

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: January 29, 2013

PROJECT ANALYST: Tanya S. Rupp

CON CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: M-10049-12 / Bio-Medical Applications of Clinton, Inc. d/b/a BMA Clinton / Add three in-center dialysis stations for a facility total of 36 in-center dialysis stations upon project completion / Sampson County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of Clinton, Inc. d/b/a BMA Clinton proposes to add three (3) in-center dialysis stations to the existing facility for a facility total of 36 in-center dialysis stations upon completion of this project.

The 2012 State Medical Facilities Plan (2012 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2012 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional dialysis facility or for any additional dialysis stations in Sampson County.

However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. In this application, BMA Clinton is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate reported in the July 2012 SDR is 3.35 patients per station, or 84%. This utilization rate was calculated based on 131 in-center dialysis patients and 39 certified dialysis stations as of December 31, 2011 (131 patients / 39 stations = 3.35 patients per station).

However, according to the information that was available to the applicant, as reported in the July 2012 SDR, there were 39 in-center dialysis stations at BMA of Clinton. Therefore, the project analyst prepared a table that reflects the facility need for additional dialysis stations based on 39 in-center dialysis stations at BMA of Clinton, as shown below:

October 1 REVIEW		
Required SDR Utilization		80%
In-Center Utilization Rate as of 12/31/11		98.0%
Certified Stations		39
Pending Stations	(1 certified on 3/15/12)	4
Total Existing and Pending Stations		43
In-Center Patients as of 12/31/11 (SDR2)		131
In-Center Patients as of 6/30/11(SDR1)		124
Difference (SDR2 - SDR1)		7
Step	Description	
(i)	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/10	0.1129
(ii)	Divide the result of step (i) by 12	0.0094
(iii)	Multiply the result of step (ii) by the number of months from the most recent month reported in the January 2012 SDR (6/30/11) until the end of calendar year 2011(6 months)	0.1129
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	145.7903
(v)	Divide the result of step (iv) by 3.2 patients per station	45.5595
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	7

Step (C) of the facility need methodology states, *“The facility may apply to expand to meet the need established, [...] up to a maximum of ten stations.”* As shown in the table above, based on the facility need methodology for dialysis stations, and based on the number of certified dialysis stations in Sampson County, the BMA Clinton facility has a need for seven additional stations. The applicant proposes to add three new stations and, therefore, the application is consistent with the facility need determination for dialysis stations.

Following is a table which illustrates the pending projects in Sampson County:

**BMA ESRD CON Projects Sampson County as of December 31, 2011
 (Date of Data Collection for July 2012 SDR)**

PROJECT ID #	FACILITY	# STATIONS AT TIME OF APPLICATION	# STATIONS ADDED	# STATIONS DELETED	FINAL # STATIONS AT BMA CLINTON
Begin with 39 Certified In-Center Dialysis Stations (Project ID #M-6053-99)					
M-8258-08	Establish FMC of Roseboro	0	10		29
M-8293-09	BMA of Clinton	29	1	0	30
M-8648-11	BMA of Clinton	30	3	0	33

According to the July 2012 SDR, which reports data taken on December 31, 2011, BMA Clinton had 39 in-center dialysis stations. The 10-station FMC of Roseboro facility (Project ID#M-8258-08) was certified on March 5, 2012. Similarly, Project ID #M-8293-09 was certified on March 12, 2012. Project ID#M-8648-11 is not yet complete.

Thus, at the completion of the above three project, BMA of Clinton will have 33 in-center dialysis stations as reflected in this application. However, BMA of Clinton was certified for 39 in-center dialysis stations when the data for the North Carolina dialysis facilities was compiled on December 31, 2011. [The July 2012 SDR shows that BMA of Clinton was certified for 39 in-center dialysis stations on December 31, 2011, but was certified for only 33 in-center dialysis stations as of June 25, 2012.] Therefore, upon completion of all of the projects, including the project in this application, BMA of Clinton would be certified for 36 in-center dialysis stations.

Policy GEN-3 in the 2012 SMFP is also applicable to this review. 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.”

