

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 12, 2017

Findings Date: December 12, 2017

Project Analyst: Julie Halatek

Team Leader: Lisa Pittman

Project ID #: E-11401-17

Facility: BMA Lenoir

FID #: 170328

County: Caldwell

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

Project: Add 7 dialysis stations for a total of 27 stations upon completion of this project, Project I.D. #E-11376-17 (relocate 14 stations to develop the new FKC Caldwell County), and Project I.D. #E-11377-17 (relocate the remaining 20 stations)

### 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) d/b/a BMA Lenoir proposes to add 7 dialysis stations to the existing facility for a total of 27 stations upon completion of this project, Project I.D. #E-11376-17 (relocate 14 stations to develop the new FKC Caldwell County), and Project I.D. #E-11377-17 (relocate the remaining 20 stations).

#### **Need Determination**

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of four dialysis stations in Caldwell County. Therefore, the July 2017 SDR does not indicate a need for additional stations in Caldwell County based on the county need

methodology, which states that the county deficit must be 10 or greater to establish a need for additional stations. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80 percent. The utilization rate reported for BMA Lenoir in the July 2017 SDR is 3.29 patients per station per week, or 82.35 percent, based on 112 in-center dialysis patients and 34 certified dialysis stations [ $112 / 34 = 3.29$ ;  $3.29 / 4 = 0.8235$  or 82.35%].

Below is a table that illustrates the facility need for additional dialysis stations at BMA Lenoir:

<b>JULY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/16		82.4%
Certified Stations		34
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>34</b>
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR2)		112
In-Center Patients as of 6/30/16 (January 2017 SDR) (SDR1)		103
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	9
	Multiply the difference by 2 for the projected net in-center change	18
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.1748
(ii)	Divide the result of Step (i) by 12	0.0146
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/16 until 12/31/17)	0.1748
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	131.5728
(v)	Divide the result of Step (iv) by 3.2 patients per station	41.1165
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>7</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is seven stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add seven new stations; therefore, the application is consistent with the facility need determination for dialysis stations.

**Policies**

There is one policy in the 2017 SMFP which is applicable to this review. POLICY GEN-3: BASIC PRINCIPLES on page 33 of the 2017 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical*

*Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

### **Promote Safety and Quality**

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), page 9; Section K.1(g), page 48; Section N.1, page 58; Section O, pages 59-61, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal would promote safety and quality.

### **Promote Equitable Access**

The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), pages 10-11; Section C.3, page 19; Section L, pages 52-56; Section N.1, page 58, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal would promote equitable access.

### **Maximize Healthcare Value**

The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c), pages 11-12; Section C, pages 15-18; Section F, pages 26-34; Section K, pages 46-49; Section N.1, page 58, and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its proposal incorporates the concepts of quality, equitable access, and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

### **Conclusion**

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant’s use of the facility need methodology in accordance with the July 2017 SDR.
- The applicant’s use of existing policies, historical data, and verifiable sources to provide future projections and demonstrate conformity with Policy GEN-3.

This determination is based on a review of the:

- Information in the application, including any exhibits.

- 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.

C

The applicant proposes to add 7 dialysis stations to the existing facility for a total of 27 stations upon completion of this project, Project I.D. #E-11376-17 (relocate 14 stations to develop the new FKC Caldwell County), and Project I.D. #E-11377-17 (relocate the remaining 20 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 North Carolina counties is a separate dialysis station planning area.*” Thus, the service area for this facility is Caldwell County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 21, the applicant provides a table showing the historical patient origin for in-center (IC), home peritoneal dialysis (PD), and home hemodialysis (HH) patients served by BMA Lenoir, as shown below.

<b>BMA Lenoir Patients by County – 6/30/2017</b>			
<b>County</b>	<b># of IC Patients</b>	<b># of HH Patients</b>	<b># of PD Patients</b>
Caldwell	110	3	10
Alexander	1	0	0
Burke	3	0	0
Catawba	1	0	0
Wilkes	0	0	1
Other States	1	0	0
<b>Total</b>	<b>116</b>	<b>3</b>	<b>11</b>

In Section C.1, page 15, the applicant provides the projected patient origin for BMA Lenoir for in-center (IC), home peritoneal dialysis (PD), and home hemodialysis (HH) patients for the first two operating years (OY) following completion of the project, as shown in the table below.

