

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DATE: January 26, 2012

PROJECT ANALYST: Les Brown

ASSISTANT CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: E-8760-11 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Hickory Home Program / Develop a kidney disease treatment center to serve as a peritoneal dialysis home training facility / Catawba 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 BMA Hickory (BMAH), whose parent company is Fresenius Medical Care Holdings, Inc., operates 33 certified dialysis stations and a peritoneal dialysis (PD) home training program in Hickory. The applicant, BMA d/b/a FMC Hickory Home Program (FMC), proposes to develop a kidney disease treatment center by establishing a freestanding facility for the PD home training program, to be located in leased space near BMAH. FMC does not propose to include any certified hemodialysis stations in the new facility.

Neither the 2011 State Medical Facilities Plan (SMFP) nor the July 2011 Semiannual Dialysis Report (SDR) provides a need methodology for determining the need for PD home training programs. 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- (2) Repealed effective July 1, 1987.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.

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Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a BMA Hickory (BMAH), whose parent company is Fresenius Medical Care Holdings, Inc., operates 33 certified dialysis stations and a peritoneal dialysis (PD) home training program in Hickory. The applicant, BMA d/b/a FMC Hickory Home Program (FMC), proposes to construct a freestanding facility for the PD home training program, to be located in leased space near BMAH. FMC does not propose to include any certified hemodialysis stations in the new facility.

Population to be served

On pages 42 and 47 the applicant identifies the PD home training population being served by BMAH currently and projected for FMC in Year 1, illustrated in the table below:

| COUNTY | CURRENT | | YEAR 1 | |
|-----------|--------------------------------|--|--------------------------------|---|
| | BMAH PD HOME TRAINING PATIENTS | BMAH PD HOME TRAINING PATIENTS % OF TOTAL* | BMAH PD HOME TRAINING PATIENTS | BMAH PD HOME TRAINING PATIENTS % OF TOTAL |
| Catawba | 14 | 45.2% | 16.6 | 52.2% |
| Burke | 5 | 16.2% | 3.4 | 10.6% |
| Caldwell | 5 | 16.2% | 4.6 | 14.5% |
| Lincoln | 4 | 12.9% | 7.2 | 22.8% |
| Alexander | 3 | 9.7% | | |
| Total | 31 | 100.0% | 31.7 | 100.0% |

* Calculated by Project Analyst. Totals may not foot due to rounding.

On page 42 the applicant states:

“BMA conservatively projects that the home patient population will remain constant, with the exception of Alexander County. ...BMA assumes that the patients of Alexander County will transfer their care to the new FMC Alexander County dialysis facility upon certification of the facility.”

Therefore, the projected patient origin includes Catawba, Burke, Caldwell and Lincoln Counties. The percentage patient origin for each of these four counties is provided in the Utilization Projections.

Need for Relocating the Proposed PD Training Program

On page 40 the applicant states:

“BMA does note that the home patient population of BMA Hickory is increasing. The BMA Hickory is [sic] facility can not be further expanded. Relocation of its peritoneal dialysis training to a new facility will allow the home hemo-dialysis training and support program to continue to expand. Failure to relocate the home peritoneal dialysis program will necessarily lead to patient congestion during training days, and especially on home clinic days. During home clinic days all home patients are scheduled for their monthly visit to the center for physician and nursing assessment of dialysis adequacy, lab draws and prescription changes as may be appropriate.”

Utilization Projections

On page 47 the applicant provides the projected utilization of FMC during each of the first two years of operation following completion of the project, as follows:

| COUNTY | OPERATING YEAR 1 PD HOME TRAINING PATIENTS (AVERAGE) | OPERATING YEAR 2 PD HOME TRAINING PATIENTS (AVERAGE) |
|--------------|--|--|
| Catawba | 16.6 | 17.2 |
| Lincoln | 7.2 | 7.9 |
| Caldwell | 4.6 | 4.6 |
| Burke | 3.4 | 3.3 |
| Total | 31.7 | 33.0 |

Totals may not foot due to rounding.

On pages 41-47 the applicant provides the following assumptions and methodology to project the number of PD home training patients:

- Determine the percentage of total dialysis patients from the proposed 4-county service area being served by home dialysis, as shown in the table below.

| County | Total Dialysis Patients 12/31/10 | Home Dialysis Patients 12/31/10 | % Home Dialysis Patients 12/31/10 |
|---------------|----------------------------------|---------------------------------|-----------------------------------|
| Catawba | 181 | 27 | 14.9% |
| Caldwell | 104 | 13 | 12.5% |
| Lincoln | 87 | 16 | 18.4% |
| Burke | 85 | 9 | 10.6% |
| Total* | 457 | 65 | 14.3% |

* Calculated by Project Analyst.

