

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 28, 2018

Findings Date: February 28, 2018

Project Analyst: Julie M. Faenza

Team Leader: Fatimah Wilson

Project ID #: E-11436-17

Facility: FMC Hickory Home Program

FID #: 110873

County: Catawba

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

Project: Relocate the existing home hemodialysis training and support program with its two dedicated dialysis stations from FMC Hickory to FMC Hickory Home Program

### 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

Bio-Medical Applications of North Carolina, Inc. (BMA) proposes to relocate the existing home hemodialysis (HH) training and support program with its two dedicated dialysis stations, currently located at FMC Hickory, to FMC Hickory Home Program (FMC Hickory Home), a separately licensed dialysis facility which operates a home peritoneal dialysis (PD) training program. The applicant does not propose to establish new dialysis stations. Upon completion of this project, FMC Hickory Home will be certified for two dialysis stations. Upon completion of this project and Project I.D. #E-11209-16, FMC Hickory will be certified for 27 dialysis stations.

### **Need Determination**

The applicant is proposing to relocate existing dialysis stations within Catawba County. Neither the county need nor the facility need methodologies in the 2017 State Medical Facilities Plan (2017 SMFP) are applicable to this review. Additionally, Policy GEN-3: *Basic Principles* is not applicable because neither need methodology is applicable to the review.

### **Policies**

There is one policy in the 2017 SMFP that is applicable to this review: Policy ESRD-2 Relocation of Dialysis Stations, on page 27.

**Policy ESRD-2: Relocation of Dialysis Stations** states:

*“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:*

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

BMA is proposing to relocate existing dialysis stations within Catawba County; therefore, the proposed project is conforming with Policy ESRD-2: Relocation of Dialysis Stations.

### **Conclusion**

The information in the application regarding conformity with Policy ESRD-2 is reasonable and adequately supported because both facilities are located in Catawba County.

This determination is based on a review of:

- the application, including any exhibits
- written comments
- remarks made at the public hearing
- responses to comments
- information which was publicly available during the review and used by the Agency

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

NC

Fresenius Medical Care Holdings, Inc. (Fresenius) is the parent company of BMA. FMC Hickory is an existing 35-station dialysis facility with a home hemodialysis (HH) training and support program including two dedicated dialysis stations. FMC Hickory Home is an existing dialysis facility which provides training and support for home peritoneal dialysis (PD) patients. BMA proposes to relocate the HH training and support program and its two dedicated stations from FMC Hickory to FMC Hickory Home. Upon completion of this project, FMC Hickory Home will be certified for two dialysis stations. Upon completion of this project and Project I.D. #E-11209-16, FMC Hickory will be certified for 27 dialysis stations.

**Patient Origin**

On page 373, the 2017 SMFP defines the service area for dialysis services 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 for this facility consists of Catawba County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 23, the applicant provides the patient origin for FMC Hickory Home and HH patients at FMC Hickory as of June 30, 2017, as shown in the table below.

<b>Patient Origin – June 30, 2017</b>		
<b>County</b>	<b>HH Patients – FMC Hickory</b>	<b>PD Patients – FMC Hickory Home</b>
Catawba	7	20
Alexander	0	1
Buncombe	1	0
Burke	1	3
Caldwell	0	2
Lincoln	0	1
Rutherford	0	1
<b>Total</b>	<b>9</b>	<b>28</b>

In Section C.1, page 14, the applicant provides the projected patient origin for FMC Hickory Home HH and PD patients for the first two operating years (OY) following project completion, as shown in the table below.

<b>FMC Hickory Home Patients by County – Operating Years 1 &amp; 2</b>						
<b>County</b>	<b>Operating Year 1 CY 2019</b>		<b>Operating Year 2 CY 2020</b>		<b>County Patients as % of Total</b>	
	<b>HH</b>	<b>PD</b>	<b>HH</b>	<b>PD</b>	<b>OY 1</b>	<b>OY 2</b>
Catawba	8.5	24.3	9.2	26.3	76.7%	78.0%
Alexander	0.0	1.0	0.0	1.0	2.3%	2.2%
Buncombe	1.0	0.0	1.0	0.0	2.3%	2.2%
Burke	1.0	3.0	1.0	3.0	9.3%	8.8%
Caldwell	0.0	2.0	0.0	2.0	4.7%	4.4%
Lincoln	0.0	1.0	0.0	1.0	2.3%	2.2%
Rutherford	0.0	1.0	0.0	1.0	2.3%	2.2%
<b>Total</b>	<b>10.5</b>	<b>32.3</b>	<b>11.2</b>	<b>34.3</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant provides the assumptions and methodology used to project patient origin on pages 14-19.

