

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: December 17, 2014

PROJECT ANALYST: Julie Halatek  
INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: E-10332-14 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Catawba Valley / Add two dialysis stations to existing facility for a total of 25 stations upon project completion / Catawba County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC Catawba Valley (FMC Catawba), whose parent company is Fresenius Medical Care Holdings Inc., (FMC), proposes to add two dialysis stations to its existing facility for a total of 25 certified dialysis stations upon project completion.

#### **Need Determination**

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and facility need methodology for determining the need for new dialysis stations. According to *Table B: Dialysis Station Need Determination by County, in the July 2014 Semiannual Dialysis Report (SDR)*, there is a surplus of two dialysis stations in Catawba County. However, the applicant is eligible to apply for additional stations in its existing facility based on the application of the facility need methodology, because the utilization rate reported for FMC Catawba in the July 2014 SDR is 3.3043 patients per station, or 82.6%. This utilization rate was calculated based on 76 in-center dialysis patients and 23 certified dialysis stations (76 patients / 23 stations = 3.3043 patients per station;  $3.3043 / 4 = 0.826$ ).

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

**OCTOBER 1 REVIEW - JULY SDR**

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/13		82.6%
Certified Stations		23
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>23</b>
In-Center Patients as of 12/31/13 (SDR2)		76
In-Center Patients as of 6/30/13 (SDR1)		70
Step	Description	
(i)	Difference (SDR2 - SDR1)	6
	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/13	0.1714
(ii)	Divide the result of Step (i) by 12	0.0143
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/12 until 12/31/13)	0.1714
(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	89.0286
(v)	Divide the result of Step (iv) by 3.2 patients per station	27.8214
	and subtract the number of certified and pending stations as recorded in SDR2 [23] to determine the number of stations needed	5

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at FMC Catawba is five stations. Step 2(C) of the facility need methodology states: “*The facility may apply to expand to meet the need established in (2)(B)(v), up to a maximum of ten stations.*” The applicant proposes to add two new stations and, therefore, is consistent with the facility need determination for dialysis stations.

**Policies**

Policy GEN-3: Basic Principles in the 2014 State Medical Facilities Plan is applicable to this review and is discussed below.

**Policy GEN-3: Basic Principles**

This policy 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 I.13, pages 4-8; Section II.1, pages 12 and 17-19; Sections II.2 and II.3, pages 22-28; Sections VII.3 and VII.5, page 47; Section XI.6(g), page 67, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section II.1, pages 14 and 19-21; Section VI, pages 41-45; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section I.3, page 5; Section II.1, page 20; Section III.9, page 33; Section V.7, pages 39-40; Section XI.6(d), pages 65-66; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access, and maximum value for resources expended in meeting the need identified in the July 2014 SDR and the 2014 SMFP. Therefore, the application is consistent with Policy GEN-3.

### **Conclusion**

In summary, the applicant adequately demonstrates that its proposal to develop two dialysis stations is consistent with the facility need determination in the July 2014 SDR and Policy GEN-3. Therefore, 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

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC Catawba Valley (FMC Catawba), whose parent company is Fresenius Medical Care Holdings Inc., (FMC), proposes

to add two dialysis stations to its existing facility for a total of 25 certified dialysis stations upon project completion.

**Population to be Served**

In Section III.7, page 31, the applicant identifies the population currently served at FMC Catawba, as shown below:

<b>Patient Origin – FMC Catawba (as of 6/30/14)</b>		
<b>County of Residence</b>	<b># In-Center Pts.</b>	<b>% of Total</b>
Catawba	73	96.1%
Alexander	2	2.6%
Lincoln	1	1.3%
<b>Total</b>	<b>76</b>	<b>100.0%</b>

In Section III.7, page 31, the applicant also provides a table to illustrate the population to be served following the addition of two dialysis stations, as shown below:

<b>Projected Patient Origin – FMC Catawba – Operating Years One and Two</b>				
<b>County</b>	<b>Operating Year 1</b>	<b>Operating Year 2</b>	<b>County Patients as % of Total</b>	
	<b>In-Center</b>	<b>In-Center</b>	<b>Year 1</b>	<b>Year 2</b>
Catawba	81.5	85.2	96.4%	96.6%
Alexander	2.0	2.0	2.4%	2.3%
Lincoln	1.0	1.0	1.2%	1.1%
<b>Total</b>	<b>84.5</b>	<b>88.2</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant adequately identifies the population it proposes to serve.

