

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: February 27, 2012

FINDINGS DATE: March 2, 2012

PROJECT ANALYST: Gregory F. Yakaboski

ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: L-8750-11 / DVA Healthcare Renal Care, Inc. d/b/a Northampton Dialysis/ Develop a new ten-station dialysis facility in Garysburg/ Northampton County

L-8753-11 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC East Northampton/ Add three dialysis stations to the existing facility in Conway for a total of 19 stations / Northampton County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NC-Northampton Dialysis

C-FMC East Northampton

The 2011 State Medical Facilities Plan (2011 SMFP) and the July 2011 Semiannual Dialysis Report (SDR) provide a county need methodology for determining the need for new dialysis stations. According to Section 2(E) of the dialysis station county need methodology, found on page 350 of the 2011 SMFP, *“If a county’s December 31, 2011 projected station deficit is ten or greater and the July SDR shows that utilization of each dialysis facility in the county is 80% or greater, the December 31, 2011 county station need determination is the same as the December 31, 2011 projected station deficit. ...”* The county need methodology for 2011 results in a need determination for 10 dialysis stations in Northampton County. In the July 2011 SDR *Table B: ESRD Dialysis Station Need Determinations by Planning Area*, a total of 83.4 in-center dialysis patients and 9.5 home patients are projected in Northampton County as of December 31, 2011. Two applications were received by the Certificate of Need Section for

development of the 10 dialysis stations. The two applicants applied for a total of 13 dialysis stations. Pursuant to the need determination in the 2011 SMFP and the July 2011 SDR, 10 dialysis stations is the limit on the number of dialysis stations that may be approved in this review. Following is a brief description of the two proposals submitted in this review:

Northampton Dialysis. DVA Healthcare Renal Care, Inc. d/b/a Northampton Dialysis (“Northampton Dialysis”) proposes to develop a new 10-station dialysis facility in Garysburg, Northampton County. In Section I.8, page 2, the applicant states the facility will offer in-center hemodialysis and home training for peritoneal dialysis. Exhibit 25 contains a line drawing depicting a total of 10 dialysis stations including one separate room labeled “private treatment.” The 2011 SMFP defines a county need for 10 dialysis stations in Northampton County. The applicant proposes to develop no more than 10 new dialysis stations in Northampton County and therefore is conforming to the need determination in the 2011 SMFP.

FMC East Northampton. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC East Northampton (“FMC East Northampton”) proposes to add three dialysis stations to its existing dialysis facility in Conway in Northampton County in response to the county need methodology. In Section I.8, page 2, the applicant states the project will add three dialysis stations, continue to offer in-center hemodialysis, and will add home training for peritoneal dialysis and home hemo-dialysis by way of this application. FMC East Northampton currently has 16 certified dialysis stations, including one station for isolation patients; therefore, after completion of this project, FMC East Northampton will have a total of 19 dialysis stations, including one isolation station. The 2011 SMFP defines a county need for a maximum of 10 dialysis stations in Northampton County. The applicant proposes to develop no more than 3 new dialysis stations in Northampton County and therefore is conforming to the need determination in the 2011 SMFP.

There is one policy in the 2011 SMFP applicable to both applications. Policy GEN-3 states:

“A CON 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 (SMFP) 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 CON 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 CON applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the SMFP as well as addressing the needs of all residents in the proposed service area.”

Northampton Dialysis.

Promote Safety and Quality

In Section II.3, pages 31-32, the applicant states:

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

Our Quality Management Program includes the following Quality Programs:

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

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

- *Improve patient outcomes*
- *Provide patient and staff 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.

...

Northampton Dialysis will be attended by Dr. Karl Brandspigel and other admitting Nephrologists who directly oversee the quality of care of the dialysis facility. In addition, Dr. Brandspigel 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 Northampton 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."

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

Promote Equitable Access

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

"Northampton 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.

Northampton 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.

Northampton 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 52, the applicant states

"Northampton 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 54, the applicant states

“Northampton 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 17 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. DVDA Healthcare Renal Care complies with all federal and state requirements pertaining to isolation of patients with communicable diseases.”

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

Maximize Healthcare Value

In Section III.9, page 42, the applicant states:

“The Northampton 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 1,600 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.*
- *Northampton 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.*
- *Northampton 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.*
- *Northampton 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.*
- *Northampton 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.

- *Northampton 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.”*

However, the applicant does not adequately demonstrate projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. Specifically, the applicant did not adequately demonstrate the proposal will maximize healthcare value. See Criterion (5) for additional discussion. The application is not consistent with Policy GEN-3 and is therefore nonconforming to this criterion.

FMC East Northampton.

Promote Safety and Quality

In Section II.1, page 24, the applicant states:

“BMA’s parent company, Fresenius Medical Care, encourages all BMA facilities to attain the FMC UltraCare certification. This is not a one time test, but rather is an ongoing process aimed at encouraging all staff, vendors, physicians, and even patients to be a part of the quality care program. Facilities are evaluated annually for UltraCare certification.”

In Section II.3, pages 31-34, the applicant describes the methods used to ensure and maintain quality of care, which include the following:

Facility programs

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

Corporate programs

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

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

FMC East Northampton adequately demonstrates that the proposal will promote safety and quality.

Promote Equitable Access

In Section II.1, pages 25-26, 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 96.8% of the In-Center dialysis treatments will be covered by Medicare or Medicaid; an additional 1.9% are expected to be covered by VA. Thus, 98.7% of the In-Center revenue is derived from government payors.

10A NCAC 2202 (b)(8) requires a commitment by BMA ‘to admit and provide services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.’ BMA provides such assurances within Section VI of this application.

...

BMA is also keenly sensitive to the second element of ‘equitable access’ - time and distance barriers. BMA continually strives to develop facilities and dialysis stations in close proximity to the patient residence. The ESRD patient population of Northampton County continues to increase. At this time, there is only one operational dialysis facility in Northampton County: FMC East Northampton. BMA has addressed the geographical issues of Northampton County. As the map below indicates, Conway is not in close proximity to Roanoke Rapids or Weldon. [see page 26 for map.] Given the locations of FMC East Northampton, the BMA Roanoke Rapids facility and the proposed FMC Weldon, it is clear that FMC East Northampton is not as convenient to serve the patients of northern Northampton County. BMA has appropriately addressed the needs of the dialysis patient population residing in western Northampton County through its dialysis facility at BMA Roanoke Rapids and the planned FMC Weldon facility.”

In Section VI.1 (a), page 49, 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 projects the patient population of the FMC East Northampton facility to be 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>FMC East Northampton</i>	<i>58.90%</i>	<i>55.40%</i>	<i>90.74%</i>	<i>53.60%</i>	<i>85.70%</i>

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 80.3% of North Carolina dialysis treatments in BMA facilities in FY 2010. Medicaid treatments represented an additional 4.3% of treatments in BMA facilities for FY 2010. Low income and medically underinsured persons will continue to have access to all services provided by BMA.

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 will be constructed in compliance with applicable sections of North Carolina State Building Code, Vol. #1-General Construction, which lists minimum requirements for the handicapped applicable to institutional and residential structures. In addition, wheelchairs are always available for transporting patients who are unable to stand or walk.”

In Section VI.7, pages 46-47, the applicant states,

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

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

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

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

Maximize Healthcare Value

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

“BMA is projecting a capital expenditure of \$59,604 for this project. This is a capital cost of only \$19,880 per station; a new 10 station dialysis facility can not be completed for costs this low. This expenditure is necessary in the normal course of business. BMA is not seeking State or Federal monies to add these four [sic] stations to the facility; BMA is not seeking charitable contributions to for [sic] this project. 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 close to the patient homes. ...”

In Section III.9, pages 40, the applicant states

“Costs are not just those costs to the facility, but also include costs to the patient, and to some degree the transportation agencies providing transportation services for the patients. BMA has considered likely alternatives to this proposal and has selected the most cost effective overall alternative.”

FMC East Northampton adequately demonstrates projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. Therefore, the applicant adequately demonstrates the proposal will maximize healthcare value. The application is consistent with Policy GEN-3 and is conforming to this criterion.

Both applications are conforming to the need determination in the 2011 SMFP for 10 dialysis stations in Northampton County. However, the limit on the number of dialysis stations that may be approved in this review is 10. Collectively, the two applicants propose a total of 13 dialysis stations. Therefore, even if both applications were conforming or conditionally conforming to all statutory and regulatory review criteria, both applications cannot be approved. (See the Comparative Analysis section for the decision.)

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

C-Both Applicants

There is currently one dialysis facility located in Northampton County, which is FMC East Northampton. The facility is located at 121 North Church Street in Conway. The facility had been known as FMC Rich Square and is listed as such in the July 2011 SDR. However, the facility’s name changed effective April, 1, 2011. *Table A: Inventory of Dialysis Stations and Calculation of Utilization Rates* in the July 2011 SDR indicates that, as of December 31, 2010, 54 in-center dialysis patients were dialyzing on 16 dialysis stations. Pursuant to the need methodology in the 2011 SMFP and the July 2011 SDR, there is a need for 10 additional dialysis stations in Northampton County.

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

Population to be Served

In Section III.7, page 35, 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:

Northampton Dialysis -Projected Patient Origin

COUNTY	YEAR ONE: 2012/2013		YEAR TWO: 2013/2014		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	In-center patients	Home dialysis patients	In-center patients	Home dialysis patients	Year 1	Year 2
Northampton*	36	3	41	6	100%	100%
TOTAL	36	3	41	3**	100%	100%

*On page 35, the application states “Harnett”, however, the entire application references Northampton County. Therefore, the project analyst concludes the word “Harnett” is a typographical error.

