ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional

NC = Nonconforming NA = Not Applicable

Decision Date: July 13, 2018 Findings Date: July 13, 2018

Project Analyst: Tanya S. Rupp Team Leader: Gloria C. Hale Assistant Chief: Lisa Pittman

Project ID #: M-11502-18

Facility: Fresenius Kidney Care Rockfish

FID #: 170017 County: Cumberland

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

Project: Change of scope for Project I.D. #M-11286-17 to develop FKC Rockfish as a 20-

station dialysis facility by merging with the FKC Hope Mills project, CON Project

ID #M-11344-17

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.

 \mathbf{C}

Bio-Medical Applications of North Carolina, Inc. (BMA, or the applicant), d/b/a Fresenius Kidney Care Rockfish (FKC Rockfish) proposes a change of scope to Project ID #M-11286-17: develop a new 10-station dialysis facility, FKC Rockfish, by relocating five dialysis stations from FMC Dialysis Services South Ramsey and five dialysis stations from FMC Services of West Fayetteville. Another application filed by BMA, Project ID #M-11344-17, proposed to develop a new 10-station dialysis facility, FKC Hope Mills, by relocating 5 stations from FMC Dialysis Services South Ramsey and 5 stations from FMC Dialysis Services North Ramsey. All of the existing facilities and each proposed new facility were to be located in Cumberland County. This application proposes to consolidate the two previously approved applications, such that the applicant now proposes a new 20-station dialysis facility to be

located at the same site in Fayetteville as the previously approved FKC Rockfish facility. As with the original applications, the applicant does not propose to add new dialysis stations to an existing facility or to establish new dialysis stations in Cumberland County.

In Section D, page 18, the applicant provides a table to illustrate the projects, as shown below:

Fresenius Kidney Care Rockfish

| | FACIL | FACILITY LOSING STATIONS | | |
|----------------------------------|--------------|--------------------------|--------------------------|------------------|
| FACILITY | FKC South | FMC North | FMC WEST FAYETTEVILLE | END# STATIONS |
| | RAMSEY | RAMSEY | FATETIEVILLE | STATIONS |
| Fresenius Kidney Care Rockfish | 5 | 0 | 5 | 10 |
| Fresenius Kidney Care Hope Mills | 5 | 5 | 0 | 10 |
| Total Stations Relocated | 10 | 5 | 5 | 20 |

Need Determination

The applicant proposes to relocate existing dialysis stations that had been previously approved to be relocated within Cumberland County to develop two new dialysis facilities, to one dialysis facility. Therefore, there are no need methodologies in the 2018 State Medical Facilities Plan (2018 SMFP) that are applicable to this review.

Policies

There are two policies that are applicable to this review: Policy GEN-4: *Energy Efficiency and Sustainability for Health Service Facilities* and Policy ESRD-2: *Relocation of Dialysis Stations*. Each policy is discussed in detail below.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities on page 33 of the 2018 SMFP states:

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

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

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

The proposed capital expenditure for this project is greater than \$2 million, but less than \$5 million; therefore, Policy GEN-4 is applicable to this review. In Section B.5, pages 9 - 10, the applicant documents the plans it will implement to assure improved energy efficiency and water conservation in the proposed facility. On page 9, the applicant states:

"Fresenius Medical Care, parent organization to the applicant, is committed to ensuring the building will maximize improved energy efficiency. The building plumbing systems will be designed to ensure conservation of water. The exterior building envelope, consisting of roofing, wall, and glass systems, will meet current requirements for energy conservation."

Policy ESRD-2: Relocation of Dialysis Stations, on page 27 of the 2018 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 a contiguous county 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 develop a new 20-station dialysis facility, FKC Rockfish, in Cumberland County, by combining two previously approved projects to develop two 10-station dialysis facilities by relocating existing Cumberland County dialysis stations. Because all of the facilities involved are or will be located in Cumberland County, there will be no change in the total dialysis station inventory in Cumberland County following completion of this project.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion, because the applicant demonstrates conformity to Policy GEN-4 and Policy ESRD-2.

- (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.

 \mathbf{C}

The applicant was previously approved, in two separate applications (Project ID #M-11286-17 and Project ID #M-11344-17), to develop two ten-station dialysis facilities in Fayetteville and Hope Mills by relocating existing dialysis stations at existing BMA facilities within Cumberland County. This application represents a change of scope of Project ID# M-11286-17, and proposes to consolidate those two previously approved projects to develop a new 20-station dialysis facility, FKC Rockfish in Fayetteville.

