

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 20, 2019

Findings Date: September 20, 2019

Project Analyst: Julie M. Faenza

Team Leader: Gloria C. Hale

Project ID #: J-11736-19

Facility: Fresenius Kidney Care Eno River

FID #: 170324

County: Durham

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

Project: Relocate no more than 4 dialysis stations from FMC Dialysis Services of Briggs Avenue pursuant to Policy ESRD-2 for a total of no more than 14 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) proposes to relocate four dialysis stations from FMC Dialysis Services of Briggs Avenue (FMC Briggs) to Fresenius Kidney Care Eno River (FKC Eno River), a new 10-station facility approved but not yet developed, for a total of 14 dialysis stations at FKC Eno River upon completion of this project and Project I.D. #J-11373-17 (develop a new 10-station facility by relocating four stations from FMC Dialysis Services of West Pettigrew and six stations from Freedom Lake Dialysis Unit).

Need Determination

The applicant does not propose to add stations via either the facility need methodology or the county need methodology published in the 2019 State Medical Facilities Plan (SMFP) or the

July 2019 Semiannual Dialysis Report (SDR). Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2019 SMFP which is applicable to this review. Policy ESRD-2: Relocation of Dialysis Stations, on page 25 of the 2019 SMFP, is applicable to this review because the applicant proposes to relocate dialysis stations. Policy ESRD-2 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.”*

Both FMC Briggs and FKC Eno River are in Durham County; as a result, there will be no change in the dialysis station inventory. 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 proposes to relocate four dialysis stations from FMC Briggs to FKC Eno River, a new 10-station facility approved but not yet developed, for a total of 14 dialysis stations at FKC Eno River upon completion of this project and Project I.D. #J-11373-17 (develop a new 10-station facility by relocating four stations from FMC Dialysis Services of West Pettigrew and six stations from Freedom Lake Dialysis Unit). Upon completion of this project, FMC Briggs will have a total of 25 certified dialysis stations.

The applicant did not propose to offer home hemodialysis (HH) or peritoneal dialysis (PD) training and support at FKC Eno River as part of Project I.D. #J-11373-17, and it does not propose to add those services as part of this application.

Patient Origin

On page 369, the 2019 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 is Durham County. Facilities may serve residents of counties not included in their service area.

In Section C, pages 15-16, the applicant states there is no historical patient origin, as FKC Eno River is not yet operational, and projects to serve 47 Durham County patients by the end of the second full operating year following project completion. On pages 16-17, the applicant provides the assumptions and methodology it used to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, page 17, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“Patients with End Stage Renal Disease require dialysis treatment on a regular and consistent basis in order to maintain life. As a general rule, patients will receive three treatments per week. The NC SMFP recognizes that this patient population requires frequent and regular treatment. ... Failure to receive dialysis care will ultimately lead to the patient’s demise.

The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment. ... BMA has identified the population to be served as 45 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project.”

In Section C, page 16, the applicant states that, in addition to the 33.3 patients projected to transfer to the new 10-station facility proposed as part of Project I.D. #J-11373-17, it identified 10 patients not receiving dialysis at the time of the original application who support the proposed project and who signed letters indicating their willingness to consider transferring their care to FKC Eno River. Exhibit C-3.3 contains nine letters of support from patients who began receiving dialysis after July 2017, as well as 16 other recent letters of support from patients willing to consider transferring their care to FKC Eno River.

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

- Project I.D. #J-11373-17 projected 33.3 patients would transfer from other facilities to the proposed FKC Eno River, and those projections were determined to be reasonable and adequately supported.
- The applicant adequately documents the willingness of additional patients to consider transferring care to FKC Eno River.

Projected Utilization

In Section C, page 17, the applicant projects to serve 45 Durham County patients by the end of the first operating year and 47 Durham County patients by the end of the second operating year following project completion.

In Section C, pages 16-17, the applicant provides the assumptions and methodology it used to project utilization, which are summarized below.

