sites for Nash County Dialysis.
- (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- **BMA Rocky Mount** – In Section II.1, page 17, the applicant states, “BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”
- C- **Nash County Dialysis** – In Section II.1, pages 17-18, the applicant states, “Total Renal Care, Inc. d/b/a Nash County 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.”

.2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station*

per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

- NA- **BMA Rocky Mount** – The applicant does not propose a new facility.
- C- **Nash County Dialysis** – The applicant projects to serve 39 in-center patients on 12 dialysis stations at the end of Operating Year 1, which is 3.25 patients per station per week ($39 / 12 = 3.25$). The applicant provides the assumptions and methodology used to project utilization in Section II, pages 13-15, and Section III.7, pages 29-32. The applicant provides letters from 32 patients who would consider transferring their care to the proposed facility in Exhibit 12. See Criterion (3) for additional discussion which is incorporated hereby as if set forth fully herein.
 - (b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- **BMA Rocky Mount** – In Sections II.1, page 18 and III.7, page 43, the applicant projects to serve 132 in-center patients by the end of Operating Year 1, which is 3.22 patients per station ($132 / 41 = 3.22$). See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.
- NA- **Nash County Dialysis** – The applicant proposes a new facility.
 - (c) *An applicant shall provide all assumptions, including the specific methodology by which patient utilization is projected.*
- C- **BMA Rocky Mount** – In Section II, pages 18-22, and Section III.7, pages 38-43, the applicant provides the assumptions and methodology used to project utilization of the facility. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.
- C- **Nash County Dialysis** – In Section II, pages 18-22, and in Section III.7, pages 29-34, the applicant provides the assumptions and methodology used to project utilization of the facility. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

.2204 SCOPE OF SERVICES

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

- (1) *diagnostic and evaluation services;*

- C- **BMA Rocky Mount** – These services are provided by Nash General Hospital. See Section V.1, page 48.
- C- **Nash County Dialysis** – These services will be provided by Nash Health Care Systems and Wilson Medical Center. See Section V.1, page 39.
- (2) *maintenance dialysis;*
- C- **BMA Rocky Mount** – This service is provided by BMA Rocky Mount. See Section V.1, page 48.
- C- **Nash County Dialysis** – This service will be provided by Nash County Dialysis. See Section V.1, page 39.
- (3) *accessible self-care training;*
- C- **BMA Rocky Mount** – These services are provided by BMA Rocky Mount. See Section V.1, page 48.
- C- **Nash County Dialysis** – These services will be provided by Nash County Dialysis. See Section V.1, page 39.
- (4) *accessible follow-up program for support of patients dialyzing at home;*
- C- **BMA Rocky Mount** – This service is provided by BMA Rocky Mount. See Section V.1, page 48, and Section V.2(d), pages 49-50.
- C- **Nash County Dialysis** – This service will be provided by Nash County Dialysis. See Section V.1, page 39, and Section V.2(d), page 40.
- (5) *x-ray services;*
- C- **BMA Rocky Mount** – These services are provided by Nash General Hospital or Boice-Willis Clinic. See Section V.1, page 48.
- C- **Nash County Dialysis** – These services will be provided by Nash Health Care Systems and Wilson Medical Center. See Section V.1, page 39.
- (6) *laboratory services;*
- C- **BMA Rocky Mount** – These services are provided by SPECTRA. See Section V.1, page 48.
- C- **Nash County Dialysis** – These services will be provided by Dialysis Laboratories. See Section V.1, page 39.
- (7) *blood bank services;*

- C- **BMA Rocky Mount** – These services are provided by Nash General Hospital. See Section V.1, page 48.
- C- **Nash County Dialysis** – These services will be provided by Nash Health Care Systems and Wilson Medical Center. See Section V.1, page 39.
- (8) *emergency care;*
- C- **BMA Rocky Mount** – These services are provided by BMA Rocky Mount and Nash General Hospital. See Section V.1, page 48.
- C- **Nash County Dialysis** – These services will be provided by Nash Health Care Systems and Wilson Medical Center. See Section V.1, page 39.
- (9) *acute dialysis in an acute care setting;*
- C- **BMA Rocky Mount** – This service is provided by Nash General Hospital. See Section V.1, page 48.
- C- **Nash County Dialysis** – These services will be provided by Nash Health Care Systems and Wilson Medical Center. See Section V.1, page 39.
- (10) *vascular surgery for dialysis treatment patients;*
- C- **BMA Rocky Mount** – This service is provided by Raleigh Access Center, Hardee’s Heart Center, or Triangle Interventional Center. See Section V.1, page 48.
- C- **Nash County Dialysis** – These services will be provided by Nash Health Care Systems and Wilson Medical Center. See Section V.1, page 39.
- (11) *transplantation services;*
- C- **BMA Rocky Mount** – These services are provided by Duke University Medical Center. See Section V.1, page 48.
- C- **Nash County Dialysis** – These services will be provided by Carolinas Medical Center. See Section V.1, page 39.
- (12) *vocational rehabilitation counseling and services; and*
- C- **BMA Rocky Mount** – These services are provided by Nash County Vocational Rehabilitation. See Section V.1, page 48.
- C- **Nash County Dialysis** – These services will be provided by the N.C. Department of Vocational Rehabilitation. See Section V.1, page 39.
- (13) *transportation.*

-C- **BMA Rocky Mount** – This service is provided by Tar River Transit. See Section V.1, page 48.

