

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: November 1, 2013

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

PROJECT I.D. NUMBER: N-10153-13 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Bladen Home Dialysis / Develop a new freestanding home training and support program for peritoneal dialysis patients / Bladen 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 North Carolina, Inc. (BMA) d/b/a FMC Bladen Home Dialysis proposes to develop a new freestanding home training program for peritoneal dialysis (PD) patients. Bladen Home Dialysis will lease existing space at 507 Doctors Drive, Elizabethtown, NC 28303 (primary site). BMA does not propose to include any certified in-center or home hemodialysis stations in the new facility.

Neither the 2013 State Medical Facilities Plan (SMFP) nor the July 2013 Semiannual Dialysis Report (SDR) provides a need methodology for determining the need for PD home training programs. Likewise, there are no policies in the SMFP 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- (2) Repealed effective July 1, 1987.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 North Carolina, Inc. (BMA) d/b/a FMC Bladen Home Dialysis proposes to develop a home peritoneal dialysis program in leased space in Elizabethtown, Bladen County. BMA does not propose to include any certified in-center or home hemodialysis stations in the new facility.

Population to be Served

In Section III.7, page 61, the applicant projects that 100% of its patients projected to be served by FMC Bladen Home Dialysis will be from Bladen County, as illustrated in the following table:

FMC BLADEN COUNTY PD	OPERATING YEAR 1 7/1/14 - 6/30/15	OPERATING YEAR 2 7/1/15 - 6/30/16	COUNTY PATIENTS AS PERCENT OF TOTAL	
			YEAR 1	YEAR 2
Bladen County	5	6	100.0%	100.0%
Total	5	6	100.0%	100.0%

The applicant projects to serve five home PD patients in Operating Year One and six home PD patients in Operating Year Two. The applicant adequately identifies the population proposed to be served.

Demonstration of Need

In Section III.7, pages 51 – 61, the applicant describes a growing trend in patients preferring home PD training and support, both in North Carolina and in Bladen County. On pages 51 – 52, the applicant states:

“The home patient population of Bladen County is increasing. The home patient population of North Carolina is growing. The information in the following chart is extracted from the January SDR for the years indicated. The row labeled State Wide reports the total ESRD patient population across North Carolina. The row labeled Home reflects the total home patient population for each year. The row labeled Bladen Home reflects the home patient population of Bladen County for each of the years. The last column in each row calculates the five year average annual change in the ESRD patient population (the same methodology used by Medical Facilities Planning to develop the county five year average annual change rate).”

BMA notes that the home patient population of Bladen County has doubled in the 12 months between the January2012 and January2013 reporting.”

Below is a table from page 42 of the application that illustrates the statements made by the applicant:

SDR DATA	JANUARY 2009	JANUARY 2010	JANUARY 2011	JANUARY 2012	JANUARY 2013	AVERAGE % CHANGE
State-Wide ESRD	13,099	13,607	13,985	14,455	14,863	3.21%
Raw Change	--	508	378	470	408	
% Change	--	3.88%	2.78%	3.36%	2.82%	
State-Wide Home	1,219	1,346	1,472	1,609	1,841	10.88%
Raw Change	--	127	126	137	232	
% Change	--	10.42%	9.36%	9.31%	14.42%	
Bladen County Home	5	5	4	7	14	38.75%
Raw Change	--	0	-1	3	7	
% Change	--	0.00%	-20.00%	75.00%	100.00%	

The applicant concludes that the number of dialysis patients who choose home dialysis training and support is increasing in the state as a whole and in Bladen County. In fact, the data shows the Bladen County home patient population has grown three times faster than the North Carolina home patient population as a whole.

In addition, the applicant identified 19 North Carolina counties which it states have a similar ESRD patient population as Bladen County, which the applicant states is between 81 and 126 total patients. Within that patient population, the applicant then compares the home dialysis patient population, the number of ESRD facilities and providers, poverty and income levels, and age and race characteristics in 15 of the 19 counties. Referencing Table B on page 12 of the January 2013 SDR, on page 52, the applicant states:

“BMA suggests this range of 81 — 126 ESRD patients is reflective of Bladen and other similar sized patient ESRD patient populations. It would not be appropriate to compare Bladen County to Cumberland County which is a contiguous county. Cumberland County has a patient population more than five times the size of Bladen County. Further, while Bladen County has an ESRD patient population of only 96 patients (as reported in the SDR), BMA considered that some smaller sized populations would be appropriate since ESRD patient populations do ebb and flow with regard to total size.

However, BMA also includes populations through 126 because on the whole the ESRD patient population of North Carolina, and Bladen County specifically, is increasing. Thus, BMA offers the following list of similar sized patient populations.”