As with the original applications, the applicant does not propose in this application to add new dialysis stations to an existing facility or to establish new dialysis stations in Cumberland County. The 20 stations proposed in this application will be relocated from existing Cumberland County dialysis facilities, as shown in the following table from Section D, page 18 of the application:

Fresenius Kidney Care Rockfish 20 Station Facility

| | FACILITY LOSING STATIONS | | | NEW FKC ROCKFISH |
|----------------------------------|--------------------------|------------------------|--------------------------|---------------------|
| FACILITY | FKC SOUTH RAMSEY | FMC North RAMSEY | FMC WEST FAYETTEVILLE | END# STATIONS |
| Fresenius Kidney Care Rockfish | 5 | 0 | 5 | 10 |
| Fresenius Kidney Care Hope Mills | 5 | 5 | 0 | 10 |
| Total Stations Relocated | 10 | 5 | 5 | 20 |

In addition, the applicant does not propose to provide home therapies at the proposed new facility.

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis services as "the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area." Thus, the service area for this facility is Cumberland County. Facilities may also serve residents of counties not included in their service area.

Fresenius Kidney Care Rockfish will be a new facility and thus has no historical patient origin to report.

In Section C.15, page 16, the applicant identifies the in-center patient population it proposes to serve during the first two full fiscal years of operation following project completion, as illustrated in the table below:

| County | AS OF 12/31/2018 | OY 1 CY 2019 | OY 2 CY 2020 | PATIENTS | INTY S AS % OF FAL |
|------------|---------------------|-----------------|-----------------|----------|--------------------------|
| | | | | OY 1 | OY 2 |
| Cumberland | 50.0 | 52.6 | 55.3 | 79.0% | 79.8% |
| Hoke | 9.0 | 9.0 | 9.0 | 13.5% | 13.0% |
| Robeson | 5.0 | 5.0 | 5.0 | 7.5% | 7.2% |
| Total | 64 | 66 | 69 | 100.0% | 100.0% |

In the table above, the applicant rounds down to the nearest whole number for the totals in each of the first two fiscal years of operation. In Section C.15, page 16, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In each of the two original applications, (Project ID #sM-11286-17 and M-11344-17, the applicant adequately demonstrated the need the population proposed to be served by a new dialysis facility had for the new facility. In Section C.15 of this application, on page 17, the applicant discusses the reason for the consolidation of the two facilities into one 20-station dialysis facility. The applicant states it will serve the same patient population as proposed in each of the two separate dialysis facilities and save over \$1 million. The applicant describes additional considerations as follows:

• "A single facility will require only one RN clinic manager, as opposed to two RN clinic managers if two facilities are developed.

- *Utilities for a single facility will be less than the total for two facilities.*
- Rent for a single facility will be less than the total for two facilities. The proposed facility, comprised of 20 stations will have 8,736 square feet as opposed to the two previously approved facilities which each had 7,828 square feet. BMA has budgeted rent at \$21 per square foot for the facility. Eliminating 7,823 square feet for FKC Hope Mills, and adding only 908 square feet at FKC Rockfish represents a cost savings of \$145,320 in the first operating year.
- The Social Worker and Dietician were planned to be 0.4 FTE allocations for both FKC Rockfish and FKC Hope Mills. This necessarily meant sharing the FTE allocations with other facilities. By combining the two facilities, BMA will reduce staff travel costs."

The information is reasonable and adequately supported for the following reasons:

- The applicant proposes to serve the same population of dialysis patients in one 20-station facility to be located in Fayetteville as was proposed in the previously submitted applications for two 10-station dialysis facilities.
- The applicant proposes a cost savings of over \$1 million by combining the two projects.
- The proposed facility will be located on the same site as one of the original applications (FKC Rockfish), which the applicant states is only five miles from the second previously approved facility; therefore, patients who would have dialyzed at FKC Hope Mills will not be inconvenienced by BMA's decision to develop only one facility.

Projected Utilization

In Section C.15, page 16, the applicant provides projected utilization as illustrated in the following table:

| COUNTY | 12/31/2018 | OY 1 | OY 2 | COUNTY PTS. A | S % OF TOTAL |
|------------|------------|---------|---------|---------------|--------------|
| | | CY 2019 | CY 2020 | OY 1 | OY 2 |
| Cumberland | 50.0 | 52.6 | 55.3 | 79.0% | 79.8% |
| Hoke | 9.0 | 9.0 | 9.0 | 13.5% | 13.0% |
| Robeson | 5.0 | 5.0 | 5.0 | 7.5% | 7.2% |
| Total | 64.0 | 66.0 | 69.0 | 100.0% | 100.0% |

In Section C.15, page 16, the applicant states the total number of projected patients is based on the sum of the total projected patients by county of residents from the two previously approved projects in Cumberland County.