** On page 35, the application says “3” but it should be a “6.”

The applicant adequately identified the population proposed to be served.

Need Analysis

The assumptions and methodology used to project in-center utilization are provided in Section II, pages 11-28, and Section III.7, pages 35-40. The applicant repeats the same discussion three times in Section II and once again in Section III.7. The following quote is from pages 35-37.

“The July 2011 SDR Table B indicates that there were 88 dialysis patients in Northampton County as of December 31, 2010.

DVA Healthcare Renal Care, Inc [sic] uses the following assumptions in projecting a future census for the Northampton County ESRD dialysis patient population.

- *DVA assumes that a significant number of Northampton County in-center ESRD dialysis patients are leaving Northampton County three times a week to receive their dialysis treatments at facilities outside of Northampton County.*
- *DVA assumes that ESRD patients residing in Northampton County will want to dialyze at a facility in dialysis facility [sic] in Northampton County.*

- *The patient population in Northampton County will be projected forward using the current Five Year Average Annual Change Rate as published in the July 2011 SDR.*
- *DVA assumes that the percentage of patients dialyzing on home therapies will increase at the current Five Year Average Annual change Rate as published in the July 2011 SDR. The July 2011 SDR indicates that as of December 31, 2010, 10.2% of the dialysis patients in Northampton County were home dialysis patients.*
- *The July 2011 SDR indicates that the Rich Square Dialysis Unit (BMA Northampton) in Conway in Northampton County had an in-center dialysis patient population of 54 in-center dialysis patients as of December 31, 2010 (July 2011 SDR, Table A).*
- *It is evident that several of the in-center patients being treated at the BMA Conway location are out of county resident. [sic]*

DVA begins with the ESRD patient population of 88 total dialysis patients in Northampton County as of December 31, 2010.

DVA projects this census forward for one year, using the Five Year Average Annual Change Rate of 5.6% as published in the July 2011 SDR. This is the projected patient census as of December 31, 2011.

$$\bullet \quad 88 \times 0.056 = 4.928 + 88 = 92.928 \text{ or } 92.9$$

DVA again projects that census forward for one year, using the Five Year Average Annual Change Rate of 5.6% as published in the July 2011 SDR. This is the projected patient census for December 31, 2012.

$$\bullet \quad 92.9 \times 0.056 = 5.2024 + 92.9 = 98.1024 \text{ or } 98.1$$

DVA then projects this census forward for one half year, using the Five Year Average Annual Change Rate of 5.6% as published in the July 2010 SDR. This is the projected patient census for June 30, 2013. This is day before the projected certification date for the project.

$$\bullet \quad 98.1 \times 0.028 = 2.7468 + 98.1 = 100.8468 \text{ or } 100.8$$

On June 30, 2013, DVA is projecting that there will be 100.8 total dialysis patients residing in Northampton County. DVA notes that this calculation methodology is consistent with that in the SDR Table B. It is our understanding that recent discussions with Craig Smith regarding projections of station rates (SDR, Table A) have indicated that the CON Section does not employ partial patients in utilization calculations. DVA merely wants to demonstrate that the projections up to this point are consistent with the

SDR methodology, and therefore no effort has been made to round down or up to whole patients nor is it appropriate at this point to employ a rounding process. This is not a utilization calculation or projection.

Given that the calculations will project 100.8 total patients as of June 30, 2013, DVA will now reduce this number by the percentage of patients using home therapies. The July 2011 SDR indicates that 10.2% of the patients residing in Northampton County were home dialysis patients.

- $100.8 \times 0.102 = 10.2816$ or 10.3
- $100.8 - 10.3 = 90.5$

DVA assumes that of the 90.5 ESRD dialysis patients projected to be residing in Northampton County on June 30, 2013, will be in-center patients.

DVA assumes that Fresenius Medical Care was serving 54 Harnett [sic] County in-center patients at its Conway facility [(“FMC East Northampton”)] on December 31, 2010. Based on the information in Table B of the July 2011 SDR, it is unreasonable to assume that 100% of the in-center patients dialyzing in the BMA facility were Northampton County residents. It is reasonable to assume that some number less than [sic] 54 in-center patients dialyzing at the BMA facility in Conway were residents of other county(s) traveling to Northampton County for their treatments. We have determined after a thorough review of Table B of the July 2011 SDR that the BMA Conway facility was dialyzing approximately 49 in-center patients from Northampton County.”

Table B of the July 2011 SDR contains no information which would permit the applicant to determine the number of in-center patients dialyzing at FMC East Northampton who are residents of Northampton County. Indeed, what can be determined from Table A and Table B in the July SDR is that not all Northampton County residents undergoing dialysis utilize the only facility physically located in Northampton County. According to Table B, there were 88 Northampton County residents undergoing dialysis as of December 31, 2010. As of that same date, 54 patients were utilizing FMC East Northampton. A review of an application submitted in 2007 (Project ID # L-7957-07) (a public record) shows that 17% of FMC East Northampton’s patients were residents of Bertie and Hertford counties. Furthermore, FMC East Northampton reports that, as of June 30, 2011, 49 of the 56 patients utilizing the facility were residents of Northampton County. Northampton Dialysis’ assumption that not all of the in-center patients dialyzing at FMC East Northampton are residents of Northampton County is reasonable and credible under the circumstances.

On page 37, the applicant states:

“It is reasonable to conclude that this census of Northampton County residents receiving their dialysis treatments at the BMA Conway facility will grow in proportion with the Northampton County Five Year Average Annual Change Rate. DVA offers the following projections for this patient population.

DVA begins with the reported patient population of the Rich Square Dialysis Unit (BMA Northampton) as of December 31, 2010, less patients who did not live in Northampton County as of December 31, 2010, but were shown as part of the patient census in the July 2011 SDR. DVA assumes that the 49 in-center patients are residents of Northampton County.

- *49 in-center patients*

DVA projects this census forward for one year, using the Five Year Average Annual Change Rate of 5.6% as published in the July 2011 SDR. This is the projected Rich Square Dialysis Unit (BMA Northampton) in-center patient census for December 31, 2011.

- $49 \times 0.056 = 2.744 + 49 = 51.744$ or 51.7

DVA projects this census forward for one year, using the Five Year Average Annual Change Rate 5.6% as published in the July 2011 SDR. This is the projected Rich Square Dialysis Unit (BMA Northampton) in-center patient census for December 31, 2012.

- $51.7 \times 0.056 = 2.8952 + 51.7 = 54.5952$ or 54.6

DVA projects this census forward for one half year, using the Five Year Average Annual Change Rate 13.1 [sic] as published in the July 2011 SDR. This is the projected Rich Square Dialysis Unit (BMA Northampton) [FMC East Northampton] in-center patient census for June 30, 2013.

- $54.6 \times 0.028 = 1.5288 + 54.6 = 56.1288$ or 56.1

DVA notes that the projected aggregate Northampton County patient population for the Fresenius Medical Care Rich Square Dialysis Unit (BMA Northampton) could reasonably be expected to total 56.1 in-center patients by June 30, 2013.”

In Section III, pages 38-40, the applicant states it obtained data from the Southeastern Kidney Council ESRD, as shown in the table below. The applicant states

“The chart below indicates the zip codes and identifying communities in Northampton County that have identified in-center dialysis patients. The information in the chart indicates the number of in-center patients that resided in each zip code as of December 31, 2011, March 31, 2012 [sic] and June 30, 2013 [sic].

County	Zip Code	City/Town	12/31/2010	3/31/2011	6/30/2011
Northampton	27820	Conway	8	8	8
Northampton	27831	Garysburg	19	19	20

Northampton	27832	Gaston	12	14	13
Northampton	27845	Jackson	12	11	9
Northampton	27853	Margarettsville	2	2	2
Northampton	27862	Pendleton	0	1	1
Northampton	27866	Pleasant Hill	2	1	1
Northampton	27867	Potecasi	0	0	0
Northampton	27869	Rich Square	12	13	15
Northampton	27876	Seaboard	3	4	5
Northampton	27897	Woodland	7	7	7

The zip code for each of these counties is referenced in the zip code data published by the Southeastern Kidney Council ESRD Network 6. This means that the patient numbers ins [sic] each of those zip codes identified in the above chart live in Northampton County.

There are at least four communities that are located in southwestern Northampton County that have no Northampton County dialysis facility anywhere near where they live. These communities are Garysburg, Gaston, Jackson and Seaboard. These four communities had 46 in-center patients as of December 31, 2010, 48 in-center patients as of March 31, 2011 and 47 in-center patients as of June 30, 2011.

DVA Healthcare Renal Care, Inc. d/b/a Northampton Dialysis will take all referrals that are made by Nephrologists that have admitting and rounding privileges in the facility. Northampton Dialysis will offer Nephrologists who practice in Northampton County and surrounding counties the opportunity to apply for admitting privileges.

Northampton Dialysis projects that a significant portion of the 46 in-center patients identified above will transfer to the facility when it opens. We expect that many patients will learn of the new facility and will apply for admission through their Nephrologist while the facility is under construction. These patients will make up the waiting list and will be the first patients to be admitted to the facility after certification.

In order to identify a patient population, Northampton Dialysis is projecting that 70% of the in-center patients identified in the Zip Code of Residence for Patients Currently Dialyzing in Network 6 Units (grouped by State and County and current as of 01/03/2011 and based on December 31, 2010 data) and living in zip codes 27831 (Garysburg - 19 patients), 27845 (Jackson - 12 patients), 27876 (Seaboard - 3 patients) and 27832 (Gaston - 12 patients). In each case, these communities are located [sic] to our proposed facility, Garysburg, than to the BMA Conway facility.