Source: 2011 SDR

- Determine the percentage of home dialysis patients from each county currently being served by BMAH PD home dialysis, as shown in the table below.

| County | Total Home Dialysis Patients 9/30/11* | BMAH Home PD Dialysis Patients 9/30/11 | % BMAH Home PD Dialysis Patients 9/30/11 |
|---------------|---------------------------------------|--|--|
| Catawba | 25 | 14 | 56.0% |
| Caldwell | 14 | 5 | 35.7% |
| Lincoln | 11 | 4 | 36.4% |
| Burke | 13 | 5 | 38.5% |
| Total* | 63 | 28 | 44.4% |

* Calculated by Project Analyst.

Source: Southeastern Kidney Council

- Project FMC PD home training patients at the end of Years 1 (6/30/13) and 2 (6/30/14), using the percentages calculated in the tables above.

| | Catawba | Caldwell | Lincoln | Burke |
|--|----------------|-----------------|----------------|--------------|
| Total Dialysis Patients 12/31/10 | 181.0 | 104.0 | 87.0 | 85.0 |
| 5-Year Average Annual Change Rate* | 0.037 | -0.004 | 0.091 | -0.013 |
| Total Dialysis Patients 6/30/13 | 198.2 | 103.0 | 108.3 | 82.3 |
| % Home Dialysis Patients | 14.9% | 12.5% | 18.4% | 10.6% |
| Total Home Patients 6/30/13 | 29.6 | 12.9 | 19.9 | 8.7 |
| % BMAH Home PD Patients | 56.0% | 35.7% | 36.4% | 38.5% |
| FMC PD Home Training Patients 6/30/13 (End of Year 1) | 16.6 | 4.6 | 7.2 | 3.4 |
| Total Dialysis Patients 6/30/14 | 205.6 | 102.6 | 118.1 | 81.2 |
| % Home Dialysis Patients | 14.9% | 12.5% | 18.4% | 10.6% |
| Total Home Patients 6/30/14 | 30.7 | 12.8 | 21.7 | 8.6 |
| % BMAH Home PD Patients | 56.0% | 35.7% | 36.4% | 38.5% |
| FMC PD Home Training Patients 6/30/14 (End of Year 2) | 17.2 | 4.6 | 7.9 | 3.3 |

*Source: July 2012 SDR.

The total FMC PD home training patients for the first two years of operation are summarized in the table below.

**FMC Projected PD Home Training
 Patients (Average)**

| County | Year 1 | Year 2 |
|---------------|---------------|---------------|
| Catawba | 16.6 | 17.2 |
| Caldwell | 4.6 | 4.6 |
| Lincoln | 7.2 | 7.9 |
| Burke | 3.4 | 3.3 |
| Total | 31.7 | 33.0 |

On page 75 the applicant projects the number of PD home treatments during the first two years of operation, and the assumptions and methodology used in the utilization projections.

“Operating Year 1: The beginning of Operating Year 1 is July 1, 2012. BMA has projected to begin the first year of operation with 28 PD patients, ending the year with 31.7 patients. The average number of patients is 29.9. BMA has rounded down and multiplied 29 patients X 144 annual treatments.

Operating Year 2: BMA has projected to begin the second year of operation with 31.7 PD patients, ending the year with 33 PD patients. The average number of patients is 32.4. BMA has rounded down and multiplied 32 patients X 144 annual treatments."

In supplemental information the applicant states:

"PD is done daily. However, billing / reimbursement is essentially the same as for traditional in-center treatment. Thus, BMA reports billing for 144 [annual] treatments."

The utilization projections for the first two years of operation are shown in the table below.

| | Year 1 | Year 2 |
|----------------------|--------|--------|
| PD Home Patients | 29 | 32 |
| Treatments Per Year | 144 | 144 |
| Annual PD Treatments | 4,176 | 4,608 |

The applicant adequately identifies the population to be served and demonstrates the need for the PD home training program based on the population it proposes to serve. Therefore, the application is conforming 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.

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On page 41 the applicant states:

"To the extent that this is a reduction of services at BMA Hickory [a separate BMA facility], BMA has appropriately demonstrated that this relocation will not adversely affect the BMA Hickory facility or the home patients of that facility. The new facility is proposed to be developed within one half mile of the BMA Hickory facility."