**Analysis of Need**

The applicant states that need for the proposed expansion is based on the following factors:

- Utilization at FMC Catawba is at 82.61 percent as of the publication of the July 2014 SDR, which contains data from December 31, 2013. See Table A in the July 2014 SDR and pages 29-30 of the application.
- Utilization at BMA Hickory, the only other dialysis facility in Catawba County, is at 89.39 percent as of the publication of the July 2014 SDR, which contains data from December 31, 2013. See Table A in the July 2014 SDR and page 33 of the application.
- Using the facility need methodology provided in the July 2014 SDR [found in the table under the “Facility Need Methodology” heading under Criterion (1)], the applicant qualifies to add up to five additional dialysis stations to FMC Catawba. See page 29 of the application.

- The applicant’s projections state that FMC Catawba will have 84 in-center patients with 25 stations and 84 percent utilization at the end of Operating Year One (ending December 31, 2016). See pages 30-31 and 33 of the application.

*Projected Utilization*

The applicant provides information on the historical and projected utilization of FMC Catawba, as shown in the table below:

<b>Historical &amp; Projected Utilization – FMC Catawba – Operating Years One &amp; Two*</b>						
County	12/31/2013	OY 1	OY 2	County Patients as a % of Total		
	In-Center	In-Center	In-Center	12/31/2013	OY 1	OY 2
Catawba	73	81.5	85.2	96.1%	96.4%	96.6%
Alexander	2	2	2	2.6%	2.4%	2.3%
Lincoln	1	1	1	1.3%	1.2%	1.1%
<b>Total**</b>	<b>76</b>	<b>84.5</b>	<b>88.2</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>
Utilization %	82.61%	84.00%	88.00%			
Patients per Station	3.30	3.36	3.52			

\*According to the applicant, Operating Year One = January 1, 2016 – December 31, 2016; Operating Year Two = January 1, 2017 – December 31, 2017.

\*\*The applicant stated that it rounded down its projected patient count to the nearest number when calculating utilization projections; the Project Analyst did the same.

As shown in the table above, at the end of Operating Year 1, the applicant projects to serve 84 in-center dialysis patients on 25 certified dialysis stations, or 3.36 patients per station per week, which is a utilization rate of 84 percent [ $84 / 25 = 3.36$ ;  $3.36 / 4 = 0.84$ ]. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

*Assumptions and Methodology Used*

The applicant used the facility need methodology to determine that it could apply for up to five additional stations. See the table under the “Facility Need Methodology” heading in Criterion (1). The applicant states that it chose to apply for two stations.

In Section III.7, pages 30-32, the applicant states that it used the following assumptions:

- Operating Year One = January 1, 2016 through December 31, 2016
- Operating Year Two = January 1, 2017 through December 31, 2017
- The Catawba County patient population currently dialyzing at FMC Catawba will increase at the 4.5 percent five year average annual change rate (AACR) published in the July 2014 SDR.
- No change in the number of Alexander and Lincoln County patients is projected.

- The Alexander and Lincoln County patient population currently dialyzing at FMC Catawba do so by choice and will continue to dialyze at FMC Catawba after development of the project.

