

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 29, 2012  
PROJECT ANALYST: Gregory F. Yakaboski  
CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: A-8795-12 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Macon County/ Develop a new seven-station dialysis facility in Franklin/ Macon County

A-8799-12 / Total Renal Care of North Carolina, LLC d/b/a Macon County Dialysis/ Develop a new seven-station dialysis facility in Franklin/ Macon 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.

NC- FMC Macon County

C- Macon County Dialysis

The 2012 State Medical Facilities Plan (2012 SMFP) and the January 2012 Semiannual Dialysis Report (January 2012 SDR) provide a Dialysis Station Adjusted Need Determination for Macon County. In the 2012 SMFP Table 14A on page 368 states “*Number of Dialysis Stations Needed: Minimum 5; Maximum as projected in the January 2012 SDR*”. The January 2012 SDR states “*In response to a petition submitted to the North Carolina State Health Coordinating Council on behalf of the residents of Macon County, the North Carolina 2012 State Medical Facilities Plan includes an adjusted need determination for a new dialysis facility in Macon County, with a minimum of five dialysis stations, as projected in the July 2011 Semiannual Dialysis Report and a maximum of the number ‘projected as needed’ in the most recent ‘Semiannual Dialysis Report’ available prior to the Certificate of Need application due date. The adjusted need determination is intended to allow development of a local facility in order to minimize travel for dialysis patients over hazardous mountain roads, particularly in adverse weather.*” The January 2012 SDR Table

14A identifies the number of dialysis stations needed in Macon County as 7. In the January 2012 SDR *Table B: ESRD Dialysis Station Need Determinations by Planning Area*, a total of 23.9 in-center dialysis patients and 6.2 home patients are projected in Macon County as of June 30, 2012. Two applications were received by the Certificate of Need Section for development of the 7 dialysis stations. The two applicants applied for a total of 14 dialysis stations. Pursuant to the need determination in the 2012 SMFP and the January 2012 SDR, 7 dialysis stations is the limit on the number of dialysis stations that may be approved in this review. Following is a brief description of the two proposals submitted in this review:

**FMC Macon County.** Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Macon County (“FMC Macon County”) proposes to develop a new 7-station dialysis facility in Franklin, Macon County in response to the adjusted need determination. Throughout the application the applicant refers to the proposed facility as either BMA or FMC Macon County. The 2012 SMFP defines an adjusted need determination of a maximum of 7 dialysis stations in Macon County. The applicant proposes to develop no more than 7 new dialysis stations in Macon County. However, the line drawing in Exhibit 28 shows an eighth hemodialysis station, thus the application provides contradictory information and therefore the application is nonconforming to the need determination in the 2012 SMFP.

**Macon County Dialysis.** Total Renal Care of North Carolina, LLC d/b/a Macon County Dialysis (“Macon County Dialysis”) proposes to develop a new 7-station dialysis facility in Franklin, Macon County in response to the adjusted need determination. The 2012 SMFP defines an adjusted need determination for 7 dialysis stations in Macon County. The applicant proposes to develop no more than 7 new dialysis stations in Macon County and therefore is conforming to the adjusted need determination in the 2012 SMFP.

Both applications state they are conforming to the adjusted need determination in the 2012 SMFP for 7 dialysis stations in Macon County. However, the limit on the number of dialysis stations that may be approved in this review is 7. Collectively, the two applicants propose a total of 14 dialysis stations. Therefore, even if both applications were conforming or conditionally conforming to all statutory and regulatory review criteria, both applications cannot be approved. (See the Comparative Analysis section for the decision.)

There is one policy in the 2012 SMFP applicable to both applications. Policy GEN-3 states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

## **FMC Macon County**

### Promote Safety and Quality

In Section II.1, page 28, 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 31-34, the applicant describes the methods used to ensure and maintain quality of care, which include the following:

*“Facility programs*

- 1) Quality Improvement Program;*
- 2) Staff Orientation and Training; and*
- 3) In-service Education*

*Corporate programs*

- 1) Technical Audits;*
- 2) Continuous Quality Improvement*

*External Surveys - DFS Certification Surveys  
Core Indicators of Quality; and  
Single Use Dialyzers”*

FMC Macon County does adequately demonstrates that the proposal will promote safety and quality.

### Promote Equitable Access

In Section II.1, pages 29-31, 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 87.8% of the In-Center dialysis treatments will be covered by Medicare or Medicaid; an additional 1.5% are expected to be covered by VA. Thus, 89.2% 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 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. BMA continually strives to develop facilities and dialysis stations in close proximity to the patient residence. BMA is an advocate of community based treatment delivery when such is possible and appropriate. The local ESRD population, County Commissioners, and SHCC agree with a community based delivery system for Macon County. Development of a seven station dialysis facility in Franklin is appropriate.*

*As a result of the petition submitted to the SHCC, BMA believes that in general in the ESRD patient population of the area will consider transferring their care to the proposed FMC Macon County facility. The new facility would be a shorter commute and thus, more convenient for the patient dialysis treatment and care. BMA is making every effort to ensure that adequate health resources are available in close proximity to the dialysis patient home.”*

In Section VI.1 (a), page 52, 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 requirement of federal, state, and local bodies.”*

In Section VI.2, page 54, 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 will be 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 55, the applicant states,

*“BMA’s 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.”*

FMC Macon County adequately demonstrates that medically underserved groups will have equitable access to the proposed services.

#### Maximize Healthcare Value

In Section II.1, page 30, the applicant states,

*“BMA is projecting a capital expenditure of \$1,084,522 for this project. This expenditure is necessary in the normal course of business. BMA is not seeking State or Federal monies to accomplish this transfer [sic] of stations; BMA is not seeking charitable contributions to accomplish this transfer [sic] of stations. Rather, BMA through its parent company, FMC is taking on the financial burden to complete this transfer [sic] of stations in an effort to bring dialysis treatment close to the patient homes. ...”*

FMC Macon County adequately demonstrates projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. However, the applicant has not demonstrated that either the primary or the secondary sites are suitable for the proposed project which calls into question the reasonableness of both the projected capital costs and the operating costs set forth in the proformas. See Criterion (5) for discussion. Therefore, the applicant does not adequately demonstrate the proposal will maximize healthcare value. The application is not consistent with Policy GEN-3 and is nonconforming to this criterion.

#### **Macon County Dialysis**

##### Promote Safety and Quality

In Section II.3, pages 21-23, the applicant states:

*“DaVita Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita’s Quality Management Program is facilitated by a dedicated clinical team of Registered Nurses who make up our Clinical Support Services and Biomedical Quality Management Coordinators working under the direction of our Director of Clinical Support Services and Area Biomedical Administrator. These efforts receive the full support and guidance of the clinical executive leadership team of DaVita. Combined, this group brings hundreds of years of ESRD experience to the program. The program exemplifies DaVita’s total commitment to enhancing the quality of patient care through its willingness to devote the necessary resources to achieve our clinical goals.*

*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 to implement and maintain ongoing quality improvement programs.*
- *Quality Biomedical Team- experienced specialists in all aspects of Biomedical requirements (i.e., water treatment, reuse, 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.*

...

*Macon County Dialysis will be attended by Dr. Bryson Fleming and other admitting Nephrologists who directly oversee the quality of care of the dialysis facility. In addition, Dr. Fleming will serve as Medical Director and will provide the overall medical supervision of the dialysis unit. The facility unit 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 addresses Macon 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 patient outcomes."*

Macon County Dialysis adequately demonstrates how the proposal will promote safety and quality.

#### Promote Equitable Access

In Section VI.1(a), page 40, the applicant states:

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

*Macon 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.*

*Macon 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 41, the applicant states

*"Macon County Dialysis will satisfy all state requirements and local building codes to allow equal access for handicapped patients. Many of our patients are 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 are trained to assist handicapped persons into and out of their dialysis treatment stations.”*

In Section VI.7, page 43, the applicant states

*“Macon 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 27 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 of North Carolina, LLC complies with all federal and state requirements pertaining to isolation of patients with communicable diseases.”*

In Section VI.1(c), page 40, the applicant projects that that 82.8% of its patients will have some or all of their services paid for by Medicare or Medicaid (79.7 Medicare and 3.1 Medicaid). On page 40, the applicant also provides the basis for these projections as follows:

*“These are average percentages of patients who are currently dialyzing at the Sylva Dialysis Center in Jackson County. Jackson County is contiguous to Macon County. ...”*

See discussion in Criterion (13c).

Macon County Dialysis adequately demonstrates how the proposal will promote equitable access to the proposed services.

### Maximize Healthcare Value

In Section III.9, page 31, the applicant states:

*“The Macon 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, operates over 1,809 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.*
- *Macon 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.*



- *Macon County Dialysis will utilize the reuse process that contains costs and the amount of dialyzer waste generated by the facility. The dialyzers will be purchased under a national contract in order to get the best quality dialyzer for the best price.*
- *Macon 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.*
- *Macon 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.*
- *Macon 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.”*

Macon County Dialysis adequately demonstrates projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. The applicant demonstrates that both the proposed primary and secondary sites are suitable for the projected project. Therefore, the applicant adequately demonstrates the proposal will maximize healthcare value. The application is consistent with the adjusted need determination in the 2012 SMFP, the January 2012 SDR and Policy GEN-3 and is conforming to this criterion.

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

#### C-Both Applications

There are currently no dialysis facilities located in Macon County. *Table B: ESRD Dialysis Station Need Determinations by Planning Area* in the January 2012 SDR indicates that, as of June 30, 2011, there were 29 total patients from Macon County and projects 23.9 in-center patients as of June 30, 2012. Pursuant to the adjusted need determination in the 2012 SMFP and the January 2012 SDR, there is a need for 7 additional dialysis stations in Macon County.

**FMC Macon County** proposes to develop a new 7-station dialysis facility in Franklin, Macon County in response to the adjusted need determination. BMA will be leasing space

from a property developer to be named. The property developer will develop the building to BMA specifications and will own the building. In Section I.8, page 2, the applicant states the facility will offer in-center dialysis and home dialysis therapies to include home peritoneal dialysis and home hemodialysis.