According to maps.google.com, the distance from BMAH to the proposed primary PD home training site at 1985 Tate Boulevard SE is .7 miles. The distance to the secondary site at 1930 Tate Boulevard SE is .2 miles.

Although the PD home training service is being relocated, the applicant demonstrates that the needs of the population presently served at BMAH will continue to be adequately met after the project is completed. 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.

CA

In Section III.9, page 50, the applicant states:

“BMA of North Carolina has considered continuing to provide home peritoneal dialysis at BMA Hickory dialysis facility. However, the home program census is increasing. The home number of patients choosing home hemo-dialysis is increasing significantly. Relocation of the home peritoneal dialysis program will allow the BMA Hickory facility to utilize existing home training space exclusively for home hemo-dialysis. Providing home hemo-dialysis training and support at the BMA Hickory facility will be more convenient and allow the facility and staff to focus exclusively on hemo-dialysis.”

In supplemental information, the applicant states that only two rooms at BMAH are dedicated to home training, used for both home hemodialysis and PD training. With both PD and home hemodialysis patient populations increasing, relocation of the PD training program will allow the existing two training rooms to be used exclusively for home hemodialysis patients, while providing adequate space for separate PD training. The applicant states that home training is being conducted in BMA centers in the surrounding counties of Burke, Caldwell and soon in Alexander. However, patients choose the centers where they want to be served and BMA is responding to their preferences.

The application is conforming with all other applicable statutory and regulatory review criteria. See Criteria (3), (5), (6), (7), (8), (13), (14), (18a), (20) and 10A NCAC 14C. 2200. The applicant adequately demonstrates that the proposal is its least costly or most effective alternative. The application is conforming with this criterion and approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Hickory Home Program shall materially comply with all representations made in the certificate of need application.**

2. **FMC Hickory Home Program shall establish a freestanding home dialysis training and support program exclusively for peritoneal dialysis patients, with no hemodialysis stations.**
 3. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Hickory Home Program 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.

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In Section VIII.1, page 65, the applicant states that the proposed capital cost of the project is \$684,107, including \$542,617 for upfit costs, \$31,675 for equipment and furniture, and \$109,815 for miscellaneous costs. On page 67 the applicant states that the capital cost will be funded with accumulated reserves. Exhibit 10 includes the audited financial statements of Fresenius Medical Care Holdings, Inc., the parent company of Bio-Medical Applications of North Carolina, Inc. As of December 31, 2010, FMC Holdings had \$163,292,000 in cash and cash reserves. Exhibit 24 contains a letter from the Vice President of Fresenius Medical Care Holdings, which states: *"As Vice President, I am authorized and do hereby authorize the development of this [FMC PD training] home dialysis program in Catawba County, North Carolina for capital costs of \$684,107."*

In Section X.1, page 73, the applicant states the facility's proposed charges per treatment for each payment source are as follows:

| SOURCE OF PAYMENT | HOME PD |
|----------------------|------------|
| Commercial Insurance | \$1,220.00 |
| Medicare | \$234.00 |
| Medicaid | \$143.09 |
| VA | \$193.29 |
| Private Pay | \$1,220.00 |

On page 73 the applicant states:

"Note: The commercial charges above do not reflect actual reimbursement rates, and should not be taken as absolute. It is industry standard for providers to have contractual relationships with various payors, resulting in less reimbursement than the stated charge."

On page 35 FMC states that it accepts the Medicare bundled rate of \$234 per treatment, which includes ancillary services such as laboratory tests and pharmaceutical support, as shown in the table below.

“Pharmaceutical support such as Epogen (EPO), Calcigex, Engerix, Iron Dextran and IV antibiotics will be available and provided to patients on order of the physician. These pharmaceuticals help ameliorate effects of the diseases processes such as anemia, hypocalcemia, susceptibility to Hepatitis B, damages to bone chemistry and infection, respectively.”

FMC charges non-Medicare payors additional fees for these services, as shown in the table below.

| Ancillary Services | Year 1 | Year 2 |
|--------------------|---------|---------|
| Pharmaceuticals | \$72.91 | \$75.10 |
| Laboratory Tests | \$80.78 | \$83.20 |

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-X.4, pages 58-65, the applicant reports projected revenues and expenses as follows:

| | OPERATING YEAR 1 | OPERATING YEAR 2 |
|-----------------------|------------------|------------------|
| Gross Patient Revenue | \$3,032,086 | \$3,353,824 |
| Less Deductions | \$872,947 | \$963,252 |
| Total Net Revenue | \$2,159,139 | \$2,390,572 |
| Total Operating Costs | \$1,722,546 | \$1,872,265 |
| Net Profit | \$436,593 | \$518,307 |

The applicant projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. The applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming with this criterion.

