

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: February 27, 2014
FINDINGS DATE: March 6, 2014
PROJECT ANALYST: Fatimah Wilson
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: N-10178-13 / Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Laurinburg / Add four stations for a total of 30 stations upon project completion / Scotland County

N-10189-13 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Scotland County / Add two stations for a total of 14 stations upon project completion / Scotland County

N-10201-13 / Total Renal Care of North Carolina, LLC d/b/a Scotland County Dialysis / Develop a new ten-station dialysis facility in Laurinburg / Scotland County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C- All Applications

The 2013 State Medical Facilities Plan (2013 SMFP) and the July 2013 Semiannual Dialysis Report (July 2013 SDR) provide a county need methodology for determining the need for new dialysis stations. According to Section 2(E) of the dialysis station need methodology, found on page 394 of the 2013 SMFP, *“If a county’s December 31, 2013 projected station deficit is 10 or greater and the July SDR shows that utilization of each dialysis facility in the county is 80 percent or greater, the December 31, 2013 county station need determination is the same as the December 31, 2013 projected station deficit.”* The July 2013 SDR shows a projected station deficit in Scotland County of 11 dialysis stations. The projected station deficit resulted in a need determination in the 2013 SMFP for 11 dialysis stations pursuant to

the county need methodology. Three applications were received by the Certificate of Need Section for development of the 11 dialysis stations. The three applicants applied for a total of 16 dialysis stations. Pursuant to the need determination in the 2013 SMFP and the July 2013 SDR, 11 dialysis stations is the limit on the number of dialysis stations that may be approved in this review.

BMA Laurinburg. Bio-Medical Applications of North Carolina, Inc. (“BMA”) d/b/a BMA Laurinburg proposes to add four dialysis stations to its existing dialysis facility in Laurinburg, Scotland County, in response to the county need methodology. In Section I.9, page 3, the applicant states the project will add four new dialysis stations. In Section II.2, page 32, the applicant states that it provides home training and home dialysis services. The applicant’s written presentation from the Public Hearing also states that they provide training for peritoneal dialysis and home hemodialysis for those patients who choose to dialyze at home. Exhibit 1 contains a copy of the applicant’s Medicare Certification Letter documenting the facility is certified for 26 dialysis stations and approval by the Acute and Home Care Licensure and Certification Section to add home hemodialysis and peritoneal dialysis support services. Exhibit 28 contains a line drawing depicting a total of 30 dialysis stations, including one separate room labeled isolation. Therefore, upon project completion, BMA Laurinburg will be certified for 30 dialysis stations, including one isolation station. The applicant proposes to develop no more than four new dialysis stations in Scotland County and therefore is conforming to the need determination in the 2013 SMFP and the July 2013 SDR.

FMC Scotland County. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Scotland County proposes to add two dialysis stations to its existing dialysis facility in Laurinburg, Scotland County in response to the county need methodology. In Section I.9, page 3, the applicant states the project will add two new dialysis stations. In Section II.1, page 11, the applicant states that it does not offer home training, but that patients who are candidates for home training are referred to BMA Laurinburg. Exhibit 1 contains a copy of the applicant’s Medicare Certification Letter documenting the facility is certified for 12 dialysis stations. Exhibit 28 contains a line drawing depicting a total of 14 dialysis stations including one isolation station. Therefore, upon project completion, FMC Scotland County will be certified for a total of 14 dialysis stations, including one isolation station. The applicant proposes to develop no more than two new dialysis stations in Scotland County and therefore is conforming to the need determination in the 2013 SMFP and the July 2013 SDR.

Scotland County Dialysis. Total Renal Care, Inc. (“TRC”) d/b/a Scotland County Dialysis proposes to develop a new 10-station dialysis facility in Laurinburg, Scotland County in response to a county need determination for dialysis stations in the 2013 SMFP. In Section I.9, page 3, the applicant states the proposed project will add 10-new dialysis stations, offering in-center hemodialysis, home hemodialysis and peritoneal dialysis training and support. Exhibit 40 contains a line drawing depicting a total of 10 dialysis stations including one separate room labeled “private treatment” and one PD Training Room. The applicant proposes to develop no more than 10-new dialysis stations in Scotland County and therefore is conforming to the need determination in the 2013 SMFP and the July 2013 SDR.

The applicants each state they are conforming to the need determination in the 2013 SMFP for 11 new dialysis stations in Scotland County. However, the limit on the number of new dialysis stations that may be approved in this review is 11. Collectively, the three applicants propose to develop a total of 16 new dialysis stations. Therefore, even if all applications were conforming or conditionally conforming to all statutory and regulatory review criteria, all the applications cannot be approved. (See the Comparative Analysis section for the decision).

There is one policy in the 2013 SMFP applicable to all 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.”

BMA Laurinburg

Promote Safety and Quality

The applicant, BMA Laurinburg, is a subsidiary of Fresenius Medical Care Holdings, Inc. (FMC). The applicant describes how its proposal will promote safety and quality in Section I, page 5 and Section II, pages 27 and 35-37. The applicant states in Section I, page 5:

*“FMC’s commitment to the quality and availability of dialysis services is evidenced in its organizational structure. The **Clinical Services Department**, within the Dialysis Division (Bio-Medical Applications, or BMA) serves as a central resource for the entire FMC network of health care providers. The department is devoted to assuring all FMC facilities are provided with the best procedures and equipment available and consistently meet the highest possible standards. Professional staff is available to assist facility managers and medical personnel with questions and concerns relative to clinical operations. Additionally, the department provides such services as an ongoing Clinical Review Program, guidelines for the comprehensive training of staff members, a Quality Assurance Program and a full range of services to support home care.*

*Another important resource for the provision of quality care is FMC’s **Technical Services Department**. The primary focus of this department is to oversee the technical and mechanical aspects of dialysis. The department is further supported by [by] a research and quality control team that consistently leads the industry in dealing with technically complex issues facing dialysis providers.*

...

The result of these services support the commitment and assurance that every patient receives care of the highest standards each time he or she is treated at an FMC facility.”

In addition, in Section II, page 27, the applicant states BMA’s parent company, FMC, “encourages all BMA facilities to attain the FMC UltraCare® certification”, an ongoing quality care program focused on delivering optimum care to patients through “innovative programs, the latest technology, continuous quality improvement and a focus on superior customer service.” UltraCare training is provided to all employees.

In Section II.3, pages 35-37, 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; and*
- 2) Continuous Quality Improvement*

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

Furthermore, BMA Laurinburg participates in FMC’s continuous quality improvement program whereby the facility is monitored by a Regional Quality Team for quality improvement, regulatory compliance, systems education and technical proficiency. Activities of the Regional Quality Team include discussion of clinical variance reports and mortality reviews. Follow-up on issues raised at Quality Improvement Committee meetings, in addition to unannounced audits, are performed to improve quality of care.

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

Promote Equitable Access

In Section II.1, page 28, 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 85.9% of the In-Center dialysis treatments will be covered by Medicare or Medicaid; an additional 5.7% are expected to be covered by VA. Thus, 91.6% 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. At this time, Scotland County has two operational dialysis facilities. As the dialysis patient population of Scotland County, and BMA facilities within the County, continue to increase, the need for dialysis stations will continue to increase. BMA will apply to develop new dialysis facilities when needed. Such was the case for the FMC Scotland County facility several years ago. In this application, BMA is applying for four additional stations to meet a growing need in Scotland County and the BMA Laurinburg facility.

Over the years, BMA has sought to develop new facilities and new dialysis stations in an effort to make dialysis convenient to the patient. This application to add four dialysis stations to BMA Laurinburg is another example of BMA efforts to meet the needs of the ESRD patient population of Scotland County."

In Section VI.1 (a), page 55, 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 58, the applicant states,

"The design of the facility is such that handicapped persons will have easy access to the facility; the facility will comply with ADA requirements. It was constructed in compliance with applicable sections of North Carolina State Building Code, Vol. #1-General Construction, which lists minimum requirements for the handicapped

applicable to institutional and residential structures. In addition, wheelchairs are always available for transporting patients who are unable to stand or walk.”

In Section VI.7, page 60, the applicant states,

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

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

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

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

Maximize Healthcare Value

The applicant describes how its proposal will maximize health care value for resources expended in Section II, page 28, and Section III.9, page 46. In Section II, page 28, the applicant states, “BMA is not projecting a capital expenditure for this project.” Since the majority of BMA Laurinburg’s patients are covered by government payers, BMA “*must work diligently to control costs of delivery for dialysis. BMA does.*” In addition, in Section III.9, page 46, the applicant states:

“The facility can accommodate additional stations without capital expenditure. One of the very basic premises of our CON law is to control cost of healthcare and prevent unnecessary duplication of existing health care resources. Approval of this application will certainly meet this goal.”

The applicant adequately demonstrates that the proposal will maximize healthcare value. Consequently, the applicant demonstrates that the projected volumes for the proposed service incorporate the basic principles in meeting the needs of the patients to be served. The application is consistent with the facility need determination in the July 2013 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

FMC Scotland County

Promote Safety and Quality

The applicant, FMC Scotland County, is a subsidiary of Fresenius Medical Care Holdings, Inc. (FMC). The applicant describes how its proposal will promote safety and quality in

Section I, page 5 and Section II, pages 22 and 30-32. The applicant states in Section I, page 5:

*“FMC’s commitment to the quality and availability of dialysis services is evidenced in its organizational structure. The **Clinical Services Department**, within the Dialysis Division (Bio-Medical Applications, or BMA) serves as a central resource for the entire FMC network of health care providers. The department is devoted to assuring all FMC facilities are provide with the best procedures and equipment available and consistently meet the highest possible standards. Professional staff is available to assist facility managers and medical personnel with questions and concerns relative to clinical operations. Additionally, the department provides such services as an ongoing Clinical Review Program, guidelines for the comprehensive training of staff members, a Quality Assurance Program and a full range of services to support home care.*

*Another important resource for the provision of quality care is FMC’s **Technical Services Department**. The primary focus of this department is to oversee the technical and mechanical aspects of dialysis. The department is further supported be [by] a research and quality control team that consistently leads the industry in dealing with technically complex issues facing dialysis providers.*

...

The result of these services support the commitment and assurance that every patient receives care of the highest standards each time he or she is treated at an FMC facility.”

In addition, in Section II, page 22, the applicant states BMA’s parent company, FMC, “encourages all BMA facilities to attain the FMC UltraCare® certification”, an ongoing quality care program focused on delivering optimum care to patients through “innovative programs, the latest technology, continuous quality improvement and a focus on superior customer service.” UltraCare training is provided to all employees.

In Section II.3, pages 30-32, 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

- 3) Technical Audits; and*
- 4) Continuous Quality Improvement*

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

Furthermore, FMC Scotland County participates in FMC's continuous quality improvement program whereby the facility is monitored by a Regional Quality Team for quality improvement, regulatory compliance, systems education and technical proficiency. Activities of the Regional Quality Team include discussion of clinical variance reports and mortality reviews. Follow-up on issues raised at Quality Improvement Committee meetings, in addition to unannounced audits, are performed to improve quality of care.

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

Promote Equitable Access

In Section II.1, page 23, 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 91.4% of the In-Center dialysis treatments will be covered by Medicare or Medicaid; an additional 4.1% are expected to be covered by VA. Thus, 95.5% 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. At this time, Scotland County has two operational dialysis facilities. As the dialysis patient population of Scotland County, and BMA facilities within the County, continue to increase, the need for dialysis stations will continue to increase. BMA will apply to develop new dialysis facilities when needed. Such was the case for the FMC Scotland County facility several years ago. In this application, BMA is applying for four additional stations to meet a growing need in Scotland County and the BMA Laurinburg facility.

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

In Section VI.1 (a), page 48, 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 51, the applicant states,

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

In Section VI.7, page 53, the applicant states,

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

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

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

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

Maximize Healthcare Value

The applicant describes how its proposal will maximize health care value for resources expended in Section II, page 23, and Section III.9, page 38-39. In Section II, page 23, the applicant states:

“BMA is projecting a capital expenditure of only \$5,300 for this project. This expenditure is necessary in the normal course of doing dialysis 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 addition of stations. Rather, BMA, through its parent company, FMC is taking on the financial burden to complete this addition of stations in an effort to bring dialysis treatment closer to the patient homes. ...”

On page 28, the applicant states that since the majority of BMA Laurinburg’s patients are covered by government payers, BMA *“must work diligently to control costs of delivery for dialysis. BMA does.”* In addition, in Section III.9, page 38-39, the applicant states:

“The facility can accommodate two additional stations without significant capital expenditure. One of the very basic premises of our CON law is to control cost of healthcare and prevent unnecessary duplication of existing health care resources. Approval of this application will certainly meet this goal.”

The applicant adequately demonstrates that the proposal will maximize healthcare value. Consequently, the applicant demonstrates that the projected volumes for the proposed service incorporate the basic principles in meeting the needs of the patients to be served. The application is consistent with the facility need determination in the July 2013 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

Scotland County Dialysis

Promote Safety and Quality

In Section II.3, pages 25-26, the applicant states:

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

Our Quality Management Program includes the following Quality Programs:

- *Quality Improvement Methodology- utilizing outcome-driven, patient centered management programs to measure, monitor and manage outcomes.*
- *Computerized Information System- integrating clinical and laboratory information for comprehensive outcomes tracking and reporting.*
- *Teammate and Patient Education Program- ensuring continuous updates and training to ensure high quality patient care.*
- *Quality Assessment Audit Program- systematically utilizing a comprehensive detailed assessment tool to assure the highest quality standards in every facility.*
- *Quality Management Team- experienced clinical facilitators 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.

...

Scotland County Dialysis will be attended by Dr. Jonathan Nester and other admitting Nephrologists who directly oversee the quality of care of the dialysis facility. In addition, Dr. Nestor 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.”

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

Promote Equitable Access

In Section VI.1(a), page 44, the applicant states:

“Scotland 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.

Scotland 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.

Scotland 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 47, the applicant states:

“Scotland 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 48, the applicant states:

“Scotland 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 29 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 44, the applicant projects that 89.6% of its patients will have some or all of their services paid for by Medicare or Medicaid. On page 40, the applicant also provides the basis for these projections as follows:

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

See discussion in Criterion 13(c) which is incorporated hereby as if set forth fully herein.

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

Maximize Healthcare Value

In Section III.9, page 34, the applicant states:

“The Scotland 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 1,900 dialysis facilities nationwide. The corporation has a centralized purchasing department that negotiates national contracts with numerous vendors in order to secure the best product available at the best price. We will be purchasing the equipment for this project under this procedure.*
- Scotland 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.*
- Scotland 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.*
- Scotland 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.*
- Scotland 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.

- *Scotland 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.”*

Scotland 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 county need determination in the 2013 SMFP, the July 2013 SDR and Policy GEN-3 and is conforming to this criterion.

Summary

All applications are conforming to the need determination in the 2013 SMFP and the July 2013 SDR for 11 dialysis stations in Scotland County. However, the limit on the number of dialysis stations that may be approved in this review is 11. Collectively, the three applicants propose a total of 16 dialysis stations. Therefore, even if all the applications were conforming or conditionally conforming to all statutory and regulatory review criteria, all the applications cannot be approved. See the Conclusion following the Comparative Analysis for the decision.

