

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

CORRECTED

Decision Date: August 17, 2018

Findings Date: August 17, 2018

Project Analyst: Ena Lightbourne

Team Leader: Gloria C. Hale

Project ID #: J-11510-18

Facility: Fresenius Kidney Care Holly Springs

FID #: 180261

County: Wake

Applicant: Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Holly Springs

Project: Develop a new 10-station dialysis facility in Holly Springs, Wake County by relocating four existing certified dialysis stations from BMA of Raleigh Dialysis, four existing certified dialysis stations from FMC New Hope Dialysis, and two existing certified dialysis stations from Southwest Wake County Dialysis.

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a/ Fresenius Kidney Care Holly Springs (FKC Holly Springs) proposes to develop a new 10-station dialysis facility in Holly Springs, Wake County by relocating four existing certified dialysis stations from BMA of Raleigh Dialysis, four existing certified dialysis stations from FMC New Hope Dialysis, and two existing certified dialysis stations from Southwest Wake County Dialysis.

Need Determination

The applicant does not propose to increase the number of licensed beds in any category, add any new health services or acquire equipment for which there is a need determination in the 2018 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2018 SMFP that are applicable to this review. Criterion (1) is not applicable to this review.

Policies

There is one policy in the 2018 SMFP that is applicable to this review: *Policy ESRD-2 Relocation of Dialysis Stations*, on page 27.

Policy ESRD-2: Relocation of Dialysis Stations

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

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

The applicant proposes to relocate existing dialysis stations within Wake County, thus there will be no change to the dialysis inventory of Wake County. Therefore, the application is consistent with Policy ESRD-2.

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 reasons stated above.

- (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, Bio-Medical Applications of North Carolina, Inc. d/b/a/ FKC Holly Springs proposes to develop a new 10-station dialysis facility in Holly Springs, Wake County by relocating four existing certified dialysis stations from BMA of Raleigh Dialysis, four existing certified dialysis stations from FMC New Hope Dialysis, and two existing certified dialysis stations from Southwest Wake County Dialysis.

Patient Origin

On page 365 the 2018 SMFP defines the service area for dialysis stations 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 counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

In Section C. 1, page 16, the applicant provides the projected patient origin for in-center dialysis patients for the first two years of operation following completion of the project as follows:

| County | Operating Year 1 (1/1/20-12/31/20) | | Operating Year 2 (1/1/21-12/31/21) | |
|--------------|---------------------------------------|---------------|---------------------------------------|---------------|
| | In-Center Patients | % of Total | In-Center Patients | % of Total |
| Wake | 33.4 | 100.0% | 34.8 | 100.0% |
| Total | 33.0 | 100.0% | 34.0 | 100.0% |

In Section C.1, pages 16-17, 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 Section C.2, page 18, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services.

“The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment, and the stated desires of the patients to have dialysis at the proposed FKC Holly Springs location.

These patients are currently receiving dialysis care and treatment at another location. However:

- that location is not as convenient for the patient;*
- that location requires more time for travel to and from dialysis treatment;*
- that location involves more expense related to travel (fuel costs are not insignificant).”*

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

- The applicant demonstrates the need to develop a new dialysis facility by relocating existing dialysis stations consistent with Policy ESRD-2. The discussion regarding Policy ESRD-2 found in Criterion (1) is incorporated herein by reference.
- The applicant demonstrates, through signed patient letters, that existing FMC Apex, Cary Kidney Center, BMA of Fuquay Varina, and BMA of Raleigh patients would be better served by a new facility located in Holly Springs.

Projected Utilization

In Section C.1, pages 16-17, the applicant describes its need methodology assumptions for projecting utilization of the proposed facility as follows:

1. The applicant has plotted the residence location of patients dialyzing at the Fresenius related dialysis facilities in Wake County. The applicant determined that there are a significant number of dialysis patients residing in the area of Holly Springs.
2. The applicant assumes that 32 patients dialyzing at a BMA facility will complete the transfer to the Holly Springs facility based upon the reduction in travel distance. The applicant has included 32 letters of support (Exhibit C-1) from in-center patients who reside in close proximity to the proposed facility and who expressed willingness to relocate there.
3. The applicant assumes that the Wake County dialysis patients transferring to the new FKC Holly Springs facility are a part of the Wake County ESRD patient population as a whole, and that this population will increase at a rate commensurate with the Wake County Five Year Average Annual Change Rate (AACR) of 4.3% as published in the draft July 2018 Semi-Annual Dialysis Report (SDR).
4. Operating Year (OY) One is projected to be calendar year (CY) 2020; and OY 2 is projected to be CY 2021.