Promote Safety and Quality

In Section II.1, page 21, the applicant states:

“BMA is a high quality health care provider. 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.”

On page 22, the applicant provides more detailed information about UltraCare. The applicant states,

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

There are six underlying elements of UltraCare:

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

Every year since its launch in 2004, FMCNA staff participates in various supplementary training courses designed to incorporate these underlying elements into their work lives. In addition to professional certifications and regular training in their respective responsibilities, all employees engaged in patient care must achieve annual re-certification related to their UltraCare training. New employees participate in specialized Destination UltraCare training to ensure the mission is pervasive throughout our corporate culture.”

In addition, in Exhibit 13, the applicant provides a copy of Fresenius Medical Care’s Quality Improvement policies and procedures. Exhibit 11 contains a copy of BMA’s policy with regard to water quality in its facilities. The applicant adequately demonstrates how its proposal will promote safety and quality in the provision of dialysis services in Sampson County.

Promote Equitable Access

In Section II.1, pages 22 - 23, the applicant states,

“BMA has removed the economic barriers with regard to access to treatment. The overwhelming majority of dialysis treatments are covered by Medicare / Medicaid; in fact, within this application, BMA is projecting that 87.2% of the In-Center dialysis treatments will be covered by Medicare or Medicaid; an additional 8.4% are expected to be covered by VA. Thus, 95.6% of the In-Center revenue is derived from government payors. These projections reflect the current payor mix at BMA Clinton.

...

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. At this time, Sampson County has two operational dialysis facilities. The July 2012 SDR reports that Sampson County ESRD patient population is growing at an Average Annual Change Rate of 3.0%. As the dialysis patient population of Sampson County continues to increase, the need for

dialysis stations will continue to increase. ... BMA is planning to add three stations so that an adequate supply of necessary health resources remains in closer proximity to the residence location of patients residing in this area of Sampson County.”

In addition, in Section VI.1, page 46, the applicant states that in FY 2011, 79.7% of BMA North Carolina dialysis patients had some or all of their treatments paid for by Medicare. 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.”

The applicant adequately demonstrates how its proposal will promote access to medically underserved groups.

Maximize Healthcare Value

In Section XI, page 69, the applicant states,

“BMA is not projecting a capital expenditure for this project. BMA is able to do this project at no cost because the space was vacated by the stations which transferred to FMC Roseboro is available for use. In projects which do involve capital expenditure BMA does not seek State or Federal monies to accomplish routine expansions or relocations; BMA does not seek charitable contributions to accomplish expansions. Rather, BMA, through its parent company, FMC assumes the financial burden to complete addition of stations in an effort to ensure an adequate number of stations are available for the patients choosing to dialyze at BMA Clinton. As an additional consideration, BMA notes that the overwhelming majority of dialysis treatments are reimbursed through Medicare, Medicaid, or other government payor sources. ... The point here is that government payors are working from a fixed payment schedule, often at significantly lower reimbursement rates than the posted charges. As a consequence, BMA must work diligently to control costs of delivery for dialysis. BMA does.”

In addition, in Section XI, page 66, the applicant states,

“Methods, [sic] which BMA of North Carolina dialysis facilities utilize to maintain efficient energy operations and, therefore, contain utility costs, are as follows:

HVAC System

- 1. The operating efficiency will current industry standards for high Energy Efficient Rating [sic].*
- 2. Systems are controlled via 7 day, 24 hour set back time clock,*
- 3. Systems are maintained and serviced quarterly along with air filter replacement.*

ENERGY CONSERVATION MEASURES

1. *Energy efficient exit signs,*
2. *Water flow restrictors at sink faucets,*
3. *Water conserving flush toilets,*
4. *Optical sensor water switches*
5. *External insulation wrap for hot water heaters*

WATER TREATMENT EQUIPMENT

1. *A percentage of the concentrate water is re-circulated into supply feed water, therefore, [sic] lowering the quantity of water discharged in the drain,*
2. *Water treatment equipment electric motors are three phase, which run cooler and draw less amperage.”*

The applicant adequately demonstrates how its proposal will maximize healthcare value. Additionally, the applicant demonstrates projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. See Criteria (3) and (13c) for additional discussion.

