ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DATE: February 10, 2012

PROJECT ANALYST: Paula Quirin
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: F-8755-11/ Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Cabarrus County Home Dialysis Program/ Relocate existing certified dialysis station(s) from BMA Charlotte to establish a new freestanding home dialysis training and support center for peritoneal dialysis and home hemodialysis / Cabarrus County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Cabarrus County Home Dialysis Program provides the following project description in Section I.8, page 2 of the application: "*Bio-Medical Applications of North Carolina, Inc. (BMA) proposes to transfer two dialysis* [sic] *from BMA Charlotte into Cabarrus County and develop a new freestanding home dialysis training and support program. The center will offer home training and support for both peritoneal dialysis and home hemodialysis."* The applicant proposes to develop a new "kidney disease treatment center" [as defined in G.S. 131E-176(14e)] by relocating one or more existing dialysis stations from Mecklenberg County to Concord in Cabarrus County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Therefore, neither of the two need methodologies in the 2011 State Medical Facilities Plan (2011 SMFP) is applicable to the review. However, Policy ESRD-2, found on page 33 of the 2011 SMFP, is applicable to this review. Policy ESRD-2 states:

"Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of Need applicant proposing to relocate dialysis stations to contiguous counties shall:

1. *demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent Dialysis Report, and*
2. *demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent Dialysis Report."*

In Section III.5, page 32, the applicant states:

"BMA is proposing to transfer one dialysis stations [sic] *into Cabarrus County from Mecklenberg County."* Mecklenberg County is contiguous to Cabarrus County. The applicant provides the following table illustrating *"the county station deficit surplus before and after the transfer is completed."*

County	***Station Surplus/Deficit***	***Stations Transferred***	***Net Result Deficit/ Surplus***
Cabarrus	*-24*	*+1*	*-23*
Mecklenberg	*+15*	*-1*	*+14*

The project analyst verified that the above information regarding projected station deficits and surpluses in Cabarrus and Mecklenberg counties, which are reported in Table B: ESRD Dialysis Station Need Determination in the July 2011 North Carolina Semiannual Dialysis Report, is correct.

In Section III,8, page 35, the applicant states:

"BMA Charlotte is currently serving at least one patient from Cabarrus County. Further, the relocation of these stations will not create a surplus of stations in Cabarrus County, nor will the relocations create a deficit in the counties losing stations."

However, throughout the application, the applicant provides inconsistent information concerning the number of stations it proposes to relocate from BMA Charlotte. Initially, the applicant states two stations will be relocated (see page 2, 10, 17). Elsewhere in the application, the applicant states only one station will be relocated (see page 23, 30, 31, and 32). Furthermore, Exhibit 28 contains a line drawing which shows the proposed facility would have 4 dialysis stations.

The proposal would not result in a surplus of dialysis stations in Cabarrus County or a deficit of stations in Mecklenberg County regardless of whether the applicant proposes to relocate one, two

or four stations given that no one was approved to develop any of the 23 stations that were available to be applied for in the July 2010 SDR. Furthermore, according to the January 2012 SDR, 20 of those 23 stations are still needed. The denials are still under appeal as of the date of this decision. Consequently, the application is consistent with Policy ESRD-2 in the 2011 SMFP and the application is conforming with this criterion.

(2) Repealed effective July 1, 1987.

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

NC

In Section I.9, page 2, and in Section II.1, page 10, the applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Cabarrus County Home Dialysis Program proposes to relocate existing dialysis stations from BMA Charlotte (Mecklenberg County) to establish a new kidney disease treatment center [as defined in G.S. 131E-176(14e)] dedicated to home hemodialysis and peritoneal dialysis training in Concord (Cabarrus County).

In Section II.9, page 15, the applicant identifies the population to be served by the proposed project, as follows:

> *"BMA reasonably expects that 100% of the patient population of this facility resides well within 30 miles of the facility. Thirty miles from Concord covers the entirety of Cabarrus County. BMA is not proposing to serve patients from other counties at this facility."*

In Section III.3, page 30, the applicant states:

> *"BMA is proposing to transfer a single existing and certified dialysis station from BMA Charlotte to develop a dedicated home training facility in Concord, Cabarrus County. As noted in the Policy ESRD-2 discussion (Section II of this application), there is currently a surplus of dialysis stations in Mecklenberg County and a deficit of stations in Cabarrus County. BMA proposes to mitigate a portion of the Cabarrus County deficit by transferring one surplus station to Cabarrus County. This action will not create a station deficit within Burke, Catawba, Lincoln or Gaston Counties, nor will it create a station surplus in Cabarrus County. The transferring facility BMA Charlotte, is* ***currently serving*** *patients from Cabarrus County.*
> …

