

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 28, 2018

Findings Date: October 5, 2018

Project Analyst: Bernetta Thorne-Williams

Assistant Chief: Lisa Pittman

Project ID #: E-11528-18

Facility: BMA Lenoir

FID #: 170328

County: Caldwell

Applicant: Bio-Medical Applications of North Carolina, Inc.

Project: Change of scope for three projects: Project ID# E-11376-17 (develop a new facility by relocating 14 stations from BMA Lenoir to a new facility), Project ID# E-11377-17 (relocate the remaining 20 stations at BMA Lenoir to a new site) and Project ID# E-11401-17 (add 7 stations to BMA Lenoir). Upon completion of this project, Project ID# E-11377-17 and Project ID# E-11401-17, BMA Lenoir will be certified for a total of 41 stations. Project ID# E-11376-17 will not be developed.

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a BMA Lenoir proposes a change of scope (COS) for three projects: Project ID# E-11376-17 (develop a new facility by relocating 14 stations from BMA Lenoir to a new facility), Project ID# E-11377-17 (relocate the remaining 20 stations at BMA Lenoir to a new site) and Project ID# E-

11401-17 (add 7 stations to BMA Lenoir). Upon completion of this project, Project ID# E-11377-17 and Project ID# E-11401-17, BMA Lenoir will be certified for a total of 41 stations. Project ID# E-11376-17 will not be developed. The proposed newly expanded BMA Lenoir dialysis would be located at 1208 Hickory Boulevard, SW, in Caldwell County.

### **Need Determination**

The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2018 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

### **Policies**

There is one policy in the 2018 SMFP which is applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service*. The total capital costs for the proposed COS project will exceed \$2 million, but is less than \$5 million.

*Policy GEN-4* states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.*

In Section B, page 9, the applicant states BMA is, “very cognizant of the need to provide services while maintain energy efficiency. Fresenius Medical Care, the parent organization to the applicant, is committed to ensuring the building will maximize improved energy.” On pages 9-10, the applicant describes the project’s plan to assure improved energy efficiency

and water conservation. Therefore, the COS application remains consistent with Policy GEN-4.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant demonstrates conformity to this criterion and to Policy GEN-4.

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

### **C**

The applicant proposes a COS for three projects: Project ID# E-11376-17 (develop a new facility by relocating 14 stations from BMA Lenoir to a new facility), Project ID# E-11377-17 (relocate the remaining 20 stations at BMA Lenoir to a new site) and Project ID# E-11401-17 (add 7 stations to BMA Lenoir). Upon completion of this project, Project ID# E-11377-17 and Project ID# E-11401-17, BMA Lenoir will be certified for a total of 41 stations. Project ID# E-11376-17 will not be developed. The proposed newly expanded BMA Lenoir dialysis would be located at 1208 Hickory Boulevard, SW, in Caldwell County.

### **Patient Origin**

On page 365, the 2018 SMFP defines the service area for dialysis stations as, “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Caldwell County. Facilities may serve residents of counties not included in their service area.

In Section C, page 11, the applicant states that, “*by combining the projects into a single 41 station facility, BMA is conserving future operational expense. The expanded BMA Lenoir facility can serve the same patient population as projected in the applications for FKC*

*Caldwell County [Project I.D. # E-11376-17] and BMA Lenoir [Project I.D. # E-11377-17 and Project I.D. # E-11401-17]. No patients will be adversely affected.”*

The applicant provides the projected patient population by county of residence for in-center (IC), home hemodialysis (HH) and peritoneal dialysis (PD) patients for the first two years of operation for Project I.D. # E-11376-17, Project I.D. # E-11377-17 and Project I.D. # E-11401-17 in Section C, pages 16-17, respectively in the current application. The table provided on page 16 of the projected patient population for Project I.D. #E-11377-17 is identical to the table on page 17, which illustrates the projected patient population for Project I.D. # E-11401-17. The tables below illustrate the projected patient population as stated in Project I.D. #E-11376-17 (Section C.1, page 18), Project I.D. # E-11377-17 (Section C.1, page 22), and Project I.D. # E-11401-17 (Section C.1, page 15).