The applicant states that it then applied the assumptions to the stated methodology, as shown in the table below:

<b>FMC Catawba County – In-Center Patient Projections</b>	
Catawba County patient population at FMC Catawba – 6/30/2014	73
Use one-half of AACR to project Catawba County patient population – 12/31/2014 (six months)	$0.045 / 12 = 0.00375$ ; $0.00375 \times 6 = 0.0225$ $73 \times 0.0225 = 1.6$ ; $73 + 1.6 = 74.6$
Project Catawba County population using AACR – forward one year – 12/31/2015	$74.6 \times 0.045 = 3.4$ ; $74.6 + 3.4 = 78$
Add three patients – Alexander & Lincoln counties Beginning census – 12/31/2015	$78 + 3 = 81$
Project Catawba County population using AACR – forward one year – 12/31/2016	$78 \times 0.045 = 3.5$ ; $78 + 3.5 = 81.5$
Add three patients – Alexander & Lincoln counties Ending census – 12/31/2016 (Operating Year One)	$81.5 + 3 = 84.5$
Project Catawba County population using AACR – forward one year – 12/31/2017	$81.5 \times 0.045 = 3.7$ ; $81.5 + 3.7 = 85.2$
Add three patients – Alexander & Lincoln counties Ending census – 12/31/2017 (Operating Year Two)	$85.2 + 3 = 88.2$

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth at FMC Catawba. The applicant adequately demonstrates the need that this population has for the services proposed.

**Access to Services**

In Sections VI.1(b) and VI.1(c), page 42, the applicant provides the current and projected payor mix for the proposed services at FMC Catawba, as shown in the table below. The applicant projects no change from the current payor mix upon project completion:

<b>FMC Catawba Current / Projected Payor Mix</b>	
<b>Payor Source</b>	<b>In-Center</b>
Commercial Insurance	4.68%
Medicare	81.70%
Medicaid	4.94%
VA	0.97%
Medicare / Commercial	7.72%
Total	100.00%

The applicant adequately demonstrates 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 proposed services.

## **Conclusion**

In summary, the applicant adequately:

- Identifies the population it proposes to serve.
- Demonstrates the need that this population has for the services proposed.
- Demonstrates 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 proposed services.

Consequently, 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

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

CA

In Section III.9, page 33, the applicant identified the alternatives considered and the reasons the applicant concluded they were not the most effective alternative, as described below:

1. Not Apply for Stations – the applicant states this option is not an effective alternative because it would not resolve the need for additional stations at FMC Catawba, where the facility need methodology has determined it qualifies for up to five additional stations.
2. Apply for Fewer Stations – the applicant states this option is not an effective alternative because even with the two-station addition, FMC Catawba is projected to exceed 80 percent utilization by the end of the first operating year.
3. Relocate Stations from its BMA Hickory Facility – the applicant states this option is not an effective alternative because both facilities are already exceeding the 80 percent utilization threshold. The applicant states that transferring stations to FMC Catawba would increase the existing high utilization rate at BMA Hickory.

4. Add Two Stations – the applicant states this option is the most effective alternative because it is the least costly alternative that will also meet the needs of the patients currently at and projected to be served at FMC Catawba.

The applicant adequately demonstrates the need for two additional stations based on the number of in-center patients it projects to serve. The discussion regarding need and projected utilization found in Criterion (3) is incorporated herein by reference.

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

The applicant adequately demonstrates that the proposal to add two dialysis stations is its least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Catawba Valley shall materially comply with all representations made in the certificate of need application.**
  2. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Catawba Valley shall develop and operate no more than two additional stations for a total of no more than 25 certified stations following completion of this project.**
  3. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Catawba Valley shall install plumbing and electrical wiring through the walls for no more than two additional stations for a total of no more than 25 stations, which shall include any home hemodialysis or isolation stations.**
  4. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Catawba Valley shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section 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

In Sections VIII.1(b) and VIII.1(c), pages 49-50, the applicant projects the capital cost for FMC Catawba will be \$6,000, which includes \$500 for ancillary water equipment; \$2,500 for patient chairs; and \$3,000 for patient TVs. In Section IX, page 53, the applicant projects no working capital (start-up and initial operating expenses) associated with the proposed project, since FMC Catawba is currently operational.

In Section VIII.2, page 50, and Section VIII.5, page 51, the applicant states the entire capital cost of the project will be funded with accumulated reserves of Fresenius Medical Care Holdings, Inc. (FMC Holdings). Exhibit 24 contains a letter dated September 15, 2014, signed by the Vice President of FMC Holdings, which states that FMC Holdings is authorizing the use of \$6,000 from cash reserves to add two stations to FMC Catawba.