The applicant adequately identifies the population to be served.

**Analysis of Need**

In Section C.2, page 19, the applicant states:

*“Patients with End Stage Renal Disease require dialysis treatment on a regular and consistent basis in order to maintain life. ... Failure to receive dialysis care will ultimately lead to the patient’s demise.*

*Home dialysis patients – PD and home hemodialysis – require the same regular dialysis treatment regimen. The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment.*

...

*Dialysis schedules at times which are not convenient for the patient will adversely affect patient compliance and lead to higher missed treatment rates. Home dialysis affords the patient maximum flexibility with scheduling treatment at times which are convenient, and in the patient residence. The patient has total control of the treatment.*

*Dialysis in a setting which is not convenient for the patient, similarly leads to patient compliance issues and higher missed treatment rates.*

*Approval of this application will allow BMA to relocate an entire home hemodialysis training and support program, and its two hemodialysis stations, to the FMC Hickory Home Program. This will enhance patient training opportunities and ultimately will*

*assure home patients of continued access to care in a convenient setting, at times which are convenient for the patient.”*

Projected Utilization

In Section C.1, page 14, the applicant provides the projected patient utilization for FMC Hickory Home HH and PD patients for the first two operating years (OY) following completion of the project, as shown in the table below.

<b>FMC Hickory Home Patients by County – Operating Years 1 &amp; 2</b>						
<b>County</b>	<b>Operating Year 1 CY 2019</b>		<b>Operating Year 2 CY 2020</b>		<b>County Patients as % of Total</b>	
	<b>HH</b>	<b>PD</b>	<b>HH</b>	<b>PD</b>	<b>OY 1</b>	<b>OY 2</b>
Catawba	8.5	24.3	9.2	26.3	76.7%	78.0%
Alexander	0.0	1.0	0.0	1.0	2.3%	2.2%
Buncombe	1.0	0.0	1.0	0.0	2.3%	2.2%
Burke	1.0	3.0	1.0	3.0	9.3%	8.8%
Caldwell	0.0	2.0	0.0	2.0	4.7%	4.4%
Lincoln	0.0	1.0	0.0	1.0	2.3%	2.2%
Rutherford	0.0	1.0	0.0	1.0	2.3%	2.2%
<b>Total</b>	<b>10.5</b>	<b>32.3</b>	<b>11.2</b>	<b>34.3</b>	<b>100.0%</b>	<b>100.0%</b>

In Section C.1, pages 14-19, the applicant provides the assumptions and methodology used to project utilization, which are summarized below:

- The applicant assumes all current HH patients will transfer from FMC Hickory to FMC Hickory Home, and will begin its projections for HH patient growth with the census of HH patients at FMC Hickory as of June 30, 2017.
- The applicant begins patient projections for PD patient growth with the census at FMC Hickory Home as of June 30, 2017.
- The applicant assumes that only one HH patient may be trained on each station at a time, due to the amount of time required to train an HH patient and a caregiver on the procedures for HH.
- The applicant assumes that an HH patient and caregiver will receive an average of 25 training treatments prior to discharge over a period of approximately six weeks.
- The applicant assumes that a single dedicated HH training station can train up to eight patients per year.
- The applicant assumes that the PD and HH patient population currently receiving treatment through FMC Hickory and FMC Hickory Home and who currently reside in Catawba County will increase at a rate of 8.1 percent, which is the Five Year Average Annual Change Rate (AACR) for Catawba County published in the July 2017 SDR.

- The applicant assumes no population growth for the patients who utilize the facility and live outside of Catawba County, but assumes that those patients will continue to dialyze at FMC Hickory Home and are added to the calculations when appropriate.
- The project is scheduled for completion on December 31, 2018. OY1 is CY 2019. OY2 is CY 2020.

In Section C.1, page 15, the applicant provides the calculations used to arrive at the projected HH and PD patient census for OY1 and OY2 as summarized in the table below.

FMC Hickory Home	HH	PD
Starting point of calculations is Catawba County patients dialyzing at FMC Hickory (HH) and FMC Hickory Home (PD) on June 30, 2017.	7	20
Catawba County patient population is projected forward by six months to December 31, 2017. Projection is based on one-half of the AACR for Catawba County (8.1%).	$7 \times 1.0405 = 7.28$	$20 \times 1.0405 = 20.8$
Catawba County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (8.1%).	$7.28 \times 1.081 = 7.87$	$20.8 \times 1.081 = 22.5$
The patients from other counties are added. This is the projected census on December 31, 2018 and the starting census for this project.	$7.87 + 2 = 9.87$	$22.5 + 8 = 30.5$
Catawba County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (8.1%).	$7.87 \times 1.081 = 8.51$	$22.5 \times 1.081 = 24.3$
The patients from other counties are added. This is the projected census on December 31, 2019 (OY1).	$8.51 + 2 = 10.51$	$24.3 + 8 = 32.3$
Catawba County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (8.1%).	$8.51 \times 1.081 = 9.20$	$24.3 \times 1.081 = 26.3$
The patients from other counties are added. This is the projected census on December 31, 2020 (OY2).	$9.20 + 2 = 11.20$	$26.3 + 8 = 34.3$

