

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 31, 2017

Findings Date: March 31, 2017

Project Analyst: Jane Rhoe-Jones

Team Leader: Fatimah Wilson

Project ID #: L-11285-17

Facility: Fresenius Medical Care South Rocky Mount

FID #: 130370

County: Nash

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

Project: Relocate four dialysis stations from FMC Spring Hope to FMC South Rocky Mount for a total of 16 stations upon completion of this project

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a Fresenius Medical Care South Rocky Mount (FMC South Rocky Mount) proposes to relocate four dialysis stations from FMC Spring Hope to FMC South Rocky Mount for a total of 16 certified dialysis stations upon completion of this project.

Need Determination

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2017 Semiannual Dialysis Report (SDR), the county need methodology shows

there is no county need determination for Nash County. Therefore, the applicant is not eligible to apply for additional stations in its existing facility based on the county need methodology. The applicant is also not eligible to apply for additional stations in its existing facility based on the facility need methodology. The applicant does not propose to add new dialysis stations to an existing facility. Therefore, neither of the two ESRD need methodologies in the 2017 SMFP are applicable to the review.

Policies

Policy ESRD-2 is applicable to this review. Policy ESRD-2 of the 2017 SMFP states:

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

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

The applicant proposes to relocate four dialysis stations from FMC Spring Hope to FMC South Rocky Mount, both in Nash County. According to the January 2017 SDR, Table B, there is a deficit of four dialysis stations in Nash County. After the proposed relocation of four dialysis stations from FMC Spring Hope, there will still be a deficit of four dialysis stations in Nash County. The applicant adequately demonstrates that the proposal will not result in a greater deficit or surplus in the number of dialysis stations in Nash County as a result of the proposed project. Therefore, the application is conforming to Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with Policy ESRD-2. Therefore, the application is conforming to this criterion.

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

women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

BMA d/b/a FMC South Rocky Mount proposes to relocate four dialysis stations from FMC Spring Hope to FMC South Rocky Mount for a total of 16 certified dialysis stations upon completion of this project.

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 Nash County. Facilities may serve residents of counties not included in their service area.

In Section C-8, page 24, the applicant provides the historical patient origin for FMC South Rocky Mount in-center (IC), home hemodialysis (HH) and peritoneal dialysis (PD) patients as of December 31, 2016, which is summarized in the following table:

FMC SOUTH ROCKY MOUNT as of December 31, 2016				
County of Residence	IC Patients	HH Patients	PD Patients	Percent In-Center
Nash	33	1	3	75.0%
Edgecombe	11	2	3	25.0%
TOTAL	44	3	6	100.0%

In Section C-1, page 18, the applicant provides the projected patient origin for FMC South Rocky Mount for the first two years of operation following completion of the project as follows:

FMC SOUTH ROCKY MOUNT						
	OPERATING YEAR 1 CY2018		OPERATING YEAR 2 CY2019		COUNTY PATIENTS AS A PERCENT OF TOTAL IN-CENTER	
	IN-CENTER	HOME*	IN-CENTER	HOME*	YEAR 1	YEAR 2
Nash	42.1	4.8	46.3	5.3	76.4%	78.0%
Edgecombe	12	5	12	5	21.7%	20.2%
Wilson	1	0	1	0	1.8%	1.7%
TOTAL	55.1	9.8	59.3	10.3	100.0%	100.0%

*The “Home” category includes both hemodialysis and peritoneal dialysis patients.

As shown in the table above, the applicant projects to serve one patient from Wilson County at the FMC South Rocky Mount facility upon project completion. The applicant was not serving any Wilson County patients as of December 31, 2016. In Exhibit C-1, the applicant

includes a letter of support from the Wilson County patient stating their intent to transfer their dialysis care to the FMC South Rocky Mount facility upon project completion. The Wilson County patient lives in Zip Code 27822 (Elm City) and currently dialyzes at FMC Spring Hope. The patient states, “*Since the location of FMC South Rocky Mount is closer to my residence location, it would be more convenient for me than my current dialysis facility. Dialyzing at the new location would mean less time involved in transportation ...*” Elm City is 30 minutes/21.4 miles to 43 minutes/32.4 miles distance from FMC Spring Hope (patient’s current dialysis facility) and 10 minutes/7.4 miles distance from FMC South Rocky Mount (patient’s proposed dialysis facility). [MapQuest]

The applicant provides the assumptions and methodology used to project patient origin on pages 18-20. The applicant adequately identifies the population to be served.