SMFP Policy GEN-4, regarding Energy Efficiency and Sustainability for Health Service Facilities is not applicable in this review because there is no projected capital cost for the project.

In summary, the application is consistent with Policy GEN-3, and the application is conforming to this criterion.

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

C

Bio-Medical Applications of Clinton, Inc. d/b/a BMA Clinton proposes to add three in-center dialysis stations to the existing facility, pursuant to a Facility Need Determination, for a facility total of 36 stations upon completion of this project.

Population to be Served

In Section III.7, page 34 of the application, the applicant projects the following payor mix:

COUNTY	OPERATING YEAR 1	OPERATING YEAR 2	COUNTY PATIENTS AS	
	CY 2014	CY 2015	PERCENT OF TOTAL	
	IN-CENTER	IN-CENTER	YEAR 1	YEAR 1

	PATIENTS	PATIENTS		
Sampson	114	117	98.3%	98.3%
Bladen	1	1	0.9%	0.9%
Duplin	1	1	0.9%	0.9%
Total	116	119	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section II, pages 13 – 14, 15 - 18, and in Section III.7, pages 34 - 35, the applicant provides the assumptions and methodology it used to project its need for three additional dialysis stations at the BMA Clinton facility. Specifically, on page 34, the applicant states,

“This project is scheduled for completion December 31, 2013. Thus Operating Year 1 is the period from January 1, 2014 through December 31, 2014; Operating Year 2 is the period from January 1, 2015 through December 31, 2015.

The following, from the Section II discussion regarding 10A NCAC 14C .2203(b) is reprinted here for ease of the Project Analyst.

...

...BMA Clinton is serving two patients from Bladen and Duplin Counties. BMA assumes that the patient population of BMA Clinton will be comprised primarily of patients from Sampson County; the patients from Bladen and Duplin counties are projected to continue dialysis at BMA Clinton as a function of patient choice. Within this application, BMA projects the Sampson County ESRD patient population to continue to grow commensurate with the Sampson County Five Year Average Annual Change Rate as published in the July 2012 SDR; that rate is 3.0%. BMA will not project any increase in the Bladen and Duplin County patient population.”

On page 35, the applicant provides a table to illustrate the projected population for the BMA Clinton facility. See the following table:

BMA begins with the patients residing in Sampson County as of July 1, 2012	106
--	-----

Project forward for six months to December 31, 2012. Growth is calculated at one-half of the Sampson County Five Year AACR. ¹	106 x 1.015 = 107.6
Project forward for 12 months to December 31, 2013.	107.6 x 1.03 = 110.8
Add two patients from Bladen and Duplin Counties. This is beginning census for the project.	110.8 + 2 = 112.8
Sampson County patients projected forward 12 months to December 31, 2014.	110.8 x 1.03 = 114.1
Add two patients from Bladen and Duplin Counties. This is census for end of Operating Year 1.	114.1 + 2 = 116.1
Sampson County patients projected forward 12 months to December 31, 2015.	114.1 x 1.03 = 117.6
Add two patients from Bladen and Duplin Counties. This is census for end of Operating Year 2.	117.6 + 2 = 119.6

Therefore, in Operating Year one, the applicant projects to serve 116 in-center patients on 36 stations, which is 3.2 patients per station, or 80.5% utilization [$116 / 36 = 3.22$; $3.22 / 4 = 0.805$]. Likewise, in Operating Year two, the applicant projects to serve 119 in-center patients on 36 stations, which is 3.30 patients per station, or 82.6% utilization [$119 / 36 = 3.30$; $3.30 / 4 = 0.826$]. In the first operating year, the applicant projects to serve at least 3.2 patients per station per day, as required by 10A NCAC 14C .2203(b). The applicant's assumptions are based on historical utilization in the BMA Clinton facility, and the 3.0% Five Year AACR in Sampson County. Furthermore, the assumptions are based on projected growth of only Sampson County patients, to which the applicant then added the remaining patients who currently receive dialysis services at BMA Clinton, but who reside in a county other than Sampson. It is possible that additional patients from those other counties could also choose to dialyze at BMA Clinton, and thus the patient census from outside Sampson County could grow; however, since growth projections include only Sampson County residents, the numbers are conservative and reasonable. Therefore, projected utilization is based on reasonable and supported assumptions regarding continued growth in the BMA Clinton facility.

