

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 27, 2017

Findings Date: March 6, 2017

Project Analyst: Gregory F. Yakaboski

Assistant Chief: Martha J. Frisone

COMPETITIVE REVIEW

Project ID #: E-11234-16

Facility: FMC of Hickory

FID #: 955790

County: Catawba

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

Project: Add six dialysis stations to existing facility for a total of 35 dialysis stations upon completion of this project and Project ID# E-11209-16 (relocate 6 stations to new FKC Newton facility)

Project ID #: E-11238-16

Facility: FMC of Catawba Valley

FID #: 010648

County: Catawba

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

Project: Add four dialysis stations for a total of 23 stations upon completion of this project and Project ID# E-11209-16 (relocate 6 stations to new FKC Newton facility)

Project ID #: E-11261-16

Facility: Catawba County Dialysis

FID #: 160450

County: Catawba

Applicant: Total Renal Care of North Carolina, LLC

Project: Develop a new 10-station dialysis facility

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

FMC Hickory
FMC Catawba Valley
Catawba County Dialysis

Bio-Medical Applications of North Carolina, Inc. (BMA), d/b/a FMC of Hickory (**FMC Hickory**) proposes to add six dialysis stations to the existing facility for a total of 35 dialysis stations upon completion of this project and Project ID# E-11209-16 (relocate 6 stations to new FKC Newton facility).

Bio-Medical Applications of North Carolina, Inc., d/b/a FMC Catawba Valley (**FMC Catawba Valley**) proposes to add four dialysis stations for a total of 23 stations upon completion of this project and Project ID# E-11209-16 (relocate 6 stations to new FMC Newton facility).

Total Renal Care of North Carolina, LLC (TRC) d/b/a Catawba County Dialysis (**Catawba County Dialysis**) proposes to develop a new 10-station dialysis facility.

Need Determination

The 2016 State Medical Facilities Plan (2016 SMFP) and the July 2016 Semiannual Dialysis Report (July 2016 SDR) provide a county need methodology for determining the need for new dialysis stations. According to Section 2(E) of the dialysis station need methodology, found on page 373 of the 2016 SMFP, *“If a county’s December 31, 2016 projected station deficit is 10 or greater and the July SDR shows that utilization of each dialysis facility in the county is 80 percent or greater, the December 31, 2016 county station need determination is the same as the December 31, 2016 projected station deficit.”* The July 2016 SDR shows a projected station deficit in Catawba County of 10 dialysis stations. The projected station deficit resulted in a need determination in the 2016 SMFP for 10 dialysis stations pursuant to the county need methodology. Three applications were received by the Healthcare Planning and Certificate of Need Section (CON Section or Agency) for development of the 10 dialysis stations. The three applicants applied for a total of 20 dialysis stations. Pursuant to the need determination in the 2016 SMFP and the July 2016 SDR, 10 dialysis stations is the limit on the number of dialysis stations that may be approved in this review.

Policies

The following policy is applicable to all three applications in this review:

- **POLICY GEN-3: BASIC PRINCIPLES**

The following policy is applicable only to the application for Catawba County Dialysis:

- **POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES**

POLICY GEN-3: BASIC PRINCIPLES 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.”

FMC Hickory.

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 11, 13-14, Section O, pages 63-68 and referenced exhibits. The information provided by the applicant is reasonable and adequately 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, pages 12-14, Section C, pages 21-22, Section L, pages 54-58 and referenced exhibits. The information provided by the applicant is reasonable and adequately 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, pages 13-14, Section F, pages 31-38, Section N, pages 60-62, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would 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 county need. Therefore, the application is consistent with Policy GEN-3.

FMC Catawba Valley.

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 11, 13-14, Section O, pages 60-66 and referenced exhibits. The information provided by the applicant is reasonable and adequately 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, page 12-14, Section C, page 20, Section L, pages 52-56 and referenced exhibits. The information provided by the applicant is reasonable and adequately 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, pages 13-14, Section F, pages 29-36, Section N, pages 58-59, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would 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 county need. Therefore, the application is consistent with Policy GEN-3.

Catawba County Dialysis.

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B-4, pages 8-9, Section N, page 56, Section O, page 57, and referenced exhibits. The information provided by the applicant is reasonable and adequately 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, page 9, Section C, pages 17-18, Section L, pages 50-54, Section N, page 56 and referenced exhibits. The information provided by the applicant is reasonable and adequately 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, page 10, Section F, pages 26-32, Section N, page 56, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would 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 facility need as identified by the applicant. The application is consistent with Policy GEN-3.

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES states:

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

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

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

In Section B, pages 10-12, **Catawba County Dialysis** provides a written statement describing the proposed project’s plan to assure improved energy efficiency and water conservation. The application is consistent with Policy GEN-4.

Conclusion

In summary, all applications are conforming to the county need determination in the 2016 SMFP and the July 2016 SDR for 10 dialysis stations in Catawba County and Policy GEN-3. Furthermore, Catawba County Dialysis adequately demonstrates that its proposal is consistent with Policy GEN-4. However, the limit on the number of dialysis stations that may be approved in this review is 10. Collectively, the three applicants propose a total of 20 dialysis stations. Therefore, even if all the applications were conforming or conditionally conforming

to all statutory and regulatory review criteria, all the applications cannot be approved. See the Conclusion following the Comparative Analysis for the decision.

- (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

FMC Hickory
FMC Catawba Valley
Catawba County Dialysis

FMC Hickory proposes to add six dialysis stations to the existing facility for a total of 35 dialysis stations upon completion of this project and Project ID# E-11209-16 (relocate 6 stations to new FKC Newton facility). FMC Hickory offers a home hemodialysis program.

Patient Origin

On page 369, the 2016 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 consists of Catawba County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 24, the applicant provides a table showing the historical patient origin for both in-center (IC) patients and home hemodialysis (HH) patients served by FMC Hickory, as shown below:

Dialysis Patients as of 6/30/2016

COUNTY	IC PATIENTS	HH
Catawba	109	5
Alexander	1	0
Burke	8	2
Caldwell	6	1
Lincoln	3	1
Total	127	9

In Section C, page 17, the applicant identifies the patient population it proposes to serve during the first two years of operation following project completion, as illustrated in the table below:

COUNTY	OPERATING YEAR 1 CY2018			OPERATING YEAR 2 CY2019			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Catawba	116.0	5.9	0	124.0	6.3	0	84.7%	85.6%
Alexander	1.0	0.0	0	1.0	0.0	0	0.7%	0.7%
Burke	8.0	2.0	0	8.0	2.0	0	6.9%	6.6%
Caldwell	6.0	1.0	0	6.0	1.0	0	4.9%	4.6%
Lincoln	3.0	1.0	0	3.0	1.0	0	2.8%	2.6%
Total	134.0	9.9	0	142.0	10.3	0	100.0%	100.0%

The applicant provides the assumptions and methodology for the projections above on pages 17-19. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section B-2, pages 9-11, the applicant states the need for the proposed project is based on a county need determination. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference. See also Section C-2, pages 20-21.

Projected Utilization

In Section C, page 17, the applicant provides projected utilization during the first two years of operation following project completion, as illustrated in the table below:

COUNTY	OPERATING YEAR 1 CY2018			OPERATING YEAR 2 CY2019			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Catawba	116.0	5.9	0	124.0	6.3	0	84.7%	85.6%
Alexander	1.0	0.0	0	1.0	0.0	0	0.7%	0.7%
Burke	8.0	2.0	0	8.0	2.0	0	6.9%	6.6%
Caldwell	6.0	1.0	0	6.0	1.0	0	4.9%	4.6%
Lincoln	3.0	1.0	0	3.0	1.0	0	2.8%	2.6%
Total	134.0	9.9	0	142.0	10.3	0	100.0%	100.0%

In Section C, pages 17-21, the applicant provides the assumptions and methodology used to project utilization. On pages 17-18, the applicant provides a table illustrating how utilization was projected, which is summarized below:

- Operating Year 1 = Calendar Year 2018 (CY2018)
- Operating Year 2 = Calendar Year 2019 (CY2019)
- BMA notes that as of June 30, 2016, FMC Hickory was serving 18 in-center patients who are not residents of Catawba County. BMA assumes they are at FMC Hickory by choice and will continue to dialyze at FMC Hickory. However, BMA does not project an increase in this segment of the population utilizing FMC Hickory.

- BMA states that to project annual growth of the in-center patients who are residents of Catawba County it applied the Five Year Average Annual Growth Rate (AAGR) for Catawba County (6.9%) published in the July 2016 SDR.
- Effective December 31, 2017, BMA subtracts out the 12 in-center patients from Catawba County who currently utilize the FMC Hickory facility but are projected to transfer to the FKC Newton facility upon that facility becoming certified.

The following table illustrates application of these assumptions and the methodology used.

Begin with the in-center patients from Catawba County utilizing FMC Hickory as of June 30, 2016.	109
Project the census forward six months to December 31, 2016 using one half of the 6.9% AAGR	$1.0345 \times 109 = 112.80$
Project this patient population forward one year to December 31, 2017 using the 6.9% AAGR	$1.069 \times 112.8 = 120.58$
Subtract out the 12 Catawba County in-center patients projected to transfer to FKC Newton	$120.58 - 12 = 108.58$
Add in the 18 FMC Hickory in-center patients who reside outside Catawba County. Beginning census for Operating Year 1 (CY2018)	$108.58 + 18 = 126.58$
Project the Catawba County resident patient population forward one year to December 31, 2018 using the 6.9% AAGR	$1.069 \times 108.58 = 116$
Add in the 18 FMC Hickory in-center patients who reside outside Catawba County. This is the projected ending census for Operating Year 1 (CY2018).	$116 + 18 = 134$
Project the Catawba County resident patient population forward one year to December 31, 2019 using the 6.9% AAGR	$1.069 \times 116 = 124$
Add in the 18 FMC Hickory in-center patients who reside outside Catawba County. This is the projected ending census for Operating Year 2 (CY2019).	$124 + 18 = 142$

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2018) the facility is projected to serve 134 in-center patients and at the end of OY2 (CY2019) the facility is projected to serve 142 in-center patients.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.83 patients per station per week or 95.71% ($134 \text{ patients} / 35 \text{ stations} = 3.8286 / 4 = .9571$ or 95.71%).
- OY2: 4.05 patients per station per week or 101.42% ($142 \text{ patients} / 35 \text{ stations} = 4.0571 / 4 = 1.0142$ or 101.42%).

