## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: June 1, 2017
Findings Date: June 1, 2017

Project Analyst: Gloria C. Hale
Team Leader: Fatimah Wilson

Project ID #: F-11306-17
Facility: FMC Charlotte
FID #: 955947
County: Mecklenburg
Applicant: Bio-Medical Applications of North Carolina, Inc.
Project: Add 7 dialysis stations for a total of 44 stations upon completion of this project, and Project I.D. #F-11099-15 (relocate 6 stations to FMC Aldersgate)

## REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte proposes to add seven dialysis stations for a total of 44 certified dialysis stations upon completion of this project and Project I.D. #F-11099-15 (relocate six stations to FMC Aldersgate).

**Need Determination**

The 2017 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for Mecklenburg County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for FMC Charlotte in the January 2017 SDR is 3.49 patients per station per week. This utilization rate was calculated based on 150

in-center dialysis patients and 43 certified dialysis stations as of June 30, 2016 (150 patients /43 stations = 3.49 patients per station per week). Application of the facility need methodology indicates that seven additional stations are needed for this facility, as illustrated in the following table.

| **APRIL 1 REVIEW-JANUARY SDR** | | |
|---|---|---|
| Required SDR Utilization | | 80% |
| Center Utilization Rate as of 6/30/16 | | 87.21% |
| Certified Stations | | 43 |
| Pending Stations | | 0 |
| **Total Existing and Pending Stations** | | **43** |
| In-Center Patients as of 6/30/16 (SDR2) | | 150 |
| In-Center Patients as of 12/31/15 (SDR1) | | 142 |
| **Step** | **Description** | **Result** |
| (i) | Difference (SDR2 - SDR1) | 8 |
| | Multiply the difference by 2 for the projected net in-center change | 16 |
| | Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/15 | .1127 |
| (ii) | Divide the result of step (i) by 12 | .0094 |
| (iii) | Multiply the result of step (ii) by 6 (the number of months from 6/30/16 until 12/31/16) | .0564 |
| (iv) | Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2 | 158.4600 |
| (v) | Divide the result of step (iv) by 3.2 patients per station | 49.5188 |
| | and subtract the number of certified and pending stations to determine the number of stations needed | **6.5188** |

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is seven stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the January 2017 SDR. Step (C) of the facility need methodology states, *"The facility may apply to expand to meet the need established …, up to a maximum of ten stations."* The applicant proposes to add seven new stations and, therefore, is consistent with the facility need determination for dialysis stations.

**Policies**

There is one policy in the 2017 SMFP which is applicable to this review: *Policy GEN-3: Basic Principles*. *Policy GEN-3*, on page 33, 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."*

The applicant addresses *Policy GEN-3* as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), page 12, Section O, pages 65-67, and Exhibit O-1. 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(b), page 13, Section L, pages 57-58, and Exhibit L-1. 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(c) and (d), pages 14-15, Section C, pages 18-21, and Section N, page 63. 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.

**Conclusion**

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the January 2017 SDR and with *Policy GEN-3: Basic Principles*. Therefore, the application is conforming to this criterion.

(2) Repealed effective January 1, 1987.

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte proposes to add seven dialysis stations for a total of 44 certified dialysis stations upon completion of this project and Project I.D. #F-11099-15 (relocate six stations to FMC Aldersgate).

## Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis stations as "*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*" Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 25, the applicant provides the historical in-center, home hemodialysis (HH), and peritoneal dialysis (PD) patient origin for FMC Charlotte as of December 31, 2016, which is summarized in the following table:

**FMC Charlotte**
**Historical Patient Origin**
**December 31, 2016**

| County | In-Center Patients | HH Patients | PD Patients |
|---|---|---|---|
| Mecklenburg | 149 | 24 | 47 |
| Cabarrus | 0 | 1 | 2 |
| Gaston | 1 | 1 | 3 |
| Rowan | 0 | 0 | 1 |
| Stanly | 0 | 0 | 1 |
| Union | 3 | 3 | 6 |
| South Carolina | 1 | 3 | 1 |
| Other States | 2 | 0 | 0 |
| **TOTAL** | **156** | **32** | **61** |