**FKC Caldwell Patients by County  
 Project I.D # E-11376-17**

| COUNTY       | OY1<br>2019    | OY2<br>2020    | COUNTY<br>PATIENTS AS A<br>PERCENT<br>OF TOTAL |               |
|--------------|----------------|----------------|--|---------------|
|              | IC<br>Patients | IC<br>Patients | OY1  | OY2           |
| Caldwell     | 46.3           | 48.7           | 100.0%   | 100.0%        |
| <b>Total</b> | <b>46</b>      | <b>48</b>      | <b>100.0%</b>                                  | <b>100.0%</b> |

Source: Project I.D. # E-11376-17, page 18

**BMA Lenoir Patients by County  
 Project I.D # E-11377-17**

| COUNTY       | OY 1<br>CY 2019 |                |                | OY 2<br>CY 2020 |                |                | COUNTY<br>PATIENTS AS A<br>PERCENT<br>OF TOTAL |               |
|--------------|-----------------|----------------|----------------|-----------------|----------------|----------------|--|---------------|
|              | IC<br>PATIENTS  | HH<br>PATIENTS | PD<br>PATIENTS | IC<br>PATIENTS  | HH<br>PATIENTS | PD<br>PATIENTS | OY 1   | OY 2          |
| Caldwell     | 89              | 3              | 12             | 94              | 3              | 12             | 100.0%   | 100.0%        |
| <b>Total</b> | <b>89</b>       | <b>3</b>       | <b>12</b>      | <b>94</b>       | <b>3</b>       | <b>12</b>      | <b>100.0%</b>                                  | <b>100.0%</b> |

Source: Project I.D. # E-11377-17, page 22

**BMA Lenoir Patients by County  
 Project I.D # E-11401-17**

| County        | Operating Year 1<br>CY 2019 |          |           | Operating Year 2<br>CY 2020 |          |           | County Patients as a<br>Percent of Total |               |
|---------------|-----------------------------|----------|-----------|-----------------------------|----------|-----------|--|---------------|
|               | IC                          | HH       | PD        | IC                          | HH       | PD        | OY 1                                     | OY 2          |
| Caldwell      | 84.9                        | 3.4      | 11.4      | 89.3                        | 3.6      | 11.9      | 94.3%                                    | 94.6%         |
| Alexander     | 1.0                         | 0.0      | 0.0       | 1.0                         | 0.0      | 0.0       | 0.9%                                     | 0.9%          |
| Burke         | 3.0                         | 0.0      | 0.0       | 3.0                         | 0.0      | 0.0       | 2.8%                                     | 2.7%          |
| Catawba       | 1.0                         | 0.0      | 0.0       | 1.0                         | 0.0      | 0.0       | 0.9%                                     | 0.9%          |
| Wilkes        | 0.0                         | 0.0      | 1.0       | 0.0                         | 0.0      | 1.0       | 0.9%                                     | 0.9%          |
| <b>Total*</b> | <b>89</b>                   | <b>3</b> | <b>12</b> | <b>94</b>                   | <b>3</b> | <b>12</b> | <b>100.0%</b>                            | <b>100.0%</b> |

Source: Section C.1, page 15 of Project I.D. # E-11401-17

Note: Tables may not foot due to rounding.

\*Rounded down to the whole patient.

In Section C, page 21 of the change of scope application, the applicant identified the combined projected patient origin including appropriate growth during a six month delay in project completion, as illustrated below.

**BMA Lenoir Patients by County  
 Project I.D. # E-11528-18**

| COUNTY        | OPERATING YEAR 1<br>FY2020 |                |                | OPERATING YEAR 2<br>FY2021 |                |                | COUNTY<br>PATIENTS AS A<br>PERCENT OF<br>TOTAL |               |
|---------------|----------------------------|----------------|----------------|----------------------------|----------------|----------------|--|---------------|
|               | IC<br>PATIENTS             | HH<br>PATIENTS | PD<br>PATIENTS | IC<br>PATIENTS             | HH<br>PATIENTS | PD<br>PATIENTS | YEAR 1   | YEAR 2        |
| Caldwell      | 134.0                      | 3.41           | 10.2           | 141.0                      | 3.58           | 10.8           | 97.6%  | 96.9%         |
| Alexander     | 0.0                        | 0.0            | 0.0            | 0.0                        | 0.0            | 0.0            | 0.0%   | 0.0%          |
| Burke         | 2.0                        | 0.0            | 0.0            | 2.0                        | 0.0            | 0.0            | 1.3%   | 1.2%          |
| Catawba       | 2.0                        | 0.0            | 0.0            | 2.0                        | 0.0            | 0.0            | 1.3%   | 1.2%          |
| Wilkes        | 0.0                        | 0.0            | 1.0            | 0.0                        | 0.0            | 1.0            | 0.7%   | 0.6%          |
| <b>TOTAL*</b> | <b>138</b>                 | <b>3.0</b>     | <b>11.0</b>    | <b>145.0</b>               | <b>3.0</b>     | <b>11.0</b>    | <b>100.0%</b>                                  | <b>100.0%</b> |

Rounded down to nearest whole number

On page 11 of the current application, the applicant states BMA Lenoir projects to serve the same patient population as identified in its previous applications. The applicant adequately identified the population to be served.