> *BMA proposes to relocate a single dialysis stations* [sic] *to develop the Cabarrus County Home Dialysis Program facility. Within this application, BMA has projected to be serving eight patients at the end of the first year of operations for this facility; four of these patients are projected to be home hemo-dialysis patients. Home hemo-dialysis does require training which utilizes the dialysis station. Training is generally accomplished one patient at a time. With a projection of four hemo-dialysis patients, BMA is projecting a utilization rate of 4 patients per station."* [Emphasis in original]

Note: The applicant does not state how many Cabarrus County residents are currently being served at BMA Charlotte.

On page 31, the applicant states:

> *"BMA Charlotte is currently a 46 station dialysis facility offering both in-center and home dialysis training and support. Relocation of a single station will leave BMA Charlotte with 45 stations. BMA notes that it has also projected to transfer six stations from BMA Charlotte to the FMC Matthews facility; that project is scheduled for completion at June 30, 2012, the same date this project is scheduled for completion. Therefore, projections of future station utilization at BMA Charlotte will reflect 39 stations.*
>
> *BMA projects the census of the BMA Charlotte facility by projecting growth if the facility census using the Mecklenberg County Five Year Average Annual Change rate as published in the July 201 SDR. That rate is 5.1%.*

BMA begins with the in-center patient population Residing in BMA Charlotte patient population fo [sic] *Mecklenberg County as* [sic] *June 30, 2011*	*118*
BMA projects growth of this patient population For 12 months to June 30, 2012	*(118 X .051) + 118 = 124*

> *BMA projects utilization at the BMA Charlotte facility for June 30, 2012 also considers that four patients are also projected to transfer from BMA Charlotte to FMC Matthews upon completion of the transfer project. Thus the net census would be 120. Utilization is projected to be as follows:*
>
> *120 Patients dialyzing on 39 stations = 3.07 patients per station*
> *120/ (4 X 39) = .769 or 76.9% utilization*
>
> *It is clear that transferring one station to FMC Cabarrus County Home Dialysis Program will not adversely impact the patients remaining at BMA Charlotte.*

Cabarrus County has a 24 station deficit. At this rate, essentially anywhere in the county would be beneficial for the patients of the county. However, BMA has selected a site near the cross roads of I-85 and US 601 in order to make the home training facility more accessible for the home patient population of the area."

In Section III.5, page 32, the applicant provides the following table which the applicant states *"demonstrates the county station deficit surplus before and after the transfer is completed."*

County	***Station Surplus/Deficit***	***Stations Transferred***	***Net Result Deficit/ Surplus***
Cabarrus	*-24*	*+1*	*-23*
Mecklenberg	*+15*	*-1*	*+14*

The applicant states that the relocation will not adversely affect patients who will continue to dialyze at BMA Charlotte. However, the applicant provides inconsistent statements regarding the number of stations to be relocated from BMA Charlotte. Initially the applicant states the project involves transfer of two stations (see pages 2, 10 and 17). Elsewhere in the application, there are multiple references to relocating a single station (see page 23, 30, 31, and page 32). However, Exhibit 28 contains a line drawing which shows the proposed facility would have 4 dialysis stations.

Need Analysis

On page 32, the applicant states:

"There is a growing need for dialysis treatment. The July 2011 SDR reports a 24 station deficit in Cabarrus County. BMA is aware that 23 stations are currently in litigation arising from the 2010 County Need Determination.

In addition to the 23 station deficit, the SDR [sic] *that there were 28 home dialysis patients residing in Cabarrus County as of December 31, 2010. The Southeastern Kidney Council zip code report for June 30, 2011 reports that there were 211 dialysis patients residing in Cabarrus County. Of these 211 patients, 171 were in-center patients, six were home hemo-dialysis patients and 33 were home peritoneal dialysis patients; one patient was classified as 'Other'. Thus, one can conclude that home patient population of the county has increased by a least 11 patients in six months. If annualized this would be a raw change of 22 patients in a single year. This is the equivalent of an annual change of greater than 78% within this segment of the ESRD patient population of Cabarrus County."*

The following table illustrates the number of Cabarrus County home patients between December 31, 2010 and October 4, 2011.