Analysis of Need

In Section C-2, page 21, the applicant describes the need for the proposed project as follows:

“BMA has begun projections of the patient population to be served with the existing patients of FMC South Rocky Mount and a projection of four patients who will transfer their care to the FMC South Rocky Mount facility. Letters of support from four patients who will transfer their care are included in Exhibit C-1. Within this application, BMA has projected a patient population of 55.1 rounded down to 55 in-center patients, to be dialyzing at the FMC South Rocky Mount facility at the end of the first year. Utilization by 55 patients on 16 dialysis stations is calculated to be 3.4375 patients per station, or 85.94% utilization.

This application is for relocation of existing in-center dialysis stations to FMC South Rocky Mount. Thus, this application will not impact the home dialysis patient population of FMC South Rocky Mount.

The patient population projected to utilize the FMC South Rocky Mount facility indeed has a need for the stations at this location. The need of this population for the proposed services is a function of the individual patient need for dialysis care and treatment.”

The applicant is eligible to relocate stations to the FMC South Rocky Mount facility based on Policy ESRD-2.

Projected In-center Utilization

The applicant projects that Operating Years One and Two for the proposed project will be CY2018 and CY2019, respectively. In Section C-1, page 19, the applicant provides its methodology for projecting IC utilization as follows:

FMC SOUTH ROCKY MOUNT IN-CENTER OY1 & OY2 CY2018 & CY2019	
In-center Methodology:	
BMA begins with the facility census of Nash County patients as of December 31, 2016.	33
BMA projects this census forward one year to December 31, 2017.	$(33 \times .10) + 33 = 36.3$
BMA adds the 2 patients residing in Nash County and expected to transfer their care to the facility upon project completion.	$36.3 + 2 = 38.3$
Add the 11 patients currently dialyzing at the facility, residing in Edgecombe County.	$38.3 + 11 = 49.3$
Add the 2 patients from Edgecombe and Wilson Counties. This is the starting census for Operating Year 1.	$49.3 + 2 = 51.3$
BMA projects this Nash County patient population forward for 12 months to December 31, 2018.	$(51.3 \times .10) + 51.3 = 56.63$
Add the 13 patients from Edgecombe and Wilson Counties. This is the ending census for Operating Year 1.	$56.63 + 13 = 69.63$
BMA projects this Nash County patient population forward for 12 months to December 31, 2019.	$(69.63 \times .10) + 69.63 = 75.593$
Add the 13 patients from Edgecombe and Wilson Counties. This is the ending census for Operating Year 2.	$75.593 + 13 = 88.593$

In Section C-1, pages 18-19, the applicant states its in-center assumptions as follows:

1. *BMA assumes that the FMC South Rocky Mount patient population of Nash County residents is increasing at a rate equal to the Nash County Five Year Average Annual Change Rate [AACR]. That rate is 10.0% as published in the January 2017 SDR.*
2. *BMA has included four patient letters of support for this project. These four patients are dialyzing at FMC Spring Hope (in Nash County). Based upon the patient support letters, BMA is projecting that these patients will transfer to the FMC South Rocky Mount facility once the project is completed and stations certified. In projections of future patient populations BMA will reflect these transfers to be effective December 31, 2017.*
3. *The January 2017 SDR does not report a census at the FMC South Rocky Mount facility census [sic] (for June 30, 2016). FMC South Rocky Mount was not certified until August 10, 2016.*
4. *The ESRD Data Collections Forms for the period ended December 31, 2016 indicate that the FMC South Rocky Mount census was 44 patients. These ESRD Forms are due to DHR Healthcare Planning not later than February 24, 2016, [2017] after the beginning of the review period for this application. Thus, the forms will be available to the CON Project Analyst from Agency staff during the pendency of the review for this application.*
5. *Of the 44 in-center patients at FMC South Rocky Mount as of December 31, 2016, 11 patients resided in other counties. BMA will not demonstrate any growth of this*

segment of the patient population, but will add these 11 patients at appropriate points in time.