**Analysis of Need**

In Section C.16, pages 14-17, the applicant discusses the need for this change of scope and the components of it:

- In Project I.D. # E-11376-17, the applicant was approved to develop FKC Caldwell County, a new 14 station facility by relocating 14 stations from BMA Lenoir. This project will not be developed. The 14 stations will remain at BMA Lenoir.

- In Project I.D. # E-11377-17, the applicant was approved to relocate BMA Lenoir to a new location less than one mile from its current location. BMA Lenoir will continue to have 34 stations because Project I.D. # E-11376-17 will not be developed.
- In Project I.D. # E-11401-17, the applicant was approved to add 7 stations to BMA Lenoir pursuant to the facility need methodology in the 2017 State Medical Facilities Plan (2017), for a total of 27 dialysis stations at BMA Lenoir following completion of Project I.D. # E-11376-17 and Project I.D. # E-11377-17.
- In the current application, the applicant proposes development of these projects into one facility that will consist of 41 dialysis stations to be located at 1208 Hickory Boulevard SW in Lenoir. On page 14, the applicant states that the proposed site is approximately one mile from the existing facility.

On page 15, the applicant states with regard to the development of a new 14-station facility by relocating stations from BMA Lenoir as proposed in Project I.D. # E-11376-17, *“the proposed landlord informed BMA that the site was no longer available – the existing tenant had asked to extend their lease. Thus, BMA was going to have to find another site for development of FKC Caldwell County.”*

With regard to Project I.D. # E-11377-17, the applicant states, *“the premises was not equipped with a sprinkler fire suppressions system ... The cost of adding a sprinkler system was cost prohibitive. Thus, BMA was going to have to find another site for the development of the relocated BMA Lenoir facility.”*

On page 15, the applicant states that in searching for new sites to accommodate BMA Lenoir, a site was located large enough to accommodate the development of the proposed 41-station facility. The applicant submitted a letter requesting a material compliance determination on June 8, 2018. The material compliance request was approved on June 15, 2018, which allowed the applicant to relocate the facility to 1208 Hickory Boulevard, SW instead of 125 Hospital Avenue, as proposed in the application.

The information is reasonable and adequately supported for the following reasons:

- the applicant proposes to serve the same population as was previously approved;
- cost savings; and
- the site of the proposed facility is approximately one mile from the existing facility. Therefore, patients will not be inconvenienced by BMA’s decision to develop only one facility.

### Projected Utilization

In Section C.15, page 17, the applicant provides the facility census for BMA Lenoir as of December 31, 2017, as illustrated below.

| <b>BMA Lenoir Dialysis Patients<br/>as of December 31, 2017</b> |                        |                        |                        |
|---|------------------------|------------------------|------------------------|
| <b>COUNTY</b>   | <b>IC<br/>Patients</b> | <b>HH<br/>Patients</b> | <b>PD<br/>Patients</b> |
| Caldwell  | 118.0                  | 3.0                    | 9.0                    |
| Burke   | 2.0                    | 0.0                    | 0.0                    |
| Catawba   | 2.0                    | 0.0                    | 0.0                    |
| Wilkes  | 0.0                    | 0.0                    | 1.0                    |
| <b>Total</b>  | <b>122.0</b>           | <b>3.0</b>             | <b>10.0</b>            |

In Section C.15, page 21, the applicant provides the projected utilization for BMA Lenoir, for operating year 1 and operating year 2, as illustrated below.

| <b>BMA Lenoir<br/>Total Projected Patients</b> |   |   |
|--|---|---|
|  | <b>Operating Year 1<br/>FY2020<br/>(7/1/2019-6/30/2020)</b> | <b>Operating Year 2<br/>FY2021<br/>(7/1/2020-6/30/2021)</b> |
| <b>In-Center Pts</b>                           | 138.0   | 145.0   |
| <b>Home Hemodialysis Pts</b>                   | 3.0   | 3.0   |
| <b>Peritoneal dialysis Pts</b>                 | 11.0  | 11.0  |
| <b>Total</b>                                   | <b>152.0</b>  | <b>159.0</b>  |

In-Center Utilization

The applicant provides the assumptions for the projected in-center utilization on page 18, as summarized below:

- The applicant was serving 122 in-center patients at BMA Lenoir as of December 31, 2017. The applicant assumes these patients will continue to dialyze with BMA Lenoir.
- In Project I.D. # E-11376-17, the applicant projected to relocate 14 stations and that 38 patients would transfer their care to the proposed new FKC Caldwell facility. In this application, the applicant assumes the 38 patients will continue to dialyze at the relocated BMA Lenoir facility, as the FKC Caldwell facility will not be developed.
- The proposed change of scope project is scheduled for completion on June, 30, 2019, which represents a delay of six months over the previously approved projects.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Caldwell County which is 5.2% to project the Caldwell County patient population forward.
- The applicant does not project an increase in the patient population for Burke and Catawba counties.
- Operating Year 1 (OY1) = Fiscal Year 2020 (July 1, 2019 - June 30, 2020).
- Operating Year 2 (OY2) = Fiscal Year 2020 (July 1, 2020 - June 30, 2021).
- The applicant does not propose the relocation of stations nor the transfer of patients from BMA Lenoir to FKC Caldwell (Project I.D. # E-11376-17). FKC Caldwell will

not be developed, but rather those stations and patients will be incorporated into the proposed change of scope project represented in this application.

In Section C, page 19, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

|  |                              |
|--|------------------------------|
| Begin with Caldwell County patients dialyzing at BMA Lenoir as of December 31, 2017.   | 118                          |
| Project the Caldwell County patient population forward one year to December 31, 2018 using the Five-Year Average Annual Change Rate for Caldwell County of 5.2%        | $118 \times 1.052 = 124.1$   |
| Project the Caldwell County patient population forward six months to June 30, 2019 using one half the Five-Year Average Annual Change Rate for Caldwell County of 2.6% | $124.1 \times 1.026 = 127.4$ |
| Project the Caldwell County patient population forward one year to June 30, 2020 using the Five-Year Average Annual Change Rate for Caldwell County of 5.2%            | $127.4 \times 1.052 = 134$   |
| <b>OY1:</b> Add two patients from Burke County and two patients from Catawba County. This is the projected census for OY 1.  | $134 + 4 = 138$              |
| Project the Caldwell County patient population forward one year to June 30, 2021 using the Five-Year Average Annual Change Rate for Caldwell County of 5.2%            | $134 \times 1.052 = 141$     |
| <b>OY2:</b> Add four patients from Burke and Catawba counties. This is the projected census for OY 2.  | $141 + 4 = 145$              |

On pages 19-21, the applicant projects to serve 138 in-center patients in OY1 and 145 in-center patients in OY2. Thus, the applicant projects that BMA Lenoir will have a utilization rate of 84.15% or 3.37 patients per station per week ( $138 \text{ patients} / 41 \text{ stations} = 3.3658 / 4 = 0.8415$  or 84.15%) in OY1. The projected utilization of 3.37 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Home Hemodialysis and Peritoneal Dialysis

The applicant currently provides home hemodialysis and peritoneal dialysis at BMA Lenoir. On pages 19-20, the applicant provides the assumptions and methodology used for its home hemodialysis and peritoneal dialysis home training programs. The applicant projects its three home hemodialysis patients and its nine peritoneal dialysis patients from Caldwell County forward using the Caldwell County Five Year AACR. The applicant does not grow its one peritoneal dialysis patient from Wilkes County.

Projected utilization is reasonable and adequately supported for the following reasons:

- the applicant begins its utilization projection with the existing patients of BMA Lenoir,



- the applicant grows the Caldwell County patient population by the January 2018 SDR Caldwell County Five Year AACR and holds the patient population from outside Caldwell County constant, and
- the resulting utilization rate at BMA Lenoir by the end of the first year is above the minimum standard of 3.2 patients per station per week.

**Access**

In the previously approved applications, Project I.D's E-11376-17, E-11377-17 and E-11401-17, in Section L.1, the applicant stated the residents of the service area would have access to the proposed services, including those residents who are low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups.

In Section L.1(a), pages 44-45, of the COS application, the applicant states that each of FMC's 112 facilities in 48 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons regardless of their ability to pay. In Section L.7, page 48, the applicant provides the historical payor mix for calendar year (CY) 2017 for BMA Lenoir, as illustrated below.

| <b>Payment Source</b>       | <b>Percent of Total Patients</b> |
|-----------------------------|----------------------------------|
| Self Pay/ Indigent/ Charity | 1.47%                            |
| Medicare                    | 62.28%                           |
| Medicaid                    | 4.12%                            |
| Commercial Insurance        | 6.74%                            |
| Medicare / Commercial       | 18.24%                           |
| Misc. (VA)                  | 7.15%                            |
| <b>Total</b>                | <b>100.0%</b>                    |

As illustrated in the table above, in CY2017 84.64% of all BMA Lenoir patients were Medicare or Medicaid recipients. On page 45, the applicant projects to serve 84.9% Medicare or Medicaid recipients in PY2, which is similar to 2017's payor mix for BMA Lenoir.