- The applicant begins its utilization projections with the 33.3 Durham County ESRD patients it projected to serve at FKC Eno River upon offering services as part of Project I.D. #J-11373-17.
- The applicant adds 10 additional Durham County dialysis patients who were not receiving dialysis services when Project I.D. #J-11373-17 was submitted, but who signed letters of support and indicated a willingness to consider transferring care to FKC Eno River.
- The applicant assumes the Durham County patient population projected to be served at FKC Eno River will increase annually at a rate of 4.6 percent, which is the Five Year Average Annual Change Rate (AACR) for Durham County published in the July 2019 SDR.
- The applicant assumes both Project I.D. #J-11373-17 and the current proposed project will be developed concurrently and completed at the same time.
- Both projects are scheduled for completion on December 31, 2020. OY1 is CY 2021. OY2 is CY 2022.

In Section C, page 17, the applicant provides the calculations used to arrive at the projected patient census for OY1 and OY2, as summarized in the table below.

| FKC Eno River Patient Projections | |
|---|------------------------------|
| Starting point of calculations is Durham County patients who are projected as the starting census for FKC Eno River in Project I.D. #J-11373-17. | 33.3 |
| 10 Durham County patients who signed letters of support indicating they'd consider transferring care to FKC Eno River are added to the projected FKC Eno River starting patient census as of December 31, 2020. | $33.3 + 10 = 43.3$ |
| Durham County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (4.6%). This is the projected census on December 31, 2021 (OY1). | $43.3 \times 1.046 = 45.29$ |
| Durham County patient population is projected forward by one year to December 31, 2022, using the Five Year AACR (4.6%). This is the projected census on December 31, 2022 (OY2). | $45.29 \times 1.046 = 47.38$ |

The applicant rounds down and projects to serve 45 patients on 14 stations, which is 3.21 patients per station per week ($45 \text{ patients} / 14 \text{ stations} = 3.21$), by the end of OY1 and 47 patients on 14 stations, which is 3.36 patients per station per week ($47 \text{ patients} / 14 \text{ stations} = 3.36$), by the end of OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

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

- The applicant bases projections on calculations previously determined to be reasonable and adequately supported in Project I.D. #J-11373-17.
- The applicant provides adequate documentation to support the projection of additional patients who will consider transferring to FKC Eno River.
- The applicant uses the Five Year AACR for Durham County as published in the July 2019 SDR to project growth of Durham County residents.
- The applicant's projected utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Access

In Section C, page 20, the applicant states:

“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

In Section L, page 55, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

| FKC Eno River Projected Payor Mix CY 2022 | |
|--|-------------------|
| Payment Source | % Patients |
| Self-Pay/Indigent/Charity | 0.39% |
| Insurance* | 8.98% |
| Medicare* | 66.71% |
| Medicaid* | 6.20% |
| Medicare/Commercial | 13.14% |
| Misc. (including VA) | 4.57% |
| Total | 100.00% |

*Including any managed care plans.

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 reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this 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 proposes to relocate four dialysis stations from FMC Briggs to FKC Eno River, a new 10-station facility approved but not yet developed, for a total of 14 dialysis stations at FKC Eno River upon completion of this project and Project I.D. #J-11373-17 (develop a new 10-station facility by relocating four stations from FMC Dialysis Services of West Pettigrew and six stations from Freedom Lake Dialysis Unit).

According to the July 2019 SDR, FMC Briggs had 29 certified dialysis stations as of May 31, 2019. Its utilization as of December 31, 2018 was 90.52 percent or 3.62 patients per station per week (105 patients dialyzing on 29 stations). Upon completion of this project, FMC Briggs will have 25 certified dialysis stations.