The applicant’s methodology for serving in-center patients is shown in the following table, from page 17:

| FKC Holly Springs | In-Center |
|---|-----------------------------|
| Begin with 32 Wake County in-center dialysis patients who have signed letters of support for this project. BMA assumes the patients will transfer as of December 31, 2019 | 32 in-center patients |
| Project growth of the patient census for one year, to December 31, 2020. This is the ending census for Operating Year 1. | $32 \times 1.043 = 33.38$ |
| Project growth of the patient census for one year, to December 31, 2021. This is the ending census for Operating Year 2. | $33.38 \times 1.043 = 34.8$ |

The applicant rounds down to the nearest whole number and projects to serve 33 in-center patients or 3.3 patients per station per week ($33 / 10 = 3.3$) by the end of the Operating Year 1 and 34 in-center patients or 3.4 patients per station per week ($34 / 10 = 3.4$) by the end of Operating Year 2 for the proposed 10-station facility. 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 in-center utilization is based on reasonable and adequate supported assumptions regarding continued growth.

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

- The applicant projects the starting patient census for the proposed facility based on existing patients who live in Wake County and currently dialyze at a BMA facility, each of whom has signed a letter expressing an intent to transfer dialysis care to the proposed FKC Holly Springs facility.
- The applicant’s growth projections are based on an assumption that the dialysis patient census will increase annually by 4.3%, which is consistent with the Five Year AACR for Wake County, reported in the draft July 2018 SDR.

Access

In Section C.3, page 19, the applicant states that Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.

In Section L.1, page 64, the applicant projects the following payor mix during the second full fiscal year of operation following the completion of the project as illustrated in the following table.

Projected Payor Mix-Project Year 2

| Payor Category | Dialysis Services as Percent of Total |
|----------------------------|--|
| Self- Pay/indigent/Charity | 2.71% |
| Medicare | 47.49% |
| Medicaid | 9.76% |
| Commercial Insurance | 8.95% |
| Medicare/Commercial | 27.85% |
| Medicare/Medicaid | 0.00% |
| Miscellaneous (incl. VA) | 3.24% |
| Other | 0.00% |
| Total | 100.00% |

The projected payor mix is reasonable and adequately supported.

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 reason:

- The applicant adequately identifies the population to be served
- The applicant adequately explains why the population to be served needs the services proposed on the application
- Projected utilization is reasonable and adequately supported
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and 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.

C

The applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a/ FKC Holly Springs proposes to develop a new 10-station dialysis facility in Holly Springs, Wake County by relocating four existing certified dialysis stations from BMA of Raleigh Dialysis, four existing

certified dialysis stations from FMC New Hope Dialysis, and two existing certified dialysis stations from Southwest Wake County Dialysis.

The following tables from Section D, pages 25, 28 and 31, show the projected relocation of stations from the three existing dialysis facilities to the proposed FKC Holly Springs facility, and the number of stations remaining after the relocation to the proposed new facility:

BMA Raleigh

| | # of stations | Description | Project ID # (if applicable) |
|--------|----------------------|---|-------------------------------------|
| (i) | 50 | Total # of existing certified stations as of the most recent SDR | |
| (ii) | 0 | # of stations to be added as part of this project | |
| (iii) | -4 | # of stations to be deleted as part of this project | |
| (iv) | 6 | # of stations previously approved to be added but not yet certified | J-11237-16 |
| (v) | -6 | # of stations previously approved to be deleted but not yet certified | J-11220-16 |
| (vi) | 0 | # of stations proposed to be added in an application still under review | |
| (vii) | 0 | # of stations proposed to be deleted in an application still under review | |
| (viii) | 46 | Total # of stations upon completion of all facility projects | |

FMC New Hope

| | # of stations | Description | Project ID # (if applicable) |
|--------|----------------------|---|-------------------------------------|
| (i) | 36 | Total # of existing certified stations as of the most recent SDR | |
| (ii) | 0 | # of stations to be added as part of this project | |
| (iii) | -4 | # of stations to be deleted as part of this project | |
| (iv) | 6 | # of stations previously approved to be added but not yet certified | J-11317-16 |
| (v) | -6 -4 | # of stations previously approved to be deleted but not yet certified | J-11271-16 J-11372-16 |
| (vi) | 0 | # of stations proposed to be added in an application still under review | |
| (vii) | 0 | # of stations proposed to be deleted in an application still under review | |
| (viii) | 28 | Total # of stations upon completion of all facility projects | |

Southwest Wake County Dialysis

| | # of stations | Description | Project ID # (if applicable) |
|--------|----------------------|---|-------------------------------------|
| (i) | 30 | Total # of existing certified stations as of the most recent SDR | |
| (ii) | 0 | # of stations to be added as part of this project | |
| (iii) | -2 | # of stations to be deleted as part of this project | |
| (iv) | 6 | # of stations previously approved to be added but not yet certified | J-11146-16 |
| (v) | -6 | # of stations previously approved to be deleted but not yet certified | J-11133-16 |
| (vi) | 0 | # of stations proposed to be added in an application still under review | |
| (vii) | 0 | # of stations proposed to be deleted in an application still under review | |
| (viii) | 28 | Total # of stations upon completion of all facility projects | |

In Section D, pages 25 – 32, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated or relocated will be adequately met following the completing of the projects.