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

C-All Applications

There are currently two dialysis facilities operating in Scotland County, both of which are operated by Fresenius Medical Care of North Carolina, Inc. d/b/a Bio-Medical Applications of North Carolina, Inc. BMA Laurinburg is located on Lauchwood Drive, and FMC Scotland County is located on Aberdeen Road, both in Laurinburg. The July 2013 SDR *Table A: Inventory of Dialysis Stations and Calculation of Utilization Rates* indicates that, as of December 31, 2012, there were 128 in-center dialysis patients in the two operational Scotland County facilities dialyzing on 38 dialysis stations. *Table B: ESRD Dialysis Station Need Determination by Planning Area*, in the July 2013 SDR projects that, as of December 31, 2013, there will be 155 Scotland County residents in need of in-center dialysis treatments and a total of 38 dialysis stations. This means utilization in the County would be 102%, with 4.08 patients per station [155 patients / 38 stations = 4.08 patients per station. 155 / (38 x 4)

= 1.02]. The 2013 SMFP and the July 2013 SDR have thus identified a need for 11 additional dialysis stations in Scotland County. 3.2 patients per station is considered to be the number of patients which would ensure the provision of quality dialysis care, according to the July 2013 SDR.

BMA Laurinburg proposes to add four dialysis stations to the existing facility for a total of 30 stations upon project completion. The applicant states they currently have and will continue to 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 43, the applicant provides projected patient origin for the first two years of operation following completion of the proposed project, as illustrated in the following table.

BMA Laurinburg -Projected Patient Origin

COUNTY	YEAR ONE: 2015			YEAR TWO: 2016			COUNTY PATIENTS AS A PERCENT OF TOTAL	
	In-Center	PD	Home Hemo	In-Center	PD	Home Hemo	Year 1	Year 2
Scotland	71.2	4.8	1.0	75.0	4.1	2.1	73.1%	73.8%
Robeson	18.4	1.0	0.0	18.8	1.0	0.0	18.4%	18.0%
Richmond	1.0	0.0	0.0	1.0	0.0	0.0	0.9%	0.9%
Marlboro, SC	8.0	0.0	0.0	8.0	0.0	0.0	7.6%	7.3%
TOTAL	98.6	5.8	1.0	102.8	5.1	2.1	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve.

Need Analysis

The assumptions and methodology used to project in-center utilization are provided in Section II, pages 13-16, and Section III.7, pages 40-44. The following quote is from page 40.

“BMA is proposing to add four dialysis stations to BMA Laurinburg for a total of 30 dialysis stations at the facility. This application is filed pursuant to a County Need Determination in the July 2013 SDR. The SDR reports an 11 station deficit in Scotland County.

Assumptions

1. This project is scheduled for completion December 31, 2014.
 Operating Year 1: January 1, 2015 through December 31, 2015.
 Operating Year 2: January 1, 2016 through December 31, 2016.
2. The July 2013 SDR reports that BMA Laurinburg was operating at 83.65% utilization with a census of 87 patients dialyzing on 26 certified dialysis stations as of December 31, 2012.

3. *BMA does not assume that the patient population of Scotland County will grow at the Scotland County Five Year Average Annual Change Rate as published in the July 2013 (10.9%). Rather, BMA will use a much more conservative growth rate of 5.3%.*

...
4. *BMA notes that 26 of the 97 [87] patients are not residents of Scotland County. Of these 26, 17 are residents of Robeson County. In this application BMA will demonstrate growth of the Robeson County patients at a rate of 2.6%. ...*
5. *BMA will not project growth of the patients residing in Richmond County, or in Marlboro County, South Carolina. However, BMA does assume that these patients are dialyzing at BMA Laurinburg as a function of patient choice. BMA assumes these patients will continue to dialyze at BMA Laurinburg. These patients will be added to the BMA Laurinburg patient census at appropriate points in time, as BMA demonstrates its methodology and calculations of future patient populations of the facility.*
6. *As noted above, BMA will utilize a growth factor of 5.3% for the Scotland County patient population and 2.6% for the Robeson County patient population. The basis for this growth factor is included within the information provided in Exhibit 32 [30], Tab F. BMA has calculated a Five Year Average Annual Change Rate for Scotland County using the more correct data from the BMA Laurinburg and BMA Laurinburg facilities. The corrected information is included in Exhibit 32 [30], Tab B. BMA incorporated this information into the Patient Origin Report as provided by DHSR Medical Facilities Planning Section and included at Exhibit 32 [30], Tab C. The resultant corrected information is included at Exhibit 32 [30], Tab D.*
7. *BMA assumes that the home patient population of BMA Laurinburg will increase in similar fashion as the in-center patient population. As of December 31, 2012, BMA was serving six home patients. Each of these was utilizing peritoneal dialysis. In projections of future patient populations to be served, BMA will assume that one home patient in Operating Year 1 and 2 will convert to home hemo-dialysis.*
8. *BMA will demonstrate growth of only the home patients residing in Scotland County. BMA notes that the projections within this CON application are based upon the home patient population as of December 31, 2012. The facility home patient population as of June 30, 2013 was 10 home patients.”*

On pages 42-43, the applicant set forth the methodology utilized to project utilization.

“The next table represents BMA calculations of future patient in-center population at BMA Laurinburg

<i>BMA begins with the 61 Scotland County in-center dialysis patients, and 17 Robeson County in-center patients served as of December 31, 2012</i>	<i>61 Scotland County patients 17 Robeson County patients</i>
<i>BMA projects this patient population forward for 12 months to December 31, 2013</i>	<i>Scotland County: (61 X .053) + 61 = 64.2 Robeson County (17 X .026) + 17 = 17.4</i>
<i>BMA projects this in-center patient population forward for 12 months to December 31, 2014. This is the projected certification date of this project.</i>	<i>Scotland County: (64.2 X .053) + 64.2 = 67.6 Robeson County (17.4 X .026) + 17.4 = 17.9</i>
<i>BMA adds the patients from Richmond and Marlboro Counties as discussed. This is the beginning census for this project.</i>	<i>67.6 + 17.9 + 1 + 8 = 94.5</i>
<i>BMA projects the Scotland and Robeson County in-center patient population forward for 12 months to December 31, 2015. This is the projected ending census for Operating Year 1.</i>	<i>Scotland County: (67.6 X .053) + 67.6 = 71.2 Robeson County (17.9 X .026) + 17.9 = 18.4</i>
<i>BMA adds the patients from Richmond and Marlboro Counties as discussed. This is the ending census for Operating Year 1.</i>	<i>71.2 + 18.4 + 1 + 8 = 98.6</i>
<i>BMA projects the Scotland and Robeson County in-center patient population forward for 12 months to December 31, 2016. This is the projected ending census for Operating Year 2.</i>	<i>Scotland County: (71.2 X .053) + 71.2 = 75.0 Robeson County (18.4 X .026) + 18.4 = 18.8</i>
<i>BMA adds the patients from Richmond and Marlboro Counties as discussed. This is the ending census for Operating Year 2.</i>	<i>75.0 + 18.8 + 1 + 8 = 102.8</i>

The next table represents BMA calculations of future patient in-center [home] population at BMA Laurinburg.

<i>BMA begins with the 5 Scotland County home dialysis patients [December] 31, 2012.</i>	<i>5 PD patients</i>
<i>BMA projects this patient population forward for 12 months to December 31, 2013</i>	<i>(5 X .053) + 5 = 5.3</i>
<i>BMA projects this home patient population forward for 12 months to December 31, 2014.</i>	<i>(5.3 X .053) + 5.3 = 5.5</i>

<i>BMA adds the home patient from Robeson County. This is the projected certification for this project.</i>	$5.5 + 1 = 6.5$
<i>BMA projects this home patient population of Scotland County forward for 12 months to December 31, 2015.</i>	$(5.5 \times .053) + 5.5 = 5.8$
<i>BMA adds the home patient from Robeson County. This is the ending census for Operating Year 1. BMA Notes that one of the home patients is assumed to have begun home hemo-dialysis in this year.</i>	$5.8 + 1 = 6.8$
<i>BMA projects this home patient population of Scotland County forward for 12 months to December 31, 2016.</i>	$(5.8 \times .053) + 5.8 = 6.2$
<i>BMA adds the home patient from Robeson County. This is the ending census for Operating Year 2. BMA Notes that another of the home patients is assumed to have begun home hemo-dialysis in this year.</i>	$6.2 + 1 = 7.2$

On pages 15, 16, 18, 21, 22, 42, 43 and 44, the applicant projects the facility will serve 98 in-center patients or 3.27 in-center patients per station per week ($98 / 30 = 3.266$) by the end of Year One, which exceeds the 3.2 patients per station per week required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable, credible, and supported assumptions. Specifically, continued growth at the facility is adequately supported by the historic growth. Therefore, the applicant adequately demonstrates the need for the proposed stations.

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

FMC Scotland County proposes to add two dialysis stations to the existing facility for a total of 14 stations upon project completion. The applicant does not offer home training, but will refer patients who are candidates for home training to the BMA Laurinburg facility.

Population to be Served

In Section III.7, page 36, 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 Scotland County -Projected Patient Origin

COUNTY	YEAR ONE:	YEAR TWO:	COUNTY PATIENTS AS A PERCENT OF TOTAL	
	2015	2016	Year 1	Year 2
	In-Center	In-Center		
Scotland	47.9	50.4	100.0%	100.0%
TOTAL	47.9	50.4	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve.

Need Analysis

The assumptions and methodology used to project in-center utilization are provided in Section II, pages 13-15, and Section III.7, pages 35-37. The following quote is from page 35.

“BMA is proposing to add two dialysis stations to FMC Scotland County for a total of 14 dialysis stations at the facility. This application is filed pursuant to a County Need Determination in the July 2013 SDR. The SDR reports an 11 station deficit in Scotland County.

Assumptions

1. *This project is scheduled for completion December 31, 2014.
Operating Year 1: January 1, 2015 through December 31, 2015.
Operating Year 2: January 1, 2016 through December 31, 2016.*
2. *The July 2013 SDR reports that FMC Scotland County was operating at 85.42% utilization with a census of 41 patients dialyzing on 12 certified dialysis stations as of December 31, 2012.*
3. *BMA does not assume that the patient population of Scotland County will grow at the Scotland County Five Year Average Annual Change Rate as published in the July 2013 (10.9%). Rather, BMA will use a much more conservative growth rate of 5.3%.*

...
4. *BMA notes that 100% of the patient population of FMC Scotland County resides within Scotland County.*

...”

On pages 36-37, the applicant set forth the methodology utilized to project utilization.

“The next table represents BMA calculations of future patient in-center population at FMC Scotland County.

<i>BMA begins with the 41 Scotland County in-center dialysis patients served as of December 31, 2012</i>	<i>41 In-center patients</i>
<i>BMA projects this patient population forward for 12 months to December 31, 2013 using a growth rate of 5.3%</i>	<i>(41 X .053) + 41 = 43.2</i>
<i>BMA projects this in-center patient population forward for 12 months to</i>	<i>(43.2 X .053) + 43.2= 45.5</i>

<i>December 31, 2014. This is the projected certification date of this project.</i>	
<i>BMA projects this in-center patient population forward for 12 months to December 31, 2015. This is the projected ending census for Operating Year 1.</i>	$(45.5 \times .053) + 45.5 = 47.9$
<i>BMA projects this in-center patient population forward for 12 months to December 31, 2016. This is the projected ending census for Operating Year 2.</i>	$(47.9 \times .053) + 47.9 = 50.4$

On pages 14, 15, 16, 18, 36 and 37, the applicant projects the facility will serve 47 in-center patients or 3.36 in-center patients per station per week ($47 / 14 = 3.357$) by the end of Year One, which exceeds the 3.2 patients per station per week required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable, credible, and supported assumptions. Specifically, continued growth at the facility is adequately supported by the historic growth. Therefore, the applicant adequately demonstrates the need for the proposed stations.

In summary, the applicant adequately identified the population to be served and demonstrated the need this population has for the addition of two dialysis stations to the existing FMC Scotland County facility. Therefore, the application is conforming to this criterion.

Scotland County Dialysis proposes to develop a new 10-station dialysis facility in Scotland County. The applicant proposes that the new dialysis facility will offer in-center hemodialysis, home hemodialysis training and support and peritoneal dialysis training and support. An unrelated developer will purchase the property and build the shell building. Scotland County Dialysis will then lease the building, up-fit the shell, hire and train teammates and purchase dialysis machines and equipment needed to operate the facility.

Population to be Served

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

COUNTY	YEAR ONE: 2015/2016		YEAR TWO: 2016/2017		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	In-center patients	Home dialysis patients	In-center patients	Home dialysis patients	Year 1	Year 2
Scotland	31	1	34	1	94.1%	94.6%
Robeson	2	0	2	0	5.9%	5.4%
TOTAL	33	1	36	1	100.0%	100.0%

The applicant adequately identified the population proposed to be served.

Need Analysis

The assumptions and methodology used to project in-center utilization are provided in Section II, pages 13-22, and Section III.7, pages 30-33. The following quotes are from pages 30-31.

“The July 2013 SDR Table B indicates that there were 148 dialysis patients in Scotland County as of December 31, 2012 including 8 home patients. ...

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

- *TRC assumes that a significant number of Scotland County in-center ESRD dialysis patients are leaving Scotland County three times a week to receive their dialysis treatments at facilities outside Scotland County.*
- *TRC assumes that all ESRD patients prefer to dialyze at a facility that is convenient and close to their place of residence. Specifically, ESRD patients residing in Scotland County will want to dialyze at a dialysis facility in Scotland County. Since a significant number of ESRD patients who live in Scotland County are apparently leaving the county to obtain their dialysis treatments elsewhere, if those patients have a choice of a facility that is closer and has greater flexibility and availability of shift times such as the new facility would provide, many of them will find it more convenient to transfer to a facility within Scotland County.*
- *The patient population in Scotland County will be projected forward using the current Five Year Average Annual Change Rate of 10.9% as published in the July 2013 SDR.*
- *TRC assumes that the percentage of patients dialyzing on home therapies on June 30, 2015 will be the same as the percentage published in the July 2013 SDR. The July 2013 [SDR] indicates that as of December 31, 2012, 5.4% of the dialysis patients in Scotland County were home dialysis.*
- *A new facility should project its growth by taking into account patient proximity to its location, and also allowing for the continued growth of existing dialysis facilities in the County by focusing its projections on patients served by sister facilities of the proponent of the application in other counties. This approach build the new facility’s growth projections upon the existing referral patterns that have brought patients to its sister facilities [sic].*
- *Letters of support from patients indicating a willingness to consider transferring to a new facility are strong evidence of patient support and commitment.”*

On page 30, the applicant the applicant states,

“The July 2013 SDR Table B indicates that there were 148 dialysis patients living in Scotland County as of December 31, 2012 including 8 home patients. Of the 140 in-center patients, 128 were receiving dialysis from a Scotland County facility and the other 12 were receiving dialysis from a facility outside Scotland County. See the table below excerpted from the 12/31/2012 Patient Origin Data Chart which is included as Exhibit 11.