In Section D, page 24, the applicant states the relocation will have no effect on the patients currently utilizing the stations. The applicant states the proposed station relocation is scheduled to be completed on December 31, 2020, but the facility currently demonstrates a need for nine additional stations via the facility need methodology. The applicant states it will submit an application for the October 1, 2019 review period, proposing to add four stations at FMC Briggs, which will immediately backfill the stations proposed to be relocated. The applicant provides the facility need calculations showing the need for nine additional stations at FMC Briggs via the facility need methodology on page 25.

In Section D, page 27, the applicant projects to be serving 100 patients at FMC Briggs as of the date of the station relocation. In Section D, pages 26-27, the applicant provides the assumptions and methodology it uses to project utilization, which are summarized below.

- The applicant begins its utilization projections with the patient population of FMC Briggs as of June 30, 2019.
- The applicant states it was serving two patients from Chatham County, one patient from Caldwell County, and one patient from Tennessee at FMC Briggs as of June 30, 2019. The applicant assumes the patients from Chatham County will continue to utilize FMC Briggs by choice, and adds them to the calculations where appropriate, but assumes the patients from Caldwell County and Tennessee are transient patients who will not continue to receive dialysis services at FMC Briggs.
- As part of Project I.D. #J-11373-17, nine patients were projected to transfer from FMC Briggs to FKC Eno River upon project completion. The applicant projects these patients to transfer as of December 31, 2020 and subtracts them from the calculations where appropriate.

- The applicant assumes that the Durham County patient population dialyzing at FMC Briggs will increase annually at a rate of 4.6 percent, which is the Five Year AACR for Durham County published in the July 2019 SDR.
- The applicant assumes both Project I.D. #J-11373-17 and the current proposed project will be developed concurrently and completed at the same time.
- Both projects are scheduled for completion on December 31, 2020. OY1 is CY 2021. OY2 is CY 2022.

In Section D, page 27, the applicant provides the calculations used to arrive at the projected patient census at the time of the station transfer from FMC Briggs to FKC Eno River, as summarized in the table below.

| FMC Briggs Patient Projections | |
|---|------------------------------|
| Starting point of calculations is Durham County patients dialyzing at FMC Briggs as of June 30, 2019.* | 100 |
| Durham County patient population is projected forward by six months to December 31, 2019, using one-half of the Five Year AACR (4.6%). | $100 \times 1.023 = 102.3$ |
| Durham County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (4.6%). | $102.3 \times 1.046 = 107.0$ |
| Nine Durham County patients projected to transfer care to FKC Eno River are subtracted from calculations as of December 31, 2020. | $107 - 9 = 98$ |
| The two patients from Chatham County are added to the patient population. This is the projected census on December 31, 2020, when the stations will be relocated. | $98 + 2 = 100$ |

*In the table on page 27, the applicant states it starts with the patients dialyzing at FMC Briggs as of December 31, 2018. Based on the applicant’s statements elsewhere and the calculations in the remainder of the table, it is clear this was a typo and the applicant intended to list the date as June 30, 2019.

The applicant projects to be serving 100 patients on 25 stations at FMC Briggs as of December 31, 2020, which is a utilization rate of 100 percent or 4.0 patients per station per week.

On page 27, the applicant states:

“BMA is well aware that utilization rates in excess of four patients per station necessarily result in a third or evening dialysis shift. For this reason, as has been discussed within this Section of the application, BMA will apply for four dialysis stations by application of the Facility Need Methodology.”

If the application proposing to add four stations to FMC Briggs via the facility need methodology is submitted for the October 1, 2019 review period and is approved, the applicant will be serving 100 patients on 29 stations as of December 31, 2020, which is a utilization rate of 86.3 percent, or 3.45 patients per station per week.

In Section D, page 26, the applicant states there will be no impact on access by medically underserved groups to the services to be transferred because the applicant projects that the stations will be immediately backfilled.

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 needs of the population currently using the services to be 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 proposes to relocate four dialysis stations from FMC Briggs to FKC Eno River, a new 10-station facility approved but not yet developed, for a total of 14 dialysis stations at FKC Eno River upon completion of this project and Project I.D. #J-11373-17 (develop a new 10-station facility by relocating four stations from FMC Dialysis Services of West Pettigrew and six stations from Freedom Lake Dialysis Unit).