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need for the three additional dialysis stations at the BMA Clinton facility. Consequently, 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

¹ Average Annual Change Rate, as identified in the July, 2012 Semi Annual Dialysis Report.

- (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.

CA

The applicant proposes to add three in-center dialysis stations to its existing facility, for a facility total of 36 in-center dialysis stations following project completion. In Section III.9, page 36, the applicant states that it considered different alternatives before proposing this project, which include not applying for any stations at the facility, and applying for fewer dialysis stations. The applicant adequately explains why it chose the selected alternative over the other alternatives. Furthermore, the application is conforming to all other applicable statutory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a) and (20) for additional discussion. Therefore, the applicant adequately demonstrates that the selected proposal is its least costly or most effective alternative to meet the identified facility need for three dialysis stations at BMA Clinton. Consequently, the application is conforming to this criterion and is approved subject to the following conditions:

1. **Bio-Medical Applications of Clinton, Inc. d/b/a BMA Clinton shall materially comply with all representations made in its certificate of need application.**
 2. **Bio-Medical Applications of Clinton, Inc. d/b/a BMA Clinton shall develop and operate no more than three additional dialysis stations for a total of 36 certified stations which shall include any home hemodialysis training or isolation stations.**
 3. **Bio-Medical Applications of Clinton, Inc. d/b/a BMA Clinton shall install plumbing and electrical wiring through the walls for three additional dialysis stations for a total of 36 dialysis stations which shall include any isolation stations.**
 4. **Bio-Medical Applications of Clinton, Inc. d/b/a BMA Clinton shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**
 5. **Bio-Medical Applications of Clinton, Inc. d/b/a BMA Clinton 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.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VII, pages 55 – 56, the applicant states there are no capital costs or start-up or operating costs associated with this project, since dialysis machines are leased. In Section IX, page 58, the applicant further states that there will be no start-up or initial operating expenses associated with the proposed project.

Exhibit 24 includes a letter dated September 17, 2012 from the Vice President of Fresenius Medical Care Holdings, Inc., which states in part:

“BMA is submitting a Certificate of Need Application to add three dialysis stations to the existing facility for a facility total of 36 stations upon completion of this project. The project does not require any capital expense on behalf of BMA.”

In Exhibit 10, the applicant provides the audited financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ended December 31, 2010 and 2011. As of December 31, 2011, Fresenius Medical Care Holdings, Inc. and Subsidiaries had cash and cash equivalents totaling \$204,142,000 with \$13,864,539 in total assets and \$8,388,027 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds, if required, for the proposed project.

The Medicare/Medicaid rates in Section X.1 of the application are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. The applicant projects net revenue on page 60, in Section X.2 of the application. The applicant projects operating expenses on page 63, in Section X.4 of the application. The applicant projects revenue in excess of expenses in each of the first two operating years following completion of the project, as illustrated in the table below.

	PROJECT YEAR 1	PROJECT YEAR 2
Net Revenue	\$4,332,932	\$4,453,040
Operating Expenses	\$4,284,610	\$4,416,224
Profit	\$ 48,332	\$ 36,816

*Source: Application pages 60 and 63.