<b>BMA Lenoir 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>IC</b>	<b>HH</b>	<b>PD</b>	<b>IC</b>	<b>HH</b>	<b>PD</b>	<b>OY 1</b>	<b>OY 2</b>
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>

**Note:** Tables may not foot due to rounding.  
 \*Rounded down to the whole patient.

The applicant provides the assumptions and methodology for the projections above on pages 15-18. The applicant adequately identifies the population it proposes to serve.

**Analysis of Need**

In Section C.2, page 18, the applicant states the need for the proposed project is based on the need for regular and consistent dialysis treatment for patients with end stage renal disease. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference. See also Section B.2, page 7.

**Projected Utilization**

In Section C.1, page 15, the applicant provides projected utilization during the first two years of operation following project completion, as illustrated in the table below:

<b>BMA Lenoir 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>IC</b>	<b>HH</b>	<b>PD</b>	<b>IC</b>	<b>HH</b>	<b>PD</b>	<b>OY 1</b>	<b>OY 2</b>
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>

**Note:** Tables may not foot due to rounding.  
 \*Rounded down to the whole patient.

In Section C.1, pages 15-18, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below:

- The applicant assumes 38 in-center patients currently receiving treatment at BMA Lenoir will transfer to FKC Caldwell County, which was conditionally approved for development on October 27, 2017. The proposed facility will have 14 stations relocated from BMA Lenoir and is proposed to be certified as of December 31, 2018.

- The applicant assumes that the patient population currently receiving treatment at BMA Lenoir and who currently reside in Caldwell County will increase at a rate of 5.2 percent, which is the Five Year Average Annual Change Rate (AACR) for Caldwell County published in the July 2017 SDR, whether they transfer to FKC Caldwell County or not.
- The applicant assumes no increase for the patients who utilize the facility and live outside of Caldwell County, but assumes that those patients will continue to dialyze at BMA Lenoir and are added to the calculations when appropriate.
- The applicant assumes that the single patient from another state who was receiving treatment at BMA Lenoir as of June 30, 2017 was a transient patient who will not be counted in future projections.
- The project is scheduled for completion on December 31, 2018. OY1 is CY 2019. OY2 is CY 2020.

In Section C.1, page 16, the applicant provides the calculations used to arrive at the projected in-center patient census for OY1 and OY2 as summarized in the table below.

<b>BMA Lenoir</b>	<b>In-Center Dialysis</b>
Starting point of calculations is Caldwell County patients dialyzing at BMA Lenoir on June 30, 2017.	110
Caldwell County patient population is projected forward by six months to December 31, 2017. Projection is based on one-half of the AACR for Caldwell County (5.2%).	$110 \times 1.026 = 112.9$
Caldwell County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (5.2%).	$112.9 \times 1.052 = 118.7$
The 38 patients projected to transfer to FKC Caldwell County as part of Project I.D. #E-11376-17 are subtracted.	$118.7 - 38 = 80.7$
The five patients from other counties are added. This is the projected census on December 31, 2018 and the starting census for this project.	$80.7 + 5 = 85.7$
Caldwell County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (5.2%).	$80.7 \times 1.052 = 84.9$
The five patients from other counties are added. This is the projected census on December 31, 2019 (OY1).	$84.9 + 5 = 89.9$
Caldwell County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (5.2%).	$84.9 \times 1.052 = 89.3$
The five patients from other counties are added. This is the projected census on December 31, 2020 (OY2).	$89.3 + 5 = 94.3$

The applicant projects to serve 89 in-center patients on 27 stations, which is 3.3 patients per station per week ( $89 \text{ patients} / 27 \text{ stations} = 3.3$ ), by the end of OY1 and 94 in-center patients on 27 stations, which is 3.48 patients per station per week ( $94 \text{ patients} / 27 \text{ stations} = 3.48$ ), by the end of OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). The July 2017 SDR states that BMA Lenoir's utilization was 3.29 patients per station per week (a utilization rate of 82.35 percent) as of December 31, 2016. In this application, the applicant projects the Caldwell

County in-center patient census will increase annually by 5.2 percent, which is the Caldwell County AACR published in the July 2017 SDR.

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. Therefore, the applicant adequately demonstrates the need to add 7 dialysis stations to its existing facility for a total of 27 dialysis stations upon project completion and the completion of associated projects.