Reported in Southeastern Kidney Council Zip Code Report as of	**In-center Patients**	**Home HD**	**Home PD**	**Total Home Patients**	**Other**	**Total**
December 31, 2010				28		
January 3, 2011	186	4	27	31		217
June 30, 2011	171	6	33	39	1	211
July 13, 2011	171	6	33	39	1	211
October 4, 2011	171	6	33	39	0	210

Source: www.esrdnetwork6.org

As shown above, there was an increase of 11 home patients between December 31, 2010 and June 30, 2011, which is a 39% increase in six months. However, the total number of home patients has not increased between June 30, 2011 and October 4, 2011.

The compound annual growth rate (CAGR) for all home dialysis patients statewide between July 2007 – July 2011 was only 10.11%, as illustrated in the table below.

	# Patients as of 7/2007	**# Patients as of 7/2011**	**CAGR**
All ESRD Patients	12,408	14,232	3.49%
All Home Patients	1,057	1,554	10.11%

Source: July 2011 SDR and Section III.7, page 33.

In Section III.7, page 33, the applicant states:

> *"BMA works closely with Metrolina Kidney Associates (MNA). MNA is the largest nephrology practice in south central North Carolina. MNA is providing physician coverage and Medical Director leadership in dialysis facilities from Anson and Stanly Counties on the east to Gaston and Lincoln Counties on the west. MNA Administration reports that their practice has been providing medical care for 115 Cabarrus County patients suffering with Chronic Kidney Disease (CKD) in stages 3,4, and 5.*
>
> …
>
> *The home patient population of North Carolina is growing. The information in the following chart is extracted from the July SDR for the years indicated. The row labeled State Wide* [sic] *reports the total ESRD patient population across North Carolina. The row labeled Home reflects the total home patient population for each year. The last column in each row calculates the five year average annual change in the ESRD patient population.*

SDR Data	*Jul-07*	*Jul-08*	*Jul-09*	*Jul-10*	*Jul-11*	
State Wide	*12408*	*12947*	*13319*	*13751*	*14232*	
Raw Change		*539*	*372*	*432*	*481*	
% Change		*0.04343972*	*0.02873252*	*0.032243487*	*0.03497927*	*0.348966*
Home	*1057*	*1183*	*1251*	*1344*	*1554*	
Raw Change		*126*	*68*	*93*	*210*	
% Change		*0.1192053*	*0.05748098*	*0.07434053*	*0.15625*	*0.1018192*

The above information is very significant. The information indicates that the home patient population is growing at a rate nearly three times the State ESRD population as a whole.

Consider the following summary of the above:

1. *There is a dramatic increase in the home patient population in North Carolina;*

2. *The home patient population of Cabarrus County is currently changing at an annualized rate of 78%;*

3. *There is a large CKD patient population under the care if MNA physicians in Cabarrus County.*

4. *CKD Stage 4 patients will need dialysis within 2 years of Cabarrus County is currently changing at an annualized rate of 78%;*

5. *Cabarrus County has an exceptionally large dialysis station deficit of 24 stations.*

The above points all combine to support development of this freestanding home dialysis training and support program for Cabarrus County. BMA believes it is appropriate to seek CON approval to develop this freestanding home program in Cabarrus County.

In addition to the above, BMA notes that BMA Charlotte facility is currently serving at least one home hemo-dialysis patient from Cabarrus County."

Note: The applicant does not provide the exact number of Cabarrus County residents served at BMA Charlotte.

Projected Utilization

In Section II.1, page 19, the applicant provides the assumptions and methodology used to project utilization for the proposed facility, as follows:

"1. As noted, MNA is currently providing CKD care for 115 dialysis patients from Cabarrus County. Dr. George Hart, president of MNA, has agreed to serve as Medical Director for this facility. Dr. Hart has also indicated that he and his associates will refer patients to the facility.

2. MNA is providing care for a significant number of CKD patients who reside in Cabarrus County. Those patients are currently in various stages of disease progression as follows:

Stage 3 86 patients
Stage 4 25 patients
Stage 5 4 patients

3. Based upon its experience, BMA assumes that 10% of Stage 3 patients, 25% of Stage 4 patients and 50% of Stage 5 patients will require dialysis within 2 years. Based upon this experience, BMA and MNA project the following number of new dialysis patients within two years:

	# Pts	***Need Dialysis Within 2 Years***	***Net new patients***
Stage 3	*86*	*10%*	*8.6*
Stage 4	*25*	*25%*	*6.25*
Stage 5	*4*	*50%*	*2*
Total new patients			*16.85*

4. Based upon recent trends within dialysis BMA assumes that half of the above new patients will begin dialysis utilizing home therapies. Thus, BMA reasonably projects to see eight new dialysis patients as this new program is begun.