Population to be Served

In Section III.7, page 44, 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:

**FMC Macon County -Projected Patient Origin**

	YEAR ONE: 2013/2014		YEAR TWO: 2014/2015		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	In-center patients	Home dialysis patients	In-center patients	Home dialysis patients	Year 1	Year 2
Macon County	21.1	4.5	21.9	4.6	100%	100%
TOTAL	21.1	4.5	21.9	4.6	100%	100%

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, pages 23-25, and Section III.7, pages 42-45. The following quote is from pages 42-43.

“Assumptions

- 1) *Based upon the strength of the local community support and the support of the County Commissioners, BMA assumes that the ESRI) patients of Macon County desire to dialyze at a facility within Macon County. No patient should have to leave the county for dialysis care and treatment.*
  
- 2) *BMA assumes that once the facility is certified, 90% of the in-center dialysis patients residing in Macon County will seek admission to the new FMC Macon County. BMA could assume 100%. However, absolutes are difficult to support. Patients always have the choice of dialysis provider. Further, given the mountainous terrain, BMA can not say with all certainty that all patients would be closer to Franklin, or that Franklin would be more convenient for all patients. Thus, BMA assumes that despite the first Assumption, that not all patients will make the transition to the new FMC Macon County.*
  
- 3) *BMA assumes that only 50% of the existing home dialysis patient population will transfer their care to the new FMC Macon County. After training is completed and dialysis begins at home, the home patients generally travel to the center only once per*

month. Thus, travel does not represent the same rigorous burden as experienced by the in-center patient population. Therefore, BMA believes it is reasonable to project only 50% of the current home population will transfer to the new facility.

4) BMA does assume that once the facility is opened and certified, that new dialysis patients residing within Macon County will seek admission to the closest facility— FMC Macon County.

5) BMA assumes that the ESRD patient population of Macon County will increase at the Macon County Five Year Average Annual Change Rate as published in the January 2012 SDR. That rate is: 3.8%.

6) BMA assumes that the percentage of home PD patients and home hemo-dialysis patients will remain constant for the first two years of this project. Based upon the SEKC data for December 31, 2011, PD patients represented 87.5% of the home patient population and home hemo-dialysis represented 12.5% of the home patient population.

7) BMA assumes that the CON Project Analyst will not require the applicant to demonstrate 3.2 patients per station, in accordance with GS 131E-183(b).”

On pages 43-44, the applicant set forth the methodology utilized to project utilization

“BMA will begin its projections with the known patient population of Macon County as of December 31, 2011. BMA will project the patient population to increase commensurate with the Macon County Five Year Average Annual Change Rate. Finally BMA will apply the assumptions from above to offer projections of a patient population to be served.

	<i>In-Center</i>	<i>Home</i>
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<i>BMA begins with the patient population as of December 31, 2011</i>	21	8
<i>BMA projects this population forward for 12 months to December 31, 2012, using the Macon County Five Year Average Annual Change Rate.</i>	$(21 \times .038) + 21 =$ 21.8	$(8 \times .038) + 8$ 8.3
<i>BMA projects this population forward for six months to June 30, 2013. This is the projected certification date of this project.*</i>	$(21.8 \times .038) + 21.8$ =22.6	$(8.3 \times .038) + 8.3$ = 8.6
<i>BMA projects this population forward for 12 months to June 30, 2014, using the Macon County Five Year Average Annual Change Rate. This is the end of Operating Year 1</i>	$(22.6 \times .038) + 22.6$ 23.5	$(8.6 \times .038) + 8.6$ 8.9
<i>BMA projects this population forward for 12 months to June 30, 2015, using the Macon County Five Year Average Annual Change Rate. This is the end of Operating Year 2</i>	$(23.5 \times .038) + 23.5$ = 24.4	$(8.9 \times .038) + 8.9$ = 9.3

\*The applicant made a mathematical error which does not effect the projected utilization. In projecting the population forward for six months to June 30, 2013 the applicant should have used .019 as the Average Annual Change Rate since the calculation was only for a period of six months. The correct calculation is  $22.6 \times 1.019 = 23.03$ . Carried forward the next step is  $23.03 \times 1.038 = 23.9$  for the end of Operating Year One. Since rounding is incorrect the projected number of in-center patients for the end of Operating Year One remains 23.

*Thus, BMA projects the census to be 33.7 total patients as of June 30, 2015.*

*BMA has assumed that only 90% of the in-center patients would actually transfer their care to the new facility. This is not to say that BMA will restrict admissions. Rather this is to say that BMA seeks to offer conservative estimates of patients to be served and resulting revenues. Thus, BMA offers the following projections of In-Center patients to be served for Operating Years land 2.*

*In-Center Census*

*Operating Year 1:       $23.5 \times .9 = 21.1$*   
*Operating Year 2:       $24.4 \times .9 = 21.9$*

*Home Census*

*Operating Year 1:       $8.9 \times .5 = 4.5$*   
*Operating Year 2:       $9.3 \times .5 = 4.6$*

*Based upon the forgoing discussion, the following table represents BMA projections of patients to be served at the new FMC Macon County. Due to the small number of home patients, BMA will project to serve a single home hemo-dialysis patient and three PD patients. BMA has rounded down to the whole number based upon past guidance from*

*Mr. Craig R. Smith, Chief of the CON Section.*

<i>Operating Year 1</i>		<i>Operating Year 2</i>	
<i># Pts Dialyzing In-Center</i>	<i># Pts Dialyzing at Home</i>	<i># Pts Dialyzing In-Center</i>	<i># Pts Dialyzing at Home</i>
21.1	4.5	21.9	4.6

On page 44, the applicant states “BMA notes that the assumption that all patients of a county will want to dialyze at a dialysis within the county is not unreasonable.” However, the applicant adopted a more conservative approach.

Projected utilization is based on reasonable and supported assumptions. 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 a new 7-station dialysis facility. Therefore, the application is conforming to this criterion.

**Macon County Dialysis** proposes to develop a new seven-station kidney disease (also known as end stage renal disease (ESRD)) treatment center offering in-center hemodialysis and home training for peritoneal dialysis. An unrelated developer will purchase the property and build a shell building. Macon County Dialysis will lease the building. Macon County Dialysis will then up-fit the shell building, hire and train teammates, purchase dialysis machines and the equipment needed to operate the facility.

Population to be Served

In Section III.7, page 27, 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:

**Macon County Dialysis -Projected Patient Origin**

	YEAR ONE: 2013/2014		YEAR TWO: 2014/2015		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	In-center patients	Home dialysis patients	In-center patients	Home dialysis patients	Year 1	Year 2
Macon County	23	9	24	10	97.0%	97.1%
Georgia	0	1	0	1	3.0%	3.0%

TOTAL	23	10	24	11	100.0%	100.0%
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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, pages 11-14, and Section III.7, pages 27-30. The following quote is from pages 27-28.

*“The January 2012 SDR Table B indicates that there were 29 dialysis patients in Macon County as of June 30, 2011.*

*Total Renal Care of North Carolina, LLC uses the following assumptions in projecting a future census for the Macon County ESRD dialysis patient population.*

- *TRC assumes that all of the End Stage Renal Disease patients residing in Macon County leave Macon County to receive their dialysis treatments or training and follow-up for peritoneal dialysis and home hemodialysis since there is no dialysis facility located in the county.*
- *TRC assumes that ESRD patients residing in Macon County will want to dialyze at a dialysis facility in Macon County.*
- *TRC assumes that most, if not all of the ESRD patients, live closer to the town of Franklin in Macon County than to a dialysis facility located outside of the county.*
- *The patient population in Macon County will be projected forward using the current Five Year Average Annual Change Rate of 3.8% as published in the January 2012 SDR.*
- *TRC assumes that ESRD patients will want to keep their same Nephrologist.*
- *TRC assumes that ESRD patients will want to keep their same dialysis provider.*
- *TRC assumes that patients with Chronic Kidney Disease will want to be followed by the same Nephrologist if they have to transition to dialysis treatments.*
- *The five-year average annual change rate for the home-trained patients living in Macon County is 16.5%. However, the home-trained patient population living in Macon County grew from 4 patients as of June 30, 2007 to 6 patients as of June 30, 2011, a 50% patient growth or an average of 12.5% per year. See Exhibit 14 for the data from the last five years.*

On page 28, the applicant states

*“Most of the hemodialysis patients living in Macon County, including in-center and home-trained patients are receiving their treatments and follow-up at the Sylva Dialysis Center in Sylva in Jackson County.*

*The Sylva Dialysis Center is currently providing in-center hemodialysis to nineteen in-center patients and seven patients trained in peritoneal dialysis who live in Macon County. Several of the patients are being transported by Macon County Transit and Macon Valley Nursing and Rehabilitation Center.”*

The Sylva Dialysis Center in Jackson County is also a Total Renal Care of North Carolina, Inc. facility. Jackson County is contiguous to Macon County.

On page 28-30, the applicant set forth the methodology utilized to project utilization.