The projected utilization of 3.83 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth at FMC Hickory.

Access

In Section L, pages 54-55, the applicant states that each of BMA’s 105 facilities in 42 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. The table below shows the CY2015 payment sources of the facility and shows that 88.33% of the patients were Medicare or Medicaid recipients

Payment Source	Percent of Total Patients
Private Pay	2.34%
Commercial Insurance	7.77%
Medicare	71.99%
Medicaid	1.31%
Miscellaneous (Incl. VA)	1.55%
Other: Medicare Commercial	15.03%
Total	100.00%

Source: Section L-7, page 58.

The applicant projects 90.59% of its patients will be Medicare or Medicaid recipients in CY2019. 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

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the services proposed and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

FMC Catawba Valley proposes to add four dialysis stations for a total of 23 stations upon completion of this project and Project ID# E-11209-16 (relocate 6 stations to new FKC Newton facility). FMC Catawba Valley does not offer a home hemodialysis or peritoneal dialysis program nor is one proposed as part of this project.

Patient Origin

On page 369, the 2016 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 consists of Catawba County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 22, the applicant provides a table showing the historical patient origin for the in-center (IC) patients served by FMC Catawba Valley, as shown below:

Dialysis Patients as of 6/30/2016

COUNTY	IC PATIENTS
Catawba	90
Burke	1
Total	91

In Section C, page 17, the applicant identifies the patient population it proposes to serve during the first two years of operation following project completion, as illustrated in the table below:

COUNTY	OPERATING YEAR 1 CY2018			OPERATING YEAR 2 CY2019			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Catawba	76.5	0	0	81.7	0	0	98.7%	98.8%
Burke	1.0	0	0	1.0	0	0	1.3%	1.2%
Total*	77.0	0	0	82.0	0	0	100.0%	100.0%

*Rounded down to the nearest whole patient.

The applicant provides the assumptions and methodology for the projections above on pages 17-19. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section B-2, pages 9-11, the applicant states the need for the proposed project is based on a county need determination. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference. See also Section C-2, pages 19-20.

Projected Utilization

In Section C, page 17, the applicant provides projected utilization during the first two years of operation following project completion, as illustrated in the table below:

COUNTY	OPERATING YEAR 1 CY2018			OPERATING YEAR 2 CY2019			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Catawba	76.5	0	0	81.7	0	0	98.7%	98.8%
Burke	1.0	0	0	1.0	0	0	1.3%	1.2%
Total*	77.0	0	0	82.0	0	0	100.0%	100.0%

*Rounded down to the nearest whole patient.

In Section C, pages 17-20, the applicant provides the assumptions and methodology used to project utilization. On pages 17-19, the applicant provides a table illustrating how utilization was projected, which is summarized below:

- Operating Year 1 = Calendar Year 2018 (CY2018)
- Operating Year 2 = Calendar Year 2019 (CY2019)
- BMA notes that as of June 30, 2016 FMC Catawba Valley was serving one in-center patient who is not a resident of Catawba County. BMA assumes this patient is at FMC Catawba Valley by choice and will continue to dialyze at FMC Catawba Valley. However, BMA does not project an increase in the Burke County patient population utilizing FMC Catawba Valley.
- BMA states that to project annual growth of the in-center patients who are residents of Catawba County it applied the Five Year Average Annual Growth Rate (AAGR) for Catawba County (6.9%) published in the July 2016 SDR.
- Effective December 31, 2017, BMA subtracts out the 28 in-center patients from Catawba County who currently utilize the FMC Catawba Valley facility but are projected to transfer to the FKC Newton facility upon that facility becoming certified.

The following table illustrates application of these assumptions and the methodology used.

Begin with the in-center patients from Catawba County utilizing FMC Catawba Valley as of June 30, 2016.	90
Project the census forward six months to December 31, 2016 using one half of the 6.9% AAGR	$1.0345 \times 90 = 93.1$
Project this patient population forward one year to December 31, 2017 using the 6.9% AAGR	$1.069 \times 93.1 = 99.5$
Subtract out the 28 Catawba County in-center patients projected to transfer to FKC Newton	$99.5 - 28 = 71.5$
Project the Catawba County resident patient population forward one year to December 31, 2018 using the 6.9% AAGR	$1.069 \times 71.5 = 76.4$
Add in the 1 FMC Catawba Valley in-center patient who resides in Burke County. This is the projected ending census for Operating Year 1 (CY2018).	$76.4 + 1 = 77.4$
Project the Catawba County resident patient population forward one year to December 31, 2019 using the 6.9% AAGR	$1.069 \times 76.4 = 81.7$
Add in the 1 FMC Catawba Valley in-center patient who resides in Burke County. This is the projected ending census for Operating Year 2 (CY2019).	$81.7 + 1 = 82.7$

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2018) the facility is projected to serve 77 in-center patients and at the end of OY2 (CY2019) the facility is projected to serve 82 in-center patients.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.35 patients per station per week or 83.69% ($77 \text{ patients} / 23 \text{ stations} = 3.3478 / 4 = .8369$ or 83.69%).

- OY2: 4.05 patients per station per week or 101.42% (82 patients / 23 stations = 3.5652/4 = .8913 or 89.13%).

The projected utilization of 3.35 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth at FMC Catawba Valley.

Access

In Section L, pages 52-53, the applicant states that each of BMA’s 105 facilities in 42 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. The table below shows the CY2015 payment sources of the facility and shows that 92.09% of the patients were Medicare or Medicaid recipients

Payment Source	Percent of Total Patients
Private Pay	2.97%
Commercial Insurance	4.32%
Medicare	77.85%
Medicaid	3.39%
Miscellaneous (Incl. VA)	0.62%
Other: Medicare Commercial	10.85%
Total	100.00%

Source: Section L-7, page 56.

The applicant projects 94.02% of its patients will be Medicare or Medicaid recipients in CY2019. 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

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the services proposed and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

Catawba County Dialysis.

Patient Origin

On page 369, the 2016 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 consists of Catawba County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 13, the applicant provides the projected patient origin for Catawba County Dialysis for in-center (IC), home hemodialysis (HH) and peritoneal (PD) patients the first two years of operation following completion of the project as follows:

COUNTY	OPERATING YEAR 1 CY2018			OPERATING YEAR 2 CY2019			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Catawba	34	2	4	36	3	5	100%	100%
Total	34	2	4	36	3	5	100%	100%

The applicant should have listed Caldwell County for one of the HH patients based on the fact that Exhibit C contains a letter from a home hemodialysis patient, a patient of Dr. Gregory Pisel, stating she would consider transferring her care to the proposed Catawba County Dialysis facility. Dr. Pisel has agreed to serve as the medical director of Catawba County Dialysis.

The applicant provides the assumptions and methodology used to project patient origin on pages 13-17. The applicant adequately identifies the population to be served.

Analysis of Need

In Section B, page 6, the applicant states the need for the proposed project is based on a county need determination. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference. See also Section C-2, page 17.

Projected Utilization-IC Patients

In Section C, page 13, the applicant provides projected utilization during the first two years of operation following project completion, as illustrated in the table below:

COUNTY	OPERATING YEAR 1 CY2018			OPERATING YEAR 2 CY2019			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Catawba	34	2	4	36	3	5	100%	100%
Total	34	2	4	36	3	5	100%	100%

In Section C, pages 13-17, the applicant provides the assumptions and methodology used to project utilization. On page 14, the applicant illustrates how in-center patient utilization was projected, which is summarized below:

- OY1 is July 1, 2018 – June 30, 2019 (OY1)
- OY2 is July 1, 2019 – June 30, 2020 (OY2)

- There is a need for 10 additional stations in Catawba County pursuant to Table C in the July 2016 SDR.
- At the beginning of OY1, 32 Catawba County residents requiring in-center dialysis will transfer to the proposed Catawba County Dialysis facility.
- Forty five residents of Catawba County who are currently utilizing in-center dialysis and who are patients Dr. Gregory Pisel, a Nephrologist with Hickory Adult Care Medicine and Kidney Specialists, signed letters stating that they would consider transferring their care to the proposed Catawba County Dialysis. See also Exhibit C-1. Dr. Pisel has agreed to be the Medical Director of the proposed Catawba County Dialysis facility. (See Exhibit I-3 and application page 40).
- In-center patient population is projected to grow at 6.9%, the Five Year Average Annual Growth Rate (AAGR) for Catawba County pursuant to Table B in the July 2016 SDR.

The following table illustrates application of these assumptions and the methodology used.

TRC projects 32 in-center patients, all of whom reside in Catawba County as of July1, 2018.	32
TRC projects this patient population forward one year to June 30, 2019 using the 6.9% AAGR. This is the projected ending census for Operating Year 1 (7/1/18-6/30/19) .	$1.069 \times 32 = 34.208$
TRC projects the Catawba County resident patient population forward one year to June 30, 2020 using the 6.9% AAGR. This is the projected ending census for Operating Year 2 (7/1/19-6/30/20) .	$1.069 \times 34.208 = 36.568$

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (7/1/18-6/30/19) the facility is projected to serve 34 in-center patients and at the end of OY2 (7/1/19-6/30/20) the facility is projected to serve 36 in-center patients.

- OY1: 3.4 patients per station per week or 85.0% ($34 \text{ patients} / 10 \text{ stations} = 3.4 / 4 = .85$ or 85.0).
- OY2: 3.6patients per station per week or 90.0% ($36 \text{ patients} / 10 \text{ stations} = 3.6/4 = .9$ or 90.0%).