In Exhibit 4, the applicant provides the audited financial statements for FMC Holdings for the fiscal years that ended on December 31, 2013 and December 31, 2012. As of December 31, 2013, FMC Holdings had \$275,719,000 in cash and cash equivalents, \$16,597,314,000 in total assets, and \$8,521,824,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the project.

In Section X.1, pages 54-55, the applicant provides the allowable charges per treatment for each payment source for FMC Catawba as follows:

<b>FMC Catawba</b>	
<b>Payment Source</b>	<b>Allowable Charge Per In-Center Treatment</b>
Private Pay	\$1,425.00
Commercial Insurance	\$1,425.00
Medicare	\$239.00
Medicaid	\$140.23
VA	\$231.12
Medicare/Medicaid	\$239.00
Medicare/Commercial	\$239.00
State Kidney Program	\$100.00
Other: Self/Indigent	\$1,425.00

The applicant states that the commercial charges listed does not reflect actual reimbursement, due to industry standard contracts. In addition, the applicant states that Medicare began a “bundling” reimbursement program in 2010. “Bundling” refers to lumping all charges for a treatment together instead of paying each ancillary charge separately. The applicant states that while Medicare will provide additional reimbursement for certain co-morbid conditions, the average reimbursement per treatment has been \$240.

On page 55, the applicant states:

*“In November 2013, Medicare announced further cuts to reimbursement for dialysis treatment. These cuts amount to a 12% reduction in revenues and will be phased in over several years. The following table demonstrates the projected Medicare reimbursement by calendar year. BMA will use these rates within the application and its projections of revenues.”*

The applicant provides a table on page 55, referenced above, that shows the following information:

<b>Anticipated Medicare Reimbursement by Year</b>	
<b>Year</b>	<b>Medicare Rate</b>
2014	\$239.02
2015	\$239.02
2016	\$229.46
2017	\$220.28
2018	\$211.47
2019	\$211.47

In Section X.4, pages 60-61, the applicant projects revenues and expenses for FMC Catawba as follows:

<b>FMC Catawba</b>		
	<b>Operating Year 1</b>	<b>Operating Year 2</b>
Total Net Revenue	\$3,547,161	\$3,627,825
Total Expenses	\$3,081,058	\$3,169,359
<b>Net Profit</b>	<b>\$466,103</b>	<b>\$458,466</b>

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable and adequately supported. See Section X.3, pages 57-59, for the applicant's assumptions regarding revenue calculations.

In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and charges. Therefore, 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

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC Catawba Valley (FMC Catawba), whose parent company is Fresenius Medical Care Holdings Inc., (FMC), proposes to add two dialysis stations to its existing facility for a total of 25 certified dialysis stations upon project completion.

The July 2014 SDR identifies the following dialysis facilities and utilization rates for Catawba County:

<b>Dialysis Facilities – Catawba County – July 2014 SDR</b>				
<b>Facility</b>	<b>Owner</b>	<b>City</b>	<b># of Stations</b>	<b>Utilization %</b>
FMC of Catawba Valley	BMA/FMC	Conover	23	82.61%
FMC of Hickory	BMA/FMC	Hickory	33*	89.39%*

\*At the time the July 2014 SDR data was collected (12/31/2013), FMC of Hickory had 33 certified stations and two stations with CON approval that were not yet developed.

The July 2014 SDR, Table B, shows there is a surplus of two dialysis stations in Catawba County; however, in this application, the applicant is applying for additional stations based on the facility need methodology. The applicant adequately demonstrates the need for two additional stations at FMC Catawba based on the number of in-center patients projected to be served. As reported in the July 2014 SDR, as of December 31, 2013, the 23-station FMC Catawba facility was operating at 82.61 percent capacity, with 76 in-center patients ( $76 / 23 = 3.3043478$ ;  $3.3043478 / 4 = 0.8261$  or 82.61%). The target utilization for dialysis stations, pursuant to 10A NCAC 14C .2203(b), is 80 percent, or 3.2 patients per station per week, as of the end of the first operating year of the facility. Based on the calculations above, the applicant is eligible to expand its facility and may apply for additional stations. Upon completion of the proposed project, the facility will have 25 stations serving up to 84 patients at the end of Operating Year One, which is a utilization rate of 84 percent ( $84 / 25 = 3.36$ ;  $3.36 / 4 = 0.84$  or 84%), which is conforming to the requirement in 10A NCAC 14C .2203(b).