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

DVA begins with the projected patient population of 27 [sic] patients as noted above. This is the projected census as of December 31, 2010.

- *46 in-center patients X .7 = 32.2 or 32 in-center patients as of December 31, 2010*

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

- *32 X 0.056 = 1.792 + 32 = 33.792 or 33.8*

DVA projects this census forward one year, using the Five Year Average Annual Change Rate as published in the July 2011 SDR. This is the projected patient census for December 31, 2012.

- *33.8 X 0.056 = 1.8928 + 33.8 = 35.6928 or 35.7*

DVA projects this census forward for one half year, using the Five Year Average Annual Change Rate as published in the July 2011 SDR. This is the projected patient census for June 30, 2013.

- *35.7 X 0.028 = .9996 + 35.7 = 36.6996 or 30.9 [sic]*

DVA projects this census forward one year, using the Five Year Average Annual Change Rate as published in the July 2011 SDR. This is the projected patient census for June 30, 2014, the end of operating year one.

$$30.9 \times 0.56 \text{ [sic]} = 4.2837 + 32.4 = 36.6837 \text{ or } 36.7$$

DVA projects this census forward one year, using the Five Year Average Annual Change Rate as published in the July 2011 SDR. This is the projected patient census for June 30, 2015, the end of operating year two.

$$36.7 \times 0.131 \text{ [sic]} = 4.7684 + 36.7 = 41.4684 \text{ or } 41.5$$

DVA is not projecting that 100% of the new patients in Northampton County would become DVA patients. DVA has

- *Projected growth for the entire patient population in Northampton County*
- *Reduced that population by the appropriate percentage of home patients*
- *Projected growth of the Fresenius Medical Care population and then subtracted that from the projected population as a whole*
- *Identified several communities in Northampton County that are not being served by a facility in Northampton County or that live a significant distance from the BMA Conway facility*

- *DVA is projecting to serve 36 in-center patients by the end of operating year one for a utilization rate of 90% or 306 patients per station*
- *DVA is projecting to serve 41 in-center patients by the end of operating year two for a utilization rate of 102% or 4.1 patients per station*
- *Northampton will apply for additional dialysis stations under the facility need methodology after the first year of operation when the facility reaches 80% utilization”*

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. DVA has been working with Nephrologists throughout North Carolina for several years to promote the home therapies. The July 2011 SDR indicates that there were nine home-trained patients living in Northampton County as of December 31, 2010.

Northampton Dialysis will use a conservative projection of serving three home-trained patients in peritoneal dialysis during operating year one and six home-trained patients in peritoneal dialysis by the end of operating year two. These projections are based on the education and promotion of home therapies by the Nephrologists associated with Albemarle Nephrology who will have admitting and rounding privileges at Northampton Dialysis. One of the Nephrologists will be serving as Medical Director of the facility.” (Emphasis in original.)

Note: On pages 16, 22, 28 and 40, the applicant states the facility is projected to serve 41 in-center patients by the end of Year Two. However, the application contains a number of mathematical and/or typographical errors. The following steps in the applicant’s methodology are incorrect. The correct calculations are in brackets.

- $35.7 \times 0.028 = .9996 + 35.7 = 36.6996$ or 30.9 [should say 36.7]
- 30.9 [should say 36.7] $\times 0.56$ [should be 0.056] = 4.2837 [should be 2.0552] + 32.4 [should be 36.7] = 36.6837 [should be 38.7552] or 36.7 [should be 38.8]
- 36.7 [should be 38.8] $\times 0.131$ [should be 0.056] = 4.7684 [should be 2.178] + 36.6 [should be 38.8] = 41.4684 [should be 40.9728] or 41.5 [should be 40]

As shown above, applying the applicant’s stated assumptions and methodology consistently from start to finish results in a projection of 40 in-center patients by the end of Year Two, not 41.

On pages 16, 22, 28 and 40 the applicant projects the proposed facility will serve 36 in-center patients or 3.6 patients per station per week ($36/10 = 3.6$) 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 and supported assumptions. Therefore, the applicant adequately demonstrates the need for the proposed stations.

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need this population has for the proposed new 10-station dialysis facility in Northampton County. Therefore, the application is conforming to this criterion.

FMC East Northampton proposes to add three dialysis stations to the existing facility for a total of 19 stations upon project completion.

Population to be Served

In Section III.7, page 38, the applicant provides current patient origin, as illustrated in the table below.

County	Number of In-Center Patients as of 6/30/11
Northampton	49
Bertie	3
Hertford	4
Total	56

In Section III.7, page 37, the applicant provides projected patient origin during the first two operating years upon project completion, as illustrated in the following table.

County	# of In-Center Patients		County Patients as a Percent of Total Patients	
	Year One	Year Two	Year One	Year Two
Northampton	56.17	59.32	88.92%	89.44%
Bertie	3	3	4.75%	4.52%
Hertford	4	4	6.33%	6.03%
Total	63.17	64.32*	100%	100%

In Section III.7, page 38, the applicant states:

“BMA also proposes to add home dialysis therapies to this facility. BMA proposes that some patients may choose home dialysis as an option once the facility begins to offer this modality. BMA suggests that one patient will transition from in-center dialysis to home hemo-dialysis in the second year of operations. BMA also suggests that an additional in-center patient will begin home peritoneal dialysis in the second year of operations.”

In Section III.7, pages 37-38, the applicant states

“Projections of future patient populations of FMC East Northampton are derivative of the current patient population. The patient population of FMC

Northampton is then expected to increase at a rate commensurate with the Northampton County Five Year Average Annual Change Rate as published in the July 2011 SDR. That rate is 5.6%. BMA does not project an increase for the patients of Bertie and Hertford Counties. Both counties have existing dialysis facilities. BMA assumes that the patients who reside in Bertie and Hertford are dialyzing at FMC East Northampton County dialysis facility as a function of patient choice, and that these patients will continue to dialyze at the facility.”

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 12-21, and Section III.7, pages 37-39. The applicant repeats the same discussion three times in Section II and once again in Section III.7. The following quote is from pages 36-38.

“1. BMA has filed this application in response to a County Need Determination in the July 2011 SDR. The Need Determination is for 10 stations. BMA is applying for three stations. Northampton County is a large county stretching east - west and situated along the North Carolina-Virginia state border. When BMA representatives met with the County Manager to discuss this proposal, the County Manager remarked about the expanse of the county; the county is more than 45 miles wide at its widest point, reaching from Lake Gaston on the west to the Meherrin River on the east.

BMA is currently serving a significant number of Northampton County ESRD patients at its BMA Roanoke Rapids dialysis facility; many of these patients have already proposed to transfer to the new FMC Weldon facility which is now under development.

Northampton County is a very rural county. The predominant thoroughfare is US 158 running east-west from Murfreesboro (Hertford County) to Roanoke Rapids (Halifax County). US 158 is predominantly a two lane highway. Due to the width of the county, and the limitations of the highway infrastructure, many patients residing on the west side of the county do not wish to travel to the east side of the county for dialysis treatment.

On the west side of the county, the county is only less than seven miles across (from north to south). The patients residing in the western areas of the county are more proximate to Roanoke Rapids than to Conway on the east side of the county. For example, patients residing in the Garysburg community have a commute of approximately five miles to dialysis treatment at BMA Roanoke Rapids. Once the FMC Weldon project is completed, the commute will be reduced to only three miles. These same patients would face a commute of approximately 28 miles if they received dialysis at FMC East Northampton County.

BMA considered that a facility maybe developed in Jackson, the county seat. However, the commute from the Garysburg area to Jackson is a distance of approximately 15 miles, still more than three times the travel distance to Roanoke Rapids and Weldon.

BMA has contacted the patients of the Garysburg area and other patients residing in western Northampton County. These patients are not interested in transferring their care to the FMC Northampton County dialysis facility. These patients have signed letters of support indicating that they are not interested in transferring their care away from the BMA Roanoke Rapids facility. Those patients who have supported the FMC Weldon project similarly have expressed an intent to continue forward with their plans to transfer to the FMC Weldon facility upon completion of that project.

Considering this information, BMA has chosen to apply for only three of the 10 available dialysis stations.

2. FMC Northampton is currently operating at 87.5% capacity with a census of 56 patients dialyzing on 16 certified dialysis stations. BMA does not project to operate a third dialysis shift at FMC East Northampton due to a lack of patient interest.

3. BMA assumes that the patient population of FMC East Northampton will increase at a rate commensurate with the Northampton County Five Year Average Annual Change Rate as published in the July 2011 SDR. That rate is: 5.6%.

4. BMA projects that this three station expansion will be completed and certified by December 31, 2012. Operating Year 1 is the period from January 1, 2013 through December 31, 2013. Operating Year 2 is the period from January 1, 2014 through December 31, 2014.”

...

