

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: August 23, 2013

PROJECT ANALYST: Tanya S. Rupp
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: M-10115-13 / Bio-Medical Applications of Clinton, Inc. d/b/a BMA Clinton / Offer home peritoneal dialysis and home hemodialysis training and support, including dedicating two existing certified stations for home hemodialysis / 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.

NA

Bio-Medical Applications of Clinton, Inc. d/b/a BMA Clinton, an existing 36-station kidney disease treatment center, proposes to offer home peritoneal dialysis and home hemodialysis training and support services, including dedicating two existing certified stations for home hemodialysis training and support. BMA Clinton will remain at its current site, which is 1740 Southeast Boulevard, Clinton.

BMA does not propose to develop a new kidney disease treatment center, develop new dialysis stations, or relocate existing dialysis stations. The 2013 State Medical Facilities Plan (SMFP) and the January 2013 Semiannual Dialysis Report (SDR) do not provide a methodology for determining the need for home peritoneal dialysis or home hemodialysis training and support services. Furthermore, there are no policies in the 2013 SMFP that are applicable to this proposal. Therefore, this criterion is not applicable to this application.

- (2) Repealed effective July 1, 1987.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, an existing 36-station kidney disease treatment center, proposes to offer home peritoneal dialysis (PD) and home hemodialysis training and support services, including dedicating two existing, certified dialysis stations for home hemodialysis training and support. BMA does not propose to develop a new kidney disease treatment center, develop new dialysis stations, or relocate existing dialysis stations.

According to NCGS 131E-176(16)e, “*New Institutional Health Service*” is defined as:

*“A change in a project that was subject to certificate of need review and for which a certificate of need was issued, **if the change is proposed during the development of the project or within one year after the project was completed.** For purposes of this subdivision, a change in a project is a change of more than fifteen percent (15%) of the approved capital expenditure amount or the addition of a health service that is to be located in the facility, or portion thereof, that was constructed or developed in the project.”* [emphasis added]

A certificate of need for Project ID #M-10049-12 was issued on March 1, 2013 to add three certified dialysis stations to BMA Clinton. Those three stations were certified on April 8, 2013. The present application was filed on April 15, 2013, only seven days after the three stations authorized by the certificate of need issued for Project ID#M-10049-12 were certified. Since the applicant now proposes to offer home PD and home hemodialysis training and support services, including dedicating two existing certified stations for home hemodialysis, this proposal constitutes a “*A change in a project that was subject to certificate of need review and for which a certificate of need was issued,*” and thus requires a certificate of need.

Population to be Served

In Section III.7, pages 52 - 53, the applicant states the population proposed to be served at BMA Clinton following the completion of this project is the same as the patient population currently served at BMA Clinton. On page 52, the applicant states the patient population will be comprised primarily of Sampson County patients, although the facility will not turn away patients in need of dialysis who are residents of a county other than Sampson County. Specifically, on page 53, the applicant states:

“BMA will not project to serve home dialysis patients from other counties for the following reasons:

1. *On March 26, 2013 the CON Section provided Fresenius Medical Care (parent to BMA) a No Review Determination for the RAI Care Centers Goldsboro dialysis facility to add home therapies. BMA is projecting to have that program certified by mid year 2013. This is approximately one year prior to the implementation of this project.*
2. *On March 27, 2013 the CON Section provided Fresenius Medical Care (parent to BMA) a No Review Determination for its RAI West College—Warsaw dialysis facility to add home therapies. BMA is projecting to have that program certified by mid year 2013. This is approximately one year prior to the implementation of this project.*
3. *The RAI centers were acquired by Fresenius Medical Care, parent to BMA, in 2012.*
4. *BMA Clinton has traditionally not served any patients from Pender County. This has not been by design, but rather a function of patient referrals. BMA believes that as a general practice, the ESRD patients of Pender County have travelled south to Wilmington for their nephrology physician coverage. The nephrology physicians from Wilmington do not have admitting privileges at BMA Clinton.*
5. *BMA is not projecting to serve home patients from Bladen County. Bladen County home patients have been served by the local facility or by BMA Fayetteville or BMA Lumberton.”*

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

BMA Clinton is currently certified for 36 dialysis stations and will be certified for 36 stations upon completion of this project. This proposal will not increase the number of certified dialysis stations at BMA Clinton. Rather, two of the 36 existing certified dialysis stations will be dedicated to home hemodialysis training and support services.