BMA Raleigh

- The applicant projects the future population of BMA Raleigh beginning with the facility census of 182 patients as of December 31, 2017. The applicant increases the Wake County patient population using the Wake County Five Year AACR of 5.6% as published in the January 2018 SDR.
- The applicant projects the starting patient census for the proposed facility based on existing patients who live in Wake County and currently dialyze at BMA Raleigh, each of whom has signed a letter expressing their intent to transfer dialysis care to the proposed FKC Holly Springs facility.
- In Section D.1, page 26, the applicant calculates the in-center patient census for BMA Raleigh starting December 31, 2017 through December 31, 2019, summarized as follows:

| | |
|---|------------------------------|
| Begin with the facility census of Wake County residents as of December 31, 2017 | 182 |
| Project this patient population forward for 6 months to June 30, 2018, using half of the Wake County Five Year Average Annual Change Rate | $182 \times 1.028 = 187.1$ |
| Subtract 5 patients projected to transfer to FMC Morrisville and FMC White Oak | $187.1 - 5 = 182.1$ |
| Project this population forward for 12 months to June 30, 2019, using the Wake County Five Year Average Annual Change Rate (AACR) of 5.6% | $182.1 \times 1.056 = 192.4$ |
| Subtract 12 patients projected to transfer to FMC Rock Quarry | $192.4 - 12 = 180.4$ |
| Project this population forward for 6 months to December 31, 2019. This is the projected completion date for this project. | $180.4 \times 1.028 = 185.5$ |
| Add one out of county patient | $185.5 + 1 = 186.5$ |
| Round to the next whole number. This is the number of patients projected to be dialyzing at BMA Raleigh on December 31, 2019. | 187 |

The applicant projects 187 patients to be dialyzing at BMA Raleigh on December 31, 2019. The facility will have 46 dialysis stations. Utilization is projected to be 4.1 patients per station per week or 101.63%.

FMC New Hope

- The applicant projects the future population of FMC New Hope beginning with the facility census of 126 patients as of December 31, 2017. The applicant increases the Wake County patient population using the Wake County Five Year AACR of 5.6% as published in the January 2018 SDR.
- The applicant states “*As BMA demonstrates growth of the census at the facility, BMA will also include patient transfers to other BMA projects.*” The applicant’s growth projections are based on an assumption that the dialysis patient census will increase annually by 5.6%, which is consistent with the Five Year AACR for Wake County, reported in the January 2018 SDR.
- In Section D.1, page 29, the applicant calculates the in-center patient census for FMC New Hope starting December 31, 2017 through December 31, 2019, summarized as follows:

| | |
|---|------------------------------|
| Begin with the facility census of Wake County residents as of December 31, 2017 | 126 |
| Project this patient population forward for 6 months to June 30, 2018, using half of the Wake County Five Year Average Annual Change Rate | $126 \times 1.028 = 129.5$ |
| Subtract 5 patients projected to transfer to FMC White Oak. | $129.5 - 5 = 124.5$ |
| Project this population forward for 6 months to December 31, 2018 | $124.5 \times 1.028 = 128.0$ |
| One Johnston County patient is projected to transfer to FKC Selma. This does not affect the projected Wake County Patient Population. | |
| Project the Wake County population forward for 6 months to June 30, 2019. | $128.0 \times 1.028 = 131.6$ |
| Subtract 8 patients projected to transfer to FMC Rock Quarry. | $131.6 - 8 = 123.6$ |
| Project this population forward for 6 months to December 31, 2019. This is the projected completion date for this project. | $123.6 \times 1.028 = 127.1$ |
| Add the 5 out of county patients | $127.1 + 5 = 132.1$ |
| Round to the next whole number. This is the number of patients projected to be dialyzing at BMA Raleigh [FKC New Hope] on December 31, 2019.* | 133 |

*The Project Analyst's corrections are in brackets.

The applicant projects 133 patients to be dialyzing at the FMC New Hope on December 31, 2019. The facility will have 28 dialysis stations. Utilization is projected to be 4.75 patients per station per week, or 118.75%.