COUNTY	ESRD CENSUS	HOME PATIENTS	% HOME
--------	-------------	---------------	--------

Scotland	126	9	7.4%
Orange	125	11	8.7%
Richmond	123	12	9.9%
Rutherford	119	29	25.7%
Franklin	117	14	12.4%
Surry	109	14	13.2%
Lee	109	8	7.4%
Hoke	108	4	4.0%
Person	106	10	9.8%
Beaufort	106	17	16.5%
Caldwell	100	12	11.8%
Pender	99	11	11.5%
Bladen	96	14	14.7%
Pasquotank	91	10	10.7%
Martin	88	8	9.4%
Burke	85	17	19.5%
Lincoln	83	19	23.5%
Hertford	82	6	7.3%
Chatham	81	5	6.2%

On page 54, the applicant states:

“BMA has evaluated each of the above listed Counties to determine the predominant dialysis provider serving each. Each of the above counties is currently served by a single provider within the County, with the exception of Franklin County. Within Franklin County, DaVita operates the outpatient dialysis facility and Fresenius Medical Care operates a free standing Peritoneal Dialysis facility. In addition, BMA has recently filed a CON application seeking approval to develop a new 10 station dialysis facility in Franklin County.

...

... BMA will offer comparisons between the counties served by FMC and DaVita. The facility in Surry County is operated by Health Systems Management, and is affiliated with Wake Forest School of Medicine. The facilities in Chatham, Lee and Orange Counties are managed by Renal Research Institute with strong ties to academic research. The affiliation with teaching hospitals distinguishes and separates the facilities in Surly, Chatham, Lee and Orange Counties.

Thus, BMA proposes a comparison of the following Counties and their respective dialysis patient populations:”

PRIMARY PROVIDER	COUNTY	ESRD CENSUS	HOME PATIENTS	% HOME
------------------	--------	-------------	---------------	--------

DaVita	Bladen	96	14	14.7%
DaVita	Franklin	117	14	12.4%
DaVita	Hertford	82	6	7.3%
DaVita	Hoke	108	4	4.0%
DaVita	Martin	88	8	9.4%
DaVita	Pasquotank	91	10	10.7%
DaVita	Pender	99	11	11.5%
DaVita	Person	106	10	9.8%
DaVita	Richmond	123	12	9.9%
DaVita	Rutherford	119	29	25.7%
FMC	Beaufort	106	17	16.5%
FMC	Burke	85	17	19.5%
FMC	Caldwell	100	12	11.8%
FMC	Lincoln	83	19	23.5%
FMC	Scotland	126	9	7.4%

The applicant identified 15 counties in North Carolina that have a dialysis patient population between 81 and 126 total patients served by either DaVita or FMC (parent company to BMA) as the dialysis provider.

In addition, on page 55, the applicant provides another table which ranks the percentage of home patients for each provider, as shown below:

PRIMARY PROVIDER	COUNTY	ESRD CENSUS	HOME PATIENTS	% HOME
DaVita	Bladen	96	14	14.7%
DaVita	Rutherford	119	29	25.7%
DaVita	Franklin	117	14	12.4%
DaVita	Pender	99	11	11.5%
DaVita	Pasquotank	91	10	10.7%
DaVita	Richmond	123	12	9.9%
DaVita	Person	106	10	9.8%
DaVita	Martin	88	8	9.4%
DaVita	Hertford	82	6	7.3%
DaVita	Hoke	108	4	4.0%
FMC	Lincoln	83	19	23.5%
FMC	Burke	85	17	19.5%
FMC	Beaufort	106	17	16.5%
FMC	Caldwell	100	12	11.8%
FMC	Scotland	126	9	7.4%

On pages 55 – 56, the applicant compares the percent of home dialysis patients for each of the two providers, and concludes that BMA has more patients who are home trained. The applicant states:

“Within the above table, BMA notes that in counties served by DaVita the percentage of home patients ranges from 4.0% in Hoke County to 25.7% in Rutherford County. In fact, Rutherford County is the only county higher than Bladen within the Counties

served by DaVita. Five of the counties have less than 10% of the ESRD patients dialyzing at home.

BMA also notes that there are five counties within the table served predominantly by FMC (parent to BMA). Of these five counties, three have higher percentages of home patients than does Bladen County and only one is less than 10%.”

On pages 56 – 58, the applicant compares age, race, poverty level and per capital income of those 15 counties to determine whether any of those factors are correlated to the choice of home dialysis rather than in-center dialysis. The applicant concludes that there is no significant correlation between any of the factors and whether home or in-center dialysis treatments are favored. However, the applicant concludes there is a correlation between the percentage of those patients choosing to dialyze at home and the provider of choice. On page 58, the applicant states:

“Based upon the foregoing discussion and comparison with regard to poverty levels, per capita income, age and race, BMA notes the single characteristic which seems to common [sic] among ESRD patient populations of these Counties is the predominant provider. From this comparison, BMA suggests that its presence in Bladen County will enhance patient access to home therapies. Furthermore, the BMA collaboration with Carolina Kidney Care physicians will result in more patients choosing home dialysis.”