Projected utilization is reasonable and adequately supported for the following reasons:

- The proposed location of the new facility is the same location as the previously approved FKC Rockfish facility, which the applicant states is approximately five miles from the previously approved FKC Hope Mills facility.
- The projected utilization is equal to the sum of the projected utilizations of the two previously approved projects, and patient origin has not changed.
- Projected utilization was found to be reasonable in the previously approved applications and the applicant does not propose any changes in this change of scope application that would affect that determination.

Access

In Project I.D. #M-11286-17 and Project ID #M-11344-17, the applicant adequately demonstrated the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed dialysis services. The applicant proposes no changes in the current application that would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served in Project ID #M-11286-17 and Project ID #M-11344-17, and the applicant does not project a change in those populations.
- Projected utilization was deemed reasonable and adequately supported in Project ID #M-11286-17 and Project ID #M-11344-17, and the applicant projects a combined projected utilization based on those projects.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed dialysis services (payor mix) at FKC Rockfish, and the applicant adequately supports its assumptions.
- (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.

The applicant was previously approved, in two separate applications (Project ID #M-11286-17 and Project ID #M-11344-17), to develop two ten-station dialysis facilities in Fayetteville and Hope Mills by relocating existing dialysis stations at existing BMA facilities within Cumberland County. This change of scope application proposes to consolidate those two previously approved projects and develop a new 20-station dialysis facility, FKC Rockfish in Fayetteville. As with the original applications, the applicant does not propose in this application to add new dialysis stations to an existing facility or to establish new dialysis stations in Cumberland County. The 20 stations proposed in this application will be relocated from existing Cumberland County dialysis facilities, as shown in the following table from Section D, page 18 of the application:

Fresenius Kidney Care Rockfish 20 Station Facility

| | FACILITY LOSING STATIONS FKC FMC FMC WEST SOUTH NORTH FAYETTEVILLE | | | NEW FKC ROCKFISH |
|----------------------------------|---|--------|---|---------------------|
| FACILITY | | | | END# STATIONS |
| | RAMSEY | RAMSEY | | 211110110 |
| Fresenius Kidney Care Rockfish | 5 | 0 | 5 | 10 |
| Fresenius Kidney Care Hope Mills | 5 | 5 | 0 | 10 |
| Total Stations Relocated | 10 | 5 | 5 | 20 |

In Section D.1, pages 19 - 23, the applicant discusses how the needs of existing dialysis patients at FMC Dialysis Services South Ramsey, FMC Dialysis Services North Ramsey and FMC Services of West Fayetteville will continue to be met after the relocation of stations to the proposed FKC Rockfish dialysis facility. Each is discussed below.

FMC Dialysis Services South Ramsey

In Section D.1, pages 19 - 20, the applicant provides the assumptions used to project utilization for FMC Dialysis Services South Ramsey for December 31, 2018, the date when FKC Rockfish is projected to be operational. The assumptions are summarized as follows:

- FMC Dialysis Services South Ramsey is currently certified for 51 dialysis stations as reported in the January 2018 SDR. Ten dialysis stations will be relocated to FKC Rockfish, leaving 41 dialysis stations at FMC Dialysis Services South Ramsey.
- As of December 31, 2017 there were 160 patients dialyzing at FMC Dialysis Services South Ramsey: 157 from Cumberland County, and one each from Hoke, Robeson and Sampson counties.
- The applicant projects that seven Cumberland County patients who currently dialyze at FMC Dialysis Services South Ramsey will transfer their care to FKC Rockfish as of December 31, 2018, when FKC Rockfish is projected to become operational.
- The applicant projects the Cumberland County patient population will grow at an annual rate of 3.3%, which is the Five Year Average Annual Change Rate (AACR) for

Cumberland County, published in the January 2018 SDR. No growth will be projected for patients living outside Cumberland County.

• The three patients from Hoke, Robeson and Sampson counties will be added at the end of the growth calculations.

Based on the above assumptions, the applicant projects utilization at FMC Dialysis Services South Ramsey from December 31, 2017 through December 31, 2018 as follows:

| FMC DIALYSIS SERVICES SOUTH RAMSEY | | | | |
|---|---------------------|--|--|--|
| Begin with the Cumberland County ESRD patient population of FMC Dialysis Services South Ramsey as of December 31, 2017. | 157 | | | |
| Project this population forward 12 months to December 31, 2018, applying the Cumberland County Five Year AACR of 3.3%. | 157 x 1.033 = 162.2 | | | |
| Subtract seven Cumberland County patients projected to transfer their care to FKC Rockfish. | 162.2 – 7 = 155.2 | | | |
| Add three patients from Hoke, Robeson and Sampson counties | 155.2 + 3 = 158.2 | | | |

The applicant projects that as of December 31, 2018, the projected date of certification for FKC Rockfish, FMC Dialysis Services South Ramsey will have 158 in-center dialysis patients dialyzing on 41 stations for a utilization rate of 3.8 patients per station per week, or 96.3% of capacity [158/41 = 3.85; 3.85/4 = 0.963 or 96.3%].