Southwest Wake County Dialysis

- The applicant projects the future population of Southwest West County Dialysis beginning with the facility census of 113 patients as of December 31, 2017. The applicant will project an increase of the Wake County patient population using the Wake County Five Year AACR of 5.6% as published in the January 2018 SDR.
- The applicant states “As BMA demonstrates growth of the census at the facility, BMA will also include patient transfers to other BMA projects.” Twenty-Four patients will transfer from Southwest Wake County Dialysis to FMC White Oak and FMC Morrisville on June 30, 2018, and eight patients will transfer and to FMC Rock Quarry on June 30, 2019. The applicant projects that no patients from Southwest Wake County Dialysis will transfer to the new FKC Holly Springs facility.

- In Section D.1, page 32, the applicant calculates the in-center patient census for Southwest Wake County Dialysis starting December 31, 2017 through December 31, 2019, summarized as follows:

| | |
|---|---|
| Begin with the facility census of Wake County residents as of December 31, 2017 | 113 |
| Project this patient population forward for 6 months to June 30, 2018, Using half of the Wake County Five Year Average Annual Change Rate | $113 \times 1.028 = 116.2$ |
| Subtract 20 [24] patients projected to transfer to FMC Morrisville and/or FMC White Oak. | $116.20 - 20 [24] = 96.2 [92.2]$ |
| Project this population forward for 12 months to December 31, 2019 | $96.2 [92.2] \times 1.056 = 101.6 [97.4]$ |
| Subtract 8 patients projected to transfer to FMC Rock Quarry. | $101.6 [97.4] - 8 = 93.6 [89.4]$ |
| Project this population forward for 6 month to December 31, 2019. This is the projected completion date for this project. | $93.6 [89.4] \times 1.028 = 96.2 [91.9]$ |
| Round to the next whole number. This is the number of patients projected to be dialyzing at BMA Raleigh [Southwest Wake County Dialysis] on December 31, 2019.* | 97 [92] |

*The Project Analyst’s corrections are in brackets.

The applicant projects 92 patients to be dialyzing at the Southwest Wake County Dialysis on December 31, 2019. The facility will have 28 dialysis stations. Utilization is projected to be 3.29 patients per station per week, or 82.25%.

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

- The applicant projects the patient census for BMA Raleigh, FMC New Hope and Southwest Wake County Dialysis based on existing BMA Raleigh, FMC New Hope and Southwest Wake County Dialysis patients, and those patients who have signed letters expressing their intention to transfer their care to other BMA facilities.
- The applicant’s growth projections are based on an assumption that patient census will increase at an annual rate of 5.6%, which is consistent with the Five Year AACR for Wake County, as reported in Table D of the January 2018 SDR.

Further, in Section D, page 32, the applicant states the following: *“The relocation of stations as described within this application will not alter or affect 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.”*

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.

CA

The applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a/ FKC Holly Springs proposes to develop a new 10-station dialysis facility in Holly Springs, Wake County by relocating four existing certified dialysis stations from BMA of Raleigh Dialysis, four existing certified dialysis stations from FMC New Hope Dialysis, and two existing certified dialysis stations from Southwest Wake County Dialysis.

In Section E, pages 33-34, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo - The applicant states there are a significant number of dialysis patients dialyzing with BMA and residing in close proximity to the proposed FKC Holly Springs facility. These patients can be better served by development of this facility.
- Relocation of Stations from other Dialysis Facilities in Wake County - The applicant acknowledges that the July 2018 SDR will reflect a growth rate of 4.3% for the Wake County ESRD patient population. The applicant states given the need for additional stations as the ESRD patient population increases, the applicant has elected to source the stations for FKC Holly Springs from dialysis facilities which will generate additional stations using the Facility Need Methodology.
- Development of a Facility in another area of Wake County – The applicant states evaluation of the existing patient populations served by BMA and Fresenius related facilities, indicates that BMA is serving a patient population in the area of Holly Springs which might be better served by the proposed new facility.
- Development of a Larger Facility, with more In-Center Dialysis Stations – The applicant states after evaluation of the population served, it was determined that the FKC Holly

Springs should not apply for more than 10 stations. The applicant has projected to serve a population of 32 in-center patients at the end of the first year of operations. Thus, the facility projects to serve a patient population of sufficient size to meet the Performance Standards at 10A NCAC 14C .2203.

- Include Home Therapies – The applicant states BMA has home therapy programs at several facilities within Wake County, including the BMA Fuquay Varina facility, approximately six miles from the primary site of FKC Holly Springs. Thus, BMA contains construction and development costs by not adding home therapies at this proposed facility.