<i>Provider Number</i>	<i>Facility Name</i>	<i>Facility County</i>	<i>Home Patients</i>	<i>In-Center</i>	<i>County Total</i>
34-2540	BMA Laurinburg	Scotland	6	87	93
34-2664	FMC of Scotland County	Scotland	0	41	41
34-2539	Dialysis Care of Richmond County	Richmond	0	6	6
34-2579	Dialysis Care of Hoke County	Hoke	0	5	5
34-2592	Dialysis Care Kannapolis (DaVita)	Rowan	1	0	1
34-2638	Southern Pines Dialysis Center (DaVita)	Moore	0	1	1
34-2555	Dialysis Care of Moore County (DaVita)	Moore	1	0	1
	Scotland Totals		8	140	148

According to the July 2013 SDR Table B: ESRD Dialysis Station Need Determination by Planning Area, there were 148 Scotland County dialysis patients as of December 31, 2012. As demonstrated in the above table, 12 Scotland County residents received in-center dialysis services at facilities outside the County (87 + 41 = 128; 140 – 128 = 12).

On page 31, the applicant states,

“TRC provided in-center dialysis to 12 residents of Scotland County at facilities outside of the County. As demonstrated by the patient support letters in Exhibit 12, as of September 1, 2013, that number had grown to 15 patients.”

On pages 31-33, the applicant set forth the methodology utilized to project utilization.

“Thus, based on the patient support letters included in Exhibit 12, TRC begins its projections with 23 Scotland County patients and 2 Robeson County patients as of September 1, 2013.

First, TRC projects the Scotland County patient census forward for one year using the Five Year Average Annual Change Rate of 10.9% as published in the July 2013 SDR. This is the projected patient census as of September 1, 2014.

$$23 \times 1.109 = 25.5$$

In-Center Patients at Certification

TRC again projects that census forward for one year, using the Five Year Average Annual Change Rate of 10.9% as published in the July 2013 SDR. This is the projected Scotland County patient census for September 1, 2015, the projected certification date for the project.

$$25.5 \times 1.109 = 28.2$$

In addition, there are 2 Robeson County patients who have indicated by support letters that they would consider transferring to the new facility. We have not applied the Five Year Average Annual Change Rate to these patients since Robeson County's change rate would be different from Scotland County's.

Based on these calculations, on September 1, 2015, the projected certification date for the project, TRC is projecting that it will have 28 Scotland County in-center patients and 2 Robeson County in-center patients for a total of 30 in-center patients.

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

28.2 X 1.109 = 31.2 or 31 Scotland County plus 2 Robeson County in-center patients for a total of 33 in-center patients as of August 31, 2016, the end of operating year one

31.2 X 1.109 = 34.6 or 34 Scotland County plus 2 Robeson County in-center patients for a total of 36 in-center patients as of August 31, 2017, the end of operating year two

Calculating the Future Number of Home Peritoneal Dialysis Patients

In addition to the assumptions stated above, TRC makes the following assumptions regarding home patients:

According to CMS Dialysis Facility Compare, BMA of Laurinburg does not offer Home Hemodialysis Services and FMC of Scotland County offers no home training services at all, therefore we assume that all of the home patients served by BMA of Laurinburg are Home PD patients. ...

The SEKC data, which was current as of 4/3/2012 showed that Scotland County had 9 home patients, 8 home PD patients and 1 home hemodialysis patient. Since this is the most up to date data that is available regarding the breakdown of home patients, we assume that the ratio of approximately 1 home hemodialysis to 8 home PD patients is still valid.

*We have indicated in this Certificate of Need application that we intend to provide training and follow-up for home-trained patients in peritoneal dialysis. Total Renal Care has been working with Nephrologists throughout North Carolina for several years to promote the home therapies. The July 2013 SDR indicates that there were 8 home-trained patients living in Scotland County as of December 31, 2012. Based on our assumptions, we are going to assume that 7 of the 8 home patients are home PD patients and 1 is a home hemodialysis patient. Based on the Patient Origin Date[a] excerpted above, we know that 2 of the home patients are receiving their treatments at DaVita facilities outside of Scotland County. Based on the assumptions above, it is logical to assume that 1 of these patients is home hemodialysis and one is home peritoneal dialysis patient. See **Exhibit 15** signed by a peritoneal dialysis patient who lives in Scotland County, but travels to McColl for lab draws and support meeting with the clinical team.*

Based on these assumptions and data, TRC begins it[s] projections with 1 home PD patient on December 12 [31], 2012, and projects this census forward for 8 months (through August 31, 2013), using the Five Year Average Annual Change Rate of 10.9% as published in the July 2013 SDR.

$$1 \times 1.0726 = 1.4$$

TRC again applies the Five Year Average Annual Change Rate of 10.9% to project this forward for one year to August 31, 2014.

$$1.1 \times 1.109 = 1.2$$

Peritoneal Dialysis Patients at Certification

TRC again projects that census forward for one year, using the Five Year Average Annual Change Rate of 10.9% as published in the July 2013 SDR. This is the projected home PD patient census for September 1, 2015, the projected certification date for the project.

$$1.2 \times 1.109 = 1.3$$

Based on these calculations, on September 1, 2015, the projected certification date for the project, TRC is projecting that it will have 1 home PD patient.

Home PD Patients at the End of Operating Years One and Two

1.3 X 1.109 = 1.5 or 1 home PD patient as of August 31, 2016, the end of operating year one

1.5 X 1.109 = 1.6 or 1 home PD patient as of August 31, 2017, the end of operating year two”

The project analyst notes that the assumption above regarding home hemodialysis services at BMA Laurinburg made by Scotland County Dialysis is incorrect. BMA Laurinburg was approved on March 6, 2013 by the Acute and Home Care Licensure and Certification Section for the addition of home hemo-dialysis and support services and peritoneal dialysis and support services effective July 1, 2012.

On pages 15, 16, 19, 22, 29, 32 and 33, the applicant projects the facility will serve 33 in-center patients or 3.3 in-center patients per station per week ($33 / 10 = 3.3$) by the end of Year One, which exceeds the 3.2 patients per station per week required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable, credible, and supported assumptions. Specifically, the applicant documents that as many as 33 in-center patients would be interested in transferring to the proposed facility. Continued growth of this population is also adequately supported by the five year average annual change rate as published by the agency in the July 2013 SDR. Therefore, the applicant adequately demonstrates the need for the proposed 10-station facility.

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need this population has for the proposed new 10-station dialysis facility in Scotland 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-All Applications

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

C-All Applications

BMA Laurinburg. In Section III.9, pages 44-46, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – BMA Laurinburg is at 84% utilization, and the applicant projects it will exceed 80% utilization by the end of the first operating year for the proposed project. BMA also serves a significant number of Scotland County dialysis patients and expects this patient population to continue to increase, so the applicant rejected this alternative.
- 2) Develop a New Facility – The applicant could have chosen to develop a new facility pursuant to the County Need Determination, but rejected this alternative because it is not consistent with reasonable planning and expenditure of capital dollars.
- 3) Add Four Stations: BMA chose this alternative as most effective and least costly to meet the growing demand for services at BMA Laurinburg.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the BMA Laurinburg proposal is the least costly or most effective alternative to meet the need. Consequently, the application is conforming to this criterion.

FMC Scotland County. In Section III.9, pages 37-39, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – FMC Scotland County is at 85% utilization, and the applicant projects it will exceed 80% utilization by the end of the first operating year for the proposed project, so the applicant rejected this alternative.
- 2) Develop a New Facility – The applicant could have chosen to develop a new facility pursuant to the County Need Determination, but rejected this alternative because it is not consistent with reasonable planning and expenditure of capital dollars.
- 3) Add Two Stations: BMA chose this alternative as most effective and least costly to meet the growing demand for services at FMC Scotland County.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the FMC Scotland County proposal is the least costly or most effective alternative to meet the need. Consequently, the application is conforming to this criterion.

Scotland County Dialysis. In Section III.9, pages 34-35, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo –the applicant dismissed this alternative based on the large number of dialysis patients who live in Scotland County that travel outside their county of residence for dialysis treatments. Therefore, doing nothing would not be in the best interest of their patients.
- 2) Develop a New 10-Station Facility – the applicant chose this alternative in order to bring additional dialysis services and a new provider to the patients who live in Scotland County.

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative based on the following:

- The July 2013 SDR shows a projected station deficit in Scotland County of 11 dialysis stations. The station deficit resulted in a need determination in the 2013 SMFP for 11 new dialysis stations in Scotland County pursuant to the county need methodology.
- Many dialysis patients living in Scotland County travel outside their county of residence for dialysis treatments. On page 30, the applicant states:

“The July 2013 SDR Table B indicates that there were 148 dialysis patients living in Scotland County as of December 31, 2012 including 8 home patients. Of the 140 in-center patients, 128 were receiving dialysis from a Scotland County facility and the other 12 were receiving dialysis from a facility outside Scotland County. See

the table below excerpted from the 12/31/2012 Patient Origin Data Chart which is included as Exhibit 11.”

<i>Provider Number</i>	<i>Facility Name</i>	<i>Facility County</i>	<i>Home Patients</i>	<i>In-Center</i>	<i>County Total</i>
34-2540	BMA Laurinburg	Scotland	6	87	93
34-2664	FMC of Scotland County	Scotland	0	41	41
34-2539	Dialysis Care of Richmond County	Richmond	0	6	6
34-2579	Dialysis Care of Hoke County	Hoke	0	5	5
34-2592	Dialysis Care Kannapolis (DaVita)	Rowan	1	0	1
34-2638	Southern Pines Dialysis Center (DaVita)	Moore	0	1	1
34-2555	Dialysis Care of Moore County (DaVita)	Moore	1	0	1
	<i>Scotland Totals</i>		8	140	148

- DVA Healthcare Renal Care will up-fit the shell building that will be built by the developer. A centralized purchasing department will secure the dialysis chairs and TVs, negotiating the best product available at the best price.
- The facility will be a modern, state-of-the-art dialysis facility that will serve the needs of the ESRD dialysis patients living in the identified service area.
- A Scotland County Dialysis Bio-medical Technician 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.
- Patients will not have to travel an unreasonable distance to dialyze.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the Scotland County Dialysis proposal is the least costly or most effective alternative to meet the need. Consequently, the application is conforming to this criterion.

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

C- All Applications

BMA Laurinburg. In Section VIII.1, page 65, the applicant states, “*BMA will not incur any capital costs associated with this project.*” In Section IX, page 69, the applicant states that there will be no start-up costs or initial operating expenses since the facility is an existing facility. The applicant states in comments at the Public Hearing that:

“This facility has previously been certified for as many as 32 dialysis stations. When BMA developed the FMC Scotland County facility, we simply vacated existing space and removed the equipment from the treatment floor. The plumbing and electrical components are within the dialysis cabinetry and can be restored to full operation without capital expense. ...”

In Section VIII.5, page 66, the applicant refers to Exhibit 24 for a letter of commitment for the project signed by the Vice President of Fresenius Medical Care Holdings, Inc., the parent company of Bio-Medical Applications of North Carolina, Inc. This letter states, in part:

“BMA proposes to add four dialysis stations to its BMA Laurinburg facility for a facility total of 30 dialysis stations upon completion of this project. The project does not require any capital costs on behalf of BMA. As Vice President, I am authorized and do hereby authorize the addition of four new dialysis stations.”

In Exhibit 10, the applicant provides a copy of the most recent audited financial reports for FMC. As of December 31, 2012, Fresenius Medical Care Holdings, Inc. and Subsidiaries had cash and cash equivalents totaling \$341,071,000 with \$17,841,509,000 in total assets and \$9,469,431,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the financial security of the applicant.

In Section X.1, page 70, the applicant projects the projected allowable charges per treatment for each payment source as follows:

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

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

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. In Section X.2-X.4, pages 71-76, the applicant reported projected revenues and expenses as follows:

BMA LAURINBURG	CURRENT YEAR	YEAR ONE	YEAR TWO
Gross Revenue	\$5,291,323	\$5,743,382	\$6,079,051
Contractual Adjustments	\$1,008,698	\$1,093,841	\$1,171,043
Net Revenue	\$4,282,626	\$4,649,541	\$4,908,008
Total Operating Costs	\$3,474,953	\$3,800,646	\$3,979,822
Net Profit	\$807,673	\$848,895	\$928,186

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

According to the Centers for Medicare & Medicaid Services (CMS), the End-Stage Renal Disease Prospective Payment System (ESRD PPS) base rate for CY 2012 was \$234.81.¹ The applicant appears to use the CY 2012 ESRD PPS reimbursement rates in its pro formas.

In Section X.1, pages 70-71, the applicant does not reduce the Medicare reimbursement rate by 20 percent as part of its allowable charges per treatment by payor source.² While Medicare will routinely pay for 80 percent of Medicare-approved dialysis treatments, the patient is responsible for the remaining 20 percent. Thus the total revenue for each Medicare patient would be 100% of the maximum allowable charge.

Moreover, in Section X.2, page 71, the applicant provides a table with a line item labeled “*Other Deductions from Revenue (Total Contractual Allowances)*” and deducts more than 20 percent of the gross patient service revenue as contractual allowances. In Section X.4, page 76, the applicant provides a table showing actual and estimated annual operating expenses. The applicant includes a line item for bad debt and charity expenses in its annual operating expenses. Between contractual adjustments and bad debt/charity items, the applicant reduces its gross revenue for the current operating year, Operating Year One, and Operating Year Two by 23.9 percent, 23.9 percent, and 24.1 percent, respectively.

In Section X.5, page 78, the applicant discusses the impact of a potential cut in Medicare reimbursement rates due to the implementation of the American Taxpayer Relief Act of 2012. The applicant states that Medicare reimbursement rates may be cut as much as 9 percent. The applicant states that if a cut of 9 percent were to happen, the facility would have less profit and less tax liability. A proposed rule was published in the Federal Register on July 8, 2013 proposing a Medicare ESRD PPS base rate of \$216.95 (which would have been a cut of 12% from the CY 2013 Medicare ESRD PPS base rate). However, the final rule, published in the Federal Register and effective on December 10, 2013, fixed the CY 2014 Medicare ESRD PPS base rate at \$239.02. The applicant, in its alternate pro formas, demonstrates that even if the

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

² Medicare patient documents state that Medicare routinely pays for 80 percent of Medicare-approved dialysis treatments and the patient pays the remaining 20 percent (subject to deductible as well). <http://www.medicare.gov/coverage/dialysis-services-and-supplies.html>, accessed 2/17/2014.

Medicare reimbursement rate were as low as \$213, the facility will still generate revenues exceeding expenses during the first two operating years of the project.

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

FMC Scotland County. In Section VIII.1, page 58, the applicant states the capital cost is projected to be \$5,300. In Section IX, page 63, the applicant states that there will be no start-up costs or initial operating expenses since the facility is an existing facility.

In Section VIII, pages 58-62, the applicant states it will fund the capital costs of the project with accumulated reserves of Fresenius Medical Care Holdings, Inc., the parent company of Bio-Medical Applications of North Carolina, Inc. Exhibit 24 contains a letter, dated September 16, 2013, 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 add two dialysis stations to its FMC Scotland County facility for a facility total of 14 dialysis stations upon completion of this project. The project requires the following capital expense on behalf of BMA.

Capital Expense: \$5,300

As Vice President, I am authorized and do hereby authorize the addition of two dialysis stations, for capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$5,300 as may be needed for this project.”

In Exhibit 10, the applicant provides a copy of the most recent audited financial reports for FMC. As of December 31, 2012, Fresenius Medical Care Holdings, Inc. and Subsidiaries had cash and cash equivalents totaling \$341,071,000 with \$17,841,509,000 in total assets and \$9,469,431,000 in net assets (total assets less total liabilities). The applicant adequately demonstrated the availability of sufficient funds for the capital and working capital needs of the project.