In Section III.7, pages 52 – 65, the applicant discusses the need for home hemodialysis and home PD training and support services in Clinton.

The applicant calculated the percentage of dialysis patients who are home trained in Sampson County, based on data internal to BMA and the data reported in the January 2013 SDR. On page 53, the applicant states:

“BMA has evaluated the ESRD patient population of North Carolina by review of the recent SDRs and the last published Southeastern Kidney Council Zip Code report, March 31, 2012.

- a. The January 2013 SDR Table B indicates that as of June 30, 2012, 12.6% of the North Carolina ESRD patient population utilize home dialysis.

NC ESRD Patients	14,619
NC Home Patients	1,841
% Home	12.6%

- b. The SEKC Zip Code data for March 31, 2012 indicates a similar percentage of home patients.

	<i>In-Center</i>	<i>Home</i>	<i>IC PD</i>	<i>Total</i>
<i>Patients</i>	12836	1697	2	14535
<i>% Population</i>	88.31%	11.68%	0.01%	100%

- c. The SEKC report further defines the home population by home modality: PD or HH.”

	<i>Home HD</i>	<i>Home PD</i>	<i>Total</i>
<i>Patients</i>	277	1420	1697
<i>% Population</i>	16.3%	83.7%	100%

On page 54, the applicant states the home dialysis patient population in North Carolina has increased at a faster rate than the in-center dialysis patient population, based on an analysis of SEKC North Carolina patient population data from 2007 through 2012.

On pages 54 – 55, the applicant states:¹

“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 January 2013 SDR; that rate is 3.0%. Changes in the home patient population will reflect an overall increase of home patients and smaller increases within the in-center patient population as more patients choose to dialyze at home.

BMA will not project any increase in the patient populations of other counties who may be choosing to dialyze at BMA Clinton.

The Sampson County population is similar to, but does not mirror the North Carolina population.”

On page 55, the applicant provides a table that compares demographic data for North Carolina with Sampson County, as shown below:

¹ The applicant’s need methodology, specifically pages 52 – 60, consists of several bulleted and numbered paragraphs. The analyst has chosen to eliminate the numbers and letters in the quoted material, but has left the paragraph breaks as they are in the application.

US Census Bureau Data		
Population Cohort	North Carolina Percentage	Sampson County Percentage
Age 65+	13.2%	14.6%
Black Persons	22.0%	27.7%
Hispanic or Latino	8.6%	16.9%
High School Graduate or Higher	84.1%	74.8%
Persons Below Poverty Level	16.1%	21.0%

On page 55, the applicant states:

“The January 2013 SDR Table B indicates that Sampson County had 18 home patients as of June 30, 2012. Thus 11% of the Sampson County ESRD patient population was home dialysis patients. This is only slightly different than the State wide average of 11.68% home dialysis.”

On pages 56 – 57, the applicant discusses the existence of home dialysis training and support programs in Sampson and contiguous counties. The applicant states:

“The CMS website offering comparison of dialysis facilities reports only one facility within 50 miles of Clinton, N.C. offering home hemo-dialysis training and support: BMA Fayetteville, 43 miles from Clinton. ...

The same CMS website reports six facilities within 50 miles of Clinton, N.C. offering home PD training and support: BMA operates four of the six facilities. After the FMC Roseboro facility (also in Sampson County), 13 miles from Clinton, the next closest program offering PD is 34 miles away. ...