In Section E.2, page 34, the applicant states that BMA has chosen the most cost effective alternative because of the residence location of the patients currently being served by BMA at area dialysis facilities and those projected to be served. In addition, the applicant states projections of cost are reasonable, and are not significantly different from other similar developments by BMA across North Carolina.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to the meet the need for the following reasons:

- Maintaining the status quo is not an effective alternative due to the fact there are a significant number of dialysis patients dialyzing with BMA and residing in close proximity to the proposed FKC Holly Springs.
- Relocating stations from any of its other dialysis facilities in Wake County is not an effective alternative because the need to add stations back to the facility must be considered given the need for additional stations as the ESRD patient population increases.
- Developing a facility in another area of Wake County would not address the need to serve the patient population in Holly Springs.
- Developing a larger facility, with more in-center dialysis stations, is not an effective alternative because the size of the proposed facility is sufficient to meet the Performance Standards at 10A NCAC 14C .2203.
- Offering home therapies at the proposed facility would not be an effective alternative due to the number of BMA facilities providing home therapies in Wake County.

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. **The applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a/ Fresenius Kidney Care Holly Springs shall materially comply with the representations made in the certificate of need application.**
 2. **Pursuant to Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. d/b/a/ Fresenius Kidney Care Holly Springs shall develop a new kidney disease treatment center to be known as Fresenius Kidney Care Holly Springs by relocating four existing certified dialysis stations from BMA of Raleigh Dialysis, four existing certified dialysis stations from FMC New Hope Dialysis, and two existing certified dialysis stations from Southwest Wake County Dialysis.**
 3. **The applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a/ Fresenius Kidney Care Holly Springs shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations which shall include isolation stations.**
 4. **Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 4 dialysis stations at BMA Raleigh for a total of no more than 46 dialysis stations at BMA Raleigh, 4 dialysis stations at FMC New Hope for a total of no more than 28 dialysis stations at FMC New Hope, and 2 dialysis stations at Southwest Wake County for a total of no more than 28 dialysis stations at Southwest Wake County.**
 5. **The applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a/ Fresenius Kidney Care Holly Springs 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, Bio-Medical Applications of North Carolina, Inc. d/b/a/ Fresenius Kidney Care Holly Springs proposes to develop a new 10-station dialysis facility in Holly Springs, Wake County by relocating four existing certified dialysis stations from BMA of Raleigh Dialysis, four existing certified dialysis stations from FMC New Hope Dialysis, and two existing certified dialysis stations from Southwest Wake County Dialysis.

Capital and Working Capital Costs

In Section F.1, page 36, the applicant projects the total capital cost of the project as shown in the table below:

Capital Costs

| | |
|---------------------|--------------------|
| Construction Costs | \$1,019,048 |
| Miscellaneous Costs | \$ 763,995 |
| Total | \$1,783,043 |

In Section F, pages 39-40, the applicant projects that start-up costs will be \$124,185 and initial operating expenses will be \$960,230 for a total working capital of \$1,084,397. On pages 39-40, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F.2, page 37, the applicant states that the capital cost will be funded as shown in the table below:

Sources of Capital Cost Financing

| Type | Bio-Medical Applications of North Carolina, Inc. | Total |
|------------------------------|--|--------------------|
| Loans | \$0 | \$0 |
| Accumulated reserves or OE * | \$1,783,044 | \$1,783,044 |
| Other (Specify) | \$0 | \$0 |
| Total Financing | \$1,783,044 | \$1,783,044 |

* OE = Owner's Equity

In Section F.13 page 41, the applicant states that the working capital needs of the project will be funded as shown in the table below:

| Sources of Financing for Working Capital | | Amount |
|--|--|--------------------|
| (a) | Unrestricted cash | \$ 0 |
| (b) | Unrestricted Market securities | \$ 0 |
| (c) | Accounts receivable | \$ 0 |
| (d) | Commercial Loan | \$ 0 |
| (e) | Line of credit | \$ 0 |
| (f) | Other: FMC Accumulated Reserves | \$1,084,397 |
| (g) | Total | \$1,084,397 |

Exhibit F-1 contains a letter dated May 15, 2018 from Senior Vice President and Treasurer for Fresenius Medical Care Holdings, Inc., authorizing and committing cash reserves of Fresenius Medical Care Holdings for the capital costs of the project. Exhibit F-2 contains a copy of the balance sheet for Fresenius Medical Care Holdings, Inc., for the year ending in December 31, 2016 and 2017. For year ending December 31, 2017, Fresenius Medical Care Holdings, Inc. had \$569,818,000 in cash and cash equivalents, \$19,822,127,000 of total assets and \$10,542,494,000 in net assets (total assets less total liabilities).

