

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 7, 2017

Findings Date: April 7, 2017

Project Analyst: Julie Halatek

Team Leader: Lisa Pittman

Project ID #: J-11271-16

Facility: Fresenius Medical Care Rock Quarry

FID #: 160555

County: Wake

Applicant: Fresenius Medical Care Rock Quarry, LLC

Project: Develop a new 10-station dialysis facility by relocating six stations from FMC New Hope Dialysis and four stations from Wake Dialysis Clinic

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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

Fresenius Medical Care Rock Quarry, LLC (FMCRQ) proposes to develop a new 10-station dialysis facility, Fresenius Medical Care Rock Quarry (FMC Rock Quarry) by relocating six existing certified dialysis stations from FMC New Hope Dialysis (FMC New Hope) and four existing certified dialysis stations from Wake Dialysis Clinic (WDC). All three facilities are located in Wake County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of the project, FMC Rock Quarry will be certified for 10 dialysis stations, FMC New Hope will be certified for 30 stations (36 - 6), and WDC will be certified for 46 stations [50 - 4 - 6 (J-11220-16) + 6 (J-11240-16)]. The applicant does not propose to provide home therapies.

Need Determination

The applicant proposes to relocate existing dialysis stations within Wake County; therefore, there are no need methodologies in the 2016 State Medical Facilities Plan (2016 SMFP) applicable to this review.

Policies

POLICY GEN-3: BASIC PRINCIPLES on page 39 of the 2016 SMFP is not applicable to this review because neither the county nor facility need methodology is applicable to this review.

POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES on page 39 of the 2016 SMFP is not applicable to this review because the applicant does not propose a capital expenditure greater than \$2 million.

However, *POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS* on page 33 of the 2016 SMFP is applicable to this review.

POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS 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 [sic] county is currently serving residents of that contiguous [sic] 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 develop a new 10-station dialysis facility, FMC Rock Quarry, in Wake County, by relocating 10 existing Wake County dialysis stations: six from FMC New Hope and four from WDC. Because all three facilities are located in Wake County, there is no change in the total dialysis station inventory in Wake County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with Policy ESRD-2 in the 2016 SMFP. 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

The applicant proposes to develop FMC Rock Quarry, a new 10-station Wake County dialysis facility, by relocating six existing certified dialysis stations from FMC New Hope and four existing certified dialysis stations from WDC. All three facilities are located in Wake County.

FMC Rock Quarry's parent company, Bio-Medical Applications of North Carolina, Inc. (BMA), and related entities operate 105 dialysis facilities across the state of North Carolina, including other dialysis facilities in Wake County.

Patient Origin

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

FMC Rock Quarry will be a new facility in Wake County; therefore, it has no existing patient origin.

In Section C.1, page 20, the applicant provides the projected patient origin for FMC Rock Quarry for in-center patients for the first two operating years following completion of the project, Calendar Years (CY) 2019 and 2020, as follows:

FMC Rock Quarry – Projected Patient Origin – CYs 2019 & 2020				
County	OY 1 – CY 2019	OY 2 – CY 2020	County Patients as % of Total	
	# Patients	# Patients	OY 1	OY 2
Wake	33.8	35.7	100.0%	100.0%
Total*	33.0	35.0	100.0%	100.0%

*“Rounded down to the whole patient.”

In Sections C.1-2, pages 19-21, the applicant provides the assumptions and data utilized to project patient origin. Exhibit C-1 contains 40 letters of support from existing patients utilizing a FMCRQ facility in Wake County.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section C.2, pages 20-21, the applicant states the need for the proposed project is based on the expressed desire of patients currently receiving care at an existing BMA facility to receive care at a facility more convenient and closer to his or her home, as well as the lack of a dialysis facility in the area of the proposed new facility.

Projected Utilization

In Section C.1, page 19, the applicant provides projected utilization during the first two years of operation following project completion, as illustrated in the table below:

FMC Rock Quarry – Projected Patient Origin – CYs 2019 & 2020				
County	OY 1 – CY 2019	OY 2 – CY 2020	County Patients as % of Total	
	# Patients	# Patients	OY1	OY2
Wake	33.8	35.7	100.0%	100.0%
Total*	33.0	35.0	100.0%	100.0%

*"Rounded down to the whole patient."