BMA has surveyed its existing home dialysis programs in Sampson County and in counties contiguous to Sampson: Johnston, Harnett, and Cumberland. Both BMA Dunn (Harnett County) and BMA Fayetteville (Cumberland County) were serving home dialysis patients from Sampson County. ...

...

SEKC zip code reports for March 31, 2012 report five home hemo-dialysis patients residing in Sampson County. Based upon the analysis of other nearby home dialysis programs, and noting that BMA Fayetteville offers the only home hemo-dialysis program within 50 miles of Clinton, North Carolina, BMA assumes that the two home hemo-dialysis patients from Sampson County [and being followed by the BMA Fayetteville Home Training Program] will transfer their care to the BMA Clinton facility upon completion of this project.

BMA assumes the other three home hemo-dialysis patients are going to another provider and will not transfer their care to the BMA Clinton facility upon completion of the project.

Five home hemo-dialysis patients within a patient population of 18 home patients equates to 27.8% of the home patient population. Absent any unfavorable differences in the Sampson County ESRD patient population as compared with the State wide percentage of home hemo-dialysis patients, BMA assumes the home hemo-dialysis patient population of the county to increase at the County five year average change rate.

...

Based upon the proximity of BMA Clinton and the distance to other home hemo-dialysis training programs (there is only one within 50 miles of Clinton: BMA Fayetteville), BMA assumes that a majority of future Sampson County patients choosing home hemo-dialysis will choose to receive their training and follow-up care through the BMA Clinton facility.

...

BMA does assume that as the home patient population of Sampson County increases, some of the new patients will choose BMA Clinton for their training and follow-up care.”

On page 58, the applicant projects the following numbers of patients who will receive home hemodialysis and home PD training at BMA Clinton:

OPERATING YEAR 1		OPERATING YEAR 2	
HH	PD	HH	PD
4	2	6	4

On pages 59 – 64, the applicant describes the assumptions and methodology used to project home and in-center patients to be served at BMA Clinton following project completion. On page 59, the applicant states:

“BMA discussion of methodology is comprised of three parts. BMA will first project growth of the existing Sampson County in-center patient population to be served by the BMA Clinton facility. BMA has assumed that two patients per year would change from in-center dialysis to home dialysis. Further, BMA assumed that one patient would choose PD and the other patient would choose home hemo-dialysis. Within Part I of the calculations BMA will project growth for the Sampson County patient population of BMA Clinton.

In Part II of its methodology, BMA will demonstrate growth of the entire ESRD patient population of Sampson County. Within this projection, BMA will determine the number of patients projected to be home dialysis patients. Further, BMA will project the number of new home hemo-dialysis patients and home PD patients.”

On page 60, the applicant provides the following table which illustrates the first part of its methodology.

Sampson County patients utilizing BMA Clinton as of March 31, 2013*	95
Project forward for 9 months to December 31, 2013, using the Sampson County 5-year average annual change rate	$[95 \times (.03/12 \times 9)] + 95 = 97.1$
Project this population forward for 6 months to June 30, 2014 [the projected completion date]	$[97.1 \times (.03/12 \times 6)] + 97.1 = 98.6$
Project this population forward for 12 months to June 30, 2015	$98.6 \times 1.03 = 101.6$
Subtract two patients projected to change to home dialysis during the first year of operations. This is the ending census for Operating Year 1	$101.6 - 2 = 99.6$
Project forward for 12 months to June 30, 2016	$99.6 \times 1.03 = 102.5$
Subtract two patients projected to change to home dialysis during the first year of operations. This is the ending census for Operating Year 2	$102.5 - 2 = 100.0$

On page 61, the applicant provides the following table, which illustrates the second part of its methodology.