Home Hemodialysis and Peritoneal Dialysis

In Section C.1, page 17, the applicant states that it expects its Caldwell County home peritoneal dialysis patient census will continue to increase annually at a rate of 5.2 percent, which is the Caldwell County AACR published in the July 2017 SDR, and that patients from other counties will continue to be added to the utilization calculations, though no growth will be projected for patients residing outside of Caldwell County. On page 17, the applicant provides the calculations used to arrive at the projected home peritoneal dialysis patient census for OY1 and OY2 as summarized in the table below.

<b>BMA Lenoir</b>	<b>Home PD Dialysis</b>
Starting point of calculations is Caldwell County home PD patients dialyzing at BMA Lenoir on June 30, 2017.	10
Caldwell County patient population is projected forward by six months to December 31, 2017. Projection is based on one-half of the AACR for Caldwell County (5.2%).	$10 \times 1.026 = 10.3$
Caldwell County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (5.2%).	$10.3 \times 1.052 = 10.8$
The one patient from Wilkes County is added. This is the projected census on December 31, 2018 and the starting census for this project.	$10.8 + 1 = 11.8$
Caldwell County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (5.2%).	$10.8 \times 1.052 = 11.4$
The one patient from Wilkes County is added. This is the projected census on December 31, 2019 (OY1).	$11.4 + 1 = 12.4$
Caldwell County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (5.2%).	$11.4 \times 1.052 = 11.9$
The one patient from Wilkes County is added. This is the projected census on December 31, 2020 (OY2).	$11.9 + 1 = 12.9$

In Section C.1, page 17, the applicant states that it expects its Caldwell County home hemodialysis patient census will continue to increase annually at a rate of 5.2 percent, which is the Caldwell County AACR published in the July 2017 SDR. On page 18, the applicant provides the calculations used to arrive at the projected home hemodialysis patient census for OY1 and OY2 as summarized in the table below.

<b>BMA Lenoir</b>	<b>Home Hemodialysis</b>
Starting point of calculations is Caldwell County home hemodialysis patients dialyzing at BMA Lenoir on June 30, 2017.	3
Caldwell County patient population is projected forward by six months to December 31, 2017. Projection is based on one-half of the AACR for Caldwell County (5.2%).	$3 \times 1.026 = 3.1$
Caldwell County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (5.2%).	$3.1 \times 1.052 = 3.2$
Caldwell County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (5.2%). This is the projected census on December 31, 2019 (OY1).	$3.2 \times 1.052 = 3.4$
Caldwell County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (5.2%). This is the projected census on December 31, 2020 (OY2).	$3.4 \times 1.052 = 3.6$

**Access**

In Section L.1, page 52, the applicant states that each of BMA’s 109 facilities in 48 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons.

The applicant projects that 86.11 percent of the dialysis patients at BMA Lenoir will have some or all of their services paid for by Medicare and/or Medicaid in CY 2020. The applicant states its projected payor mix is based on the facility payor mix on June 30, 2017. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

**Conclusion**

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses historical data that is clearly cited and is reasonable to use to make the assumptions used by the applicant with regard to identifying the population to be served and with regard to demonstrating the need the population projected to be served has for the proposed services.
- The applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need the population projected to be served has for the proposed services.
- The applicant uses historical data to project future access to the services it provides for all residents, including underserved groups.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- 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.

- (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 does not propose to reduce or eliminate a service or relocate a facility or service. Therefore, 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

In Section E, page 25, the applicant describes the alternatives it considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo – The applicant states that maintaining the status quo is not an effective alternative because utilization at BMA Lenoir will end up exceeding 100 percent.
- Apply for Fewer Stations - The applicant states this is not an effective alternative because the applicant projects that utilization will exceed 80 percent at the end of the first operating year even with adding seven stations.

After considering the above alternatives, the applicant states the proposed project represented in the application is the most effective alternative to meet the identified need for seven additional stations at BMA Lenoir.

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

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses reasonable and adequately supported assumptions to project utilization.
- The data cited is reasonable to use to support the assumptions of the applicant with regard to the least costly or most effective alternative for development of the proposed project.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- 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 and is approved subject to the following conditions.

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to the facility need determination in the July 2017 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than 7 additional dialysis stations for a total of no more than 27 certified stations at BMA Lenoir upon completion of this project, Project I.D. #E-11376-17 (relocate 14 stations to develop the new FKC Caldwell County), and Project I.D. #E-11377-17 (relocate the remaining 20 stations), which shall include any home hemodialysis training or isolation stations.**
  - 3. Bio-Medical Applications of North Carolina, Inc. shall install plumbing and electrical wiring through the walls for no more than seven dialysis stations which shall include any isolation stations.**
  - 4. Bio-Medical Applications of North Carolina, Inc. 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 to add 7 dialysis stations to the existing facility for a total of 27 stations upon completion of this project, Project I.D. #E-11376-17 (relocate 14 stations to develop the new FKC Caldwell County), and Project I.D. #E-11377-17 (relocate the remaining 20 stations).