Projected utilization for FMC Dialysis Services South Ramsey is reasonable and adequately supported for the following reasons:

- The applicant's growth projections are based on an assumption that the Cumberland County patient census will increase at an annual rate of 3.3%, which is consistent with the Five Year AACR for Cumberland County, as reported in Table D of the January 2018 SDR.
- The projected utilization is 3.8 patients per station per week as of December 31, 2018, the projected certification date for FKC Rockfish. This number exceeds the minimum standard of 3.2 in-center patient per station per week as required by 10A NCAC 14C .2203(b).

FMC Dialysis Services North Ramsey

In Section D.1, pages 22 - 23, the applicant provides the assumptions used to project utilization for FMC Dialysis Services North Ramsey for December 31, 2018, the date when FKC Rockfish is projected to be operational. The assumptions are summarized as follows:

• FMC Dialysis Services North Ramsey is currently certified for 40 dialysis stations as reported in the January 2018 SDR. Five dialysis stations will be relocated to FKC Rockfish, pursuant to this project; and pursuant to Project ID #M-11397-17, five stations will be relocated from FMC West Fayetteville to FMC Dialysis Services North Ramsey. Thus, the FMC Dialysis Services North Ramsey facility will remain at 40 stations.

- As of December 31, 2017 there were 131 patients dialyzing at FMC Dialysis Services North Ramsey: 121 from Cumberland County, and ten from Harnett County.
- The applicant projects that five Cumberland County patients who currently dialyze at FMC Dialysis Services North Ramsey will transfer their care to FKC Rockfish as of December 31, 2018, when FKC Rockfish is projected to become operational.
- The applicant projects the Cumberland County patient population will grow at an annual rate of 3.3%, which is the Five Year AACR for Cumberland County, published in the January 2018 SDR. No growth will be projected for patients living outside Cumberland County.
- The ten patients from Harnett County will be added at the end of the growth calculations.

Based on the above assumptions, the applicant projects utilization at FMC Dialysis Services North Ramsey from December 31, 2017 through December 31, 2018 as follows:

| FMC DIALYSIS SERVICES NORTH RAMSEY | | | | |
|---|---------------------|--|--|--|
| Begin with the Cumberland County ESRD patient population of FMC Dialysis Services North Ramsey as of December 31, 2017. | 121 | | | |
| Project this population forward 12 months to December 31, 2018, applying the Cumberland County Five Year AACR of 3.3%. | 121 x 1.033 = 125.0 | | | |
| Subtract five Cumberland County patients projected to transfer their care to FKC Rockfish. | 125.0 - 5 = 120.0 | | | |
| Add ten patients from Harnett County | 120.0 + 10 = 130.0 | | | |

The applicant projects that as of December 31, 2018, the projected date of certification for FKC Rockfish, FMC Dialysis Services North Ramsey will have 130 in-center dialysis patients dialyzing on 40 stations for a utilization rate of 3.25 patients per station per week, or 81.25% of capacity [130/40 = 3.25; 3.25/4 = 0.8125 or 81.25%].

Projected utilization for FMC Dialysis Services North Ramsey is reasonable and adequately supported for the following reasons:

- The applicant's growth projections are based on an assumption that the Cumberland County patient census will increase at an annual rate of 3.3%, which is consistent with the Five Year AACR for Cumberland County, as reported in Table D of the January 2018 SDR.
- The projected utilization is 3.25 patients per station per week as of December 31, 2018, the projected certification date for FKC Rockfish. This number exceeds the minimum standard of 3.2 in-center patient per station per week as required by 10A NCAC 14C .2203(b).