6. *BMA plans this project for completion by December 31, 2017.*

<i>Last Operating Year:</i>	<i>August 10 – December 31, 2016*</i>
<i>Interim Year 1:</i>	<i>January 1 – December 31, 2017</i>
<i>Operating Year 1:</i>	<i>January 1 – December 31, 2018</i>
<i>Operating Year 2:</i>	<i>January 1 – December 31, 2019”</i>

*The applicant states that the initial certification for FMC South Rocky Mount was completed on August 10, 2016. The facility does not have a complete 12 month operations history to report.

The applicant projects to serve 55 in-center patients or 3.4 patients per station per week ($55/16 = 3.4$) by the end of Operating Year 1 and 59 in-center patients or 3.7 patients per station per week ($59/16 = 3.7$) by the end of Operating Year 2 for the proposed 16-station facility. This satisfies 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).

In this application, the applicant assumes a projected annual rate of growth of 10% for the Nash County dialysis patient census, which is consistent with the Nash County Five Year Average Annual Change Rate (2011-2015 – Source: January 2017 SDR). The applicant states it rounded the calculation of patients down to the whole patient. Exhibit C-1 contains copies of letters, dated December 2016, from four in-center patients who are currently receiving dialysis services at FMC Spring Hope and who are expressing support for the proposed project and their intention to consider utilizing the FMC South Rocky Mount facility. The four in-center patients who provided the letters of support in Exhibit C-1 identify themselves as residents of Edgecombe (1), Nash (2) and Wilson (1) counties.

Home Hemodialysis and Peritoneal Dialysis Utilization

The applicant currently provides HH and PD treatment. In Section C-8, page 24, the applicant provides historical utilization for HH and PD. In Section C-1, page 20, the applicant provides the projected utilization for HH and PD and the assumptions and methodology used to project utilization.

Projected utilization for in-center and home hemodialysis and peritoneal dialysis are based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section L-1(a), pages 59-60, the applicant states that each of BMA’s 107 facilities in 46 North Carolina Counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons. In Section L-7, page 63, the applicant provides the historical payor mixes for FMC South Rocky Mount and FMC Spring Hope. In FY 2016, the applicant reports that 88.4% of its total patients at FMC

South Rocky Mount had some or all of their services paid for by Medicare or Medicaid; while 91.3% of the total patients at FMC Spring Hope had some or all of their services paid for by Medicare or Medicaid. Form C, pages 81-82, shows the applicant projects that 94% of the projected in-center patients at will have some or all of their services paid for by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for four additional stations at FMC South Rocky Mount, 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.

C

The applicant proposes to relocate four existing dialysis stations from the FMC Spring Hope facility to FMC South Rocky Mount, both in Nash County, for a total of 16 stations upon completion of this project.

In Section D-1, pages 29-32 of the application, the applicant provides the assumptions used to project FMC Spring Hope's utilization on December 31, 2017, and discusses how it will continue to meet the needs of dialysis patients at FMC Spring Hope after the relocation of four stations to the FMC South Rocky Mount facility.

The applicant's assumptions are summarized as follows:

- BMA proposes to relocate four stations from FMC Spring Hope to FMC South Rocky Mount. Projections begin with the FMC Spring Hope census on December 31, 2016.
- FMC Spring Hope does not provide home dialysis. The facility was serving the 51 in-center patients as of December 31, 2016 (Per the applicant, "*information from the ESRD Data Collection Forms, to be submitted to DHSR / Healthcare Planning and Certificate of Need in February 2017*").

FMC Spring Hope Patient Origin	December 31, 2016 Patient Census
Nash	48
Edgecombe	1
Franklin	1
Wilson	1
TOTAL	51

- BMA projects growth of the Nash County patients at the Nash County Five Year Average Annual Change Rate of 10%. No growth is applied to patients residing in other counties and dialyzing at FMC Spring Hope. Patients from other counties will be added when necessary.
- BMA will subtract the four patients (effective December 31, 2017) that provided letters of support and expressed interest in transferring to FMC South Rocky Mount upon completion of the project. Two patients reside in Nash County, one patient resides in Edgecombe County and one patient resides in Wilson County.