In Section C.1, pages 19-20, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below:

- A number of dialysis patients reside in southeast Raleigh in the general area of the proposed facility. 40 of those patients have signed letters of support indicating an interest in transferring to the proposed facility.
- The applicant assumes that 32 of the 40 patients who signed letters indicating a willingness to consider transfer will actually transfer to the proposed facility.
- The project is scheduled for completion on December 31, 2018. OY1 is CY 2019. OY2 is CY 2020.
- The applicant assumes that Wake County patients transferring to the proposed facility will remain part of the Wake County ESRD patient population, and will increase at a rate of 5.6 percent, the Five Year Average Annual Change Rate (AACR) for Wake County as published in the July 2016 Semiannual Dialysis Report (SDR).

In Section C.1, page 20, the applicant provides the calculations used to arrive at the projected in-center patient census for OY1 and OY2 as summarized in the table below.

FMC Rock Quarry	In-Center Dialysis
Begin with 32 in-center patients from Wake County who are projected to transfer to FMC Rock Quarry upon facility certification (January 1, 2019).	32
Wake County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (5.6%).	$(32 \times 0.056) + 32 = 33.8$
Wake County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (5.6%).	$(33.8 \times 0.056) + 33.8 = 35.7$

The applicant projects to serve 33 in-center patients on 10 stations, which is 3.3 patients per station per week (33 patients / 10 stations = 3.3), by the end of OY1 and 35 in-center patients on 10 stations, which is 3.5 patients per station per week (35 patients / 10 stations = 3.5), by the end of OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C.2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. Therefore, the applicant adequately demonstrates the need to develop a new 10-station dialysis facility.

Home Hemodialysis and Peritoneal Dialysis

In Section C.1, page 19, the applicant states that the proposed facility will not include a home therapies program and that patients who are candidates for home dialysis treatments will be referred to WDC.

Access

In Section L.1(a), pages 74-75, the applicant states that each of BMA’s 105 facilities (including affiliations) in 42 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons. On page 75, the applicant projects the payor mix for the second operating year of the project, and it projects that 84.4 percent of projected patients 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 the proposed 10-station facility, and demonstrates the extent to which all residents, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons,

racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

FMC Rock Quarry proposes to develop a new 10-station dialysis facility, FMC Rock Quarry, by relocating six existing certified dialysis stations from FMC New Hope and four existing certified dialysis stations from WDC. All three facilities are located in Wake County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

Upon completion of this project, FMC New Hope will be certified for 30 stations (36 - 6), and WDC will be certified for 46 stations [50 - 4 - 6 (J-11220-16) + 6 (J-11240-16)]. In Section D.1, pages 33-39, the applicant discusses how the needs of dialysis patients at FMC New Hope and WDC will continue to be met after the relocation of stations to the proposed FMC Rock Quarry dialysis facility.

FMC New Hope

In Section D.1, pages 33-36, the applicant provides the assumptions used to project utilization for FMC New Hope for December 31, 2018, the date when FMC Rock Quarry is to be operational. The assumptions are summarized as follows:

- FMC New Hope is certified for 36 dialysis stations as reported in the July 2016 SDR. Six dialysis stations will be relocated to FMC Rock Quarry, leaving 30 dialysis stations at FMC New Hope.
- As of June 30, 2016 there were 118 patients dialyzing at FMC New Hope; 114 from Wake County and four from Johnston County.
- The applicant projects that four Wake County patients and one Johnston County patient who currently dialyze at FMC New Hope and who submitted letters of support for a project to develop FMC White Oak (Project I.D. #J-11220-16) will transfer to FMC White Oak as of June 30, 2018, when FMC White Oak becomes operational.
- The applicant projects that eight patients from FMC New Hope will transfer their care to FMC Rock Quarry. These transfers are expected to take place December 31, 2018, when FMC Rock Quarry becomes operational.
- FMC Rock Quarry projects the Wake County population will grow at an annual rate of 5.6 percent, which is the Five Year AACR published in the July 2016 SDR. No growth will be projected for patients living outside Wake County.
- The three remaining patients from Johnston County are added at the end of the calculations for each year.