In Section E, page 28, 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 maintaining the status quo fails to account for patient growth in the area of FKC Eno River and will result in more patients than the facility will have capacity for; therefore, this is not an effective alternative.
- **Relocate More Than Four Stations:** the applicant states it must demonstrate the need for the stations it proposes to relocate, and it cannot demonstrate the need to relocate more than four stations; therefore, this is not an effective alternative.

- Relocate Fewer than Four Stations: the applicant states relocating fewer than four stations will not meet the needs of the growing patient population in the area of FKC Eno River; therefore, this is not an effective alternative.

On pages 28-29, the applicant states its proposal is the most effective alternative because it is the most cost-effective way to meet the need for additional dialysis stations to serve Durham County patients living near FKC Eno River.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

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. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. 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 four dialysis stations from FMC Dialysis Care of Briggs Avenue to Fresenius Kidney Care Eno River for a total of no more than 14 certified stations at Fresenius Kidney Care Eno River upon completion of this project and Project I.D. #J-11373-17 (develop a new 10-station facility by relocating four stations from FMC Dialysis Services of West Pettigrew and six stations from Freedom Lake Dialysis Unit).**
- 3. Bio-Medical Applications of North Carolina, Inc. shall install plumbing and electrical wiring through the walls at Fresenius Kidney Care Eno River for no more than four additional stations for a total of no more than 14 stations upon completion of this project and Project I.D. #J-11373-17, which shall include any isolation stations.**

- 4. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify four stations at FMC Dialysis Care of Briggs Avenue for a total of no more than 25 stations at FMC Dialysis Care of Briggs Avenue.**
 - 5. Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to relocate four dialysis stations from FMC Briggs to FKC Eno River, a new 10-station facility approved but not yet developed, for a total of 14 dialysis stations at FKC Eno River upon completion of this project and Project I.D. #J-11373-17 (develop a new 10-station facility by relocating four stations from FMC Dialysis Services of West Pettigrew and six stations from Freedom Lake Dialysis Unit).

Capital and Working Capital Costs

On Form F.1a in Section Q, the applicant projects the total capital cost to be \$15,000 for patient chairs, patient TVs, and water connections. On Form F.1b in Section Q, the applicant does not project any other changes to capital expenditure projections made in Project I.D. #J-11373-17.

In Section F, pages 31-32, the applicant states it is providing updated start-up expenses and initial operating expenses since the information provided by the applicant in Project I.D. #J-11373-17 assumed only 10 stations. In Project I.D. #J-11373-17, the applicant projected \$129,723 in start-up expenses and \$1,051,653 for eight months of initial operating expenses, for a total working capital cost of \$1,181,376. In the current application, on pages 31-32, the applicant projects \$239,417 in start-up expenses and \$1,002,898 for six months of initial operating expenses, for a total working capital cost of \$1,242,315. On pages 32-34, the applicant provides the assumptions and methodology used to project working capital costs.

Availability of Funds

In Section F, pages 30-31 and 34-35, the applicant states it will fund all capital and working capital costs of the proposed project with accumulated reserves. Exhibit F-2 contains a letter from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., the applicant's parent company, authorizing the use of accumulated reserves for the capital needs of the project, as well as "*...any start-up expenses and initial operating expenses as may be needed for this project.*"

The letter in Exhibit F-2 further states:

“This project is to be funded through Fresenius Medical Care Holdings, Inc., accumulated reserves. Our 2017 Consolidated Balance Sheet reflects more than \$1.8 billion in cash, and total assets exceeding \$20 billion.”