In Section X.1, page 64, the applicant projects the projected allowable charges per treatment for each payment source as follows:

FMC Scotland County	
Allowable Charge per Treatment by Payment Source	
	In-Center
Commercial Insurance*	\$1,375.00
Medicare	\$234.00

Medicaid	\$137.29
VA	\$146.79
Private Pay	\$1,375.00

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

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. In Section X.2-X.4, pages 65-69, the applicant reported projected revenues and expenses as follows:

FMC SCOTLAND COUNTY	CURRENT YEAR	YEAR ONE	YEAR TWO
Gross Revenue	\$1,933,962	\$2,121,740	\$2,263,996
Contractual Adjustments	\$239,044	\$263,246	\$281,967
Net Revenue	\$1,694,918	\$1,858,494	\$1,982,029
Total Operating Costs	\$1,691,218	\$1,713,230	\$1,805,045
Net Profit	\$3,700	\$145,264	\$176,984

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

According to the Centers for Medicare & Medicaid Services (CMS), the End-Stage Renal Disease Prospective Payment System (ESRD PPS) base rate for CY 2012 was \$234.81.³ The applicant appears to use the CY 2012 ESRD PPS reimbursement rates in its pro formas.

In Section X.1, pages 64-65, the applicant does not reduce the Medicare reimbursement rate by 20 percent as part of its allowable charges per treatment by payor source.⁴ While Medicare will routinely pay for 80 percent of Medicare-approved dialysis treatments, the patient is responsible for the remaining 20 percent. Thus the total revenue for each Medicare patient would be 100% of the maximum allowable charge.

Moreover, in Section X.2, page 65, the applicant provides a table with a line item labeled “*Other Deductions from Revenue (Total Contractual Allowances)*” and deducts more than 20 percent of the gross patient service revenue as contractual allowances. In Section X.4, page 69, the applicant provides a table showing actual and estimated annual operating expenses. The applicant includes a line item for bad debt and charity expenses in its annual operating expenses. Between contractual adjustments and bad debt/charity items, the applicant reduces its gross revenue for the current operating year, Operating Year One, and Operating Year Two by 17.6 percent, 17.7 percent, and 17.7 percent, respectively.

³ “End-Stage Renal Disease Prospective Payment System,” Payment System Fact Sheet Series, ICN 905143, December 2012.

⁴ Medicare patient documents state that Medicare routinely pays for 80 percent of Medicare-approved dialysis treatments and the patient pays the remaining 20 percent (subject to deductible as well). <http://www.medicare.gov/coverage/dialysis-services-and-supplies.html>, accessed 2/17/2014.

In Section X.5, page 70, the applicant discusses the impact of a potential cut in Medicare reimbursement rates due to the implementation of the American Taxpayer Relief Act of 2012. The applicant states that Medicare reimbursement rates may be cut as much as 9 percent. The applicant states that if a cut of 9 percent were to happen, the facility would have less profit and less tax liability. A proposed rule was published in the Federal Register on July 8, 2013 proposing a Medicare ESRD PPS base rate of \$216.95 (which would have been a cut of 12% from the CY 2013 Medicare ESRD PPS base rate). However, the final rule, published in the Federal Register and effective on December 10, 2013, fixed the CY 2014 Medicare ESRD PPS base rate at \$239.02. The applicant, in its alternate pro formas, demonstrates that even if the Medicare reimbursement rate were as low as \$213, the facility will still generate revenues exceeding expenses during the first two operating years of the project.

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

Scotland County Dialysis. In Section VIII.1, page 54, the applicant states the capital cost is projected to be \$1,574,557. In Section IX, page 58, the applicant states that the total working capital needed will be \$881,613 (\$150,088 in start-up expenses and \$731,525 in initial operating expenses.)

In Section VIII.2-3, pages 55-56 and Exhibit 33, 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 33 contains a letter, dated September 12, 2013, from the Chief Accounting Officer of DaVita, Inc. which states:

“I am the Chief Accounting Officer of DaVita HealthCare Partners, Inc. (“DaVita”), which is the parent and 100% owner of Total Renal Care of North Carolina, Inc. (“Total Renal Care”). I also serve as the Chief Accounting Officer of Total Renal Care, which will be applying for a certificate of need to develop a new End Stage Renal Disease hemodialysis facility in Laurinburg in Scotland County, which is projected to open in the third quarter of 2015.

DaVita, through Total Renal Care has committed cash reserves in the total amount of \$2,556,170 for the capital costs, start up costs and the working capital needed for this new facility. Our company is absolutely committed to the development and operation of this new facility, and we will ensure that these funds are made available. This letter will confirm the amounts that we have projected for each of the three categories and explain the basis for each figure.

...

As Chief Accounting Officer of DaVita and Total Renal Care, I can confirm that we will provide all of these funds and any other funds that may prove to be necessary to make this project financially feasible. ...”

In Exhibit 34, the applicant provides the audited financial statements for DaVita Healthcare Partners Inc. for the fiscal years ended December 31, 2012 and 2011. As of December 31, 2012, DaVita had \$533,748,000 in cash and cash equivalents, \$16,018,596,000 in total assets and \$4,508,740,000 in net assets (total assets less total liabilities). The applicant adequately demonstrated the availability of sufficient funds for the capital and working capital needs of the project.

In Section X.1, page 60, the applicant projects the projected allowable charges per treatment for each payment source as follows:

SCOTLAND COUNTY DIALYSIS	
Source of Payment	Charge Per Treatment
Medicare	\$192.28
Medicaid	\$143.00
Medicare/Medicaid	\$240.36
Commercial Insurance	\$1,442.00
VA	\$193.00
Medicare/Commercial	\$240.36

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

According to the Centers for Medicare & Medicaid Services (CMS), the End-Stage Renal Disease Prospective Payment System (ESRD PPS) base rate for CY 2013 was \$240.36.⁵ As noted above, the applicant reduces its ESRD PPS base rate by 20% to account for patient responsibility. In Section X.2, page 61, and Section X.4, page 64, the applicant also provides documentation that bad debt and charity expenses were deducted from the treatment revenues.

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. In Section X.2-X.5, pages 60-65, the applicant reported projected revenues and expenses as follows:

SCOTLAND COUNTY DIALYSIS	YEAR ONE	YEAR TWO
Projected Net Revenue	\$1,503,583	\$1,641,098
Total Operating Costs	\$1,477,387	\$1,570,835
Net Profit	\$26,196	\$70,263

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

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

⁵ “End-Stage Renal Disease Prospective Payment System,” Payment System Fact Sheet Series, ICN 905143, December 2012.

- (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-All Applications

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA currently operates the only two dialysis facilities located in Scotland County. BMA Laurinburg is currently certified for 26 stations and FMC Scotland County is currently certified for 12 stations, as shown in the table below.

Scotland County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/12	# In-Center Patients 12/31/2012	% Utilization	Patients Per Station
BMA Laurinburg	26	87	83.65%	3.3
FMC Scotland County	12	41	85.42%	3.4

Source: July 2013 SDR, Table A.

The 2013 SMFP and the July 2013 SDR provide a County Need Determination for new dialysis stations in Scotland County. According to Section 2(E) of the dialysis station need methodology, found on page 394 of the 2013 SMFP, *“If a county’s December 31, 2013 projected station deficit is 10 or greater and the July SDR shows that utilization of each dialysis facility in the county is 80 percent or greater, the December 31, 2013 county station need determination is the same as the December 31, 2013 projected station deficit. ...”* The July 2013 SDR Table 14B identifies the number of dialysis stations needed in Scotland County as 11. Three applications were received by the Certificate of Need Section for development of the 11 dialysis stations. The three applicants applied for a total of 16 dialysis stations. Pursuant to the need determination in the 2013 SMFP and the July 2013 SDR, 11 dialysis stations is the limit on the number of dialysis stations that may be approved in this review.

BMA Laurinburg proposes to add four dialysis stations to the existing facility in Laurinburg, in Scotland County. The applicant adequately demonstrates the need to add four stations to the existing facility. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. Therefore, the applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

FMC Scotland County proposes to add two dialysis stations to the existing facility in Laurinburg, in Scotland County. The applicant adequately demonstrates the need to add two stations to the existing facility. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. Therefore, the applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

Scotland County Dialysis proposes to develop 10 new dialysis stations at a new facility in Laurinburg, in Scotland County. The applicant adequately demonstrates the need to develop 10 stations to develop a new facility. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. Therefore, the applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

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

C- All Applications

BMA Laurinburg. In Section VII.1, page 61, the applicant projects the following staffing during the first two operating years.

POSITION	TOTAL FTEs YEARS 1 AND 2
RN (dc)	5.00
Technician (dc)	8.00
Clinical Manager (dc)	1.00
Admin (dc)	0.20
Dietician	0.75
Social Worker	0.75
Home Training Nurse (dc)	1.50
Chief Tech	0.10
Equipment Tech	0.50
In-Service	0.20
Clerical	1.00
TOTAL	19.00

dc: direct care staff

As shown in the above table, the applicant proposes a total of 19 FTE positions, 15.7 of which will be direct care positions (RN, Technicians, Clinic Manager and Home Training

Nurse). In written comments submitted by the applicant at the Public Hearing on November 19, 2013, the applicant states:

“It is not unusual for the home training staff to supplement staffing on the dialysis treatment floor. Further, the facility manager is an RN. The facility manager is also prepare [sic] to provide direct patient care in the facility treatment area when necessary.”

In Section VII.4, page 62, the applicant states that it does not anticipate having any difficulty staffing the proposed facility.

The applicant proposes a total of 11-hours of operation per day, 66-hours of operation per week and 3,432 hours of operation per year at the facility as shown in the table below.

HOURS OF OPERATION								
	TIME	MON	TUES	WED	THURS	FRI	SAT	TOTAL
Morning	6:00AM – 12:00PM	6	6	6	6	6	6	36
Afternoon	12:00PM-5:00PM	5	5	5	5	5	5	30
Evening	5:00PM-10:00PM							
Total		11	11	11	11	11	11	66
Total Hours of Operation per Year (66 total weekly hours X 52 weeks per year)								3,432

The following table shows the number of direct care staff positions (FTEs) the applicant proposes based on the number of hours the facility will operate, as shown in the table below.

	# FTEs	Hrs/Yr/FTE	TOTAL FTE HOURS (ANNUAL)	TOTAL HRS OF OPERATION (ANNUAL)	FTE HRS/HRS OF OPERATION
RN	5.00	2,080	10,400	3,432	3.03
Techs	8.00	2,080	16,640	3,432	4.85
Clinical Manager	1.00	2,080	2,080	3,432	0.61
Admin	0.20	2,080	416	3,432	0.12
Home Training Nurse	1.50	2,080	3,120	3,432	0.91
Total	15.70	2,080	32,656	3,432	9.52

Based on the proposed operating hours for the facility, the applicant proposes to be operational for 3,432 hours a year. In Section VII, page 61, the applicant projects 15.7 total direct care FTEs. Assuming one FTE works 2,080 hours annually, 15.7 FTEs would work a total of 32,656 hours annually, which is sufficient to cover the 3,432 hours of operation. The applicant proposes more than sufficient direct care staff to provide the proposed services.

In addition, the proposed facility projects to serve 98 in-center patients in Year One on 30 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 (30 stations)	30	30
Afternoon (30 Stations)	30	30

As shown in the table above, the proposed 30-station facility would be able to dialyze up to a maximum of 120 in-center patients on 30 dialysis stations, assuming one patient per station per shift and two shifts per day, Monday through Saturday. On page 43 the applicant states it projects to serve 98 in-center patients in Year One and 102 in-center patients on 30 stations in Year Two.

In Section V.4(c), page 52, the applicant states that Muhammad Iqbal, MD has agreed to continue to serve as the Medical Director of the existing facility. Exhibit 21 contains a letter from Muhammad Iqbal, MD which states:

“I am writing as the Medical Director of FMC of Laurinburg to wholeheartedly endorse the application by Bio-Medical Applications of North Carolina to expand the center and add six in-center hemo-dialysis stations. I have agreed to continue serving as the Medical Director for this facility. ...” [sic]

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

FMC Scotland County. In Section VII.1, page 54, the applicant projects the following staffing during the first two operating years.

POSITION	TOTAL FTEs YEARS 1 AND 2
RN (dc)	2.50
Technician (dc)	5.00
Clinical Manager (dc)	1.00
Admin (dc)	0.20
Dietician	0.25
Social Worker	0.25
Chief Tech	0.10
Equipment Tech	0.25
In-Service	0.25
Clerical	1.00
TOTAL	10.80

dc: direct care staff

As shown in the above table, the applicant proposes a total of 10.80 FTE positions, 8.7 of which will be direct care positions. In Section VII.4, page 55, the applicant states that it does not anticipate having any difficulty staffing the proposed facility.

The applicant proposes a total of 11-hours of operation per day, 66-hours of operation per week and 3,432 hours of operation per year at the facility as shown in the table below.

HOURS OF OPERATION								
	TIME	MON	TUES	WED	THURS	FRI	SAT	TOTAL
Morning	6:00AM – 12:00PM	6	6	6	6	6	6	36
Afternoon	12:00PM-5:00PM	5	5	5	5	5	5	30
Evening	5:00PM-10:00PM							
Total		11	11	11	11	11	11	66
Total Hours of Operation per Year (66 total weekly hours X 52 weeks per year)								3,432

The following table shows the number of direct care staff positions (FTEs) the applicant proposes based on the number of hours the facility will operate, as shown in the table below.

	# FTEs	Hrs/Yr/FTE	TOTAL FTE HOURS (ANNUAL)	TOTAL HRS OF OPERATION (ANNUAL)	FTE HRS/HRS OF OPERATION
RN	2.50	2,080	5,200	3,432	1.52
Techs	5.00	2,080	10,400	3,432	3.03
Clinical Manager	1.00	2,080	2,080	3,432	0.61
Admin	0.20	2,080	416	3,432	0.12
Total	8.70	2,080	18,096	3,432	5.27

Based on the proposed operating hours for the facility, it will be open 3,432 hours a year. In Section VII, page 54, the applicant projects 8.7 total direct care FTEs. Assuming one FTE works 2,080 hours annually, 8.7 FTEs would work a total of 18,096 hours annually, which is sufficient to cover the 3,432 hours of operation. The applicant proposes more than sufficient direct care staff to provide the proposed services.

In addition, the proposed facility projects to serve 47 in-center patients in Year One on 14 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 (14 stations)	14	14
Afternoon (14 Stations)	14	14

As shown in the table above, the proposed 14-station facility would be able to dialyze up to a maximum of 56 in-center patients on 14 dialysis stations, assuming one patient per station per shift and two shifts per day, Monday through Saturday. On page 36 the applicant states it projects to serve 47 in-center patients in Year One and 50 in-center patients on 14 stations in Year Two.

In Section V.4(c), page 45, the applicant states that Muhammad Iqbal, MD has agreed to continue to serve as the Medical Director of the existing facility. Exhibit 21 contains a letter from Muhammad Iqbal, MD stating:

“I am writing as the Medical Director of FMC of Scotland County to wholeheartedly endorse the application by Bio-Medical Applications of North Carolina to expand the center and add two in-center hemo-dialysis stations. I have agreed to continue serving as the Medical Director for this facility. ...”