FMC Services of West Fayetteville

In Section D.1, pages 20 - 21, the applicant provides the assumptions used to project utilization for FMC Services of West Fayetteville for December 31, 2018, the date which FKC Rockfish is projected to be operational. The assumptions are summarized as follows:

- FMC Services of West Fayetteville is currently certified for 40 dialysis stations as reported in the January 2018 SDR. Five dialysis stations will be relocated to FKC Rockfish, pursuant to this project; and pursuant to Project ID #M-11314-17, five stations will be relocated from FMC West Fayetteville back to FMC Dialysis Services North Ramsey. Thus, the FMC Dialysis Services North Ramsey facility will remain at 40 stations.
- As of December 31, 2017 there were 165 in-center patients dialyzing at FMC Services of West Fayetteville: 145 of those patients were from Cumberland County, 13 were from Hoke County, three were from Robeson County, one each were from Sampson and Guilford counties and two were from other states.
- The applicant projects that 22 Cumberland County patients currently dialyzing at FMC Services of West Fayetteville will transfer their care to FKC Rockfish, consistent with the previously approved application. These transfers are expected to take place December 31, 2018, when FKC Rockfish becomes operational.
- The applicant states that, of the 13 Hoke County patients dialyzing at FMC Services of West Fayetteville, six intend to transfer their care to FKC Rockfish upon project completion, consistent with the previously approved application. The remaining seven Hoke County patients will remain at FMC Services of West Fayetteville.
- The applicant states it considers the patients from Guilford County and other states to be transient patients and will not calculate their return to the facility for future projections.
- There are four remaining patients from Sampson and Robeson counties who are added at the end of the calculations.

Based on the above assumptions, in Section D.1, page 22, the applicant calculates the in-center patient census for FMC Services of West Fayetteville starting December 31, 2016 through December 31, 2018, as follows:

| FMC Services of West Fayetteville | | | |
|--|---------------------|--|--|
| The applicant begins with the Cumberland County ESRD patient population of FMC Services of West Fayetteville as of December 31, 2017. | 145 | | |
| Project the Cumberland County ESRD patient population forward 12 months to December 31, 2018, applying the Cumberland County Five Year AACR of 3.3%. | 145 x 1.033 = 149.8 | | |
| Subtract 22 Cumberland County patients projected to transfer to FKC Rockfish. | 149.8 - 22 = 127.8 | | |
| Add seven of 13 Hoke County patients (six Hoke County patients transfer to FKC Rockfish) | 127.8 + 7 = 134.8 | | |
| Add 4 Hoke County patients from Robeson and Sampson counties. | 134.8 + 4 = 138.8 | | |

The applicant projects that as of December 31, 2018, FMC Services of West Fayetteville will have 139 (rounded up from 138.8) in-center dialysis patients dialyzing on 40 stations for a utilization rate of 3.475 patients per station per week, or 86.9% of capacity [139 / 40 = 3.475; 3.475 / 4 = 0.8687 or 86.9%].

Projected utilization for FMC Services of West Fayetteville is reasonable and adequately supported for the following reasons:

- The applicant's growth projections are based on an assumption that the Cumberland County patient census will increase at an annual rate of 3.3%, which is consistent with the Five Year AACR for Cumberland County, as reported in Table D of the January 2018 SDR.
- The projected utilization is 3.475 patients per station per week as of December 31, 2018, the projected certification date for FKC Rockfish. This number exceeds the minimum standard of 3.2 in-center patient per station per week as required by 10A NCAC 14C .2203(b).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

(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

The applicant was previously approved, in two separate applications (Project ID #M-11286-17 and Project ID #M-11344-17), to develop two ten-station dialysis facilities in Fayetteville and Hope Mills by relocating existing dialysis stations at existing BMA facilities within Cumberland County. This application represents a change of scope of Project ID# M-11286-17, and proposes to consolidate those two previously approved projects to develop a new 20-station dialysis facility, FKC Rockfish in Fayetteville.

In Section E, page 24, the applicant states there was only one alternative to consolidating the two previously approved projects into one 20-station dialysis facility, which was either to apply for the consolidation and change of scope, or not.

The applicant provides the following points to demonstrate that the proposed project represented in this application is the most effective alternative to meet the identified need:

- The applicant states that consolidating the two projects into one represents a total cost savings of over \$1 million.
- The applicant states developing one facility requires one RN clinic manager and fewer staff positions overall, since staffing will be for one facility; therefore, there is additional cost savings.
- The applicant states that rent for a single facility represents a cost savings of nearly \$150,000 in the first operating year.

The applicant states on page 24, "Given the residence location of the existing patients projected to be served by the facility, and growth of the patient census, the applicant has made the most cost effective choice."