The applicant projects to serve a total of 10 HH patients by the end of OY 1 and 11 HH patients by the end of OY 2. The required performance standard promulgated by 10A NCAC 14C .2203(b) requires the applicant to project to serve 3.2 patients **per station per week** by the end of the first operating year. This performance standard is based on the idea that a typical in-center dialysis treatment lasts approximately four hours; most dialysis facilities offer two shifts per day; and since in-center dialysis takes place three days per week, with most facilities open six days per week, each station can serve a maximum of four in-center patients per week. The performance standard does not contain language that distinguishes what type of patients are being served or what type of treatment the station is being used for in requiring that dialysis facilities meet the standard of 3.2 patients per station per week.

On pages 17-18, the applicant states that stations will not serve more than one patient at a time. The applicant states that HH patients train for approximately six hours per day, four days per week, for a period of six weeks, and further states that when the patient is not training on a dialysis station, staff is likely to be doing administrative work, patient education, or participating in clinic days. Thus, it is impossible for the applicant to meet the required performance standard of serving 3.2 patients per station per week.

On pages 17-18, the applicant suggests a different performance standard that should be used instead of 10A NCAC 14C .2203(b), due to the nature of the type of services that will be offered on the dedicated HH training stations. The applicant states that a comparable standard to the 3.2 patients per station per week required by 10A NCAC 14C .2203(b) would be to serve seven patients per year on each station. On page 18, the applicant provides its assumptions and methodology for its proposed performance standard, as summarized below.

<b>Proposed Performance Standard</b>	<b>Calculations</b>
The existing standard is 3.2 patients per station per year and there are 52 weeks per year. The two numbers are multiplied to determine the number of treatments that should be performed on each station per year.	$3.2 \times 52 = 166.4$
Based on its experience, the applicant states that each new HH patient will complete an average of 25 treatments over six weeks before being discharged to dialyzing at home.	$166.4 / 25 = 6.656$
The applicant states that with regard to dialysis, there are no partial patients, only whole patients – so the applicant rounds to the nearest whole patient.	$6.656 = 7$

The applicant suggests that the performance standard of seven patients per station per year is the most appropriate standard to meet; thus, the applicant would have needed to project to serve 14 patients by the end of the second operating year. However, the applicant does not meet this standard by the end of either the first operating year (10 patients) or the second operating year (11 patients).

On pages 18-19, the applicant states that there is more involved in training and supporting HH patients than just the average of 25 training treatments that a patient learning how to dialyze at home undergoes. The applicant provides a chart on page 18 summarizing the HH census for FMC Hickory for YTD 2017 (approximately 10+ months), which is reproduced below.

<b>FMC Hickory HH Patient Census YTD 2017</b>	
Beginning census	9
New patients trained/began HH	2
New patient began training but stopped short of completion	1
Deaths	1
Changed modality/returned to in-center dialysis	1
Patient who received transplant	1
Total patients relying on HH stations	15

The applicant states that, if the patients in the table above are considered, the two stations meet the proposed minimum of seven patients per station per year. On page 19, the applicant states, *“The census alone is not a complete picture of utilization.”*

During the public hearing for this proposed project, on January 19, 2018, the applicant also stated, in response to comments made by a member of the public, that it had not considered factors such as the need for any retraining for HH patients who had successfully completed training but needed reminders, or for respite treatments for HH patients giving their caregivers

a break. The applicant stated that the lack of these factors as part of the projections for patient utilization made the projections more conservative.

While the applicant provides qualitative factors it believes should contribute to the consideration of whether the projected utilization meets the performance standard proposed by the applicant, the applicant fails to provide any quantitative factors that can be used to assess the validity of including the qualitative factors in its proposed performance standard. The applicant does not provide any context such as how many treatments are needed by each of the individual patients referenced in the table above, or how many retraining sessions a patient may need, or how many treatments are involved during a period of respite treatments. Without quantitative factors, there is no context in which to use the additional qualitative information provided by the applicant, and no way to make a reasonable and adequately supported determination that the applicant can meet its own proposed performance standard.