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

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

C

Bio-Medical Applications of Clinton, Inc. d/b/a BMA Clinton BMA proposes to add three in-center dialysis stations to the existing BMA Clinton dialysis facility, located in Central Sampson County, based on the facility need methodology found on page 366 of the 2012

SMFP. This methodology provides a basis for demonstrating a need for additional dialysis stations in facilities in which the County Need methodology does not show a need, but the current utilization is 3.2 patients per station or greater. The July 2012 SDR shows that, as of June 25, 2012, the BMA Clinton facility had a utilization rate of 83.9%, based on 3.35 patients per station [131 patients / 39 stations = 3.35], based on a schedule of two shifts per day, six days per week. The applicant adequately demonstrates that the 36 in-center dialysis stations will be utilized at an 83.0% utilization rate in the second year of operation, based on 119 patients [119 / 36 = 3.35 patients per station per week]. This utilization projection is based on the Five Year Average Annual Change Rate (AACR) in Clinton County which has been 3.0% for the past five years, as published in the North Carolina State Health Coordinating Council's July 2012 Semi Annual Dialysis Report. The applicant adequately demonstrates the need to add three dialysis stations to the existing facility for a total of 36 stations upon completion of these three projects. BMA Clinton is the only provider of dialysis services in Sampson County. In addition, the applicant reports that the FMC Roseboro facility was dialyzing 28 patients on 10 in-center stations as of January 11, 2013, for a utilization rate of 2.8%. That facility was certified on March 5, 2012 and is still in its first operating year. Therefore, the applicant adequately demonstrates that the proposed project will not result in the unnecessary duplication of existing or approved dialysis facilities in Sampson County, and the application is conforming to this criterion.

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

C

In Section VII.1, page 51, the applicant provides current and projected staffing for the BMA Clinton facility following the addition of three stations, as illustrated in the following table:

POSITION	CURRENT FTES	# OF FTE POSITIONS TO ADD	# FTE POSITIONS TO ELIMINATE	TOTAL FTE POSITIONS
RN	5.75	0	0	5.75
Technician	13.00	0	0	13.00
Clinical Manager	1.00	0	0	1.00
Administrative	0.20	0	0	0.20
Social Worker	1.00	0	0	1.00
Dietician	0.75	0	0	0.75
Medical Records	1.00	0	0	1.00
Chief Technician	0.50	0	0	0.50
Equipment Technician	3.00	0	2.00	1.00
In-Service	0.40	0	0	0.40
Clerical	1.00	0	0	1.00
Totals	27.6	0	2.00	25.6

In Section V.4(c), page 43, the applicant states that Dr. Emily Sun currently serves as medical director of the BMA Clinton facility. In Exhibit 21 the applicant provides an August 3, 2012 letter from Dr. Sun supporting the proposed addition of three dialysis stations and confirming her commitment to continue in her role as medical director of the facility. The information provided

in Section VII and in the pro forma financial statements regarding projected staffing is reasonable and credible and supports a finding of conformity to this criterion.

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

C

In Section V.1, page 39, the applicant states that Sampson Regional Medical Center and Sampson Outpatient Diagnostics will provide ancillary and support services to BMA Clinton, including diagnostic and emergency services. In addition, the applicant states Cape Fear Valley Medical Center will provide blood bank services and SPECTRA Labs will provide laboratory services. Furthermore, the applicant states that Wayne Memorial Hospital will also provide additional ancillary and support services, including acute dialysis in an acute care setting and laboratory services. The applicant states transportation services will be provided by Sampson County Social Services Enroute, and by Sampson County Department of Aging. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

- (11) Repealed effective July 1, 1987.

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

NA

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

C

In Section VI.1(a), page 46, the applicant provides a table showing the current patient population at BMA Clinton, as reproduced in the table below:

FACILITY	MEDICAID / LOW INCOME	ELDERLY (65 +)	MEDICARE	WOMEN	RACIAL MINORITIES
BMA Clinton	52.8%	50.9%	98.2%	52.8%	93.5%

In Section VI.1, page 46, the applicant states:

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. ... Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

...

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

In addition, in Section VI.1(d), page 47, the applicant provides the current in-center dialysis payor mix at BMA Clinton, as shown in the table below:

BMA CLINTON PAYOR SOURCE	PERCENT OF TOTAL
Commercial Insurance	4.3%
Medicare	82.0%
Medicaid	5.2%
VA	8.4%
Other (Self/indigent)	0.2%
Total	100.0%

Furthermore, in Section VI.1, page 46, the applicant states “...*Medicare represented 79.7% of North Carolina Dialysis treatments in BMA facilities in FY 2011. Medicaid treatments represented an additional 4.8% of treatments in BMA facilities for FY 2011.*” In Section VI.1(e), page 48, the applicant states it defines uncollectible accounts as ‘Bad Debt’ and states BMA Clinton provided for \$455,319 in bad debt in FY 2011.