In Section C.1, page 18, the applicant provides the projected patient origin for FMC Charlotte for operating year one (OY1), Calendar Year (CY) 2018, and OY2, CY2019, following completion of the project, as follows:

**FMC Charlotte**
**Projected Patient Origin**

| | OY1 | | | OY2 | | | County Patients as a Percent of Total | |
|---|---|---|---|---|---|---|---|---|
| **County** | **In-Center Patients** | **HH Patients** | **PD Patients** | **In-Center Patients** | **HH Patients** | **PD Patients** | **OY1 CY2018** | **OY2 CY2019** |
| Mecklenburg | 145.3 | 26.5 | 51.8 | 152.5 | 27.8 | 54.4 | 89.2% | 89.7% |
| Cabarrus | 0.0 | 1.0 | 2.0 | 0.0 | 1.0 | 2.0 | 1.2% | 1.1% |
| Gaston | 1.0 | 1.0 | 3.0 | 1.0 | 1.0 | 3.0 | 2.0% | 1.9% |
| Rowan | 0.0 | 0.0 | 1.0 | 0.0 | 0.0 | 1.0 | 0.4% | 0.4% |
| Stanly | 0.0 | 0.0 | 1.0 | 0.0 | 0.0 | 1.0 | 0.4% | 0.4% |
| Union | 3.0 | 3.0 | 6.0 | 3.0 | 3.0 | 6.0 | 4.8% | 4.6% |
| South Carolina | 1.0 | 3.0 | 1.0 | 1.0 | 3.0 | 1.0 | 2.0% | 1.9% |
| **TOTAL** | **150.3** | **34.5** | **65.8** | **157.5** | **35.8** | **68.4** | **100.0%** | **100.0%** |

The applicant provides the assumptions and methodologies used to project in-center, HH, and PD patient origin in Section C.1, pages 18-21. The applicant adequately identifies the population to be served.

## Analysis of Need

In Section B.4, page 12, the applicant states the application is filed pursuant to the facility need methodology in the 2017 SMFP, and utilizes data from the January 2017 SDR to apply the facility need methodology, in Section B.2, page 10, to demonstrate how the facility qualifies for seven additional stations. In Section C.1, pages 18-19, the applicant provides the following assumptions for projecting in-center patients:

1. The current patient population at FMC Charlotte and who reside in Mecklenburg County are a part of the Mecklenburg County ESRD patient population as a whole and as such will increase at the Five Year Average Annual Change Rate (AACR) for Mecklenburg County of 5.0% as published in the January 2017 SDR.

2. The two patients from other states are transient patients and therefore will not be projected to dialyze at FMC Charlotte. The remaining patients who are not from Mecklenburg County will be added, however no growth is calculated for these patients.

3. Eight patients are projected to transfer from FMC Charlotte to Fresenius Medical Care (FMC) Regal Oaks (Project I.D. #F-10369-15) upon completion of that project. Therefore, eight patients will be subtracted from FMC Charlotte on June 30, 2017.

4. Ten patients will transfer from FMC Charlotte to FMC Aldersgate (Project I.D. #F-11099-15) upon completion of that project. Therefore, 10 patients will be subtracted from FMC Charlotte on December 31, 2017.

5. The proposed project is to be completed on December 31, 2017.

6. The applicant states that OY1 will be Calendar Year (CY) 2018 and OY2 will be CY 2019.

*Projected Utilization of In-Center Patients*

The applicant provides its methodology for projecting utilization for in-center patients for OY1 and OY2, in Section C.1, page 20, as follows:

| | In-Center Patients |
|---|---|
| The applicant begins with the Mecklenburg County in-patient census at the facility on December 31, 2016. | 149 |
| The Mecklenburg County in-center patient census is projected forward six months to June 30, 2017, increased by one-half the Five Year AACR for Mecklenburg County of 5%. | {149 x (0.05/12 x 6)} + 149 = 152.7 |
| The applicant subtracts eight in-center patients who will transfer to FMC Regal Oaks. | 152.7 – 8 = 144.7 |
| The census of Mecklenburg County in-center patients is increased by one-half the Five Year AACR for Mecklenburg County of 5% to project the census forward one year to December 31, 2017. | {144.7 x (0.05/12 x 6)} + 144.7 = 148.3 |
| The applicant subtracts 10 patients projected to transfer to FMC Aldersgate. | 148.3 – 10 = 138.3 |
| The applicant adds the five patients from Gaston and Union counties and South Carolina. This is the starting census for OY1. | 138.3 + 5 = 143.3 |
| The census of Mecklenburg County in-center patients is increased by the Five Year AACR for Mecklenburg County of 5% to project the census forward one year to December 31, 2018. | (138.3 x 0.05) + 138.3 = 145.2 |
| The applicant adds the five patients from Gaston and Union counties and South Carolina. This is the ending census for OY1. | 145.2 + 5 = 150.2 |
| The census of Mecklenburg County in-center patients only is projected forward one year and increased by the Five Year AACR for Mecklenburg County of 5% to December 31, 2019. | (145.2 x 0.05) + 145.2 = 152.5 |
| The applicant adds the five patients from Gaston and Union counties and South Carolina. This is the ending census for OY2. | 152.5 + 5 = 157.5 |

The applicant states, on page 21, that it projects to serve 150 in-center patients or 3.41 patients per station per week (150 patients/ 44 dialysis stations = 3.41) by the end of OY1. Therefore, the applicant's projected utilization exceeds the minimum of 3.2 patients per

station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

*Projected Utilization of HH patients*

In Section C.1, page 21, the applicant provides the methodology for projecting in-center patients, increasing the HH patient population residing in Mecklenburg County annually by applying the AACR of 5% for Mecklenburg County and by adding HH patients residing in other counties, as follows:

| | HH Patients |
|---|---|
| The applicant begins with the Mecklenburg County HH patient census at the facility on December 31, 2016. | 24 |
| The Mecklenburg County HH patient census is projected forward one year to December 31, 2017, increased by the Five Year AACR for Mecklenburg County of 5%. | (24 x 0.05) + 24 = 25.2 |
| The census of Mecklenburg County HH patients is increased by the Five Year AACR for Mecklenburg County of 5% to project the census forward one year to December 31, 2018. | (25.2 x 0.05) + 25.2 = 26.5 |
| The applicant adds eight HH patients from other counties. This is the projected ending census for OY1. | 26.5 + 8 = 34.5 |
| The census of Mecklenburg County HH patients is increased by the Five Year AACR for Mecklenburg County of 5% to project the census forward one year to December 31, 2019. | (26.5 x 0.05) = 27.8 |
| The applicant adds eight HH patients from other counties. This is the projected ending census for OY2. | 27.8 + 8 = 35.8 |

As depicted in the table above and stated by the applicant, on page 21, it projects to serve 34 HH patients in OY1 and 35 HH patients in OY2.

*Projected Utilization of PD patients*

In Section C.1, page 21, the applicant provides the methodology for projecting PD patients, increasing the PD patient population residing in Mecklenburg County annually by applying the AACR of 5% for Mecklenburg County and by adding PD patients residing in other counties, as follows:

| | PD Patients |
|---|---|
| The applicant begins with the Mecklenburg County PD patient census at the facility on December 31, 2016. | 47 |
| The Mecklenburg County PD patient census is projected forward one year to December 31, 2017, increased by the Five Year AACR for Mecklenburg County of 5%. | (47 x 0.05) + 47 = 49.4 |
| The census of Mecklenburg County PD patients is increased by the Five Year AACR for Mecklenburg County of 5% to project the census forward one year to December 31, 2018. | (49.4 x 0.05) + 49.4 = 51.9 |
| The applicant adds 14 PD patients from other counties. This is the projected ending census for OY1. | 51.9 + 14 = 65.9 |
| The census of Mecklenburg County PD patients is increased by the Five Year AACR for Mecklenburg County of 5% to project the census forward one year to December 31, 2019. | (51.9 x 0.05) = 54.5 |
| The applicant adds 14 PD patients from other counties. This is the projected ending census for OY2. | 54.5 + 14 = 68.5 |

As depicted in the table above and stated by the applicant, on page 21, it projects to serve 65 PD patients in OY1 and 68 PD patients in OY2.