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. The applicant uses the Five Year AACR for Catawba County as published in the July 2017 SDR to project future utilization and applies that projected growth rate to the appropriate patient population. However, the applicant fails to meet the required performance standard promulgated in 10A NCAC 14C .2203(b) as well as its own proposed performance standard. Therefore, the applicant does not adequately demonstrate the need to relocate the HH training and support program, with its two dedicated HH training stations, from FMC Hickory to FMC Hickory Home.

### **Access to Services**

In Section C.3, pages 19-20, the applicant states:

*“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.*

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

In Section L.1, page 55, the applicant projects that 63.74 percent of patients at FMC Hickory Home will have some or all of their expenses paid by either Medicare or Medicaid. However, the applicant does not provide adequate information to determine its projected payor mix is reasonable and adequately supported. The applicant provides no assumptions or methodology to explain how it determined its projected payor mix. Please see the discussion regarding access found in Criterion (13c) for more information. The applicant does not adequately demonstrate the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

### **Conclusion**

The Agency reviewed the following:



- the application, including any exhibits
- written comments
- remarks made at the public hearing
- responses to comments
- information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for the following reasons:

- The applicant does not adequately demonstrate the need to relocate the HH training and support program with its two dedicated dialysis stations from FMC Hickory to FMC Hickory Home.
  - The applicant does not adequately demonstrate the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

### C

BMA proposes to relocate the HH training and support program and its two dedicated stations from FMC Hickory to FMC Hickory Home. Upon completion of this project, FMC Hickory Home will be certified for two dialysis stations. Upon completion of this project and Project I.D. #E-11209-16, FMC Hickory will be certified for 27 dialysis stations.

In Section D.1, pages 26-29, the applicant discusses how the needs of dialysis patients at FMC Hickory will continue to be met following the relocation of stations to FMC Hickory Home. The applicant states that the two stations to be relocated have been exclusively used at FMC Hickory for HH training and support.

The applicant provides the following assumptions used to project future utilization at FMC Hickory:

- As part of Project I.D. #E-11209-16, six dialysis stations will be relocated to a new dialysis facility to be developed, FKC Newton. Along with the stations, the application projected 12 existing patients from FMC Hickory would transfer care to the new facility. The applicant continues to project that these 12 patients will transfer with the stations when FKC Newton is operational (currently projected for December 31, 2018).
- FMC Hickory was serving a single patient from another state on June 30, 2017, and will not consider that patient in projections.

- The applicant will not consider HH patients due to the proposed relocation of the program from FMC Hickory to FMC Hickory Home.
- The Catawba County patient population dialyzing at FMC Hickory will be projected to grow at a rate of 8.1 percent, the Five Year AACR for Catawba County, as published in the July 2017 SDR.
- Dialysis patients receiving treatment at FMC Hickory who reside in other counties will not be projected to grow in population but will be added to the calculations when appropriate.

The applicant projects the growth of the patient population dialyzing at FMC Hickory as summarized in the table below.

FMC Hickory	Calculations
Starting point of calculations is Catawba County in-center patients dialyzing at FMC Hickory as of June 30, 2017.	106
Catawba County patient population is projected forward by six months to December 31, 2017. Projection is based on one-half of the AACR for Catawba County (8.1%).	$106 \times 1.0405 = 110.3$
Catawba County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (8.1%).	$110.3 \times 1.081 = 119.2$
Subtract 12 patients projected to transfer care to FKC Newton.	$119.2 - 12 = 107.2$
The 15 patients from other counties are added. This is the projected census on December 31, 2018.	$107.2 + 15 = 122.2$

The applicant projects to serve 123 in-center patients as of December 31, 2018. If the applicant were to project to serve 123 patients on 27 stations, the utilization rate would be 113.89 percent, or 4.56 patients per station per week ( $123 / 27 = 4.56$ ;  $4.56 / 4 = 113.89\%$ ), well in excess of the maximum capacity of dialysis stations of 4 patients per station per week.

On page 27, the applicant states that FMC Hickory currently has a third shift in the evenings, which serves four patients, and the applicant projects that this third shift will continue to serve the four patients as of December 31, 2018. The applicant further states on page 28 that based on its existing utilization rate, when it applies the facility need methodology calculations, the result is that FMC Hickory will be eligible to apply for an additional four dialysis stations during the application review cycle beginning April 1, 2018. The applicant states that if it assumes the prospective application for four additional stations is approved, the applicant will have the certificate of need to add four stations to FMC Hickory around the first week of October 2018, before the six stations projected to relocate to FKC Newton are decertified from FMC Hickory. On page 29, the applicant states it has filed many successful applications for additional stations in the past.