The projected utilization of 3.4 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected in-center utilization is based on reasonable and adequately supported assumptions regarding continued growth at Catawba County Dialysis.

Projected Utilization-Home PD Patients

The applicant provides projected utilization for its PD patients in Section C.1, page 16, as follows:

Operating Year	Start Date	Beginning Census of PD Patients	Ending Census of PD Patients
Operating Year 1	7/1/2018	3	4
Operating Year 2	7/1/2019	4	5

On page 16, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- Exhibit C-1 contains six letters of support for the proposed facility from current PD patients who live in Catawba County indicating that they would consider transferring their care to Catawba County Dialysis, if approved.
- TRC assumes three of the six patients who signed letters of support for the proposed facility will transfer their care to Catawba County Dialysis upon certification.
- TRC assumes that the PD patients will increase one patient each year.

While the percentage growth rate (25%) between the start of OY1 and the end of OY1 may on its face appear “excessive” the increase is only from three patients to four. By the end of OY2, the total number of PD patients (5) is less than the number of existing PD patients who expressed an interest in using the facility (6).

Projected Utilization-HH Patients

The applicant provides projected utilization for its HH patients in Section C.1, pages 16-17, as follows:

Operating Year	Start Date	Beginning Census of HH Patients	Ending Census of HH Patients
Operating Year 1	7/1/2018	1	2
Operating Year 2	7/1/2019	2	3

On page 16, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- Exhibit C-1 contains one letter of support for the proposed facility from a current HH patient who lives in Caldwell County indicating that she would consider transferring her care to Catawba County Dialysis, if approved.

- TRC assumes that the patient who signed the letter of support for the proposed facility would transfer her care to Catawba County Dialysis upon certification.
- TRC assumes that the HH patients will increase by one patient each year.

Projected PD and HH utilization is based on reasonable and adequately supported assumptions regarding continued growth at Catawba County Dialysis.

Access

In Section L, page 50, the applicant states that Catawba County Dialysis, by policy, will make its services available to all persons without qualification, including low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. See also pages 50-54 for discussion regarding access. In Section L.1, page 51, the applicant projects 85.5% of its patients will be Medicare or Medicaid recipients. 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

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the proposed 10-station facility in Catawba County and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, 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

FMC Hickory
FMC Catawba Valley
Catawba County Dialysis

- (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.

C

FMC Hickory
FMC Catawba Valley
Catawba County Dialysis

FMC Hickory. In Section E-1, pages 28-30, the applicant discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo – the applicant states that additional stations are needed at FMC Hickory to assure patients of a convenient time and location for continued access to dialysis. (See also Section C, pages 20-21)
2. Develop a new 10-station dialysis facility in Catawba County- The applicant states that it could have sought to develop a new 10-station in-center dialysis facility in Catawba County in addition to its three in-center dialysis facilities in Catawba County (two existing and one approved/under development). However, the applicant states that it does not believe that there is an existing or projected patient population of sufficient size in Catawba County not already supported or about to be supported by an in-center dialysis facility. However, the need determination methodology determines the number of stations needed, not the number of facilities. Regardless of whether the 10 additional stations are located in a new facility or added to one or more existing or approved facilities, Catawba County residents are projected to need 10 more stations.
3. Add more than six stations to the FMC Hickory facility– The applicant states that the building at FMC Hickory physically cannot be expanded beyond a total of 35 stations. If this application is approved, FMC Hickory would have a total of 35 stations.
4. Apply for fewer than six stations at the FMC Hickory facility- The applicant states that an evaluation of the location of its existing patients showed that more patients resided closer to the FMC Hickory facility, therefore, it applied for the six stations at FMC Hickory and, in the companion application which is part of this review, applied for four stations at FMC Catawba Valley.
5. Relocate existing stations from FMC Catawba Valley to FMC Hickory- The applicant states that both existing and projected utilization of the FMC Catawba facility is high. Utilization of FMC Catawba Valley was at 91.0% in the July 2016 SDR and projected to exceed that performance standard in CY2018 even after stations and patients are transferred to the new in-center dialysis facility (FKC Newton) that BMA has under development in Catawba County.

After considering these alternatives to its proposal, the applicant believes its most cost effective alternative is to add six stations to ensure adequate access for the patients of FMC Hickory.

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.

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need for six more stations at FMC Hickory. Therefore, the application is conforming to this criterion.

FMC Catawba Valley. In Section E-1, pages 26-28, the applicant discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo – the applicant states that additional stations are needed at FMC Catawba Valley to assure patients of a convenient time and location for continued access to dialysis. (See also Section C, pages 19-20)
2. Develop a fourth in-center dialysis facility in Catawba County- The applicant states that it could have sought to develop a new 10-station in-center dialysis facility in Catawba County in addition to its three in-center dialysis facilities in Catawba County (two existing and one approved/under development). However, the applicant states that it does not believe that there is an existing or projected patient population of sufficient size in Catawba County not already supported or about to be supported by an in-center dialysis facility. However, the need determination methodology determines the number of stations needed, not the number of facilities. Regardless of whether the 10 additional stations are located in a new facility or added to one or more existing or approved facilities, Catawba County residents are projected to need 10 more stations.
3. Add six stations to the FMC Catawba Valley facility– The applicant states that an evaluation of the location of its existing patients showed that more patients resided closer to the FMC Hickory facility, therefore, it applied for the six stations at FMC Hickory in the companion application which is part of this review. Further, projected utilization at FMC Catawba facility while supporting four additional stations does not support six additional stations.
4. Relocate existing stations from FMC Hickory to the FMC Catawba Valley facility- The applicant states that utilization of the FMC Hickory facility is high. Utilization of FMC Hickory was at 89.29% in the July 2016 SDR and thus did not justify relocating stations from FMC Hickory to the FMC Catawba Valley facility.

After considering these alternatives to its proposal, the applicant believes its most cost effective alternative is to add four stations to ensure adequate access for the patients of FMC Catawba Valley.

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.

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need for four additional stations at FMC Catawba Valley. Therefore, the application is conforming to this criterion.

Catawba County Dialysis. In Section E-1, page 24, the applicant discusses the two alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo – Currently, all of the existing and approved facilities are owned and operated by one company. The July 2016 SDR determined that residents of Catawba County need 10 additional stations. The applicant states that maintaining the status quo would deny Catawba County residents a choice of providers.
2. Locate a facility in another location of Catawba County – the applicant states that the proposed location provides the best geographical access to the identified patient population and the population center of the County.

After considering these alternatives to its proposal the applicant believes its most effective alternative is to develop the proposed 10-station facility in Hickory.

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.

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need for a 10-station facility in Hickory. Therefore, the application is conforming to this criterion.

- (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

FMC Hickory FMC Catawba Valley Catawba County Dialysis

FMC Hickory proposes to add six dialysis stations to the existing facility for a total of 35 dialysis stations upon completion of this project and Project ID# E-11209-16 (relocate 6 stations to new FKC Newton facility). FMC Hickory offers a home hemodialysis program.

Capital and Working Capital Costs

In Section F, page 31, the applicant states that there are no projected capital costs associated with the proposed project.

In Section F, pages 34-35, the applicant states that there are no working capital needs for the proposed project since FMC Catawba Valley is an existing facility.

Financial Feasibility

In the projected revenue and expense statement (Section R, Form B), the applicant projects revenues will exceed operating expenses in both of the first two operating years following completion of the proposed project, as shown in the table below.

FMC HICKORY		
REVENUE AND EXPENSES		
	OY 1	OY 2
	CY 2018	CY 2019
Gross Revenue	\$77,214,561	\$87,885,418
Deductions from Gross Patient Revenue	(\$68,989,090)	(\$78,250,809)
Net Revenue	\$8,225,471	\$9,634,609
Operating Expenses	(\$6,249,884)	(\$6,957,038)
Net Income	\$1,975,586	\$2,677,571

The assumptions used by the applicant in preparation of the pro formas 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 on reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the operating needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

FMC Catawba Valley proposes to add four dialysis stations for a total of 23 stations upon completion of this project and Project ID# E-11209-16 (relocation of 6 stations to new FMC Newton facility). FMC Catawba Valley does not offer a home hemodialysis or peritoneal dialysis program nor is one proposed as part of this project.

Capital and Working Capital Costs

In Section F, page 29, the applicant states that there are no projected capital costs associated with the proposed project.

In Section F, pages 32-33, the applicant states that there are no working capital needs for the proposed project since FMC Catawba Valley is an existing facility.

Financial Feasibility

In the projected revenue and expense statement (Section R, Form B), the applicant projects revenues will exceed operating expenses in both of the first two operating years following completion of the proposed project, as shown in the table below.

FMC CATAWBA VALLEY REVENUE AND EXPENSES		
	OY 1 CY 2018	OY 2 CY 2019
Gross Revenue	\$44,326,620	\$47,281,728
Deductions from Gross Patient Revenue	(\$40,249,677)	(\$42,932,989)
Net Revenue	\$4,076,943	\$4,348,739
Operating Expenses	(\$3,091,071)	(\$3,258,307)
Net Income	\$985,873	\$1,090,432

The assumptions used by the applicant in preparation of the pro formas 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 on reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the operating needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

Catawba County Dialysis proposes to develop a new 10-station dialysis facility.

Capital and Working Capital Costs

In Section F-1, page 26, the applicant states the capital costs associated with the proposed project are \$2,722,202. Additionally, in Section F, pages 29-30, the applicant projects a need for \$977,077 in working capital [\$186,077 start-up expenses + \$791,000 initial operating expenses = \$977,077] for the proposed facility.

Availability of Funds

In Section F, page 28, the applicant states it will finance the capital costs with accumulated reserves/owner’s equity of TRC. In Section F, page 31, the applicant states that it will finance the working capital costs with case reserves.