In summary, the applicant adequately identifies the patient origin and adequately demonstrates the need for seven additional dialysis stations at FMC Charlotte.

**Access**

In Section C.3, page 22, the applicant states that BMA has a long history of serving the underserved population in the state and that each facility serves *"low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons."* The applicant further states that BMA will continue to provide access to all persons, including low income and medically underinsured persons. In Section L.7, page 61, the applicant states that 75.15% of FMC Charlotte's patients were Medicare or Medicaid recipients in CY2016. In Section L.1, page 58, the applicant projects that 75% of all of FMC Charlotte's 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 seven additional stations at FMC Charlotte, and demonstrates the

extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. 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

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

CA

In Section E.1, page 29, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that the facility's projected utilization will be greater than 80% at the end of OY1, therefore maintaining the status quo would result in higher utilization rates and potentially cause admissions to be restricted. Therefore, this is not the most effective alternative.

- Apply for Fewer Stations – The applicant states that its projected utilization will exceed 3.2 patients per station, therefore adding less stations would not be appropriate. Therefore, this is not the most effective alternative.

- Relocate stations to FMC Charlotte – The applicant states it considered relocating dialysis stations from other BMA facilities in Mecklenburg County to FMC Charlotte, however all of the other facilities are operating at over 80% of capacity with the exception of the new FMC Southwest Charlotte facility. Therefore, this is not the most effective alternative.

In Section C.2, page 22, the applicant states that the projected population at FMC Charlotte has a need for the additional stations and that *"failure to add stations will lead to higher in-center utilization rates at the facility."* Therefore, the proposed alternative represented in the application is the most effective alternative to meet the identified need.

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 the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte shall materially comply with all representations made in the certificate of need application.**

2. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte shall develop and operate no more than seven additional dialysis stations for a total of no more than 44 certified stations upon completion of the project and Project I.D. #F-11099-15 (relocate six stations to FMC Aldersgate), which shall include any isolation or home hemodialysis stations.**

3. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte shall install plumbing and electrical wiring through the walls for seven additional dialysis stations for a total of no more than 44 dialysis stations which shall include any home hemodialysis training or isolation stations.**

4. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte 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.**

(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

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte proposes to add seven dialysis stations for a total of 44 certified dialysis stations upon completion of this project and Project I.D. #F-11099-15 (relocate six stations to FMC Aldersgate).

**Capital and Working Capital Costs**

In Section F.2, page 31, the applicant projects that the capital costs of the project will be $3,750 which will consist of $750 for (RO) water treatment equipment and $3,000 for other equipment and furniture. In Sections F.10-F.12, page 30, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project since FMC Charlotte is an existing facility.

**Availability of Funds**

In Section F.2, page 32, the applicant states it will finance the capital costs with accumulated reserves/owner's equity. Exhibit F-1 contains a letter dated March 15, 2017 signed by the

Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., the parent company of the applicant, which states that it has committed cash reserves in the amount of $3,750 for the proposed project. In Exhibit F-2, the applicant provides the consolidated financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries which indicates that as of December 31, 2015, it had $249,300,000 in cash and cash equivalents, $19,332,539,000 in total assets and $10,144,288,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

**Financial Feasibility**

The applicant provides pro forma financial statements for the first two years of the project in Section R. In Section R, Form C of the pro formas, the applicant provides the allowable charges per treatment for each payment source in OY1, as illustrated in the table below:

**Allowable Charges**
**OY1**

| Payor | In-Center Charge |
|---|---|
| Self Pay/Indigent/ Charity | $226.58 |
| Commercial Insurance | $1,144.06 |
| Medicare | $245.79 |
| Medicaid | $209.23 |
| Medicare/Commercial | $293.66 |
| Medicare/Medicaid | $0.00 |
| Misc. (Inc. VA) | $315.78 |

In Section R, Form C, the applicant states in its assumptions for in-center patients, PD patients, and HH patients, it uses the calculated average annual number of patients, rounded down, to calculate the respective revenues for each modality. The table below illustrates these assumptions:

| In-Center Patients | | | |
|---|---|---|---|
| Year | Beginning Census | Ending Census | Average Number of Patients Rounded Down |
| OY1 (CY2018) | 143.3 | 150.3 | 146 |
| OY2 (CY2019) | 150.3 | 157.5 | 153 |
| **PD Patients** | | | |
| OY1 (CY2018) | 63.4 | 65.8 | 64 |
| OY2 (CY2019) | 65.8 | 68.4 | 67 |
| **HH Patients** | | | |
| OY1 (CY2018) | 33.2 | 34.5 | 33 |
| OY2 (CY2019) | 34.5 | 35.8 | 35 |

The applicant provides pro forma financial statements for the first two operating years of the project following completion. In 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.

| | OY1 (CY2018) | OY2 (CY2019) |
|---|---|---|
| Total Treatments | 21,637 | 22,675 |
| Total Gross Revenues (Charges) | $143,611,868 | $150,710,508 |
| Deductions from Gross Revenues | $128,028,106 | $134,348,266 |
| Total Net Revenue | $15,583,761 | $16,362,241 |
| Total Operating Expenses (Costs) | $11.165,971 | $11,567,792 |
| **Net Income** | **$4,417,790** | **$4,794,449** |

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

**Conclusion**

In summary, the applicant adequately demonstrates 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

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte proposes to add seven dialysis stations for a total of 44 certified dialysis stations upon completion of this project and Project I.D. #F-11099-15 (relocate six stations to FMC Aldersgate).

On page 373, the 2017 SMFP defines the service area for dialysis stations as *"the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area."* Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

According to the January 2017 SDR, there are 22 dialysis facilities in Mecklenburg County. Of these, 16 are operational and six are under development. The applicant or its parent company owns and operates 11 dialysis facilities, DaVita Healthcare Partners, Inc. (DaVita) operates eight facilities, DSI Renal, Inc. (DSI) operates two facilities, and Carolinas Medical Center (CMC) operates one facility, as shown in the table below.

**Mecklenburg County Dialysis Facilities**

| Facility | Owner | Location | Number of Certified Stations | Utilization as of June 30, 2016 |
|---|---|---|---|---|
| BMA Beatties Ford | BMA | Charlotte | 32 | 98.44% |
| BMA Nations Ford | BMA | Charlotte | 28 | 100.00% |
| BMA of East Charlotte | BMA | Charlotte | 25 | 90.00% |
| BMA of North Charlotte | BMA | Charlotte | 36 | 92.36% |
| BMA West Charlotte | BMA | Charlotte | 29 | 83.62% |
| Brookshire Dialysis | DaVita | Charlotte | 0 | 0.00% |
| Carolinas Medical Center | CMC | Charlotte | 9 | 25.00% |
| Charlotte Dialysis | DaVita | Charlotte | 36 | 86.88% |
| Charlotte East Dialysis | DaVita | Charlotte | 34 | 75.00% |
| DSI Charlotte Latrobe Dialysis | DSI | Charlotte | 24 | 63.54% |
| DSI Glenwater Dialysis | DSI | Charlotte | 42 | 76.19% |
| FMC Charlotte | BMA | Charlotte | 43 | 87.21% |
| FMC Matthews | BMA | Matthews | 21 | 108.33% |
| FMC of Southwest Charlotte* | BMA | Charlotte | 0 | 0.00% |
| FMC Regal Oaks* | BMA | Charlotte | 0 | 0.00% |
| FKC Southeast Mecklenburg County* | BMA | Charlotte | 0 | 0.00% |
| FMC Aldersgate* | BMA | Charlotte | 0 | 0.00% |
| Huntersville Dialysis | DaVita | Huntersville | 10 | 75.00% |
| Mint Hill Dialysis | DaVita | Mint Hill | 16 | 71.88% |
| North Charlotte Dialysis Center | DaVita | Charlotte | 41 | 82.93% |
| South Charlotte Dialysis | DaVita | Charlotte | 22 | 88.64% |
| University City Dialysis* | DaVita | Charlotte | 10 | 0.00% |