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

Scotland County Dialysis. In Section VII.1, page 50, the applicant projects the following staffing during the first two operating years.

POSITION	TOTAL FTES YEARS 1 AND 2
RN (dc)	1.50
RN HT (dc)	0.40
Patient Care Technician (dc)	4.50
Bio-Med Tech	0.30
Admin (dc)	1.00
Dietician	0.30
Social Worker	0.30
Unit Secretary	1.00
TOTAL	9.30

*dc: direct care staff

As shown in the above table, the applicant proposes a total of 9.3 full-time equivalent (FTE) positions, 6.4 of which will be direct care positions. In Section VII.4, page 51, the applicant states that it does not anticipate having any difficulty staffing the proposed facility.

The applicant proposes a total of 10-hours of operation per day, 60-hours of operation per week and 3,120 hours of operation per year at the facility as shown in the table below.

HOURS OF OPERATION								
	TIME	MON	TUES	WED	THURS	FRI	SAT	TOTAL
Morning	6:00AM – 10:00 AM	4	4	4	4	4	4	24
Afternoon	10:00AM-4:00PM	6	6	6	6	6	6	36
Evening	4:00PM-8:00PM							
Total		10	10	10	10	10	10	60
Total Hours of Operation per Year (60 total weekly hours X 52 weeks per year)								3,120

The following table shows the number of direct care staff positions (FTEs) the applicant proposes based on the number of hours the facility will operate, as shown in the table below.

	# FTES	HRS/YR/FTE	TOTAL FTE HOURS (ANNUAL)	TOTAL HRS OF OPERATION (ANNUAL)	FTE HRS/HRS OF OPERATION
RN	1.50	2,080	3,120	3,120	1.00
RN HT	0.40	2,080	832	3,120	0.27

Techs	4.50	2,080	9,360	3,120	3.00
Total	6.40	2,080	13,312	3,120	4.27

Based on the proposed operating hours for the facility, it will be open 3,120 hours a year. In Section VII, page 50, the applicant projects 6.4 total direct care FTEs. Assuming one FTE works 2,080 hours annually, 6.4 FTEs would work a total of 13,312 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 33 in-center patients in Year One on 10 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 (10 stations)	10	10
Afternoon (10 Stations)	10	10

As shown in the table above, the proposed 10-station facility would be able to dialyze up to a maximum of 40 in-center patients on 10 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 10-stations.

In Section V.4(c), page 40, the applicant states that Jonathan Nestor, MD has agreed to serve as Medical Director of the facility. Exhibit 25 contains a letter from Jonathan Nestor, MD stating that he has agreed to serve as Medical Director of the proposed facility. The letter in Exhibit 25 states in part,

“I am a physician and Board Certified Nephrologist with a practice in Scotland County, where I understand that DaVita and its affiliate, Total Renal Care, Inc., will be proposing to establish a new dialysis facility. I am writing this letter to confirm my interest and willingness to serve as medical director for the new dialysis facility. ...”

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.

C- All Applications

BMA Laurinburg. In Section V.1-2, pages 49-51, the applicant lists the providers of the necessary ancillary and support services already being provided. In Exhibits 16-18 and 21-22, the applicant documents how the project will be coordinated with the existing health care system. Exhibit 16 contains a copy of an affiliation agreement with Scotland Memorial

Hospital. The project analyst notes that the hospital affiliation agreement provided by the applicant in Exhibit 16 is not signed; however, being an existing facility, it is not unreasonable to assume that a working relationship between BMA Laurinburg and Scotland Memorial Hospital is already in place. It is also noted that 10A NCAC 14C .2202(b)(1) is not applicable to this facility as BMA Laurinburg is not a new facility but an existing facility. The information provided in Section V and the referenced Exhibits is reasonable and credible and supports a finding of conformity with this criterion.

FMC Scotland County. In Section V.1-2, pages 42-44, the applicant lists the providers of the necessary ancillary and support services already being provided. In Exhibits 16-18 and 21-22, the applicant documents how the project will be coordinated with the existing health care system. Exhibit 16 contains a signed copy of an affiliation agreement with Scotland Memorial Hospital. It is also noted that 10A NCAC 14C .2202(b)(1) is not applicable to this facility as FMC Scotland County is not a new facility but an existing facility. The information provided in Section V and the referenced Exhibits is reasonable and credible and supports a finding of conformity with this criterion.

Scotland County Dialysis. In Section V.1-2, pages 38-39, the applicant lists the providers of the necessary ancillary and support services. In Exhibits 7, 8, and 21, the applicant documents how the project will be coordinated with the existing health care system. In Section II.1, page 11, the applicant states “*A representative with Scotland Memorial Hospital has signed a letter of intent to establish a patient transfer agreement with Scotland County Dialysis upon issuance of the Certificate of Need.*” Exhibit 7 contains a copy of a letter dated August 26, 2013 from the President and Chief Executive Officer, Scotland Health Care System, 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. We will provide the following services to patients receiving their dialysis treatments at Scotland County Dialysis:

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

The 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-All 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-All Applications

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

NA- BMA Laurinburg
NA- FMC Scotland County
C-Scotland County Dialysis

Scotland County Dialysis proposes to have an unrelated developer construct a 7,400 square foot building on Parcel ID # 01006702001 on Lauchwood Drive in Laurinburg. In Section XI.6(d), page 70, the applicant states that *“the facility will be constructed with energy-efficient glass, mechanically operated patient access doors and energy-efficient cooling and heating.”* In Section XI.6(g), pages 70 – 71, the applicant states the facility will be constructed in compliance with all laws and regulations pertaining to staffing, fire and safety equipment, physical environment and other relevant health safety requirements. The applicant adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative, and that the construction costs will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges which is incorporated hereby as if set forth fully herein. Therefore, the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as

medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C-BMA Laurinburg
C-FMC Scotland County
NA-Scotland County Dialysis

BMA Laurinburg. In Section VI.1(a), page 55, the applicant states:

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. Fresenius Medical Care Holdings, Inc. parent company to BMA, currently operates 100 facilities in 42 North Carolina Counties (includes our affiliations with RRI facilities); in addition, BMA has seven facilities under development or pending CON approval. Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. The patient population of the BMA Laurinburg facility currently comprised of the following:

<i>Facility</i>	<i>Medicaid/Low Income</i>	<i>Elderly (65+)</i>	<i>Medicare</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>BMA Laurinburg</i>	<i>51.8%</i>	<i>41.2%</i>	<i>75.3%</i>	<i>57.6%</i>	<i>83.5%</i>

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 79.5% [75.3%] of the facility treatment reimbursement is from Medicare.

...

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

In addition, in Section VI.1(b), page 56, the applicant provides the current in-center dialysis payor mix at BMA Laurinburg, as shown in the table below.

BMA LAURINBURG PAYOR SOURCE	PERCENT OF TOTAL	
	IN-CENTER	HOME
Commercial	7.9%	26.3%
Medicare	76.6%	59.4%
Medicaid	9.3%	0.0%
VA	5.7%	14.3%

Self/Indigent	0.5%	0.0%
Total	100.0%	100.0%

FMC Scotland County. In Section VI.1(a), page 48, the applicant states:

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. Fresenius Medical Care Holdings, Inc. parent company to BMA, currently operates 100 facilities in 42 North Carolina Counties (includes our affiliations with RRI facilities); in addition, BMA has seven facilities under development or pending CON approval. Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. The patient population of the BMA Laurinburg facility currently comprised of the following:

Facility	Medicaid/Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
FMC Scotland County	38.5%	48.7%	79.5%	41.0%	69.2%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 79.5% of the facility treatment reimbursement is from Medicare.

...

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

In addition, in Section VI.1(b), page 49, the applicant provides the current in-center dialysis payor mix at FMC Scotland County, as shown in the table below.

FMC SCOTLAND COUNTY PAYOR SOURCE	PERCENT OF TOTAL
Commercial Insurance	0.50%
Medicare	93.60%
Medicaid	1.78%
VA	4.13%
Total	100.00%

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

	Total # of Medicaid Eligibles as % of Total Population As of June 2010	Total # of Medicaid Eligibles Age 21 and older as % of Total Population As of June 2010	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)

Scotland County	30.0%	12.9%	21.5%
Statewide	17.0%	6.7%	19.7%

*Source: DMA Website: <http://www.ncdhhs.gov/dma/pub/index.htm>. More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly with respect to dialysis services.

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

The United States Renal Data System, in its *2013 USRDS Annual Data Report* (page 216) provides the following national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ...”*⁶

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

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

The report states, on page 118, that the overall Medicare expenditures for chronic kidney disease for 2011 were \$45.5 billion, including Medicare Part D.

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

Number and Percent of Dialysis Patients by Age, Race and Gender 2012		
	# of ESRD Patients	% of Dialysis Population
Ages		

⁶ www.usrds.org/adr.aspx

0-19	73	0.5%
20-34	751	5.0%
35-44	1,442	9.7%
45-54	2,644	17.7%
55-64	4,013	26.9%
65+	5,995	40.2%
Gender		
Female	6,692	44.9%
Male	8,226	55.1%
Race		
African American	9,346	62.7%
White/Caucasian	5,191	34.8%
Other	380	2.6%

Source: Southeastern Kidney Council (SKC) Network 6.
Table includes North Carolina statistics only.⁷

BMA Laurinburg and FMC Scotland County demonstrate that they provide adequate access to medically underserved populations. Therefore, the applications are conforming to this criterion.

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

C– All Applications

BMA Laurinburg. In Section VI.1(f) page 58, 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 60, the applicant states “*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.*”

FMC Scotland County. In Section VI.1(f) page 51, 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 52, the applicant states “*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.*”

Scotland County Dialysis. In Section VI.1(f), page 46, the applicant states “*Scotland 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 48, the applicant states “*There have been no civil rights equal access complaints filed within the last five*

⁷ www.esrdnetwork6.org/publications/reports.html

years against any facility operated by Total Renal Care, Inc. or by any facility in North Carolina owned by DaVita HealthCare Partners 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- All Applications

BMA Laurinburg. In Section VI.1(c), page 56, the applicant provides the projected payor mix for in-center dialysis patients.

BMA LAURINBURG PAYOR SOURCE	PERCENT OF TOTAL	
	IN-CENTER	HOME
Commercial	6.0%	26.3%
Medicare	78.6%	59.4%
Medicaid	9.3%	0.0%
VA	5.7%	14.3%
Self/Indigent	0.5%	0.0%
Total	100.0%	100.0%

The applicant projects 87.9% of its in-center patients will have some or all of their care paid for by Medicare or Medicaid (78.6 percent Medicare plus 9.3 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 84.8% of North Carolina dialysis treatments in BMA facilities in FY 2012. Medicaid treatments represented an additional 4.5% of treatments in BMA facilities for FY 2012. 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 FY2012 totaled 85.9% (76.6 Medicare and 9.3 Medicaid) while for the proposed project in Scotland County the combined Medicare/Medicaid payments were 87.9%. On page 56, the applicant states:

“BMA has projected a slight decrease in the commercial payor mix at FMC [sic] Laurinburg. BMA has proposed that BMA would redirect one or two of the patients with commercial insurance to the FMC Scotland County facility. There is not any significant difference in the location of the two facilities.

FMC Scotland County is approximately 3.2 miles north of BMA Laurinburg. BMA will be working with the admissions team to re-direct one or two new dialysis patients, who reside on the north side of Laurinburg or Scotland County, with commercial insurance, to the FMC Scotland County facility. ... ”

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

FMC Scotland County. In Section VI.1(c), page 50, the applicant provides the projected payor mix for in-center dialysis patients.

Payor	In-Center Patients
Commercial Insurance	4.5%
Medicare	89.6%
Medicaid	1.8%
VA	4.1%
Total	100.0%

The applicant projects 91.4% of its in-center patients will have some or all of their care paid for by Medicare or Medicaid (89.6 percent Medicare plus 1.8 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 84.8% of North Carolina dialysis treatments in BMA facilities in FY 2012. Medicaid treatments represented an additional 4.5% of treatments in BMA facilities for FY 2012. Low income and medically underinsured persons will continue to have access to all services provided by BMA.”

The project analyst notes that FMC Scotland County’s state-wide Medicare and Medicaid payments for dialysis treatments in FY2012 totaled 95.38% (93.60 Medicare and 1.78 Medicaid) while for the proposed project in Scotland County the combined Medicare/Medicaid payments were 91.4%. On page 50, the applicant states:

“FMC Scotland County financial performance has been marginal due to the very low commercial mix at the facility. As noted above, the most recent historical review indicates that 0.5% of revenue has been from commercial insurance. BMA will be working with the admissions team to re-direct one or two new dialysis patients, who reside on the north side of Laurinburg or

Scotland County, with commercial insurance, to the FMC Scotland County facility. ...

BMA will not mandate patient admission to one facility or another. However, given the close proximity of the two facilities, it is reasonable to conclude that some patients with commercial insurance would choose FMC Scotland County.”

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

Scotland County Dialysis. In Section VI.1(a), page 44, the applicant states:

“Scotland 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.

...

Scotland 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 45, the applicant projects that that 89.6% of its patients will have some or all of their services paid for by Medicare or Medicaid (85.4 Medicare and 4.2 Medicaid), as illustrated in the following table.

**Scotland County Dialysis
Utilization by Payor Source**

PAYOR SOURCE	PERCENT UTILIZATION BY PAYOR SOURCE
Medicare	21.9%
Medicaid	4.2%
Medicare/Medicaid	30.2%
Commercial Insurance	7.3%
VA	3.1%
Medicare/Commercial	33.3%
TOTAL	100.0%

In Section VI.1(c), pages 44-45, the applicant states:

“TRC currently does not have any facilities in Scotland County from which to draw this information. Therefore we have based our payor mix on the average percentages of patients who are currently dialyzing at Dialysis Care

of Richmond County. Dialysis Care of Richmond County is a DaVita owned facility in Richmond County, which is contiguous to Scotland County. The pertinent demographics of Richmond County, while not identical to Scotland County, are similar. Moreover, there are 6 dialysis patients in Scotland County who dialyze in Richmond County at a TRC facility, who are expected to transfer to the new TRC facility in Scotland County, so it is reasonable to use the payor mix from Dialysis Care of Richmond County as a basis for the payor mix for the Scotland County facility.”

The applicant is correct that Richmond County is contiguous to Scotland County. US Census Bureau data shows substantial similarities in the economic status of the two counties. The poverty level in Scotland County is similar to Richmond County. The families living below the poverty level is 30.6% in Scotland County and 24.8% in Richmond County. The per capita income is \$16,589 in Scotland County and \$16,720 in Richmond County. Further, as of July 2009, the population of Scotland County was 36,157 and 46,639 in Richmond County. As of July 2009, the total Medicaid eligible population in Scotland County was 10,855 and was 13,035 in Richmond County. Thus it is reasonable to assume that these two contiguous counties are comparable in economic status.

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- All Applications

BMA Laurinburg. In Section VI.5, page 59, the applicant states that patients have access to dialysis services through Nephrologists who apply for and receive medical staff privileges to admit patients to the facility. Further, the applicant states:

“BMA Laurinburg has an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.

...

The Nephrologists expect to continue receiving referrals from the local physician community, home health agencies, and acute care facilities. In addition, referrals will also be received from Scotland Memorial Hospital.”

The applicant adequately demonstrates that BMA Laurinburg will provide a range of means by which a person can access the services. Therefore, the application is conforming to this criterion.