5. BMA will assume that approximately half of patients will continue to utilize Peritoneal Dialysis and that half will dialyze using home hemo-dialysis. Home hemo-dialysis has historically seen very low utilization. However, in recent years the numbers of patients dialyzing on home hemo dialysis has increased. Given the recent surge in this segment of the patient population, BMA believes it is reasonable to project that 50% of home patients in the new facility will be home hemo-dialysis patients."

However, the applicant provides no documentation to support its assumption that 50% of new patients will begin dialysis as home patients. In fact, as of July 2011, home patients as a percentage of total ESRD patients is only 10.9%.

	Jul-07	Jul-08	Jul-09	Jul-10	Jul-11
Total Home Patients	1,057	1,183	1,251	1,344	1,554
Total Dialysis Patients	12,408	12,947	13,319	13,751	14,232
Home Patients as % of Total Dialysis Patients	8.5%	9.1%	9.4%	9.8%	10.9%

Source: Section III.7, page 33.

"6. BMA assumes that the patient population of Cabarrus County will increase at a rate surpassing the current published Five Year Average Annual Change rate of 8.3%. However, in an effort to provide most conservatives estimates of patient populations to be served, BMA will increase the projected patient census of the facility at a rate equal to the Cabarrus County five Year Average Annual Change Rate of 8.3%."

In Section II.9, page 20, the applicant projects utilization for Years 1 and 2, as shown in the following table.

Cabarrus County	**Projected Census 6/30/12**	**Operating Year 1 7/1/12-6/30/13**	**Operating Year 2 7/1/13-6/30/14**	**County Patients as a Percent of TOTAL**	
	# Pts Dialyzing at Home	**# Pts Dialyzing at Home**	**# Pts Dialyzing at Home**	**Year 1**	**Year 2**
Home Hemo	2	4	8	100%	100%
Home PD	2	4	8		
TOTAL	4	8	16	100%	100%

As shown in the table above, the applicant proposes serving only 4 home hemodialysis patients at the end of the first operating year. Because the applicant proposes to develop a new facility, pursuant to 10A NCAC 14C .2203(a), the applicant is required to document the need for at least 10 stations based on 3.2 patients per station per week which means the applicant must reasonably project to serve at least 32 home hemodialysis patients by the end of the first operating year [32/10 =3.2]. The applicant does not do so.

Furthermore, the applicant does not provide documentation to support a 100% increase in projected total home dialysis patients from Year 1 to Year 2 as shown above. The CAGR for home patients statewide was only 10.11% between July 2007 and July 2011. Although the number of Cabarrus County home patients increased 39% in the first six months of 2011, there was no growth between June 2011 and October 2011. High growth percentages in Cabarrus County are in part due to the relatively small numbers. [Example: an increase from 1 to 2 patients is a one hundred percent increase but only 1 additional patient. An increase from 100 to 101 is still an increase of only 1 patient, but only a 1% increase]. The applicant does not adequately demonstrate that projected utilization of the proposed home training facility in the second operating year is based upon reasonable and supported assumptions.

Moreover, the applicant provides inconsistent information concerning the number of stations it proposes to relocate from BMA Charlotte. Initially, the applicant states two stations will be relocated (see page 2, 10, 17). Later in the application, the applicant states that only one station will be relocated (see page 23, 30, 31, and 32). Furthermore, Exhibit 28 contains a line drawing which shows the proposed facility would have 4 dialysis stations.

In summary, the applicant did not adequately demonstrate the need the population proposed to be served has for a new "kidney disease treatment center" (as defined in G. S. 131E-176(14e) dedicated to home hemodialysis and peritoneal dialysis training. Therefore, the application is nonconforming with 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.

C

The applicant proposes to relocate 1- 4 stations from BMA Charlotte to a new facility in Cabarrus County. On page 31, the applicant states:

> *"BMA Charlotte is currently a 46 station dialysis facility offering both in-center and home dialysis training and support. Relocation of a single station will leave BMA Charlotte with 45 stations. BMA notes that it has also projected to transfer six stations from BMA Charlotte to the FMC Matthews facility; that project is scheduled for completion at June 30, 2012, the same date this project is scheduled for completion. Therefore, projections of future station utilization at BMA Charlotte will reflect 39 stations.*
>
> *BMA projects the census of the BMA Charlotte facility by projecting growth if the facility census using the Mecklenberg County Five Year Average Annual Change rate as published in the July 201 SDR. That rate is 5.1%.*

BMA begins with the in-center patient population Residing in BMA Charlotte patient population fo [sic] *Mecklenberg County as* [sic] *June 30, 2011*	*118*
BMA projects growth of this patient population For 12 month to June 30, 2012	*(118 X .051) + 118 = 124*

BMA projects utilization at the BMA Charlotte facility for June 30, 2012 also considers that four patients are also projected to transfer from BMA Charlotte to FMC Matthews upon completion of the transfer project. Thus the net census would be 120. Utilization is projected to be as follows:

120 Patients dialyzing on 39 stations = 3.07 patients per station
120/ (4 X 39) = .769 or 76.9% utilization

It is clear that transferring one station to FMC Cabarrus County Home Dialysis Program will not adversely impact the patients remaining at BMA Charlotte."