Exhibit F contains a letter dated September 14, 2016, from the Chief Accounting Officer of DaVita, the parent company of Total Renal Care of North Carolina, LLC, which authorizes and commits cash reserves for the project capital costs of \$2,722,202 and for the working capital costs of \$977,077. Exhibit F-7 DaVita’s Form 10-K for the fiscal year ended December 31, 2014, not 2015. The 2014 financials are more than 20 months old as of the application submission date. However, the Agency has DaVita’s Form 10-K for the year ended December 31, 2015 in Project I.D. # F-11154-16. As of December 30, 2015, DaVita had \$1,499,116,000

in cash and cash equivalents, \$18,514,875,000 in total assets and \$5,084,172,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

Financial Feasibility

In the projected revenue and expense statement (Section R, Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

CATAWBA COUNTY DIALYSIS		
Revenue and Expenses		
	OY1	OY2
Gross Patient Revenue	\$1,817,711	\$2,081,490
Deductions form Gross Patient Revenue	(\$188,874)	(\$207,812)
Net Patient Revenue	\$1,628,838	\$1,873,678
Operating Expenses	(\$1,582,000)	(\$1,721,258)
Net Income	\$46,838	\$152,421

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.

Exhibit C contains a letter from a home hemodialysis patient which states that she would consider transferring her care to the proposed Catawba County Dialysis facility. The applicant projects two home hemodialysis patients at the end of OY1 and three home hemodialysis patients at the end of OY2. This projected growth in home hemodialysis patients was questioned in written comments. In Form C, the applicant projects \$224,638 in revenue from home hemodialysis treatments in OY2. This equates to approximately \$75,000 per home hemodialysis patient ($\$224,638 / 3 \text{ patients} = \$74,879$). As shown in the table above, in OY2 the applicant is projecting net income of \$152,421. Thus, even if the applicant projected only one home hemodialysis patient for OY2, or 0.00% growth, there would still be a positive net income of \$2,421 in OY2 ($\$152,421 - \$150,000 [2 \times \$75,000] = \$2,421$). This analysis makes no other adjustments for costs that vary with the number of treatments provided or contractual adjustments. The net income if there is only one HH patient instead of three would potentially be higher with these adjustments to the costs.

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

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital, working capital and operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding

projected utilization, revenues (charges) and operating costs. 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

FMC Hickory
 FMC Catawba Valley
 Catawba County Dialysis

The 2016 SMFP and the July 2016 SDR provide a County Need Determination for new dialysis stations in Catawba County. According to Section 2(E) of the dialysis station need methodology, found on page 373 of the 2016 SMFP, *“If a county’s December 31, 2016 projected station deficit is 10 or greater and the July SDR shows that utilization of each dialysis facility in the county is 80 percent or greater, the December 31, 2016 county station need determination is the same as the December 31, 2016 projected station deficit.”* The July 2016 SDR shows a projected station deficit in Catawba County of 10 dialysis stations. The projected station deficit resulted in a need determination in the 2016 SMFP for 10 dialysis stations pursuant to the county need methodology.

On page 369, the 2016 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 consists of Catawba County. Facilities may also serve residents of counties not included in their service area.

There are currently two existing dialysis facilities and one approved dialysis facility in Catawba County: FMC Hickory (existing); FMC Catawba Valley (existing); and FKC Newton (approved). All three are owned and operated by the same entity - Bio-Medical Applications of North Carolina, Inc.

FMC Hickory is currently certified for 35 stations and FMC Catawba Valley is currently certified for 25 stations, as shown in the table below.

Catawba County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/15	# In-Center Patients 12/31/2015	% Utilization	Patients Per Station
FMC of Catawba Valley	25	91	91.00%	3.64
FMC of Hickory	35	125	89.29%	3.57
Total	60	216	90.00%	3.60

Source: July 2016 SDR, Table A.

FKC Newton will be created by relocating six existing dialysis stations from each existing facility. As illustrated above, the average utilization rate for the 60 existing stations is 90.00%. Assuming no growth in the number of in-center patients, the utilization rate for 70 stations (60 existing stations + 10 need determination) would be 3.1 patients per station [$216/70 = 3.1$]. However, the AAGR over the last five years was 6.9%. Thus, it is reasonable to expect that the number of patients will increase. The July 2016 SDR projects 225 in-center patients by December 31, 2016. The utilization rate for 70 stations and 225 in-center patients would be 3.2 patients per station or 80% [$225/70 = 3.2$; $3.2/4 = 0.8$].

FMC Hickory proposes to add six dialysis stations to the existing facility in Hickory, in Catawba County. The applicant adequately demonstrates the need to add six additional stations at FMC Hickory based on the number of in-center patients it proposes to serve. The discussion on projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations in Catawba County. Consequently, the application is conforming to this criterion.

FMC Catawba Valley proposes to add four dialysis stations to the existing facility in Conover, in Catawba County. The applicant adequately demonstrates the need to add four additional stations at FMC Catawba Valley based on the number of in-center patients it proposes to serve. The discussion on projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations in Catawba County. Consequently, the application is conforming to this criterion.

Catawba County Dialysis proposes to develop 10 new dialysis stations at a new ESRD facility in Hickory, in Catawba County. The applicant adequately demonstrates the need to develop a new 10-station facility based on the number of in-center patients it proposes to serve. The discussion on projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations 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

FMC Hickory
FMC Catawba Valley
Catawba County Dialysis

FMC Hickory. In Section H, page 41, the applicant provides the following table to illustrate current and projected staffing in full time equivalents (FTEs) for FMC Hickory. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart.

POSITION	CURRENT # FTES	# FTES TO BE ADDED	PROJECTED # FTES
Registered Nurse	5.50	0.75	6.25
Technician (PCT))	12.75	2.00	14.75
Clinical Manager	1.00		1.00
Director of Operations	0.25		0.25
Dietician	0.90	0.20	1.10
Social Worker	0.90	0.20	1.10
Home Training Nurse	1.00		1.00
Chief Tech	0.25		0.25
Equipment Tech	1.20	0.30	1.50
In-Service	0.25		0.25
Clerical	2.00	0.30	2.30
Total	26.00	3.75	29.75

As illustrated in the table above, the applicant projects to add 3.75 FTEs at FMC Hickory.

In Section H, page 44, the applicant provides the projected direct care staff for FMC Hickory in OY 2, as shown below in the table:

DIRECT CARE POSITIONS	# FTES	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	6.25	2,080	13,000	3,120	4.17
Technician (PCT)	14.75	2,080	30,680	3,120	9.83
Total	21	2,080	43,680	3,120	14.0

In Section H, page 43, the applicant states dialysis services will be available from 6:00 AM to 5:00 PM, Monday through Saturday, for a total of 11 hours per day/ 66 hours per week. However, on page 44, the applicant provides conflicting information regarding hours of operation. On page 43, total hours per year is reported to be 3,432. But on page 44, total hours per year is reported to be only 3,120. FMC Hickory does not explain this discrepancy in the application as submitted. As a result, the # of FTE hours per hour of operation would be as shown in the following table.

DIRECT CARE POSITIONS	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	13,000	3,432	3.78
Technician (PCT)	30,680	3,432	8.90
Total	43,680	3,432	12.70

In Section I, page 46, the applicant identifies Dr. David Harvey as the Medical Director of the facility. In Exhibit I-5, the applicant provides a copy of a letter signed by Dr. Harvey of Piedmont Nephrology and Hypertension Associates, PA supporting the project and confirming his commitment to serve as Medical Director. In Section H, pages 42, the applicant describes the methods used to recruit and fill vacant or new positions.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

FMC Catawba Valley. In Section H, page 39, the applicant provides the following table to illustrate current and projected staffing in full time equivalents (FTEs) for FMC Catawba Valley. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart.

POSITION	CURRENT # FTEs	# FTEs TO BE ADDED	PROJECTED # FTEs
Registered Nurse	2.75	0.75	3.50
LPN	1.00		1.00
Technician (PCT))	6.00	1.50	7.50
Clinical Manager	1.00		1.00
Administrator	0.15		0.15
Dietician	0.50	0.17	0.67
Social Worker	0.50	0.17	0.67
Chief Tech	0.20		0.20
Equipment Tech	0.75	0.20	0.95
In-Service	0.25		0.25
Clerical	1.00	0.30	1.30
Total	14.1	3.09	17.19

As illustrated in the table above, the applicant projects to add 3.09 FTEs at FMC Catawba Valley.

In Section H, page 42, the applicant provides the projected direct care staff for FMC Catawba Valley in OY 2, as shown below in the table:

DIRECT CARE POSITIONS	# FTEs	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	3.5	2,080	7,280	3,120	2.33
Technician (PCT)	7.5	2,080	15,600	3,120	5.00
Total	11	2,080	22,880	3,120	7.33

In Section H, page 41, the applicant states dialysis services will be available from 6:00 AM to 5:00 PM, Monday through Saturday, for a total of 11 hours per day/ 66 hours per week. However, on page 42, the applicant provides conflicting information regarding hours of operation. On page 41, total hours per year is reported to be 3,432. But on page 42, total hours per year is reported to be only 3,120. FMC Catawba Valley does not explain this discrepancy in the application as submitted. As a result, the # of FTE hours per hour of operation would be as shown in the following table.

DIRECT CARE POSITIONS	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	7,280	3,432	2.12
Technician (PCT)	15,600	3,432	4.55
Total	22,800	3,432	6.67

In Section I, page 44, the applicant identifies Dr. Richard Paul as the Medical Director of the facility. In Exhibit I-5, the applicant provides a copy of a letter signed by Dr. Paul of Piedmont Nephrology and Hypertension Associates, PA supporting the project and confirming his commitment to serve as Medical Director. In Section H, pages 40, the applicant describes the methods used to recruit and fill vacant or new positions.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

Catawba County Dialysis. In Section H, page 34, the applicant provides the following table to illustrate the projected staffing in full time equivalents (FTEs) for Catawba County Dialysis. The applicant states the Medical Director will not be employed by the facility, and thus is not reflected on the staffing chart.