<i>Northampton County</i>	<i>In-Center</i>
<i>BMA begins with Northampton County patients utilizing the FMC East Northampton dialysis facility as of June 30, 2011.</i>	<i>49 Northampton County patients</i>
<i>BMA projects growth of this patient population using the Northampton County Five Year Average Annual Change Rate for six months to December 31, 2012.</i>	<i>[49 X (.056 / 12 X 6)] + 49=50.4</i>
<i>BMA projects this patient population forward for 12 months to December 31, 2012. This is the projected certification date for this project.</i>	<i>(50.4 X .056) + 50.4 = 53.2</i>
<i>BMA adds the 7 patients from Bertie and Hertford Counties. This is the projected beginning census for this project.</i>	<i>53.2 + 7 = 60.2</i>
<i>BMA projects the patient population from Northampton County forward for 12 months at 5.6%. This is the projected Northampton County patient population for</i>	<i>(53.2 X .056) + 53.2 = 56.2</i>

<i>December 31, 2013. This is the end of Operating Year 1.</i>	
<i>BMA adds the 7 patients from Bertie and Hertford Counties. This is the projected ending census for Operating Year 1.</i>	$56.2 + 7 = 63.2$
<i>BMA projects the patient population from Northampton y [sic] forward for 12 months at 5.6%. This is the projected ampton [sic] County patient population for December 31, 2014. [sic] the end of Operating Year 2.</i>	$(56.2 \times .056) + 56.2 = 59.3$
<i>BMA adds the 7 patients from Bertie and Hertford Counties. This is the projected ending census for Operating Year 2.</i>	$59.3 + 7 = 66.3$

...

In Section III.7, pages 38-39, the applicant states,

“BMA projected utilization calculation [sic] are a function of the projected year end census rounded down to the whole number. Utilization at FMC East Northampton is expected to be:

Operating Year 1

*63 patients dialyzing on 19 stations = 3.315 patients per station
 $63 / (4 \times 19) = 0.829$ or 82.9%*

Operating Year 2

*64 patients dialyzing on 19 stations = 3.37 patients per station
 $64 / (4 \times 19) = 0.842$, or 84.2%”*

In the table above where the applicant illustrates how projected utilization was calculated, the applicant projects 66 in-center patients by the end of Year Two. However, on page 38, the applicant states *“BMA also proposes to add home dialysis therapies to this facility. BMA proposes that some patients may choose home dialysis as an option once the facility begins to offer this modality. BMA suggests that one patient will transition from in-center dialysis to home hemo-dialysis in the second year of operations. BMA also suggests that an additional in-center patient will begin home peritoneal dialysis in the second year of operations.”* Thus, the applicant projects 64 in-center patients in Year Two, not 66.

On pages 13, 14, 17, 18, 20 and 21, the applicant projects the facility will serve 63 in-center patients or 3.3 in-center patients per station per week ($63/19 = 3.3$) 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 and supported assumptions. Therefore, the applicant adequately demonstrates the need for the proposed stations.

In summary, the applicant adequately identified the population to be served and demonstrated the need this population has for three additional dialysis stations. Therefore, the application is conforming to this criterion.

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

NA-Both Applicants

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

NC-Northampton Dialysis
C-FMC East Northampton

Northampton Dialysis. In Section III.9, pages 41-42, the applicant describes the alternatives it considered prior to the submission of its application. However, the application is not conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (5), (7) and (18a) for discussion. Therefore, the applicant did not adequately demonstrate that the proposal is its least costly or the most effective alternative to meet the need. Consequently, the application is nonconforming to this criterion.

FMC East Northampton. In Section III.9, pages 39-40, the applicant describes the alternatives it considered prior to the submission of its application. The application is conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a), (20), and 10A NCAC 14C .2200 for discussion. The applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion.

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

NC-Northampton Dialysis
C-FMC East Northampton

Northampton Dialysis. In Section VIII.1, page 60, the applicant states the capital cost is projected to be \$1,177,548. In Section IX, page 42, the applicant states that the total working capital needed will be \$888,874 (\$142,060 in start-up expenses and \$746,814 in initial operating expenses.)

In Section VIII.2-3, pages 60-61, and Section IX, page 64, and Exhibit 22, 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 DVA Healthcare Renal Care, Inc. Exhibit 22 contains a letter, dated September 12, 2011, from the Vice President and Controller of DaVita, Inc. which states:

“I am the Chief Accounting Officer of DaVita, Inc. DaVita, Inc. is the parent and owner of DVA Healthcare Renal Care, Inc. We are submitting a Certificate of Need application to develop a ten-station ESRD hemodialysis facility in Garysburg in Northampton County. The project calls for a capital expenditure of \$1,177,548 start-up expenses of \$142,060. [sic] and a working capital requirement of \$746,814.

DaVita and DVA Healthcare Renal Care, Inc. have committed cash reserves in the amount of \$2,066,422 for this project. We will ensure that these funds are made available for the development and operation of this project. As Chief Accounting Officer of DVA Healthcare Renal Care, Inc., I can also confirm that we will provide all of the funds that we receive from DaVita for this project to DVA Healthcare Renal Care for the development of this project.”

In Exhibit 21, the applicant provides audited financial statements for DaVita, Inc. which document that DaVita, Inc. had \$539,459,000 in cash and cash equivalents as of December 31, 2009. The project analyst notes that in a previous application the applicant submitted more recent audited financial statements which document that DaVita, Inc. had \$860,117,000 in cash and cash equivalents as of December 31, 2010. The applicant adequately demonstrated the availability of sufficient funds for the capital and working capital needs of the project.

In Section X, pages 65-70, the applicant projects revenues will exceed expenses in the second year of operation after completion of the project. The rates in Section X.1, page 65, are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services.

However, revenues and expenses are based, in part, on the projected number of treatments in Years One and Two. In Section III.7, page 40, the applicant states

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

The applicant provides the assumptions for and calculations of the number of treatments on page 67 of the application. However, the number of treatments on page 67 are not consistent with the projected utilization provided in Section II, pages 11-28, and Section III.7, pages 35-40. On page 67, the applicant states *“The operating year one revenue projections include an average of 28 in-center and 4 home-trained patients being treated during the year. The number of in-center patients is based on 23 in-center patients being treated at the beginning of the year (at the beginning of the ramp up period) with a growth during the year to 33 in-center patients.”* However, in Sections II and III, the applicant projects 36 in-center patients by the end of Year One. The applicant based its Year One revenue projections on the incorrect number of in-center patients. Also on page 67, the applicant states *“The operating year two revenue projections include an average of 34 in-center and 4.5 home-trained patients being treated during the year. The number of in-center patients is based on 33 in-center patients being treated at the beginning*

of the year with a growth during the year to 35 in-center patients.” However, in Sections II and III, the applicant projects starting Year Two with 35 in-center patients and ending Year Two with 41 in-center patients [which should be 40]. Based on the above, the applicant does not adequately demonstrate that projected revenues are based on reasonable and credible assumptions.

Furthermore, the applicant states that certain expenses in Years One and Two are based on the number of treatments. The following table illustrates a number of discrepancies between the stated assumptions and projected expenses.

Expense Line Item	Assumption (Average Cost per Treatment)	Total \$ Amount in Section X.4	# of Treatments Calculated by Analyst*	# of Treatments in Section X.3, page 69
Line 4 Other Medical Supply	\$3	\$17,632	5,877	5,706
Line 7 Medical Supplies Chronic	\$18	\$93,419	5,190	5,706
Line 8 Medical Supplies Home	\$30	\$20,607	687	702
Line 15 Lab	\$3	\$18,018	6,006	5,706
Line 16 Plant Operation & Maint.	\$4	\$23,509	5,877	5,706
Line 19 Other Operating Supply	\$6	\$35,263	5,877	5,706
Line 35 Bad Debts/Charity	\$7	\$39,942	5,706	5,706

*by dividing the Total \$ Amount in Section X.4 by the Average Cost per Treatment

As shown in the table above, the number of treatments as calculated by the Analyst equals what the applicant provides on page 69 for only one line item (Line 35). It is noted that for Line 15, the number of treatments as calculated by the Analyst equals total projected treatments without the 5 percent adjustment for missed treatments. The applicant does not adequately demonstrate that projected expenses are based on reasonable and credible assumptions.

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

FMC East Northampton. In Section VIII.1, page 57, the applicant states the capital cost is projected to be \$59,640. In Section IX, page 61, the applicant states that there will be no start-up costs or initial operating expenses.

In Section VIII, pages 58-59, 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 15, 2011, 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 three dialysis stations to the FMC East Northampton County dialysis facility in Northampton County.

...

As Vice President, I am authorized and do hereby authorize the addition of three 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 \$59,640 as may be needed for this project.”

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

In Section X, pages 62-68, the applicant projects revenues will exceed expenses in the first two years of operation after completion of the project. The rates in Section X.1, page 62, are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services. The applicant adequately demonstrates that projected revenues and expenses are based on reasonable and supported assumptions.

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

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

C-Both Applicants

Northampton Dialysis. The 2011 SMFP and the July 2011 SDR indicates a need for 10 additional dialysis stations in Northampton County. Northampton Dialysis proposes to develop a new 10-station dialysis facility on Route 46 just east of the intersection with Interstate 95 in Garysburg, in southwestern Northampton County. See Criterion (1) for discussion regarding conformity to the need determination in the 2011 SMFP and the July 2011 SDR. The applicant adequately demonstrates the need for the 10-station facility. See Criterion (3) for discussion regarding demonstration of need. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Therefore, the application is conforming to this criterion.

FMC East Northampton. The 2011 SMFP and the July 2011 SDR indicates a need for 10 additional dialysis stations in Northampton County. The applicant proposes to add three dialysis stations to the existing FMC East Northampton facility for a total of 19 dialysis stations upon completion of this project. See Criterion (1) for discussion regarding conformity to the need determination in the 2011 SMFP and the July 2011 SDR. The applicant adequately demonstrates the need for the three additional dialysis stations. See

Criterion (3) for discussion regarding demonstration of need. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Therefore, the application is conforming to this criterion.