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc., d/b/a Fresenius Care Rockfish shall materially comply with all representations made in the certificate of need application.
- 2. Pursuant to Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. shall relocate no more than ten dialysis stations from FMC Dialysis Services of South Ramsey, no more than five dialysis stations from FMC Services of West Fayetteville, and no more than five stations from FMC Dialysis Services of North Ramsey.
- 3. Bio-Medical Applications of North Carolina, Inc., d/b/a Fresenius Care Rockfish shall install plumbing and electrical wiring through the walls for no more than 20 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 ten dialysis stations at FMC Dialysis Services of South Ramsey for a total of no more than 41 dialysis stations at FMC Dialysis Services of South Ramsey upon project completion.
- 5. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify five dialysis stations at FMC Services of West Fayetteville for a total of no more than 40 dialysis stations at FMC Services of West Fayetteville upon completion of this project and Project ID# M-11314-17 (add five dialysis stations).
- 6. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify five dialysis stations at FMC Dialysis Services of North Ramsey for a total of no more than 40 dialysis stations at FMC Dialysis Services of North Ramsey upon completion of this project and Project ID #M-11397-17 (add five dialysis stations).
- 7. Bio-Medical Applications of North Carolina, Inc. shall relinquish the certificate of need for Project ID #M-11344-17 to the Agency upon completion of this project.
- 8. Bio-Medical Applications of North Carolina, Inc., d/b/a Fresenius Kidney Care Rockfish 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.

 \mathbf{C}

The applicant was previously approved, in two separate applications (Project ID #M-11286-17 and Project ID #M-11344-17), to develop two ten-station dialysis facilities in Fayetteville and Hope Mills by relocating existing dialysis stations at existing BMA facilities within Cumberland County. This application represents a change of scope of Project ID# M-11286-17, and proposes to consolidate those two previously approved projects to develop a new 20-station dialysis facility, FKC Rockfish in Fayetteville.

Capital and Working Capital Costs

The total capital cost is now expected to be \$2,163,062, an increase of \$594,049 over the previously approved Project I.D. #M-11286-17 capital cost of \$1,569,013, which is above the allowed 115 percent overage for capital expenditures. The following table compares the previously approved capital cost and the proposed capital cost in this application, as reported in Section F.1, page 26:

| FKC ROCKFISH – PREVIOUSLY APPROVED VS. PROPOSED CAPITAL EXPENDITURES | | | | |
|--|-----------------------------|------------------------|-----------------------|--|
| ITEM/CATEGORY | PREVIOUSLY APPROVED COST | TOTAL PROPOSED COST | TOTAL OVERRUN COST | |
| Cost of Construction | \$1,047,563 | \$1,482,788 | \$435,225 | |
| RO Water Treatment Equipment | \$ 225,000 | \$ 225,000 | \$ 0 | |
| Other Equipment / Furniture | \$ 145,077 | \$ 241,011 | \$ 95,943 | |
| Architect / Engineering Fees | \$ 94,281 | \$ 133,451 | \$ 39,170 | |
| Contingency | \$ 57,092 | \$ 80,812 | \$ 23,720 | |
| Total | \$1,569,013 | \$2,163,062 | \$594,049 | |

Totals may not sum due to rounding by applicant

In Sections F.10 and F.11, pages 29 and 30, the applicant projects \$189,528 in start-up expenses and \$1,727,216 in initial operating costs, respectively, for a total working capital of \$1,916,744.

Availability of Funds

In Section F.2, page 27, and Section F.13, page 31, the applicant states it will finance the capital costs and working capital costs respectively, with accumulated reserves of Fresenius Medical Care, Inc., as shown below:

Accumulated Reserves / Owner's Equity

| | TOTAL |
|----------------------|-------------|
| Capital Costs | \$594,049 |
| Working Capital | \$1,916,744 |
| Total to be Financed | \$2,465,793 |

Exhibit F-1 contains a letter dated April 16, 2018, from the Senior Vice President & Treasurer for Fresenius Medical Care Holdings, Inc. (FMCH), as the parent company of BMA, which confirms authorization and commitment of the cash reserves for the full project capital costs

as well as "any additional funds as may be necessary for start-up costs in the new location." Exhibit F-2 contains the Consolidated Financial Statements for FMCH which indicates that it had \$357.9 million in cash and cash equivalents as of December 31, 2016. The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

In Section R of the application, the applicant provides pro forma financial statements for the first two fiscal 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 in the table below.

| PROJECTED REVENUES AND OPERATING EXPENSES | | | | |
|---|-----------------------------|-----------------------------|--|--|
| FKC Rockfish | OPERATING YEAR 1 CY 2019 | OPERATING YEAR 2 CY 2020 | | |
| Total Treatments (adjusted for missed treatments) | 9,633 | 10,077 | | |
| Total Gross Revenues (Charges) | \$38,416,404 | \$40,187,076 | | |
| Total Net Revenue | \$ 2,636,274 | \$ 2,757,784 | | |
| Average Net Revenue per Treatment | \$ 273.67 | \$ 273.67 | | |
| Total Operating Expenses (Costs) | \$ 2,590,823 | \$ 2,675,273 | | |
| Average Operating Expense per Treatment | \$ 268.95 | \$ 265.48 | | |
| Net Income | \$ 45,451 | \$ 82,511 | | |

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- 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.