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 Calendar Year 2008 – 2009 respectively. The data in the table was obtained on January 5, 2013. More current data, particularly with regard to the estimated uninsured percentages, was not available.

COUNTY	TOTAL # MEDICAID ELIGIBLES AS % OF TOTAL POPULATION JUNE 2010	TOTAL # MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION JUNE 2010	% UNINSURED CY 2008 - 09 (ESTIMATE BY CECIL G. SHEPS CENTER)
Sampson	25.0%	10.1%	24.0%
Statewide	17.0%	6.7%	19.7%

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

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

In addition, the Centers for Medicare & Medicaid Services (CMS) website states:

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

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.”²

Additionally, the United States Renal Data System, in its *2011 USRDS Annual Data Report* shows the following statistics for FY 2009 in Network 6, which includes North Carolina, South Carolina, and Georgia:

**Percent of Dialysis Patients by Race/
 Ethnicity**

RACIAL GROUP	% OF DIALYSIS POPULATION
White/Caucasian	30.5%
African American	67.2%
Native American	0.6%
Asian	1.1%
Hispanic	2.6%

Percent of Dialysis Patients by Age

AGE GROUP	% OF DIALYSIS POPULATION
0 – 19	0.35%
20 – 44	13.4%
45 – 64	41.6%
65 – 74	22.8%
75 +	21.8%

Further data from that report also provides national statistics:

“On December 31, 2009, more than 362,000 ESRD patients were receiving hemodialysis therapy....

² See, for example: www.cms.gov; www.medpac.gov

Nine in ten prevalent hemodialysis patients had some type of Medicare coverage in 2009, with 40 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2009 reaching 10.8 and 10.2 percent for hemodialysis and peritoneal dialysis patients, respectfully.”

Based on the historical utilization data provided by the applicant, based on the information from CMS, and based on the projections provided by the applicant, the applicant demonstrates that it provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.1(f), page 48, the applicant states

“BMA of Clinton does not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will continue to treat all patients the same regardless of race or handicap status. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, BMA Clinton is obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans With Disabilities Act.

Thus, the applicant shows that minorities and handicapped persons will continue to have access to dialysis services at BMA Clinton following the addition of three stations. In Section VI.6, page 50, the applicant states there have been no civil rights equal access complaints or violations filed against BMA Clinton in the last five years. The application is conforming to this criterion.

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

C

In Sections VI.1(c), page 47, the applicant projects the following payor mix at BMA Clinton, based on its historical payor mix:

SOURCE OF PAYMENT	PERCENT
Commercial Insurance	4.3%
Medicare	82.0%
Medicaid	5.2%
VA	8.4%
Other (Self/indigent]	0.2%
Total	100.0%

In Section VI.1(d), page 48, the applicant states “BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.” [emphasis in original] The applicant demonstrates it will provide adequate access to medically underserved groups. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5(b), page 49 of the application, the applicant states that all patients in need of dialysis treatment will be admitted to BMA Clinton through one of the staff Nephrologists. In addition, the applicant states referrals will also come from Cape Fear Valley³, as well as practicing physicians in the area. In Exhibit 16 the applicant provides a copy of a hospital transfer agreement between BMA Clinton and Cape Fear Valley Health System, the parent company of Cape Fear Valley Medical Center. The application is conforming to this criterion

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

C

In Section V.3(a), pages 41 - 42, the applicant states:

“Exhibit 19 includes a letter from Sam Long Director of Operations for BMA Clinton requesting to establish a Health Occupations Agreement with Sampson Community College and Fayetteville Technical Community College. ... Students are provided tours through the facilities and discussions regarding the different aspects of dialysis and facility operations.”