*“We have determined the number of patients that the Macon County Dialysis proposes to serve at the end of operating year 1 and operating year 2 though the calculations that follow. The calculations have been computed for the patients living in Macon County*

***Macon County in-center patients dialyzing at Total Renal Care of North Carolinas Inc. d/b/a Sylva Dialysis Center located in Jackson County***

*Utilization Projection: using the Five Year Average Annual Change Rate of 3.8% of the Macon County in-center patients receiving in-center dialysis at the Sylva Dialysis Center*

*January 1, 2012-December 31, 2012 - 19 in-center patients X 1.38 [sic – should be 1.038] = 19.722 [result is correct]*

*January 1, 2013-June 30, 2013 - 19.722 in-center patients X 1.019 = 20.741*

[Note- mathematical error.  $19.722 \times 1.019 = 20.0967$  not 20.741]

*July 1, 2013-June 30, 2014 - 20.741 in-center patients X 1.038 = 21.529158*

[Math correction carried forward  $20.741 \times 1.038 = 20.86$  not 21.529]

*July 1, 2014-June 30, 2015 - 21.529158 patients X 1.038=22.347266*

[Math correction carried forward:  $20.86 \times 1.038 = 21.653$  not 22.347]

*Operating Year 1 is projected to begin July 1, 2013 and end June 30, 2014*

*Operating Year 2 is projected to begin July 1, 2014 and end June 30, 2015*

**Macon County in-center patients being dialyzed by another provider outside of North Carolina**

*The January 2012 Semiannual Dialysis Report indicated that there were 23 in-center dialysis patients living in Macon County as of June 30, 2011. The Southeastern Kidney Council has published a zip code report dated January 9, 2012 (See Exhibit 15) that indicates there were 21 in-center patients living in Macon County as of that date. If the TRC Sylva Dialysis Center was dialyzing 19 of the in-center patients as of January 1, 2012, then the other two must be receiving their dialysis treatments outside of North Carolina.*

*Utilization Projection: using the Five Year Average Annual Change Rate of 3.8% of the Macon County in-center patients receiving in-center dialysis at a facility other than the Sylva Dialysis Center:*

*January 1, 2012-December 31, 2012 - 2 in-center patients X 1.038 = 2.076*

*January 1, 2013-June 30, 2013 - 2.076 in-center patients X 1.019 = 2.115444*

*July 1, 2013-June 30, 2014 - 2.115444 in-center patients X 1.038 = 2.195830872*

*July 1, 2014-June 30, 2015 - 2.195830872 patients X 1.038 = 2.279272445*

*Operating Year 1 is projected to begin July 1, 2013 and end June 30, 2014*

*Operating Year 2 is projected to begin July 1, 2014 and end June 30, 2015”*

*Based on the above information Macon County Dialysis can project that at least 23 in-center patients will be admitted during the first year of operation, with most of the patients transferring from the Sylva Dialysis Center and the facility outside of North Carolina. This is a utilization of 82% or 3.28 patients per station. During the second year of operation, one additional in-center patient is projected to be admitted to the facility. This is a utilization rate of 85% or 3.4 patients per station. All of the Macon County patients receiving their in-center treatments at the Sylva Dialysis Center have signed letters of support for this CON application, indicating that they would transfer to a facility located in Franklin. The other two patients are projected to transfer since they will be receiving services in their home state and home county.*

**NOTE: The patient numbers for operating year 1 and 2 will be used to determine the number of treatments, operating revenue and operating expenses). The in-center and home-trained patient numbers cited in Operating Year 1 and Operating Year 2 will be used to determine the number of treatments in Section X of this application.”**

Projected utilization of 20.86 in-center patients transferring from Sylva Dialysis Center at the end of Year One plus projected utilization of 2.19 in-center patients currently using a facility outside of North Carolina equates to 23.05 projected in-center patients at the end of Year



One ( $20.86 + 2.19 = 23.05$ ). Projected utilization is based on reasonable and supported assumptions. Therefore, the applicant adequately demonstrates the need for the proposed stations.

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need this population has for the proposed new 7-station dialysis facility in Macon County. 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.

NC- FMC Macon County  
C-Macon County Dialysis

**FMC Macon County.** In Section III.9, page 45, the applicant describes the alternatives it considered prior to the submission of its application. However, the application is not conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (5), (8), (12), (13c), (18a) and 10A NCAC 14C .2200 for discussion. In addition, in Section XI, pages 73-75, the applicant describes the location of both the primary and secondary sites for the facility. Exhibits 30 and 31 document that the primary and secondary sites are both available for acquisition. In Section II.1, page 11, the applicant states

*“BMA neither owns nor controls either of the sites but has included information on two sites which are available for acquisition.*

*BMA will pursue acquisition of the primary site immediately upon award of the Certificate of Need. In as much as BMA is not proposing to own the site, but rather to lease the property. BMA will work diligently with a property developer to ensure timely acquisition of the site.*

*If the primary site is not available at the time the CON is awarded, BMA will work with the property developer to acquire the secondary site.”*

The proposed primary site located at 232 Cunningham Road, Franklin, described in Exhibit 30, details a site with approximately 9,600 square feet in existing structures. The complex consists of 12 units divided between two separate buildings. One building consists of 5 units and the second building consists of 7 units (see Exhibit 30). Thus, on average, each unit is 800 square foot ( $9,600 / 12 = 800$ ). Therefore, the smaller building consists of 4,000 square feet ( $800 \times 5 =$

4,000) and the larger building consists of 5,600 square feet ( $800 \times 7 = 5,600$ ). In section XI, page 78, the applicant states that the total square feet needed for the proposed facility is 6,396. The largest existing building on the site is 796 square feet smaller than the necessary square footage for the proposed facility ( $6,396 - 5,600 = 796$ ). Further, the applicant provides no documentation from any source that the existing buildings could be expanded, or, if they were expanded if the stated operating costs in the proforma's are accurate or sufficient. Therefore, the proposed location has not been demonstrated as a viable option for the proposed facility.

Further, while the proposed secondary site, described in Exhibit 31, consisting of over 8,000 square feet is available for lease the property description contained in Exhibit 31 states that only 4,000 square feet is currently available for lease. The applicant is proposing a facility of 6,396 square feet. Therefore, the application does not demonstrate that the secondary site is a viable option for the proposed facility in that there is not sufficient space available for lease to meet the requirements of the proposed facility. In addition, in both Exhibit 30 (primary site) and Exhibit 31 (secondary site) the applicant only provides data from what appears to be a real estate listing as documentation that power and water will be available at each site. This is insufficient documentation that power and water are actually available at either the primary or secondary site. The applicant does not provide a water or power bill for either site nor does the applicant provide documentation from a town official verifying that either site has power and water available. The applicant does not document that power and water will be available at the proposed site.

Therefore, the applicant did not adequately demonstrate that the proposal is its least costly or the most effective alternative to meet the need. Consequently, the application is nonconforming to this criterion.

**Macon County Dialysis.** In Section III.9, pages 30-31, the applicant describes the alternatives it considered prior to the submission of its application. The application is conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a), (20), and 10A NCAC 14C .2200 for discussion. In Section XI, pages 61-63, the applicant describes the location of both the primary site located at 161 Iotla Street, Franklin and secondary site located at 80 Westgate Plaza, Franklin, for the facility. Furthermore, in Section XI.1, page 61, the applicant states "*Attached as Exhibit 12 is a copy of a letter from R. Gregg Hill of RHGC Investments, LLC indicating his intent to negotiate the purchase of property and construct a shell building. Once the shell building is constructed, Total Renal Care of North Carolina, LLC will up-fit the shell building. This exhibit also contains a copy of the DaVita Minimum Base Building Improvements and the DaVita Inc. Standard Lease Agreement.*" Exhibit 12 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. Exhibit 9 contains a copy of a bill dated February 16, 2012 from Duke Energy for 161 Iotla St and an email from Duke Energy stating that Duke Energy does provide service to 80 Westgate Plaza, Franklin. The correspondence in Exhibit 9 documents that electrical service and capacity is available for both the proposed primary and secondary sites. In Section XI.5(e), page 65, the applicant states that "*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.*” Exhibit 10 also contains a copy of a water and sewer bill dated January 27, 2012 for the proposed primary location, 161 Iotla Street, Franklin which documents the availability of water at the proposed site. Exhibit 12 contains an email dated February 17, 2012 from Michael Grubermann, CZO, Town of Franklin stating that both the primary and secondary sites are currently served by the Town of Franklin’s water and sewer services.

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.

NC- FMC Macon County  
C- Macon County Dialysis

**FMC Macon County.** In Section VIII.1, page 59, the applicant states the capital cost is projected to be \$1,084,522. In Section IX, pages 63-64, the applicant states that the total working capital needed will be \$732,283 (\$45,819 in start-up expenses and \$686,464 in initial operating expenses.)

The capital cost is to develop a 7 station dialysis facility in 6,396 square feet of leased space, as described in Criterion (4) and 10A NCAC 14C .2202(b)(5) of these findings the 2 proposed sites are not able to accommodate the facility as proposed, thus the applicant has not demonstrated that the proposed capital expense is sufficient to develop the proposed dialysis facility.

In Section VIII, pages 60-61, the applicant states it will fund the capital costs and working capital needs of the project with accumulated reserves of Fresenius Medical Care Holdings, Inc., the parent company of National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc.. Exhibit 24 contains a letter, dated March 15, 2012, from the Vice President of Fresenius Medical Care Holdings, Inc. which states:

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

*BMA proposes to develop a new seven station dialysis facility in Franklin, Macon County pursuant to the adjusted need determination in the January 2012 Semiannual Dialysis Report. The project calls for the following capital expenditure on behalf of BMA.*

*Capital Expenditure*

*\$1,084,522*

*As Vice President, I am authorized and do hereby authorize the development of this new seven station dialysis facility, Fresenius Medical Care of Macon County, for capital costs of \$1,084,522. Further, I am authorized and do hereby authorize and commit cash reserves for the start up and working capital which may be needed for this project.”*

Exhibit 10 contains the audited financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries which show \$163,292,000 cash and cash equivalents and more than \$2.7 billion in current assets as of December 31, 2010. The applicant adequately demonstrated the availability of sufficient funds for the capital needs and working capital of the project.

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

FMC MACON COUNTY	YEAR ONE	YEAR TWO
Projected Net Revenue	\$1,138,188	\$1,187,180
# Dialysis Treatments	3,696	3,852
Average Net Revenue per Treatment	\$307.95	\$308.19

FMC MACON COUNTY	YEAR ONE	YEAR TWO
Projected Operating Costs	\$1,095,443	\$1,140,432
# Dialysis Treatments*	3,696	3,852
Average Cost per Treatment	\$296.38	\$296.06

\*Includes home dialysis treatments.