The projected payor mix is reasonable and adequately supported.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identified the population to be served in Project I.D.'s E-11376-17, E-11377-17, and E-11401-17 and the applicant does not project a change in that population or in why that population needs the services proposed.
- Projected utilization was deemed reasonable and adequately supported in Project I.D.'s E-11376-17, E-11377-17, and E-11401-17 and the applicant does not project any significant changes.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant proposes a COS for three projects: Project ID# E-11376-17 (develop a new facility by relocating 14 stations from BMA Lenoir to a new facility), Project ID# E-11377-17 (relocate the remaining 20 stations at BMA Lenoir to a new site) and Project ID# E-11401-17 (add 7 stations to BMA Lenoir). Upon completion of this project, Project ID# E-11377-17 and Project ID# E-11401-17, BMA Lenoir will be certified for a total of 41 stations. Project ID# E-11376-17 will not be developed. The proposed newly expanded BMA Lenoir dialysis would be located at 1208 Hickory Boulevard, SW, in Caldwell County.

In Project I.D. # E-11401-17 the applicant did not propose a reduction or elimination of a service or the relocation of a service. In Project I.D.'s # E-11376-17 (develop a new facility by relocating 14 stations from BMA Lenoir) and E-11377-17 (relocate the entire facility), the applicant was found conforming with this criterion.

In Project I.D. # E-11376-17, the applicant proposed the development of a new 14-station facility to be known as FKC Caldwell County. This project will not be developed. Therefore those stations and patients will remain at BMA Lenoir.

In Project I.D. # E-11377-17, the applicant proposed the relocation of BMA Lenoir. However, in a subsequent letter requesting a material compliance approval for a site change, the applicant was approved (June 15, 2018), to relocate the facility to 1208 Hickory Boulevard, SW instead of 125 Hospital Avenue, as proposed in this application.

In the current application, the applicant proposes a change of scope which would allow BMA Lenoir to be developed as a 41-station facility by not doing Project I.D. # E-11376-17, and combining Project I.D.'s # E-11377-17 and # E-11401-17 (add 7 stations to BMA Lenoir).

Therefore, Criterion (3a) is not applicable to this review because the applicant does not propose to:

- reduce a service
- eliminate a service
- relocate a facility or service that has not received prior approval to do so.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that Criterion (3a) is not applicable to this review.

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

### CA

The applicant proposes a COS for three projects: Project ID# E-11376-17 (develop a new facility by relocating 14 stations from BMA Lenoir to a new facility), Project ID# E-11377-17 (relocate the remaining 20 stations at BMA Lenoir to a new site) and Project ID# E-11401-17 (add 7 stations to BMA Lenoir). Upon completion of this project, Project ID# E-11377-17 and Project ID# E-11401-17, BMA Lenoir will be certified for a total of 41 stations. Project ID# E-11376-17 will not be developed. The proposed newly expanded BMA Lenoir dialysis would be located at 1208 Hickory Boulevard, SW, in Caldwell County.

In Section C, pages 14-17, the applicant discusses the need for the change of scope. In Section E, page 43, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- Maintain the Status Quo - The applicant could have developed the three previously approved projects which included the development of a new 14-station facility. However, each of those projects had delays or complications. Therefore, this option was not considered to be an effective alternative.
- Submit the Application as Proposed - The applicant states the change of scope of the previously approved projects is more cost effective because it will require only one Registered Nurse (RN) clinic manager, have lower utility charges and have lower rent as compared to the relocation of BMA Lenoir and development of a new facility.

On page 23, the applicant states that its change of scope proposal is the most effective alternative because, *“The proposal does not increase the proposed cost of development. The proposal will generate operational efficiencies and cost savings.”*

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The applicant was approved in the following projects:
  - Project I.D. # E-11376-17 to develop a new 14-station facility to be known as FKC Caldwell County, which will not be developed. The 14 stations will remain at BMA.
  - Project I.D. # E-11377-17 to relocate BMA Lenoir.
  - Project I.D. # 11401-17 to add seven stations to BMA Lenoir.
- The development of a single 41-station facility will not cost any more than the three previously approved projects combined.
- The development of the change of scope project, as proposed, will reduce the number of RN clinical managers needed.
- The proposed project will allow for reduced utilities and rent.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Lenoir shall materially comply with all representations made in this application and the representations made in Project I.D. # E-11377-17 and Project I.D. # E-11401-17. Where representations conflict, Bio-Medical Applications of North Carolina, Inc. shall materially comply with the last made representation.**
- 2. Bio-Medical Applications of North Carolina, Inc. shall not develop Project I.D. # E-11376-17 and shall relinquish the certificate of need upon completion of this change of scope project.**
- 3. The total approved capital expenditure is \$1,959,630.**

4. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Lenoir shall be certified for no more than 41 dialysis stations including any isolation or home hemodialysis training stations.**
  5. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Lenoir shall install plumbing and electrical wiring through the walls for no more than 41 dialysis stations which shall include any isolation stations.**
  6. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Lenoir shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes a COS for three projects: Project ID# E-11376-17 (develop a new facility by relocating 14 stations from BMA Lenoir to a new facility), Project ID# E-11377-17 (relocate the remaining 20 stations at BMA Lenoir to a new site) and Project ID# E-11401-17 (add 7 stations to BMA Lenoir). Upon completion of this project, Project ID# E-11377-17 and Project ID# E-11401-17, BMA Lenoir will be certified for a total of 41 stations. Project ID# E-11376-17 will not be developed. The proposed newly expanded BMA Lenoir dialysis would be located at 1208 Hickory Boulevard, SW, in Caldwell County.

**Capital and Working Capital Costs**

In Section F.1, page 24, the applicant illustrates the approved capital costs for the previously approved projects and states that this COS does not involve additional capital costs, as shown below.

|  | CON Project # | Approved Capital Costs |
|--|---------------|------------------------|
| FKC Caldwell County                            | E-11376-17    | \$1,959,630            |
| BMA Lenoir relocate facility                   | E-11377-17    | \$2,624,459            |
| BMA Lenoir add seven stations                  | E-11401-17    | \$26,250               |
| <b>Total Previously Approved Capital Costs</b> |               | <b>\$4,610,339</b>     |

However, Project I.D. # E-11376-17 is not going to be developed as proposed. The capital expenditure of \$1,959,630 is still necessary to move those 14 stations to the replacement facility. The approval of this application is conditional on the relinquishment of the certificate for Project I.D. # E-11376-17. In this application, the projected capital cost was \$0 because the previous approvals were sufficient. The approved capital cost for this project is \$1,959,630. (Note: the filing fee for this project was in paid 2017).

In Section R, the applicant provides the assumptions used to project capital cost in each original project. In Section F, page 28, the applicant states that there will be no start-up costs or initial operating expenses associated with the proposed project.

### **Availability of Funds**

In Section F, page 26, the applicant states that the capital cost will be funded as shown in the table below.

| Type                         | Bio-Medical Applications of North Carolina, Inc. | Total              |
|------------------------------|--|--------------------|
| Loans                        | \$0  | \$0                |
| Accumulated reserves or OE * | \$4,610,339                                      | \$4,610,339        |
| Bonds                        | \$0  | \$0                |
| Other (Specify)              | \$0  | \$0                |
| <b>Total Financing **</b>    | <b>\$4,610,339</b>                               | <b>\$4,610,339</b> |

\* OE = Owner's Equity

Exhibit F.1 contains a letter dated June 15, 2018, from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, which states,

*“The combined development cost will not exceed the already CON approved cost for the three projects. BMA was approved for a total of \$4,610,339 to develop the three CON projects (FKC Caldwell County, \$1,959,630; BMA Lenoir relocation, \$2,624,459; BMA Lenoir seven station expansion, \$26,250).*

*As Senior Vice President, I have previously approved the above noted expenditures. By this letter, I am authorized and do hereby authorize the joining of the three noted projects into a single 41 station dialysis facility, for combined costs of \$4,610, 339.”*

Exhibit F.2 contains the Balance Sheet for Fresenius Medical Care Holdings, Inc. and Subsidiaries which indicates that it had \$569.8 million in cash and cash equivalents as of December 31, 2017, \$19.8 billion in total assets and \$10.5 billion in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds.

### **Financial Feasibility**

In Section R of the previous three applications, Project I.D's # E-11376-17, E-11377-17 and E-11401-17, the applicant provided pro forma financial statements for the first two years of the project. The applicant projected that revenues would exceed operating expenses in the first two operating years for each of those projects. The applicant includes that information in the current COS application.

The applicant provided pro forma financial statements for the first two years of the project for the proposed COS application in Section R. In the pro forma financial statement (Form B),

the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

|   | <b>Operating Year 1<br/>FY2020</b> | <b>Operating Year 2<br/>FY2021</b> |
|---|------------------------------------|------------------------------------|
| Total Treatments                        | 19,858                             | 20,896                             |
| Total Gross Revenues (Charges)          | \$92,940,184                       | \$89,355,413                       |
| Total Net Revenue                       | \$7,443,375                        | \$7,121,773                        |
| Average Net Revenue per Treatment       | \$374.83                           | \$340.82                           |
| Total Operating Expenses (Costs)*       | \$5,742,503                        | \$5,965,490                        |
| Average Operating Expense per Treatment | \$289.18                           | \$285.48                           |
| Net Income                              | \$1,700,872                        | \$1,156,284                        |