With the applicant's additional assumptions that FMC Hickory will continue to serve four in-center patients on an evening shift and that it will successfully apply for and receive a certificate of need for four additional stations at FMC Hickory prior to December 31, 2018, the applicant calculates that it will be able to continue to serve all in-center patients at FMC Hickory. The applicant's additional calculations are summarized below.

<b>FMC Hickory – More Assumptions</b>	<b>Calculations</b>
Starting point of calculations is all in-center patients dialyzing at FMC Hickory as of December 31, 2018.	123
Remove four patients who are being served on an evening shift from the utilization calculations.	$123 - 4 = 119$
Add four stations assumed to be approved around October 2018 to the remaining 27 stations at FMC Hickory.	$27 + 4 = 31$

The applicant now projects to serve 119 in-center patients on 31 stations for a utilization rate of 95.97 percent, or 3.84 patients per station per week ( $119 / 31 = 3.84$ ;  $3.84 / 4 = 95.97\%$ ). The applicant's projections are based on reasonable and adequately supported assumptions.

In Section D.2, page 29, the applicant states that the relocation of stations from FMC Hickory to FMC Hickory Home will have no impact on any underserved medical groups or their ability to continue to obtain needed healthcare.

### **Conclusion**

The Agency reviewed the following:

- the application, including any exhibits
- written comments
- remarks made at the public hearing
- responses to comments
- 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 describes the methodology and assumptions used to project utilization.
  - The applicant provides historical data, projected demographics, and verifiable sources which support its assumptions and projections.
- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

NC

In Section E.1, page 30, the applicant states that it considered maintaining the status quo, which was the only alternative to applying. The applicant states that after considering the status quo, it decided that the operational efficiencies to be gained by combining the home training programs, and the creation of an exclusive environment for the home dialysis population, made applying to transfer the training program and associated stations the most effective alternative to meet the identified need.

However, the application is not conforming to all other statutory and regulatory review criteria, and thus is not approvable. The discussion regarding projected utilization found in Criteria (3) and the performance standard found in 10A NCAC 14C .2203, and the discussions regarding access found in Criteria (3), (13c), and (18a) are incorporated herein by reference. A project that cannot be approved cannot be an effective alternative.

### **Conclusion**

The Agency reviewed the following:

- the application, including any exhibits
- written comments
- remarks made at the public hearing
- responses to comments
- information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate that this proposal is the least costly or most effective alternative to meet the identified 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**

BMA proposes to relocate the HH training and support program and its two dedicated stations from FMC Hickory to FMC Hickory Home. Upon completion of this project, FMC Hickory Home will be certified for two dialysis stations. Upon completion of this project and Project I.D. #E-11209-16, FMC Hickory will be certified for 27 dialysis stations.

### **Capital and Working Capital Costs**

In Section F.1, page 31, the applicant projects no capital costs to develop the project. In Sections F.10 and F.11, page 34, the applicant states that there are no projected start-up expenses or initial operating expenses because it is an existing facility that is already operational.

### **Financial Feasibility**

The applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years, as shown in the table below.

<b>Projected Revenues and Operating Expenses</b>		
<b>FMC Hickory Home</b>	<b>Operating Year 1 CY 2019</b>	<b>Operating Year 2 CY 2020</b>
Total Treatments	6,076	6,372
Total Gross Revenues (Charges)	\$24,231,088	\$25,411,536
Total Net Revenue	\$3,081,147	\$3,231,249
Total Operating Expenses (Costs)	\$1,858,947	\$1,927,446
<b>Net Income/Profit</b>	<b>\$1,222,199</b>	<b>\$1,303,803</b>

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. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

**Conclusion**

The Agency reviewed the following:

- the application, including any exhibits and supplemental information
- written comments
- remarks made at the public hearing
- responses to comments
- 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 sufficient funds for the operating needs of the proposal.
  - The applicant adequately demonstrates 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**

Fresenius Medical Care Holdings, Inc. (Fresenius) is the parent company of BMA. FMC Hickory is an existing 35-station dialysis facility with a home hemodialysis (HH) training and support program including two dedicated dialysis stations. FMC Hickory Home is an existing dialysis facility which provides training and support for home peritoneal dialysis (PD) patients. BMA proposes to relocate the HH training and support program and its two dedicated stations from FMC Hickory to FMC Hickory Home. Upon completion of this project, FMC Hickory

Home will be certified for two dialysis stations. Upon completion of this project and Project I.D. #E-11209-16, FMC Hickory will be certified for 27 dialysis stations.

On page 373, the 2017 SMFP defines the service area for dialysis services 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 for this facility consists of Catawba County. Facilities may also serve residents of counties not included in their service area.

According to Table B of the July 2017 SDR, there are two existing dialysis facilities and two approved but not yet operational dialysis facilities in Catawba County, as shown in the table below.