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

 \mathbf{C}

The applicant was previously approved, in two separate applications (Project ID #M-11286-17 and Project ID #M-11344-17), to develop two ten-station dialysis facilities in Fayetteville and Hope Mills by relocating existing dialysis stations at existing BMA facilities within Cumberland County. This application represents a change of scope of Project ID# M-11286-17, and proposes to consolidate those two previously approved projects to develop a new 20-station dialysis facility, FKC Rockfish in Fayetteville.

On page 365, the 2018 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 Cumberland County. Facilities may serve residents of counties not included in their service area.

In Project I.D. #M-11286-17, the applicant adequately demonstrated that the project would not result in the unnecessary duplication of existing or approved dialysis services and no changes are proposed in this application that affect that determination.

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.

 \mathbf{C}

The applicant was previously approved, in two separate applications (Project ID #M-11286-17 and Project ID #M-11344-17), to develop two ten-station dialysis facilities in Fayetteville and Hope Mills by relocating existing dialysis stations at existing BMA facilities within Cumberland County. This application represents a change of scope of Project ID# M-11286-17, and proposes to consolidate those two previously approved projects to develop a new 20-station dialysis facility, FKC Rockfish in Fayetteville.

In Section H.8, page 39, the applicant provides an updated staffing chart to illustrate an increase in proposed staffing for FKC Rockfish, since the facility now proposes 20 stations rather than ten. The following table combines the previously approved staffing for FKC Rockfish and the proposed changes in this change of scope application:

| Position | #FTES | #FTES | DIFFERENCE |
|-------------------|------------|---------|------------|
| | M-11286-17 | CURRENT | |
| | | APP. | |
| Registered Nurse | 1.50 | 3.00 | 1.50 |
| Technician (PCT)) | 4.00 | 6.00 | 2.00 |
| Clinical Manager | 1.00 | 1.00 | 0.40 |
| Administrator | 0.15 | 0.20 | 0.40 |
| Dietician | 0.40 | 0.80 | 0.00 |
| Social Worker | 0.40 | 0.80 | 0.05 |
| Chief Tech | 0.15 | 0.15 | 0.05 |
| Equipment Tech | 0.60 | 0.85 | 0.25 |
| In-Service | 0.15 | 0.20 | 0.00 |
| Clerical | 0.75 | 1.00 | 0.25 |
| Total | 9.10 | 14.00 | 4.90 |

As illustrated in the table above, the applicant projects to begin the proposed 20-station facility with 14.0 FTEs. The assumptions and methodology used to project staffing are provided in Section H.8, page 39.

In Project I.D. #M-11286-17, the application was found conforming to this criterion, and the applicants propose no changes in the current application that would affect that determination, notwithstanding the increase in the number of FTEs as noted above.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(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.

 \mathbf{C}

In Project I.D. #M-11286-17, the application was found conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that 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

In Project ID #M-11286-17, the applicant did not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant did not project to provide the proposed dialysis services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. The applicant proposes no changes in the current application that would affect that determination. Therefore, Criterion (9) is not applicable to this review.

- (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

In Project ID #M-11286-17, the applicant was not an HMO. In this application, the applicant does not propose any change that would affect that determination. Therefore, Criterion (10) is not applicable to this review.

- (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 application under review is for a change of scope for Project I.D. #M-11286-17. In the original application, the applicant proposed to lease and upfit 2,927 square feet of space in which to develop the proposed 10-station dialysis facility. This change of scope application proposes to develop a 20-station dialysis facility by consolidating Project ID #M-11286-17 and Project ID #M-11344-17. Thus the applicant proposes to increase the total square footage of the facility by approximately 829 square feet, as shown in the table below from Section K.7, page 46:

FKC Rockfish Proposed Facility

| TREATMENT AREA | PREVIOUSLY APPROVED SQUARE FEET | ESTIMATED NEW SQUARE FEET | ESTIMATED TOTAL SQUARE FEET |
|-------------------|---------------------------------|---------------------------|-----------------------------|
| Dialysis Stations | 2,793 | 821 | 3,614 |
| Isolation Room | 134 | 8 | 142 |
| Total Square Feet | 2,927 | 829 | 3,756 |

In Section K.7, page 46, the applicant states the increase in square footage is necessary to accommodate the additional dialysis stations proposed in this change of scope application.