FMC Scotland County. In Section VI.5, page 52, the applicant states that patients have access to dialysis services through Nephrologists who apply for and receive medical staff privileges to admit patients to the facility. Further, the applicant states:

“FMC Scotland County has an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.

...

The Nephrologists expect to continue receiving referrals from the local physician community, home health agencies, and acute care facilities. In addition, referrals will also be received from Scotland Memorial Hospital.”

The applicant adequately demonstrates that FMC Scotland County will provide a range of means by which a person can access the services. Therefore, the application is conforming to this criterion.

Scotland County Dialysis. In Section VI.5, page 47, the applicant states:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral by a Nephrologist with privileges at Scotland County Dialysis Center. These referrals will come from primary care physicians or specialty physicians in the Scotland County and surrounding Counties or transfer referrals from other Nephrologists outside of the immediate area. Patients, families and friends may obtain access by contacting a Nephrologist with privileges at Scotland County Dialysis. Should a patient contact Scotland County Dialysis either directly or indirectly, the patient will be referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. Patients from outside Scotland County Dialysis service area requesting transfer to this facility will be processed in accordance with the facility transient policies that comprise **Exhibit 28**. The patient, again, will be referred to a qualified Nephrologist for final evaluation who then makes the referral for the admission of the patient.”* [Emphasis in original]

The applicant adequately demonstrates that it will provide a range of means by which a person can access services at Scotland County Dialysis. Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C-All Applications

BMA Laurinburg. In Section V.3(a), page 51, the applicant states “*Exhibit 19 is a letter from Kristi Roberts, Area Manager to Robeson Community College nursing program encouraging the school to include the BMA Laurinburg facility in their clinical rotations for nursing students.*” The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion.

FMC Scotland County. In Section V.3(a), page 44, the applicant states, “*Exhibit 19 is a letter from Kristi Roberts, Area Manager to Robeson Community College nursing program encouraging the school to include the FMC Scotland County facility in their clinical rotations for nursing students.*” The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion.

Scotland County Dialysis. In Section V.3(b), page 40, the applicant states, “*Scotland County Dialysis will be available to serve as a clinical rotation site for nursing and CNA students.*” Exhibit 23 contains a copy of a letter from Tim Brown, Group Facility Administrator for DaVita to Dr. W. Dale McInnis, President of Richmond Community College. The information provided in Section V.3 and referenced exhibits are reasonable and credible and support a finding of conformity with this criterion.

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

C- All Applications

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA currently operates the only two dialysis facilities located in Scotland County. BMA Laurinburg is currently certified for 26 stations and FMC Scotland County is currently certified for 12 stations, as shown in the table below.

Scotland County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/12	# In-Center Patients 12/31/2012	% Utilization	Patients Per Station
BMA Laurinburg	26	87	83.65%	3.3
FMC Scotland County	12	41	85.42%	3.4

Source: July 2013 SDR, Table A.

The 2013 SMFP and the July 2013 SDR provide a County Need Determination for new dialysis stations in Scotland County. According to Section 2(E) of the dialysis station need methodology, found on page 394 of the 2013 SMFP, *“If a county’s December 31, 2013 projected station deficit is 10 or greater and the July SDR shows that utilization of each dialysis facility in the county is 80 percent or greater, the December 31, 2013 county station need determination is the same as the December 31, 2013 projected station deficit. ...”* The July 2013 SDR Table 14B identifies the number of dialysis stations needed in Scotland County as 11. Three applications were received by the Certificate of Need Section for development of the 11 dialysis stations. The three applicants applied for a total of 16 dialysis stations. Pursuant to the need determination in the 2013 SMFP and the July 2013 SDR, 11 dialysis stations is the limit on the number of dialysis stations that may be approved in this review.

BMA Laurinburg. In Section V.7, pages 53-54, the applicant discusses how any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality and access to the proposed services. The applicant states:

“Approval of this application will not alter the competitive nature of dialysis facilities and providers serving Scotland County. Approval of this application will enhance patient access to care.

...

This facility will have added value stemming from the strength of our relationship with Dr. Iqbal and his associates. ...

...

BMA readily acknowledges that a County Need Determination, as currently exists for Scotland County, potentially introduces a competitive element into Scotland County. ...

A new provider in Scotland County will not create competitive advantages. ...

BMA strives for clinical excellence and seeks to ensure that each patient has the best care at every treatment. Quality is not an element where BMA, or Fresenius Medicare Care (parent to BMA) is prepared to compromise. ...

BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. ...

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

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

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

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

The application is conforming to this criterion.

FMC Scotland County. In Section V.7, pages 46-47, the applicant discusses how any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality and access to the proposed services. The applicant states:

“Approval of this application will not alter the competitive nature of dialysis facilities and providers serving Scotland County. Approval of this application will enhance patient access to care.

...

This facility will have added value stemming from the strength of our relationship with Dr. Iqbal and his associates. ...

...

BMA readily acknowledges that a County Need Determination, as currently exists for Scotland County, potentially introduces a competitive element into Scotland County. ...

A new provider in Scotland County will not create competitive advantages. ...

BMA strives for clinical excellence and seeks to ensure that each patient has the best care at every treatment. Quality is not an element where BMA, or Fresenius Medicare Care (parent to BMA) is prepared to compromise. ...

BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. ...

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

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

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

- ◆ The applicant adequately demonstrates the need to add two dialysis stations to FMC Scotland County and that it is a cost-effective alternative;
- ◆ The applicant adequately demonstrates that it will continue to provide quality services; and
- ◆ The applicant demonstrates that it will continue to provide adequate access to medically underserved populations.

The application is conforming to this criterion.

Scotland County Dialysis. In Section V.7, pages 42-43, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services. On page 42, the applicant states:

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

...

Both providers, TRC and BMA, must meet the same rigid standards of care established by the Centers for Medicare and Medicaid, as monitored and audited by the North Carolina Division of Health Service Regulation, Licensure and Certification Section. ...

TRC does not project any impact to cost effectiveness of either provider as a result of competition.

...

This proposal will positively impact public transportation funds. Development of a new ten-station dialysis facility by TRC in Laurinburg in Scotland County will ultimately mean less time involved in commuting to or from dialysis and a corresponding reduction in fuel costs for the Scotland County patients who are traveling out of county for their treatments.”

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

- The applicant adequately demonstrates the need to develop a new 10-station facility in Scotland County and that it is a cost-effective alternative;
- The applicant adequately demonstrates it will provide quality services; and
- The applicant demonstrates it 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.

C–BMA Laurinburg
C–FMC Scotland County
NA- Scotland County Dialysis

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

FMC Scotland County. The applicant currently provides dialysis services at the FMC Scotland County facility. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the FMC Scotland County facility operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C- All Applications

BMA Laurinburg'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.

FMC Scotland 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.

Scotland 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

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) Utilization rates;

-C- **BMA Laurinburg** - See Section II.1, page 11, which indicates the facility had an 83.65% utilization rate as of December 31, 2012.

-C- **FMC Scotland County** - See Section II.1, page 11, which indicates the facility had an 85.42% utilization rate as of December 31, 2012.

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

.2202(a)(2) Mortality rates;

-C- **BMA Laurinburg** - In Section IV.2, page 47, the applicant reports 2010, 2011 and 2012 facility mortality rates of 18.3%, 9.5% and 18.4%, respectively.

-C- **FMC Scotland County** - In Section IV.2, page 40, the applicant reports 2010, 2011 and 2012 facility mortality rates of 16.5%, 2.2% and 9.2%, respectively.

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

.2202(a)(3) The number of patients that are home trained and the number of patients on Home dialysis;

-C- **BMA Laurinburg** - In Section IV.3, page 47, the applicant states that BMA Laurinburg had 10 home-trained patients in 2013.

-C- **FMC Scotland County** - In Section IV.3, page 40, the applicant states that FMC Scotland County is not certified to provide home training and support services. Patients who are candidates for home training are referred to BMA Laurinburg.

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

.2202(a)(4) The number of transplants performed or referred;

-C- **BMA Laurinburg** - In Section IV.4, page 47, the applicant states BMA Laurinburg referred 12 patients for transplant evaluation in 2012. BMA Laurinburg had no patient to receive a transplant in 2012.

-C- **FMC Scotland County** - In Section IV.4, page 40, the applicant states FMC Scotland County referred three patients for transplant evaluation in 2012. FMC Scotland County had one patient to receive a transplant in 2012.

- NA- **Scotland County Dialysis** - The applicant proposes a new facility.
.2202(a)(5) *The number of patients currently on the transplant waiting list;*
- C- **BMA Laurinburg** - In Section IV.5, page 47, the applicant states that BMA Laurinburg has four patients on the transplant waiting list.
- C- **FMC Scotland County** - In Section IV.5, page 40, the applicant states that FMC Scotland County has three patients on the transplant waiting list.
- NA- **Scotland County Dialysis** - The applicant proposes a new facility.
.2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- **BMA Laurinburg** - See Section IV.6, page 47, the applicant reports a total of 203 hospital admissions in 2012; 141 were non-dialysis related and 62 were dialysis-related.
- C- **FMC Scotland County** - See Section IV.6, page 40, the applicant reports a total of 168 hospital admissions in 2012; 120 were non-dialysis related and 48 were dialysis-related.
- NA- **Scotland County Dialysis** - The applicant proposes a new facility.
.2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*
- C- **BMA Laurinburg** - In Section IV.7, page 48, the applicant reports that in 2012 there were no patients with an infectious disease, and no patients converted to infectious status in 2012.
- C- **FMC Scotland County** - In Section IV.7, page 41, the applicant reports that in 2012 there were no patients with an infectious disease, and no patients converted to infectious status in 2012.
- NA- **Scotland County Dialysis** - The applicant proposes a new facility.
(b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*
- .2202(b)(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100*
- NA- **BMA Laurinburg** - BMA Laurinburg is an existing facility.
- NA- **FMC Scotland County** - FMC Scotland County is an existing facility.
- C- **Scotland County Dialysis** - Exhibit 7 contains a signed letter of intent from Scotland Health Care System agreeing to enter into a Patient Transfer Agreement with Scotland County Dialysis and to provide the following services to patients receiving their dialysis treatments at Albemarle Dialysis:
- Acute Dialysis
 - Emergency Room Care
 - Diagnostic Evaluation Services
 - X-ray Services
 - Special, Immunological and Routine Laboratory Services

- Blood Banking Services
- Surgical Services including Vascular Surgery

.2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

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

-NA- **BMA Laurinburg** - BMA Laurinburg is an existing facility
-NA- **FMC Scotland County** - FMC Scotland County is an existing facility
-C- **Scotland County Dialysis** - Exhibit 8 contains a letter from Carolina Medical Center agreeing to enter into a Transplant Agreement for Scotland County Dialysis including the components identified above.

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

-NA- **BMA Laurinburg** - BMA Laurinburg is an existing facility
-NA- **FMC Scotland County** - FMC Scotland County is an existing facility
-C- **Scotland County Dialysis** - Exhibit 9 provides site specific documentation of the availability of power and Exhibit 37 provides site specific documentation of the availability water from the City of Laurinburg.

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

-NA- **BMA Laurinburg** - BMA Laurinburg is an existing facility
-NA- **FMC Scotland County** - FMC Scotland County is an existing facility
-C- **Scotland County Dialysis** - See Exhibit 9, in which the applicant provides copies of written policies and procedures for back up for electrical service in the event of a power outage.

.2202(b)(5) *For new facilities, the location of the site on which the services are to be operated.*

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

-NA- **BMA Laurinburg** - BMA Laurinburg is an existing facility
-NA- **FMC Scotland County** - FMC Scotland County is an existing facility
-C- **Scotland County Dialysis** - The applicant provides written documentation of

availability and commitment to pursue acquiring the proposed primary and/or secondary site in Section XI, Questions 1-3, pages 66-68 and Exhibits 36-38.

.2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- **BMA Laurinburg** - See Sections II.1, page 13; VII.2, page 62 and XI.6(g), page 82.

-C- **FMC Scotland County** - See Sections II.1, page 13; VII.2, page 55 and XI.6(g), page 75.

-C- **Scotland County Dialysis** - See Sections II.1, page 12; VII.2, page 50 and XI.6(g), page 70.

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

-C- **BMA Laurinburg** - The applicant provides the following projected patient origin on pages 16 and 22 of the application, as shown below.

BMA Laurinburg -Projected Patient Origin

COUNTY	YEAR ONE: 2015			YEAR TWO: 2016			COUNTY PATIENTS AS A PERCENT OF TOTAL	
	In-Center	PD	Home Hemo	In-Center	PD	Home Hemo	Year 1	Year 2
Scotland	71.2	4.8	1.0	75.0	4.1	2.1	73.1%	73.8%
Robeson	18.4	1.0	0.0	18.8	1.0	0.0	18.4%	18.0%
Richmond	1.0	0.0	0.0	1.0	0.0	0.0	0.9%	0.9%
Marlboro, SC	8.0	0.0	0.0	8.0	0.0	0.0	7.6%	7.3%
TOTAL	98.6	5.8	1.0	102.8	5.1	2.1	100.0%	100.0%

See Section II.1 pages 13-16 and Section III.7, pages 40–44 of the application and the discussion in Criterion (3) with regard to the methodology and assumptions the applicant uses to project patient origin which is incorporated hereby as if set forth

-C- **FMC Scotland County** - The applicant provides the following projected patient origin on pages 15 and 36 of the application, as shown below.

FMC Scotland County -Projected Patient Origin

COUNTY	YEAR ONE: 2015	YEAR TWO: 2016	COUNTY PATIENTS AS A PERCENT OF TOTAL	
	In-Center	In-Center	Year 1	Year 2
Scotland	47.9	50.4	100.0%	100.0%
TOTAL	47.9	50.4	100.0%	100.0%

See Section II.1 pages 13-15 and Section III.7, pages 35–37 of the application and the discussion in Criterion (3) with regard to the methodology and assumptions the applicant uses to project patient origin which is incorporated hereby as if set forth

-C- **Scotland County Dialysis** - The applicant provides the following projected patient origin on page 29 of the application, as shown below.

Scotland County Dialysis -Projected Patient Origin

COUNTY	YEAR ONE: 2015/2016		YEAR TWO: 2016/2017		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	In-center patients	Home dialysis patients	In-center patients	Home dialysis patients	Year 1	Year 2
Scotland	31	1	34	1	94.1%	94.6%
Robeson	2	0	2	0	5.9%	5.4%
TOTAL	33	1	36	1	100.0%	100.0%

See Section III.7, pages 29–33 of the application and the discussion in Criterion (3) with regard to the methodology and assumptions the applicant uses to project patient origin which is incorporated hereby as if set forth fully herein.

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

 - NA- **BMA Laurinburg** - BMA Laurinburg is an existing facility
 - NA- **FMC Scotland County** - FMC Scotland County is an existing facility
 - C- **Scotland County Dialysis** - In Section III.8, page 33, the applicant states, “All patients are projected to live within 30 miles of the proposed Scotland County Dialysis.” See Exhibit 16 for a map indicating a 30-mile radius from the proposed site of the facility.

- .2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*

 - C- **BMA Laurinburg** - In Section II.1, page 17, the applicant states, “BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”
 - C- **FMC Scotland County** - In Section II.1, page 15, the applicant states, “BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”
 - C- **Scotland County Dialysis** - In Section II.1, page 16, the applicant states, “Total Rena Care, Inc. d/b/a Scotland County Dialysis will admit and provide dialysis services to patients who have no insurance or other source of payment if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a*

need in the State Medical Facilities Plan that is based on an adjusted need determination.