CATAWBA COUNTY DIALYSIS			
POSITION	CURRENT # FTEs	# FTEs TO BE ADDED	PROJECTED # FTEs
Registered Nurse	0	2.0	2.0
Technician (Patient Care)	0	4.0	4.0
Administrator	0	1.0	1.0
Dietician	0	0.5	0.5
Social Worker	0	0.5	0.5
Home Training RN	0	0.5	0.5
Administrative Assistant	0	1.0	1.0
Bio-med Technician	0	0.3	0.3
Total	0	9.8	9.8

As illustrated in the table above, the applicant projects a total of 9.8 FTEs at Catawba County Dialysis.

In Section H-7, page 37, the applicant provides the projected direct care staff for Catawba County Dialysis in OY 2, as shown below in the table:

CATAWBA COUNTY DIALYSIS					
DIRECT CARE POSITIONS	# FTEs	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	2	2,080	4,160	3,120	1.33
Patient Care Tech	4	2,080	8,320	3,120	2.67
Total	6	2,080	12,480	3,120	4.00

In Section I-2, page 35, the applicant identifies Dr. Greg Pisel, as the Medical Director of the proposed facility. In Exhibit I-3, the applicant provides a copy of an August 2016 letter signed by Dr. Pisel, of Hickory Adult Medicine and Kidney Specialists, P.A., supporting the project and confirming his commitment to serve as Medical Director. In Section H-3, pages 36, the applicant states that vacant staff positions are filled by one or more of the following: the DaVita Teammate Recruiter, Teammate Referral Program and/or Student Internship Program. The applicant states on page 36 that DaVita offers a wide range of teammate benefits and maintains a competitive salary structure in order to attract qualified teammates.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the 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.

C

FMC Hickory
FMC Catawba Valley
Catawba County Dialysis

FMC Hickory. In Section I, page 45, the applicant identifies the necessary ancillary and support services and indicates how they are or will be made available. 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 45-47. Exhibits I-1 through I-4, respectively, contain copies of agreements for home training, lab services, acute services and transplantation services. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

FMC Catawba Valley. In Section I, page 43, the applicant identifies the necessary ancillary and support services and indicates how they are or will be made available. 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 43-45. Exhibits I-1 through I-4, respectively, contain copies of agreements for home training, lab services, acute services and transplantation services. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

Catawba County Dialysis. In Section I-1, page 39, the applicant identifies the necessary ancillary and support services and indicates how they will be made available. The applicant discusses coordination with the existing health care system on pages 39-41. Exhibits I-1 and I-3 contain documents from DaVita, DaVita Laboratory Services, Inc., and Dr. Greg Pisel (Medical Director), respectively, documenting availability of the necessary ancillary and support services. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care 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

FMC Hickory
FMC Catawba Valley
Catawba County Dialysis

- (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

FMC Hickory
FMC Catawba Valley
Catawba County Dialysis

- (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

FMC Hickory
FMC Catawba Valley

C

Catawba County Dialysis

Catawba County Dialysis. In Section K.2, page 46, the applicant states it proposes to lease and upfit 6,221 square feet of an existing building located at 1270 25th Street Place SE in Hickory. In Section K, page 45, the applicant states the facility will be constructed in compliance with all laws and regulations pertaining to staffing, fire and safety equipment, physical environment and other relevant health safety requirements. In Section B, pages 10-12, and Section K, page 44, the applicant describes its plans for energy-efficiency and water conservation. Costs and charges are described by the applicant in Section R of the application. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

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

C

FMC Hickory
FMC Catawba Valley

NA

Catawba County Dialysis

FMC Hickory. In Section L, page 58, the applicant reports that 88.33% of the patients who received treatments at FMC Hickory had some or all of their services paid for by Medicare or Medicaid in the past year. The table below shows the historical payment sources of the facility in CY2015:

Payment Source	Percent of Total Patients
Private Pay	2.34%
Commercial Insurance	7.77%
Medicare	71.99%
Medicaid	1.31%
Miscellaneous (Incl. VA)	1.55%
Other: Medicare Commercial	15.03%
Total	100.00%

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

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Catawba	16%	51%	23%	16%	9%	18%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

*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., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The Southeastern Kidney Council Network 6 Inc. Annual Report provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

Source: <http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).

The applicant adequately demonstrates that it currently provides access to medically underserved populations. Therefore, the application is conforming to this criterion.

FMC Catawba Valley. In Section L, page 56, the applicant reports that 92.09% of the patients who received treatments at FMC Catawba Valley had some or all of their services paid for by Medicare or Medicaid in the past year. The table below shows the historical payment sources of the facility in CY2015:

Payment Source	Percent of Total Patients
Private Pay	2.97%
Commercial Insurance	4.32%
Medicare	77.85%
Medicaid	3.39%
Miscellaneous (Incl. VA)	0.62%

Other: Medicare Commercial	10.85%
Total	100.00%

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

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Catawba	16%	51%	23%	16%	9%	18%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

*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., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The *Southeastern Kidney Council Network 6 Inc. Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

Source: <http://www.esrdnetwork6.org/utls/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).

The applicant adequately demonstrates that it currently provides access to medically underserved populations. Therefore, the application is conforming to this criterion.

Catawba County Dialysis does not currently provide services.

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

C

FMC Hickory
 FMC Catawba Valley

NA

Catawba County Dialysis

FMC Hickory. In Section L, page 56, the applicant states “*BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations*” In Section L, page 57, the applicant states “*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.*” The application is conforming to this criterion.

FMC Catawba Valley. In Section L, page 54, the applicant states “*BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations*” In Section L, page 55, the applicant states “*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.*” The application is conforming to this criterion.

Catawba County Dialysis does not currently provide services.

- (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

FMC Hickory
FMC Catawba Valley
Catawba County Dialysis

FMC Hickory. In Section L, page 54, the applicant states: “*It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.*” In Section L, page 55, the applicant projects that 90.59% of all patients in CY2019 will have all or part of their services paid for by Medicare and or Medicaid, as indicated in the table below:

Payment Source	Percent of Total Patients
Commercial Insurance	4.29%
Medicare	70.67%
Medicaid	1.92%
Medicare/ Commercial	18.00%
Miscellaneous (Incl. VA)	2.20%
Other: Self/Indigent/Charity	2.93%
Total	100.00%

The projected payor mix is based on the historical payor mix. The applicant adequately demonstrates that medically underserved populations will have access to the proposed services. Therefore, the application is conforming to this criterion.

FMC Catawba Valley. In Section L, page 52, the applicant states: *“It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”* In Section L, page 53, the applicant projects that 94.02% of all patients in CY2019 will have all or part of their services paid for by Medicare and or Medicaid, as indicated in the table below:

Payment Source	Percent of Total Patients
Commercial Insurance	4.89%
Medicare	76.03%
Medicaid	8.68%
Medicare/ Commercial	9.31%
Miscellaneous (Incl. VA)	1.09%
Total	100.00%

The projected payor mix is based on the historical payor mix. The applicant adequately demonstrates that medically underserved populations will have access to the proposed services. Therefore, the application is conforming to this criterion.

Catawba County Dialysis. In Section C-3, pages 17-18, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. ...

Payment will not be required upon admission. Therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

In Section L-3, page 53, the applicant states:

“Catawba County Dialysis makes no effort to categorize patients into groups according to their financial ability to obtain medical care. Physicians identify the patients in need of dialysis services and only then will a financial counselor and/or social worker evaluate their medical insurance and financial status.”

In Section L-1, page 51, the applicant projects that 85.5% of all patients in OY2 will have all or part of their services paid for by Medicare and Medicaid, as indicated below in the table.

CATAWBA COUNTY DIALYSIS PROJECTED PAYOR MIX PROJECT YEAR 2 (7/1/19 – 6/30/20)				
PAYOR TYPE	PERCENT OF TOTAL PATIENTS	PERCENT OF IN-CENTER PATIENTS	Percent of HH Patients	Percent of PD Patients
Medicare	72.3%	74.1%	64.3%	64.0%
Medicaid	2.1%	2.5%	0.0%	0.0%
Commercial Insurance	11.1%	5.6%	35.7%	36.0%
Medicare/ Commercial	11.1%	13.7%	0.0%	0.0%
VA	1.1%	1.2%	0.0%	0.0%
Other: Self/ Indigent/Charity	2.3%	2.9%	0.0%	0.0%
Total	100.0%	100.0%	100.0%	100.0%

On page 51, the applicant states “*Since DaVita does not operate any dialysis facilities in Catawba County or any other counties contiguous to Catawba County, we have chosen to use the weighted in-center payor mix data contained in Section L, page 71 (Exhibit L-1(b)) of the Fresenius Kidney Care Newton CON application that was submitted on July 15, 2016 and the home training payor mix contained in the FMC Hickory Home Training CON application Required State Agency Findings on page 13 (Exhibit L-1(b)).*

- *TRC assumes that the payor mix in the Fresenius Kidney Care Newton CON application are accurate*
- *TRC assumes that the payor mix for peritoneal dialysis and home hemodialysis contained in the FMC Hickory Home Training CON were accurate”*

The applicant adequately demonstrates that medically underserved populations will have 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

FMC Hickory
 FMC Catawba Valley
 Catawba County Dialysis

FMC Hickory. In Section L, page 57, the applicant states “*Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC Hickory has 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 applicant adequately demonstrates that FMC Hickory will offer a range of means by which a person can access the services. Therefore, the application is conforming to this criterion.

FMC Catawba Valley. In Section L, 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. FMC Catawba County 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 applicant adequately demonstrates that FMC Catawba Valley will offer a range of means by which a person can access the services. Therefore, the application is conforming to this criterion.

Catawba County Dialysis. In Section L-4, page 53, the applicant states:

"Patients with End Stage Renal Disease have access to dialysis services upon referral by a nephrologist with privileges at Catawba County Dialysis. ... Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies, found at Exhibit L-3. ..."