The agency received clarifying information from the applicant on March 15, 2017, which is summarized as follows:

- The application contains letters of support from four patients who dialyze at FMC Spring Hope and who propose to transfer their care to FMC South Rocky Mount. Two patients reside in Nash County, one resides in Edgecombe County and one resides in Wilson County.
- In the applicant's discussion for Criterion 3a, it is stated that FMC Spring Hope had a census of 51 patients on December 31, 2016, which includes 48 patients from Nash County, one patient from Edgecombe County, one patient from Franklin County, and one patient from Wilson County.
- After the transfers, and before growing the census, FMC Spring Hope would have 46 Nash County patients and the one patient from Franklin County.
- The applicant states, "... *When drafting this portion [calculations on page 30, specifically the 4th line] of the application, the intent was to return to the representation that 3 patients were residents of other counties; however 2 of those patients are projected to transfer, so it would have been more clear to refer to only the remaining out of county patient (the patient from Franklin County).*"

The following table which is on page 30 of the application was revised by the project analyst based on the above clarifying information received from the applicant.

FMC SPRING HOPE	
BMA begins with the Nash County patient census as of December 31, 2016.	48
BMA projects this census forward for one year to December 31, 2017.	$(48 \times .010) + 48 = 52.8$
BMA subtracts 2 Nash County patients projected to transfer to FMC South Rocky Mount	$52.8 - 4 = 48.8$
BMA adds the 1 patient from Franklin County. The two patients from Edgecombe and Wilson Counties are projected to transfer to FMC South Rocky Mount.	$48.8 + 3 = 51.8$
Projected Census for December 31, 2017	51.8

The following table which is from the clarifying information received from the applicant on March 15, 2017 is another representation of the projected census at FMC Spring Hope, after growth of the Nash County patient population, and allows for patient transfers to FMC South Rocky Mount.

FMC Spring Hope	Projected Census December 31, 2017
Nash	50.8
Franklin	1
TOTAL*	51.8

*The applicant rounds up as noted on page 30 of the application.

The following information is from the application, Section D-1, pages 29-32.

- On December 31, 2017, the applicant projects the FMC Spring Hope census to be 51.8 patients, rounded to 52 patients. Also on this date, FMC Spring Hope will have 12 certified stations; as four stations are to be relocated to FMC South Rocky Mount.
- Utilization by 52 patients dialyzing on 12 stations is 108.33% or 4.33 patients per station.
- The applicant states that utilization rates exceeding 100% is indicative of a third dialysis shift. The applicant states that BMA is committed to adding dialysis stations to the FMC Spring Hope facility. The January 2017 SDR reports FMC Spring Hope's utilization rate 94.38%, or 3.9334 patients per station.
- ...
- ... Because the facility was operating above the 80% threshold, the applicant states that it would qualify for more dialysis stations based on the Facility Need Methodology in March 2017. The following calculations demonstrate the facility could apply for up to five dialysis stations in the April 2017 CON review cycle.

L-11285-17 FMC SPRING HOPE APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/16		98.34%
Certified Stations		15
Pending Stations		1
Total Existing and Pending Stations		16
In-Center Patients as of 6/30/16 (SDR2)		59
In-Center Patients as of 12/31/15 (SDR1)		51
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	0.3137
(ii)	Divide the result of step (i) by 12	0.0261
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/16 until 12/31/16)	0.1569
(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	68.2549
(v)	Divide the result of step (iv) by 3.2 patients per station	21.3297
	and subtract the number of certified and pending stations to determine the number of stations needed	5

On March 15, 2017, the applicant filed as it stated in Section D, page 31, a CON application to add four dialysis stations to FMC Spring Hope (Project ID# L-11305-17). If approved, the facility will become certified for 16 in-center dialysis stations.

On pages 31-32, the applicant states,

“Utilization on 16 stations by 60 patients is equivalent to 3.753 patients per station, or 93.75% utilization. While this is a high utilization rate, BMA notes that failure to prepare for the four patients to transfer their care to FMC South Rocky Mount would actually result in a utilization rate exceeding four patients per station, forcing the facility to a third, or evening shift.

This application will ensure access to care in a convenient setting for those patients who have been admitted at a facility other than FMC South Rocky Mount. BMA expects that no patients will be denied service by the proposed relocation (and decertification) of stations at FMC Spring Hope.”

In on page 32, the applicant further states,

“This relocation of stations will not have any effect upon the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care. Patients needing dialysis

services will continue to have access to dialysis at either their current dialysis facility, or in a BMA facility closer to their residence location.