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, 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 Eno River | Operating Year 1 CY 2021 | Operating Year 2 CY 2022 |
| Total Treatments | 6,534 | 6,857 |
| Total Gross Revenues (Charges) | \$41,102,835 | \$43,139,650 |
| Total Net Revenue | \$2,050,179 | \$2,151,774 |
| Average Net Revenue per Treatment | \$314 | \$314 |
| Total Operating Expenses (Costs) | \$2,005,797 | \$2,068,137 |
| Average Operating Expense per Treatment | \$307 | \$302 |
| Net Income/Profit | \$44,383 | \$83,638 |

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.

C

The applicant proposes to relocate four dialysis stations from FMC Briggs to FKC Eno River, a new 10-station facility approved but not yet developed, for a total of 14 dialysis stations at FKC Eno River upon completion of this project and Project I.D. #J-11373-17 (develop a new 10-station facility by relocating four stations from FMC Dialysis Services of West Pettigrew and six stations from Freedom Lake Dialysis Unit).

On page 369, the 2019 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 is Durham County. Facilities may serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Durham County as of December 31, 2018.

| Durham County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018 | | | | |
|---|--------------|--------------------------------|-----------------------------|--------------------|
| Dialysis Facility | Owner | # of Certified Stations | # In-Center Patients | Utilization |
| FMC Dialysis Services of Briggs Avenue | BMA | 29 | 105 | 90.52% |
| FMC Dialysis Services West Pettigrew | BMA | 24 | 74 | 77.08% |
| Freedom Lake Dialysis Center | BMA | 26 | 94 | 90.38% |
| FKC Eno River* | BMA | 0 | 0 | 0.00% |
| FMC South Durham Dialysis | BMA | 18 | 66 | 91.67% |
| Bull City Dialysis** | DaVita | 16 | 44 | 68.75% |
| Bull City Dialysis* | DaVita | 0 | 0 | 0.00% |
| Downtown Durham Dialysis* | DaVita | 0 | 0 | 0.00% |
| Durham Dialysis | DaVita | 25 | 98 | 98.00% |
| Durham Regional Dialysis | DaVita | 10 | 14 | 35.00% |
| Durham West Dialysis | DaVita | 27 | 79 | 73.15% |
| Hope Valley Dialysis* | DaVita | 0 | 0 | 0.00% |
| Research Triangle Park Dialysis | DaVita | 10 | 21 | 52.50% |
| Southpoint Dialysis | DaVita | 16 | 69 | 107.81% |

Source: Section G, page 38; July 2019 SDR, Table B.

* Facility under development or which was not operational at the time of data collection for the July 2019 SDR.

**Per Project I.D. #J-11450-18, this facility is being relocated to a new location.

In Section G, pages 39-40, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Durham County. The applicant states:

“This is an application to relocate four dialysis stations to FKC Eno River, a CON approved, but not yet developed facility. To the extent that the SDR identifies a station

surplus, an approval of this application will not change the inventory of stations in Durham County, this application will not duplicate services.

Further, BMA has identified 10 new dialysis patients who have expressed their desire to transfer their care to this facility upon completion of the project. These patients have expressed that this facility is closer to their residence location (than their current dialysis facility) and would be more convenient for their care.”

The applicant adequately demonstrates that the proposal will 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 certified dialysis stations in Durham County.
- The applicant adequately demonstrates the need patients have for the additional dialysis stations at this specific location in addition to the approved stations.

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

On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

| FKC Eno River Projected FTEs – Both OYs 1 & 2 (CYs 2021 & 2022) | |
|--|-------------|
| Position | FTEs |
| Administrator | 1.00 |
| Registered Nurses | 2.00 |
| Patient Care Technicians | 4.00 |
| Dietitian | 0.40 |
| Social Worker | 0.40 |
| Maintenance | 0.60 |
| Administration/Business Office | 0.50 |
| FMC Director Operations | 0.15 |
| In-Service | 0.15 |
| Chief Technician | 0.15 |
| Total | 9.35 |

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, page 41, the applicant describes the methods it uses to recruit or fill new positions and its proposed training and continuing education programs. The applicant provides supporting documentation in Exhibits H-3.1 and H-3.2. In Exhibit H-4, the applicant provides a letter from the proposed medical director expressing his support for the proposed project and indicating his intent to serve as medical director for the facility.