-C- **Nash County Dialysis** – This service will be provided by Tar River Transit. See Section V.1, page 39.

.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- **BMA Rocky Mount** – In Section VII.1, page 59, the applicant provides the proposed staffing. In Section VII.2, page 60, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion which is incorporated hereby as if set forth fully herein.

-C- **Nash County Dialysis** – In Section VII.1, page 51, the applicant provides the proposed staffing. In Section VII.2, page 52, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion which is incorporated hereby as if set forth fully herein.

(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- **BMA Rocky Mount** – See Section VII.5, page 60, and Exhibits 14 and 15.

-C- **Nash County Dialysis** – See Section VII.5, page 53, and Exhibits 27 and 37.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the need determination in the 2013 SMFP and the July 2013 SDR, no more than 19 dialysis stations may be approved in this review for Nash County. Because BMA Rocky Mount proposes an additional 11 stations and Nash County Dialysis proposes an additional 12 stations, for a total of 23 stations, both of the applications cannot be approved as proposed. The analyst considered all of the information in each application and reviewed each application individually against all applicable review criteria and the analyst conducted a comparative analysis of the proposals. Based on that review and for the reasons set forth below and in the rest of the findings, the application submitted by BMA Rocky Mount, Project I.D. #L-10182-13, is approved for 7 dialysis stations and the application submitted by Nash County Dialysis, Project I.D. #L-10211-13, is approved for 12 dialysis stations.

SMFP Principles

Basic Principle 12 regarding the Availability of Dialysis Care as contained in Chapter 14, page 361 of the 2013 SMFP states:

“Availability of Dialysis Care: 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 schedule;*
- c. Services in rural, remote areas.”*

Home Training

BMA Rocky Mount – In Section II, page 13, the applicant states:

“BMA has proposed to relocate the home training program from BMA Rocky Mount to the new FMC South Rocky Mount Dialysis facility. The new facility will have more space dedicated to the home training program. The current BMA Rocky Mount facility can not be physically expanded. Consequently, the growing home dialysis program is operated in limited space. Additional space in the new location will enhance home training and support for home dialysis patients.

In subsequent deliberations regarding the home program, BMA has determined to maintain a small home training presence at the BMA Rocky Mount facility. This does not change the projections within CON Project ID # L-10177-13, the BMA proposal to develop FMC South Rocky Mount. ...”

Nash County Dialysis – In Section V.2(d), page 40, the applicant states, *“Nash County Dialysis will provide home training in peritoneal dialysis and follow-up and home training in*

home hemodialysis and fillow-up [sic].” The applicant goes on to describe the program available for the support of patients dialyzing at home.

With regard to home training, both applications are equally effective since both propose to make it available in their Nash County facilities.

Hours of Availability

BMA Rocky Mount – In Section VII.10, page 61, the applicant states dialysis services will be available from 6:00 AM to 5:00 PM, Monday through Saturday. BMA Rocky Mount does not propose a third shift.

Nash County Dialysis – In Section VII.10, page 54, the applicant states dialysis services will be available from 6:00 AM to 4:00 PM, Monday through Saturday. Nash County Dialysis does not propose a third shift.

With regard to hours of operation, the applications are equally effective because they both propose two shifts per day, six days per week.

Services in rural, remote areas

Nash County is not a remote area. Regardless of whether Nash County is considered rural or not, both applications are equally effective since BMA Rocky Mount is located in Rocky Mount and Nash County Dialysis would be located in Rocky Mount.

Facility Location

Both applicants propose locations in Rocky Mount, Nash County. According to Google Maps, the proposed locations of the competing applications are only 0.1 of a mile apart. With regard to location, both applications are equally effective alternatives.

Access by Underserved Groups

BMA Rocky Mount – In Sections VI.1(b) & (c), pages 54-55, the applicant states that 84.2 percent of its in-center patients will have some or all of their services covered by Medicare or Medicaid. BMA Rocky Mount based its projected payor mix on the current payor mix at BMA Rocky Mount.