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

NC- Northampton Dialysis
C-FMC East Northampton

Northampton Dialysis. In Section VII.1, page 55, the applicant projects the following staffing during the first two operating years.

POSITION	TOTAL FTEs YEARS 1 AND 2
RN (dc)	1.5
RN HT (dc)	0.25
Pt. Care Technician (dc)	4.5
Bio-Med Tech	0.3
Admin (dc)	1.0
Dietician	0.3
Social Worker	0.3
Unit Secretary	1.0
Other-reuse	0.5
TOTAL	9.65

*dc: direct care staff

As shown in the above table, the applicant proposes a total of 9.65 full-time equivalent (FTE) positions, 7.25 of which will be direct care positions. In Section VII.4, page 57, the applicant states that it does not anticipate having any difficulty staffing the proposed facility.

The following table shows hours of operation as proposed by the applicant in Section VII, on page 58:

WEEKLY HOURS OF OPERATION				
DAY	MORNING	AFTERNOON	EVENING	TOTAL
Monday	3	3	0	6
Tuesday	3	3	0	6
Wednesday	3	3	0	6
Thursday	3	3	0	6
Friday	3	3	0	6
Saturday	3	3	0	6
Sunday	0	0	0	0
Total	18	18	0	36
Total Hours Operation per Year (weekly hours x 52)				1,872

The following table shows the number of FTE direct care staff positions the applicant proposes based on the number of hours the facility will operate, as reported by the applicant in Section VII, page 58:

	# FTEs	Hrs/Yr/FTE	TOTAL FTE HOURS (ANNUAL)	TOTAL HRS OF OPERATION (ANNUAL)	FTE HRS/HRS OF OPERATION
RN	1.5	2,080	3,120	1,872	1.67
RN HT	.25	2,080	520	1,872	.28
Techs	4.5	2,080	9,360	1,872	5
Total	6.25	2,080	13,000	1,872	6.94

Based on the proposed operating hours for the facility, it will be open 1,872 hours a year. In Section VII, page 56, the applicant projects 6.25 total direct care FTEs. Assuming one FTE works 2,080 hours annually, 6.25 FTEs would work a total of 13,000 hours annually, which is sufficient to cover the 1,872 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 36 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 16, 22, 28 and 40, the applicant states it projects to serve 41 in-center patients in Year Two on 10 stations. However, the applicant made mathematical and/or typographical errors. Based on the applicant’s stated assumptions and methodology, the facility would serve only 40 patients by the end of Year Two. Furthermore, in Section III, page 40, the applicant states that “Northampton will apply for additional dialysis stations under the facility need methodology after the first year of operation when the facility reaches 80% utilization.”

In Section V.4(c), page 47, the applicant states that Dr. Karl Brandspigel has agreed to serve as Medical Director of the proposed facility, that he is a Nephrologist associated with Albemarle Nephrology and that Dr. Brandspigel, along with two additional Nephrologists associated with Albemarle Nephrology, Dr. Greg Warren and Dr. Ravi Ramsamooj, will develop additional referral relationships with other referring primary care physicians in Northampton County. In Section VII.6, page 57, the applicant states that Dr. Brandspigel will be backed up by the Nephrologists associated with Albemarle Nephrology. In Section VII.7-8, page 57, the applicant states Dr. Brandspigel, Dr. Warren and Dr. Ramsamooj serve Elizabeth City Dialysis Center, Edenton Dialysis Center and Ahoskie Dialysis Center and that all three have admitting privileges at Albemarle Hospital in Elizabeth City.

Exhibit 14 contains letters of support for the proposed project from the three Nephrologists associated with Albemarle Nephrology. The letter from Dr. Brandspigel states

“I have been informed that DaVita Inc., operating as DVA Healthcare Renal Care, Inc. d/b/a Northampton Dialysis, is submitting a Certificate of Need application to the State of North Carolina to develop a new ten-station End Stage Renal Disease outpatient hemodialysis facility in Northampton County. As a practicing physician, I support the efforts of DVA Healthcare Renal Care to expand this much needed service in Northampton County.

The addition of this new facility in our community will enhance the quality of life for patients with End Stage Renal Disease.”

However, the application does not contain documentation that shows that Dr. Brandspigel has agreed to serve as Medical Director for Northampton Dialysis. Therefore, the applicant does not adequately demonstrate that a Medical Director will be available for the proposed facility.

In summary, the applicant did not adequately demonstrate the availability of resources, including a medical director. Consequently, the application is nonconforming to this criterion.

FMC East Northampton. 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)	3.0
Technician (dc)	7.0
Clinical Manager (dc)	1.0
Admin (dc)	0.15
Dietician	0.30
Social Worker	0.40
Home Training Nurse (dc)	0.25
Medical Records	0.50
Chief Tech	0.20
Equipment Tech	0.50
In-Service	0.15
Clerical	1.0
TOTAL	14.45

*dc: direct care staff

As shown in the above table, the applicant proposes a total of 14.45 FTE positions, 11.4 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 following table shows hours of operation as proposed by the applicant in Section VII.10, on page 56:

WEEKLY HOURS OF OPERATION				
DAY	MORNING	AFTERNOON	EVENING	TOTAL
Monday	4	4	0	
Tuesday	4	3	0	
Wednesday	4	4	0	
Thursday	4	3	0	
Friday	4	4	0	
Saturday	4	3	0	
Sunday	0	0	0	0
Total	24	21	0	45
Total Hours Operation per Year (weekly hours x 52)				2,340

The following table shows the number of FTE direct care staff positions the applicant proposes based on the number of hours the facility will operate, as reported by the applicant in Section VII, page 56:

	# FTES	Hrs/Yr/FTE	TOTAL FTE HOURS (ANNUAL)	TOTAL HRS OF OPERATION (ANNUAL)	FTE HRS/HRS OF OPERATION
RN	3	2,080	6,240	2,340	2.71
Techs	7	2,080	14,560	2,340	6.22
Clinical Manager	1	2,080	2,080	2,340	0.88
Admin	.15	2,080	312	2,340	.13
Home Training Nurse	.25	2,080	520	2,340	0.22
Total	11.4	2,080	23,712	2,340	10.13

Based on the proposed operating hours for the facility, it will be open 2,340 hours a year. In Section VII, page 54, the applicant projects 11.4 total direct care FTEs. Assuming one FTE works 2,080 hours annually, 11.4 FTEs would work a total of 23,712 hours annually, which is sufficient to cover the 2,340 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 63 in-center patients in Year One on 19 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 (19 stations)	19	19
Afternoon (19 Stations)	19	19

As shown in the table above, the proposed 19-station facility would be able to dialyze up to a maximum of 76 in-center patients on 19 dialysis stations, assuming one patient per station per shift and two shifts per day, Monday through Saturday. On page 38 the applicant states it projects to serve 63 in-center patients in Year One on 19 stations. On page 39 the applicant states it projects to serve 64 in-center patients in Year Two on 19 stations.

In Section V.4(c), page 46, the applicant states that Lorenzo Santarina, MD has agreed to continue to serve as Medical Director of the facility. Exhibit 21 contains a letter from Lorenzo Santarina, MD stating that he is the current Medical Director and will continue to serve in this capacity upon completion of the project. Dr. Santarina is associated with Valley Hypertension-Nephrology Associates, P.A. which is located in Roanoke Rapids. The letter in Exhibit 21 states *“I am pleased to inform you that I have agreed to continue serving as the Medical Director for this facility. ... As you know, our practice has been providing nephrology services in Halifax and surrounding counties for many years. I, and my physician partners, enjoy an extensive network of physician relationships in this northern area of North Carolina. Many physicians in the area refer their patients to our practice as these patients demonstrate the need for nephrology services. We also provide care for the renal patients admitted to Halifax Regional Hospital and other hospitals in surrounding counties.”* The information regarding staffing provided in Section VII is reasonable and credible and supports a finding of conformity with this criterion.

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

C-Both Applicants

Northampton Dialysis. In Section V.1-2, pages 45-46, the applicant lists the providers of the necessary ancillary and support services. In Exhibits 7, 8, 11 and 12, the applicant documents how the project will be coordinated with the existing health care system. The information provided in Section V and the referenced Exhibits is reasonable and credible and supports a finding of conformity with this criterion.

FMC East Northampton. In Section V.1, page 43, the applicant lists the providers of the necessary ancillary and support services. In Exhibits 16, 17, 18 and 20, the applicant documents how the project will be coordinated with the existing health care system. The information provided in Section V and the referenced Exhibits is reasonable and credible and supports a finding of conformity with this criterion.

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

NA-Both Applicants

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

NA-Both Applicants

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

C- Northampton Dialysis
NA-FMC East Northampton

Northampton Dialysis proposes to have an unrelated developer construct a 6,255 square foot building on Parcel ID # 01-01089 on Highway 46 at the intersection with I-95 in Garysburg. In Section XI.6(d), page 74, 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 65 – 66, the applicant states the facility will be constructed in compliance with all laws and regulations pertaining to fire and safety equipment, and other health and safety requirements. The applicant adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative, and that the construction costs will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges. Therefore, the application is conforming to this criterion.