Based on the above assumptions, the applicant projects utilization at FMC New Hope from June 30, 2016 through December 31, 2018 as follows:

FMC New Hope	
FMCQR begins with the Wake County ESRD patient population of FMC New Hope as of June 30, 2016.	114
FMCQR projects this population forward 12 months to June 30, 2017, applying the Wake County Five Year AACR of 5.6%.	$(114 \times 0.056) + 114 = 120.4$
FMCQR projects this population forward 12 months to June 30, 2018, applying the Wake County Five Year AACR of 5.6%.	$(120.4 \times 0.056) + 120.4 = 127.1$
FMCQR subtracts four Wake County patients projected to transfer to FMC White Oak.	$127.1 - 4 = 123.1$
FMCQR projects this population forward six months to December 31, 2018, applying the Wake County Five Year AACR of 5.6%.	$[123.1 \times (0.056 / 12 \times 6)] + 123.1 = 126.6$
FMCQR subtracts eight Wake County patients projected to transfer to FMC Rock Quarry.	$126.6 - 8 = 118.6$
FMCQR adds the three Johnston County patients to obtain the ending census for December 31, 2018, the date FMC Rock Quarry is projected to be certified.	$118.6 + 3 = 121.6$ (rounded up to 122)

The applicant projects that as of December 31, 2018, FMC New Hope will have 122 in-center dialysis patients dialyzing on 30 stations for a utilization rate of 4.07 patients per station per week, or 101.8 percent of capacity ($122 / 30 = 4.07$; $4.07 / 4 = 1.018$ or 101.8%).

On pages 34-35, the applicant states that FMC New Hope has 11 patients dialyzing on a third shift as of October 31, 2016, and states:

“The applicant assumes FMC New Hope will continue to operate the third shift, and that the shift will have 11 patients dialyzing. Thus, the effective utilization at FMC New Hope on December 31, 2018 would be a function of 111 patients dialyzing on 30 stations. Utilization is calculated to be 3.70 patients per station.” [$111 / 30 = 3.7$; $3.7 / 4 = 0.925$ or 92.5%].

The applicant states on page 35 that BMA will apply to add six dialysis stations at FMC New Hope in response to a Facility Need Methodology applicable with the January 2017 SDR, and that this filing would happen in March 2017. The applicant states that if it is approved for the six dialysis stations, and assuming this application, Project I.D. #J-11271-16, is approved, FMC New Hope would have a total of 36 dialysis stations at completion of both projects ($30 + 6 = 36$). This would result in 122 patients dialyzing on 36 stations (during traditional shifts) for a utilization rate of 3.39 patients per station per week, or 84.75 percent utilization ($122 / 36 = 3.39$; $3.39 / 4 = 0.8475$ or 84.75%).

The applicant demonstrates that the needs of the population presently served at FMC New Hope will continue to be adequately met following the proposed relocation of six dialysis stations from FMC New Hope to FMC Rock Quarry.

WDC

In Section D.1, pages 36-38, the applicant provides the assumptions used to project utilization for WDC for December 31, 2018, the date which FMC Rock Quarry is projected to be operational. The assumptions are summarized as follows:

- WDC is certified for 50 dialysis stations as reported in the July 2016 SDR. The applicant assumes that Project I.D. #s J-11220-16 and J-11240-16, which will result in a net of no change in the number of stations at WDC, will be approved. The applicant also assumes that this application (Project I.D. #J-11271-16) will be approved, and four dialysis stations will be relocated to FMC Rock Quarry, leaving 46 dialysis stations at WDC.
- As of June 30, 2016 there were 204 in-center patients dialyzing at WDC; 200 from Wake County, three from Johnston County, and one from Franklin County.
- The applicant projects that five Wake County patients and three Johnston County patients who currently dialyze at WDC and who submitted letters of support for a project to develop FMC White Oak (Project I.D. #J-11220-16) will transfer to FMC White Oak as of June 30, 2018, when FMC White Oak becomes operational.
- The applicant projects that six patients from WDC will transfer their care to FMC Rock Quarry. These transfers are expected to take place December 31, 2018, when FMC Rock Quarry becomes operational.
- FMCRQ projects the Wake County population will grow at an annual rate of 5.6 percent, which is the Five Year AACR published in the July 2016 SDR. No growth will be projected for patients living outside Wake County.
- The one remaining patient from Franklin County is added at the end of the calculations for each year.