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

In Section F.1, pages 26-27, the applicant projects the capital cost for the proposed project will be \$26,250, used for water treatment equipment and furniture. The dialysis machines will be leased. In Sections F.10 and F.11, page 30, 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.

### **Availability of Funds**

In Section F.2, page 28, the applicant states it will finance the capital costs and working capital costs with accumulated reserves. Exhibit F-1 contains a letter dated September 15, 2017 from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., authorizing and committing \$26,250 in capital costs for the project.

Exhibit F-2 contains a copy of Fresenius Medical Care Holdings, Inc. and Subsidiaries (FMC) Consolidated Financial Statements for the years ending December 31, 2016 and 2015. These statements indicate that as of December 31, 2016, FMC had \$357,899,000 in cash and cash equivalents, \$20,135,661,000 in total assets and \$10,533,297,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

### **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>BMA Lenoir</b>	<b>Operating Year 1 CY 2019</b>	<b>Operating Year 2 CY 2020</b>
Total Treatments	12,893	13,634
Total Gross Revenues (Charges)	\$58,137,182	\$62,712,027
Total Net Revenue	\$5,667,059	\$6,234,874
Total Operating Expenses (Costs)	\$4,150,969	\$4,344,842
<b>Net Income/Profit</b>	<b>\$1,516,090</b>	<b>\$1,890,032</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 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.

### **Conclusion**

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses reasonable and adequately supported assumptions to project utilization.
- Historical data is used to provide future projections of costs and charges and demonstrate financial feasibility of the project.
- Documentation of sufficient funding for the capital needs of the project is provided and is credible.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- 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.

- (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 to add 7 dialysis stations to the existing facility for a total of 27 stations upon completion of this project, Project I.D. #E-11376-17 (relocate 14 stations to develop the new FKC Caldwell County), and Project I.D. #E-11377-17 (relocate the remaining 20 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 North Carolina counties is a separate dialysis station planning area.*” Thus, the service area for this facility is Caldwell County. Facilities may also serve residents of counties not included in their service area.

BMA Lenoir is the only existing dialysis center in Caldwell County. In Project I.D. #E-11376-17, the applicant was approved to develop FKC Caldwell County by transferring 14 stations from BMA Lenoir and that facility is projected to be operational in late 2018. There are no other providers of dialysis services in Caldwell County. According to the July 2017 SDR, the applicant was serving 112 patients on 34 existing certified stations. Based on that data, the applicant demonstrates that as of December 31, 2016, the facility was operating at 82.35 percent of capacity or 3.29 patients per station per week ( $112 \text{ patients} / 34 \text{ stations} = 3.29 / 4 = .8235$  or 82.35%).

In Section C.1, pages 15-16, the applicant demonstrates that BMA Lenoir will serve a total of 89 in-center patients at the end of Operating Year One (CY 2019) for a utilization rate of 82.5 percent or 3.3 patients per station per week ( $89 \text{ patients} / 27 \text{ stations} = 3.3 / 4 = .825$  or 82.5%). The projected utilization of 3.3 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates the need to add seven additional stations to BMA Lenoir based on the number of in-center patients it proposes to serve. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need for the proposed services.
- The applicant provides adequate documentation that the proposed services will not result in the unnecessary duplication of existing or approved health service capabilities or facilities.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- 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.

- (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 38, the applicant provides the following table to illustrate projected staffing in full time equivalents (FTEs) for BMA Lenoir in OY2. The applicant does not propose to add additional FTEs when the stations are added. The applicant states the Medical Director is not directly employed by the facility, and thus is not reflected on the staffing chart.