Financial Feasibility

The applicant provided pro forma financial statements in Section R for the first two full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project as shown in the table below:

| | 1 st Full Fiscal Year 2020 | 2 nd Full Fiscal Year 2021 |
|---|--|--|
| Total Treatments | 4,742 | 5,038 |
| Total Gross Revenues (Charges) | \$18,911,096 | \$20,091,544 |
| Total Net Revenue | \$ 1,463,194 | \$ 1,554,528 |
| Average Net Revenue per Treatment | \$ 309 | \$ 309 |
| Total Operating Expenses (Costs) | \$ 1,440,319 | \$ 1,489,892 |
| Average Operating Expense per Treatment | \$ 304 | \$ 296 |
| Net Income | \$ 22,875 | \$ 64,636 |

The assumption used by the applicant is 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.

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.

C

The applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a/ FKC Holly Springs proposes to develop a new 10-station dialysis facility in Holly Springs, Wake County by relocating four existing certified dialysis stations from BMA of Raleigh Dialysis, four existing certified dialysis stations from FMC New Hope Dialysis, and two existing certified dialysis stations from Southwest Wake County Dialysis.

On page 365 the 2018 SMFP defines the service area for dialysis stations 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 counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

The applicant operates twelve dialysis facilities in Wake County. In addition, FMC has been approved to develop three additional facilities in Wake County, FMC Morrisville, FMC White Oak, and FMC Rock Quarry, but the facilities were not yet operational on June 30, 2017. DaVita is the only other provider of dialysis services in Wake County, and currently operates one dialysis center. DaVita has been approved to develop one additional facility in Wake County, Oak City Dialysis, but the facility was not yet operational on June 30, 2017. The existing and approved Wake County dialysis facilities are shown below:

| Facility Name | Provider | Location | #of stations | Utilization |
|------------------------------------|-----------------|-----------------|---------------------|--------------------|
| BMA of Fuquay-Varina Kidney Center | FMC | Fuquay-Varina | 28 | 75.00% |
| BMA Raleigh Dialysis | FMC | Raleigh | 50 | 88.00% |
| Cary Kidney Center | FMC | Cary | 28 | 83.93% |
| FMC Apex | FMC | Apex | 20 | 76.25% |
| FMC Central Raleigh | FMC | Raleigh | 19 | 78.95% |
| FMC Eastern Wake | FMC | Rolesville | 17 | 69.12% |
| FMC Millbrook | FMC | Raleigh | 17 | 76.47% |
| FMC New Hope Dialysis | FMC | Raleigh | 36 | 86.11% |
| FMC Northern Wake | FMC | Wake Forest | 16 | 60.94% |
| Southwest Wake County Dialysis | FMC | Raleigh | 30 | 93.33% |
| Wake Dialysis Clinic | FMC | Raleigh | 50 | 98.00% |
| Zebulon Kidney Center | FMC | Zebulon | 28 | 88.39% |
| FMC Morrisville* | FMC | Morrisville | 10 | NA |
| FMC White Oak* | FMC | Garner | 12 | NA |
| FMC Rock Quarry | FMC | Raleigh | 0 | NA |
| Wake Forest Dialysis Center | DaVita | Raleigh | 2 | 90.91% |
| Oak City Dialysis* | DaVita | Raleigh | 0 | NA |

Source: Table B of the January SDR

*CON-approved, but not operational dialysis centers

As shown in the table above, seven of the 13 operational dialysis facilities in Wake County were operating above 80% utilization (3.2 patients per station per week), and eleven of the

thirteen operational facilities in Wake County were operating at or above 75% utilization (3.0 patients per station per week), as of June 30, 2017.

In Section G, pages 45-46, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wake County. The applicant states:

“Approval of this application will not unnecessarily duplicate any existing health Service. This applicant seeks to relocate 10 existing and certified dialysis stations to a new location in the county. Approval of this application will not create additional stations in the county, but does enhance community based delivery of health care. FKC Holly Springs ends the first year with 33 patients dialyzing on 10 stations, representing 80% [82.5%] utilization.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The proposal would not result in an increase in the number of dialysis stations in Wake County.
- The applicant adequately demonstrates that the proposed new dialysis facility is needed in addition to the existing or approved dialysis facilities in Wake County.

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.

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

C

In Section H.1, page 47, the applicant provides projected staffing for the proposed services as illustrated in the following table.

| Position | Projected Staffing OY 2 (CY 2021) |
|----------------------|---|
| Medical Director | This a contract position; not an employee of the facility |
| RN | 1.50 |
| Patient Care Tech | 3.50 |
| Dietician | 0.33 |
| Social Worker | 0.33 |
| Clinical Manager | 1.00 |
| Admin (FMC Dir. Ops) | 0.15 |
| In Service | 0.15 |
| Clerical | 0.75 |
| Chief Tech | 0.15 |
| Equipment Tech | 0.50 |
| Total | 8.36 |

The assumptions and methodology used to project staffing are provided in Section H. Adequate costs for health manpower and management positions proposed by the applicant are budgeted in Form A, Section R.