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

NA-Northampton Dialysis
C-FMC East Northampton

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2010 and CY2008-2009, respectively. The data in the table was obtained February 6, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	Total # of Medicaid Eligibles as % of Total Population As of June 2010	Total # of Medicaid Eligibles Age 21 and older as % of Total Population As of June 2010	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
Northampton	28%	14.5%	21.7%
Bertie	27%	13.8%	20.4%
Hertford	26%	12.7%	21.5%
Statewide	17%	6.7%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the dialysis services to be offered at Northampton Dialysis and FMC East Northampton.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

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

Northampton Dialysis proposes a new facility.

FMC East Northampton. In Section VI.1(b), pages 49-50, the applicant reports that 94.9% of the patients who received treatments at FMC East Northampton had some or all of their services paid for by Medicare or Medicaid [90.4% Medicare + 4.5% Medicaid = 94.9%]. The applicant demonstrated that medically underserved populations currently have adequate access to FMC East Northampton's existing services. Therefore, the application is conforming to this criterion.

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

NA – Northampton Dialysis
C- FMC East Northampton

Northampton Dialysis proposes a new facility.

FMC East Northampton. 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(a), page 53, the applicant states "*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.*" The application is conforming with this criterion.

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

C-Both Applicants

Northampton Dialysis. In Section VI.1(a), page 29, the applicant states:

“Northampton Dialysis, by policy, will make dialysis vices 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..

...

Northampton 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 51, the applicant projects that that 89.2% of its patients will have some or all of their services paid for by Medicare or Medicaid, as illustrated in the following table.

**Northampton Dialysis
Utilization by Payor Source**

PAYOR SOURCE	PERCENT UTILIZATION BY PAYOR SOURCE
Medicare	23.0%
Medicaid	2.4%
Medicare/Medicaid	36.1%
Commercial Insurance	8.4%
VA	2.4%
Medicare/Commercial	27.7%
TOTAL	100.0%

In Section VI.1(c), page 51, the applicant states:

“These are average percentages of patients who are currently dialyzing at the Ahoskie Dialysis Center facility. Hertford County is contiguous to Northampton County and located to the east of Northampton County. ...”

The applicant is correct that Hertford County is contiguous to Northampton County. US Census Bureau data shows substantial similarities in the economic status of the two counties. The poverty level in Northampton County is the same as in Hertford County. The families living below the poverty level is 32.0% in Northampton County and 31.9% in Hertford County. The per capita income is \$30,694 in Northampton County and \$26,985 in Hertford County. Further, as of July 2011, the population of Northampton County was 22,150 and 25,016 in Hertford County. As of July 2009, the total Medicaid eligible population in Northampton County was 6,111 and was 6,310 in Hertford 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.

FMC East Northampton. 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	3.3%
Medicare	90.4%
Medicaid	4.5%
VA	1.3%
Other [Specify] Self/Indigent	0.6%
Total	100.0%

The applicant projects 94.9% of its in-center patients will have some or all of their care paid for by Medicare or Medicaid (90.4 percent Medicare plus 4.5 percent Medicaid). The applicant demonstrates that it will provide adequate access to medically underserved populations. Therefore, the application is conforming with this criterion.

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

C-Both Applicants

Northampton Dialysis. In Section VI.5, pages 52-53, the applicant describes the range of means by which patients will have access to the proposed services. The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity with this criterion.

FMC East Northampton. In Section VI.5, page 52, the applicant describes the range of means by which patients will have access to the proposed services. The information

provided in Section VI.5 is reasonable and credible and supports a finding of conformity with this criterion.

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

C-Both Applicants

Northampton Dialysis. In Section V.3(c), page 47, the applicant states that it sent a letter to the President of Halifax Community College. Exhibit 13 contains a copy of the letter to the President of Halifax Community College, which states “*We want to offer to extend our services as a clinical training site for nursing students of the community college once the facility is operational. ... We will offer the dialysis specific orientation to the nursing students. This will include observation, hands on opportunities in certain areas of treatment, interaction with the dialysis patients and the ability to prepare or initiate Care Plans under the supervision of a nursing instructor from the community college or a registered nurse at the facility.*” The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion.

FMC East Northampton. In Section V.3(a), page 45, the applicant states “*Exhibit 19 contains a letter from Anita Harris, FMC Director of Operations, inviting the Director of Nursing Education Services to consider the FMC East Northampton facility for inclusion in their clinical rotations. This letter also seeks to establish a formal agreement regarding a clinical rotation through FMC East Northampton center for the Health Occupations students.*” The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion.

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

NC- Northampton Dialysis C-FMC East Northampton

Northampton Dialysis. See Sections II, III, VI, VII, and X. The information provided in Section X does not adequately demonstrate that the proposed project would have a positive impact on the cost-effectiveness of the proposed services because the applicant does not adequately demonstrate that projected revenues and expenses are based on reasonable and

supported assumptions. Therefore the applicant does not adequately demonstrate that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. See Criterion (5) for additional discussion regarding projected revenues and operating costs.

Furthermore, the applicant does not adequately demonstrate that the proposed project would have a positive impact on the quality of the proposed services because the applicant does not adequately demonstrate that a Medical Director will be available for the proposed facility. See Criterion (7) for additional discussion regarding the availability of a Medical Director.

Therefore, the application is nonconforming with this criterion.

FMC East Northampton. See Sections II, III, VI, VII, and X. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the proposal would have a positive impact on cost-effectiveness, quality and access to the proposed services because:

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

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

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

NA – Northampton Dialysis
C-FMC East Northampton

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

FMC East Northampton. The applicant currently provides dialysis services in Northampton County. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, FMC East Northampton operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy within the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

NC- Northampton Dialysis
C- FMC East Northampton

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

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

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

.2202 INFORMATION REQUIRED OF APPLICANT

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

(1) *Utilization rates;*

-NA- **Northampton Dialysis**- The applicant proposes a new facility.

-C- **FMC East Hampton** - See Section III.2, pages 38-39, and the July 2011 SDR.

(2) *Mortality rates;*

-NA- **Northampton Dialysis**- The applicant proposes a new facility.

-C- **FMC East Northampton**- See Section II.I, page 10.

(3) *The number of patients that are home trained and the number of patients on home dialysis;*

-NA- **Northampton Dialysis**- The applicant proposes a new facility.

-C- **FMC East Northampton**- In Section II.I, page 10, the applicant states “*FMC East Northampton does not currently have a home training program. Patients desiring to perform home dialysis are referred to the BMA Roanoke*”

Rapids dialysis facility. BMA is proposing to add home dialysis to the facility by way of this application.”

(4) *The number of transplants performed or referred;*

-NA- **Northampton Dialysis**- The applicant proposes a new facility.

-C- **FMC East Northampton**- See Section II.I, page 10.

(5) *The number of patients currently on the transplant waiting list;*

-NA- **Northampton Dialysis**- The applicant proposes a new facility.

-C- **FMC East Northampton**- See Section II.I, page 10.

(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

-NA- **Northampton Dialysis**- The applicant proposes a new facility.

-C- **FMC East Northampton**- See Section II.I, pages 10-11.

(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*

-NA- **Northampton Dialysis**- The applicant proposes a new facility.

-C- **FMC East Northampton**- See Section II.I, page 11.

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

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

-C- **Northampton Dialysis**- Exhibit 7 contains a letter dated September 8, 2011 signed by the President of Albermarle Hospital stating that the hospital will enter into a Patient Transfer Agreement with the applicant when a Certificate of Need is issued. The letter describes the services that the hospital will provide to patients of the dialysis facility. In Section II, page 10, the applicant also states “*Northampton Dialysis will seek out other area hospitals, including Halifax Regional Medical Center, to establish patient transfer agreements once the Certificate of Need has been awarded.*”

-NA- **FMC East Northampton-** The applicant does not propose to develop a new facility.

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

(A) *timeframe for initial assessment and evaluation of patients for transplantation,*

(B) *composition of the assessment/evaluation team at the transplant center,*

(C) *method for periodic re-evaluation,*

(D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*

(E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-C- **Northampton Dialysis-** Exhibit 8 contains a letter dated September 6, 2011, signed by the Assistant Vice President of Carolinas Medical Center, stating that the hospital will enter into a Transplant Agreement with the applicant when a Certificate of Need is issued. The letter includes the requirements listed in (A-E) of this rule. In Section II, page 10, the applicant also states “*Northampton Dialysis will seek out other area transplant centers to establish transplant agreements once the Certificate of Need has been awarded.*”

-NA- **FMC East Northampton-** The applicant does not propose to develop a new facility.

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

-C- **Northampton Dialysis-** Exhibit 23 contains a letter dated September 13, 2011 from Dominion North Carolina Power stating that electrical service and capacity is available for both the proposed primary and secondary sites. In Section XI.5(f), page 75, the applicant states “*The site will be served by standing power service.*” In Section XI.6(e), page 75, the applicant states that “*The facility will be located in an area that is supplied by potable water. Exhibit 10 of the application describes the procedures that will be in place so that the facility will comply with 42 C.F.R. Section 405.2100. The facility will modify the existing water by providing for dechlorination, softening, reverse osmosis water systems combined with pyrogen filters for bacteria removal.*” Exhibit 23 contains a letter from the Northampton County Public Works Department confirming that there “*Water and Sewer available at Parcel # 0100307 [the secondary site].*” The applicant’s documentation is not as clear as it could be whether water and sewer is available at the proposed primary site. Therefore, the

analyst contacted Chris Wheeler, a public official with the Northampton County Public Works Department and confirmed that water and sewer are available at the primary site.

-NA- **FMC East Northampton-** The applicant does not propose to develop a new facility.