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

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, pages 43-44, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service will be made available:

| FKC Eno River – Ancillary and Support Services | |
|---|--|
| Services | Provider |
| Self-care training (in-center) | FMC West Pettigrew |
| Home training | |
| HH | FMC West Pettigrew |
| PD | FMC West Pettigrew |
| Accessible follow-up program | FMC West Pettigrew |
| Psychological counseling | Durham County Mental Health, Carolina Outreach Behavioral Health |
| Isolation – hepatitis | On site |
| Nutritional counseling | On site |
| Social Work services | On site |
| Acute dialysis in an acute care setting | Duke Regional Hospital |
| Emergency care | Provided on site by staff prior to ambulance transport to hospital |
| Blood bank services | Duke Regional Hospital |
| Diagnostic and evaluation services | Duke Regional Hospital, Duke Radiology |
| X-ray services | Duke Regional Hospital, Duke Radiology |
| Laboratory services | On site |
| Pediatric nephrology | Duke University Medical Center, UNC Healthcare |
| Vascular surgery | Carolina Vascular Associates, Duke Regional Vascular Surgery |
| Transplantation services | Duke University Medical Center, UNC Healthcare |
| Vocational rehabilitation & counseling | Durham County Vocational Rehabilitation Services |
| Transportation | GO Durham Access |

The applicant provides supporting documentation in Exhibits I-1 through I-4.

In Section I, page 44, the applicant describes its existing relationships with other local health care and social service providers.

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

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

The applicant does 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 does not project to provide the proposed 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. 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

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, page 47, the applicant states it does not propose to construct new space or upfit or renovate existing space as part of the proposed project. Line drawings are included in Exhibit K-2.

Project I.D. #J-11373-17 was conforming to this criterion, and the applicant does not propose to change the clinical space of the proposed facility or make any other changes in the current application which 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.

(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 Eno River is not an existing facility. In Section L, page 54, the applicant provides the historical payor mix at FMC Briggs during CY 2018, as shown in the table below.

| FMC Briggs Historical Payor Mix CY 2018 | |
|--|-------------------|
| Payment Source | % Patients |
| Self-Pay/Indigent/Charity | 0.66% |
| Insurance* | 10.55% |
| Medicare* | 66.41% |
| Medicaid* | 7.05% |
| Medicare/Commercial | 11.29% |
| Misc. (including VA) | 4.04% |
| Total | 100.00% |

*Including any managed care plans.

In Section L, page 53, the applicant provides the following comparison.

| | Percentage of Total Patients Served by FMC Briggs during the Last Full OY | Percentage of the Population of Durham County |
|-------------------------------------|---|---|
| Female | 34.7% | 52.3% |
| Male | 65.3% | 47.7% |
| Unknown | 0.0% | 0.0% |
| 64 and Younger | 55.4% | 86.9% |
| 65 and Older | 44.6% | 13.1% |
| American Indian | 0.0% | 0.9% |
| Asian | 1.0% | 5.5% |
| Black or African-American | 88.1% | 37.3% |
| Native Hawaiian or Pacific Islander | 2.0% | 0.1% |
| White or Caucasian | 5.0% | 53.7% |
| Other Race | 4.0% | 2.5% |
| Declined / Unavailable | 0.0% | 0.0% |

Sources: BMA Internal Data, US Census Bureau

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

FKC Eno River is not an existing facility. Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 54, that no BMA facilities have any obligation to provide uncompensated care or community service under any federal regulations.