The applicant states that many of the current staff of Fresenius Medical Care are expected to transfer to the new facility. In Exhibit I-6 the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services.

In Section H, pages 47-48, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

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.

C

In Section I.1, page 51, the applicant provides a table, reproduced below, showing the ancillary and support Service necessary for the proposed services, and how each will be made available.

| FKC Holly Springs Ancillary and Support Services | |
|---|--|
| SERVICES | PROVIDER |
| In-center dialysis/maintenance | FKC Holly Springs |
| Self-care training (in-center) | Referral to BMA of Fuquay Varina Kidney Center |
| Home training HH PD Accessible follow-up program | Referral to BMA of Fuquay Varina Kidney Center |
| Psychological counseling | Referral (Wake County Mental Health) |
| Isolation – hepatitis | FKC Holly Springs |
| Nutritional counseling | FKC Holly Springs |
| Social Work services | FKC Holly Springs |
| Acute dialysis in an acute care setting | Referral (UNC Health Care) |
| Emergency care | FKC Holly Springs, 911, Hospital |
| Blood bank services | Referral (UNC Rex Hospital) |
| Diagnostic and evaluation services | Referral (UNC Rex Hospital) |
| X-ray services | Referral (UNC Rex Hospital) |
| Laboratory services | Spectra (Exhibit I-2) |
| Pediatric nephrology | Referral (UNC) |
| Vascular surgery | Referral (Raleigh Access Center, Triangle Access Center Rex Vascular, Premier Surgical) |
| Transplantation services | Referral (UNC) |
| Vocational rehabilitation & counseling | Referral (Wake County Vocational Rehabilitation Services) |
| Transportation | Wake County Area Transit (JCATS) |

In Section I, pages 52-54, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-3 and I-4.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

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.

- (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

The applicant does not propose 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. The applicant states all of the patients projected to be served by this facility reside within Health Service Area (HSA) IV and none of the projected patients are expected to be residents of another HSA.

- (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

The applicant is not an HMO. 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

In Section K, pages 56-57, the applicant states that the project involves up fitting 6,500 square feet of leased space to be constructed at 105 Cotton Lane, Holly Springs, NC 27540. Line drawings are provided in Exhibit K-1.

On pages 56-57, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On pages 56-62, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibits K-4 through K-6.

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.

- (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

FKC Holly Springs is not an existing facility; however in Section L.1, page 67, the applicant reports that 84.92% of the patients who receive treatments at BMA of Raleigh Dialysis had some or all of their services paid for by Medicare or Medicaid, and that

83.8% of the patients who received treatments at FMC New Hope Dialysis had some or all of their services paid for by Medicare or Medicaid, in CY 2017. Southwest Wake County Dialysis had 84.13% of patients receiving treatment who had some or all their services paid by Medicaid or Medicaid in CY 2017. The table below shows the historical (CY 2017).

| Payment Source CY 2017 | BMA of Raleigh Dialysis Percent of Total Patients | FMC New Hope Dialysis Percent of Total Patients | Southwest Wake County Dialysis Percent of Total Patients |
|---------------------------|--|--|---|
| Self-Pay/Indigent/Charity | 3.26% | 1.64% | 0.21% |
| Medicare | 54.93% | 49.94% | 45.37% |
| Medicaid | 5.92% | 9.06% | 14.36% |
| Commercial Insurance | 10.56% | 12.21% | 10.56% |
| Medicare/Commercial | 24.07% | 24.80% | 24.40% |
| Medicare/Medicaid | 0.00% | 0.00% | 0.00% |
| Miscellaneous (Incl. VA) | 1.26% | 2.36% | 5.10% |
| Other: | 0.00% | 0.00% | 0.00% |
| Total | 100.00% | 100.00% | 100.00% |

Note: 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 and Ethnic Minority* | % Persons in Poverty** | % < Age 65 with a Disability | % < Age 65 without Health Insurance ** |
| 2017 Estimate | 2017 Estimate | 2017 Estimate | 2017 Estimate | 2017 Estimate | 2017 Estimate | 2017 Estimate |
| Wake | 11% | 51% | 40% | 9% | 6% | 9% |
| Statewide | 16% | 51% | 37% | 15% | 10% | 12% |

Source: <http://www.census.gov/quickfacts/table/US/PST045217>; Latest Data 7/1/17 as of 7/17/18

* Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. 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., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar

to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

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, in Section L.3, page 65, the applicant states,

“Fresenius related facilities in North Carolina do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

In Section L.6, page 66, the applicant states that during the last five years no patient civil rights access complaints have been filed against any BMA North Carolina facility.