In the ProFormas in Section X, the applicant projects that revenue will exceed expenses in the first two years of operation after completion of the project. The rates in Section X.1, page 67, are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services. However, the operating costs are based, in part, on the proposed sites. The proposed primary and secondary locations are not sufficient for the project proposed which casts doubt on the reasonableness of both the projected capital costs and operating costs as set forth in the proformas. See discussion in 10A NCAC 14C .2202 (b)(5) on pages 39-40 of these findings, which discussion is incorporated herein in its entirety. The applicant does not adequately demonstrate that projected revenues and expenses are based on reasonable and supported assumptions.

Therefore, the applicant does not adequately demonstrate that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Consequently, the application is not conforming with this criterion.

**Macon County Dialysis.** In Section VIII.1, page 49, the applicant states the capital cost is projected to be \$967,776. In Section IX, page 42, the applicant states that the total working capital needed will be \$778,591 (\$100,838 in start-up expenses and \$677,753 in initial operating expenses.)

In Section VIII.2-3, pages 49-50, and Section IX, page 53, and Exhibit 30, the applicant states it will fund the capital and working capital needs of the proposed project from the cash reserves of DaVita Inc., the parent company of Total Renal Care of North Carolina, LLC.

Exhibit 30 contains a letter, dated March 12, 2012, from the Chief Accounting Officer of DaVita, Inc. which states:

*“I am the Chief Accounting Officer of DaVita, Inc., the parent and 100% owner of Total Renal Care of North Carolina, LLC. I also serve as the Chief Accounting Officer of Total Renal Care, Inc. which owns 855 of the ownership interests in Total Renal Care of North Carolina, LLC (“TRC”).*

*We are submitting a Certificate of Need application to develop a seven-station ESRD hemodialysis facility in Franklin in Macon County. The project calls for a capital expenditure of \$967,776., start-up expenses of \$100,838 and a working capital requirement of \$677,753.*

*DaVita and Total Renal Care of North Carolina, LLC have committed cash reserves in the amount of \$1,746,367 for this project. We will ensure that these funds are made available for the development and operation of this project. As Chief Accounting Officer of Total Renal Care of North Carolina, LLC, I can also confirm that we will provide all of the funds that we receive from DaVita for this project to Total Renal Care of North Carolina, Inc. for the development of this project.”*

In Exhibit 31, page F-5, the applicant provides audited financial statements for DaVita, Inc. which document that DaVita, Inc. had \$393,752,000 in cash and cash equivalents as of December 31, 2011. The applicant adequately demonstrated the availability of sufficient funds for the capital and working capital needs of the project.

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

### Net Revenue

MACON COUNTY DIALYSIS	YEAR ONE	YEAR TWO
Projected Net Revenue	\$1,497,113	\$1,642,188
# Dialysis Treatments	4,836	5,304
Average Net Revenue per Treatment	\$309.57	\$309.61

### Operating Costs

MACON COUNTY DIALYSIS	YEAR ONE	YEAR TWO
Projected Operating Costs	\$1,355,506	\$1,459,786
# Dialysis Treatments*	4,836	5,304
Average Cost per Treatment	\$280.29	\$275.22

\*Includes home dialysis treatments.

In the ProFormas in Section X, the applicant projects that revenue will exceed expenses in the first two years of operation after completion of the project. The rates in Section X.1, page 54, are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare

and Medicaid Services. The applicant adequately demonstrates that projected revenues and expenses are based on reasonable and supported assumptions.

Therefore, the applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Consequently, 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-Both Applications

**FMC Macon County.** The 2012 State Medical Facilities Plan (2012 SMFP) and the January 2012 Semiannual Dialysis Report (January 2012 SDR) provide a Dialysis Station Adjusted Need Determination for Macon County. In the 2012 SMFP Table 14A on page 368 states *“Number of Dialysis Stations Needed: Minimum 5; Maximum as projected in the January 2012 SDR”*. The January 2012 SDR states *“In response to a petition submitted to the North Carolina State Health Coordinating Council on behalf of the residents of Macon County, the North Carolina 2012 State Medical Facilities Plan includes an adjusted need determination for a new dialysis facility in Macon County, with a minimum of five dialysis stations, as projected in the July 2011 Semiannual Dialysis Report and a maximum of the number ‘projected as needed’ in the most recent ‘Semiannual Dialysis Report’ available prior to the Certificate of Need application due date. The adjusted need determination is intended to allow development of a local facility in order to minimize travel for dialysis patients over hazardous mountain roads, particularly in adverse weather.”* The January 2012 SDR Table 14A identifies the number of dialysis stations needed in Macon County as 7. FMC Macon County proposes to develop a new 7-station dialysis facility in Franklin, in Macon County. The application conforms to the need determination in the 2012 SMFP and the January 2012 SDR. In both Year One and Year Two the applicant projects serving 21 in-center patients and 4 home patients. The applicant adequately demonstrates the need for the 7-station facility, however, only one such facility can be approved. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Therefore, the application is conforming to this criterion.

**Macon County Dialysis.** The 2012 State Medical Facilities Plan (2012 SMFP) and the January 2012 Semiannual Dialysis Report (January 2012 SDR) provide a Dialysis Station Adjusted Need Determination for Macon County. In the 2012 SMFP Table 14A on page 368 states *“Number of Dialysis Stations Needed: Minimum 5; Maximum as projected in the January 2012 SDR”*. The January 2012 SDR states *“In response to a petition submitted to the North Carolina State Health Coordinating Council on behalf of the residents of Macon County, the North Carolina 2012 State Medical Facilities Plan includes an adjusted need determination for a new dialysis facility in Macon County, with a minimum of five dialysis stations, as projected in the July 2011 Semiannual Dialysis Report and a maximum of the number ‘projected as needed’ in the most recent ‘Semiannual Dialysis Report’ available prior to the Certificate of Need application due date. The adjusted need determination is intended to allow development of a local facility in order to minimize travel for dialysis*

*patients over hazardous mountain roads, particularly in adverse weather.”* The January 2012 SDR Table 14A identifies the number of dialysis stations needed in Macon County as 7. Macon County Dialysis proposes to develop a new 7-station dialysis facility in Franklin, in Macon County. The application conforms to the need determination in the 2012 SMFP and the January 2012 SDR. In Year One the applicant projects serving 23 in-center patients and 10 home patients. In Year Two the applicant projects serving 24 in-center patients and 11 home patients. The applicant adequately demonstrates the need for the 7-station facility, however, only one such facility can be approved. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Therefore, the application is conforming to this criterion.

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

C- Both Applications

**FMC Macon County.** In Section VII.1, page 56, the applicant projects the following staffing during the first two operating years.

POSITION	TOTAL FTES YEARS 1 AND 2
RN (dc)	1.0
Technician (dc)**	2.5
Clinical Manager (dc)	1.0
Admin (dc)	0.15
Dietician	0.20
Social Worker	0.20
Home Training Nurse (dc)	0.25
Chief Tech	0.10
Equipment Tech	0.30
In-Service	0.10
Clerical	0.50
<b>TOTAL</b>	<b>6.3</b>

dc: direct care staff

\*\* Table in Section VII.1, page 56, has contradictory information regarding number of Technicians. States both 2.5 and 1.5 FTE for Technicians. In Section X, page 71, the applicant has budgeted for 2.5 Technicians.

As shown in the above table, the applicant proposes a total of 6.3 FTE positions, 4.9 of which will be direct care positions. In Section VII.4, page 57, 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 58:

<b>WEEKLY HOURS OF OPERATION</b>				
<b>DAY</b>	<b>MORNING</b>	<b>AFTERNOON</b>	<b>EVENING</b>	<b>TOTAL</b>
Monday	5	5	0	10
Tuesday	5	5	0	10
Wednesday	5	5	0	10
Thursday	5	5	0	10
Friday	5	5	0	10
Saturday	5	5	0	10
Sunday	0	0	0	0
<b>Total</b>	<b>30</b>	<b>30</b>	<b>0</b>	<b>60</b>
<b>Total Hours Operation per Year (weekly hours x 52) 3,120</b>				

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, page 56:

	<b># FTES</b>	<b>HRS/Yr/FTE</b>	<b>TOTAL FTE HOURS (ANNUAL)</b>	<b>TOTAL HRS OF OPERATION (ANNUAL)</b>	<b>FTE HRS/HRS OF OPERATION</b>
RN	1.0	2,080	2,080	3,120	0.66
Techs	2.5	2,080	5,200	3,120	1.66
Clinical Manager	1.0	2,080	2,080	3,120	0.66
Admin	0.15	2,080	312	3,120	0.1
Home Training Nurse	0.25	2,080	520	3,120	0.17
<b>Total</b>	<b>4.9</b>	<b>2,080</b>	<b>10,192</b>	<b>3,120</b>	<b>3.27</b>

Based on the proposed operating hours for the facility, it will be open 3,120 hours a year. In Section VII, page 56, the applicant projects 4.9 total direct care FTEs. Assuming one FTE works 2,080 hours annually, 4.9 FTEs would work a total of 10,192 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 21 in-center patients in Year One on 7 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 (7 stations)	7	7
Afternoon (7 Stations)	7	7

As shown in the table above, the proposed 7-station facility would be able to dialyze up to a maximum of 28 in-center patients on 7 dialysis stations, assuming one patient per station per shift and two shifts per day, Monday through Saturday. On page 44 the applicant states it projects to serve 21 in-center patients in both Year One and Year Two on 7 stations.

In Section V.4(c), page 49, the applicant states that George Hart, MD has agreed to serve as Medical Director of the proposed facility. Exhibit 21 contains a letter from George Hart, MD stating that *“Should Fresenius Medical Care be successful in obtaining the approval to move forward with the project, I am willing to serve as the Medical Director for this facility.”* Dr. Hart is associated with Metrolina Nephrology which has offices in and around Charlotte.

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

**Macon County Dialysis.** In Section VII.1, page 44, the applicant projects the following staffing during the first two operating years.