In Section V.4(c), page 67, the applicant states the physicians of Carolina Kidney Care will provide referrals and treatment for those Bladen County patients who choose to dialyze at home. In Exhibit 21 the applicant provides a letter dated April 3, 2013, signed by Dr. Ezra McConnell, which states in part:

“I am writing on behalf of Carolina Kidney Care’s eleven nephrologists to endorse the Certificate of Need application....

... Recently, we have seen an increase in the home dialysis patient population. I and my fellow nephrologists believe that this trend will continue and that the ‘new normal’ will be more patients utilizing home dialysis....

My associates and I have been providing nephrology services for patients residing in Bladen and surrounding counties for many years. We have well established relationships with physicians in the region. Last year Carolina Kidney Care opened a clinic for patients with kidney disease in Elizabethtown. The number of patients seen at this clinic has grown rapidly. The addition of a home peritoneal dialysis training program closer to their homes will be beneficial to patients needing this service.”

Thus, the applicant states that its presence in the county, as well as its affiliation with the nephrologists associated with Carolina Kidney Care will enhance patient access to home therapies.

On pages 58 – 60, the applicant provides the following assumptions on which it bases its determination of need in Bladen County for home PD dialysis training and support services:

1. *“This project is scheduled for completion and certification at [sic] June 30, 2014. Operating Year 1 is the period from July 1, 2014 through June 30, 2015. Operating Year 2 is the period from July 1, 2015 through June 30, 2016.*
2. *BMA currently provides home PD training and support for some of the home patients from Bladen County.*
3. *BMA assumes that the nephrology physicians of Carolina Kidney Care will refer home patients to the new facility. This assumption is a function of the CKC support for this application.*
4. *BMA assumes that all of the future patients of the facility will be residents of Bladen County. BMA has home training programs in Sampson, Cumberland and Robeson Counties which are contiguous to Bladen on the west-northeast sides of the County.*
5. *BMA is not proposing that home dialysis patients being followed by the existing provider in Bladen County will transfer their care to the new facility. BMA assumes that those patients will continue to dialyze with their current facility. However, BMA will not deny admission to any patient with proper referral by a nephrology physician with admitting privileges at the facility.*
6. *BMA does assume that the home dialysis patients residing in Bladen County and being followed by Carolina Kidney Care nephrology physicians will transfer their care to the new facility. This assumption is based upon the continuity of care that the patient will receive and the significantly reduced burden of travel to either Fayetteville or Lumberton currently experienced by the patient.*
7. *BMA assumes that the home patient population of Bladen County will continue to increase, much as the ESRD patient population of North Carolina and Bladen County has in recent years. The number of home patients within the ESRD patient population as a whole is increasing at a higher rate than the ESRD patient population itself. BMA has already demonstrated that the ESRD patient population of North Carolina is growing at a rate of 3.21% annually. At the same time the home patient population of our State is increasing at a rate of 10.88% at the same time. Thus it is obvious that more and more patients needing dialysis treatment are opting for home dialysis.*
8. *BMA assumes that more patients will choose home peritoneal dialysis as a result of development of this facility, coupled with the presence of Carolina Kidney Care physicians. The January 2013 SDR Table B reports, among other things, the*

ESRD patient population for each County in our State, to include the number of patients utilizing home dialysis.

9. *BMA assumes that more patients will choose home peritoneal dialysis as a result of development of this facility, coupled with the presence of Carolina Kidney Care physicians.*
10. *BMA assumes that the home patient population of Bladen County will increase to a level of 20% home patient population. This growth is a function of more patients choosing home dialysis and more patients referred to home dialysis from by the nephrology physicians of Carolina Kidney Care. Further, Bladen County is a large rural county. To the extent that more patients may be referred to home dialysis, then fewer patients are traveling long distance for dialysis treatment in Elizabethtown three days per week.*
11. *BMA will project growth of the Bladen County ESRD patient population at the Bladen County Five Year Average Annual Change Rate as published in the January 2013 SDR. That rate is 5.2%.*
12. *BMA will project that 20% of the future ESRD patient population of Bladen County will choose home dialysis.*
13. *BMA does not assume that all of the future home patients will choose to dialyze with BMA. BMA assumes that half of the new patients in the first operating year of this project will choose to dialyze with BMA. BMA assumes that one new patient from the Second Operating Year will choose to dialyze with BMA.”*