\*Form A had slightly higher total operating expenses, however, the difference is not material to the project.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital cost are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

C

The applicant proposes a COS for three projects: Project ID# E-11376-17 (develop a new facility by relocating 14 stations from BMA Lenoir to a new facility), Project ID# E-11377-

17 (relocate the remaining 20 stations at BMA Lenoir to a new site) and Project ID# E-11401-17 (add 7 stations to BMA Lenoir). Upon completion of this project, Project ID# E-11377-17 and Project ID# E-11401-17, BMA Lenoir will be certified for a total of 41 stations. Project ID# E-11376-17 will not be developed. The proposed newly expanded BMA Lenoir dialysis would be located at 1208 Hickory Boulevard, SW, in Caldwell County.

According to the January 2018 SDR, there is only one operational dialysis facility in Caldwell County, which is BMA Lenoir. BMA proposed the relocation of 14 stations to develop Fresenius Kidney Care Caldwell County which will not be developed, as a result this COS application.

The applicant adequately demonstrates that the current COS would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrated that the previously approved applications would not result in unnecessary duplication of existing or approved health service capabilities or facilities, and nothing in this application affects that determination.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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

The proposed application is a COS for Project I.D's # E-11376-17, E-11377-17 and E-11401-17. In the current application, the applicant proposes to develop BMA Lenoir as a 41-station facility by merging the previously approved projects into one single facility. Although, the proposed application is a COS, none of the previously approved applications would have separately operated with as many in-center stations as proposed in this application. Therefore, review of the proposed staffing is necessary to ensure the facility will operate with sufficient staffing.

In Section H, page 34, the applicant provides current and projected staffing for the proposed services as illustrated in the following table.



|                       | <b>Current<br/>CY2017</b> | <b>FTE Positions<br/>to be<br/>Added</b> | <b>Projected<br/>FTEs<br/>OY2</b> |
|-----------------------|---------------------------|--|-----------------------------------|
| Registered Nurse      | 5.50                      | 3.00                                     | 8.50                              |
| Home Training Nurse   | 1.33                      | 0.00                                     | 1.33                              |
| Patient Care Tech.    | 12.75                     | 7.00                                     | 19.75                             |
| Dietitian             | 1.00                      | 0.40                                     | 1.40                              |
| Social Worker         | 1.00                      | 0.40                                     | 1.40                              |
| Clinical Manager      | 1.00                      | 0.00                                     | 1.00                              |
| Admin. (FMC Dir. Ops) | 0.20                      | 0.00                                     | 0.20                              |
| In-Service            | 0.25                      | 0.10                                     | 0.35                              |
| Clerical              | 1.00                      | 0.75                                     | 1.75                              |
| Chief Tech            | 0.10                      | 0.10                                     | 0.20                              |
| Equipment Tech        | 1.00                      | 0.40                                     | 1.40                              |
| <b>TOTAL</b>          | <b>25.13</b>              | <b>12.15</b>                             | <b>37.28</b>                      |

In the previously approved applications and in the proposed COS application, the applicant states that the medical director is a contracted position. Dr. Robert Qualheim was identified as the medical director in the previously approved applications. Exhibit I.5 contains a letter dated June 13, 2018 from Dr. Qualheim expressing his support for the proposed project and his willingness to continue as the medical director of BMA Lenoir.

The assumptions and methodology used to project staffing are provided in Section R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R.

In Project I.D's # E-11376-17, E-11377-17 and E-11401-17, the applications were conforming to this criterion.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 I, page 37, the applicant states:

*“This is a Change of Scope CON application. There will be no changes necessary as a consequence of this application to merge the BMA and FKC Caldwell County facilities.”*

In Project I.D’s # E-11376-17, E-11377-17 and E-11401-17, the applications were conforming to this criterion and the applicant proposes no changes in the current change of scope application that would affect that determination.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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.

C

In Project I.D. # E-11376-17, the applicant proposed to lease and upfit 2,875 square feet of space. In Project I.D. # E-11377-17, the applicant proposed to lease and upfit 5,257 square feet of space in which to relocate BMA Lenoir. The applicant received a material compliance determination on June 15, 2018 to relocate the facility to 1208 Hickory Boulevard, SW instead of 125 Hospital Avenue, as proposed in Project I.D. # E-11377-17. In Project I.D. # E-11401-17, the applicant did not propose to construct any new space or to renovate any existing space.