POSITION	TOTAL FTEs YEARS 1 AND 2
RN (dc)	1.5
RN HT (dc)	0.3
Patient Care Technician (dc)	3.0
Bio-Med Tech	0.2
Admin (dc)	.5
Dietician	0.3
Social Worker	0.3
Unit Secretary	1.0
Other-reuse	0.5
<b>TOTAL</b>	<b>7.4</b>

\*dc: direct care staff

As shown in the above table, the applicant proposes a total of 7.4 full-time equivalent (FTE) positions, 5.3 of which will be direct care positions. In Section VII.4, page 46, 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, on page 47:

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
<b>Total Hours Operation per Year (weekly hours x 52) 3,120</b>				

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, page 47:

	# 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
RN HT	.3	2,080	624	3,120	0.2
Techs	3.0	2,080	6,240	3,120	2.0
Total	4.8	2,080	9,984	3,120	3.2

Based on the proposed operating hours for the facility, it will be open 3,120 hours a year. In Section VII, page 44, the applicant projects 4.8 total direct care FTEs. Assuming one FTE works 2,080 hours annually, 4.8 FTEs would work a total of 9,984 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 23 in-center patients in Year One on 7 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 (7 stations)	7	7
Afternoon (7 Stations)	7	7

As shown in the table above, the proposed 7-station facility would be able to dialyze up to a maximum of 28 in-center patients on 7 dialysis stations, assuming one patient per station per shift and two shifts per day, Monday through Saturday. On pages 27-30, the applicant states it projects to serve 24 in-center patients in Year Two on 7 stations.

In Section V.4(c), page 36, the applicant states that Bryson Fleming, MD has agreed to serve as Medical Director of the facility. Exhibit 21 contains a letter from Bryson Fleming, II, MD

stating that has agreed to serve as Medical Director of the proposed facility and is associated with Mountain Kidney & Hypertension Associates in Asheville. The letter in Exhibit 21 states

*“As you know, our group at Mountain Kidney & Hypertension Associates in Asheville has supplied nephrology services to the physicians and patients of Macon County for over 35 years. We have an outstanding relationship with the physicians in this area and they refer the majority of their nephrology patients to our group. We also help care for all of the renal patients that are admitted to Mission Hospitals, Inc. for other tertiary care services such as cardiac, neuro and trauma. We plan to have an increased presence in Macon County when this facility is developed and we will be available for inpatient and outpatient nephrology consultations at the Angel Medical Center.”*

The information regarding the availability of resources, including health manpower and management personnel, for the provision of the services 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.

NC- FMC Macon County  
C- Macon County Dialysis

**FMC Macon County.** In Section V.1-2, pages 47-48, 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. In Section II.1, page 10, the applicant states *“BMA has included two requests to establish hospital agreements in Exhibit 17. [sic- should read Exhibit 16] BMA has contacted both Murphy Medical Center and Mission Hospitals seeking to establish appropriate agreements. BMA notes that in the absence of the agreement the applicant be found “Conditionally Conforming” and conditioned to provide an executed agreement subsequent to the review and prior to issuance of the actual Certificate of Need.”* However, the applicant did not provide either a letter of intent to sign a written agreement from an acute care hospital or a signed written agreement from an acute care hospital. Therefore, the information provided in Section V and the referenced Exhibits is not reasonable and credible. The application is nonconforming with this criterion.

**Macon County Dialysis.** In Section V.1-2, pages 34-35, the applicant lists the providers of the necessary ancillary and support services. In Exhibits 7, 8, 17, 18 and 21, the applicant documents how the project will be coordinated with the existing health care system. In Section II.1, page 10, the applicant states *“A representative of Mission Hospitals has signed a letter of intent to establish a patient transfer agreement with Macon County Dialysis upon issuance of the Certificate of Need.”* Exhibit 7 contains a copy of a letter dated February 15, 2012 from the Director of Adult Medical Surgical, Mission Hospitals which states *“Our Hospital will enter into a Patient Transfer Agreement with Total Renal Care of North Carolina when they are issued a Certificate of Need.”* 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- Both Applications

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

### C-Both Applications

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2010 and CY2008-2009, respectively. The data in the table was obtained June 1, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	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 CY 2008-2009 (Estimate by Cecil G. Sheps Center)
Macon County	17%	7.5%	19.8%
Statewide	17%	6.7%	19.7%

\*Source: DMA Website: <http://www.ncdhhs.gov/dma/pub/index.htm>

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 dialysis services to be offered at FMC Macon County and Macon County Dialysis.

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.

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. About 25% of the Medicare-covered patients had employer group health plans as primary insurance, with Medicare as the secondary payer. Additionally, about 5% of the Medicare dialysis patients were also eligible for Medicaid. Also, the CMS website states:

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

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

In Section VI.1(a), page 52, of the FMC Macon County application 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 79.7% of North Carolina dialysis treatments in BMA facilities in FY 2011. Medicaid treatments represented an additional 4.8% of treatments in BMA facilities for FY 2011. Low income and medically underinsured persons will continue to have access to all services provided by BMA.*

In Section VI.1(c), page 40, of the Macon County Dialysis application, the applicant projects that that 82.8% of its patients will have some or all of their services paid for by Medicare or Medicaid stating

*“These are average percentages of patients who are currently dialyzing at the Sylva Dialysis Center in Jackson County. Jackson County is contiguous to Macon County. ...”*

Both applicants propose a new facility. Both serve medically uninsured dialysis patients in other North Carolina facilities.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access

by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C– Both Applications

**FMC Macon County** In Section VI.1(f) page 54, 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, page 55, the applicant states “*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.*”

**Macon County Dialysis** In Section VI.1(f), page 41, the applicant states “*Macon 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, page 43, 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 of North Carolina, LLC or by any facility in North Carolina owned by DaVita, Inc.*”

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

C- Both Applications

**FMC Macon County.** In Section VI.1(c), page 53, the applicant provides the projected payor mix for in-center dialysis patients.

Payor	In-Center Patients
Commercial Insurance	9.8%
Medicare	81.5%
Medicaid	6.3%
VA	1.5%
Other [Specify] Self/Indigent	0.9%
<b>Total</b>	<b>100.0%</b>

The applicant projects 87.8% of its in-center patients will have some or all of their care paid for by Medicare or Medicaid (81.5 percent Medicare plus 6.3 percent Medicaid). In Section VI.1(a), page 52, 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 79.7% of North Carolina dialysis treatments in BMA facilities in FY 2011. Medicaid treatments represented an additional 4.8% of treatments in BMA facilities for FY 2011. Low income and medically underinsured persons will continue to have access to all services provided by BMA.*

The project analyst notes that BMA’s state-wide Medicare and Medicaid payments for dialysis treatments in FY2011 totaled 84.5% (79.7 Medicare and 4.8 Medicaid) while for the proposed project in Macon County the combined Medicare/Medicaid payments were 87.8%. The applicant did not provide a basis for the difference.

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

**Macon County Dialysis.** In Section VI.1(a), page 40, the applicant states:

*“Macon 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, handicap. We will serve patients regardless of ethnic or socioeconomic situation..*

...

*Macon 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), page 40, the applicant projects that that 82.8% of its patients will have some or all of their services paid for by Medicare or Medicaid (79.7 Medicare and 3.1 Medicaid), as illustrated in the following table.

**Macon County Dialysis  
Utilization by Payor Source**

PAYOR SOURCE	PERCENT UTILIZATION BY PAYOR SOURCE
Medicare	15.6%



Medicaid	3.1%
Medicare/Medicaid	23.4%
Commercial Insurance	7.8%
VA	9.4%
Medicare/Commercial	40.7%
TOTAL	100.0%

In Section VI.1(c), page 40, the applicant states:

*“These are average percentages of patients who are currently dialyzing at the Sylva Dialysis Center in Jackson County. Jackson County is contiguous to Macon County. ...”*

The applicant is correct that Jackson County is contiguous to Macon County. US Census Bureau data shows substantial similarities in the economic status of the two counties. The poverty level in Macon County is the same as in Jackson County. The families living below the poverty level is 27.3% in Macon County and 25.3% in Jackson County. The per capita income is \$30,066 in Macon County and \$29,477 in Jackson County. Further, as of July 2009, the population of Macon County was 33,922 and 40,271 in Jackson County. As of July 2009, the total Medicaid eligible population in Macon County was 5,846 and was 5,553 in Jackson County. Thus it is reasonable to assume that these two contiguous counties are comparable in economic status. Furthermore, the Jackson County Sylva Dialysis Center is where almost all of the Macon County patients currently receive dialysis.

The applicant demonstrated 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- Both Applications

**FMC Macon County.** In Section VI.5, pages 54-55, 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.

**Macon County Dialysis.** In Section VI.5, pages 42-43, 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-Both Applications

**FMC Macon County.** In Section V.3(a), pages 48-49, the applicant states “*Exhibit 19 is a letter from Jim Swann, FMC Director of Market Development to Western Carolina University nursing program director seeking to establish an affiliation agreement between FMC Macon County and the school.*” The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion.

**Macon County Dialysis.** In Section V.3(c), page 36, the applicant states “*See Exhibit 20 for a copy of letters from Southwestern Community College.*” Exhibit 20 contains a copy of a letter from the Program Coordinator-Associate Degree Nursing Program of Southwestern Community College, which states “*I understand that you are interested in offering to extend services as a clinical training site for nursing students once the facility is operational, offering dialysis specific orientation to our nursing students. ...*

*Our college will consider entering into an agreement with Total Renal Care of North Carolina, LLC d/b/a Macon County Dialysis upon completion of the development of the dialysis center.*” 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.

NC- FMC Macon County  
C- Macon County Dialysis

Macon County has no dialysis facilities. Therefore, development of a dialysis facility will improve patient access to dialysis services and could affect competition. DaVita has dialysis facilities in three nearby counties. BMA has a facility south of Macon County in Clayton, GA.