Therefore, using the dialysis patient population as of June 30, 2012 and the Bladen County Five Year Average Annual Change Rate (AACR) of 5.2%, both of which are published in the 2013 January 2013 SDR, the applicant grows the total dialysis patient population of Bladen County through June 30, 2016, the end of the second project year. See the following calculations, based on a beginning census of 96 in-center dialysis patients and a 5.2% AACR:

$$\begin{aligned} 96 \times 1.052 &= 101.0 && \text{(to June 30, 2013)} \\ 101.0 \times 1.052 &= 106.2 && \text{(to June 30, 2014)} \\ 106.2 \times 1.052 &= 111.8 && \text{(to June 30, 2015)} \\ 111.8 \times 1.052 &= 117.6 && \text{(to June 30, 2016)} \end{aligned}$$

BMA then calculates 20% of the patient population and projects the following number of dialysis patients who will receive home training in the first and second project years:

$$\text{Operating Year One (7/1/14 – 6/30/15)} \quad 111.8 \text{ patients} \times 20\% = 22.4$$

Operating Year Two (7/1/15 – 6/30/16) 117.6 patients x 20% = 23.5

On pages 60 – 61, the applicant projects how many of the home patients in Bladen County it projects to serve in Project Years 1 and 2. The applicant states:

“... BMA is currently serving some of the Bladen County home patient population. BMA will project one home peritoneal dialysis patient to transfer care to the new FMC Bladen Home Program upon certification. BMA is serving one home hemodialysis patient from Bladen County and does not project that patient to transfer to the new facility; the new facility is PD only.

Further, BMA notes that the current home patient population of Bladen County is comprised of 14 patients according to the January 2013 SDR. BMA does not anticipate that patients of the current provider in Bladen County will change their care to the new facility. However, BMA will not prohibit any patient from transferring their care with proper referral from a physician with admitting privileges. BMA projections of a patient population to be served include the one transferring patient and half of the future home patient population of Bladen County.

Thus, patient populations to be served are projected as follows:

*Current, per January 2013 SDR: 14 home patients
BMA is providing treatment for 2 (1 is home hemo dialysis)
BMA assumes DaVita is providing treatment for: 12*

*Operating Year 1, BMA projections 22.4 home patients
BMA is providing treatment for: 2
BMA assumes DaVita is providing treatment for: 12
New Home patients: 8
BMA assumes 4 patients will dialyze with BMA
BMA assumes 4 patients will dialyze with DaVita*

*Operating Year [2], BMA projections 23.5 home patients
BMA is providing treatment for 6 (1 is home hemo dialysis)
BMA assumes DaVita is providing treatment for: 16
Operating Year 2 new patients: 1
BMA assumes the one new patients [sic] will dialyze with BMA*

Thus, at the end of Operating Year 1, BMA projects to serve 5 of the 22.4 patients projected to choose home PD in Bladen County. At the end of Operating Year 2, BMA projects to serve 6 of the 23.5 patients projected to choose home PD in Bladen County.

The project analyst tested the applicant’s assumptions with regard to the home patient population comprising 20% of the entire ESRD patient population in Bladen County. The analyst looked at Table B of past SDRs from January 2010 to January 2013 for Bladen County, and found the following:

SDR VERSION	TOTAL NO. BLADEN CO. ESRD PATIENTS	NUMBER HOME PATIENTS	PERCENT HOME
January 2010	91	5	5.5%
July 2010	92	3	3.3%
January 2011	92	4	4.4%
July 2011	95	4	4.2%
January 2012	94	7	7.5%
July 2012	95	11	11.5%
January 2013	95	14	14.7%

Rates from the July 2013 SDR, which was not available when this application was submitted, showed a total ESRD patient population in Bladen County of 106 and a home patient population of 17.

The analyst notes that, according to the data provided in the January 2010 SDR through the January 2011 SDR, there was little growth in home patients. From July 2011 through July 2013, the percentage of home ESRD patients grew by 324% [(17.8% patients in July 2013 / 4.2% in July 2011) – 1 = 3.238]. Alternatively, the number of dialysis patients receiving home therapies in Bladen County grew by 345% between July 2011 and July 2013 [(17.8 patients July 2013 / 4 patients July 2011) – 1 = 3.45]. This growth occurred without offering new home PD training and support services in the County. If the percentage of home trained patients in Bladen County were increased by the AACR from the January 2013 SDR (5.2%), then by the end of Operating Year Two, the percentage of Bladen County ESRD patients who choose home dialysis training would be 17.5%, without the introduction of a new home dialysis provider in the county. Therefore, it is reasonable to assume that, with the recent growth in home training for dialysis patients in Bladen County combined with the introduction of a new provider, particularly a provider that is connected to a group of eleven nephrologists who treat patients in the county, the percentage of home trained patients in Bladen County could comprise 20% of the Bladen County dialysis patient population. Furthermore, the data in the July 2013 SDR, as noted in a note to the above table, which was not available to the applicant at the time the application was prepared, shows the percent and number of home patients in Bladen County grew by even more than the AACR that was published in the January 2013 SDR.