Nash County Dialysis – In Section VI.1(c), pages 45-46, the applicant states that 86.5 percent of its in-center patients will have some or all of their services covered by Medicare or Medicaid. In Section VI.1(c), pages 45-46, the applicant states:

“TRC currently does not have any facilities in Nash County from which to draw this information. Therefore we have based our payor mix on the average percentages of patients who are currently dialyzing at Wilson Dialysis Center. Wilson Dialysis Center is a DaVita owned facility in Wilson County, which is contiguous to Nash County. The pertinent demographics of Wilson County, while not identical to Nash

County, are similar. Moreover, there are several dialysis patients in Wilson County who dialyze in Wilson County at a TRC facility, who are expected to transfer to the new TRC facility in Nash County, so it is reasonable to use the payor mix from Wilson Dialysis Center as a basis for the payor mix for the Nash County facility. ...”

Nash County Dialysis based its projected payor mix on the payor mix for patients currently dialyzing at Wilson Dialysis Center, some of who are projected to transfer to the proposed Nash County Dialysis facility. Wilson County is contiguous to Nash County and the demographics are similar.

Generally, the application proposing the highest Medicare/Medicaid percentage is the most effective alternative with regard to this comparative factor. Nash County Dialysis proposes the highest percentage of patients to have some or all of their services paid for by Medicare or Medicaid. Therefore, the Nash County Dialysis application is the more effective alternative with regard to this comparative factor.

Access to Ancillary and Support Services

BMA Rocky Mount – In Sections V.1 and V.2, pages 48-49, the applicant lists the providers of the necessary ancillary and support services. In Exhibits 16, 17, 18 and 19, the applicant documents how the project will be coordinated with the existing health care system. BMA Rocky Mount has an existing transfer agreement with Nash General Hospital. Nash General Hospital is located in Rocky Mount. According to Google Maps, Nash General Hospital is approximately 0.6 of a mile from BMA Rocky Mount.

Nash County Dialysis – In Section V.1 and V.2, pages 39-40, the applicant lists the providers of the necessary ancillary and support services. In Exhibits 7, 8, 17, 19 and 22, the applicant documents how the project will be coordinated with the existing health care system. Exhibit 7 contains a copy of a letter of intent from Nash General Hospital, as well as one from Wilson Medical Center, to enter into a Patient Transfer Agreement with the facility. Nash General Hospital is located in Rocky Mount. According to Google Maps, Nash General Hospital is approximately 0.4 of a mile from the proposed primary site.

Both applications are equally effective with regard to access to ancillary and support services.

Service to Nash County Residents

Currently 186 of the 216 in-center dialysis patients who reside in Nash County receive treatment at facilities controlled by the parent company of BMA Rocky Mount, Fresenius Medicare Care Holdings, Inc. (FMC). There are two existing FMC-owned facilities in Rocky Mount—BMA Rocky Mount and FMC of Spring Hope. The Medical Director for BMA Rocky Mount, Dr. Michael Holland of Boice-Willis Clinic, states that his group “...has been providing nephrology services to area residents for many years. I have ongoing relationships with physicians in the region and have an active role in the care of dialysis patients admitted to area hospitals.”

DaVita, Inc. (DaVita), the ultimate parent company of Total Renal Care, Inc. d/b/a Nash County Dialysis, identifies 15 of the 216 in-center dialysis patients who reside in Nash County as receiving treatment in one of its facilities; however, none of these facilities are located within Nash County. Additionally, while the December 31, 2012 data included in the July 2013 SDR indicates that 15 of the 216 in-center patients from Nash County receive treatment in DaVita-owned facilities, the applicant indicates that 25 Nash County residents are currently receiving treatment at DaVita-owned facilities. Of the 43 in-center patients projected to utilize the facility at the end of Operating Year Two, the applicant projects that 37, or 86 percent, will be residents of Nash County.

With regard to service to Nash County patients, both applications are equally effective.

Access to Alternative Providers

Currently, there are two existing dialysis facilities and one approved dialysis facility in Nash County. All three of these facilities are owned and operated by FMC. Currently, 186 of the 216 in-center dialysis patients who reside in Nash County receive treatment at FMC-operated facilities.

DaVita does not currently operate any dialysis facilities in Nash County. However, DaVita does operate two facilities in Wilson County; one facility in Edgecombe County; and one facility in Franklin County. Wilson, Edgecombe, and Franklin counties are contiguous to Nash County. The applicant reports that it currently serves 25 Nash County residents in one of its facilities.

Therefore, with regard to providing dialysis patients access to an alternative provider in Nash County, the proposal submitted by Nash County Dialysis is the most effective alternative.

Revenues and Operating Costs

In Section X of the application, each applicant projects the revenues and operating costs for the first two operating years of the proposed project, as shown in the tables below. Generally, the application proposing the lower average net revenue per treatment and the lower average operating cost per treatment is the more effective alternative.