The applicant adequately demonstrates that the proposal would not result in the unnecessary duplication of existing or approved dialysis capabilities or facilities in Catawba County. Consequently, 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 VII.1, page 46, the applicant provides projected staffing for FMC Catawba upon project completion, as illustrated in the following table:

<b>FMC Catawba Full-Time Equivalent (FTE) Positions</b>			
	<b>Current</b>	<b>ADD</b>	<b>Total</b>
RN	3.50	0.50	4.00
Tech	8.65	0.85	9.50
Clinical Manager	1.00	-	1.00
FMC Director of Operations	0.15	-	0.15
Dietician	0.50	-	0.50
Social Worker	0.60	-	0.60
Chief Tech	0.25	-	0.25
Equip Tech	0.75	-	0.75
In-Service	0.20	-	0.20
Clerical	1.00	-	1.00
<b>Total FTEs</b>	<b>16.60</b>	<b>1.35</b>	<b>17.95</b>

The applicant projects a total of 17.95 FTE positions upon project completion. In Section VII.4, page 47, the applicant states it anticipates no difficulty recruiting additional staff for the facility. In Section V.4(b), page 38, the applicant states the current Medical Director for FMC Catawba is Richard Paul, MD. Exhibit 21 contains a letter dated August 19, 2014 and signed by Dr. Paul endorsing the facility expansion and which also indicates his willingness to continue to serve as Medical Director of the facility. The applicant adequately demonstrates the availability of resources, including health manpower and management personnel, for

provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

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

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In Section V.1, page 36, the applicant identifies the providers of the necessary ancillary and support services for FMC Catawba. The applicant provides further detail of the ancillary and support services in Sections V.2 through V.7, pages 37-40, and in Exhibits 19, 21, 22, 25, and 26. The applicant adequately demonstrates that necessary ancillary and support services are available and will continue to be available, and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers: (i) would be available under a contract of at least 5 years duration; (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO; (iii) would cost no more than if the services were provided by the HMO; and (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

C

In Section VI.1, page 41, the applicant provides the patient population of FMC Catawba as shown in the table below:

<b>Facility</b>	<b>Medicaid / Low Income</b>	<b>Elderly (65+)</b>	<b>Medicare</b>	<b>Women</b>	<b>Racial Minorities</b>
FMC Catawba	2.6%	40.8%	81.6%	39.5%	22.7%

On page 41, the applicant states:

*“Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 65% [sic] of the facility treatment reimbursement is from Medicare.”*

In Section VI.1(b), page 42, the applicant provides the current payor mix for FMC Catawba, as illustrated in the following table.

<b>FMC Catawba Current Payor Mix</b>	
<b>Payor Source</b>	<b>In-Center</b>
Commercial Insurance	4.68%
Medicare	81.70%
Medicaid	4.94%
VA	0.97%
Medicare / Commercial	7.72%
Total	100.00%

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Catawba County and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Catawba County	16.6%	6.2%	19.1%
Statewide	16.5%	6.7%	19.7%

\*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/31/2013, page 99*).<sup>1</sup>

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race, or gender. However, a direct comparison to the applicant’s current payor mix would be of little value. The population data by age, race, or gender do not include information on the number of elderly, minorities, women, or handicapped persons utilizing health services.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ....”*<sup>2</sup> (p. 216)

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender, and race, which show that 65.4% were white, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p.218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states:

*“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.”* (p. 216).