Sampson County dialysis patient population as of June 30, 2012 (January 2013 SDR)	170
Project forward for one year to June 30, 2013, using the Sampson County 5-year average annual change rate	$170 \times 1.03 = 175.1$
Project forward for one year to June 30, 2014	$175.1 \times 1.03 = 180.4$
Project forward for one year to June 30, 2015	$180.4 \times 1.03 = 185.8$
Project forward for one year to June 30, 2016	$185.8 \times 1.03 = 191.3$

On page 61, the applicant states:

“Determine Sampson County ESRD patient population by application of N.C. percentages.

BMA has established that the NC ESRD patient population is comprised of the following:

*PD: 72.2%
 HH: 27.8%”*

Based on these percentages, the applicant determined how many Sampson County dialysis patients are home dialysis patients, as illustrated in the table below.

YEAR ENDING	SAMPSON COUNTY TOTAL ESRD PATIENT POPULATION	IN-CENTER PATIENT POPULATION (12.6% OF TOTAL)	HOME PATIENT POPULATION (87.4% OF TOTAL)
6/30/2015	185.8	162.4	23.4

6/30/2016	191.3	167.2	24.1
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On page 62, the applicant provides the following table:

DATE	TOTAL ESRD PATIENT POPULATION	IN-CENTER PATIENT POPULATION	HH PATIENT POPULATION (27.8%)	PD PATIENT POPULATION (72.2%)
6/30/2015	185.8	162.4	6.5	16.9
6/30/2016	191.3	167.2	6.7	17.4

On page 62, the applicant states:

“As BMA has noted, there is only one other dialysis facility within 50 miles of BMA Clinton offering home hemo-dialysis. ... due to travel distances, BMA assumes that a majority of the home hemo-dialysis patients will be receiving care and treatment through the BMA Clinton facility.”

BMA has also noted that of the 18 home dialysis patients reported within the January 2013 SDR, BMA is serving five of those patients [27.8%]. Thus there are 13 patients who are going to another provider of dialysis for their care and treatment. BMA will not project any of these patients to transfer to the BMA Clinton facility upon completion of this project. However, BMA will not deny treatment to these patients with proper referral from a nephrology physician with admitting privileges at BMA Clinton.”

On page 63, the applicant provides the following table:

DATE	HOME PATIENT POPULATION	PATIENTS NOT DIALYZING AT BMA	PATIENTS DIALYZING AT BMA	POSSIBLE NEW PATIENTS AT BMA CLINTON
6/30/2015	23	3 HH	2 HH	1 HH
		10 PD	3 PD	4 PD
6/30/2016	24	3 HH	2 HH	2 HH
		10 PD	3 PD	4 PD

On pages 63 – 64, the applicant states:

“There are four PD patients who could be admitted to the BMA Clinton facility in Operating Years 1 and 2. BMA will not project that 100% of this patient population will be referred to the BMA Clinton facility. Rather, BMA does assume an equal number of referrals to BMA Clinton and other providers.”

BMA has assumed that the two home hemo-dialysis patients residing in Sampson County and being followed by BMA Fayetteville would transfer their care to the BMA Clinton facility upon completion of this project. In addition, there is one HH patient who could be admitted to the BMA Clinton facility in Operating Year 1, and two HH patients who could be admitted in Operating Year 2. Based upon travel distance,

BMA will project that the one patient will be referred to the BMA Clinton facility in Operating Year 1. BMA assumes that one of the home hemo-dialysis patients will choose BMA Clinton in Operating Year 2.

...

In addition to the previous discussion of the projected Sampson County ESRD patient population as a whole, BMA has also projected that two in-center patients each year would change modality to home dialysis. These patients must be added to the projections of patients to be served....

...