The applicant provides inconsistent information concerning the number of stations it proposes to relocate from BMA Charlotte. Initially, the applicant states two stations will be relocated (see page 2, 10, 17). Elsewhere in the application, the applicant states only one station will be relocated (see page 23, 30, 31, and 32). Furthermore, Exhibit 28 contains a line drawing which shows the proposed facility would have 4 dialysis stations. However, whether the applicant proposes to relocate one, two or four stations from BMA Charlotte, that facility would have enough stations to serve the patients expected to utilize it, as shown below.

# Patients BMA Charlotte	**# Stations**	**Patients per Station***
120	39	3.07
120	38	3.16
120	37	3.24
120	36	3.33

* Patients per station = # patients / # stations. Example: 120 / 39 = 3.07

The applicant adequately demonstrates that the needs of the population presently served will be met adequately at BMA Charlotte following the relocation. Therefore, the application is conforming with this criterion

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

NC

In Section III.9, page 35, the applicant describes the alternatives it considered. However, the application is not conforming to all other applicable statutory and regulatory review criteria. See Criteria (3), (5), (6), (18a) and the Criteria and Standards for End Stage Renal Disease Services promulgated in 10 A NCAC 14C .2200. Therefore, the applicant did not adequately demonstrate that the proposal is its most effective alternative. Consequently, the application is nonconforming with this criterion.

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

NC

In Section XI, page 50, the applicant states that it will upfit 2,400 square feet of leased space at 1921 Concord Lake Road in Concord. In Section VIII.1, page 50, the applicant projects a total capital cost of $433,962, as shown in the table below.

Construction Contract Costs	$338,584
Equipment / Furniture Costs	$25,150
Architect/Engineering Fees	$30,473
Contingency	39,755
TOTAL	**$433,9626**

In Section IX, pages 57, the applicant projects that start-up costs will be $25,243 and initial operating expenses will be $334,839, for a total working capital cost of $360,082 [$25,243 + $334,839 = $360,082]. The applicant states that the capital and working capital needs of the project will be funded with the accumulated reserves of Fresenius Medical Care Holdings, Inc., the ultimate parent of BMA.

Exhibit 24 contains a letter from the Vice President of Fresenius Medical Care Holdings, Inc., which states:

> *"This is to inform you that Fresenius Medical Care Holdings, Inc. is the parent company of National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc.*
>
> …
>
> *As Vice President, I am authorized and do hereby authorize the development of this home dialysis program in Cabarrus County, North Carolina for capital costs of $433,962. Further, I am authorized and do hereby authorize and commit all necessary cash and cash reserves for the start up and working capital which may be needed for this project."*

Exhibit 10 contains the audited financial statements for Fresenius Medical Care Holdings, Inc. As of December 31, 2010, Fresenius Medical Care Holdings, Inc. had $163,292,000 in cash and cash equivalents, $12,017,618,000 in total assets and $6,561,629,000 in total net assets (total

assets less total liabilities). Therefore, the applicant adequately demonstrated the availability of sufficient funds for the capital and working capital needs of the project.

In Section X.1, page 58, the applicant provides the following projected reimbursement rates:

Payment source	Home PD	Home Hemo
Commercial Insurance	$1,220.00	$1,375.00
Medicare	$234.00	$234.00
Medicaid	$61.32	$137.29
VA	$193.29	$147.85
Medicaid	$1,220.00	$1,375.00

On page 58, the applicant states: *"Medicare will provide additional reimbursement for some co-morbid conditions; however, for CON application purposes, BMA will use only the basic rate of $234. This will necessarily result in slightly lower Medicare reimbursement projections; however, the complexity of the Medicare 'kickers' is driven by patient specific data and does not lend itself to the reporting format of the CON application; the $234 rate is the minimum by Medicare."*

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.

In Section X.2, pages 61-62, the applicant provides the rates and payor mix shown in the tables below.