**FMC Macon County.** See Sections II, III, VI, VII, and X. In particular, see Section V.7, pages 50-51, in which FMC Macon County discusses the impact of the proposed project on competition in the service area. The information provided in Section X does not adequately

demonstrate that the proposed project would have a positive impact on the cost-effectiveness of the proposed services because the applicant does not adequately demonstrate that projected capital costs and expenses are based on reasonable and supported assumptions. Therefore the applicant does not demonstrate that the financial feasibility of the proposal is based on reasonable projections of capital costs and operating costs. See Criterion (5) for additional discussion regarding projected capital costs and operating costs which discussion is incorporated herein in its entirety.

Therefore, the application is nonconforming with this criterion.

**Macon County Dialysis.** See Sections II, III, V, VI and VII. In particular, see Section V.7, page 39, in which Macon County Dialysis discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to dialysis services in Macon County. This determination is based on the information in the application, and the following:

- ◆ The applicant adequately demonstrates the need to develop a new 7-station dialysis facility in Macon County and that it is a cost-effective alternative;
- ◆ The applicant will provide quality services; and
- ◆ The applicant will provide adequate access to medically underserved populations.

Therefore, the application is conforming to this criterion

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

NA- FMC Macon County  
C- Macon County Dialysis

**FMC Macon County** does not have an existing facility in Macon County.

**Macon County Dialysis** does not have an existing facility in Macon County. However, the applicant currently provides dialysis services in three surrounding counties: Cherokee, Swain and Jackson. The facilities are: 1) Smokey Mountains Dialysis Center in Murphy; 2) Sylva Dialysis Center in Sylva; and 3) Cherokee Dialysis Center in Cherokee. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, all three of the listed facilities 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.

- (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.

NC- FMC Macon County  
C- Macon County Dialysis

**FMC Macon County's** application is not conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as promulgated in 10A NCAC 14C .2200. See discussion below.

**Macon 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;*  
-NA- Both Applications -The applicant's both propose a new facility.
  - (2) *Mortality rates;*  
-NA- Both Applications -The applicant's both propose a new facility.
  - (3) *The number of patients that are home trained and the number of patients on home dialysis;*  
-NA- Both Applications -The applicant's both propose a new facility.
  - (4) *The number of transplants performed or referred;*  
-NA- Both Applications -The applicant's both propose a new facility.
  - (5) *The number of patients currently on the transplant waiting list;*  
-NA- Both Applications -The applicant's both propose a new facility.
  - (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*  
-NA- Both Applications -The applicant's both propose 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.*

-NA- Both Applications -The applicant's both propose 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.*

-NC- **FMC Macon County-** In Section II.1, page 10, the applicant states "*BMA has included two requests to establish hospital agreements in Exhibit 17. [sic- should read Exhibit 16] BMA has contacted both Murphy Medical Center and Mission Hospitals seeking to establish appropriate agreements. BMA notes that in the absence of the agreement the applicant be found "Conditionally Conforming" and conditioned to provide an executed agreement subsequent to the review and prior to issuance of the actual Certificate of Need.*" However, the applicant did not provide either a letter of intent to sign a written agreement from an acute care hospital or a signed written agreement from an acute care hospital. Therefore, the application is non-conforming with this rule.

-C- **Macon County Dialysis-** Exhibit 7 contains a letter dated February 15, 2012 signed by the Director of Adult Medical Surgical Units, Mission Hospital, 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. In Section II, page 10, the applicant also states "*Macon 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.*

- C- **FMC Macon County- Exhibit 17** contains a copy of a *“Transplant Center Evaluation Services Agreement”* between Duke University Medical Center and Fresenius Medical Care Macon County.
  
- C- **Macon County Dialysis-** Exhibit 8 contains a letter dated February 15, 2012, 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. The letter includes the requirements listed in (A-E) of this rule. In Section II, page 10, the applicant also states *“Macon 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.*
  
- NC- **FMC Macon County-** In both Exhibit 30 (primary site- 232 Cunningham Road, Franklin with an existing building and fully paved parking) and Exhibit 31 (secondary site-31 Poplar Grove Road, Franklin with an existing building and paved parking) the applicant only provides data from what appears to be a real estate listing as documentation that power and water will be available at each site. This is insufficient documentation that power and water are actually available at either the primary or secondary site. The applicant does not provide a water or power bill for either site nor does the applicant provide documentation from a town official verifying that either site has power and water available. The applicant does not document that power and water will be available at the proposed site. Therefore, the application is nonconforming to this rule.
  
- C- **Macon County Dialysis-** Exhibit 9 contains a copy of a bill dated February 16, 2012 from Duke Energy for 161 Iotla St and an email from Duke Energy stating that Duke Energy does provide service to 80 Westgate Plaza, Franklin. The correspondence in Exhibit 9 documents that electrical service and capacity is available for both the proposed primary and secondary sites. In Section XI.5(e), page 65, the applicant states that *“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 dechlorinization, softening, reverse osmosis water systems combined with pyrogen filters for bacteria removal.”* Exhibit 10 also contains a copy of a water and sewer bill dated January 27, 2012 for the proposed primary location, 161 Iotla Street, Franklin which documents the availability of water at the proposed site. Exhibit 12 contains an email dated February 17, 2012 from Michael Grubermann, CZO, Town of Franklin stating that both the primary and secondary sites are currently served by the Town of Franklin’s water and sewer services.

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

-C- **FMC Macon County-** In Section II.1, page 11, the applicant states “*Copies of back-up procedures are included in Exhibit 12.*” Exhibit 12 contains copies of written policies and procedures for back up electrical services in the event of a power outage. The power failure back up procedures include procedures for both when there is an emergency generator present and when the facility does not have an emergency generator (Hand Cranking the Blood Pump).

-C- **Macon County Dialysis-** In Section XI.5(f), page 65, 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 11 contains a copy of the policies and procedures for temporary power outages.*” Exhibit 11 also documents that the Sylva Dialysis Center will serve as the backup facility in case of loss of power.

(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.*

-NC- **FMC Macon County-** In Section XI, pages 73-75, the applicant describes the location of both the primary and secondary sites for the facility. Exhibits 30 and 31 document that the primary and secondary sites are both available for acquisition. In Section II.1, page 11, the applicant states

*“BMA neither owns nor controls either of the sites but has included information on two sites which are available for acquisition.*

*BMA will pursue acquisition of the primary site immediately upon award of the Certificate of Need. In as much as BMA is not proposing to own the site, but rather to lease the property. BMA will work diligently with a property developer to ensure timely acquisition of the site.*

*If the primary site is not available at the time the CON is awarded, BMA will work with the property developer to acquire the secondary site.”*

The proposed primary site located at 232 Cunningham Road, Franklin, described in Exhibit 30, details a site with approximately 9,600 square feet in two existing structures. The complex consists of 12 units in two separate buildings. One

building consists of 5 units and the second building consists of 7 units (see Exhibit 30). Thus, on average, each unit is 800 square foot ( $9,600/12 = 800$ ). Therefore, the smaller building consists of 4,000 square feet ( $800 \times 5 = 4,000$ ) and the larger building consists of 5,600 square feet ( $800 \times 7 = 5,600$ ). In section XI, page 78, the applicant states that the total square feet needed for the proposed facility is 6,396. The largest existing building on the site is 796 square feet smaller than the stated size of the proposed facility ( $6,396 - 5,600 = 796$ ). Therefore, the proposed location is not sufficient as a viable option for the proposed facility.

Further, while the proposed secondary site located at 31 Poplar Grove Road, Franklin, described in Exhibit 31, consisting of over 8,000 square feet is available for lease the property description contained in Exhibit 31 states that only 4,000 square feet is currently available for lease. The applicant is proposing a facility of 6,396 square feet. Therefore, the application does not demonstrate that the secondary site is a viable option for the proposed facility in that there is not sufficient space available for lease to meet the requirements of the proposed facility.

- C- **Macon County Dialysis** – In Section XI, pages 61-63, the applicant describes the location of both the primary site located at 161 Iotla Street, Franklin and secondary site located at 80 Westgate Plaza, Franklin, for the facility. Furthermore, in Section XI.1, page 61, the applicant states “*Attached as Exhibit 12 is a copy of a letter from R. Gregg Hill of RHGC Investments, LLC indicating his intent to negotiate the purchase of property and construct a shell building. Once the shell building is constructed, Total Renal Care of North Carolina, LLC will up-fit the shell building. This exhibit also contains a copy of the DaVita Minimum Base Building Improvements and the DaVita Inc. Standard Lease Agreement.*” Exhibit 12 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- **FMC Macon County**- In Section XI.6(g), page 77, 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 Section VII. 1-2, pages 56-57, the applicant indicates staffing will meet or exceed minimum requirements. See Exhibit 11 for the inside facility Water Service Treatment Documentation. 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- **Macon County Dialysis**– In Section XI.5(g), pages 65-66, 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 Section VII.1-2, pages 44-45, the applicant indicates staffing will meet or exceed minimum requirements. See Exhibit 10 for the Water Culture Policy. Exhibit 13 contains a copy of the Health and Safety Policy & Procedure Manual. Exhibit 36 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- **FMC Macon County**- The information regarding patient origin and all of the assumptions and methodology is found Section III.7, pages 39-45.
- C- **Macon County Dialysis** –The information regarding patient origin and all of the assumptions and methodology are found in Section II, pages 11-14, and in Section III.7, pages 27-30.
- (8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- C- **FMC Macon County**- In Section III.8, page 45, the applicant states that none of the patients projected to dialyze at FMC Macon County will have to drive more than 30 miles to the proposed facility.
- C- **Macon County Dialysis** – In Section III.8, page 30, the applicant states that none of the patients projected to dialyze at Macon County Dialysis will have to drive more than 30 miles to the proposed facility.
- (9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*
- C- **FMC Macon County**- See Section VI.1(d), page 53.
- C- **Macon County Dialysis** – See Section II, page 15.

**.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- **Both Applications** – The applications are based on an adjusted need determination in the State Medical Facilities Plan.

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

-NA- **Both Applications** -The applicant's both propose a new facility.