<b>BMA Lenoir – Proposed Facility Staffing</b>	
<b>Position</b>	<b>Projected # of FTEs</b>
Registered Nurse	5.50
Home Training Nurse	1.33
Patient Care Technician	12.75
Dietitian	1.00
Social Worker	1.00
Clinical Manager	1.00
Administration	0.20
In-Service	0.25
Clerical	1.00
Chief Tech	0.10
Equipment Tech	1.00
<b>Total</b>	<b>25.13</b>

In Section H.7, page 41, 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>
Registered Nurse	5.50	2,080	11,440	3,744	3.06
Home Training Nurse	1.33	2,080	2,766.4	3,744	0.74
Patient Care Technician	12.75	2,080	26,520	3,744	7.08
<b>Total</b>	<b>19.58</b>	<b>2,080</b>	<b>40,726.4</b>	<b>3,744</b>	<b>10.88</b>

In Section H.6, page 43, the applicant states dialysis services will be available from 5:00 AM to 5:00 PM, Monday through Saturday, for a total of 12 hours per day / 72 hours per week.

In Section I.3, page 43, the applicant identifies Dr. Robert Qualheim 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. Qualheim supporting the project and confirming his commitment to continue to serve as Medical Director. In Section H.3, page 39, the applicant describes the methods used to recruit and fill positions at the facility.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides appropriate documentation of the availability of adequate health manpower and management personnel for the provision of the proposed dialysis services.
- The applicant provides appropriate and credible documentation of support from the current and continuing Medical Director of Carolina Dialysis.
- The applicant provides appropriate and credible documentation of the availability of other resources, including methods of recruitment and documentation of staff training, necessary for the provision of the proposed dialysis services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- 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.

- (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 42, the applicant identifies the necessary ancillary and support services that serve BMA Lenoir. 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 43-44. Exhibits I-2 through I-4, respectively, contain copies of agreements for lab services, acute care services, and transplantation services.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides appropriate and credible documentation of the availability of necessary ancillary and support services for the provision of the proposed dialysis services.
- The applicant provides credible documentation of ongoing coordination with the existing health care system.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- 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.

- (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, pages 55-56, the applicant reports that 86.7 percent of the patients who received treatments at BMA Lenoir had some or all of their services paid for by Medicare or Medicaid in CY 2016. The historical payor mix for patients dialyzing at BMA Lenoir is shown in the table below.

<b>BMA Lenoir Historical Payor Mix CY 2016</b>	
<b>Payment Source</b>	<b>% Total Patients</b>
Self-Pay/Indigent/Charity	-0.29%
Medicare	68.47%
Medicaid	3.82%
Commercial Insurance	6.51%
Medicare/Commercial	14.41%
Misc. (including VA)	7.08%
<b>Total</b>	<b>100.00%</b>



In Section L.7, page 56, the applicant states the negative amount listed as self-pay/indigent/charity in the table 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**
Caldwell	19%	51%	12%	16%	14%	15%
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).

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant’s historical payor mix is adequate documentation that it currently provides services to medically underserved populations.
- The applicant’s historical payor mix is adequate documentation of the extent to which medically underserved populations utilize the applicant’s existing services.

This determination is based on a review of the:

<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)

- Information in the application, including any exhibits.
- 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.

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

C

In Section L.3(d), page 54, the applicant states that it has no obligation to provide uncompensated care or community service under federal regulations. In Section L.6, page 55, the applicant states there have been no civil rights access complaints filed within the last five years.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides credible information about its lack of obligation to provide any uncompensated care or community service under any federal regulations.
- The applicant states it has not had any civil rights access complaints filed against it within the last five years.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- 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.

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

C

In Section L.1(a), page 52, the applicant states: *"It is 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 53, the applicant projects that 86.11 percent of all patients in CY 2020 who will receive dialysis treatments at BMA Lenoir will have all or part of their services paid for by Medicare and/or Medicaid, as shown in the table below.

<b>BMA Lenoir Projected Payor Mix CY 2020</b>				
<b>Payment Source</b>	<b>% Total Patients</b>	<b>% IC Patients</b>	<b>% HH Patients</b>	<b>% PD Patients</b>
Self-Pay/Indigent/Charity	0.08%	0.08%	0.00%	0.00%
Medicare	65.58%	65.58%	80.67%	80.67%
Medicaid	4.90%	4.90%	0.00%	0.00%
Commercial Insurance	5.60%	5.60%	19.33%	19.33%
Medicare/Commercial	15.63%	15.63%	0.00%	0.00%
Misc. (including VA)	8.21%	8.21%	0.00%	0.00%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>

**Note:** Totals may not foot due to rounding.

On page 56, the applicant states that reporting does not split out the difference between home hemodialysis and home peritoneal dialysis patients. The applicant states on page 53 that the projected payor mix is the same payor mix that was represented at BMA Lenoir on June 30, 2017.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant’s projected payor mix adequately demonstrates that medically underserved populations will have adequate access to the proposed services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- 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.