Home Peritoneal Dialysis	Patient payment % by Source of Revenue	# Treatments	Reimbursement per Treatment
Revenue Source Year 1			
Medicare	31%	179	$1,220.00
Medicaid	67.3%	388	$234.00
Other - Specify	1.7%	19	$193.29
VA	0%	-	-
Revenue Source Year 2			
Medicare	31%	257	$1,220.00
Medicaid	67.3%	775	$234.00
Other - Specify	1.7%	20	$193.29
VA	**0%**		

Home Hemo Dialysis	Patient payment % by Source of Revenue	# Treatments	Reimbursement per Treatment
Revenue Source Year 1			
Medicare	31%	179	$1,375.00
Medicaid	67.3%	388	$234.00
Other - Specify	1.7%	19	$193.29
VA	0%		
Revenue Source Year 2			
Medicare	31%	257	$1,375.00
Medicaid	67.3%	775	$234.00
Other - Specify	1.7%	20	$193.29
VA	0%		

However, in Section VI.1, page 43, the applicant provides a different payor mix as shown in the following table:

Payor Source	Percent of Total
Medicare	67.3%
Medicaid	0%
Medicare/Medicaid	0%
Commercial Insurance	31.0%
VA	1.7%
TOTAL	**100%**

The following table compares the different payor mixes.

	Projected Payor Mix as Stated in Section X.2	Projected Payor Mix as Stated in Section VI.1
Medicare	31.0%	67.3%
Medicaid	67.3%	0%
Commercial	0%	31%
VA	0%	1.7%

In Sections X.2-X.4, pages 59-61, the applicant projects revenues and expenses as follows:

	Operating Year 1	Operating Year 2
Commerical Insurance	$491,040	$982,080
Medicare	$181,419	$362,839

VA	$3,785	$7,571
Drug Adminstration	$738,879	$1,481,581
Gross Patient Service Revenue	$738,879	$1,481,518
Less Deductions	$196,416	$ 392,832
Total Net Revenue	$542,463	$1,088,686
Total Operating Costs	$502,259	$820,605
Net Profit	**$ 40,204**	**$268,081**

Totals may not sum due to rounding.

As shown in the above table, revenues are projected to exceed operating expenses in the first two operating years. However, the applicant's utilization projections are unsupported and unreliable. Consequently, costs and revenues that are based on the applicant's projected utilization are also not reliable. See Criterion (3) for discussion of projected utilization. Moreover, the applicant provides inconsistent information regarding the payor mix. Different payors may reimburse the facility differently, impacting net revenue. Therefore, the applicant did not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Consequently, the application is nonconforming with this criterion.

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

NC

The applicant proposes to relocate one or two existing certified dialysis stations from FMC County Dialysis Center to establish a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis home training in Concord. However, the applicant did not adequately demonstrate the need for the proposal. See Criteria (3) for discussion. Therefore, the applicant did not adequately demonstrate that the proposal would not result in unnecessary duplication of existing or approved health service capabilities or facilities, and the application is nonconforming 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 46, the applicant projects the following staffing during the first two operating years.

Position	**Total # of Full-Time Equivalents (FTEs)**
Home Training Nurse	1.00
Clinical Manager	0.25
Administrator	0.10
Dietitian	0.15

Social Worker	0.15
Clerical	0.25
Equipment Tech	0.15
In-Service	0.05
Total	**2.1**

As shown in the above table, the applicant proposes a total of 2.1 FTE positions, 1.0 of which will be direct care positions. In Section VII.4, page 47, the applicant states that it does not anticipate having any difficulty staffing the proposed facility. In Section V.4(c), page 40, the applicant states that George Hart, M.D. has agreed to serve as Medical Director for the facility. Exhibit 21 contains a letter from Dr. Hart stating his intent to serve in that role. The applicant adequately documented the availability of resources, including health manpower and management personnel, for the level of dialysis services proposed to be provided. 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 37 the applicant lists services to be provided on site and through existing health care providers. Exhibits 16 and 17 contain sample agreements between the applicant and CMC NorthEast for patient hospitalization and transplantation services, respectively. Exhibit 18 contains an agreement between the applicant and Spectra Lab for patient laboratory services. The applicant adequately documents that the necessary ancillary and support services will be available at the facility or from another provider. The applicant also adequately demonstrated 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

NA

(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 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;

NA

(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

NC

In Section VI.1(a), page 42, the applicant states:

> *"BMA has a long history of providing dialysis services to the underserved populations of North Carolina. BMA currently operates 81 facilities in 40 North Carolina Counties (includes our affiliations with RRI facilities); in addition BMA has nine facilities under development or pending CON approval. Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, woman, handicapped persons, elderly, or other traditionally underserved persons. The patient population of the FMC Cabarrus County Home Dialysis Program facility is expected to be similar to the facilities contributing stations to the project, and will likely be comprised of the following:*

Facility	***Medicaid/Low Income***	***Elderly (65+)***	***Medicare***	***Women***	***Racial Minorities***
FMC Cabarrus CountyHome Dialysis Program	*29%*	*19%*	*73%*	*44%*	*858%*

> *Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that73% of the facility treatment reimbursement is from Medicare.*
>
> *It is clear that FMC Cabarrus County Home Dialysis Program projects to provide service to historically underserved populations. It is BMA policy*

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

In Section VI.1, page 43, the applicant provides the following table which illustrates the projected payor mix for the proposed facility. In regard to payor source projections the applicant states:

"Projections of future reimbursement are a function of historical performance of the BMA Charlotte home training program. BMA Charlotte is operating in a contiguous county. BMA believes that the economic complexion of Mecklenberg County is similar to Cabarrus County and therefore appropriate to use a historical payor mix from BMA Charlotte to develop the projected payor mix for this facility."

Payor Source	**Percent of Total**
Medicare	67.3%
Medicaid	0%
Medicare/Medicaid	0%
Commercial Insurance	31.0%
VA	1.7%
TOTAL	**100%**

As shown in the above table, the applicant projects that 67% of its patients will have some or all of their care paid for by Medicare. The applicant states: *"Projections of future reimbursement are a function of historical performance of the BMA Charlotte home training program."* However, as stated in Section VI.1, the applicant projects that 0% of its patients will have some or all of their care paid for by Medicaid.

Moreover, the application includes inconsistent representations regarding projected payor mix, as shown in the table below.

	Projected Payor Mix as Stated in Section X.2	**Projected Payor Mix as Stated in Section VI.1**
Medicare	31.0%	67.3%
Medicaid	67.3%	0%
Commercial	0%	31%
VA	0%	1.7%

In summary, the applicant does not demonstrate that underserved populations would have adequate access to the proposed dialysis facility. Therefore, the application is nonconforming 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, pages 44-45, the applicant describes how patients will have access to the facility. The information provided by the applicant is reasonable and credible and supports a finding of conformity with this criterion.

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

C

In Section V.3, page 38, the applicant describes how the proposed dialysis facility will help meet the clinical training needs of area health professional training programs. Exhibit 19 contains a letter from BMA's Director of Operations for Home Therapies to the Program Chair of the Cabarrus College of Health Sciences in Concord offering the use of the proposed facility for clinical rotations for its nursing students. The information provided by the applicant is reasonable and credible and supports a finding of conformity with this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

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

NC

See Sections III.3, III.6, III.7, V.7, VI, VII, and XI.7. The information provided by the applicant in those sections is not reasonable nor credible and does not adequately demonstrate that the proposal would have a positive impact on cost-effectiveness and access to the proposed services because:

- The applicant does not adequately demonstrate that the proposal is needed in Cabarrus County and therefore the proposal cannot be considered a cost-effective alternative [see Criteria (3), (4) and (5) for additional discussion]; and
- The applicant does not demonstrate that it will provide adequate access to medically underserved populations [see Criterion (13c) for additional discussion].

Therefore, the application is nonconforming 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.

NC

The proposal is not conforming to all applicable Criteria and Standards for End Stage Renal Disease Services, as promulgated in 10A NCAC 14C Section .2200. The specific findings are discussed below.

NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) Utilization rates;

-C- See Section II.1, page 10, and Exhibit 2 (copy of the July 2011 SDR) reports 2.7 patients per station.

.2202(a)(2) Mortality rates;

-C- In Section II.1, page 10, the applicant reports a 2010 facility mortality rate of 18.0%.

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

-C- In Section II.1, page10, the applicant states that BMA Charlotte had 53 home trained patients at the end of August 2011.

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

-C- In Section II.1, page 11, the applicant reports BMA Charlotte referred 32 patients for transplants and 16 transplants were performed in 2010.

.2202(a)(5) The number of patients currently on the transplant waiting list;

-C- In Section II.1, page 11, the applicant reports BMA Charlotte has 37 patients on the transplant waiting list.

.2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;

-C- In 2010 the applicant reports BMA Charlotte had 139 hospital admissions: 9 admissions were dialysis related and 130 admissions were non-dialysis related. See Section II.1, page 11.

.2202(a)(7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.