¹<https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.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

C

In Section L.1, page 64, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Projected Payor Mix CY 2021

| Payor Category | Percent of Total Patients |
|---------------------------|----------------------------------|
| Self-Pay/Indigent/Charity | 2.7% |
| Medicare | 47.49% |
| Medicaid | 9.76% |
| Commercial Insurance | 8.95% |
| Medicare/Commercial | 27.85% |
| Medicare/Medicaid | 0.00% |
| Miscellaneous (Incl. VA) | 3.24% |
| Other: | 0.00% |
| Total | 100% |

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.7% of total services will be provided to self-pay patients and charity care patients, 75.34% to Medicare patients and 9.76% to Medicaid patients.

On page 64, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for BMA facilities in Wake County.

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.

C

In Section L, page 66, the applicant adequately describes the range of the means by which a patient will have access to the proposed services.

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.

C

In Section M.1, page 69, the applicant describes the extent to which area health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

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 demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, 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, Bio-Medical Applications of North Carolina, Inc. d/b/a/ Fresenius Kidney Care Holly Springs proposes to develop a new 10-station dialysis facility in Holly Springs, Wake County by relocating four existing certified dialysis stations from BMA of Raleigh Dialysis, four existing certified dialysis stations from FMC New Hope Dialysis, and two existing certified dialysis stations from Southwest Wake County Dialysis.

On page 365, the 2018 SMFP defines the service area for dialysis stations 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 counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

The applicant operates twelve dialysis facilities in Wake County. In addition, FMC has been approved to develop three additional facilities in Wake County, FMC Morrisville, FMC White Oak, and FMC Rock Quarry, but the facilities were not yet operational on June 30, 2017. DaVita is the only other provider of dialysis services in Wake County, and currently operates one dialysis center. DaVita has been approved to develop one additional facility in Wake County, Oak City Dialysis, but the facility was not yet operational on June 30, 2017. The existing and approved Wake County dialysis facilities are shown below:

| Facility Name | Provider | Location | #of stations | Utilization |
|--------------------------------|----------|---------------|--------------|-------------|
| BMA of Fuquay-Varina | FMC | Fuquay-Varina | 28 | 75.00% |
| BMA Raleigh Dialysis | FMC | Raleigh | 50 | 88.00% |
| Cary Kidney Center | FMC | Cary | 28 | 83.93% |
| FMC Apex | FMC | Apex | 20 | 76.25% |
| FMC Central Raleigh | FMC | Raleigh | 19 | 78.95% |
| FMC Eastern Wake | FMC | Rolesville | 17 | 69.12% |
| FMC Millbrook | FMC | Raleigh | 17 | 76.47% |
| FMC New Hope Dialysis | FMC | Raleigh | 36 | 86.11% |
| FMC Northern Wake | FMC | Wake Forest | 16 | 60.94% |
| Southwest Wake County Dialysis | FMC | Raleigh | 30 | 93.33% |
| Wake Dialysis Clinic | FMC | Raleigh | 50 | 98.00% |
| Zebulon Kidney Center | FMC | Zebulon | 28 | 88.39% |
| FMC Morrisville* | FMC | Morrisville | 10 | NA |
| FMC White Oak* | FMC | Garner | 12 | NA |
| FMC Rock Quarry | FMC | Raleigh | 0 | NA |
| Wake Forest Dialysis Center | DaVita | Raleigh | 22 | 90.91% |
| Oak City Dialysis* | DaVita | Raleigh | 0 | NA |

Source: Table B of the January 2018 SDR

*CON-approved, but not operational dialysis centers

In Section N.1, page 70, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 70, the applicant states *“The applicant does not expect this proposal to have effect on the competitive climate in Wake County.”* The applicant does not project to serve dialysis patients currently being served by another provider.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

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 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 Exhibit A-4, the applicant identifies the dialysis facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies more than 100 of this type of facility located in North Carolina.

In Section O, page 75, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred only in the BMA East Rocky Mount facility. The applicant provides documentation in Exhibit O-3 that BMA East Rocky Mount is currently back in full compliance with all of the CMS requirements as of March 1, 2017. The applicant provides additional documentation regarding the deficiencies and subsequent compliance with CMS conditions for Coverage for the facility in Exhibit O-3. After reviewing and considering information provided by the applicant and considering the quality of care provided at all of the facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2*

patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

- C- In Section C, page 16, the applicant projects to serve 33 in-center patients by the end of Operating Year 1, which is 3.3 patients per station per week (33 patients / 10 stations = 3.3). The discussion regarding projected utilization found on Criterion (3) is incorporated herein by reference.

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

- NA- The applicant is not proposing to increase the number of dialysis stations in an existing facility or in a facility that was not operational prior to the beginning of the review period.

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

- C- In Section C.1, pages 16-17, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.