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

-C- **Northampton Dialysis-** In Section XI.5(f), page 75, the applicant states “*The facility will also have a backup generator on site. The facility will provide in its procedures for temporary power outages that sometimes occur during a treatment shift. This is done by resetting the machines, all which have a provision contained in their construction for hand rotation. This is considered adequate for temporary power outages. Exhibit 9 contains a copy of the policies and procedures for temporary power outages.*” Exhibit 9 also documents that the Ahoskie Dialysis Center will serve as the backup facility in case of loss of power.

-C- **FMC East Northampton-** See Section IX.6(f), page 73, Exhibit 12 and Exhibit 30.

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

-C- **Northampton Dialysis** – In Section XI.1, pages 71-73, the applicant describes the location of both the primary and secondary sites for the facility. Furthermore, in Section XI.2, page 71, the applicant states “*Attached as Exhibit 23 is a copy of a letter from R. Gregg Hill of RHGC Investments, LLC indicating his intent to negotiate the purchase of property and construct a shell building. Once the shell building is constructed, DVA Healthcare Renal Care will up-fit the shell building. This exhibit also contains a copy of the DaVita Minimum Base Building Improvements and the DaVita Inc. Standard Lease Agreement.*” Exhibit 23 also contains a written commitment from the applicant to pursue acquiring the sites and documentation that the primary and secondary sites are available for acquisition.

-NA- **FMC East Northampton-** The applicant does not propose to develop a new facility.

- (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- **Northampton Dialysis**– In Section XI.6(g), pages 75-76, the applicant states the dialysis center will operate in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements. In Section VII.2, page 56, the applicant indicates staffing will meet or exceed minimum requirements. See Exhibit 10 for the Water Culture Policy. Exhibit 26 contains a copy of the Injury Prevention and Safety Training Program. Exhibit 27 contains a copy of a sample of an in-service training calendar like the one that will be used at the facility.
- C- **FMC East Northampton**- See Section VII. 1-2, pages 54-55, and Section XI.6(g), page 73. The applicant does not propose to develop a new facility. The existing facility operated in conformity with Medicare Conditions of Participation during the 18 months immediately preceding the date of this decision.
- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- **Northampton Dialysis** –The information regarding patient origin and all of the assumptions and methodology are found in Section II, pages 11-28, and in Section III.7, pages 35-40. Note: in a table on page 35, the applicant states all patients will be residents of Harnett County. However, elsewhere throughout the application the applicant states all patients will be residents of Northampton County.
- NA- **FMC East Northampton**- See Section III.7, pages 36-39.
- (8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- C- **Northampton Dialysis** – In Section II.7, page 16, the applicant states that none of the patients projected to dialyze at Northampton Dialysis will have to drive more than 30 miles to the proposed facility.
- NA- **FMC East Northampton**- The applicant does not propose to develop a new facility.
- (9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*
- C- **Northampton Dialysis** – See Section II, page 17.

-C- **FMC East Northampton-** See Section VI.1(d), pages 50-51.

.2203 PERFORMANCE STANDARDS

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

-C- **Northampton Dialysis** – The applicant proposes to develop a ten-station dialysis facility and to serve 36 in-center patients by the end of the first year of operation, which is 3.6 patients per station per week. See Criterion (3) for additional discussion.

-NA- **FMC East Northampton-** The applicant does not propose to develop a new facility.

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

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

-C- **FMC East Northampton-** In Section III.7, pages 36-39, the applicant projects to serve 63 in-center patients or 3.31 patients per station per week [$63 / 19 = 3.31$] by the end of the first operating year of the additional stations.

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

-C- **Northampton Dialysis** – In Section II, pages 11-28 and in Section III.7, pages 35-40, the applicant provides the assumptions and methodology used to project utilization of the proposed new stations. See Criterion (3) for discussion.

-C- **FMC East Northampton-** In Section II, pages 12-21 and Section III.7, pages 36-39, the applicant provides the assumptions and methodology used to project utilization of the proposed additional stations. See Criterion (3) for discussion.

.2204 SCOPE OF SERVICES

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

(1) *diagnostic and evaluation services;*

-C- **Northampton Dialysis**- See Section V.1, page 45.

-C- **FMC East Northampton**- See Section V.1, page 43.

(2) *maintenance dialysis*;

-C- **Northampton Dialysis**- See Section V.1, page 45.

-C- **FMC East Northampton**- See Section V.1, page 43.

(3) *accessible self-care training*;

-C- **Northampton Dialysis**- See Section V.1, page 45.

-C- **FMC East Northampton**- See Section V.1, page 43.

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

-C- **Northampton Dialysis**- See Section V.1, page 45.

-C- **FMC East Northampton**- See Section V.1, page 43.

(5) *x-ray services*;

-C- **Northampton Dialysis**- See Section V.1, page 45.

-C- **FMC East Northampton**- See Section V.1, page 43.

(6) *laboratory services*;

-C- **Northampton Dialysis**- See Section V.1, page 45.

-C- **FMC East Northampton**- See Section V.1, page 43.

(7) *blood bank services*;

-C- **Northampton Dialysis**- See Section V.1, page 45.

-C- **FMC East Northampton**- See Section V.1, page 43.

(8) *emergency care*;

-C- **Northampton Dialysis**- See Section V.1, page 45.

-C- **FMC East Northampton**- See Section V.1, page 43.

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

-C- **Northampton Dialysis**- See Section V.1, page 45.

-C- **FMC East Northampton**- See Section V.1, page 43.

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

-C- **Northampton Dialysis**- See Section V.1, page 45.

-C- **FMC East Northampton**- See Section V.1, page 43.

(11) *transplantation services;*

-C- **Northampton Dialysis**- See Section V.1, page 45.

-C- **FMC East Northampton**- See Section V.1, page 43.

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

-C- **Northampton Dialysis**- See Section V.1, page 45.

-C- **FMC East Northampton**- See Section V.1, page 43.

(13) *transportation.*

-C- **Northampton Dialysis**- See Section V.1, page 45.

-C- **FMC East Northampton**- See Section V.1, page 43.

.2205 STAFFING AND STAFF TRAINING

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

-NC- **Northampton Dialysis**- See Section VII.1-2, pages 55-57, and Section VII.10, page 58. In Section V.4, page 47, the applicant states “*Dr. Brandspigel has agreed to serve as the Medical Director of the facility. See Exhibit 14 for a letter from Dr. Brandspigel.*” However, Exhibit 14 does not contain documentation that shows that Dr. Brandspigel has agreed to serve as Medical Director. The applicant does not adequately demonstrate that a Medical Director will be available for the proposed facility.

-C- **FMC East Northampton**- See Section VII.1 & 2, pages 54-55, and Section VII.10, page 56.

(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- **Northampton Dialysis**- See Section VII.5, page 57, and Exhibit 19.

-C- **FMC East Northampton**- See Section VII.5, page 55, and Exhibits 14 and 15.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the need determination in the 2011 SMFP and the July 2011 SDR, no more than 10 new dialysis stations may be approved in this review for Northampton County. Because the two applications in this review propose a total of 13 dialysis stations, both of the applications cannot be approved. The analyst considered all of the information in each application and reviewed each application individually against all applicable review criteria and the analyst conducted a comparative analysis of the proposals.

Based on that review and for the reasons set forth below and in the rest of the findings, the application submitted by FMC East Northampton, Project ID # L-8753-11, is approved and the application submitted by Northampton Dialysis, Project ID # L-8750-11, is denied.

SMFP Principles

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

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

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

a) Home Training

Northampton Dialysis. In Section II.1, page 29, the applicant states *“Northampton Dialysis will provide the necessary resources for a follow-up program for support of patients dialyzing at home who have been trained in peritoneal dialysis. Patients on home hemodialysis will be trained at the Elizabeth City facility.”* In Section V.2 (d), page 46, the applicant states *“Northampton Dialysis will provide home training in peritoneal dialysis services and follow-up. ... Elizabeth City Dialysis Center will provide the same accessible follow-up program for patients on home hemodialysis.”* Elizabeth City is approximately 88 miles or almost 2 hours one way from Garysburg.

FMC East Northampton Dialysis. In Section II.1, page 22, the applicant states *“Patients desiring self-care training will be referred to the facility home training department for training and follow-up care.”* In Section V.2(d), page 44, the applicant states *“Patients who desire to perform home dialysis will be trained and followed by the facility Home Training Clinic. ... FMC East Northampton will provide back-up hemo-dialysis treatments to any home patient in need of temporary hemo-dialysis. Home patients will receive benefit from the services offered to home patients by the FMC East Northampton facility. These services include home visitation, assistance with problems that patients that have 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.”

With respect to home training, the **FMC East Northampton** application is the more effective alternative since it proposes to offer both home training for hemodialysis and peritoneal dialysis, including follow-up. Northampton Dialysis only proposes home training for peritoneal dialysis. Northampton Dialysis patients who qualify for and desire home hemodialysis training and follow-up would have to travel to Elizabeth City, an 88-mile one way trip from the Northampton facility. Moreover, the Northampton Dialysis application is not approvable standing alone.

b) Hours of Availability

Northampton Dialysis – In Section VII.10, page 58, the applicant states dialysis services will be available from 6:00 AM to 4:00 PM, Monday through Saturday. Northampton Dialysis Center does not propose a third shift.

FMC East Northampton – In Section VII.10, page 56, the applicant states dialysis services will be available from 7:00 AM to 5:00 PM, Monday through Saturday. FMC East Northampton does not currently operate a third shift nor does it propose a third shift.