-C- As of December 31, 2010 the applicant reports BMA Charlotte had no conversions and one patient with Hepatitis B. See Section II.1, page 11.

(b) An applicant that proposes to develop a new facility, increase the number of 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- In Section I.1, page 11, the applicant states *"BMA has requested to establish an agreement with CMC Charlotte. A copy of the correspondence with the hospital is included in Exhibit 16."* Exhibit 16 contains a copy of a letter from the Director of Operations for Fresenius Medical Care to the Division President at Carolinas Medical Center – NorthEast and a copy of the agreement including the terms required by this Rule.

.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 center program agreement and a letter from the Director of Operations for Fresenius Medical Care to the VP of Administration at Carolinas Medical Center which states: *"Enclosed you will find a Transplant Center program Agreement for evaluation and provision of patient transplantation services."*

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

-C- Exhibit 30 and 31 contains the information on the primary and secondary site sites which states each has electrical, sewer and power on 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 an Emergency/Disaster manual which contains written policies and procedures for back up for electrical service in the event of a power outage.

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

-C- In Section II.1, page 12, the applicant states:

"Site information is provided in Exhibit 30 and Exhibit 31. BMA neither owns nor controls either of the sites but has included information on two sites which are available for lease.

.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- See Sections II, pages 10- 29; VII.2, pages 46-48; and, XI.6(g), page 70. See also Exhibits 11, 12 and 14.

.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- See Section III.7, pages 35, and Criterion (3).

.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.*

-C- In Section III.8, page 35, the applicant states that 100% of the patients reside within 30 miles of the proposed facility's location.

.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, page 16, 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.*

-NC- In Section III.1, page 17, the applicant states:

"BMA has proposed to transfer two dialysis stations to the new location for development of home dialysis training and support program.

However, in Section III.3, page 30, the applicant states:

"BMA is proposing to transfer a single existing and certified dialysis station from BMA Charlotte to develop a dedicated home training facility I Concord, Cabarrus County."

The applicant provides inconsistent information regarding the number of stations in the proposed facility. Moreover, the applicant does not 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. The applicant only projects 4 home hemodialysis patient at the end of the first operating year and does not even propose 10 stations. The applicant must reasonably document at least 32 patients at the end of year one [32/10=3.2]. The applicant does not do that. Therefeore, the applicaton is nonconforming with this Rule.

.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 not 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- The applicant does not propose to increase the number of dialysis stations in an existing facility.

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

-C- The applicant provides the assumptions and methodology used to project utilization of the proposed facility in Section II.1 pages 14-15, 19-20. However, see Criterion (3) for the discussion regarding the reasonableness of the applicant's projections.

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 V.1(e), page 37, the applicant indicates that CMC-Charlotte will provide diagnostic and evaluation services. In Section II, page 20, the applicant states that *"Patients will be referred to Gaston Memorial Hospital (Gastonia) or Cabarrus Regional Medical Center for diagnostic and evaluation services."* Exhibit 16 contains a letter to the President of CMC-Northeast from FMC Director of Operations requesting an affiliation agreement to treat *"our patients who may be in need of inpatient care at a hospital."*

.2204(2) *Maintenance dialysis;*

-C- See Section V.1(c), page 37.

.2204(3) *Accessible self-care training;*

-NC- See Section V.1(d), page 37.

.2204(4) *Accessible follow-up program for support of patients dialyzing at home;*

-C- See Section V.1(d), page 37, Section II.1, page 21.

.2204(5) *X-ray services;*

-C- See Section V.1(g), page 37, and Section II, page 21.

.2204(6) *Laboratory services;*

-C- See Section V.1(h), page 37, and Section II, page 21. Exhibit 18 contains a copy of a service agreement between FMC and Spectra Labs.

.2204(7) *Blood bank services;*

-C- See Section V.1(i), page 37.

.2204(8) *Emergency care;*

-C- See Section V.1(b), page 37 and Exhibit 12.

.2204(9) *Acute dialysis in an acute care setting*;

-C- See Section V.1(a), page 37.

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

-C- See Section V.1(p), page 37.

.2204(11) *Transplantation services;*

-C- See Section V.1(f), page 37, and Exhibit 17.

.2204(12) *Vocational rehabilitation counseling and services;*

-C- See Section V.1(o), page 37.

.2204(13) *Transportation*

-C- See Section V.1(q), page 37.

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, page 46, the applicant provides the proposed staffing. The applicant states on page 47 that the proposed facility will comply with all staffing requirements set forth 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 discussion.

.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- See Section VII.5, page 47, Section II.1, page 22 and Exhibits 14 and 15.