Additionally, the applicant projects that it will serve 5 of 22.4 home trained patients in the first Operating Year, and 6 of 23.5 home trained patients in the second Operating Year. Each number represents less than 25% of the total projected number of dialysis patients in Bladen County who will choose home training and support rather than in-center dialysis. The applicant has provided documentation of a physician referral base in Bladen County with Carolina Kidney Care, and the data provided in the SDRs shows that the number of home trained patients is increasing at a faster rate than in past years.

The applicant adequately demonstrates the need for the proposed home PD and training and support services in Bladen County.

In summary, the applicant adequately identifies the population to be served and adequately demonstrates 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, page 62 of the application, the applicant discusses the alternatives it considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – continue to offer home peritoneal dialysis for Bladen County residents through BMA Fayetteville or BMA Lumberton, which is where current home patients receive their training and support. The applicant states that, due in part to the referral trends of the nephrologists at Carolina Kidney Care, the number of home trained dialysis patients in Bladen County is increasing. To maintain the status quo would necessitate that current home dialysis patients still travel to Cumberland or Robeson counties for their training and support.
- 2) Chosen alternative – offer home PD training and support at FMC Bladen Home Dialysis. Development of the home PD dialysis program as proposed in this application will provide Bladen County residents the opportunity to receive their training and support in their county, without traveling to Cumberland or Robeson counties. This alternative, according to the applicant, provides the home training and support that the Bladen County dialysis patients need. In addition, the development of the FMC Bladen Home Dialysis program will more effectively serve the increasing numbers of home dialysis patients in Bladen County.

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative to meet the need for home PD training and support services in Bladen County based on the following:

- Current and future Bladen County dialysis patients will be able to receive home PD training and support in Bladen County and continue to be served by the nephrologists with Carolina Kidney Care.

- Current and future Bladen County dialysis patients who desire home PD training and support will be able to choose from two providers located in Bladen County.

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

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the need for home PD training and support services in Bladen County. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Bladen Home Dialysis shall materially comply with all representations made in the certificate of need application.**
 - 2. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Bladen Home Dialysis shall develop no more than one home peritoneal dialysis training and support program facility in Bladen County.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Bladen Home Dialysis 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 77, the applicant states that the proposed capital cost of the project is \$277,113, including \$145,418 for construction contract costs, \$51,857 for equipment and furniture costs, \$13,088 for architect/engineering fees, and \$16,750 for RO water treatment equipment and contingency fees. In Section IX.1, page 82, the applicant states there will be start-up expenses of \$23,711 and initial operating expenses of \$189,309. According to the applicant on page 83, the initial operating period is projected to last eight months (i.e. it will take eight months for revenues to exceed expenses).

In Section VIII.2, page 78 and Section IX.4, page 84, the applicant states that the project will be funded with cash reserves of Fresenius Medical Care Holdings, Inc., the parent company of Bio-Medical Applications of North Carolina, Inc. In Exhibit 24 the applicant provides a June 17, 2013 letters signed by the Vice President of Fresenius Medical Care Holdings, Inc., which states in part:

“BMA proposes to develop a new home peritoneal dialysis program in Elizabethtown, Bladen County. ... The project calls for the following capital expenditures on behalf of BMA.

Capital Expenditure \$227,113

As Vice President, I am authorized and do hereby authorize the development of this home dialysis program in Bladen County, North Carolina for capital costs of necessary cash and cash reserves for the start up and working capital which may be needed for this project.”

In addition, in Exhibit 10 the applicant provides the audited financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ending December 31, 2012 and December 31, 2011. As of December 31, 2012, Fresenius Medical Care had \$341,071,000 in cash and cash equivalents, \$17,841,509,000 in total assets, and \$9,469,431,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

In Section VI.1(c), page 70, the applicant states reimbursement projections are based on the historical performance of home training programs in other BMA facilities. In Section X.3, pages 86 - 87, the applicant provides the assumptions with which it projects revenue for each payor source for its home PD patients. In Section X.1, page 85, the applicant states it has opted to participate in a Medicare reimbursement program which provides one basic fee which includes ancillary costs associated with dialysis treatments. Additional ancillary services are reflected separately in a table on page 87 of the application. See the following table:

Projected Reimbursement Home Peritoneal Dialysis			
FMC BLADEN HOME PD TRAINING			
Revenue Source Year 1	Patient Payment % by Revenue Source	# Treatments	Reimbursement per Treatment
Medicare	71.42%	309	\$ 234.00
Commercial	28.58%	123	\$1,375.00
Revenue Source Year 2	Patient Payment % by Revenue Source	# Treatments	Reimbursement per Treatment
Medicare	71.42%	566	\$ 234.00
Commercial	28.58%	226	\$1,375.00