- (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 55, the applicant states:

*“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. BMA Lenoir will have an open policy, which means that any Nephrologist may apply to admit patients to 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."*

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant adequately demonstrates that the facility will provide a range of means by which a person can access the services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- 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.

- (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 57, the applicant states, *"The applicant has communicated with the local student nursing programs encouraging those programs to utilize the resources of the BMA Lenoir facility to enhance the educational opportunities for the nursing student."* In Exhibit M-1, the applicant provides a copy of a letter to Caldwell Community College & Technical Institute inviting the nursing students to include BMA Lenoir in their clinical rotations.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant adequately documents that the proposed health services will accommodate the clinical needs of health professional training programs in the area.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- 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.

- (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 to add 7 dialysis stations to the existing facility for a total of 27 stations upon completion of this project, Project I.D. #E-11376-17 (relocate 14 stations to develop the new FKC Caldwell County), and Project I.D. #E-11377-17 (relocate the remaining 20 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 North Carolina counties is a separate dialysis station planning area.*” Thus, the service area for this facility is Caldwell County. Facilities may also serve residents of counties not included in their service area.

BMA Lenoir is the only existing dialysis center in Caldwell County. In Project I.D. #E-11376-17, the applicant was approved to develop FKC Caldwell County by transferring 14 stations from BMA Lenoir and that facility is projected to be operational in late 2018. There are no other providers of dialysis services in Caldwell County. According to the July 2017 SDR, the applicant was serving 112 patients on 34 existing certified stations. Based on that data, the applicant demonstrates that as of December 31, 2016, the facility was operating at 82.35 percent of capacity or 3.29 patients per station per week ( $112 \text{ patients} / 34 \text{ stations} = 3.29 / 4 = .8235$  or 82.35%).

In Section C.1, pages 15-16, the applicant demonstrates that BMA Lenoir will serve a total of 89 in-center patients at the end of Operating Year One (CY 2019) for a utilization rate of 82.5 percent or 3.3 patients per station per week ( $89 \text{ patients} / 27 \text{ stations} = 3.3 / 4 = .825$  or 82.5%). The projected utilization of 3.3 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b).

In Section N, page 58, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicant states:

*“The applicant does not expect this proposal to have effect on the competitive climate in Caldwell County. The applicant does not project to serve dialysis patients currently being served by another provider, The projected patient population for the BMA Lenoir facility begins with patients currently served by BMA, and a growth of that patient population consistent with the Caldwell County five year average annual change rate of 5.2% as published within the July 2017 SDR.”*

See also Sections B, C, E, F, G, H, and L where the applicant discusses the impact of the project on cost-effectiveness, quality, and access.

The applicant discusses how any enhanced competition in the service area, including how the proposed project will have a positive impact on cost-effectiveness, quality, and access to the proposed services in Section N, page 58. The information in the application is reasonable and adequately supported for the following reasons:

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative.
- The applicant adequately demonstrates that BMA Lenoir will continue to provide quality dialysis services.
- The applicant demonstrates that BMA Lenoir will continue to provide adequate access to medically underserved populations.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- 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.

- (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 B.4, page 9, Section O, pages 59-61, and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality in its dialysis facilities.

Fresenius Medical Care, the parent company of BMA, owns, operates, and/or is affiliated with 109 facilities in North Carolina as of September 15, 2017. In Section O and referenced exhibits, the applicant identifies the kidney disease treatment centers 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. The applicant states that two facilities, RAI West College and BMA East Rocky Mount, received Immediate Jeopardy citations within the 18 month look-back period, but states that both facilities are back in compliance and provides corresponding documentation in Exhibits O-3 and O-4. 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 information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides adequate and credible documentation of its current policies with regard to providing quality care.
- The applicant provides accurate information regarding past deficiencies and how those deficiencies were addressed.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- 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.

(21) Repealed effective July 1, 1987.

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

## C

The application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific criteria are discussed below.

### **10A 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- BMA Lenoir 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.*

-C- In Section C.1, pages 15-18, the applicant documents the need for the project and demonstrates that it will serve a total of 89 in-center patients on 27 stations at the end

of the first operating year, which is 3.3 patients per station per week or a utilization rate of 82.5 percent. The discussion regarding analysis of need 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, pages 15-18, 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.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides adequate and credible documentation that it meets the performance standard required by this Rule.
- The applicant provides all documentation of its assumptions and methodology required by this Rule.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- 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.