<b>Existing/Approved Dialysis Facilities in Catawba County – Table B July 2017 SDR</b>						
<b>Facility</b>	<b>Owner</b>	<b># Patients</b>	<b>Location</b>	<b># Certified Stations</b>	<b># Approved Stations</b>	<b>% Utilization</b>
Catawba County Dialysis	DaVita	0	Hickory	0	10	0.0%
FMC of Catawba Valley	Fresenius	93	Conover	25	-6	93.0%
FMC of Hickory	Fresenius	120	Hickory	35	-6	85.7%
FKC Newton	Fresenius	0		0	12	0.0%

Table B in the July 2017 SDR does not list FMC Hickory Home, which is a separately licensed dialysis facility providing exclusively home PD training and support. It has no stations. In Section C.8, page 23, the applicant reports that as of June 30, 2017, FMC Hickory Home had 28 PD patients.

The applicant is not increasing the number of dialysis stations in Catawba County; rather, it is relocating two dialysis stations dedicated to HH support and training to an existing facility that will increase operational efficiency. Therefore, the applicant is not duplicating any existing or approved services; it is proposing to relocate their HH training program and its dedicated dialysis stations to better serve existing patients using existing stations.

### **Conclusion**

The Agency reviewed the following:

- the application, including any exhibits and supplemental information
- written comments
- remarks made at the public hearing
- responses to comments
- 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 because it adequately demonstrates that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

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

C

In Section H.1, page 40, the applicant provides the following table to illustrate projected staffing in full time equivalents (FTEs) for FMC Hickory Home in OY2. The applicant states the Medical Director is not directly employed by the facility, and thus is not reflected on the staffing chart.

<b>FMC Hickory Home – Proposed Facility Staffing</b>	
<b>Position</b>	<b>Projected # of FTEs</b>
Home Training RN	4.50*
Dietician	0.50
Social Worker	0.50
Clinical Manager	1.00
Administrator	0.15
In-Service	0.10
Clerical	0.67
Chief Tech	0.10
Equipment Tech	0.15
<b>Total</b>	<b>7.67</b>

\*The applicant proposes to move 1.25 FTEs from FMC Hickory to FMC Hickory Home as part of this proposed project.

In Section H.7, page 42, the applicant provides the projected direct care staff for the proposed facility in OY 2 (CY 2020), as shown in the table below:

<b>Direct Care Positions</b>	<b># FTEs</b>	<b>Hours per Year per FTE</b>	<b>Total Annual FTE Hours</b>	<b>Total Annual Hours of Operation</b>	<b># FTE Hours per Hour of Operation</b>
Home Training RN	4.5	2,080	9,360	2,340	4.0
<b>Total</b>	<b>4.5</b>	<b>2,080</b>	<b>9,360</b>	<b>2,340</b>	<b>4.0</b>

In Section H.6, page 42, the applicant states dialysis services will be available from 8:00 AM to 5:00 PM, Monday through Friday, for a total of 9 hours per day / 45 hours per week.

In Section I.3, page 45, the applicant identifies Dr. David Harvey as the current and continuing Medical Director of the facility. In Exhibit I-5, the applicant provides a copy of a letter signed by Dr. Harvey supporting the project and confirming his commitment to continue to serve as Medical Director. In Section H.3, page 41, the applicant describes the methods used to recruit and fill positions at the facility.

**Conclusion**

The Agency reviewed the following:

- the application, including any exhibits and supplemental information
- written comments
- remarks made at the public hearing
- responses to comments
- 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 because the applicant adequately demonstrates the availability of appropriate staff, including the Medical Director, for the provision of the services proposed to be provided.

- (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.1, page 44, the applicant identifies the necessary ancillary and support services that serve FMC Hickory Home. Exhibit I-5 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system on pages 44-46. Exhibits I-2 through I-4, respectively, contain copies of agreements for lab services, acute care services, and transplantation services.

### **Conclusion**

The Agency reviewed the following:

- the application, including any exhibits and supplemental information
- written comments
- remarks made at the public hearing
- responses to comments
- 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 provides documentation demonstrating that necessary ancillary and support services for FMC Hickory Home are available.
  - The applicant adequately demonstrates it has coordinated with medical providers in the existing health care system.
- (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.

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the

State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.7, page 58, the applicant reports that at least 67.55 percent of the patients who received treatments at FMC Hickory Home and 92.9 percent of the patients who received treatments at FMC Hickory had some or all of their services paid for by Medicare or Medicaid in CY 2016. The historical payor mix for patients dialyzing at both FMC Hickory Home and FMC Hickory is shown in the table below.