This information is consistent with the payor mix reported by the applicant in Section VI.1(c), page 70 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 86; and Section X.4, page 88, the applicant reports projected revenues and expenses as illustrated in the following table:

FMC BLADEN		
	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$241,980	\$443,630
Total Operating Costs	\$283,964	\$373,872
Net Profit	(\$ 41,984)	\$ 69,758

As shown in the above table, the applicant projects that revenues will exceed operating expenses in the second operating year. 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

In this application, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Bladen Home Dialysis proposes to develop a new freestanding home training program facility for peritoneal dialysis (PD) patients. BMA does not propose to offer in-center dialysis or include any hemodialysis stations in the new Bladen County Home Dialysis facility. Bladen County Home Dialysis will be located in Elizabethtown and proposes to serve home PD patients from Bladen County.

According to the January 2013 SDR, there is one Kidney Disease Treatment Center in Bladen County – Southeastern Dialysis Kenansville, in Kenansville. DaVita is the owner of the facility, which is certified for 14 in-center hemodialysis stations. Southeastern Dialysis offers home PD training and support services. There are three other dialysis facilities which offer home training and support; however, these three facilities are between 36.1 and 37.9 miles from the ZIP code for the proposed Bladen County home dialysis program. See the following table:

FACILITY	TOWN	COUNTY	PROVIDER	DISTANCE FROM 28303
Fayetteville Kidney Center	Fayetteville	Cumberland	BMA/FMC	5.5 miles
Carolina Dialysis Sanford	Sanford	Lee	BMA/FMC	36.1 miles
FMC Lumberton Dialysis	Lumberton	Robeson	BMA/FMC	37.9 miles
Dialysis Care of Moore County	Pinehurst	Moore	DaVita	36.2 miles

In addition, in Project ID #M-10115-13, BMA was recently approved to dedicate two existing, certified dialysis stations to offer home PD training and support at its facility in Clinton. Clinton is in Sampson County, which is contiguous to Bladen County along its northeastern edge. According to MapQuest®, the distance from Clinton to Elizabethtown is approximately 36 miles.

The applicant adequately demonstrates the need to develop the proposed home PD facility in Elizabethtown for the provision of home PD services to serve the residents of Bladen County. 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 training and support services in Bladen 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 74, the applicant provides the proposed staffing during the first two operating years following completion of the project, as illustrated below in the table.

POSITION	PROJECTED FULL TIME EQUIVALENT POSITIONS (FTES) YEARS 1 AND 2
Clinical Manager/HT RN	1.00
Admin.	0.10
Dietitian	0.10
Social Worker	0.10
Equipment Technician	0.10
In-Service	0.10
Clerical	0.50
Total	2.00

As shown in the above table, the applicant proposes to employ a total of 2.0 FTE positions to staff the PD home training facility during the first two operating years following completion of the project. In Section V.4(c), page 67, the applicant states that Dr. Ezra McConnell will be the Medical Director for Bladen County Home Dialysis. In Exhibit 21 the applicant provides an April 3, 2013 letter from Dr. McConnell which confirms the information on page 67. In Section VII.10, page 76, the applicant states that the Bladen County Home Dialysis will operate Monday-Friday, from 7:00 AM to 5:00 PM. The applicant states further that a qualified registered nurse will be on call 24 hours a day / 7 days a week.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel, including a medical director, for the provision of PD home training and support services. Therefore, the application is conforming 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 64, the applicant provides a table that lists the proposed providers of ancillary and support services for FMC Bladen Home Dialysis. Exhibit 17 contains a copy of a transplantation agreement between FMC Bladen Home Dialysis and Duke University Medical Center. Exhibit 16 contains a hospital affiliation agreement between Cape Fear Valley Medical Center and BMA. Exhibit 18 contains a copy of a laboratory services agreement between BMA and SPECTRA Laboratories, Inc. for the provision of laboratory services. Exhibit 20 contains a copy of a home training agreement with BMA Lumberton, which states that facility will provide back up assistance if necessary. Exhibit 21 contains a letter from Carolina Kidney Care (CKC) which confirms referrals to the proposed home training program as well as follow up with the CKC nephrologists for home trained dialysis patients. That same letter confirms Dr. Ezra McConnell's commitment to serve as the medical director for the proposed 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;

NA

(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 71, the applicant states “*BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations*” In Section VI.6(a), page 72, 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