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to the proposed 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

FMC Hickory
FMC Catawba Valley
Catawba County Dialysis

FMC Hickory. In Section M, page 59, the applicant refers to a letter dated September 14, 2016 addressed to Catawba Valley Community College which states "*Fresenius would like to invite you to include the BMA Hickory dialysis facility in your list of facilities for clinical rotation of your nursing students.*" See Exhibit M-1. The information provided in Section M is reasonable and credible and supports a finding of conformity to this criterion.

FMC Catawba Valley. In Section M, page 57, the applicant refers to a letter dated September 14, 2016 addressed to Catawba Valley Community College which states “*Fresenius would like to invite you to include the BMA Hickory dialysis facility in your list of facilities for clinical rotation of your nursing students.*” See Exhibit M-1. The information provided in Section M is reasonable and credible and supports a finding of conformity to this criterion.

Catawba County Dialysis. In Section M-1, page 55, the applicant states that Catawba County Dialysis has been offered as a clinical training site for nursing students attending Catawba Valley Technical College. Exhibit M-2 contains a copy of the student training agreement with Catawba Valley Technical College. The information provided in Section M and referenced exhibits is reasonable and supports a finding of conformity 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

FMC Hickory
FMC Catawba Valley
Catawba County Dialysis

The 2016 SMFP and the July 2016 SDR provide a County Need Determination for new dialysis stations in Catawba County. According to Section 2(E) of the dialysis station need methodology, found on page 373 of the 2016 SMFP, “*If a county’s December 31, 2016 projected station deficit is 10 or greater and the July SDR shows that utilization of each dialysis facility in the county is 80 percent or greater, the December 31, 2016 county station need determination is the same as the December 31, 2016 projected station deficit.*” The July 2016 SDR shows a projected station deficit in Catawba County of 10 dialysis stations. The projected station deficit resulted in a need determination in the 2016 SMFP for 10 dialysis stations pursuant to the county need methodology.

On page 369, the 2016 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 all three applications consists of Catawba County. Facilities may also serve residents of counties not included in their service area.

There are currently two existing dialysis facilities and one approved dialysis facility in Catawba County: FMC Hickory (existing); FMC Catawba Valley (existing); and FKC Newton (approved). All three are owned and operated by the same entity - Bio-Medical Applications of North Carolina, Inc.

FMC Hickory is currently certified for 35 stations and FMC Catawba Valley is currently certified for 25 stations, as shown in the table below.

Dialysis Facility	Certified Stations 12/31/15	# In-Center Patients 12/31/2015	% Utilization	Patients Per Station
FMC of Catawba Valley	25	91	91.00%	3.64
FMC of Hickory	35	125	89.29%	3.57
Total	60	216	90.00%	3.60

Source: July 2016 SDR, Table A.

FKC Newton will be created by relocating six existing dialysis stations from each existing facility. As illustrated above, the average utilization rate for the 60 existing stations is 90.00%. Assuming no growth in the number of in-center patients, the utilization rate for 70 stations (60 existing stations + 10 need determination) would be 3.1 patients per station [216/70 = 3.1]. However, the AAGR over the last five years was 6.9%. Thus, it is reasonable to expect that the number of patients will increase. The July 2016 SDR projects 225 in-center patients by December 31, 2016. The utilization rate for 70 stations and 225 in-center patients would be 3.2 patients per station or 80% [225/70 = 3.2; 3.2/4 = 0.8].

FMC Hickory proposes to add six dialysis stations to the existing facility for a total of 35 dialysis stations upon completion of this project and Project ID# E-11209-16 (relocate 6 stations to new FKC Newton facility).

In Section N, pages 60-62, 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:

“BMA does not expect this proposal to have effect on the competitive climate in Catawba County. The application does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC Hickory facility begins with patients currently served by BMA, and a growth of that patient population consistent with the Catawba County five year average annual change rate of 6.9% as published within the July 2016 SDR.

Development of a dialysis facility by a competing provider will not impact cost effectiveness, quality or patient access to the proposed services. First and foremost, quality is not a variable within BMA facilities...

BMA facilities are already working to establish and maintain cost effectiveness without compromising patient care. ... BMA does not change the dialysis treatment based upon the payor source. ... Thus, competition is not a factor which will impact cost effectiveness or quality of care. ...

Competition among providers is more likely to have an impact on access to care. Patients do not [sic] self-refer for dialysis. Rather, patients are referred to dialysis by their nephrologist, who has admitting privileges at the dialysis facility. ...

Thus, enhanced competition within Catawba County could impact patient access to care to the extent that the nephrologist doesn't have privileges in a competing dialysis facility."

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

The information provided by the applicant in the sections referenced above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that FMC Hickory will continue to provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that FMC Hickory will continue to provide access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

FMC Catawba Valley proposes to add four dialysis stations for a total of 23 stations upon completion of this project and Project ID# E-11209-16 (relocate 6 stations to new FMC Newton facility).

In Section N, pages 60-62, 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:

"BMA does not expect this proposal to have effect on the competitive climate in Catawba County. The application does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC Catawba Valley facility begins

with patients currently served by BMA, and a growth of that patient population consistent with the Catawba County five year average annual change rate of 6.9% as published within the July 2016 SDR.

Development of a dialysis facility by a competing provider will not impact cost effectiveness, quality or patient access to the proposed services. First and foremost, quality is not a variable within BMA facilities...

BMA facilities are already working to establish and maintain cost effectiveness without compromising patient care. ... BMA doesn't change the dialysis treatment based upon the payor source. ... Thus, competition is not a factor which will impact cost effectiveness or quality of care. ...

Competition among providers is more likely to have an impact on access to care. Patients do not [sic] self-refer for dialysis. Rather, patients are referred to dialysis by their nephrologist, who has admitting privileges at the dialysis facility. ...

Thus, enhanced competition within Catawba County could impact patient access to care to the extent that the nephrologist doesn't have privileges in a competing dialysis facility."

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

The information provided by the applicant in the sections referenced above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that FMC Catawba Valley will continue to provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that FMC Catawba Valley will continue to provide access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

Catawba County Dialysis proposes to develop a new 10-station dialysis facility.

In Sections E and N, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. On page 24, the applicant states:

*“The July 2016 Semiannual Dialysis Report (**Exhibit E-1**) indicated that there is a County Station Need Determination of 10 stations in Catawba County. Presently there is only one provider in the county. We see this is [sic] an opportunity to bring in a second provider so that ESRD patients who live in the service area and in the counties contiguous to Catawba County have a choice of providers and/or a more convenient location to travel to dialysis. The primary site we are proposing is located near the population center of the county and between the two certified facilities.”*

On page 25, the applicant states *“The alternative is not the least costly since we will be establishing a new state-of-the art facility. However, it is the most effective alternative. The establishment of our facility offers the ESRD patients in Catawba County a choice of providers and a choice of who will be serving the facility as Medical Director. Catawba County Dialysis will offer patients an opportunity to receive dialysis services with the national provider with the best clinical outcomes as indicated by the Centers for Medicare and Medicaid Services. The proposed facility will provide in-center, peritoneal and home hemodialysis modalities in one location.”*

On page 56, the applicant states *“The development of Catawba County Dialysis will have no effect on any dialysis facilities located in Catawba County or in counties contiguous to it. This certificate of need application is being submitted in response to a need determination for ten new dialysis stations in Catawba County as indicated in the July 2016 Semiannual Dialysis Report in Tables B and C. The need determination in Catawba County indicates that there is a need for additional dialysis stations for the residents who live in the county. This is a great opportunity for patients, referring hospitals and physicians to have a choice of providers. ...*

Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs.”

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

The information provided by the applicant in the sections referenced above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicant adequately demonstrates that Catawba County Dialysis will provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that Catawba County Dialysis will provide access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are 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

FMC Hickory
 FMC Catawba Valley
 Catawba County Dialysis

FMC Hickory. In Section B, pages 11, 13-14, Section O, pages 63-68 and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality. On page 65, the applicant states that FMC Hickory meets the Conditions for Coverage for ESRD facilities. See also Exhibit O-2.

In Section O, page 66, the applicant states that out of more than 100 facilities located in North Carolina operated by the applicant or a related entity, only the three listed below were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application.

BMA QUALITY CARE			
FACILITY	SURVEY DATE	BACK IN COMPLIANCE	
BMA Lumberton	5/6/2015	Yes	5/29/2015
BMA East Charlotte	8/11/2015	Yes	9/9/2015
RAI West College-Warsaw	3/15/2016	Yes	4/11/2016

Based on a review of this certificate of need application and publicly available information, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

FMC Catawba Valley. In Section B, pages 11, 13-14, Section O, pages 60-66 and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality. On page 62 the applicant states that FMC Catawba Valley meets the Conditions for Coverage for ESRD facilities. See also Exhibit O-2.

In Section O, page 63, the applicant states that out of more than 100 facilities located in North Carolina operated by the applicant or a related entity, only the three listed below were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application.

BMA QUALITY CARE			
FACILITY	SURVEY DATE	BACK IN COMPLIANCE	
BMA Lumberton	5/6/2015	Yes	5/29/2015
BMA East Charlotte	8/11/2015	Yes	9/9/2015
RAI West College-Warsaw	3/15/2016	Yes	4/11/2016

Based on a review of this certificate of need application and publicly available information, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

Catawba County Dialysis. In Section B-4, pages 8-9, the applicant discusses the methods it uses to ensure and maintain quality.

In Section A.11, page 5, and Exhibit O-3, the applicant states that out of the 70 facilities located in North Carolina operated by the applicant only the four listed below were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application.

