## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

| | |
|---|---|
| Decision Date: | October 13, 2017 |
| Findings Date: | October 13, 2017 |
| | |
| Project Analyst: | Gloria C. Hale |
| Team Leader: | Fatimah Wilson |
| | |
| Project ID #: | F-11375-17 |
| Facility: | Fresenius Kidney Care Mallard Creek |
| FID #: | 170326 |
| County: | Mecklenburg |
| Applicant: | Bio-Medical Applications of North Carolina, Inc. |
| Project: | Develop a new 12-station dialysis facility by relocating 12 stations from BMA North Charlotte |

## REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. § 131E-183(a) The Department 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. (BMA) d/b/a Fresenius Kidney Care Mallard Creek (FKC Mallard Creek), proposes to develop a new 12-station dialysis facility in Charlotte by relocating 12 existing dialysis stations from BMA North Charlotte Dialysis (BMA North Charlotte). Both BMA North Charlotte and the FKC Mallard Creek location are in Mecklenburg County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. FKC Mallard Creek will be certified for 12 dialysis stations upon completion of this project

and BMA North Charlotte will be certified for 28 dialysis stations upon completion of this project and Project I.D. #F-11243-16 (add four stations).

**Need Determination**

The applicant is proposing to relocate existing dialysis stations within Mecklenburg County, therefore there are no need methodologies in the 2017 State Medical Facilities Plan (SMFP) applicable to this review.

**Policies**

There is one policy in the 2017 SMFP that is applicable to this review: *Policy ESRD-2 Relocation of Dialysis Stations,* on page 27.

*Policy ESRD-2: Relocation of Dialysis Stations* states:

> *"Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:*
>
> *1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
>
> *2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
>
> *3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report."*

The applicant proposes to develop a new 12-station dialysis facility in Charlotte, by relocating existing dialysis stations from BMA North Charlotte. Both BMA North Charlotte and the proposed facility location are in Mecklenburg County, therefore there is no change in the dialysis station inventory in Mecklenburg County. Therefore, the application is consistent with Policy ESRD-2.

**Conclusion**

In summary, the applicant adequately demonstrates that the application is consistent with all applicable policies in the 2017 SMFP.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop a new 12-station dialysis facility in Charlotte by relocating 12 existing dialysis stations from BMA North Charlotte. Both the proposed FKC Mallard Creek location and BMA North Charlotte are in Mecklenburg County. As reported in the July 2017 Semi-Annual Dialysis Report (SDR), BMA North Charlotte had 36 certified dialysis stations as of June 9, 2017. At the completion of this project and Project I.D. #F-11243-16 (add four dialysis stations), BMA North Charlotte will have 28 certified dialysis stations (36 – 12 = 24; 24 + 4 = 28).

**Patient Origin**

On page 373, the 2017 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."* The proposed new facility, FKC Mallard Creek, will be located in Mecklenburg County; thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

FKC Mallard Creek will be a new facility in Mecklenburg County and therefore has no existing patient origin.

In Section C.1, page 18, the applicant identifies the patient population it proposes to serve for operating years one (OY1) and two (OY2) following project completion for in-center patients, as illustrated in the following table:

**FKC Mallard Creek**
**Projected Patient Origin by County**

| **County** | **Operating Year 1 1/1/19 –12/31/19** | **Operating Year 2 1/1/20-12/31/20** | **County Patients as Percent of Total** | |
|---|---|---|---|---|
| | In-Center Patients | In-Center Patients | OY1 | OY2 |
| Mecklenburg | 39.5 | 41.5 | 100.0% | 100.0% |
| **Total*** | **39.0** | **41.0** | **100.0%** | **100.0%** |

*The applicant states, on page 18 of the application, that the total number of patients is *"Rounded down to the whole patient."*

In Section C.1, page 18, the applicant states that FKC Mallard Creek will not include a home therapies program, rather patients who may be candidates for home therapies will be referred to the FMC Charlotte home training program.

In Section C.1, pages 18-20, the applicant provides the assumptions and methodology used to project patient origin. The applicant states, on page 19, that it includes 35 letters of support, in Exhibit C-1, from in-center patients residing in close proximity to the proposed facility who may be better served at FKC Mallard Creek. Projected patient origin is based on the patients the applicant identifies as living in close proximity to the proposed facility. Exhibit C-1 contains copies of the 35 signed letters.

The applicant adequately identifies the population to be served.

**Analysis of Need**

The applicant proposes to develop a new 12-station dialysis facility in Charlotte by relocating 12 stations from BMA North Charlotte.

In Section C.5, page 23, the applicant states that there are 18 operational dialysis facilities in Mecklenburg County, with four additional dialysis facilities under development, however there are no dialysis facilities in the immediate area of the proposed FKC Mallard Creek facility. The applicant further states, on page 23, that there is a large patient population residing in close proximity to the proposed location who are already dialyzing at other Bio-Medical Applications of North Carolina (BMA) facilities. In Section C.1, page 18, the applicant states it has plotted the residence locations of dialysis patients receiving services at its dialysis facilities in Charlotte, stating, *"This group of patients could be better served by a new center focused on providing their dialysis care, and reducing their commute time distance for travel."* In addition, on pages 18-19, the applicant states that utilization at BMA North Charlotte has been high over the last few years, ranging from just over 92% to over 110%. The applicant states, on page 19, that BMA North Charlotte's growth rate was 8.6% as determined from data in the January 2015 SDR to projected data in the January 2018 SDR, higher than the growth rate for Mecklenburg County of 5.1%.