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

-C- **FMC Macon County**- In Section III.7, pages 38-45, the applicant provides the assumptions and methodology used to project utilization of the proposed additional stations. See Criterion (3) for discussion.

-C- **Macon County Dialysis** – In Section II, pages 11-14, and in Section III.7, pages 27-30 the applicant provides the assumptions and methodology used to project utilization of the proposed new stations. See Criterion (3) for discussion.

**.2204 SCOPE OF SERVICES**

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

(1) *diagnostic and evaluation services;*

-C- **FMC Macon County**- See Section V.1, page 47.

-C- **Macon County Dialysis**- See Section V.1, page 34.

(2) *maintenance dialysis;*

-C- **FMC Macon County**- See Section V.1, page 47.

-C- **Macon County Dialysis**- See Section V.1, page 34.

(3) *accessible self-care training;*

-C- **FMC Macon County**- See Section V.1, page 47.

-C- **Macon County Dialysis**- See Section V.1, page 34.

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

-C- **FMC Macon County**- See Section V.1, page 47.

-C- **Macon County Dialysis**- See Section V.1, page 34.

(5) *x-ray services;*

-C- **FMC Macon County**- See Section V.1, page 47.

-C- **Macon County Dialysis**- See Section V.1, page 34.

(6) *laboratory services;*

- C- **FMC Macon County**- See Section V.1, page 47.
- C- **Macon County Dialysis**- See Section V.1, page 34.

(7) *blood bank services;*

- C- **FMC Macon County**- See Section V.1, page 47.
- C- **Macon County Dialysis**- See Section V.1, page 34.

(8) *emergency care;*

- C- **FMC Macon County**- See Section V.1, page 47.
- C- **Macon County Dialysis**- See Section V.1, page 34.

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

- NC- **FMC Macon County**- See Section V.1, page 47. However, the applicant did not provide either a letter of intent to sign a written agreement or a signed written agreement from an acute care hospital. Therefore, the application is non-conforming with this rule. See Section II.1, page 10 and the response to rule 10A NCAC 14C .2202 (b)(1) above.
- C- **Macon County Dialysis**- See Section V.1, page 34. Exhibit 7 contains a letter dated February 15, 2012 signed by the Director of Adult Medical Surgical Units, Mission Hospital, stating that the hospital will enter into a Patient Transfer Agreement with the applicant when a Certificate of Need is issued.

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

- C- **FMC Macon County**- The applicant states see Section V.1, page 47.
- C- **Macon County Dialysis**- See Section V.1, page 34.

(11) *transplantation services;*

- C- **FMC Macon County**- See Section V.1, page 47.
- C- **Macon County Dialysis**- See Section V.1, page 34.

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

- C- **FMC Macon County**- See Section V.1, page 47.
- C- **Macon County Dialysis**- See Section V.1, page 34.

(13) *transportation.*

- C- **FMC Macon County**- See Section V.1, page 47.
- C- **Macon County Dialysis**- See Section V.1, page 34.

**.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- **FMC Macon County**- See Section VII.1-2, pages 56-57, and Section VII.10, page 58.

-C- **Macon County Dialysis**- See Section VII.1-2, pages 44-45, and Section VII.10, page 47.

(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- **FMC Macon County**- See Section VII.5, page 57, and Exhibits 14 and 15.

-C- **Macon County Dialysis**- See Section VII.5, page 46, and Exhibits 28, 29 and 36.

## COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2012 State Medical Facilities Plan (2012 SMFP) and the January 2012 Semiannual Dialysis Report (January 2012 SDR) a Dialysis Station Adjusted Need Determination is provided for Macon County. In the 2012 SMFP Table 14A on page 368 states *“Number of Dialysis Stations Needed: Minimum 5; Maximum as projected in the January 2012 SDR”*. The January 2012 SDR states *“In response to a petition submitted to the North Carolina State Health Coordinating Council on behalf of the residents of Macon County, the North Carolina 2012 State Medical Facilities Plan includes an adjusted need determination for a new dialysis facility in Macon County, with a minimum of five dialysis stations, as projected in the July 2011 Semiannual Dialysis Report and a maximum of the number ‘projected as needed’ in the most recent ‘Semiannual Dialysis Report’ available prior to the Certificate of Need application due date. The adjusted need determination is intended to allow development of a local facility in order to minimize travel for dialysis patients over hazardous mountain roads, particularly in adverse weather.”* The January 2012 SDR Table 14A identifies the number of dialysis stations needed in Macon County as 7. Because the two applications in this review each state they propose 7 dialysis stations for a total of 14 dialysis stations, both of the applications cannot be approved. 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 Macon County Dialysis, Project ID # A-8799-12, is approved and the application submitted by FMC Macon County, Project ID # A-8795-12, is denied.

### SMFP Principles

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

*“The NC 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.”*

#### a) Home Training

**FMC Macon County.** In Section I.8, page 2, the applicant states *“BMA proposes that the new center will offer ... home dialysis therapies to include home peritoneal dialysis and home hemo-dialysis.”* In Section II, page 33, the applicant states *“Patients who wish to perform dialysis at home, and have both the capability and supportive home environment,*

*will be referred to the Home Training department of BMA Hickory or BMA Raleigh. The patient will be trained in either peritoneal dialysis (CAPD or CCPD) or Hemodialysis.”* In Section III, page 41, the applicant also states that the proposed FMC Macon County facility will contain a dedicated home hemo-dialysis station for the provision of home hemo-dialysis training (and support). Thus, the application contains contradictory statements concerning the availability of home dialysis training in the facility or at a reasonable distance from patient’s homes.

**Macon County Dialysis.** In Section V.2 (d), page 35, the applicant states *“Macon County Dialysis will provide home training in peritoneal dialysis services and follow-up.”*

On page 35, the applicant states that *“Sylva Dialysis center will provide the same accessible training and follow-up program for patients on home hemodialysis. Sylva Dialysis Center has been serving Macon County home hemodialysis patients for several years.”* Exhibit 16 contains a copy of a home training agreement for home hemodialysis between Macon County Dialysis and Sylva Dialysis Center. [Total Renal Care of North Carolina, LLC is the parent company of both the proposed Macon County Dialysis and the existing Sylva Dialysis Center in Jackson County. As stated above, the Sylva Dialysis Center is approximately 23 miles from the proposed Macon County Dialysis Center. The Sylva Dialysis Center is where 19 of the 21 in-center dialysis patients who reside in Macon County as of January 9 2012 (See Exhibit 15) currently go for dialysis.]

In Section II., page 19, the applicant states *“Macon County Dialysis will not provide Home Hemodialysis Training due to the requirement that a dedicated dialysis station be allocated for that modality. Since the count need is seven (7) stations and one of the stations will be utilized as an isolation station, Macon County Dialysis could not justify offering this service at this time.”*

With respect to home training, the **Macon County Dialysis** application is the more effective alternative since it proposes to offer both home training and follow-up for peritoneal dialysis at the proposed Macon County Dialysis facility and home training and follow-up for home hemodialysis at the Sylva Dialysis Center which is approximately 23 miles away. FMC Macon County proposes to provide follow-up for both peritoneal dialysis and home hemodialysis at its proposed facility however, FMC Macon County proposes to offer home training at BMA Hickory or BMA Raleigh *“Patients who wish to perform dialysis at home, and have both the capability and supportive home environment, will be referred to the Home Training department of BMA Hickory or BMA Raleigh. The patient will be trained in either peritoneal dialysis (CAPD or CCPD) or Hemodialysis.”* which is not a reasonable distance for patients who reside in Macon County. Further, FMC Macon County offers contradictory statements regarding the availability of home dialysis training in the facility or at a reasonable distance from the patient’s homes. Moreover, the FMC Macon County application is not approvable standing alone.

b) Hours of Availability

**FMC Macon County** – In Section VII.10, page 58, the applicant states dialysis services will be available from 7:00 AM to 5:00 PM, Monday through Saturday. FMC Macon County does not propose a third shift.

**Macon County Dialysis** – In Section VII.10, page 47, the applicant states dialysis services will be available from 6:00 AM to 4:00 PM, Monday through Saturday. Macon County does not propose a third shift.

Both applications are equally effective with regard to hours of operation. However, the FMC Macon County application is not approvable standing alone.

c) Services in rural, remote areas

Macon County is a rural, remote area. Both applications are equally effective with regard to providing services in rural, remote areas. However, the FMC Macon County application is not approvable standing alone.

**Facility Location**

Both applicants propose locations in Franklin, Macon County. According to MapQuest the proposed locations of the competing applications are only 2.68 miles apart. With regard to location, both applications are equally effective alternatives. However, neither the primary nor secondary sites identified by FMC Macon County are adequate for the proposed facility. The primary and secondary sites proposed by Macon County Dialysis are adequate for the proposed facility. See Criterion (4) and 10A NCAC 14C .2204(b)(3) and (5) for discussion which discussion is incorporated herein in its entirety. **Macon County Dialysis** is the most effective alternative with respect to facility location. Further, the FMC Macon County application is not approvable standing alone.

**Access by Underserved Groups**

**FMC Macon County**– In Section VI.1, page 41, the applicant states that 87.8% of its in-center patients will have some or all of their services covered by Medicare or Medicaid.

FMC Macon County proposes a higher percentage of patients to have some or all of their services paid for by Medicare or Medicaid (81.5% Medicare and 6.3% Medicaid). In Section VI.1(a), page 52, the applicant states “... *Medicare represented 79.7% of North Carolina dialysis treatments in BMA facilities in FY 2011. Medicaid treatments represented an additional 4.8% of treatments in BMA facilities for FY 2011 ...*”

The project analyst notes that BMA’s state-wide Medicare and Medicaid payments for dialysis treatments in FY2011 totaled 84.5% (79.7 Medicare and 4.8 Medicaid) while for the proposed project in Macon County the combined Medicare/Medicaid payments were 87.8%. The applicant did not provide a basis for the difference.