Based on the above assumptions, in Section D.1, page 37, the applicant calculates the in-center patient census for WDC starting June 30, 2016 through December 31, 2018, illustrated as follows:

WDC	
FMCQR begins with the Wake County ESRD patient population of WDC as of June 30, 2016.	200
FMCQR projects this population forward 12 months to June 30, 2017, applying the Wake County Five Year AACR of 5.6%.	$(200 \times 0.056) + 200 = 211.2$
FMCQR projects this population forward 12 months to June 30, 2018, applying the Wake County Five Year AACR of 5.6%.	$(211.2 \times 0.056) + 211.2 = 223.0$
FMCQR subtracts five Wake County patients projected to transfer to FMC White Oak.	$223.0 - 5 = 218.0$
FMCQR projects this population forward six months to December 31, 2018, applying the Wake County Five Year AACR of 5.6%.	$[218.0 \times (0.056 / 12 \times 6)] + 218.0 = 224.1$
FMCQR subtracts six Wake County patients projected to transfer to FMC Rock Quarry.	$224.1 - 6 = 218.1$
FMCQR adds the one Franklin County patient to obtain the ending census for December 31, 2018, the date FMC Rock Quarry is projected to be certified.	$218.1 + 1 = 219.1$ (rounded up to 220)

The applicant projects that as of December 31, 2018, WDC will have 220 in-center dialysis patients dialyzing on 46 stations for a utilization rate of 4.78 patients per station per week, or 119.5 percent of capacity ($220 / 46 = 4.78$; $4.78 / 4 = 1.195$ or 119.5%).

On page 37, the applicant states:

“... . However, the Wake Dialysis Clinic also operates a third, or evening dialysis shift and a nocturnal dialysis shift. As of October 31, 2016 there were 20 patients dialyzing on the third shift and 12 patients dialyzing on the nocturnal shift.

The applicant assumes Wake Dialysis Clinic will continue to operate the third shift and a nocturnal dialysis shift. The applicant further assumes that the census on these shifts will remain constant. Thus, the effective utilization at Wake Dialysis Clinic on December 31, 2018 would be a function of 188 patients dialyzing on 46 stations. Utilization is calculated to be 4.09 patients per station.” [$188 / 46 = 4.09$; $4.09 / 4 = 1.0225$ or 102.25%].

The applicant states on page 38 that BMA will apply to add four dialysis stations at WDC in response to a Facility Need Methodology applicable with the January 2017 SDR and that this filing would happen in March 2017. The applicant states that if it is approved for the four dialysis stations, and assuming this application, Project I.D. #J-11271-16, is approved, WDC would have a total of 50 dialysis stations at completion of both projects ($46 + 4 = 50$). This would result in 188 patients dialyzing on 50 stations (during traditional shifts) for a utilization rate of 3.76 patients per station per week, or 94 percent utilization ($188 / 50 = 3.76$; $3.76 / 4 = 0.94$ or 94%).

The applicant demonstrates that the needs of the population presently served at WDC will continue to be adequately met following the proposed relocation of four dialysis stations from WDC to FMC Rock Quarry.

Conclusion

The applicant demonstrates that the needs of the population presently served at FMC New Hope and WDC will continue to be adequately met following the proposed relocation of six dialysis stations from FMC New Hope and four dialysis stations from WDC to FMC Rock Quarry 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.

C

In Section E, pages 40-41, the applicant describes the alternatives it considered prior to submitting this application for the proposed project, which include:

- Maintaining the Status Quo – the applicant states that eight of BMA’s 12 dialysis facilities in Wake County are at physical plant capacity and, therefore, cannot be further expanded to meet the need. Even with relocating stations from existing facilities to develop a new facility, the existing facilities qualify for additional stations under the Facility Need Methodology. Therefore, this is not an effective alternative.
- Develop a Facility in Another Area of Wake County - the applicant states that it evaluated existing and projected populations served by BMA, concluding that there was a population of dialysis patients in Southeast Raleigh that would be better served by a new facility. Therefore, this is not an effective alternative.
- Develop a Larger Facility – the applicant states that it considered applying for more stations at the proposed FMC Rock Quarry facility but concluded that the 10-station facility will meet the needs of the projected patients who will transfer their care to the proposed facility upon certification, and will also meet the performance standard of 10A NCAC 14C.2203. Therefore, this is not an effective alternative.
- Relocate Stations From Other Existing Facilities with Lower Utilization Rates – the applicant states that three existing facilities with lower utilization rates were considered; however, two of the three facilities are growing at rates far higher than the Five Year AACR for Wake County and the third is expected to have a census increase as physicians work with staff to ensure appropriate admissions. Therefore, this is not an effective alternative.
- Add Home Therapies at the New Facility – the applicant states that it could have added home therapies to a new facility, but there are five existing home therapy programs in Wake

County BMA facilities, and adding a sixth facility with a home therapy program would be an extra expenditure that was not the most effective use of capital. Therefore, this is not an effective alternative.

After considering the above alternatives, the applicant states that given the residence location of the existing patients projected to be served at FMC Rock Quarry and the physical plant constraints of existing BMA facilities in the county, the proposed project 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. Fresenius Medical Care Rock Quarry, LLC shall materially comply with all representations made in the certificate of need application.**
 - 2. Fresenius Medical Care Rock Quarry, LLC shall ensure that its parent company, Bio-Medical Applications of North Carolina, Inc., shall relocate no more than six dialysis stations from Fresenius Medical Care New Hope and no more than four dialysis stations from Wake County Dialysis Center.**
 - 3. Fresenius Medical Care Rock Quarry, LLC shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 - 4. Fresenius Medical Care Rock Quarry, LLC shall ensure that its parent company, Bio-Medical Applications of North Carolina, Inc., shall take the necessary steps to decertify six dialysis stations at Fresenius Medical Care New Hope for a total of no more than 30 dialysis stations at Fresenius Medical Care New Hope upon completion of this project.**
 - 5. Fresenius Medical Care Rock Quarry, LLC shall ensure that its parent company, Bio-Medical Applications of North Carolina, Inc., shall take the necessary steps to decertify four dialysis stations at Wake County Dialysis Center for a total of no more than 46 dialysis stations at Wake County Dialysis Center upon completion of this project, Project I.D. #J-11220-16, and Project I.D. #J-11240-16.**
 - 6. Fresenius Medical Care Rock Quarry, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of

the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new 10-station dialysis facility in Wake County, FMC Rock Quarry, by relocating six stations from FMC New Hope and four stations from WDC.

Capital and Working Capital Costs

In Section F.1, page 43, the applicant projects \$1,608,166 in capital costs to develop the proposed project, summarized as follows:

FMC Rock Quarry

Construction Contract	\$1,040,955
Dialysis Machines	Leased
Water Treatment Equipment	\$210,000
Other Equipment/Furniture	\$206,793
Architect/Engineering Fees	\$93,686
<u>Contingency</u>	<u>\$56,732</u>
Total	\$1,608,166

In Section F.10, page 46, the applicant states that it will have \$149,773 in start-up expenses and in Section F.11, page 47, the applicant states it will have eight months of initial operating expenses of \$1,255,503. The total estimated working capital for the project is \$1,405,276.

Availability of Funds

In Section F.2, page 44, and Section F.13, page 48, the applicant states it will finance the capital costs and working capital costs with accumulated reserves. Exhibit F-1 contains a letter dated November 15, 2016, from the Senior Vice President & Treasurer of Fresenius Medical Care Holdings, Inc. and Subsidiaries (FMC), authorizing and committing \$1,608,166 in capital costs for the project. In addition, the letter in Exhibit F-1 states, *“I am also authorized, and authorize any additional funds as may be necessary for start-up costs in the new location.”*

Exhibit F-2 contains the Consolidated Financial Statements for FMC for the years ending December 31, 2015 and December 31, 2014. These statements indicate that as of December 31, 2015, FMC had \$249.3 million 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 and working capital needs of the project.