*Projected Utilization*

In Section C.1, pages 18-20, the applicant provides the following assumptions used to project utilization:

- The applicant provides a table, in Section C.1, page 19, showing the number of dialysis patients by zip code who dialyze at several BMA facilities in Mecklenburg County who reside in close proximity to the proposed dialysis facility. The applicant provides letters from each of these 35 patients in Exhibit C-

1 indicating their willingness to transfer their care to the proposed facility because it is convenient and closer to their homes.

- The applicant states, on page 19, that it continues to project that 14 patients from the BMA North Charlotte facility will transfer their care to FMC Aldersgate, Project I.D. #F-11099-15.
- The applicant states, on page 20, that the project will be completed on December 31, 2018. Operating Year 1 (OY1) is January 1, 2019 through December 31, 2019. Operating Year 2 (OY2) is January 1, 2020 through December 31, 2020.
- The applicant assumes that the Mecklenburg County dialysis patients transferring to the new facility are part of the Mecklenburg County ESRD patient population as a whole, and that this population will increase at a rate commensurate with the Mecklenburg County Five Year Average Annual Change Rate (AACR) of 5.1%, as reported in the July 2017 SDR, beginning on August 1, 2017 and continuing through the end of OY2.

In Section C.1, page 20, the applicant provides the methodology used to project utilization for FKC Mallard Creek, summarized as follows:

| FKC Mallard Creek | In-Center Patients |
|---|---|
| Begin with 35 Mecklenburg County in-center dialysis patients who indicated, through letters of support, their willingness to transfer their care to FKC Mallard Creek upon certification of the facility. | 35 |
| The number of Mecklenburg County in-center dialysis patients is increased by application of the Mecklenburg County Five Year AACR of 5.1% which is applied for five months, from August 1, 2017 through December 31, 2017. | [35 x (.051/12 x 5)] + 35 = 35.7 |
| The number of Mecklenburg County in-center dialysis patients is increased by application of the Mecklenburg County Five Year AACR of 5.1% for one year to December 31, 2018. | 35.7 x 1.051 = 37.6 |
| The number of Mecklenburg County in-center dialysis patients is increased by application of the Mecklenburg County Five Year AACR of 5.1% for one year to December 31, 2019. This is the end of OY1. | 37.6 x 1.051 = 39.5 |
| The number of Mecklenburg County in-center dialysis patients is increased by application of the Mecklenburg County Five Year AACR of 5.1% for one year to December 31, 2020. This is the end of OY2. | 39.5 x 1.051 = 41.5 |

The applicant states, in Section C.1, page 18, that it rounds down to the whole patient. Therefore, the applicant projects that at the end of OY1, 39 patients will be dialyzing on 12 stations for a projected utilization rate of 3.25 patients per station per week (39 in-

center patients / 12 stations = 3.25) which exceeds the minimum standard of 3.2 patients per station per week as required by 10A NCAC 14C.2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need the projected population has for the proposed facility.

**Access**

In Section L.1, page 66, the applicant states,

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

In Section L.1, page 67, the applicant projects that over 82% of its in-center patients will be covered by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents, including the underserved groups, are likely to have access to the proposed services.

**Conclusion**

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population projected to be served has for the proposed services based on reasonable and supported utilization projections and assumptions, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to develop a new 12-station dialysis facility in Charlotte by relocating 12 dialysis stations from BMA North Charlotte. Both facilities' locations are in Mecklenburg County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, FKC Mallard Creek will be certified for 12 dialysis stations and BMA North Charlotte

will be certified for 28 dialysis stations upon completion of this project and Project I.D. #F-11243-16 (add four stations) (36 – 12 = 24; 24 + 4 = 28).

The applicant provides its assumptions and methodology for projecting utilization at BMA North Charlotte in Section D.1, pages 32-33, summarized as follows:

In Section D.1, page 32, the applicant states that as of June 30, 2017, there were 156 patients dialyzing at BMA North Charlotte. The patient origin for these patients is provided by the applicant on page 32, and summarized below:

**BMA North Carolina**
**Patient Origin, June 30, 2017**

| County or State | Number of Patients |
|---|---|
| Mecklenburg | 140 |
| Cabarrus | 1 |
| Cumberland | 1 |
| Gaston | 3 |
| Rowan | 1 |
| Union | 1 |
| South Carolina | 1 |
| Other States | 8 |
| **Total** | **156** |

The applicant states, on page 32, that 14 patients dialyzing at BMA North Charlotte indicated their willingness to transfer to FMC Aldersgate (Project I.D. #F-11243-16). The applicant states that eight patients from other states and one patient from Cumberland County were transient patients and therefore, are not included in the projected utilization for the facility. The Mecklenburg County population is projected to increase using the Mecklenburg County Five Year AACR of 5.1% as published in the July 2017 SDR. The applicant assumes there will be no growth in the number of patients from the remaining counties and South Carolina, therefore their numbers are added at the end of the applicant's calculations.