In Section L, page 55, the applicant states that during the last five years no patient civil rights access complaints have been filed against any BMA facilities located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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, page 55, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

| FKC Eno River Projected Payor Mix CY 2022 | |
|--|-------------------|
| Payment Source | % Patients |
| Self-Pay/Indigent/Charity | 0.39% |
| Insurance* | 8.98% |
| Medicare* | 66.71% |
| Medicaid* | 6.20% |
| Medicare/Commercial | 13.14% |
| Misc. (including VA) | 4.57% |
| Total | 100.00% |

*Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.39 percent of total services will be provided to self-pay, indigent, and charity care patients; 79.85 percent to patients who will have some or all of their care paid for by Medicare; and 6.2 percent to Medicaid patients.

On page 55, the applicant provides the assumptions and methodology it uses 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 for the following reasons:

- The projected payor mix is based in part on the historical payor mix of Freedom Lake Dialysis Center, the BMA facility closest in location to the proposed FKC Eno River facility.

- The projected payor mix is based in part on the historical payor mix of FMC Briggs, where patients have signed letters saying they intend to consider transferring to FKC Eno River.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 56, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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, page 58, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 proposes to relocate four dialysis stations from FMC Briggs to FKC Eno River, a new 10-station facility approved but not yet fully developed, for a total of 14 dialysis stations at FKC Eno River upon completion of this project and Project I.D. #J-11373-17 (develop a new 10-station facility by relocating four stations from FMC Dialysis Services of West Pettigrew and six stations from Freedom Lake Dialysis Unit).

On page 369, the 2019 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 is Durham County. Facilities may serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Durham County as of December 31, 2018.

| Durham County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018 | | | | |
|--|--------------|--------------------------------|-----------------------------|--------------------|
| Dialysis Facility | Owner | # of Certified Stations | # In-Center Patients | Utilization |
| FMC Dialysis Services of Briggs Avenue | BMA | 29 | 105 | 90.52% |
| FMC Dialysis Services West Pettigrew | BMA | 24 | 74 | 77.08% |
| Freedom Lake Dialysis Center | BMA | 26 | 94 | 90.38% |
| FKC Eno River* | BMA | 0 | 0 | 0.00% |
| FMC South Durham Dialysis | BMA | 18 | 66 | 91.67% |
| Bull City Dialysis** | DaVita | 16 | 44 | 68.75% |
| Bull City Dialysis* | DaVita | 0 | 0 | 0.00% |
| Downtown Durham Dialysis* | DaVita | 0 | 0 | 0.00% |
| Durham Dialysis | DaVita | 25 | 98 | 98.00% |
| Durham Regional Dialysis | DaVita | 10 | 14 | 35.00% |
| Durham West Dialysis | DaVita | 27 | 79 | 73.15% |
| Hope Valley Dialysis* | DaVita | 0 | 0 | 0.00% |
| Research Triangle Park Dialysis | DaVita | 10 | 21 | 52.50% |
| Southpoint Dialysis | DaVita | 16 | 69 | 107.81% |

Source: Section G, page 38; July 2019 SDR, Table B.

* Facility under development or which was not operational at the time of data collection for the July 2019 SDR.

**Per Project I.D. # J-11450-18, this facility is being relocated to a new location.

In Section N, pages 59-61, 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 59, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Durham County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FKC Eno River facility begins with patients projected to transfer their care and who supported the original CON application, Project ID # J-11373-17, coupled with 10 new dialysis patients who have expressed similar desires to transfer their care.

...

Fresenius related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients’ lives by offering a convenient venue for dialysis care and treatment, and promoting access to care.”

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 Q 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 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

On Form A in Section Q, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 127 dialysis facilities located in North Carolina.

In Section O, page 65, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care resulting in an immediate jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 127 facilities, the applicant provides 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 Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- C- Project I.D. #J-11373-17 was found to be conforming to this Rule, and the applicant proposes no changes in this application which would affect that determination.
- (b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section C, page 17, the applicant projects FKC Eno River will serve 45 patients on 14 stations, or a rate of 3.21 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 16-17, and Exhibit C-3.3, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.