Financial Feasibility

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

Projected Revenues and Operating Expenses		
FMC Rock Quarry	Operating Year 1 CY 2019	Operating Year 2 CY 2020
Total Treatments	4,742	5,038
Total Gross Revenues (Charges)	\$18,911,418	\$20,091,886
Total Net Revenue	\$2,146,786	\$2,280,791
Total Operating Expenses (Costs)	\$1,883,255	\$1,971,680
Net Income	\$263,531	\$309,111

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. Therefore, the application is conforming to this criterion.

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 develop a new 10-station dialysis facility in Wake County, FMC Rock Quarry, by relocating six stations from FMC New Hope and four stations from WDC.

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

BMA operates twelve dialysis centers in Wake County. Also, BMA has been approved to develop one additional facility in Wake County – FMC Morrisville – but the facility was not

yet operational on June 30, 2016. A second BMA facility, FMC Oak City (Project I.D. #J-11220-16), was issued a certificate of need on December 20, 2016. Wake Forest Dialysis Center (DaVita) is the only other provider of dialysis services in Wake County, and currently operates just one dialysis center. DaVita has been approved to develop one additional facility in Wake County, Oak City Dialysis, but the facility was not operational on June 30, 2016. The existing and approved Wake County dialysis facilities are shown below:

Wake County Dialysis Facilities as of December 31, 2015				
Dialysis Facility	Certified Stations	CON Issued Not Certified	% Utilization	Patients Per Station
BMA of Fuquay-Varina	22	0	95.45%	3.82
BMA of Raleigh Dialysis	50	0	92.50%	3.70
Cary Kidney Center (BMA)	28	-4	75.89%	3.04
FMC Apex (BMA)	20	0	58.75%	2.35
FMC Central Raleigh (BMA)	19	0	75.00%	3.00
FMC Eastern Wake (BMA)	14	3	110.71%	4.43
FMC Millbrook (BMA)	17	0	82.35%	3.29
FMC Morrisville (BMA)	0	10	NA	NA
FMC New Hope (BMA)	36	0	72.22%	2.89
FMC Northern Wake (BMA)	13	3	NA	NA
Oak City Dialysis (DaVita)	0	10	NA	NA
Southwest Wake (BMA)	31	-6	95.16%	3.81
Wake Dialysis Clinic (BMA)	50	0	102.50%	4.10
Wake Forest Dialysis (DaVita)	20	12	93.75%	3.75
Zebulon Kidney Center (BMA)	30	-2	81.67%	3.27

Source: July 2016 SDR, Table A.

As shown in the table above, ten of the twelve operational facilities were operating at or above 75 percent utilization (3.0 patients per station) as of December 31, 2015.

The applicant is not increasing the number of dialysis stations in Wake County; rather, it is relocating 10 of them to develop a new facility that is closer to patients living in or near the area where the new facility will be located. Therefore, it is not duplicating services; rather, it is relocating existing services by proposing to create a new facility to better serve existing patients using existing stations.

The applicant adequately demonstrates the need to relocate stations to develop a new dialysis facility in Wake County. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference. The discussion regarding the needs of the population presently served at FMC New Hope and WDC, found in Criterion (3a), is incorporated herein by reference.

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

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

C

In Section H.1, page 57, the applicant provides the proposed staffing for the new facility, which includes 10.35 full-time equivalent (FTE) employee positions, summarized as follows:

FMC Rock Quarry Proposed Staffing	
Position	Projected # of FTE Positions
Medical Director*	
RN	1.50
Patient Care Technician	5.00
Clinical Manager	1.00
Administrator	0.15
Dietitian	0.50
Social Worker	0.50
Chief Technician	0.15
Equipment Technician	0.60
In-Service	0.15
Clerical	0.80
Total FTE Positions	10.35

*The Medical Director is a contract position, not an FTE of the facility.

In Section H.3, page 58, the applicant describes its experience and process for recruiting and retaining staff.

Exhibit I-5 contains a copy of a letter dated October 26, 2016 from Dr. Samsheer Sonawane, stating that he has agreed to serve as Medical Director of FMC Rock Quarry.

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

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

C

In Section I.1, page 61, the applicant includes a list of providers of the necessary ancillary and support services that will be provided to patients receiving dialysis services at FMC Rock Quarry. Exhibits I-2, I-3, and I-4 contain documentation regarding the availability of laboratory, hospital, and kidney transplant services, respectively. Exhibit I-5 contains a letter from the physician willing to serve as Medical Director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system in Sections I.3 and I.4, pages 62-64. 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.