In Section K.7, page 43, the applicant states the facility will now consist of 8,020 square feet in the treatment area. On page 43, the applicant states,

*“The larger, 41 station dialysis facility, will obviously require additional square footage. The change is necessary in order to have sufficient space for the additional dialysis stations and properly care for the patient population of the facility.”*

In Project I.D. # E-11377-17, the applicant adequately described its plans for energy efficiency and water conservation. Although, this application includes an increase in square footage to accommodate the additional stations, the applicant does not propose any change that would affect the prior determination.

In Section C, pages 14-17, of this application, the applicant discusses the need for the proposed COS project. This application seeks approval to merge the three previously approved applications due to complications with developing those projects as proposed. On

page 15, the applicant states, “*By combining the ... projects into a 41 station dialysis facility, BMA can serve the same patient population, and conserve operational costs.*”

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

The proposed application is a COS for Project I.D's # E-11376-17, E-11377-17 and E-11401-17.

In this COS, in Section L.7, (page 48), the applicant provides the historical payor mix for calendar year (CY) 2017 for BMA Lenoir, as illustrated below.

| <b>Payment Source</b>       | <b>Percent of Total Patients</b> |
|-----------------------------|----------------------------------|
| Self Pay/ Indigent/ Charity | 1.47%                            |
| Medicare                    | 62.28%                           |
| Medicaid                    | 4.12%                            |
| Commercial Insurance        | 6.74%                            |
| Medicare / Commercial       | 18.24%                           |
| Misc. (VA)                  | 7.15%                            |
| <b>Total</b>                | <b>100.0%</b>                    |

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, the applicant was conforming to this criterion in Project I.D's # E-11376-17, E-11377-17 and E-11401-17 and the applicant proposes no changes in the current COS application that would affect that determination.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Project I.D's # E-11376-17, E-11377-17 and E-11401-17, the application was conforming to this criterion and the applicant proposes no changes in the current COS application that would affect that determination.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Project I.D's # E-11376-17, E-11377-17 and E-11401-17, the application was conforming to this criterion and the applicant proposes no changes in the current COS application that would affect that determination.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Project I.D's # E-11376-17, E-11377-17 and E-11401-17, the application was conforming to this criterion and the applicant proposes no changes in the current COS application that would affect that determination.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

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

## C

The applicant proposes a COS for Project I.D.'s # E-11376-17, E-11377-17 and E-11401-17. Project I.D. # E-11376-17 authorized the applicant to develop a new 14 station facility to be known as FKC Caldwell County. This project will not be developed. Therefore, those stations and patients will remain at the existing BMA Lenoir.

In Project I.D. # E-11377-17, the applicant was authorized to relocate BMA Lenoir. The 20 station facility was proposed to be relocated to 125 Hospital Avenue in Lenoir. In a subsequent request for material compliance letter dated June 8, 2018, the applicant was approved on June 15, 2018, to relocate the facility to 1208 Hickory Boulevard, SW.

In Project I.D. # E-11401-17, the applicant was authorized to add 7 dialysis stations to BMA Lenoir following the completion of Project I.D.'s # E-11376-17 and E-11377-17 for a total of 27 stations upon project completion.

In the current application, the applicant proposes a change of scope which would allow BMA Lenoir to be developed on as a 41-station facility by not developing Project I.D. # E-11376-17, and combining Project I.D.'s # E-11377-17 and E-11401-17. Thus, the 14 stations authorized to be relocated in Project I.D. # E-11376-17 would remain at BMA Lenoir and the 7 additional stations authorized in Project I.D. # E-11401-17 would be added (20 + 14 + 7 = 41) for a total of 41 dialysis stations at BMA Lenoir upon project completion.

According to the January 2018 SDR, there is only one operational dialysis facility in Caldwell County, which is BMA Lenoir. BMA proposed the relocation of 14 stations to develop Fresenius Kidney Care Caldwell County which will not be developed, as a result this COS application.

In Project I.D's # E-11376-17, E-11377-17 and E-11401-17, the application was conforming to this criterion and the applicant proposes no changes in the current COS application that would affect that determination. BMA remains the only provider of ESRD services in Caldwell County.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

In Section A.11, page 5, the applicant states that Bio-Medical Applications of North Carolina, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. Exhibit A.4, the applicant provides a list of its affiliates which includes those facilities operated by Bio-Medical Applications of North Carolina, Inc.

In Section O, pages 54-55, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities (BMA East Rocky Mount). The applicant states that all of the problems have been corrected as documented in Exhibit O-3. After reviewing and considering information provided by the applicant and considering the quality of care provided at 112 facilities in 48 North Carolina counties, including those related or affiliated with the applicant, the applicant provided sufficient evidence that quality care has been provided in the past. Additionally, the applicant was found conforming to this criterion in Project I.D's # E-11376-17, E-11377-17 and E-11401-17. Therefore, the application is conforming to this criterion.



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

NA

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 is not applicable to this review.