The *2013 USRDS Annual Data Report* provides 2011 ESRD spending by payor, as follows:

<sup>1</sup><http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%20%20Annual%20Report.pdf>

<sup>2</sup> [www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

<b>ESRD Spending by Payor</b>		
<b>Payor</b>	<b>Spending in Billions</b>	<b>% of Total Spending</b>
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
<b>Total</b>	<b>\$49.2</b>	<b>100.0%</b>

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race, and gender on page 101, summarized as follows:

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2013</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
<b>Gender</b>		
Female	6,845	44.5%
Male	8,544	55.5%
<b>Race</b>		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.<sup>3</sup>

The applicant demonstrates that medically underserved populations have adequate access to the services provided at FMC Catawba. Therefore, the application is conforming to this criterion.

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

C

<sup>3</sup><http://www.esrdnetwork6.org/utlils/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

In Section VI.6(a), pages 44-45, the applicant states there have been no civil rights access complaints filed against any North Carolina BMA facilities in the last five years. Therefore, 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 VI.1(c), page 42, the applicant provides the projected payor mix for the proposed services at FMC Catawba, as shown in the table below. The applicant projects no change from the current payor mix upon project completion.

<b>FMC Catawba Projected Payor Mix</b>	
<b>Payor Source</b>	<b>In-Center</b>
Commercial Insurance	4.68%
Medicare	81.70%
Medicaid	4.94%
VA	0.97%
Medicare / Commercial	7.72%
Total	100.00%

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, 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 VI.5, page 44, 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 Catawba Valley will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”*

The applicant adequately demonstrates that FMC Catawba will offer a range of means by which a person can access its services. Therefore, 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 V.3, pages 37-38, the applicant states:

*“All health related education and training programs are welcomed to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment. This experience enhances the clinical experience of the students enrolled in these programs enabling them to learn about the disease, prognosis and treatment for the patient with end stage renal disease.”*

Exhibit 19 contains a letter dated September 15, 2014 to the Department Head of the School of Health and Public Services at Catawba Valley Community College, inviting the school to include FMC Catawba in its clinical rotation schedule for student nurses.

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

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC Catawba Valley (FMC Catawba), whose parent company is Fresenius Medical Care Holdings Inc., (FMC), proposes to add two dialysis stations to its existing facility for a total of 25 certified dialysis stations upon project completion.

The July 2014 SDR identifies the following dialysis facilities and utilization rates for Catawba County:

<b>Dialysis Facilities – Catawba County – July 2014 SDR</b>				
<b>Facility</b>	<b>Owner</b>	<b>City</b>	<b># of Stations</b>	<b>Utilization %</b>
FMC of Catawba Valley	BMA/FMC	Conover	23	82.61%
FMC of Hickory	BMA/FMC	Hickory	33*	89.39%*

\*At the time the July 2014 SDR data was collected (12/31/2013), FMC of Hickory had 33 certified stations and two stations with CON approval that were not yet developed.

The July 2014 SDR, Table B, shows there is a surplus of two dialysis stations in Catawba County; however, in this application, the applicant is applying for additional stations based on the facility need methodology. The applicant adequately demonstrates the need for two additional stations at FMC Catawba based on the number of in-center patients projected to be served. As reported in the July 2014 SDR, as of December 31, 2013, the 23-station FMC Catawba facility was operating at 82.61 percent capacity, with 76 in-center patients ( $76 / 23 = 3.3043478$ ;  $3.3043478 / 4 = 0.8261$  or 82.61%). The target utilization for dialysis stations, pursuant to 10A NCAC 14C .2203(b), is 80 percent, or 3.2 patients per station per week, as of the end of the first operating year of the facility. Based on the calculations above, the applicant is eligible to expand its facility and may apply for additional stations. Upon completion of the proposed project, the facility will have 25 stations serving up to 84 patients at the end of Operating Year One, which is a utilization rate of 84 percent ( $84 / 25 = 3.36$ ;  $3.36 / 4 = 0.84$  or 84%), which is conforming to the requirement in 10A NCAC 14C .2203(b).