C

In Section VI.1(c), page 70, the applicant notes that FMC Bladen Home Dialysis is a proposed facility and thus has no historical payor mix on which to base its projected payor mix. On page 70, the applicant projects that 71.4% of the home PD patients will be Medicare or Medicaid beneficiaries, which it states is based on “*historical performance of the BMA Lumberton home training program, and specifically the peritoneal dialysis patients. BMA does not anticipate any significant changes to the home patient population.*” 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. FMC Bladen Home Dialysis 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 affiliation agreement between BMA Clinton and Cape Fear Valley Health System. The applicant adequately demonstrates that FMC Bladen Home Dialysis will offer 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 66, the applicant states:

“Exhibit 19 includes a letter from Kristina Roberts, FMC Area Manager, to Robeson Community College Nursing Department inviting the school to include the facility in its clinical rotation for nursing students. 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 June 7, 2013 from the Area Manager of Fresenius Medical Care to Robeson Community College, inviting the school to include FMC Bladen Home Dialysis 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

FMC Bladen Home Dialysis proposes to offer home PD training and support services in its proposed facility. The only other kidney disease treatment center in Bladen County is Southeastern Dialysis of Kenansville, an in-center dialysis facility operated by DaVita, which provides home PD training and support services.

In Section V.7, page 68, 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 provide quality services; and
- ◆ The applicant will 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.

NA

- (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 Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is conforming to all applicable regulatory review criteria. The specific criteria are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

- .2202(a)(1) *Utilization rates;*
-NA- FMC Bladen Home Dialysis is not an existing facility and thus and does not have historical information to report.
- .2202(a)(2) *Mortality rates;*
-NA- FMC Bladen Home Dialysis is not an existing facility and thus and does not have historical information to report.
- .2202(a)(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 is currently serving several home patients who are residing in Bladen County. These patients are being followed by either BMA Fayetteville or BMA Lumberton (patient choice of providers). Upon approval of this CON application and certification of the new facility, FMC Bladen Home Dialysis will be dedicated to the peritoneal dialysis patient population. Home hemo-dialysis will continue to be followed at the BMA Fayetteville or BMA Lumberton facility....”
- .2202(a)(4) *The number of transplants performed or referred;*
-NA- FMC Bladen Home Dialysis is not an existing facility and thus and does not have historical information to report.
- .2202(a)(5) *The number of patients currently on the transplant waiting list;*
-NA- FMC Bladen Home Dialysis is not an existing facility and thus and does not have historical information to report.
- .2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
-NA- FMC Bladen Home Dialysis is not an existing facility and thus and does not have historical information to report.
- .2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*

-NA- FMC Bladen Home Dialysis is not an existing facility and thus and does not have historical information to report.

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

.2202(b)(1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.

-C- Exhibit 16 contains a copy of a proposed affiliation agreement between Cape Fear Valley Medical Center and FMC Bladen Home Dialysis which specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility.

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

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

-C- Exhibit 17 contains a copy of a transplant agreement between Duke University Medical Center and FMC Bladen Home Dialysis dated April 1, 2013.

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

-C- In Section II, on page 12, the applicant states water and power are available at the site. In Exhibit 30, the applicant provides copies of email communications which document the availability of power and water at the primary site. In Exhibit 31, the applicant provides the same documentation for the secondary site.

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

-C- Exhibit 12 contains a copy of BMA's Emergency Disaster Procedure Manual, which details procedures for back-up electrical service in the event of a power outage. In addition, in Section II, page 12, the applicant states, "All peritoneal

dialysis patients are taught to perform manual exchange in the event of a power failure which interrupts the PD cyclers.”

.2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-C- In Exhibits 30 and 31, the applicant provides documentation which identifies both a primary and a secondary site (in case the primary site is unavailable upon certificate of need approval) which the applicant will lease for the Bladen County Home Dialysis facility.

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

-C- In Section II, page 13, and Section VII.2, page 75, the applicant documents that Bladen County Home Dialysis will provide all services in conformity with all applicable laws and regulations for staffing and safety. In addition, in Exhibit 12, the applicant provides a copy of BMA’s emergency and disaster polices and procedures manual, and Exhibit 11 contains a copy of the applicant’s water quality standards policy.

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

-C- In Section II, pages 13 - 22, and in Section III.7, pages 51 - 61, the applicant provides its assumptions regarding patient origin for the proposed FMC Bladen County Home Dialysis. In addition, in Section III.7, page 30, the applicant provides the projected patient origin for Bladen County Home Dialysis, which it projects will be comprised completely of Bladen County dialysis patients. See the following table:

FMC BLADEN COUNTY PD	OY 1 (9/30/14 – 6/30/15)	OY 2 (9/30/15 – 6/30/16)	COUNTY PATIENTS AS PERCENT OF TOTAL	
			OY 1	OY 2
Bladen	5	6	100.0%	100.0%
Total	5	6	100.0%	100.0%

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

-NA- In Section II, page 61, the applicant projects that “100% of the patient population of this facility resides within 30 miles of the facility. ... Thirty miles from the primary location for FMC Bladen Home covers the entirety of Bladen County.”