BMA projects to serve the following patients by county of residence in Operating Years 1 and 2:

COUNTY	OPERATING YEAR 1			OPERATING YEAR 2			COUNTY PTS. AS % OF TOTAL	
	IN CTR.	HH	HPD	IN-CTR.	HH	HPD	YEAR 1	YEAR 2
Sampson	99.6	4.0	3.0	100.5	6.0	6.0	99.1%	99.1%
Bladen	1.0	0.0	0.0	1.0	0.0	0.0	0.9%	0.9%
Total	100.6	4.0	3.0	101.5	6.0	6.0	100%	100%

The applicant does not propose to develop a new kidney disease treatment center, develop any new certified dialysis stations, or to relocate any existing dialysis stations. Therefore, the Criteria and Standards for End Stage Renal Disease Services, promulgated in 10A NCAC 14C .2200, including the performance standards set forth in 10A NCAC 14C .2203, do not apply to this review. There are no minimum performance standards for home hemodialysis or home PD training and support services. According to the July 2013 SDR, BMA Clinton was operating at 73.8% of capacity as of December 31, 2012, with 33 stations and 97 in-center patients [$97 / 33 / 4 = 0.738$]. Since then, three more stations have been certified, for a total of 36 stations, which would be an occupancy rate of 67.4% [$97 / 36 / 4 = 0.674$]. Thus, the facility has sufficient capacity to dedicate two existing certified dialysis stations to home hemodialysis training and support. Furthermore, on page 378, the 2013 SMFP states:

“The North Carolina State Health Coordinating Council encourages applicants for dialysis stations for provide or arrange for:

...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.”

The applicant adequately demonstrates the need for home PD and home hemodialysis training and support services at BMA Clinton.

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need for the proposal. 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

- (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

In Section III.9, pages 65 – 66 of the application, the applicant discusses the alternatives it considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – do not offer home training at BMA Clinton. The applicant states that the closest home hemodialysis training and support program is located almost 50 miles from BMA Clinton. The applicant also states that to maintain the status quo imposes a burden on dialysis patients who must pay for travel to and from home dialysis treatment and/or training.
- 2) Chosen alternative – offer home PD and home hemodialysis training and support at BMA Clinton. This alternative, according to the applicant, provides the home training and support that the Sampson County dialysis patients need.

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

- Patient care will continue to be provided by the same caregivers and Nephrologists.
- Sampson County patients who desire home hemodialysis and home PD training and support will be able to receive those services without having to leave the county.
- Patients will not have to travel as far as they do now to receive home hemodialysis and home PD training and support.

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

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the need for home PD and home hemodialysis training and

support services at BMA Clinton. Therefore, the application is conforming to this criterion and 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 the certificate of need application.**
 2. **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 the 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 VIII.1, page 84, the applicant states that the projected capital cost of the project is \$200,066, which includes \$154,350 for construction contract costs, \$15,000 for equipment and furniture costs, \$13,892 for architect/engineering fees, and \$16,824 for contingencies. In Section IX.1, page 88, the applicant states there will be no start-up or initial operating expenses associated with the project.

In Section VIII.2, page 85, the applicant states that the project will be funded with the cash reserves of Fresenius Medical Care Holdings, Inc., the ultimate parent company of BMA Clinton.

Exhibit 24 includes a letter dated April 15, 2013 from the Vice President of Fresenius Medical Care Holdings, Inc., which states in part:

“BMA is submitting a Certificate of Need Application to add home dialysis training and support for both peritoneal dialysis and home hemo-dialysis to the existing facility. The project calls for the conversion of two existing and certified dialysis stations to dedicated home hemo-dialysis training and support stations. This project will not change the number of dialysis stations at the facility. The project calls for the following capital expense on behalf of BMA:

<i>Capital Expense</i>	<i>\$200,066</i>
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As Vice President, I am authorized and do hereby authorize the development of this home training program at BMA Clinton for capital costs of \$200,066.”