C

The applicant proposes to construct a 2,927 square foot building to house the proposed services which will be located in Raleigh in Wake County. In Section F.1, page 43, the applicant lists the project costs, including \$1,040,955 for construction and \$567,211 in miscellaneous costs including water treatment equipment, furniture, architect/engineering fees, and contingency for a total project cost of \$1,608,166. In Section K.1, pages 66-67, the applicant describes its plans for energy-efficiency and water conservation. Costs and charges are described by the applicant in Section R, pages 91-95, of the application. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the

construction plans, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

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

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

C

In Section L.1, page 74, the applicant states that BMA has a long history of providing dialysis services to the underserved populations of North Carolina and that it is its policy to provide services to all patients regardless of income, racial/ethnic origin, age, or any other patient classified as underserved. In addition, the applicant describes its admission and financial policies in Section L.3, pages 76-77, and provides a copy of its admission policy in Exhibit L-1 which states that patients will be “*admitted and treated without regard to race, creed or religion, color, age, sex, disability, national origin, and or sexual orientation.*”

In Section L.7, page 78, the applicant provides the historical payor mix for FMC New Hope. Six dialysis stations will be relocated from FMC New Hope to the proposed facility and some patients will transfer to FMC Rock Quarry (See Exhibit C-1 for patients’ letters of support.) The historical payor mix is as follows:

FMC New Hope Historical Payor Mix – CY 2015	
Payor Type	% of In-Center Patients
Private Pay	3.4%
Commercial Insurance	9.1%
Medicare	53.5%
Medicaid	7.3%
Misc. (includes VA)	2.4%
Other Medicare Commercial	24.4%
Total	100.0%

In Section L.7, page 78, the applicant provides the historical payor mix for WDC. Four dialysis stations will be relocated from WDC to the proposed facility and some patients will transfer to FMC Rock Quarry (See Exhibit C-1 for patients’ letters of support.) The historical payor mix is as follows:

WDC Historical Payor Mix – CY 2015	
Payor Type	% of In-Center Patients
Private Pay	3.5%
Commercial Insurance	11.9%
Medicare	66.8%
Medicaid	3.3%
Misc. (includes VA)	0.8%
Other Medicare Commercial	13.7%
Total	100.0%

As illustrated in the tables above, 85.2 percent of FMC New Hope patients and 83.8 percent of WDC patients had some or all of their services paid for by Medicare and/or Medicaid.

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**
Wake	10%	51%	39%	12%	5%	14%
Statewide	15%	51%	36%	17%	10%	15%

Source: [http://www.census.gov/quickfacts/table_2014 Estimate as of December 22, 2015](http://www.census.gov/quickfacts/table_2014%20Estimate%20as%20of%20December%22,%202015).

*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%

<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.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 provide 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, pages 76-77, the applicant states that it has no obligations under any federal regulations to provide uncompensated care or community service. However, the applicant states that it will treat all patients the same and that it is obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.

In Section L.6, page 77, the applicant states there have been no civil rights complaints filed against any BMA North Carolina facilities within 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, page 75, the applicant provides the projected payor mix for the proposed project for the second operating year (CY 2020). The applicant states on page 75 that the projected payor mix for FMC Rock Quarry is based on the weighted in-center payor mix at FMC New Hope and WDC. The projected payor mix is illustrated as follows:

FMC Rock Quarry Projected Payor Mix – CY 2020	
Payor Type	% of In-Center Patients
Medicare	60.8%
Medicaid	5.1%
Commercial Insurance	10.6%
Medicare/Commercial	18.5%
Misc. (includes VA)	1.5%
Other (Self/Indigent/Charity)	3.4%
Total	100.0%