In Project ID #M-11286-17, the application was found conforming to this criterion. In this application, notwithstanding the increase in square footage to accommodate the additional stations, the applicant does not propose any change that would affect the finding of conformity in the original application.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the healthrelated 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;

 \mathbf{C}

The facility is not yet developed and has no patient payor mix to report. However, in Section L.7, pages 51 - 52, the applicant provides three tables to illustrate historical payor mix for CY 2017 for the three facilities that will relocate stations to the proposed FKC Rockfish (FMC South Ramsey, FMC North Ramsey and FMC West Fayetteville). See the following table, which combines the three tables on pages 51 - 52:

| PAYMENT SOURCE | FMC SOUTH RAMSEY % OF TOTAL PATIENTS | FMC NORTH RAMSEY % OF TOTAL PATIENTS | FMC WEST FAYETTEVILLE % OF TOTAL PATIENTS |
|-------------------------------|--|--|---|
| Self-Pay / Indigent / Charity | 0.72% | 0.29% | 0.15% |
| Medicare | 68.00% | 70.25% | 74.96% |
| Medicaid | 6.75% | 8.09% | 5.28% |
| Commercial Insurance | 1.69% | 5.51% | 5.56% |
| Medicare Commercial | 17.73% | 12.84% | 10.99% |
| Miscellaneous (Incl. VA) | 5.00% | 3.01% | 3.08% |
| Total | 100.00% | 100.00% | 100.00% |

Totals may not sum due to rounding

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** | |
| Cumberland | 11% | 51% | 55% | 18% | 11% | 16% | |
| Hoke | 9% | 51% | 60% | 20% | 12% | 17% | |
| Robeson | 14% | 51% | 75% | 31% | 13% | 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"

^{**&}quot;This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc.* 2014 Annual Report¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents 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. 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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, the application was conforming to this criterion in Project I.D. #M-11286-17 and the applicant proposes no changes in the current change of scope application that would affect that determination.

¹http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf

²http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015 NW-6 Annual-Report Final-11-29-2016.pdf

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that 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

 \mathbf{C}

In Project I.D. #M-11286-17 the application was conforming to this criterion and the applicant proposes no changes in the current change of scope application that would affect that determination.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that 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.

 \mathbf{C}

In Project I.D. #M-11286-17 the application was conforming to this criterion and the applicant proposes no changes in the current change of scope application that would affect that determination.

The Agency reviewed the:

- Application
- Exhibits to the application

• Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that 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.

 \mathbf{C}

In Section M.3, page 53, the applicant states "There are no changes. BMA did include a new letter to FTCC because the number of stations at FKC Rockfish is proposed to change." In Exhibit M-1, the applicant provides a copy of a letter dated April 16, 2018 to Fayetteville Technical Community College inviting the nursing students to include FKC Rockfish in their clinical rotations.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes 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 was previously approved, in two separate applications (Project ID #M-11286-17 and Project ID #M-11344-17), to develop two ten-station dialysis facilities in Fayetteville and Hope Mills by relocating existing dialysis stations at existing BMA facilities within Cumberland County. This application represents a change of scope of Project ID# M-11286-17, and proposes to consolidate those two previously approved projects to develop a new 20-station dialysis facility, FKC Rockfish in Fayetteville.

On page 365, the 2018 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 Cumberland County. Facilities may serve residents of counties not included in their service area.

In Project I.D. #M-11286-17, the applicant adequately demonstrated that the project would not result in the unnecessary duplication of existing or approved dialysis services and no changes are proposed in this application that affect that determination. This change of scope application proposes a new 20-station facility at the same location as the previously approved 10-station facility, and proposes to serve the same patient population as the previously approved application.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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, pages 55 - 58 and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality in all of its dialysis facilities, including the proposed FKC Rockfish facility.

In Section O.3, pages 58 - 59, the applicant states that out of more than 100 facilities located in North Carolina operated by the applicant or a related entity, one facility, BMA East Rocky Mount, was not in compliance with Medicare conditions of participation during the 18 months prior to submission of this change of scope application.

On page 39, the applicant states that the 18 month "look back" period will expire in July 2018. In Exhibit O, the applicant provides documentation from the Acute and Home Care Licensure and Certification Section, DHSR dated March 2, 2017 that indicates the deficiencies with which the BMA East Rocky Mount facility were cited had been corrected as of that date.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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.

 \mathbf{C}

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.
 - -C- In Section C.15, page 16, the applicant adequately demonstrates that FKC Rockfish projects to serve a total of 66 in-center patients at the end of OY 1 (CY 2019) for a utilization rate of 82.5% or 3.3 patients per station per week (66 patients / 20 stations = 3.3; 3.3 / 4 = 0.825 or 82.5%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.
 - -NA- FKC Rockfish is not an existing facility.

- (c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.
 - -C- In Section C, page 16, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.