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

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The applicant proposes to establish a freestanding PD home dialysis training and support facility near the existing BMAH facility in Hickory. The applicant adequately

demonstrates the need for the proposed facility, based on the number of patients it proposes to serve. See Criterion (3) for additional discussion. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Therefore, the application is conforming with 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.

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The following table illustrates projected staffing during the first two operating years following completion of the project, as reported by the applicant in Section VII.1, page 62.

| POSITION | PROJECTED FULL TIME EQUIVALENT POSITIONS (FTES) YEARS 1 AND 2 |
|------------------------------|---|
| Clinical Manager | 0.75 |
| Med. Director | Contract |
| Admin. (FMC Area Manager) | 0.10 |
| Dietitian | 0.50 |
| Social Worker | 0.50 |
| Home Training Nurse | 4.00 |
| Chief Tech | 0.10 |
| In-Service | 0.05 |
| Clerical | 0.75 |
| Total | 6.75 |

As shown in the above table, the applicant proposes to employ a total of 6.75 FTE positions to staff the PD home training facility during the first two operating years following completion of the project. In supplemental information the applicant states that the training center will be staffed five days a week, with an average of six to eight PD patients in the training center per day. In addition to the routine training, patients come to the center for supplemental training, supplemental lab services and counseling. RNs make periodic home visits with two RNs per visit. RNs also provide pre-dialysis home assessments, medical record documentation, and patient education in physician offices and at the hemodialysis centers. Exhibit 21 contains a letter signed by Dr. David Harvey, which states that he has agreed to serve as medical director for FMC.

The applicant adequately demonstrates the availability of adequate health manpower and management personnel, including a medical director, for the provision of PD

home training and support services. Therefore, the application is conforming with this criterion.

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

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In Section V.1, page 53, the applicant provides a list of providers of the necessary ancillary and support services. Copies of agreements with providers are included to support the application: proposed acute care hospital agreement between FMC and Catawba Valley Medical Center (Exhibit 16); transplant services agreement executed between FMC and Carolinas Medical Center (Exhibit 17); and laboratory services agreement executed between Spectra Laboratories, Inc. and Fresenius Medical Care Holdings, Inc. (Exhibit 18).

In Sections II.2, pages 34-35, the applicant further states that FMC will provide the following services: (1) in-center dialysis at BMAH, (2) social services, (3) dietary services, (4) patient education, (5) emergency care, (6) diagnostic services, (7) transplant evaluation, (8) pharmaceutical support, and, (9) PD home training.

The applicant adequately demonstrates that the necessary ancillary and support services will be provided and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming with this criterion.

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

NA

- (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 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;

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In supplemental information, the applicant provides the following in-center payor mix for the two BMA ESRD facilities in Catawba County for CY 2011.

| PAYOR SOURCE | BMA HICKORY | FMC CATAWBA COUNTY |
|----------------------|-------------|--------------------|
| Commercial Insurance | 14.9% | 13.8% |
| Medicare | 79.4% | 80.8% |
| Medicaid | 2.6% | 5.1% |
| VA | 3.1% | |
| Self- Pay / Indigent | | 0.3% |
| Total | 100.00% | 100.0% |

The applicant also provides the CY 2011 payor mix for the home training program at BMAH, the only BMA home training in Catawba County, as shown in the table below.

| PAYOR SOURCE | BMAH PD HOME TRAINING | BMAH HOME HEMODIALYSIS TRAINING |
|----------------------|-----------------------|---------------------------------|
| Commercial Insurance | 36.0% | 35.7% |
| Medicare | 63.6% | 64.3% |
| Medicaid | | |
| VA | 0.4% | |
| Self- Pay / Indigent | | |
| Total | 100.00% | 100.0% |

- (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

On page 60 the applicant states: *“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations.”* On page 61 the applicant states: *“There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.”*

- (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

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In Section VI.1(c), page 59, the applicant states that it projects its payor mix based on the historical experience of the BMAH home training program. The applicant projects the following payor mix:

| FMC HOME TRAINING | |
|----------------------|------------|
| PAYOR SOURCE | PERCENTAGE |
| Commercial Insurance | 38.0% |
| Medicare | 62.0% |
| Total | 100.00% |

The applicant demonstrates that it will provide adequate access to the elderly and medically underserved populations. Therefore, the application is conforming with this criterion.

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

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In Section VI.5(a), page 60, 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 Hickory Home Dialysis Program will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”

The applicant adequately demonstrates that it will provide a range of means by which a person can access the services. Therefore, the application is conforming 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.