<b>Historical Payor Mix – FMC Hickory &amp; FMC Hickory Home CY 2016</b>		
<b>Payment Source</b>	<b>% Total Patients</b>	
	<b>FMC Hickory Home</b>	<b>FMC Hickory</b>
Self-Pay/Indigent/Charity	-0.02%	0.19%
Medicare	62.32%	72.44%
Medicaid	-2.07%	3.81%
Commercial Insurance	33.54%	2.91%
Medicare/Commercial	5.23%	16.65%
Misc. (including VA)	1.00%	4.00%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>

In Section L.7, page 58, the applicant states the negative amount listed in the self-pay/indigent/charity and Medicaid categories in the table for FMC Hickory Home is merely an accounting function rather than a number based on patients. The applicant states that during a prior year, revenue may have been accounted for incorrectly, and when the records were corrected, the result was a negative number.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Catawba	17%	51%	24%	15%	10%	14%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table>; Latest Data 7/1/16 as of 8/22/17

\*Excludes "White alone" who are "not Hispanic or Latino"

\*\*"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina, and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*<sup>1</sup> percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28<sup>2</sup>. In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

### Conclusion

The Agency reviewed the following:

- the application, including any exhibits and supplemental information
- written comments
- remarks made at the public hearing
- responses to comments
- 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 because the applicant documents, via its historical payor mix, the extent to which medically underserved populations currently use the applicant's existing services.

- (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

<sup>1</sup><http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

<sup>2</sup>[http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015\\_NW-6\\_Annual-Report\\_Final-11-29-2016.pdf](http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf)

and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L.3(d), page 56, the applicant states that it has no obligation to provide uncompensated care or community service under federal regulations. In Section L.6, page 57, the applicant states there have been no civil rights access complaints filed within the last five years.

**Conclusion**

The Agency reviewed the following:

- the application, including any exhibits and supplemental information
- written comments
- remarks made at the public hearing
- responses to comments
- 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 it had no past obligation to provide uncompensated care, community service, or access as a result of federal regulations.
- The applicant adequately demonstrates it has had no civil rights access complaints filed against it within the last 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

NC

In Section L.1(a), page 54, the applicant states: *“It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”*

In Section L.1(b), page 55, the applicant projects that 63.74 percent of all patients in CY 2020 who will receive dialysis treatments at FMC Hickory Home will have all or part of their services paid for by Medicare and/or Medicaid, as shown in the table below.

<b>FMC Hickory Home Projected Payor Mix CY 2020</b>			
<b>Payment Source</b>	<b>% Total Patients</b>	<b>% HH Patients</b>	<b>% PD Patients</b>
Self-Pay/Indigent/Charity	1.02%	1.02%	1.02%
Medicare	57.09%	57.09%	57.09%
Medicaid	1.86%	1.86%	1.86%
Commercial Insurance	34.21%	34.21%	34.21%
Medicare/Commercial	4.79%	4.79%	4.79%
Misc. (including VA)	1.03%	1.03%	1.03%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>

The applicant does not explain how it arrived at its projected payor mix for operating year two. In Section L.7, page 58, in providing its historical payor mix, the applicant provides the payor mix for the entire patient population of FMC Hickory as well as for FMC Hickory Home. The payor mix for FMC Hickory is almost entirely comprised of in-center patients, and there is no explanation of how the applicant arrived at its projected payor mix or how it distinguished the HH patients from the in-center patients. On page 58, the applicant states:

*“Fresenius financial reporting does not report payor mix based upon patients, or modality. Rather, historical revenues are reported based upon treatment reimbursement by payor classification. Consequently, the applicant is unable to separate and report historical revenues by dialysis modality. The above [table showing historical payor mix for FMC Hickory] represents all payor source reimbursement for all treatments provided by the facility.”*

The differences in payor mix percentages are not explained in the application as submitted and thus there is no possible way to know whether the payor mix is based upon reasonable and supported assumptions. See the table below.

<b>FMC Hickory/FMC Hickory Home Payor Mix Differences</b>			
<b>Payment Source</b>	<b>FMC Hickory Historical</b>	<b>FMC Hickory Home Historical</b>	<b>FMC Hickory Home Projected</b>
Self-Pay/Indigent/Charity	0.19%	-0.02%	1.02%
Medicare	72.44%	62.32%	57.09%
Medicaid	3.81%	-2.07%	1.86%
Commercial Insurance	2.91%	33.54%	34.21%
Medicare/Commercial	16.65%	5.23%	4.79%
Misc. (including VA)	4.00%	1.00%	1.03%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>

**Conclusion**

The Agency reviewed the following:

- the application, including any exhibits and supplemental information
- written comments

- remarks made at the public hearing
- responses to comments
- information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate that its projected payor mix is based on reasonable and supported assumptions.