**Macon County Dialysis** – In Section VI.1, page 51, the applicant states that 82.8% of its in-center patients will have some or all of their services covered by Medicare or Medicaid (79.7% Medicare and 3.1% Medicaid). In Section VI.1(c), page 40, the applicant states:

*“These are average percentages of patients who are currently dialyzing at the Sylva Dialysis Center in Jackson County. Jackson County is contiguous to Macon County.  
...”*

FMC Macon County based its projected 87.8% Medicare/Medicaid payor mix on statewide averages. Macon County Dialysis based its projected 82.8% Medicare/Medicaid payor mix on patients currently dialyzing at the Sylva Dialysis Center who are projected to transfer to the proposed Macon County Dialysis facility. While FMC Macon County has the higher projected Medicare/ Medicaid payor mix due to the different basis of each applicant’s projections the two applications are equally effective alternatives. However, the FMC Macon County application is not approvable standing alone.

#### **Access to Ancillary and Support Services**

**FMC Macon County** In Section V.1-2, pages 47-48, 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. However, Exhibit 16, while labeled in the Exhibit’s contents section as “*Hospital Affiliation Agreement*”, does not contain either a *Hospital Affiliation Agreement* nor a letter of intent from a Hospital to enter into such an agreement. Rather, Exhibit 16 only contains a letter from the applicant to Murphy Medical Center asking the administrator of Murphy Medical Center to enter into an Affiliation Agreement.

**Macon County Dialysis** In Section V.1-2, pages 34-35, the applicant lists the providers of the necessary ancillary and support services. In Exhibits 7, 8, 17, 18 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 of intent from Mission Hospitals to enter into a Patient Transfer Agreement with the applicant. Mission Hospital is located in Asheville. According to MapQuest, Asheville is approximately 67 miles (a little over 1 hour driving time) from Franklin.

The **Macon County Dialysis** application is the more effective alternative with regard to access to ancillary and support services. Moreover, the FMC Macon County application is not approvable standing alone.

#### **Service to Macon County Residents**

Currently 19 of the 21 in-center dialysis patients who reside in Macon County receive treatment at the Sylva Dialysis Center which is owned by Total Renal Care of North Carolina, LLC, the owner of the proposed Macon County Dialysis. The doctor who has agreed to be the Medical Director for the proposed Macon County Dialysis facility, Dr. Bryson Fleming of Mountain Kidney & Hypertension Associates, P.A., states that his group has “*supplied nephrology services to the physicians and patients of Macon County for over*



*35 years. We have an outstanding relationship with the physicians in this area and they refer the majority of their nephrology patients to our group.”*

Fresenius Medical Care Holdings, Inc. (“Fresenius”) the ultimate parent company of Bio-Medical Applications of North Carolina, LLC d/b/a FMC Macon County does not identify any residents of Macon County currently receiving treatment in any of its facilities. Neither the applicant, nor the doctor who agreed to be the Medical Director for the proposed FMC Macon County facility, Dr. Hart of Metrolina Nephrology, references any existing relationship with residents of Macon County who are receiving dialysis treatment. Further, the FMC Macon County does not document support from any nephrologist’s currently serving in-center patients who reside in Macon County.

With regard to service to Macon County patients, the proposed project submitted by Macon County Dialysis is the more effective alternative. Moreover, the FMC Macon County application is not approvable standing alone.

### **Access to Alternative Providers**

Currently, there are no dialysis facilities in Macon County. Total Renal Care of North Carolina, LLC, the owner of the proposed Macon County Dialysis, also operates the Sylva Dialysis Center in Jackson County. Jackson County is contiguous to Macon County. Currently 19 of the 21 in-center dialysis patients who reside in Macon County receive treatment at the Sylva Dialysis Center. The Sylva Dialysis Center is approximately 23 miles from the proposed location of the Macon County Dialysis facility.

Fresenius Medical Care Holdings, Inc. (“Fresenius”) the ultimate parent company of Bio-Medical Applications of North Carolina, LLC d/b/a FMC Macon County. Fresenius does not operate any dialysis facilities in any of the North Carolina Counties contiguous to Macon County. However, Macon County is adjacent to the state line between North Carolina and Georgia. Fresenius does operate a dialysis center in Clayton, Georgia which is 24 miles from the proposed location of FMC Macon County.

Therefore, with regard to providing dialysis patients access to an alternative provider, the proposal’s are equally effective. However, the FMC Macon County application is not approvable standing alone.

### **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.

**Net Revenue**

<b>FMC MACON COUNTY</b>	<b>YEAR ONE</b>	<b>YEAR TWO</b>
Projected Net Revenue	\$1,138,188	\$1,187,180
# Dialysis Treatments	3,696	3,852
Average Net Revenue per Treatment	\$307.95	\$308.19

<b>MACON COUNTY DIALYSIS</b>	<b>YEAR ONE</b>	<b>YEAR TWO</b>
Projected Net Revenue	\$1,497,113	\$1,642,188
# Dialysis Treatments	4,836	5,304
Average Net Revenue per Treatment	\$309.57	\$309.61

The average net revenue per treatment is nearly identical. The applications are both equally effective with respect to the average net revenue per treatment. However, the FMC Macon County application is not approvable standing alone.

**Operating Costs**

<b>FMC MACON COUNTY</b>	<b>YEAR ONE</b>	<b>YEAR TWO</b>
Projected Operating Costs	\$1,095,443	\$1,140,432
# Dialysis Treatments*	3,696	3,852
Average Cost per Treatment	\$296.38	\$296.06

\*Includes home dialysis treatments.

<b>MACON COUNTY DIALYSIS</b>	<b>YEAR ONE</b>	<b>YEAR TWO</b>
Projected Operating Costs	\$1,355,506	\$1,459,786
# Dialysis Treatments*	4,836	5,304
Average Cost per Treatment	\$280.29	\$275.22

Macon County Dialysis projects the lowest average cost per treatment in Year One and FMC Macon County projects the lowest average cost per treatment in Year Two. The applications are each an equally effective alternative with regard to average operating costs per treatment. However, FMC Macon County did not provide a viable primary or secondary site which creates doubt as to the operating costs in its proformas. See Criterion (5) for additional discussion. Thus, FMC Macon County's average cost per treatment is questionable. Furthermore, the FMC Macon County application is not approvable standing alone. The application submitted by **Macon County Dialysis** is the more effective alternative with regard to average operating costs per treatment.

**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.

<b>POSITION</b>	<b>MACON COUNTY DIALYSIS</b>	<b>FMC MACON COUNTY</b>
Registered Nurse	\$52,000	\$51,896
Technician	\$26,000	\$32,864

Macon County Dialysis projects the higher annual salary for registered nurses and FMC Macon County projects the highest annual salary for technicians. The two applications are comparable with regard to direct care salaries. However, the FMC Macon County application is not approvable standing alone.

### **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. See discussion in Criterion (7).

FMC Macon County has identified George Hart, MD as its proposed medical director. The offices of Dr. George Hart, of Metrolina Nephrology, who has agreed to be the Medical Director of FMC Macon County, are located in Charlotte. According to a search on MapQuest the offices of Dr. Hart are located approximately 183 miles (approximately 3 hours driving time) from the proposed location of FMC Macon County.

Macon County Dialysis has identified Bryson Fleming, MD as it proposed medical director. The offices of Dr. Bryson Fleming, who has agreed to be the Medical Director of Macon County Dialysis, are located in Asheville. According to MapQuest, Asheville is approximately 67 miles (a little over 1 hour driving time) from the proposed location of Macon County Dialysis.

Macon County Dialysis adequately demonstrates it will have a Medical Director available at a reasonable distance to the facility (1 hour versus 3 hours). Macon County Dialysis is the more effective alternative with regard to availability of a Medical Director. Moreover, the FMC Macon County application is not approvable standing alone.

## **SUMMARY**

### **Macon County Dialysis**

The following is summary of the reasons the Macon County Dialysis application is determined to be a more effective alternative in this review than the FMC Macon County application.

- Adequately demonstrates that the financial feasibility of the proposal is based upon reasonable and supported projections of operating costs. See Criterion (5) for discussion.
- Provides a letter of intent to sign a written agreement from an acute care hospital. [10A NCAC 14C .2202(b)(1)]
- Adequately demonstrates the availability of a Medical Director whose practice is a reasonable distance to the facility.
- Adequately demonstrates the availability of a suitable location for the proposed project that can be developed at the capital costs in the application
- Proposes more effective access to ancillary and support services.
- Proposes more effective and reasonable access to home training for the residents of Macon County.

### **FMC Macon County**

The following is a summary of the reasons the FMC Macon County application is determined to be a less effective alternative in this review than the Macon County Dialysis application.

- Does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable and supported projections of operating costs. See Criterion (5) for discussion
- Does not provide a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital. [10A NCAC 14C .2202(b)(1)]
- Does not adequately demonstrate the availability of a Medical Director whose practice is within a reasonable distance to the facility.
- Does not adequately demonstrate the availability of a suitable location for the proposed project that can be developed at the capital costs in the application.
- Proposes less effective access to ancillary and support services.
- Does not propose access to home training that is a reasonable distance from the residents of Macon County.

## **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 Macon County Dialysis is the most effective alternative proposed in this review for 7 dialysis stations in Macon County and that application is approved as conditioned below. The approval of the other application would result in the approval of dialysis stations in Macon County in excess of the county need determination in the 2012 SMFP and January 2012 SDR and therefore, the FMC Macon County application is denied.

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

- 1. Total Renal Care of North Carolina, LLC d/b/a Macon County Dialysis shall materially comply with all representations made in its certificate of need application.**
- 2. Total Renal Care of North Carolina, LLC d/b/a Macon County Dialysis 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. Total Renal Care of North Carolina, LLC d/b/a Macon County Dialysis 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. Total Renal Care of North Carolina, LLC d/b/a Macon County Dialysis shall not offer or develop home hemodialysis training.**
- 5. Total Renal Care of North Carolina, LLC d/b/a Macon 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.**