In Section V.7, pages 39-40, 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 that there are no other providers of dialysis in the county. The applicant states its proposal to add two dialysis stations will enhance the quality of life for the ESRD patients. The applicant further states that this facility and others owned by the same company must operate at a maximum dollar efficiency due to fixed reimbursement rates from Medicare and Medicaid.

See also Sections II, III, V, VI, and VII where the applicant discusses the impact of the project on cost-effectiveness, quality, and access.

The applicant adequately demonstrates that any enhanced competition will have a positive impact on the cost-effectiveness, quality, and access to the proposed services based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the proposed services. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need for additional dialysis services. The discussion regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, is incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant adequately demonstrates it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is incorporated herein by reference.

Therefore, 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

The applicant currently provides dialysis services at FMC Catawba. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, FMC Catawba has operated in compliance with all Medicare Conditions of Participation within the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

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

C

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

**10A NCAC 14C .2202      INFORMATION REQUIRED OF APPLICANT**

- (a) *An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:*
  - (1) *Utilization rates;*
    - C- In Section II.1, page 10, the applicant provides the utilization rate of 82.61 percent with 76 patients dialyzing on 23 stations as reported in the July 2014 SDR.
  - (2) *Mortality rates;*

- C- In Section II.1, page 10, the applicant reports the mortality rates were 23.1 percent, 17.9 percent, and 5.8 percent in 2011, 2012, and 2013, respectively.
  - (3) *The number of patients that are home trained and the number of patients on home dialysis;*
  - NA- FMC Catawba does not provide home training or dialysis; eligible patients are referred to the BMA Hickory facility or the planned FMC Hickory Home Program.
  - (4) *The number of transplants performed or referred;*
  - C- In Section II.1, page 10, the applicant states FMC Catawba referred nine transplants in 2012 and nine in 2013. Two transplants were performed in 2012 and two were performed in 2013.
  - (5) *The number of patients currently on the transplant waiting list;*
  - C- In Section II.1, page 10, the applicant states that FMC Catawba currently has four patients on the transplant waiting list.
  - (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
  - C- In Section II.1, page 11, the applicant states that there were 93 hospital admissions in 2013. This appears to be a typo by the applicant and should read 97 since the applicant reports 8 admissions were dialysis related and 89 were non-dialysis related [ $8 + 89 = 97$ ].
  - (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
  - C- In Section II.1, page 11, the applicant states that there were no hepatitis B conversions in 2012 or 2013 and no current patients at the time of the application with an infectious disease.
- (b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*
- (1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*

- NA- FMC Catawba is an existing facility; however, in Exhibit 25, the applicant provides a signed agreement between FMC Catawba and Catawba Memorial Hospital.
  
- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
  - (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
  - (B) *composition of the assessment/evaluation team at the transplant center,*
  - (C) *method for periodic re-evaluation,*
  - (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
  - (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*
  
- NA- FMC Catawba is an existing facility; however, in Exhibit 26, the applicant provides a signed agreement between FMC Catawba and Carolinas Medical Center.
  
- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
  
- NA- FMC Catawba is an existing facility.
  
- (4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
  
- C- In Exhibit 12, the applicant provides the *Emergency Management and Disaster Planning Section* from its *FMS Clinical Services Integrated Policy and Procedure Manual*, which provides procedures for back-up electrical service in the event of a power outage for FMC Catawba.
  
- (5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
  
- NA- FMC Catawba is an existing facility.

- (6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

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

*“BMA will provide all services approved by the Certificate of Need [sic] in conformity with applicable laws and regulations. BMA staffing consistently meets CMS and State guidelines for dialysis staffing. Fire safety equipment, the physical environment, water supply and other relevant health and safety equipment will be appropriately installed and maintained at FMC Catawba Valley.”*

- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- In Section II.1, pages 12 - 13, and Section III.7, pages 30 - 32, the applicant provides the methodology and assumptions to project patient origin as presented in the following table:

<b>Projected Patient Origin – FMC Catawba – Operating Years One and Two</b>				
<b>County</b>	<b>Operating Year 1</b>	<b>Operating Year 2</b>	<b>County Patients as % of Total</b>	
	<b>In-Center</b>	<b>In-Center</b>	<b>Year 1</b>	<b>Year 2</b>
Catawba	81.5	85.2	96.4%	96.6%
Alexander	2.0	2.0	2.4%	2.3%
Lincoln	1.0	1.0	1.2%	1.1%
<b>Total</b>	<b>84.5</b>	<b>88.2</b>	<b>100.0%</b>	<b>100.0%</b>

The discussion regarding patient origin found in Criterion (3) is incorporated herein by reference.