*Facility under development.
**Facility has certified stations but is not yet operational.

As shown in the table above, all seven of BMA's operational dialysis facilities are operating above 80% utilization (3.2 patients per station per week). Four of BMA's dialysis facilities are under development. Five of the 16 operational dialysis facilities in the county are operating below 80% utilization, two DSI facilities, one CMC facility, and two DaVita facilities.

The applicant proposes to add seven dialysis stations for a total of 44 dialysis stations upon completion of the project. According to Table B in the January 2017 SDR, there is a surplus of 22 dialysis stations in Mecklenburg County. However, the applicant is applying for additional stations based on the facility need methodology. As of June 30, 2016, FMC Charlotte was serving 150 patients on 43 dialysis stations per week, which is 3.49 patients per station per week or 87.2% of capacity. The applicant does not propose to establish a new facility. In Section C.1, page 18, of the application, the applicant adequately demonstrates that FMC Charlotte will serve a total of 150 in-center patients on 44 dialysis stations at the end of OY1 (CY2018), for a utilization rate of 3.41 patients per station per week, or 85.2% of capacity (150/ 44 = 3.41; 3.41/ 4 = 85.2%). Therefore, the facility is expected to serve more

than 3.2 patients per station per week at the end of the first operating year as required by 10A NCAC 14C .2203(b). The applicant adequately demonstrates the need to develop seven additional dialysis stations at the existing facility based on the number of in-center patients it proposes to serve.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities. Therefore, the application is conforming to this criterion.

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

C

In Section H.1, page 43, the applicant provides the current and projected staffing for the facility, which will remain at 59.80 full-time equivalent (FTE) employees upon completion of the proposed project. Projected direct care staff in OY2, from Section H.7, page 46, is shown in the following table:

**FMC Charlotte**
**Direct Care Staff**
**OY2**

| Direct Care Positions | # of FTEs | Hours per Year per FTE | Total Annual FTE Hours | Total Annual Hours of Operation | #FTE Hours per Hour of Operation |
|---|---|---|---|---|---|
| RN | 9 | 2,080 | 18,720 | 4,680 | 4.00 |
| LPN | 2 | 2,080 | 4,160 | 4,680 | 0.89 |
| Patient Care Technician | 29 | 2,080 | 60,320 | 4,680 | 12.89 |
| Home Training RN | 10 | 2,080 | 20,800 | 4,680 | 4.44 |
| **Total** | 50 | 2,080 | 104,000 | 4,680 | **22.22** |

In Section H.6, page 45, the applicant states that dialysis services will be available from 7:00 AM to 10:00 PM, Monday through Saturday, however the applicant also states, on page 45, *"The facility's normal hours of operation do not include the Tuesday-Thursday-Saturday evening shift."* The applicant states that the facility will be re-opened on an on-call basis such as for a hospital-related medical emergency. The applicant's total annual hours of operation, 4,680, includes three shifts per day for a total of 15 hours per day. Therefore, the Project Analyst notes that the total hours of operation and the number of FTE hours per hour of operation reported in the table above are likely to be greater than what the facility experiences on average since the applicant states, on page 45, that re-opening for a medical emergency occurs only an average of three times weekly. In addition, the Project Analyst assumes that the full complement of direct care staffing is not required every evening or on those occasions when dialysis is needed on a medical emergency basis.