- NA- **BMA Laurinburg** - BMA Laurinburg is an existing facility
- NA- **FMC Scotland County** - FMC Scotland County is an existing facility
- C- **Scotland County Dialysis** - In Section II.1, page 19, the applicant states, “Based on these calculations, on September 1, 2015, the projected certification date for the project, TRC is projecting that it will have 28 Scotland County in-center patients and 2 Robeson County in-center patients for a total of 30 in-center patients.” The applicant then projects the Scotland County in-patient census forward by one year using the Scotland County Five Year Annual Change Rate (10.9%) as published in the July 2013 SDR. This results in an ending Scotland County in-patient census of 31 patients $[(28 \times 1.109 = 31.052 \text{ or } 31) + 2 \text{ (Robeson County in-center patients)} = 33 \text{ in-center patients}]$. Therefore, the applicant is projected to have patients 3.3 $[33 / 10 = 3.3]$ per station per week as of the end of the first operating year of Scotland County Dialysis. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein.
- .2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- **BMA Laurinburg** - In Sections II.1, page 18 and III.7, page 44, the applicant projects to serve 98 in-center patients by the end of Operating Year 1, which is 3.27 patients per station $(98 / 30 = 3.34)$. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.
- C- **FMC Scotland County** - In Sections II.1, page 16 and III.7, page 36, the applicant projects to serve 47 in-center patients by the end of Operating Year 1, which is 3.36 patients per station $(47 / 14 = 3.36)$. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.
- NA- **Scotland County Dialysis** - The applicant proposes a new facility.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- **BMA Laurinburg** - In Section II.1, pages 13-16 and Section III.7, pages 40-44, the applicant provides the assumptions and methodology used to project utilization of the proposed facility. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.
- C- **FMC Scotland County** - In Section II.1, pages 13-15 and Section III.7, pages 35-37, the applicant provides the assumptions and methodology used to project utilization of the proposed facility. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.
- C- **Scotland County Dialysis** - In Section II.1, pages 12-16 and Section III.7, pages 29-33, the applicant provides the assumptions and methodology used to project utilization of the proposed facility. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

- .2204(1) *Diagnostic and evaluation services;*
- C- **BMA Laurinburg** - In Section II.1, page 23, Section V.1, page 49 and referenced Exhibits, the applicant states that these services are provided by Scotland Memorial Hospital.
 - C- **FMC Scotland County** - In Section II.1, page V.1, page 42 and referenced Exhibits, the applicant states that these services are provided by Scotland Memorial Hospital.
 - C- **Scotland County Dialysis** - In Section II.1, page 22, Section V.1 page 49 and referenced Exhibits, the applicant states that these services will be provided by Scotland Memorial Hospital.
- .2204(2) *Maintenance dialysis;*
- C- **BMA Laurinburg** - In Section II.1, page 23, Section V.1, page 49 and referenced Exhibits, the applicant states that these services are provided by BMA Laurinburg.
 - C- **FMC Scotland County** - In Section II.1, page 18, Section V.1, page 42 and referenced Exhibits, the applicant states that these services are provided by FMC Scotland County.
 - C- **Scotland County Dialysis** - In Section II.1, page 22, Section V.1, page 38 and referenced Exhibits, the applicant states that these services will be provided by Scotland County Dialysis.
- .2204(3) *Accessible self-care training;*
- C- **BMA Laurinburg** - In Section II.1, page 23, Section V.1, page 49 and referenced Exhibits, the applicant states that these services are provided by BMA Laurinburg.
 - C- **FMC Scotland County** - In Section II.1, page 19, Section V.1, page 42 and referenced Exhibits, the applicant states that these services are provided by BMA Laurinburg.
 - C- **Scotland County Dialysis** - In Section II.1, page 22, Section V.1, page 38 and referenced Exhibits, the applicant states that Scotland County Dialysis will provide maintenance dialysis for all ESRD patients who are admitted to the facility and require maintenance dialysis.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
- C- **BMA Laurinburg** - In Section II.1, page 23 and Section V.1, page 49 and referenced Exhibits, the applicant states that these services are provided by BMA Laurinburg home training department.
 - C- **FMC Scotland County** - In Section II.1, page 19 and Section V.1, page 42 and referenced Exhibits, the applicant states that these services are provided by BMA Laurinburg home training department.
 - C- **Scotland County Dialysis** - In Section II.1, page 22, Section V.1, page 38 and referenced Exhibits, the applicant states that it will provide PD home training and that it will contract with Dialysis Care of Moore County for the provision of home hemodialysis training and support.
- .2204(5) *X-ray services;*
- C- **BMA Laurinburg** - In Section II.1, page 23, Section V.1, page 49 and referenced Exhibits, the applicant states that these services are provided by Scotland

Memorial Hospital.

- C- **FMC Scotland County** - In Section II.1, page 19, Section V.1, page 42 and referenced Exhibits, the applicant states that these services are provided by Scotland Memorial Hospital.
- C- **Scotland County Dialysis** - In Section II.1, page 23, Section V.1, page 38 and referenced Exhibits, the applicant states that these services will be provided by Scotland Memorial Hospital.
- .2204(6) *Laboratory services;*
- C- **BMA Laurinburg** - In Section II.1, page 23, Section V.1, page 49 and referenced Exhibits, the applicant states that BMA provides on site laboratory services through contract with Spectra Labs.
- C- **FMC Scotland County** - In Section II.1, page 19, Section V.1, page 42 and referenced Exhibits, the applicant states that BMA provides on site laboratory services through contract with Spectra Labs.
- C- **Scotland County Dialysis** - In Section II.1, page 23, Section V.1, page 38 and referenced Exhibits, the applicant includes a copy of an agreement with DaVita Laboratory Services, Inc. and DVA Laboratory Services, Inc. for the provision of laboratory services to DaVita affiliated facilities.
- .2204(7) *Blood bank services;*
- C- **BMA Laurinburg** - In Section II.1, page 23, Section V.1, page 49 and referenced Exhibits, the applicant states that these services are provided by Scotland Memorial Hospital.
- C- **FMC Scotland County** - In Section II.1, page 19, Section V.1, page 42 and referenced Exhibits, the applicant states that these services are provided by Scotland Memorial Hospital.
- C- **Scotland County Dialysis** - In Section II.1, page 23, Section V.1, page 38 and referenced Exhibits, the applicant states that these services will be provided by Scotland Memorial Hospital.
- .2204(8) *Emergency care;*
- C- **BMA Laurinburg** - In Section II.1, page 23, Section V.1, page 49 and referenced Exhibits, the applicant states that these services are provided by Scotland Memorial Hospital.
- C- **FMC Scotland County** - In Section II.1, page 19, Section V.1, page 42 and referenced Exhibits, the applicant states that these services are provided by Scotland Memorial Hospital.
- C- **Scotland County Dialysis** - In Section II.1, page 23, Section V.1, page 38 and referenced Exhibits, the applicant states that these services will be provided by Scotland Memorial Hospital.
- .2204(9) *Acute dialysis in an acute care setting;*
- C- **BMA Laurinburg** - In Section II.1, page 23, Section V.1, page 49 and referenced Exhibits, the applicant states that these services are provided by Scotland Memorial Hospital.
- C- **FMC Scotland County** - In Section II.1, page 19, Section V.1, page 42 and referenced Exhibits, the applicant states that these services are provided by Scotland Memorial Hospital.
- C- **Scotland County Dialysis** - In Section II.1, page 23, Section V.1, page 38 and referenced Exhibits, the applicant states that these services will be provided by

Scotland Memorial Hospital.

.2204(10)

Vascular surgery for dialysis treatment patients

-C-

BMA Laurinburg - In Section II.1, page 23, Section V.1, page 49 and referenced Exhibits, the applicant states that these services are provided by Scotland Memorial Hospital.

-C-

FMC Scotland County - In Section II.1, page 19, Section V.1, page 42 and referenced Exhibits, the applicant states that these services are provided by Scotland Memorial Hospital.

-C-

Scotland County Dialysis - In Section II.1, page 23, Section V.1, page 38 and referenced Exhibits, the applicant states that these services will be provided by Scotland Memorial Hospital.

.2204(11)

Transplantation services;

-C-

BMA Laurinburg - In Section II.1, page 24, Section V.1, page 49 and referenced Exhibits, the applicant states that these services are provided by UNC Healthcare.

-C-

FMC Scotland County - In Section II.1, page 19, Section V.1, page 42 and referenced Exhibits, the applicant states that these services are provided by Duke University Medical Center.

-C-

Scotland County Dialysis - In Section II.1, page 23, Section V.1, page 38 and referenced Exhibits, the applicant states that these services will be provided by Carolinas Medical Center

.2204(12)

Vocational rehabilitation counseling and services; and,

-C-

BMA Laurinburg - In Section II.1, page 24 and Section V.1, page 49, the applicant states that these services are provided by Scotland County Department of Social Services.

-C-

FMC Scotland County - In Section II.1, page 20 and Section V.1, page, the applicant states that these services are provided by Scotland County Department of Social Services.

-C-

Scotland County Dialysis - In Section II.1, page 23, Section V.1, page 38 and referenced Exhibits, the applicant states that these services will be provided by Scotland County Department of Social Services.

.2204(13)

Transportation

-C-

BMA Laurinburg - In Section II.1, page 24 and Section V.1, page 49, the applicant states that these services are provided by Scotland County Transportation Services through Scotland County Social Services.

-C-

FMC Scotland County - In Section II.1, page 20 and Section V.1, page 42, the applicant states that these services are provided by Scotland County Transportation Services through Scotland County Social Services.

-C-

Scotland County Dialysis - In Section II.1, page 23, Section V.1, page 38 and referenced Exhibits, the applicant states that these services will be provided by Scotland County Area Transit System.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

.2205(a)

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

-C-

BMA Laurinburg - In Section VII.1, page 61, the applicant provides the proposed staffing. In Section VII.2, page 62, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section

- 494 (formerly 405.2100). The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion which is incorporated hereby as if set forth fully herein.
- C- **FMC Scotland County** - In Section VII.1, page 54, the applicant provides the proposed staffing. In Section VII.2, page 55, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 494 (formerly 405.2100). The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion which is incorporated hereby as if set forth fully herein.
- C- **Scotland County Dialysis** - In Section VII.1, page 50, the applicant provides the proposed staffing. In Section VII.2, page 51, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 494 (formerly 405.2100). The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion which is incorporated hereby as if set forth fully herein.
- .2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
- C- **BMA Laurinburg** - In Section VII.5, page 62, the applicant refers to Exhibit 14 for a copy of FMC's Training Program Outline and Agreements. Exhibit 15 contains FMC's Continuing Education Outline.
- C- **FMC Scotland County** - In Section VII.5, page 62, the applicant refers to Exhibit 14 for a copy of FMC's Training Program Outline and Agreements. Exhibit 15 contains FMC's Continuing Education Outline.
- C- **Scotland County Dialysis** - In Section VII.5, page 52, the applicant refers to Exhibit 31 for a copy of DaVita's Training Program Description/Outline.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2013 State Medical Facilities Plan (2013 SMFP) and the July 2013 Semiannual Dialysis Report (July 2013 SDR) a Dialysis Station Need Determination is provided for Scotland County. According to Section 2(E) of the dialysis station need methodology, found on page 394 of the 2013 SMFP, *“If a county’s December 31, 2013 projected station deficit is 10 or greater and the July SDR shows that utilization of each dialysis facility in the county is 80 percent or greater, the December 31, 2013 county station need determination is the same as the December 31, 2013 projected station deficit.”* The July 2013 SDR *Table B: ESRD Dialysis Station Need Determination by Planning Area* identifies the number of dialysis stations needed in Scotland County as 11. The three applicants applied for a total of 16 dialysis stations. Pursuant to the need determination in the 2013 SMFP and the July 2013 SDR, 11 dialysis stations is the limit on the number of dialysis stations that may be approved in this review. The analyst considered all of the information in each application and reviewed each application individually against all applicable review criteria and the analyst conducted a comparative analysis of the proposals. Based on that review and for the reasons set forth below and in the rest of the findings, the application submitted by BMA Laurinburg, Project I.D. # N-10178-13 and FMC Scotland County, Project I.D. # N-10189-13 are approved and the application submitted by Scotland County Dialysis, Project I.D. # N-10201-13, is denied.

SMFP Principles

Basic Principle 2 regarding the projection of Need for Additional Dialysis Stations as outlined in Chapter 14, page 376 of the 2013 SMFP states:

“New facilities must have a projected need for at least 10 stations (or 32 patients at 3.2 patients per station) to be cost effective and to assure quality of care.”

See also 10A NCAC 14C .2203(a).

BMA Laurinburg and FMC Scotland County. BMA Laurinburg and FMC Scotland are existing dialysis care facilities; therefore, Basic Principle 2 is not applicable to the review of the applications.

Scotland County Dialysis. Scotland County Dialysis proposes to develop a new 10-station dialysis facility in Scotland County pursuant to a county need determination in the 2013 SMFP and the July 2013 SDR. Basic Principle 2 regarding the projection of Need for Additional Dialysis Stations outlined in Chapter 14 of the 2013 SMFP is applicable to the review of the Scotland County Dialysis application. Scotland County Dialysis proposes at

least 10 stations in its application. However, approval of only a portion of Scotland County Dialysis' application (less than 10 stations) would not be consistent with Basic Principle 2 or the Performance Standards for dialysis facilities, as promulgated in 10A NCAC 14C .2203(a).

Basic Principle 12 regarding the Availability of Dialysis Care as contained in Chapter 14, page 378 of the 2013 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.”*

Home Training

BMA Laurinburg. In Section II.2, page 32, 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 Laurinburg. The patient will be trained in either peritoneal dialysis (CAPD or CCPD) or Hemo-dialysis.”* In Section V.2, pages 50-51, the applicant also states, *“Patients who desire to perform home dialysis are trained and followed by the BMA Laurinburg Home Training department. Patients who are candidates for home dialysis are referred by their attending nephrologists to BMA Laurinburg Home Training. The applicant will provide back-up hemo-dialysis treatments to any home patient in need of temporary hemo-dialysis. Services offered to home patients include home visitation, assistance with problems that patients have with catheters; diagnosis of infections and assistance with placing orders of needed supplies. Social work and dietary assessments are provided for those patients on an ongoing basis. Patients are given EPO at the facility or taught to administer it to themselves at home. Laboratory testing of blood samples may be provided by the facility as prescribed by the physician.”*

FMC Scotland County. In Section II.2, page 27, 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 Laurinburg. The patient will be trained in either peritoneal dialysis (CAPD or CCPD) or Hemo-dialysis.”* In Section V.2, pages 43-44, the applicant also states, *“Patients who desire to perform home dialysis are trained and followed by the BMA Laurinburg Home Training department. Patients who are candidates for home dialysis are referred by their attending nephrologists to BMA Laurinburg Home Training. The applicant will provide back-up hemo-dialysis treatments to any home patient in need of temporary hemo-dialysis. Services offered to home patients include home visitation, assistance with problems that patients have with catheters; diagnosis of infections and assistance with placing orders of needed supplies. Social work and dietary assessments are provided for those patients on an ongoing basis. Patients are*

given EPO at the facility or taught to administer it to themselves at home. Laboratory testing of blood samples may be provided by the facility as prescribed by the physician.”