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 \$204,142,000 in cash and cash equivalents, \$13,864,539,000 in total assets, and

\$8,388,027,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In Section X.3, pages 90 - 93, the applicant provides the assumptions with which it projects revenue for each payor source, which includes a 6.5% allowance for missed treatments. See the following tables:

Projected Reimbursement Total Facility

BMA CLINTON			
TOTAL FACILITY			
Revenue Source Year 1	Patient Payment % by Revenue Source	# Treatments	Reimbursement per Treatment
Medicare	83.8%	12,230	\$ 234.00
Medicaid	5.0%	733	\$ 137.29
Commercial	2.2%	317	\$1,375.00
VA	8.9%	1,304	\$ 146.79
Revenue Source Year 2	Patient Payment % by Revenue Source	# Treatments	Reimbursement per Treatment
Medicare	83.8%	12,353	\$ 234.00
Medicaid	5.0%	740	\$ 137.29
Commercial	2.2%	321	\$1,375.00
VA	8.9%	1,317	\$ 146.79

Projected Reimbursement Home Hemodialysis

BMA CLINTON			
HOME HEMODIALYSIS TRAINING			
Revenue Source Year 1	Patient Payment % by Revenue Source	# Treatments	Reimbursement per Treatment
Medicare	10.0%	29	\$ 234.00
Medicaid	0.70%	2	\$ 137.29
Commercial	87.0%	251	\$1,375.00
VA	2.3%	7	\$ 146.79
Revenue Source Year 2	Patient Payment % by Revenue Source	# Treatments	Reimbursement per Treatment
Medicare	10.0%	72	\$ 234.00
Medicaid	0.70%	5	\$ 137.29
Commercial	87.0%	626	\$1,375.00
VA	2.3%	17	\$ 146.79

Projected Reimbursement Home Peritoneal Dialysis

BMA CLINTON			
HOME PD TRAINING			
Revenue Source Year 1	Patient Payment % by Revenue Source	# Treatments	Reimbursement per Treatment
Medicare	70.7%	153	\$ 234.00
Medicaid	1.1%	2	\$ 137.29
Commercial	27.9%	54	\$ 550.00
VA	2.2%	5	\$ 147.85
Revenue Source Year 2	Patient Payment % by Revenue Source	# Treatments	Reimbursement per Treatment

Medicare	70.7%	458	\$ 234.00
Medicaid	1.1%	7	\$ 137.29
Commercial	27.9%	161	\$ 550.00
VA	2.2%	14	\$ 147.85

This information is consistent with the payor mix reported by the applicant in Section VI.1(c), page 76 of the application: Additionally, the rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.

In Sections X.2, on page 90; and Section X.4, pages 94 - 95, the applicant reports projected revenues and expenses, as illustrated below in the table:

BMA CLINTON		
	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$4,666,157	\$5,402,497
Total Operating Costs	\$4,334,720	\$4,781,841
Net Profit	\$ 331,437	\$ 620,656

As shown in the above table, the applicant projects that revenues will exceed operating expenses in each of the first two operating years. Furthermore, projected utilization is based on reasonable, credible and supported assumptions. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. Therefore, the applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable, credible and supported projections of costs and revenues. Consequently, 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 proposes to offer home PD and home hemodialysis training and support services. According to the January 2013 SDR, the applicant or a related entity is the only provider of dialysis services in Sampson County. FMC Roseboro, located in the town of Roseboro, approximately 14 miles to the west of Clinton, was certified for ten in-center dialysis stations in March 2013. That facility currently offers in-center dialysis and home PD training and support services. In Section II, page 17, the applicant states:

“The CMS website offering comparison of dialysis facilities reports only one facility within 50 miles of Clinton, N.C. offering home hemo-dialysis training and support: BMA Fayetteville, 43 miles from Clinton.

The same CMS website reports six facilities within 50 miles of Clinton, N.C. offering home PD training and support: BMA operates four of the six facilities. After the FMC

Roseboro facility (also in Sampson County), 13 miles from Clinton, the next closest program offering PD is 34 miles away.”