In Section H.3, page 44, the applicant states that it does not anticipate any difficulties filling staff positions and that it employs aggressive recruiting and advertising efforts to hire staff,

along with providing a range of benefits and competitive salaries to attract and maintain staff. Exhibit I-5 contains a copy of a letter from Benjamin Hippen, M.D., stating his support for the project and his willingness to continue serving as the Medical Director for the facility. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed 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

In Section I.1, page 47, the applicant includes a list of providers of the necessary ancillary and support services. Exhibits I-1, I-2 and I-3 contain copies of agreements with providers for laboratory services, hospital services, and transplants, respectively.

In Section I.3, pages 49, the applicant provides a listing of nephrologists at Metrolina Nephrology Associates who have agreed to provide medical coverage at the facility and who have expressed support for the project. In addition, the applicant states, on page 49, that BMA facilities in Charlotte and Mecklenburg County have developed relationships with the area medical community over many years. Moreover, Exhibit I-5 contains a letter from the medical director of the facility that expresses his support for the proposed project.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

NA

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

(i) would be available under a contract of at least 5 years duration;

(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;

(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective January 1, 1987.

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

NA

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

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

C

In Section L.7, page 61, the applicant reports that 75.15% of the in-center patients who received treatments at FMC Charlotte had some or all of their services paid for by Medicare or Medicaid in CY2016. The table below shows the historical (CY2016) payment source for the facility for all of the facility's patients:

| Payment Source | Total Facility |
|---|---|
| Private Pay | 2.11% |
| Commercial Insurance | 21.27% |
| Medicare | 64.77% |
| Medicaid | 5.29% |
| Misc., including VA | 1.47% |
| Medicare/Commercial Insurance | 5.09% |
| **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**** |
| Mecklenburg | 10% | 52% | 51% | 15% | 6% | 19% |
| 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 IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*[1] percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

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

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

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

C

[1] http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf
[2] http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

In Section L.3, page 59, the applicant states:

> *"BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. … The applicant will treat all patients the same regardless of race or handicap status."*

In Section L.6, page 60, the applicant states there have been no civil rights complaints filed against any BMA North Carolina facility in the past five years. Therefore, the application is conforming to this criterion.

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

C

In Section L.1(b), page 58, the applicant projects that 75.0% of all patients who will receive treatments at FMC Charlotte in OY2, CY2019, will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected OY2 payor mix for the facility for all patients:

**FMC Charlotte**
**Projected Payor Mix, OY2 (CY2019)**

| Payment Source | Percent of All Patients |
|---|---|
| Private Pay | 2.69% |
| Commercial Insurance | 20.77% |
| Medicare | 64.23% |
| Medicaid | 5.77% |
| VA | 1.54% |
| Medicare/Commercial Insurance | 5.00% |
| **Total** | **100.00%** |

In Section L.1, page 58, the applicant provides the assumptions used to project payor mix. The applicant's projected payor mix is based on the facility's recent performance. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at FMC Charlotte. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, page 60, the applicant describes the range of means by which a person will have access to the dialysis services at FMC Charlotte. Any nephrologist may apply for privileges to admit patients and they make take referrals from other nephrologists, other physicians, or hospital emergency rooms. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section M.1, page 62, the applicant states that BMA has communicated with local nursing programs, inviting them to utilize FMC Charlotte as an educational opportunity for their nursing students. Exhibit M-1 contains a copy of correspondence to Central Piedmont Community College offering FMC Charlotte as a clinical training site for the college's nursing students. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

(15) Repealed effective January 1, 1987.
(16) Repealed effective January 1, 1987.
(17) Repealed effective January 1, 1987.
(18) Repealed effective January 1, 1987.

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte proposes to add seven dialysis stations for a total of 44 certified dialysis stations upon completion of this project and Project I.D. #F-11099-15 (relocate six stations to FMC Aldersgate).