This application will not have any immediate effect upon the number of dialysis stations within Nash County. The January 2017 SDR indicates Nash County has a deficit of four dialysis stations. Relocating four stations within the county obviously does not reduce the number of stations within the county. This application will not have any effect upon access to care—for any patient.”

Conclusion

The applicant demonstrates that the needs of the population presently served at FMC Spring Hope will continue to be adequately met following the proposed relocation of four dialysis stations to FMC South Rocky Mount and that access for medically underserved groups will not be negatively impacted.

Therefore, the application is conforming to this criterion.

- (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, pages 33-34, 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 maintaining the status quo is not an effective alternative because the needs would not be met of patients residing near FMC South Rocky Mount, but dialyzing at FMC Spring Hope, as there is a lack of access in the southern areas of Rocky Mount and Nash County. Therefore, this alternative was rejected.
- Apply to relocate stations from the BMA Rocky Mount dialysis facility - Utilization is reported in the January 2017 SDR as 90.48%. However, the applicant states, “... a key consideration for BMA was the opportunity to add stations back to the facility which was losing stations ... The only facility in Nash County which generates additional stations through Facility Need Methodology is FMC Spring Hope. BMA has applied for only four stations to relocate to FMC South Rocky Mount, and will only apply for four stations to add to FMC Spring Hope.” The applicant further states it believes it is important to maintain sufficient dialysis capacity for the growing patient population of Nash County. Therefore, this alternative was rejected.
- Apply to develop another new ESRD facility in Nash County - The applicant states that it may be applying to develop another facility in the future, but that is not the most expedient alternative at this time. Therefore, this alternative was rejected.

After considering the above alternatives, the applicant states that it has chosen the most efficient and cost effective alternative to meet the needs of its patients.

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 South Rocky Mount shall materially comply with all representations made in the certificate of need application. In those instances where representations conflict, FMC South Rocky Mount shall materially comply with the last made representation.**
 2. **Bio-Medical Applications of North Carolina, Inc. shall relocate no more than four dialysis stations from FMC Spring Hope to FMC South Rocky Mount for a total of no more than 16 certified stations which shall include any home hemodialysis training or isolation stations.**
 3. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Rocky Mount shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations, for a total of no more than 16 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 4. **Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify four dialysis stations at FMC Spring Hope for a total of no more than 12 dialysis stations at FMC Spring Hope upon completion of this project.**
 5. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Rocky Mount 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

The applicant proposes to relocate four existing dialysis stations from the FMC Spring Hope facility to FMC South Rocky Mount, both in Nash County, for a total of 16 stations upon completion of this project.

Capital and Working Capital Costs

In Section F-1, page 36, the applicant projects \$15,000 in capital costs to develop the proposed project. In Sections F.10-F.12, page 39, the applicant states that no start-up expenses and initial operating expenses are required because FMC South Rocky Mount is an existing facility.

Availability of Funds

In Section F-13, page 40, the applicant states it will finance the capital costs with accumulated reserves of Fresenius Medical Care Holdings, Inc. (FMCH).

Exhibit F-1 contains a letter dated January 17, 2017, from the Senior Vice President and Treasurer for FMCH, the parent company of BMA, which authorizes and commits cash reserves for the project capital costs of \$15,000 for development of this project. Exhibit F-2 contains the Consolidated Financial Statements for FMCH which indicates that it had \$249.3 million in cash and cash equivalents as of December 31, 2015, \$19.3 in total assets and \$10.1 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

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

FMC SOUTH ROCKY MOUNT		
	Operating Year 1 CY2018	Operating Year 2 CY2019
Total Treatments*	7,854	8,447
Total Gross Revenues (Charges)	\$36,376,906	\$38,741,790
Total Net Revenue	\$2,957,105	\$3,130,319
Total Operating Expenses (Costs)	\$2,608,263	\$2,738,145
Net Income	\$348,843	\$392,174

*Adjusted by the applicant for missed treatments.

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

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital 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.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to relocate four dialysis stations from FMC Spring Hope to FMC South Rocky Mount for a total of 16 certified dialysis stations upon completion of this project.

On page 369, 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 Nash County. Facilities may serve residents of counties not included in their service area.

The applicant currently operates three of four dialysis centers in Nash County. The other provider of an approved ESRD facility in Nash County is DaVita, as shown below in the table.