The applicant adequately demonstrates the need to offer home PD and home hemodialysis training and support services at BMA Clinton. See Criterion (3) for discussion of need which is incorporated hereby as if set forth fully herein. Therefore, the applicant adequately demonstrates the proposal will not result in the unnecessary duplication of existing or approved home PD or home hemodialysis training and support services in Sampson County. Consequently, the application is conforming to this criterion.

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

C

In Section VII.1, page 80, the applicant provides current and projected staffing for BMA Clinton, as illustrated in the following table:

POSITION	CURRENT FTEs	# OF FTE POSITIONS TO BE ADDED	TOTAL FTE POSITIONS
RN	4.00	0.00	4.00
Technician	9.00	0.00	9.00
Clinical Manager	1.00	0.00	1.00
Administrative	0.20	0.00	0.20
Dietician	0.80	0.00	0.80
Social Worker	0.80	0.00	0.80
Home Training Nurse	0.00	1.50	1.50
Medical Records	1.00	0.00	1.00
Chief Technician	0.20	0.00	0.20
Equipment Technician	1.00	0.00	1.00
In-Service	0.33	0.00	0.33
Clerical	1.00	0.00	1.00
Totals	19.33	1.50	20.83

In Section V.4(c), page 72, the applicant states that Dr. Kent Webb currently serves as medical director of BMA Clinton. In Exhibit 21, the applicant provides a March 28, 2013 letter from Dr. Webb supporting the project and confirming his commitment to serve 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 69, the applicant states that Sampson Regional Medical Center and Sampson Outpatient Diagnostics will provide ancillary and support services to BMA Clinton, including diagnostic services. In addition, the applicant states Cape Fear Valley Medical Center or Wayne Memorial Hospital will provide blood bank services and SPECTRA Labs will provide laboratory services. In Exhibit 18, the applicant provides a copy of the laboratory services agreement with SPECTRA. Furthermore, the applicant states that Cape Fear Valley Medical Center or Wayne Memorial Hospital will also provide additional ancillary and support services, including acute dialysis in an acute care setting. The applicant states transportation services will be provided by Sampson County Social Services Enroute, and by Sampson County Department of Aging. Vascular surgery services will be provided by Carolina Kidney Care Vascular Access Center, and vocational rehabilitation services will be provided by Sampson County Vocational Rehabilitation. In Exhibit 21, the applicant provides a March 28, 2013 letter from Dr. Webb supporting the project and confirming his commitment to serve as medical director of the facility. 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 75, 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. The patient population of BMA Clinton is expected 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>BMA Clinton</i>	<i>46.8%</i>	<i>43.8%</i>	<i>87.5%</i>	<i>51.0%</i>	<i>87.5%</i>

...

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

BMA of Clinton and BMA of North Carolina have 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 undeserved person. For example, Medicare represented 84.8% of North Carolina dialysis treatments in BMA facilities in FY 2012. Medicaid treatments represented an additional

4.5% of treatments in BMA facilities for FY 2012. Low income and medically underinsured persons will continue to have access to all services provided by BMA.”

As shown in the following table, 88.8% of BMA Clinton current in-center patients have some or all of their care paid for by Medicare or Medicaid. In Section VI.1, page 76, the applicant provides the current payor mix for BMA Clinton, as shown in the following table:

BMA CLINTON PAYOR SOURCE	IN-CENTER
Commercial Insurance	2.2%
Medicare	83.8%
Medicaid	5.0%
VA	8.9%
Other (Self/indigent]	0.1%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Sampson County and Statewide. 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 the services offered by BMA Clinton. In fact, in 2011 only 5.8 of all newly diagnosed ESRD patients (Incident ESRD patients) in North Carolina’s Network 6 were under the age of 35.²

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

² Southeastern Kidney Council ESRD Network 6 2011 Annual Report; Table 3, page 16.

women utilizing health services. Furthermore, OSBM’s website does not include information on the number of handicapped persons.