DVA Quality Care			
Facility	Survey Date	Back in Compliance	
Southeastern Dialysis Center-Kenansville	3/22/2016	Yes	6/10/2016
Durham Dialysis	3/22/2016	Yes	5/31/2016
Marshville Dialysis	2/29/2016	Yes	4/15/2016
Durham West Dialysis	10/7/2015*	Yes	9/30/2015

*Back in compliance prior to survey on 10/7/2015 per the applicant in Project I.D. # P-11248-16

Based on a review of the information in the application and publicly available information, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may

vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

FMC Hickory
FMC Catawba Valley
Catawba County Dialysis

The applications are conforming with 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- **FMC Hickory** is an existing facility.

-NA- **FMC Catawba Valley** is an existing facility.

-C- **Catawba County Dialysis.** In Section C, pages 13-17, the applicant adequately demonstrates that Catawba County Dialysis projects to serve a total of 34 in-center patients at the end of OY1 (7/1/18 – 6/30/19) for a utilization rate of 85.00% or 3.4 patients per station per week (34 patients / 10 stations = 3.4/ 4 = .85 or 85.00%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(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 Hickory.** In Section C, pages 17-21, the applicant demonstrates that FMC Hickory will serve a total of 134 in-center patients at the end of OY1 (CY2018) for a utilization rate of 95.71% or 3.83 patients per station per week (134 patients / 35 stations

= $3.8286 / 4 = .9571$ or 95.71%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

-C- **FMC Catawba Valley.** In Section C, pages 17-20, the applicant demonstrates that FMC Catawba Valley will serve a total of 77 in-center patients at the end of OY1 (CY2018) for a utilization rate of 83.69% or 3.35 patients per station per week ($77 \text{ patients} / 23 \text{ stations} = 3.3478 / 4 = .8369$ or 83.69%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

-NA- **Catawba County Dialysis** is not an existing facility.

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

-C- **FMC Hickory.** In Section C, pages 17-21, 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.

-C- **FMC Catawba Valley.** In Section C, pages 17-20, 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.

-C- **Catawba County Dialysis.** In Section C, pages 13-17, 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.

COMPARATIVE ANALYSIS

Pursuant to N.C. Gen. Stat. §131E-183(a) (1), the 2016 State Medical Facilities Plan (2016 SMFP) and the July 2016 SDR, no more than 10 dialysis stations may be approved in this review for Catawba County. The three applicants applied for a total of 20 dialysis stations. The analyst considered all of the information in each application and reviewed each application individually against all applicable review criteria and the analyst conducted a comparative analysis of the proposals. Based on that review and for the reasons set forth below and in the rest of the findings, the application submitted by Catawba County Dialysis, Project I.D. #E-11261-16, is approved and the applications submitted by FMC Hickory, Project I.D. #E-11234-16, and FMC Catawba Valley, Project I.D. # E-11238-16, are denied.

SMFP Principles

Basic Principle 12 regarding the Availability of Dialysis Care as contained in Chapter 14, page 371 of the 2016 SMFP states:

“The NC State Health Coordinating Council encourages applicants for dialysis stations to provide or arrange for:

- a. Home training and backup for patients suitable for home dialysis in the ESRD dialysis facility or in a facility that is a reasonable distance from the patient’s residence;*
- b. ESRD dialysis service availability at times that do not interfere with ESRD patients’ work schedules;*
- c. Services in rural, remote areas.”*

a) Home Training

FMC Hickory - In Section I, page 46, the applicant states, *“Patients who desire to perform home hemodialysis will be referred to the FMC Hickory home training program for training and support. Patients who desire to perform home peritoneal dialysis will be referred to the FMC Hickory Home Program facility for training and support. Patients who are candidates for home dialysis are referred by their attending nephrologists. The facility will provide back-up hemodialysis treatments to any home patient in need of temporary hemodialysis.”* In Section C, page 17, the applicant states that FMC Hickory is not certified *“to provide home peritoneal dialysis training and support... Patients who might be candidates for home peritoneal dialysis are referred to the FMC Hickory Home Program for peritoneal dialysis training and support. Both facilities are located at 1899 Tate Blvd, SE, in Hickory.”*

FMC Catawba Valley - In Section I, page 44, the applicant states, *“Patients who desire to perform home hemodialysis will be referred to the FMC Hickory facility for training and support. Patients who desire to perform home peritoneal dialysis will be referred to the FMC Hickory Home Program facility for training and support. Patients who are candidates for home dialysis are referred by their attending nephrologists. The facility will provide back-up hemodialysis treatments to any home patient in need of temporary hemodialysis.”* In Section C, page 17, the

applicant states that FMC Catawba Valley is “*not certified to provide home dialysis training and support...The facility does not have the physical plant capacity to add home training.*”

Catawba County Dialysis - In Section C, page 13, the applicant states “*The facility will house the ... peritoneal dialysis and home hemodialysis.*” In Section I, page 40, the applicant states “*For the proposed project, Catawba County Dialysis will provide protocols and routines for patient follow-up.*”

With respect to home training, **Catawba County Dialysis** is the most effective alternative because it proposes to offer both home training for hemodialysis and peritoneal dialysis, including follow-up. **FMC Hickory** is an equally effective alternative because it offers patients home hemodialysis and refers peritoneal dialysis patients to another BMA facility located at the same address as FMC Hickory. FMC Catawba Valley does not offer either home hemodialysis or peritoneal dialysis. Patients who dialyze at home are referred to FMC Hickory or FMC Hickory Home Program, respectively. Therefore, **FMC Catawba Valley** is a less effective alternative with respect to home training.

b) Hours of availability

FMC Hickory – In Section H, page 43, the applicant states dialysis services will be available from 6:00 AM to 5:00 PM, Monday through Saturday, for a total of 11 hours per day/ 66 hours per week. However, on page 44, the applicant provides conflicting information regarding hours of operation. On page 43, total hours per year is reported to be 3,432. But on page 44, total hours per year is reported to be only 3,120. FMC Hickory does not propose a third shift.

FMC Catawba Valley – In Section H, page 41, the applicant states dialysis services will be available from 6:00 AM to 5:00 PM, Monday through Saturday, for a total of 11 hours per day/ 66 hours per week. However, on page 42, the applicant provides conflicting information regarding hours of operation. On page 41, total hours per year is reported to be 3,432. But on page 42, total hours per year is reported to be only 3,120. FMC Catawba Valley does not propose a third shift.

Catawba County Dialysis – In Section H, page 37, the applicant states dialysis services will be available from 6:00 AM to 4:00 PM, Monday through Saturday, a total of 10 hours per day/ 60 hours per week or 3,120 hours per year [10 x 6 x 52 = 3,210]. Catawba County Dialysis does not propose a third shift.

All the applicants propose to offer both a first and second shift, and are scheduled to be open at least 10 hours per day, six days a week, 52 weeks per year. None of the applicants propose a third shift. With regard to hours of availability, all applications are equally effective alternatives.

c) Services in rural, remote areas

Catawba County is a rural, remote area. All applications are equally effective with regard to providing services in rural, remote areas.

Facility Location

All applicants propose locations in Catawba County. FMC Hickory and FMC Catawba Valley are existing facilities located approximately three miles apart. The approved FKC Newton facility is approximately 10.7 miles from FMC Hickory. According to Google Maps, the location of the proposed Catawba County Dialysis facility is only 2.9 miles from the FMC Hickory facility (in the direction of the approved FKC Newton facility) and 5.4 miles from the FMC Catawba Valley facility. In regards to facility location, both the primary and secondary sites identified by Catawba County Dialysis are adequate for the proposed facility. With regard to location, all the applications are equally effective alternatives.

Access by Underserved Groups

The following table compares the payor mix for Medicare, Medicaid and Self Pay/Indigent/Charity Care for the entire facility during OY2 as reported by the applicants in Section L.

	Medicare (Including Medicare/ Commercial)	Medicaid	Combined Medicare/Medicaid	Self Pay/Indigent/Charity	Total
FMC Hickory*	88.67%	1.92%	90.59%	2.93%	93.52%
FMC Catawba Valley*	85.34%	8.68%	94.02%	0.00%	94.02%
Catawba County Dialysis	87.80%	2.10%	90.30%	2.30%	93.20%

*The applicant indicates that its percentages are percentage of revenue, not percentage of patients. Catawba County Dialysis reports percentage of patients, as requested.

FMC Hickory – In Section L, page 55, the applicant states that 90.59% of its in-center patients will have some or all of their services covered by Medicare or Medicaid. The applicant states “... *Medicare represented 81.38% of North Carolina dialysis treatments in BMA facilities in FY 2015. Medicaid treatments represented an additional 4.87% of treatments in BMA facilities for FY 2015 ...*” (See page 55 of the application)

FMC Catawba Valley – In Section L, page 53, the applicant states that 94.02% of its in-center patients will have some or all of their services covered by Medicare or Medicaid. The applicant states “... *Medicare represented 81.38% of North Carolina dialysis treatments in BMA facilities in FY 2015. Medicaid treatments represented an additional 4.87% of treatments in BMA facilities for FY 2015 ...*” (See page 53 of the application)

Catawba County Dialysis – In Section L, page 51, the applicant states that 90.3% of its in-center patients will have some or all of their *services* covered by Medicare or Medicaid. On page 51, the applicant states “*Since DaVita does not operate any dialysis facilities in Catawba County or any other counties contiguous to Catawba County, we have chosen to use the weighted in-center payor mix data contained in Section L, page 71 (Exhibit L-1(b)) of the Fresenius Kidney Care Newton CON application that was submitted on July 15, 2016 and the home training payor mix contained in the FMC Hickory Home Training CON application Required State Agency Findings on page 13 (Exhibit L-1(b)).* The applicant’s assumptions are reasonable and adequately supported.

As illustrated in the table above, **FMC Hickory** and **Catawba County Dialysis** are equally effective alternatives with regards to service to underserved groups. **FMC Catawba Valley** proposes a higher Medicare/Medicaid percentage compared to FMC Hickory and Catawba County Dialysis, while FMC Catawba Valley projects 0.00% for the payor category Self Pay/ Indigent/ Charity. However, the two BMA applications report percentage of revenue while Catawba County Dialysis reports percentages of patients, as requested. While a comparison was done, it is not conclusive given the different bases for the percentages. Therefore, with regard to access by underserved groups, all the applications are equally effective alternatives.