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

c) Services in rural, remote areas

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

Facility Location

FMC East Northampton is an existing facility located on the eastern side of Northampton County in Conway. It is the only kidney disease treatment center in Northampton County. The proposed location for **Northampton Dialysis** is on the western side of Northampton County at the intersection of I-95 and N.C. 46 in Garysburg.

According to MapQuest, Garysburg is approximately 8.25 miles from Roanoke Rapids, 2.92 miles from Weldon and 22.85 miles from Conway. Conway is approximately 31 miles from Roanoke Rapids and 25.44 miles from Weldon. There are advantages and disadvantages to both locations. There is no kidney disease treatment center in western Northampton County. However, Bio-Medical Applications of North Carolina also has two dialysis facilities just over the county line in Halifax County. One is an existing dialysis facility in Roanoke Rapids. The second is an approved but undeveloped facility in Weldon. Both of these locations are easily accessible to residents of the western side of Northampton County (i.e.

Garysburg). The existing facility in Conway is more than 25 miles from the Halifax County facilities. With regard to location, both applications are equally effective alternatives. However, the Northampton Dialysis application is not approvable standing alone.

Access by Underserved Groups

Northampton Dialysis – In Section VI.1, page 51, the applicant states that 89.2% of its in-center patients will have some or all of their services covered by Medicare or Medicaid.

FMC East Northampton– In Section VI.1, page 41, the applicant states that 94.9% of its in-center patients will have some or all of their services covered by Medicare or Medicaid.

FMC East Northampton proposes the highest percentage of patients to have some or all of their services paid for by Medicare or Medicaid. Therefore, the **FMC East Northampton** application is the more effective alternative with regard to access by underserved groups. Moreover, the Northampton Dialysis application is not approvable standing alone.

Access to Ancillary and Support Services

Northampton Dialysis states in Section V.1-2, pages 45-46, and Exhibit 7, that Acute Dialysis; Emergency Services; Diagnostic Evaluation Services; X-Ray Services; Special, Immunological and Routine Laboratory Services; Blood Banking Services; and Surgical Services including Vascular Surgery will be available at Albemarle Hospital in Elizabeth City. According to MapQuest, Albemarle Hospital is located approximately 88 miles (almost 2 hours driving time) from the location of the proposed Northampton Dialysis facility. In addition, the applicant states that home hemodialysis training and follow-up will be provided at Elizabeth City Dialysis Center. Furthermore, the office of the proposed Medical Director is located in Elizabeth City. Moreover, he does not indicate in his letter of support that he intends to serve as Medical Director for the proposed Northampton Dialysis facility. See Criterion (7) for additional discussion.

FMC East Northampton provides a copy of an Acute Care/Hospital Affiliation Agreement with Halifax Memorial Hospital which is located in Roanoke Rapids. According to MapQuest, Roanoke Rapids is approximately 31 miles from Conway where the FMC East Northampton facility is located. In addition, the applicant states that training for home hemodialysis and peritoneal dialysis, including follow-up, will be provided at the FMC East Northampton facility. On page 44, the applicant states *“Home patients will receive the benefit from services offered to home patients by the FMC East Northampton facility. These services include home visitation, assistance with problems that patients have with catheters, diagnosis of infections and assistance with placing orders of needed supplies.”* Furthermore, the office of the current Medical Director is located in Roanoke Rapids and the applicant adequately documents he intends to continue to serve as Medical Director.

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

Service to Northampton County Residents

FMC East Northampton currently serves 49 in-center dialysis patients who are Northampton County residents. The nephrologists currently serving these patients will continue to do so. On the other hand, Northampton Dialysis does not currently operate an in-center dialysis facility in Northampton County. Northampton Dialysis patients are proposed to be served by nephrologists associated with Albermarle Nephrology located in Elizabeth City in Pasquotank County. The same nephrologists currently serve the Elizabeth City Dialysis Center, Edenton Dialysis Center and Ahoskie Dialysis Center. With regard to service to Northampton County patients, the proposed project submitted by FMC East Northampton is the more effective alternative.

Access to Alternative Providers

Fresenius Medical Care Holdings, Inc. (“Fresenius”) the ultimate parent company of FMC East Northampton operates the only dialysis facility in Northampton County. Fresenius also has two existing dialysis facilities in Halifax County as well as an approved but undeveloped dialysis facility in Halifax County which is contiguous to Northampton County. Furthermore, Fresenius also has the only dialysis facility in Bertie County which is also contiguous to Northampton County. DaVita, the ultimate parent company of Northampton Dialysis, has the only dialysis facility in Ahoskie in Hertford County which is also contiguous to Northampton County. Therefore, with regard to providing dialysis patients access to an alternative provider, the proposal submitted by Northampton Dialysis is the more effective alternative. However, the Northampton Dialysis application is not approvable standing alone.

Revenues and Operating Costs

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

Net Revenue

NORTHAMPTON DIALYSIS	YEAR ONE	YEAR TWO
Projected Net Revenue	\$1,355,034	\$1,835,454
# Dialysis Treatments	4,212	5,706
Average Net Revenue per Treatment	\$321.71	\$321.67

FMC EAST NORTHAMPTON	YEAR ONE	YEAR TWO
Projected Net Revenue	\$2,433,359	\$2,538,151
# Dialysis Treatments	9,043	9,189
Average Net Revenue per Treatment	\$269.09	\$276.22

FMC East Northampton projects the lowest average net revenue per treatment. Moreover, the average net revenues per treatment for Northampton Dialysis are not reliable to the extent they are based on the projected number of treatments. In Section X, Northampton Dialysis provides inconsistent and unclear information regarding the number of projected treatments which are used to calculate revenues and operating costs. See Criterion (5) for additional

discussion. Thus, Northampton Dialysis' average net revenue per treatment is questionable. The application submitted by **FMC East Northampton** is the more effective alternative with regard to average net revenue per treatment. Moreover, the Northampton Dialysis application is not approvable standing alone.

Operating Costs

NORTHAMPTON DIALYSIS	YEAR ONE	YEAR TWO
Projected Operating Costs	\$1,493,628	\$1,781,615
# Dialysis Treatments*	4,212	5,706
Average Cost per Treatment	\$354.61	\$312.24

FMC EAST NORTHAMPTON	YEAR ONE	YEAR TWO
Projected Operating Costs	\$2,392,899	\$2,503,749
# Dialysis Treatments*	9,043	9,189
Average Cost per Treatment	\$264.61	\$272.47

*Includes home dialysis treatments.

FMC East Northampton projects the lowest average cost per treatment. Moreover, the average costs per treatment for Northampton Dialysis are not reliable to the extent they are based on the projected number of treatments. In Section X, Northampton Dialysis provides inconsistent and unclear information regarding the number of treatments which are used to calculate revenues and operating costs. See Criterion (5) for additional discussion. Thus, Northampton Dialysis' average cost per treatment is questionable. The application submitted by **FMC East Northampton** is the more effective alternative with regard to average operating costs per treatment. Moreover, the Northampton Dialysis application is not approvable standing alone.

Staffing

Direct Care Staff Salaries

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

POSITION	NORTHAMPTON DIALYSIS	FMC EAST NORTHAMPTON
Registered Nurse	\$52,000	\$53,839
Technician	\$26,000	\$22,924

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

Availability of Staff

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

FMC East Northampton adequately demonstrates it will have a Medical Director. However, Northampton Dialysis did not adequately demonstrate that it would have a Medical Director. See Criterion (7) for discussion. Therefore, the FMC East Northampton application is the more effective alternative with regard to availability of staff. Moreover, the Northampton Dialysis application is not approvable standing alone.

SUMMARY

FMC East Northampton

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

- Adequately demonstrates that the financial feasibility of the proposal is based upon reasonable and supported projections of revenues and operating costs. See Criterion (5) for discussion.
- Adequately demonstrates the availability of a Medical Director. See Criterion (7) for discussion.
- Projects a higher percentage of total services to be provided to Medicare and Medicaid recipients.
- Projects a lower average cost per treatment.
- Projects a lower average net revenue per treatment.
- Proposes to provide training for both home hemodialysis and peritoneal dialysis including follow-up on site.
- Proposes more effective access to ancillary and support services.

Northampton Dialysis

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

- Does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable and supported projections of revenues and operating costs. See Criterion (5) for discussion.
- Does not adequately demonstrate the availability of a Medical Director. See Criterion (7) for discussion.
- Projects a lower percentage of total services to be provided to Medicare and Medicaid recipients.
- Projects a higher average net revenue per treatment. Moreover, the average is questionable. See Criterion (5) for discussion.

- Projects a higher average cost per treatment. Moreover, the average is questionable. See Criterion (5) for discussion.
- Proposes to provide only training for home peritoneal dialysis including follow-up on site. Training for home hemodialysis including follow-up and training would be available in Elizabeth City, an 88 mile trip one way from the proposed facility in Garysburg.
- Proposes less effective access to ancillary and support services.

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 East Northampton is the most effective alternative proposed in this review for 10 dialysis stations in Northampton County and that application is approved as conditioned below. The approval of the other application would result in the approval of dialysis stations in Northampton County in excess of the county need determination in the SMFP and July 2011 SDR and therefore, the Northampton Dialysis application is denied.

The application submitted by FMC East Northampton is approved subject to the following conditions.

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC East Northampton shall materially comply with all representations made in its certificate of need application.**
- 2. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC East Northampton shall add no more than 3 dialysis stations and be certified for no more than 19 dialysis stations, which shall include any home hemodialysis and isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC East Northampton shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations for a total of no more than 19 stations, which shall include any home hemodialysis and isolation stations.**
- 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC East Northampton 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.**