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

-C- In Section II.1(9), page 24, 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.*”

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- FMC Bladen County Home Dialysis proposes a peritoneal dialysis home training facility and does not propose to develop a facility with hemodialysis stations.

.2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-NA- FMC Bladen County Home Dialysis proposes a new peritoneal dialysis home training facility.

.2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section II, pages 26 – 36, Section II, pages 13 – 23, and in Section III.7, pages 51 - 61, the applicant provides the assumptions and methodology used to project utilization of the proposed facility. See discussion in Criterion (3) which is incorporated hereby as if set forth fully herein.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

.2204(1) *Diagnostic and evaluation services;*

-C- In Section II, page 36, and in Section V.1, page 64, the applicant states that diagnostic evaluation services will be provided by Cape Fear Valley Medical Center, Bladen County Hospital, or Lumberton Radiological Associates.

.2204(2) *maintenance dialysis;*

- C- In Section II, page 36, the applicant states: *“The facility will provide training for home peritoneal dialysis. Patients dialyzing at home receive maintenance dialysis equivalent to that received in a traditional in-center setting.”* In addition, in Section V.1, page 64, the applicant indicates that maintenance dialysis will be provided at the facility.

- .2204(3) *accessible self-care training;*
 - C- In Section II, page 37, the applicant states: *This facility will train patients to dialyze at home.”* In addition, in Section V.1, page 64, the applicant indicates that self-care training will be provided by the facility.

- .2204(4) *accessible follow-up program for support of patients dialyzing at home;*
 - C- In Section II, page 36, the applicant states, *“This is an application to develop a new home training program. The new center will focus exclusively on home peritoneal dialysis. Patients who are candidates for home hemo-dialysis will be referred to the BMA Fayetteville or BMA Lumberton home training department.”*

- .2204(5) *x-ray services;*
 - C- In Section II, page 37, and in Section V.1, page 64, the applicant states that Cape Fear Valley Medical Center, Bladen County Hospital, or Lumberton Radiological Associates will provide X-ray services.

- .2204(6) *laboratory services;*
 - C- In Section II, page 37, and in Section V.1, page 64, the applicant states laboratory services will be provided by Spectra Laboratories. See Exhibit 18 for the existing agreement with Spectra Laboratories.

- .2204(7) *blood bank services;*
 - C- In Section II, page 37, and in Section V.1, page 64, the applicant states that blood bank services will be provided by Cape Fear Valley Medical Center and Bladen County Hospital.

- .2204(8) *emergency care;*
 - C- In Section II, page 37, and in Section V.1, page 64, the applicant states that emergency care will be provided on site by BMA staff until emergency responders arrive. The facility stocks a “crash cart” in the event of a medical emergency, and all staff are appropriately trained in emergency situations.

- .2204(9) *acute dialysis in an acute care setting;*
 - C- In Section II, page 37, and in Section V.1, page 64, the applicant states that acute dialysis in an acute care setting will provided by Cape Fear Valley Medical Center and Bladen County Hospital.

- .2204(10) *vascular surgery for dialysis treatment patients;*

- C- In Section II, page 37, and in Section V.1, page 64, the applicant states that vascular surgery for dialysis treatment patients will be provided by Carolina Kidney Care Nephrology Procedure Center, Village Surgical Associates, Village Surgical Associates in Fayetteville, or by one of several surgeons who will provide services.

- .2204(11) *transplantation services;*
 - C- In Section II, page 37, and in Section V.1, page 64, the applicant states transplantation services will be provided by Duke University Medical Center. In Exhibit 17, the applicant provides a copy of the existing agreement.

- .2204(12) *vocational rehabilitation counseling and services; and*
 - C- In Section II, page 38, and in Section V.1, page 64, the applicant states vocational rehabilitation counseling and services will be provided by Vocational Rehabilitation in Lumberton.

- .2204(13) *transportation.*
 - C- In Section II, page 37, and in Section V.1, page 64, the applicant states transportation will be provided by Bladen Area Rural Transportation, or by the Department of Social Services.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

- .2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100.*
 - C- In Section VII.1 – 2, on pages 74 - 75, the applicant provides the proposed staffing. In Section VII.2, page 75, the applicant states the proposed facility will comply with all staffing requirements as stated in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for additional discussion which is incorporated hereby as if set forth fully herein.

- .2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
 - C- In Section II, page 38, and in Section V.1, page 64, the applicant describes the qualifications or certifications that are required for staff members of FMC Bladen County Home Dialysis. In addition, the applicant provides a copy of BMA's training outline in Exhibit 14. The applicant also provides a copy of BMA's Emergency Preparedness and Procedure Manual in Exhibit 12.