- (8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- FMC Catawba is an existing facility.

- (9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*

-C- In Section II.1, page 14, the applicant states:

*“BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”*

**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- FMC Catawba 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- FMC Catawba projects utilization of 3.36 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 12 - 13, and Section III.7, pages 30-32.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section II.1, pages 12 - 13, and Section III.7, pages 30-32.

**10A NCAC 14C .2204 SCOPE OF SERVICES**

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

(1) *diagnostic and evaluation services;*

-C- In Section II.1, page 16, the applicant states that patients requiring these services will be referred to Catawba Valley Medical Center.

(2) *maintenance dialysis;*

-C- In Section II.1, page 16, the applicant states that the facility will provide in-center dialysis.

(3) *accessible self-care training;*

-C- In Section II.1, page 16, the applicant states that qualified patients will be referred to BMA Hickory.

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

- C- In Section II.1, page 16, the applicant states that qualified patients will be referred to BMA Hickory for home hemodialysis training and the planned FMC Hickory Home Program for peritoneal dialysis.
- (5) *x-ray services;*
- C- In Section II.1, page 16, the applicant states that patients requiring these services will be referred to Catawba Valley Medical Center.
- (6) *laboratory services;*
- C- In Section II.1, page 16, the applicant states that it provides on-site laboratory services through Spectra Labs. Exhibit 15 contains the agreement between FMC Catawba and Spectra Labs.
- (7) *blood bank services;*
- C- In Section II.1, page 16, the applicant states that patients requiring these services will be referred to Catawba Valley Medical Center.
- (8) *emergency care;*
- C- In Section II.1, page 16, the applicant states that staff, who are appropriately trained, will provide emergency care on site until emergency responders arrive, and the facility will call 911 for patients requiring transport to the hospital in an emergency.
- (9) *acute dialysis in an acute care setting;*
- C- In Section II.1, page 16, the applicant states that patients requiring these services will be referred to Catawba Valley Medical Center.
- (10) *vascular surgery for dialysis treatment patients;*
- C- In Section II.1, page 16, the applicant states that patients requiring these services will be referred to Dr. Randall Bast of Horizon Surgical in Lenoir.
- (11) *transplantation services;*
- C- In Section II.1, page 17, the applicant states that it has a transplant agreement with Carolinas Medical Center. Exhibit 26 contains a copy of the transplant agreement between FMC Catawba and Carolinas Medical Center.
- (12) *vocational rehabilitation counseling and services; and*
- C- In Section II.1, page 17, the applicant states that patients requiring these services will be referred to the NC Department of Health and Human Services Vocational Rehabilitation and Independent Living Services.

(13) *transportation.*

- C- In Section II.1, page 22, the applicant states that these services are provided by Greenway Transport, Catawba County DSS, Premier Medical Transportation, or Specialty Support.

**10A NCAC 14C .2205            STAFFING AND STAFF TRAINING**

(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.*

- C- In Section II.1, page 17, the applicant states that sufficient staffing for each shift is provided. In Section VII.2, page 47, the applicant states that all staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*

- C- In Section II.1, page 17, and Sections VII.3 and VII.5, page 47, the applicant describes the training and continuing education required for all FMC Catawba clinical employees. The applicant states that new employees are required to successfully complete a ten-week training program and complete a 90 day probationary period. The applicant further states that training includes dialysis techniques, safety precautions, CPR, and federal regulations. The applicant states that training is continually updated as needed. Exhibit 9 contains an outline of the training program and Exhibit 10 contains an outline of the continuing education program.