On page 373, the 2017 SMFP defines the service area for dialysis stations as *"the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area."* Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

According to the January 2017 SDR, there are 22 dialysis facilities in Mecklenburg County. Of these, 16 are operational and six are under development. A listing of these facilities is provided below:

**Mecklenburg County Dialysis Facilities**

| Facility | Owner | Location | Number of Certified Stations | Utilization as of June 30, 2016 |
|---|---|---|---|---|
| BMA Beatties Ford | BMA | Charlotte | 32 | 98.44% |
| BMA Nations Ford | BMA | Charlotte | 28 | 100.00% |
| BMA of East Charlotte | BMA | Charlotte | 25 | 90.00% |
| BMA of North Charlotte | BMA | Charlotte | 36 | 92.36% |
| BMA West Charlotte | BMA | Charlotte | 29 | 83.62% |
| Brookshire Dialysis | DaVita | Charlotte | 0 | 0.00% |
| Carolinas Medical Center | CMC | Charlotte | 9 | 25.00% |
| Charlotte Dialysis | DaVita | Charlotte | 36 | 86.88% |
| Charlotte East Dialysis | DaVita | Charlotte | 34 | 75.00% |
| DSI Charlotte Latrobe Dialysis | DSI | Charlotte | 24 | 63.54% |
| DSI Glenwater Dialysis | DSI | Charlotte | 42 | 76.19% |
| FMC Charlotte | BMA | Charlotte | 43 | 87.21% |
| FMC Matthews | BMA | Matthews | 21 | 108.33% |
| FMC of Southwest Charlotte* | BMA | Charlotte | 0 | 0.00% |
| FMC Regal Oaks* | BMA | Charlotte | 0 | 0.00% |
| FKC Southeast Mecklenburg County* | BMA | Charlotte | 0 | 0.00% |
| FMC Aldersgate* | BMA | Charlotte | 0 | 0.00% |
| Huntersville Dialysis | DaVita | Huntersville | 10 | 75.00% |
| Mint Hill Dialysis | DaVita | Mint Hill | 16 | 71.88% |
| North Charlotte Dialysis Center | DaVita | Charlotte | 41 | 82.93% |
| South Charlotte Dialysis | DaVita | Charlotte | 22 | 88.64% |
| University City Dialysis* | DaVita | Charlotte | 10 | 0.00% |

*Facility under development.
**Facility has certified stations but is not yet operational.

As shown in the table above, all seven of BMA's operational dialysis facilities are operating above 80% utilization (3.2 patients per station per week). Four of BMA's dialysis facilities are under development. Five of the 16 operational dialysis facilities in the county are operating below 80% utilization, two DSI facilities, one CMC facility, and two DaVita facilities.

In Section N.1, page 63, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

> *"BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. …In this application, BMA*

*projects that greater than 86% of the In-center patients will be relying upon government payors (Medicare /Medicaid / VA). The facility must capitalize upon every opportunity for efficiency.*

…

*This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives by offering another convenient venue for dialysis care and treatment."*

See also Sections A, B, C, H, K, L, N and O where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application 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 project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicant adequately demonstrates it will provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.

- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

(19) Repealed effective January 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina that it or an affiliated company owns and operates. In Section O.2, page 67, and Section O.3, pages 68-69, the applicant identifies three of its facilities, FMC Charlotte, BMA East Rocky Mount, and RAI West College Warsaw that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant provides documentation regarding the deficiencies and subsequent compliance with CMS Conditions for Coverage in Exhibits O-2, O-3, and in supplemental information. The applicant states, on pages 67, 69 and in supplemental information, that all three facilities are back in full compliance with

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

(21) Repealed effective January 1, 1987.

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

C

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

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

.*2203(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 Charlotte is an existing facility.

.*2203(b)* *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section C.1, page 18, the applicant projects to serve 150 in-center patients by the end of OY1, which is 3.41 patients per station per week (150/ 44 = 3.41). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

.*2203(c)* *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section C.1, pages 18-21, 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.