As illustrated in the table above, the applicant projects that 84.4 percent of all of the patients receiving dialysis services at FMC Rock Quarry in the second year of operation will have some or all of their services paid for by Medicare or Medicaid. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at FMC Rock Quarry. 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 77, the applicant describes the range of means by which a person will have access to the dialysis services at FMC Rock Quarry. The applicant states that nephrologists with medical staff privileges will admit patients to the facility for dialysis. Referrals to these nephrologists may come from other nephrologists, other physicians, or hospital emergency rooms. In addition, the applicant states that any nephrologist who applies for and receives medical staff privileges may admit patients to the facility. In Exhibit I-5, the applicant provides a letter signed by Dr. Samsher Sonawane of Wake Nephrology Associates, indicating that the practice is providing care for a significant number of ESRD patients in the southern part of Wake County and does medical rounds at the existing dialysis facilities in the county. Furthermore, the letter states confidence in the practice's ability to meet the needs of ESRD patients at FMC Rock Quarry. 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 76, the applicant states that the facility is available to all health-related education and training programs to receive instruction and to observe operations. Exhibit M-1 contains a letter from the applicant to Wake Tech Community College's Department of Nursing, inviting the school to do clinical rotations for nursing students at its proposed facility. 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 develop a new 10-station dialysis facility in Wake County, FMC Rock Quarry, by relocating six stations from FMC New Hope and four stations from WDC.

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

BMA operates twelve dialysis centers in Wake County. Also, BMA has been approved to develop one additional facility in Wake County – FMC Morrisville – but the facility was not yet operational on June 30, 2016. A second BMA facility, FMC Oak City (Project I.D. #J-11220-16), was issued a certificate of need on December 20, 2016. Wake Forest Dialysis Center (DaVita) is the only other provider of dialysis services in Wake County, and currently operates just one dialysis center. DaVita has been approved to develop one additional facility in Wake County, Oak City Dialysis, but the facility was not operational on June 30, 2016. The existing and approved Wake County dialysis facilities are shown below:

Wake County Dialysis Facilities as of December 31, 2015				
Dialysis Facility	Certified Stations	CON Issued Not Certified	% Utilization	Patients Per Station
BMA of Fuquay-Varina	22	0	95.45%	3.82
BMA of Raleigh Dialysis	50	0	92.50%	3.70
Cary Kidney Center (BMA)	28	-4	75.89%	3.04
FMC Apex (BMA)	20	0	58.75%	2.35
FMC Central Raleigh (BMA)	19	0	75.00%	3.00
FMC Eastern Wake (BMA)	14	3	110.71%	4.43
FMC Millbrook (BMA)	17	0	82.35%	3.29
FMC Morrisville (BMA)	0	10	NA	NA
FMC New Hope (BMA)	36	0	72.22%	2.89
FMC Northern Wake (BMA)	13	3	NA	NA
Oak City Dialysis (DaVita)	0	10	NA	NA
Southwest Wake (BMA)	31	-6	95.16%	3.81
Wake Dialysis Clinic (BMA)	50	0	102.50%	4.10
Wake Forest Dialysis (DaVita)	20	12	93.75%	3.75
Zebulon Kidney Center (BMA)	30	-2	81.67%	3.27

Source: July 2016 SDR, Table A.

As shown in the table above, ten of the twelve operational facilities were operating at or above 75 percent utilization (3.0 patients per station) as of December 31, 2015.

In Section N.1, page 80, the applicant discusses how any enhanced competition will have a positive impact on cost-effectiveness, quality and access to the proposed services. The applicant states,

“Fresenius related facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 84% of the In-center treatments will be reimbursed at government payors (Medicare / Medicaid / VA) rates. 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 B, C, E, F, G, H, and L where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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

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

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Exhibit A-4, the applicant lists the kidney disease treatment centers located in North Carolina that are owned and operated by the applicant or an affiliated company. In Section O.3, pages 85-86, the applicant identifies two of its 105 affiliated North Carolina facilities (BMA East Charlotte and RAI West College – Warsaw) as having been 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 states 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 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 Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C.2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- C- In Section C.1, page 19, the applicant adequately demonstrates that FMC Rock Quarry will serve at least 33 in-center patients on 10 dialysis stations at the end of the first operating year, which is 3.3 patients per station per week, or a utilization rate of 82.5 percent ($33 / 10 = 3.3$; $3.3 / 4 = 0.825$ or 82.5%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.
- (b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- NA- The applicant is seeking to develop a new 10-station dialysis facility.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 19-20, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.