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

### C

In Section L.4, page 57, 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 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.*

*.... Transient patients are accepted upon proper coordination of care with the patient’s regular nephrologist and a physician with staff privileges at the facility.”*

### **Conclusion**

The Agency reviewed the following:

- the application, including any exhibits and supplemental information
- written comments
- remarks made at the public hearing
- responses to comments
- 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 because it adequately demonstrates there are several means by which ESRD patients will have access to its services.

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

C

In Section M.1, page 59, the applicant states, “*The applicant has communicated with the local student nursing programs encouraging those programs to utilize the resources of the FMC Hickory Home Program facility to enhance the educational opportunities for the nursing student.*” In Exhibit M-1, the applicant provides a copy of a letter to Catawba Valley Community College inviting the nursing students to include FMC Hickory Home Program in their clinical rotations.

**Conclusion**

The Agency reviewed the following:

- the application, including any exhibits and supplemental information
- written comments
- remarks made at the public hearing
- responses to comments
- 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 because the applicant adequately documents its attempts to accommodate the clinical needs of health professional training programs in the area.

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

NC

Fresenius Medical Care Holdings, Inc. (Fresenius) is the parent company of BMA. FMC Hickory is an existing 35-station dialysis facility with a home hemodialysis (HH) training and support program including two dedicated dialysis stations. FMC Hickory Home is an existing dialysis facility which provides training and support for home peritoneal dialysis (PD) patients. BMA proposes to relocate the HH training and support program and its two dedicated stations from FMC Hickory to FMC Hickory Home. Upon completion of this project, FMC Hickory Home will be certified for two dialysis stations. Upon completion of this project and Project I.D. #E-11209-16, FMC Hickory will be certified for 27 dialysis stations.

On page 373, the 2017 SMFP defines the service area for dialysis services 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 for this facility consists of Catawba County. Facilities may also serve residents of counties not included in their service area.

According to Table B of the July 2017 SDR, there are two existing dialysis facilities and two approved but not yet operational dialysis facilities in Catawba County, as shown in the table below.

<b>Existing/Approved Dialysis Facilities in Catawba County – Table B July 2017 SDR</b>						
<b>Facility</b>	<b>Owner</b>	<b># Patients</b>	<b>Location</b>	<b># Certified Stations</b>	<b># Approved Stations</b>	<b>% Utilization</b>
Catawba County Dialysis	DaVita	0	Hickory	0	10	0.0%
FMC of Catawba Valley	Fresenius	93	Conover	25	-6	93.0%
FMC of Hickory	Fresenius	120	Hickory	35	-6	85.7%
FKC Newton	Fresenius	0		0	12	0.0%

Table B in the July 2017 SDR does not list FMC Hickory Home, which is a separately licensed dialysis facility providing exclusively home PD training and support. It has no stations. In Section C.8, page 23, the applicant reports that as of June 30, 2017, FMC Hickory Home had 28 PD patients.

In Section N of the application, pages 60-61, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services.

In Section N, page 60, the applicant states:

*“The applicant does not expect this proposal to have effect on the competitive climate in Catawba County. The applicant does not project to serve dialysis patients currently being served by another provider.*

...

*BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients’ lives by offering a convenient venue for dialysis care and treatment, and promoting access to care.”*



## **Conclusion**

The Agency reviewed the following:

- the application, including any exhibits and supplemental information
- written comments
- remarks made at the public hearing
- responses to comments
- information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for the following reasons:

- The applicant does not adequately demonstrate the need to relocate the HH training and support program with its two dedicated dialysis stations from FMC Hickory to FMC Hickory Home. See the discussions regarding need and effectiveness found in Criteria (3) and (4), respectively, which are incorporated herein by reference.
- The applicant does not adequately demonstrate that it will provide access to medically underserved groups. See the discussion regarding access in Criteria (3) and (13c) which is incorporated herein by reference.

(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

Fresenius owns and operates or is otherwise affiliated with 112 facilities in North Carolina as of November 15, 2017. In Section O and referenced Exhibits, the applicant identifies the one kidney disease treatment center located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation during the 18 month look-back period. However, that facility is back in compliance with the Medicare conditions of participation, and the applicant provides documentation of compliance in Exhibit O-3. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. 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.

NC

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is not conforming to all applicable criteria, as discussed below.

**10 NCAC 14C .2203 PERFORMANCE STANDARDS**

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

-NA- FMC Hickory Home is an existing facility.

(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.*

-NC- The applicant does not demonstrate that the proposed stations to be relocated from FMC Hickory to FMC Hickory Home will be utilized at a rate of at least 3.2 patients per station per week as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 14-19, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.