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

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

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.”³

In addition, the United States Renal Data System, in its 2012 USRDS Annual Data Report provides the following national statistics for FY 2010:

**The 2012 United States Renal Data System
 Selected National Statistics as of December 31, 2010⁴**

PATIENTS RECEIVING HEMODIALYSIS NATIONALLY – 376,000			
African American	38.23%	Male	55.65%
White	55.38%	Age 65+	44.35%

Further data from that report states:

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

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

ESRD Spending Nationally by Payor⁵

PAYOR	SPENDING IN BILLIONS	% OF TOTAL SPENDING
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%

³ See, for example: www.cms.gov; www.medpac.gov

⁴ United States Renal Data System 2012 USRDS Report, Chapter 1, page 225.

⁵Source: 2012 United States Renal Data System (USRDS) Annual Data Report, Chapter 11, page 340.

Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%
Total ESRD Expenditures	\$47.5	100.00%

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

**2011 Number and Percent of Dialysis Patients
 by Age, Gender, and Race⁶**

AGE	# OF ESRD PATIENTS	% OF DIALYSIS POPULATION
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African-American	5,096	54.55%
White	4,027	43.11%
Other	219	2.30%
Total	9,342	100.00%

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

In Section VI.1(f), page 77, the applicant states “*BMA of Clinton does not have any obligation to provide uncompensated care or community service under any federal regulations*” In Section VI.6(a), page 79, the applicant states: “*There have been no Civil Rights complaints lodged against BMA Clinton in the past 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

⁶ Source: Southeastern Kidney Council ESRD Network 6 2011 Annual Report; Table 3, page 16.

C

In Section VI.1(c), page 76, the applicant provides the projected payor mix for the proposed services at BMA Clinton, which is based on its historical mix. The applicant projects no change from the current payor mix for dialysis visits as shown in the table in Criterion (13a) above. The applicant projects that 88.8% of the in-center patients, 10.7% of the home hemodialysis patients, and 71.8% of the home PD patients will be Medicare or Medicaid beneficiaries. The applicant demonstrates that medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5 (a), page 78 the applicant states, *“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. BMA Clinton will have an open policy, which means that any Nephrologists may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospitals.”* In Exhibit 16, the applicant provides a copy of a hospital transfer agreement between BMA Clinton and Cape Fear Valley Health System. Additionally, on page 78, the applicant states it has a *“Kidney Options patient educational program”* that it makes available in the county. The applicant states this educational program delays the onset of end stage renal disease by educating patients in dietary and healthcare options. The applicant adequately demonstrates that BMA Clinton offers a range of means by which a person can access services. Therefore, the application is conforming to this criterion.

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

C

In Section V.3(a), page 71, 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. ... 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 March 28, 2013 letter from the Area Manager of Fresenius Medical Care to Sampson Community College, inviting the school to include BMA Clinton, including the proposed home training services for clinical training. The applicant adequately demonstrates that the facility will 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, an existing 36-station kidney disease treatment center, proposes to offer home PD and home hemodialysis training and support services, including dedicating two existing certified dialysis stations to home hemodialysis training and support services. The only other kidney disease treatment center in Sampson County is FMC of Roseboro, a new 10-station facility also operated by BMA. Neither facility currently provides home hemodialysis training and support services. FMC Roseboro does offer home PD training and support services. According to "*Dialysis Facility Compare*,"⁷ the closest dialysis facility to offer home hemodialysis training and support services is nearly 45 miles west of Clinton in Fayetteville, in Cumberland County.

In Section V.7, pages 73 - 74, the applicant discusses the effects of the proposal on competition, including how any enhanced competition will have a positive effect on the cost effectiveness, quality and access to the proposed services. See also Sections II, III, VI, and VII.

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

- ◆ The applicant adequately demonstrates the need for the proposal and that it is a cost-effective alternative;
- ◆ The applicant will continue to provide quality services; and

⁷ Taken from the U.S. Medicare Website: <http://www.medicare.gov/dialysisfacilitycompare>

- ◆ The applicant 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.

NA