In Exhibit 19 the applicant provides a copy of two letters, each dated August 8, 2012 from the Area Manager of Fresenius Medical Care to Fayetteville Technical Community College

³ The analyst concludes that *Cape Fear Valley* means Cape Fear Valley Medical Center.

and Sampson Community College, inviting nursing students to include BMA Clinton in their clinical rotation training. The applicant adequately demonstrates that it will continue to accommodate the clinical needs of area health professional training programs. Therefore, the application is conforming to this criterion

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

C

BMA Clinton proposes to add three in-center dialysis stations to its existing facility for a facility total of 36 in-center dialysis stations. Based on the historical utilization of the BMA Clinton facility, and based on the Five Year AACR for Sampson County as reported in the July 2012 SDR, the applicant projects to serve 116 patients in Operating Year One, and 119 patients in Operating Year Two. In both operating years, the applicant projects to serve at least 3.2 patients per station per day, as required by 10A NCAC 14C .2203(b).

The only other dialysis facility in Sampson County is FMC of Roseboro, a new 10-station dialysis facility also operated by BMA. There is no other provider of in-center dialysis services in Sampson County.

In Section V.7, pages 44 – 45, the applicant discusses the impact of the project in the service area as it relates to promoting cost-effectiveness, quality and access to dialysis services. See also Section II, pages 20 - 31, where the applicant discusses the impact of the project on cost-effectiveness, quality and access to dialysis services in Sampson County.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal include a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- ◆ The applicant adequately demonstrates the need to add three in-center dialysis stations to the existing facility and that it is a cost-effective alternative;
- ◆ The applicant has and will continue to provide quality services; and
- ◆ The applicant has and will continue to provide adequate access to medically underserved populations.

The application is conforming to this criterion.

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

C

BMA Clinton is an existing dialysis facility in Sampson County. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred within the eighteen months immediately preceding the date of this decision for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

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

C

The application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services. The specific criteria are discussed below.

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

.2202 INFORMATION REQUIRED OF APPLICANT

- (a) *An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:*
 - (1) *Utilization rates;*
 - C- The applicant provides utilization rates as reported in the July 2012 SDR in Section II, page 10, and Section III.7, pages 33 - 35.
 - (2) *Mortality rates;*
 - C- The applicant provides mortality rates for BMA Clinton in Section II, page 11.

- (3) *The number of patients that are home trained and the number of patients on home dialysis;*
- C- In Section II, page 11, the applicant states “*BMA Clinton does not have a home dialysis program; at the present time patients who are candidates for home training are referred to the FMC Roseboro Home Training Department.*”.
- (4) *The number of transplants performed or referred;*
- C- The applicant states there were 10 transplants referred in 2011 and no transplants were performed. See Section II, page 11 and Section IV.4, page 37.
- (5) *The number of patients currently on the transplant waiting list;*
- C- The applicant states there are currently 15 patients on the BMA Clinton transplant waiting list. See Section II, page 11, and Section IV, page 37.
- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- The applicant provides a table illustrating 2011 hospital admission rates that were both dialysis related and non-dialysis related in Section II, page 11.
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
- C- The applicant provides a table illustrating that BMA Clinton currently has one patient with hepatitis B. See Section II, page 12, and Section IV, page 38.
- (b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*
- (1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*
- NA- BMA Clinton is an existing 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.*
- NA- BMA Clinton is an existing facility.
- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- BMA Clinton is an existing facility and does not propose a replacement facility.
- (4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- In Exhibit 12, the applicant provides copies of written policies and procedures for back up for electrical service in the event of a power outage.
- (5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- NA- BMA Clinton is an existing 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- In Section II.6, page 13 and Section XI.6(g), page 67, the applicant provides documentation that services will be provided in conformity with applicable laws and regulations concerning staffing, fire safety, physical environment, and health and safety.
- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- The provides all its methodologies and assumptions with regard to patient origin in Section II.7, pages 13 - 14, and in Section III.7, pages 33 - 35 of the application.
- (8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- BMA Clinton is an existing 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- The applicant states in Section II, page 14 of the application that “BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

.2203 PERFORMANCE STANDARDS

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

-NA- BMA Clinton is an existing 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.*

-C- In Section II, pages 16 - 18, and in Section III, pages 33 - 36, the applicant documents the need for three additional stations at the BMA Clinton facility based on utilization of 3.22 patients per station per week as of the end of the first operating year of the additional stations. See Criterion (3) for discussion.