NASH COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of June 30, 2016				
Dialysis Facility/Owner	Certified Stations 6/30/2016	# In-center Patients	Percent Utilization	Patients/ Station
FMC South Rocky Mount / BMA	12	0	0.00%	0.0000
FMC of Spring Hope** / BMA	15	59	98.33%	3.9333
Rocky Mount Kidney Center / BMA	42	152	90.48%	3.6190
Nash County Dialysis*** / DaVita	0	0	0.00%	0.0000

Source: January 2017 SDR. ** Applicant states that the facility was certified for 16 stations effective August 29, 2016. *** Proposed new site. 12 stations CON issued/Not certified.

As shown in the table above, two of the three operational BMA Nash County dialysis facilities are operating above 80% utilization (3.2 patients per station). The DaVita dialysis facility is not yet operational.

The applicant provides reasonable projections for the patient population it proposes to serve in Section C, pages 18-19 of the application. The growth projections are based on a projected 10% average annual growth rate in Nash County residents. At the end of the first operating year following project completion, FMC South Rocky Mount projects the in-center utilization will be 3.4 in-center patients per station (55 patients / 16 dialysis stations = 3.4375), which is 85.9% of capacity. The applicant does not propose to increase or decrease the number of certified stations in the service area. The applicant adequately demonstrates the need to relocate four existing dialysis stations to FMC South Rocky Mount from FMC Spring Hope.

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 47, the applicant provides the current and proposed staffing for the facility. The applicant currently has 12.45 full-time equivalent (FTE) staff at the facility and proposes to add 1.51 FTE new staff as a result of this project, for a total of 13.96 FTEs. The project analyst finds it reasonable to assume that the applicant has a typographical error in the staff chart which states new positions to be added as 3.01 FTEs rather than a total of 1.51 FTE staff to be added. In Section H-3, page 47, the applicant describes its experience and process for recruiting and retaining staff. In Section I-3, page 51, the applicant identifies the medical director as Michael Holland, M.D., and Exhibit I-5 contains a copy of a letter from Dr. Holland expressing 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.

- (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 50, the applicant includes a list of providers of the necessary ancillary and support services. Exhibits I-2, 3 and 4 contain documentation for laboratory, hospital and transplant services, respectively. Exhibit I-5 contains a letter from the medical director of the facility describing the facility's established relationships with other healthcare providers. The applicant discusses coordination with the existing health care system on pages 51-52. 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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new

members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

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

NA

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

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

C

In Section L-1, pages 59-60, the applicant states that BMA has a long history of providing dialysis services to the underserved populations of North Carolina. FMC, BMA's parent company, currently operates 107 facilities in 46 North Carolina Counties, including affiliations with RRI facilities. The applicant further states it is policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor which would classify a patient as underserved. On pages 59-60, the applicant states:

“BMA of North Carolina has historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. For example, Medicare (includes Medicare Advantage treatments) represented 80.5% of North Carolina dialysis treatments in BMA facilities in FY 2016; Medicaid treatments represented an additional 5.3% of treatments in BMA facilities for FY 2016.”

In Section L-7, page 63, the applicant provides a table indicating that 94.06% of the in-center patients who received treatments at FMC South Rocky Mount in CY2016 had some or all of their services paid for by Medicare or Medicaid.

FMC SOUTH ROCKY MOUNT	
HISTORICAL PAYOR SOURCE (CY2016)	PERCENT OF TOTAL IN-CENTER PATIENTS
Self-Pay/Indigent/Charity	0.00%
Medicare	78.69%
Medicaid	1.08%
Commercial Insurance	5.97%
Medicare/Commercial	14.26%
Medicare/ Medicaid	0.00%
Miscellaneous incl. VA	0.00%
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 market.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Nash	16%	52%	48%	18%	11%	18%
Edgecombe	17%	54%	63%	26%	13%	17%
Wilson	16%	53%	52%	24%	11%	20%
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 demonstrates that it currently provides adequate 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

In Section L-3, page 61, 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 accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

In Section L-6, page 62, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section L-1, page 60, the applicant projects that 94.06% of the patients who will receive in-center treatments at FMC South Rocky Mount will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected (CY2019) payor sources for the facility for in-center patients; which is the same as the historical payor source at the FMC South Rocky Mount facility:

FMC SOUTH ROCKY MOUNT	
PROJECTED PAYOR SOURCE (OY2) (CY2019)	PERCENT OF TOTAL IN-CENTER PATIENTS
Self-Pay/Indigent/Charity	0.00%
Medicare	78.69%
Medicaid	1.08%
Commercial Insurance	5.97%
Medicare/Commercial	14.26%
Medicare/ Medicaid	0.00%
Miscellaneous incl. VA	0.00%
Total	100.00%

In Section L, pages 59-60, the applicant provides the assumptions used to project payor mix. The applicant's projected payment sources in Section L are consistent with the facility's projected (CY2019) payment sources in Section R, Form C, page 81. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at FMC South Rocky Mount. 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 62, the applicant describes the range of means by which a person will have access to the dialysis services at FMC South Rocky Mount, including referrals from nephrologists. 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 64, the applicant states that FMC South Rocky Mount has established communications with local community training programs. Exhibit M-1 contains a copy of correspondence to an area health professional training program expressing an interest on the part of the applicant to offer the facility as a clinical training site. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

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

C

The applicant proposes to relocate four dialysis stations from FMC Spring Hope to FMC South Rocky Mount for a total of 16 certified dialysis stations at FMC South Rocky Mount upon completion of this project.

On page 369, 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 Nash County. Facilities may serve residents of counties not included in their service area.

The applicant currently operates three of four current and approved dialysis centers in Nash County. DaVita is the owner of one approved ESRD facility in Nash County, as shown below in the table.

NASH COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of June 30, 2016				
Dialysis Facility/Owner	Certified Stations 6/30/2016	# In-center Patients	Percent Utilization	Patients/ Station
FMC South Rocky Mount* / BMA	12	0	0.00%	0.0000
FMC of Spring Hope** / BMA	15	59	98.33%	3.9333
Rocky Mount Kidney Center / BMA	42	152	90.48%	3.6190
Nash County Dialysis*** / DaVita	0	0	0.00%	0.0000

Source: January 2017 SDR. ** Applicant states that the facility was certified for 16 stations effective August 29, 2016. *** Proposed new site. 12 stations CON issued/Not certified.

As shown in the table above, two of the three operational BMA Nash County dialysis facilities are operating above 80% utilization (3.2 patients per station). The DaVita dialysis facility is not yet operational.

In Section N-1, page 65, the applicant discusses how any enhanced competition would have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

“FMC South Rocky Mount does not expect this proposal to have effect on the competitive climate in Nash County. The existing operational facilities in Nash County are operated by Fresenius Medical Care, parent to FMC South Rocky Mount. BMA does not project to serve dialysis patients currently being served by another provider in a contiguous county. The projected patient population for the FMC South Rocky Mount facility begins with patients currently served by BMA, and a growth of that patient population using a five year average annual change rate of 10% for the Nash County patients.

BMA does recognize that DaVita has a Certificate of Need to develop their Nash County Dialysis facility. That project has not yet been certified. Thus, there is no immediate impact to that facility. Once the DaVita facility is opened, they will have their own referring physicians. The nephrology physician is the key to admissions in any dialysis facility. Based upon their CON application for Nash County Dialysis, BMA does not expect to have any adverse impact on admissions at Nash County Dialysis.”

See additional information in Section N, as well as Sections A, B, C, D, E, F, G, H, I, K, L, and O where the applicant discusses the impact of the project on cost-effectiveness, quality and/or 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 continue provide quality services. The discussions regarding quality found in Criterion (20) is 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), (3a) 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

In Section O-3, pages 70-71, and referenced Exhibits, the applicant identifies two kidney disease treatment centers located in North Carolina, owned and operated by the applicant, 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. In Section O-3, page 71, the applicant states that both facilities are back in compliance with CMS Guidelines as of the date of submission of this application. Exhibits O-3 and O-4 contain copies of letters documenting that the facilities were determined to be back in compliance by the Centers for Medicare and Medicaid Services and the Division of Health Service Regulation. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

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

C

The application is conforming to 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- The applicant is not proposing to establish a new facility in this application.
- .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 55 in-center patients by the end of Operating Year 1, which is 3.4 patients per station per week ($55 / 16 = 3.4375$). 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 18-19, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.