Access to Ancillary and Support Services

FMC Hickory - In Section I, page 45, the applicant identifies the necessary ancillary and support services and indicates how they are or will be made available. The applicant discusses coordination with the existing health care system on pages 45-47. In Exhibits I-1 to I-4, the applicant documents how the project will be coordinated with the existing health care system. On page 47, the applicant states *“As an existing dialysis provide [sic] in Catawba County, the facility has successful relationships with both Frye Regional Medical Center and Catawba Valley Medical Center. In addition, the facility has agreements for both hospital affiliation and transplant programs.”*

FMC Catawba Valley - In Section I, page 43, the applicant identifies the necessary ancillary and support services and indicates how they are or will be made available. The applicant discusses coordination with the existing health care system on pages 43-45. In Exhibits I-1 to I-4, the applicant documents how the project will be coordinated with the existing health care system. On page 45, the applicant states *“As an existing dialysis provide [sic] in Catawba County, the facility has successful relationships with both Frye Regional Medical Center and Catawba Valley Medical Center. In addition, the facility has agreements for both hospital affiliation and transplant programs.”*

Catawba County Dialysis - In Section I, page 39, the applicant identifies the necessary ancillary and support services and indicates how they will be made available. The applicant discusses coordination with the existing health care system on pages 40-42. In Exhibits I-1 to I-4, the applicant documents how the project will be coordinated with the existing health care system. Dr. Greg Pisel of Hickory Adult Medicine and Kidney Specialists has agreed to serve as Medical Director. On pages 41-42, the applicant states that its Division Vice President, Director of Healthcare Planning and Group Facility Administrator met with Dr. Greg Pisel and staff at Hickory Adult Medicine and Kidney Specialists, Ann Peele, Executive Director of the Family Guidance Center in Hickory, several nursing homes, two transportation agencies and the Vocational Rehabilitation office in Hickory and that Catawba Valley Medical Center, Catawba Valley Technical College and Frye Regional Hospital have all been contacted. The applicant also states that *“224 patients of Dr. Pisel have been contacted and have provided support letters for the project. ... Forty-five of those letters can be found in Exhibit C-1.”*

With regard to access to ancillary and support services, all the applications are equally effective alternatives.

Service to Catawba County Residents

According to Table B in the July 2016 SDR, there were a total of 245 residents of Catawba County on dialysis, including 34 home patients. Thus there were 211 IC patients. As of that same date, FMC Hickory was serving 107 Catawba IC dialysis patients and FMC Catawba Valley was serving 88. Thus, 195 ($107 + 88 = 195$) of the 211 Catawba County IC dialysis patients were being served by a BMA facility in Catawba County. The remaining 16 Catawba County IC dialysis patients ($211 - 195 = 16$) were utilizing a facility in another county.

Catawba County Dialysis, in Exhibit C, provides 45 signed letters from current Catawba County residents utilizing in-center dialysis who are patients of Dr. Pisel, the proposed medical director. In each letter, the patient stated that, if Catawba County Dialysis is approved, they would consider transferring there.

With regard to service to Catawba County residents, all the applications are equally effective alternatives.

Access to Alternative Providers

BMA owns and operates both FMC Hickory and FMC Catawba Valley, the only two existing dialysis facilities in Catawba County and is approved to develop FKC Newton by relocating six stations from each of the existing facilities.

There are no alternate providers in Catawba County. Approval of Catawba County Dialysis, which is ultimately owned by DaVita, would introduce an alternative provider.

Therefore, with regard to providing Catawba County dialysis patients access to an alternative provider, the proposal submitted by Catawba County Dialysis is the more effective alternative.

Revenues and Operating Costs

In Section R of the application, each applicant projects the revenues and operating costs for the first two operating years of the proposed project, as shown in the tables below. Generally, the application proposing the lowest average net revenue per treatment and the lowest average operating cost per treatment is the most effective alternative.

Average Net Revenue Per Treatment

FMC HICKORY	YEAR ONE	YEAR TWO
Projected Net Revenue	\$8,225,471	\$9,634,609
# In-Center/HH Treatments	20,599	22,038
Average Net Revenue per Treatment	\$399.31	\$437.18

FMC CATAWBA VALLEY	YEAR ONE	YEAR TWO
Projected Net Revenue	\$4,076,943	\$4,348,739
# In-Center Treatments	11,116	11,856
Average Net Revenue per Treatment	366.76	366.79

CATAWBA COUNTY DIALYSIS	YEAR ONE	YEAR TWO
Projected Net Revenue	\$1,628,838	\$1,873,678
Treatments	5,635	6,079
Average Net Revenue per Treatment	\$289.06	\$308.22

Catawba County Dialysis projects the lowest average net revenue per treatment. With regard to average net revenue per treatment, Catawba County Dialysis is the most effective alternative.

Average Operating Cost Per Treatment

FMC HICKORY	YEAR ONE	YEAR TWO
Projected Operating Costs	\$6,249,884	\$6,957,038
#In-Center/HH Treatments	20,599	22,038
Average Operating Cost per Treatment	\$303.41	\$315.68

FMC CATAWBA VALLEY	YEAR ONE	YEAR TWO
Projected Operating Costs	\$3,091,071	\$3,258,307
# In-Center Treatments	11,116	11,856
Average Operating Cost per Treatment	\$278.07	\$274.82

CATAWBA COUNTY DIALYSIS	YEAR ONE	YEAR TWO
Projected Operating Costs	\$1,582,000	\$1,721,258
# In-Center/PD Treatments	5,635	6,079
Average Operating Cost per Treatment	\$280.75	\$283.15

FMC Catawba Valley projects the lowest average operating cost per treatment but Catawba County Dialysis' projected average operating cost per treatment is only \$8.33 more or 3.0% ($\$283.15 - \$274.82 = \8.33; $\$8.33/\$274.82 = 0.03$). With regard to average operating cost per treatment, FMC Catawba Valley and Catawba County Dialysis are equally effective alternatives.

Staffing

Direct Care Staff Salaries

The following table illustrates projected annual salaries during Year Two for direct care staff (registered nurses and technicians) as reported in Section H of the respective applications.

POSITION	FMC HICKORY	FMC CATAWBA VALLEY	CATAWBA COUNTY DIALYSIS
Registered Nurse	\$68,345	\$68,754	\$72,120
Home Training Nurse	\$66,004	na	\$72,120
Technicians	\$33,525	\$33,525	\$27,318

Catawba County Dialysis projects the higher annual salary for registered nurses and Home Training Nurse and FMC Hickory and FMC Catawba Valley project a higher annual salary for technicians. With regard to salaries for direct care staff, all three applications are comparable.

Availability of Staff and Medical Director

All applicants projected sufficient shifts and a sufficient number of direct care staff for the projected number of patients to be served in Year Two. Each has budgeted sufficient staff salaries. See discussion in Criterion (7).

FMC Hickory has identified Dr. David Harvey as its medical director. Dr. Harvey is currently the medical director for FMC Hickory and has agreed to continue serving in that capacity.

FMC Catawba Valley has identified Dr. Richard Paul as its medical director. Dr. Paul is currently the medical director of FMC Catawba Valley and has agreed to continue serving in that capacity.

Catawba County Dialysis has identified Dr. Greg Pisel as its proposed medical director. Dr. Pisel is a nephrologist at Hickory Adult Medicine and Kidney Specialists, P.A. whose office is located in Hickory. In Exhibit I-3, the applicant provides a copy of an August 2016 letter signed by Dr. Pisel, confirming his commitment to serve as Medical Director.

The three applications are comparable with regard to the availability of staff and a medical director.

SUMMARY

All applications were determined to be conforming with all applicable statutory and regulatory review criteria.

For each of the comparative analysis factors listed below, the applications were determined to be equally effective:

- Hours of Availability
- Services in Rural, Remote Areas
- Facility Location
- Access to Ancillary and Support Services
- Service to Catawba County Residents
- Availability of Staff and Medical Director
- Access by Underserved Groups

For each of the comparative analysis factors listed below, the application submitted by **FMC Hickory** was determined to be the most effective alternative.

- Highest Technician Salary

For each of the comparative analysis factors listed below, the application submitted by **FMC Catawba Valley** was determined to be the most effective alternative.

- Highest Technician Salary

For each of the comparative analysis factors listed below, the application submitted by **Catawba County Dialysis** was determined to be the more effective alternative.

- Access to Alternative Providers
- Average Net Revenue per Treatment
- Highest Registered Nurse Salary

CONCLUSION

N.C. Gen. Stat. §131E-183(a) (1) states that the need determination in the SMFP is the determinative limit on the number of dialysis stations that can be approved in this review. The CON Section determined that the application submitted by Catawba County Dialysis, Project I.D. # E-11261-16, is the most effective alternative proposed in this review for 10 dialysis stations in Catawba County and that application is approved as conditioned below. The approval of either the FMC Hickory application and/or the FMC Catawba Valley application and/or a portion of either application would result in the approval of dialysis stations in Catawba County in excess of the county need determination in the 2016 SMFP and July 2016 SDR and therefore, the FMC Hickory and FMC Catawba Valley applications are both denied.

The application submitted by Catawba County Dialysis is approved subject to the following conditions.

- 1. Total Renal Care of North Carolina, LLC d/b/a Catawba County Dialysis shall materially comply with all representations made in its certificate of need application.**
- 2. Total Renal Care of North Carolina, LLC d/b/a Catawba County Dialysis shall develop and be certified for no more than ten dialysis stations upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
- 3. Total Renal Care of North Carolina, LLC d/b/a Catawba County Dialysis shall install plumbing and electrical wiring through the walls for no more than ten dialysis stations, which shall include any home hemodialysis training or isolation stations.**
- 4. Total Renal Care of North Carolina, LLC d/b/a Catawba County Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**