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Exhibit 19 contains a letter dated September 28, 2011 from the Fresenius Medical Care North America – Hickory Group Director of Operations for Home Therapies to

the Associate Dean of the School of Health Services of Catawba Valley Community College, stating:

“Fresenius would like to invite you to include the Hickory Home Program dialysis facility in your list of facilities for clinical rotation of your nursing students. We feel that a dialysis facility rotation would accomplish a variety of educational purposes, to include:

- a. exposure to a patient population with chronic need for dialysis, to include the co-morbid health issues associated with End Stage Renal Disease.*
- b. exposure to the daily operation of a dialysis facility, which would involve work with a cross section of health care professionals form direct patient care staff such as the Nephrologist Physician and the Patient Care Technicians, to the ancillary staff including Social Workers, Dietitians, and Medical Records, and others as appropriate.*
- c. Exposure to the Home Training programs for Home Peritoneal dialysis.”*

The information provided in Sections V.3(a), pages 54-55, and Exhibit 19 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.

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FMC adequately demonstrates that its proposal to establish a freestanding PD home training and support facility would have a positive impact upon the cost effectiveness (See Sections V, VIII, and XI of the Application), quality (See Sections II, V and VII of the Application), and access (See Section VI of the Application) to the services proposed, for the following reasons:

- a) the applicant adequately demonstrates that the proposal is cost-effective [See Criterion (5) for additional discussion];
- b) the applicant demonstrates that it will provide adequate access to the proposed dialysis services [See Criterion (13) for additional discussion];
- c) the applicant adequately demonstrates that it will provide quality services [See Criteria (7), (8), and (20) for additional discussion].

Therefore, the application is conforming with 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.

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The applicant currently provides dialysis services at two other BMA facilities in Catawba County, BMAH and FMC Catawba Valley Dialysis. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, these facilities operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming with this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183(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.

The Criteria and Standards for End Stage Renal Disease Services, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C .2200. The specific findings are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANTS

(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;*
- .2202(a)(2) *Mortality rates;*
- .2202(a)(3) *The number of patients that are home trained and the number of patients on home dialysis;*
- .2202(a)(4) *The number of transplants performed or referred;*
- .2202(a)(5) *The number of patients currently on the transplant waiting list;*
- .2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- .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- The applicant does not propose to develop a facility with hemodialysis stations.

(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 letter to Catawba Valley Medical Center with a proposed agreement.

- .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 written agreement for transplantation services with Carolinas Medical Center.

- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- Exhibits 30 and 31 contain documentation that power and water will be available at the proposed primary and secondary sites.
- .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 Manual, as well as copies of 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- On page 13 the applicant states that it will pursue a lease agreement with the developer of the primary or secondary sites.
- .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- On page 13 the applicant states that services will be provided in conformity with applicable laws and regulations.
- .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 II.1, pages 13-19.
- .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- On pages 20-21 the applicant provides documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.
- .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- See Section II, page 22, the applicant commits to provide PD home training and support 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.

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- The applicants does not propose to establish any dialysis 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- The applicants does not propose to establish any dialysis stations.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section III.7, pages 41-47, the applicant provides the assumptions and methodology used to project utilization of the proposed PD home training facility.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

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

- C- See Section V.1(e), page 53.
- .2204(2) *Maintenance dialysis;*
 - C- See Section V.1(c), page 53.
- .2204(3) *Accessible self-care training;*
 - C- See Section V.1(d), page 53.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
 - C- See Section V.2(d), page 53.
- .2204(5) *X-ray services;*
 - C- See Section V.1(g), page 53.
- .2204(6) *Laboratory services;*
 - C- See Section V.1(h), page 53 and Exhibit 18.
- .2204(7) *Blood bank services;*
 - C- See Section V.1(i), page 53.
- .2204(8) *Emergency care;*
 - C- See Section V.1(b), page 53.
- .2204(9) *Acute dialysis in an acute care setting;*
 - C- See Section V.1(a), page 53.
- .2204(10) *Vascular surgery for dialysis treatment patients*
 - C- See Section V.1(p), page 53.
- .2204(11) *Transplantation services;*
 - C- See Section V.1(f), page 53, and Exhibit 17.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
 - C- See Section V.1(o), page 53.
- .2204(13) *Transportation*
 - C- See Section V.1(q), page 53.

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 Sections VII.2, page 62, the applicant provides the proposed staffing. The applicant states on page 63 that the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 494 (formerly 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 63, and Exhibits 14 and 15.