Average Net Revenue Per Treatment

BMA Rocky Mount	Year One	Year Two
Projected Net Revenue	\$7,011,022	\$7,091,714
# Dialysis Treatments*	19,108	19,252
Average Net Revenue per Treatment	\$366.92	\$368.36

*Includes home dialysis treatments.

Nash County Dialysis	Year One	Year Two
Projected Net Revenue	\$1,928,798	\$2,121,721
# Dialysis Treatments*	6,669	7,336
Average Net Revenue per Treatment	\$289.22	\$289.22

*Includes home dialysis treatments.

With respect to the projected average net revenue per treatment, the proposal submitted by Nash County Dialysis is the more effective alternative.

Average Operating Cost Per Treatment

BMA Rocky Mount	Year One	Year Two
Projected Operating Costs	\$5,372,268	\$5,511,318
# Dialysis Treatments*	19,108	19,252
Average Operating Cost per Treatment	\$281.15	\$286.27

*Includes home dialysis treatments.

Nash County Dialysis	Year One	Year Two
Projected Operating Costs	\$1,797,870	\$1,923,139
# Dialysis Treatments*	6,669	7,336
Average Operating Cost per Treatment	\$269.59	\$262.15

*Includes home dialysis treatments.

Nash County Dialysis projects the lowest average operating cost per treatment. With respect to the projected average operating costs per treatment, the proposal submitted by Nash County Dialysis is the more effective alternative.

Staffing

Direct Care Staff Salaries

The following table illustrates projected annual salaries during Year One for direct care staff (registered nurses and technicians) as reported in Section VII.1 of the respective applications. Generally, the application proposing the higher annual salary for direct care staff is the more effective alternative.

Position	BMA Rocky Mount	Nash County Dialysis
Registered Nurse	\$49,275	\$67,980
Technician	\$23,909	\$25,750

Nash County Dialysis projects the higher annual salary for both registered nurses and technicians. Therefore, the proposal submitted by Nash County Dialysis is the more effective alternative with respect to direct care staff salaries.

Availability of Staff and Medical Director

Both applicants projected sufficient shifts and a sufficient number of direct care staff for the projected number of patients to be served in Year Two. Both have budgeted sufficient staff salaries. Both have identified a Medical Director. See discussion in Criterion (7). With regard to the availability of staff and a Medical Director, both applications are equally effective.

SUMMARY

Both applications were determined to be conforming with all applicable statutory and regulatory review criteria.

For each of the comparative analysis factors listed below, the applications were determined to be equally effective:

- Home Training
- Hours of Availability
- Services in Rural, Remote Areas
- Facility Location
- Access to Ancillary and Support Services
- Service to Nash County Residents
- Availability of Staff and Medical Director

For each of the comparative analysis factors listed below, the application submitted by Nash County Dialysis was determined to be the more effective alternative than the application submitted by BMA Rocky Mount:

- Access by Underserved Groups
- Access to Alternative Providers
- Average Net Revenue per Treatment
- Average Operating Cost per Treatment
- Direct Care Staff Salaries

CONCLUSION

G.S.131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of dialysis stations that can be approved by the CON Section. The CON Section determined that the application submitted by Nash County Dialysis is the most effective alternative proposed in this review for 19 dialysis stations in Nash County and that application is approved as conditioned below. The approval of the BMA Rocky Mount application in its entirety would result in the approval of dialysis stations in Nash County in excess of the county need determination in the 2013 SMFP and July 2013 SDR and therefore, the BMA Rocky Mount application can only be approved for seven additional stations.

The application submitted by Nash County Dialysis is approved subject to the following conditions.

- 1. Total Renal Care, Inc. d/b/a Nash County Dialysis shall materially comply with all representations made in its certificate of need application.**
- 2. Total Renal Care, Inc. d/b/a Nash County Dialysis shall develop and be certified for no more than 12 dialysis stations upon completion of this project, which shall include any home hemodialysis training or isolation stations.**

- 3. Total Renal Care, Inc. d/b/a Nash County Dialysis shall install plumbing and electrical wiring through the walls for no more than 12 dialysis stations, which shall include any home hemodialysis training or isolation stations.**
- 4. Total Renal Care, Inc. d/b/a Nash County 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.**

The application submitted by BMA Rocky Mount is approved subject to the following conditions.

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Rocky Mount shall materially comply with all representations made in its certificate of need application.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Rocky Mount shall develop and be certified for no more than 7 dialysis stations upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Rocky Mount shall install plumbing and electrical wiring through the walls for no more than 7 dialysis stations, which shall include any home hemodialysis training or isolation stations.**
- 4. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Rocky Mount 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.**