Scotland County Dialysis. In Section II.1, page 25, the applicant states *“The facility will provide peritoneal dialysis training and support modality. This support for all modalities provided by the facility will include social services, dietary services, patient education, emergency care, diagnostic services and transplant evaluation. Scotland County Dialysis will not provide home training in hemo-dialysis. To include the home hemodialysis modality in this certificate of need application would tie up an in-center dialysis station[s] based on the current Certificate of Need Section rules. This means that the station would not be available for in-center patients, even if the station was not being utilized by a home hemodialysis patient receiving their training. ...Dialysis of Moore County facility will need to enter into an agreement with Scotland County Dialysis for the provision of home hemodialysis training and follow-up once the certificate of need has been awarded and the project is under development.”* In Section V.2 (d), page 39, the applicant states *“Scotland County Dialysis will provide home training in peritoneal dialysis services and follow-up. ... Dialysis of Moore County will provide the same accessible follow-up program for patients on home hemodialysis.”* Dialysis of Moore County is approximately 33 miles or almost 30-minutes one way from Laurinburg.

With respect to home training, **BMA Laurinburg** is the most effective alternative because it proposes to offer both home training for hemodialysis and peritoneal dialysis, including follow-up. **FMC Scotland County** is the second most effective alternative because it proposes to refer home training for hemodialysis and peritoneal dialysis, including follow-up to another BMA facility located within Scotland County (BMA Laurinburg). Scotland County Dialysis only proposes home training for peritoneal dialysis. Scotland County Dialysis patients who qualify for and desire home hemodialysis training and follow-up would have to travel to Pinehurst (Dialysis Care of Moore County), approximately 33-miles one way from the Scotland County Dialysis facility. Therefore, **Scotland County Dialysis** is the least effective alternative with respect to home training.

Hours of Availability

BMA Laurinburg – In Section VII.10, page 64, the applicant states dialysis services will be available from 6:00 AM to 5:00 PM, Monday through Saturday, for a total of 11-hours. BMA Laurinburg does not propose a third shift.

FMC Scotland County – In Section VII.10, page 57, the applicant states dialysis services will be available from 6:00 AM to 5:00 PM, Monday through Saturday, for a total of 11-hours. FMC Scotland County does not propose a third shift.

Scotland County Dialysis – In Section VII.10, page 52, the applicant states dialysis services will be available from 6:00 AM to 4:00 PM, Monday through Saturday, a total of 10-hours. Scotland County Dialysis does not propose a third shift.

All the applicants propose to offer both a first and second shift, and are scheduled to be open six days a week. None of the applicants propose a third shift. With regard to hours of availability, all applications are equally effective alternatives.

Services in rural, remote areas

Scotland County is a rural, remote area. All applications are equally effective with regard to providing services in rural, remote areas.

Facility Location

All applicants propose locations in Laurinburg, Scotland County. BMA Laurinburg and FMC Scotland County are existing facilities located approximately 4 miles apart. According to Google Maps, the location of the proposed Scotland County Dialysis facility is only 1.3 miles from the BMA Laurinburg facility and 4.7 miles from the FMC Scotland County facility. In regards to facility location, both the primary and secondary sites identified by Scotland County Dialysis are adequate for the proposed facility. With regard to location, all the applications are equally effective alternatives.

Access by Underserved Groups

BMA Laurinburg– In Section VI.1, page 56, the applicant states that 87.9% of its in-center patients will have some or all of their services covered by Medicare or Medicaid (78.6% Medicare and 9.3% Medicaid). In Section VI.1(a), page 55, the applicant states “... *Medicare represented 84.8% of North Carolina dialysis treatments in BMA facilities in FY 2012. Medicaid treatments represented an additional 4.5% of treatments in BMA facilities for FY 2012 ...*”

FMC Scotland County– In Section VI.1, page 50, the applicant states that 91.4% of its in-center patients will have some or all of their services covered by Medicare or Medicaid (89.6% Medicare and 1.8% Medicaid). In Section VI.1(a), page 48, the applicant states “... *Medicare represented 84.8% of North Carolina dialysis treatments in BMA facilities in FY 2012. Medicaid treatments represented an additional 4.5% of treatments in BMA facilities for FY 2012 ...*”

Scotland County Dialysis – In Section VI.1, page 45, the applicant states that 89.6% of its in-center patients will have some or all of their services covered by Medicare or Medicaid (21.9% Medicare, 4.2% Medicaid, 30.2% Medicare/Medicaid and 33.3% Medicare/Commercial). In Section VI.1(c), page 44, the applicant states:

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

Generally, the application proposing the highest Medicaid/Medicare percentage is the most effective alternative with regard to this comparative factor. FMC Scotland County has the highest projected Medicare/Medicaid payor mix (91.4%) based on BMA Medicare/Medicaid payor mix statewide averages. Therefore, **FMC Scotland County** is the most effective alternative with regard to access by underserved groups. Scotland County Dialysis has the second highest projected Medicare/Medicaid payor mix (89.6%) based on patients currently dialyzing at Dialysis Care of Richmond County, a DaVita owned facility in Richmond County, which is contiguous to Scotland County. The demographics of Richmond County, while not identical to Scotland County, are similar. Therefore, **Scotland County Dialysis** is the second most effective alternative with regard to access by underserved groups.

Access to Ancillary and Support Services

BMA Laurinburg - In Section V.1-2, pages 49-51, the applicant lists the providers of the necessary ancillary and support services. In Exhibits 16-19 and 21, the applicant documents how the project will be coordinated with the existing health care system. On page 52, the applicant states:

“BMA and the BMA Laurinburg facility has [sic] been serving the needs of dialysis patients for many years. These years of service have resulted in forged relationships between BMA Laurinburg and other healthcare providers and social services. It is expected that these relationships will continue into the future.”

FMC Scotland County - In Section V.1-2, pages 42-44, the applicant lists the providers of the necessary ancillary and support services. In Exhibits 16-19 and 21, the applicant documents how the project will be coordinated with the existing health care system. On page 45, the applicant states:

“BMA and the FMC Scotland County facility has [sic] been serving the needs of dialysis patients for many years. These years of service have resulted in forged relationships between FMC Scotland County and other healthcare providers and social services. It is expected that these relationships will continue into the future.”

Scotland County Dialysis - In Section V.1-2, pages 38 and 39, the applicant lists the providers of the necessary ancillary and support services. In Exhibits 7 and 8, 17-20, and 24 and 25, the applicant documents how the project will be coordinated with the existing health care system. On page 41, the applicant states:

“Tim Brown, Group Facility Administrator has met with or spoke to the following individuals representing healthcare and social service providers about plans for the proposal to develop a ten-station dialysis facility in Scotland County:

- *Jonathan Nestor – Nephrologist*
- *Robby Hall – Director of Scotland County Department of Social Services*
- *Roylin Hammond, Director of Scotland County Emergency Services and Scotland County Area Transit System*

- *Margaret Dickerson, Executive Director of Scottish Pines Rehabilitation and Nursing Center*
- *Paula Love, Program Director of Scotland Wound Healing Center*
- *Scotland Memorial Hospital*
- *Division of Vocational Rehabilitation”*

With regard to access to ancillary and support services, all the applications are equally effective alternatives.

Service to Scotland County Residents

BMA Laurinburg and FMC Scotland County currently serve 128 in-center dialysis patients who are Scotland County residents (87 BMA Laurinburg and 41 FMC Scotland County). The nephrologist currently serving these patients will continue to do so.

Currently, 17 of the 140 in-center dialysis patients (148 total dialysis patients – 8 home patients = 140 in-center patients) who reside in Scotland County receive dialysis treatment at a DaVita owned facility located outside Scotland County according to patient letters of support included in Exhibit 12 of the Scotland County Dialysis application, as shown in the table below.

Facility	# of In-Center Patients	Patient County Residence
Dialysis Care of Richmond County	7	Scotland
Dialysis Care of Hoke County	7	Scotland
McColl Dialysis Center	2	Scotland
Southern Pines Dialysis Center	1	Scotland
Total	17	

In Exhibit 25, Scotland County Dialysis provides a signed letter from Dr. Jonathan Nestor, confirming interest and willingness to serve as the Medical Director for the proposed Scotland County Dialysis facility. In Section V.4, page 40, the applicant states, “*Scotland County Dialysis will serve as a referral source for attending physicians with ESRD patients who require in-center dialysis treatments. Dr. Jonathan Nestor, who has been in practice since 1988, receives referrals from several of the primary care physicians.*” Exhibit 24 contains physician letters of support stating the existence of a working relationship with Dr. Nestor and their frequent referral of dialysis patients to his practice.

With regard to service to Scotland County residents, all the applications are equally effective alternatives.

Access to Alternative Providers

Fresenius Medical Care Holdings, Inc. (“Fresenius”), the ultimate parent company of BMA Laurinburg and FMC Scotland County operates the only two dialysis facilities in Scotland County. Therefore, with regard to providing dialysis patients access to an alternative provider, the proposal submitted by Scotland Dialysis is the more effective alternative.

Revenues and Operating Costs

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

Average Net Revenue Per Treatment

BMA LAURINBURG	YEAR ONE	YEAR TWO
Projected Net Revenue	\$4,649,541	\$4,908,008
# In-Center/Home Treatments	14,867	15,594
Average Net Revenue per Treatment	\$312.74	\$314.74

FMC SCOTLAND COUNTY	YEAR ONE	YEAR TWO
Projected Net Revenue	\$1,858,494	\$1,982,029
# In-Center Treatments	6,710	7,147
Average Net Revenue per Treatment	\$276.97	\$277.32

SCOTLAND COUNTY DIALYSIS	YEAR ONE	YEAR TWO
Projected Net Revenue	\$1,503,583	\$1,641,098
# In-Center/PD Treatments	4,817	5,260
Average Net Revenue per Treatment	\$312.14	\$312.00

FMC Scotland County projects the lowest average net revenue per treatment. With regard to average net revenue per treatment, **FMC Scotland County** is the most effective alternative.

Average Operating Cost Per Treatment

BMA LAURINBURG	YEAR ONE	YEAR TWO
Projected Operating Costs	\$3,800,646	\$3,979,822
#In-Center/Home Treatments	14,867	15,594
Average Operating Cost per Treatment	\$255.64	\$255.21

FMC SCOTLAND COUNTY	YEAR ONE	YEAR TWO
Projected Operating Costs	\$1,713,230	\$1,805,045
# In-Center Treatments	6,710	7,147
Average Operating Cost per Treatment	\$255.32	\$252.56

SCOTLAND COUNTY DIALYSIS	YEAR ONE	YEAR TWO
Projected Operating Costs	\$1,477,387	\$1,570,835
# In-Center/PD Treatments	4,817	5,260
Average Operating Cost per Treatment	\$306.70	\$298.64

FMC Scotland County projects the lowest average operating cost per treatment. With regard to average operating cost per treatment, **FMC Scotland County** is the most effective alternative.

Staffing

Direct Care Staff Salaries

The following table illustrates projected annual salaries during Year Two for direct care staff (registered nurses and technicians) as reported in Section VII.1 of the respective applications.

POSITION	BMA LAURINBURG	FMC SCOTLAND COUNTY	SCOTLAND COUNTY DIALYSIS
Registered Nurse	\$49,275	\$49,275	\$67,980
Home Training Nurse	\$57,845	N/A	\$67,980
Technicians	\$26,780	\$26,780	\$25,750

Scotland County Dialysis projects the higher annual salary for registered nurses and BMA Laurinburg and FMC Scotland County project the highest annual salary for technicians.

Availability of Staff and Medical Director

All applicants projected sufficient shifts and a sufficient number of direct care staff for the projected number of patients to be served in Year Two. Each has budgeted sufficient staff salaries. See discussion in Criterion (7).

BMA Laurinburg and FMC Scotland County have identified Muhammad Iqbal, MD as its medical director. Dr. Iqbal is currently the medical director for both facilities and has agreed to continue serving as the medical director for both facilities. The office of Dr. Iqbal is located on South King Street in Laurinburg. According to a search on Google Maps, Dr. Iqbal’s office is located approximately 3 miles from the BMA Laurinburg facility and approximately 1.5 miles from the FMC Scotland County facility.

Scotland County Dialysis has identified Jonathan Nestor, MD as its proposed medical director. The office of Dr. Jonathan Nestor, who has agreed to be the Medical Director of Scotland County Dialysis, is located in Laurinburg. Dr. Nestor’s office is located on the same street as the proposed location of the Scotland County Dialysis facility.

The three applications are comparable with regard to the availability of staff and medical director.

SUMMARY

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

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

- Hours of Availability
- Services in Rural, Remote Areas

- Facility Location
- Access to Ancillary and Support Services
- Service to Scotland County Residents
- Availability of Staff and Medical Director

For each of the comparative analysis factors listed below, the application submitted by FMC Scotland County was determined to be the most effective alternative.

- Access by Underserved Groups
- Average Net Revenue per Treatment
- Average Operating Cost per Treatment
- Highest Technician Salary

For each of the comparative analysis factors listed below, the application submitted by BMA Laurinburg was determined to be the more effective alternative.

- Home Training
- Highest Technician Salary

Approval of the Scotland County Dialysis application would result in the approval of dialysis stations in excess of the Scotland County need determination in the 2013 SMFP and the July 2013 SDR (11 available stations – 2 stations approved for FMC Scotland County, the most effective alternative in this review = 9 stations available).

Approval of only a portion of Scotland County Dialysis' application (less than 10 stations) would not be consistent with the Performance Standards for dialysis facilities, as promulgated in 10A NCAC 14C .2203(a), which requires an applicant to document the need for at least 10 stations.

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 FMC Scotland County is the most effective alternative proposed in this review for 11 dialysis stations in Scotland County and that application is approved as conditioned below (11 available stations – 2 stations approved for FMC Scotland County, the most effective alternative in this review = 9 stations available). The approval of the Scotland County Dialysis application would result in the approval of dialysis stations in Scotland County in excess of the county need determination in the 2013 SMFP and July 2013 SDR. Approval of only a portion of Scotland County Dialysis' application (less than 10 stations) would not be consistent with the Performance Standards for dialysis facilities, as promulgated in 10A NCAC 14C .2203(a), which requires an applicant to document the need for at least 10 stations. The application submitted by BMA Laurinburg is approvable because its approval would not be in excess of the Scotland County need determination in the 2013 SMFP and the July 2013 SDR, therefore, that application is approved as conditioned below.

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Scotland County shall materially comply with all representations made in its certificate of need application.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Scotland County shall develop and operate no more than two additional dialysis stations for a total of 14 certified stations which shall include any isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Scotland County shall install plumbing and electrical wiring through the walls for two additional dialysis stations for a total of 14 dialysis stations which shall include any isolation stations.**
- 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Scotland County shall not offer or develop home hemodialysis training.**
- 5. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Scotland County shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**

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

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Laurinburg shall materially comply with all representations made in its certificate of need application.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Laurinburg shall develop and operate no more than four additional dialysis stations for a total of 30 certified stations which shall include any home hemodialysis training or isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Laurinburg shall install plumbing and electrical wiring through the walls for four additional dialysis stations for a total of 30 dialysis stations which shall include any home hemodialysis training or isolation stations.**
- 4. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Laurinburg 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.**