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

-C- The applicant provides documentation of its assumptions in Section II, pages 16 - 18, and in Section III, pages 33 - 36. 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- In Section II, page 18, the applicant states patients will be referred to Sampson Regional Medical Center and Sampson Outpatient Diagnostics for diagnostic and evaluation services. See the table provided by the applicant in Section V.1, page 39.

(2) *maintenance dialysis;*

-C- In Section II, page 18, the applicant states maintenance dialysis will be provided by BMA Clinton.

(3) *accessible self-care training;*

-C- In Section II, page 18, the applicant states accessible self-care training will be provided by the FMC Roseboro home training department.

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

-C- In Section II, page 19, the applicant states an accessible follow-up program for patients choosing to dialyze at home will be provided by FMC Roseboro. Exhibit 20 provides a signed agreement between FMC Roseboro and BMA Clinton confirming that home training will be provided by FMC Roseboro.

- (5) *x-ray services;*
 - C- In Section II, page 19, the applicant states x-ray services will be provided by Sampson Outpatient Diagnostic Center or Sampson Regional Medical Center. See Section V.1, page 40. See the table provided by the applicant in Section V.1, page 39.
- (6) *laboratory services;*
 - C- In Section II, page 19, the applicant states laboratory services will be provided by SPECTRA Labs. See the table provided by the applicant in Section V.1, page 39. In addition, a copy of the laboratory services agreement is provided in Exhibit 18.
- (7) *blood bank services;*
 - C- In Section II, page 19, the applicant states patients needing blood transfusions will be referred to Cape Fear Valley Medical Center in Fayetteville or Wayne Memorial Hospital in Goldsboro. See the table provided by the applicant in Section V.1, page 39.
- (8) *emergency care;*
 - C- In Section II, page 19, the applicant states emergency care will be provided at the facility by BMA trained staff until emergency responders arrive. Thereafter, patients needing emergency care will be transported to Sampson Regional Medical Center. See also Section V.1, page 39.
- (9) *acute dialysis in an acute care setting;*
 - C- In Section II, page 19, the applicant states acute dialysis in an acute care setting will be provided by Cape Fear Valley Medical Center or Wayne Memorial Hospital. See also Section V.1, page 39.
- (10) *vascular surgery for dialysis treatment patients;*
 - C- In Section II, page 19, the applicant states vascular surgery will be provided by Village Surgical of Fayetteville, Village Surgical of Erwin, Eastern Carolina Surgical Associates, or other area surgeons. See Section II, page 19 and Section V.1, page 39. In addition, in Exhibit 16, the applicant provides a signed agreement between BMA Clinton and Cape Fear Valley Health System in which Cape Fear Valley Health System agrees to provide hospital services including vascular surgery.
- (11) *transplantation services;*
 - C- In Section II, page 19, the applicant states BMA Clinton has a transplantation agreement with UNC Hospital and Duke University Hospital. In Exhibit 17 the applicant provides a copy of that transplant agreement.
- (12) *vocational rehabilitation counseling and services; and*
 - C- In Section II, page 19, the applicant states patients in need of vocational rehabilitation services will be referred to Sampson County Vocational Rehabilitation Office.

(13) *transportation.*

- C- In Section II, page 19, the applicant states transportation will be provided by ENROUTE (a local transportation service) and the Sampson County Social Services Department of Aging.

.2205 STAFFING AND STAFF TRAINING

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

- C- The applicant states in Section II that staffing at the proposed facility will be sufficient to meet the requirements in 42 CFR 494.

(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- In Section II, page 20, the applicant describes the training provided by BMA Clinton. See also Section VII.5, page 52, and Exhibits 14 and 15.