*Projected Utilization for BMA North Charlotte*

In Section D.1, page 33, the applicant calculates the in-center patient census for BMA North Charlotte beginning June 30, 2017 through OY1 (CY2019) and OY2 (CY2020), illustrated as follows:

| BMA North Charlotte | In-Center Patients |
|---|---|
| Begin with the BMA North Charlotte patient population of Mecklenburg County, as of June 30, 2017. | 140 |
| Project this population forward for 9 months to March 31, 2018, using the Five Year AACR for Mecklenburg County of 5.1%. | [140 x (0.051 / 12 x 9)] + 140 = 145.4 |
| Subtract 14 patients projected to transfer their care to FMC Aldersgate on March 31, 2018. | 145.4 – 14 = 131.4 |
| Project this population forward for 9 months to December 31, 2018, using the Five Year AACR for Mecklenburg County of 5.1%. | [131.4 x (0.051 / 12 x 9)] + 131.4 = 136.4 |
| Subtract 16 Mecklenburg County patients projected to transfer their care to FKC Mallard Creek. | 136.4 – 16 = 120.4 |
| Add 1 patient each from Cabarrus, Rowan, and Union counties, 1 patient from South Carolina, and 3 from Gaston for a total of 7 patients. | 120.4 + 7 = 127.4 |

Thus, on December 31, 2018, BMA North Charlotte is projected to have 28 certified dialysis stations with a patient population of 128 in-center dialysis patients rounded up. Utilization is calculated to be 4.5 patients per station per week (128 / 28 = 4.5). The applicant states, on page 33, that as of the date this application was filed there were 16 patients dialyzing on the third shift. The applicant states, *"BMA assumes the third shift will continue at BMA North Charlotte, and that the shift will continue to have a census of 16 patients."* Therefore, BMA North Charlotte has a capacity of four patients per station which equates to a utilization rate of 112.5% (128 patients/ 28 stations = 4.5; 4.5/ 4 = 112.5%). The applicant states, on pages 33-34, that BMA North Charlotte's utilization exceeded 80% in the July 2017 SDR and that it intends to apply for an additional 10 dialysis stations based on the Facility Need Methodology for the October 1, 2017 review cycle. Therefore, should the additional 10 dialysis stations be approved, BMA North Charlotte would have 128 patients dialyzing on 38 stations for a utilization rate of 3.37 or 84.3%.

Thus, the proposed relocation of stations will not have an adverse impact on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

The applicant demonstrates that the needs of the population presently served at BMA North Charlotte will continue to be adequately met following the proposed relocation of 12 dialysis stations and the transfer of 16 patients to FKC Mallard Creek; and that access for medically underserved groups will not be negatively impacted.

Therefore, the application is conforming to this criterion.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section E.1, pages 36-37, the applicant discusses the alternatives considered prior to the submission of this application, summarized as follows:

1. Maintain the Status Quo – the applicant dismissed this alternative based on the fact that there is a significant number of patients dialyzing with BMA and residing in close proximity to the proposed FKC Mallard Creek facility, who can be more conveniently served by the development of the proposed facility. Therefore, the applicant determined this would not be the most effective alternative.

2. Develop Facility in Another Area in Mecklenburg County – the applicant states that based on its evaluation of existing patients served by BMA and Fresenius-affiliated facilities, coupled with projections of future patient populations, it determined that there is a significant number of patients in north Charlotte near the location of the proposed facility. Thus, the applicant determined that its chosen location was more effective than any other location.

3. Develop a Larger Facility with More Stations – after evaluation of the patient population served, the applicant states that it determined that 12 proposed stations at FKC Mallard Creek would be sufficient to meet the needs of the 35 existing BMA patients who indicated their willingness to transfer. FKC Mallard Creek will have a patient population of sufficient size to meet the Performance Standards in NCAC 14C .2203. Therefore, developing a larger facility with more than 12 stations is not the most effective alternative.

4. Offer Home Therapies at Proposed Facility – the applicant states that it could have proposed to provide home therapies at this location, however BMA offers a home therapies program at FMC Charlotte and states that construction and development costs are lowered by not adding home therapies at FKC Mallard Creek. Therefore, adding home therapies was not the most effective alternative.

Thus, the applicant states, on page 36, that given the current patients' residence locations, the physical plant capacity issues at area BMA facilities, and the projected growth of the patient population at FKC Mallard Creek, development of a new, 12-station dialysis facility in north Charlotte is the most effective alternative.

Furthermore, the application is conforming or conditionally conforming to all other applicable statutory and regulatory review criteria, and thus is approvable. An application that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the need. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Mallard Creek 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. d/b/a Fresenius Kidney Care Mallard Creek shall develop a new kidney disease treatment center to be known as FKC Mallard Creek by relocating 12 dialysis stations from BMA North Charlotte.**

3. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Mallard Creek shall install plumbing and electrical wiring through the walls for no more than 12 dialysis stations, 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 12 dialysis stations at BMA North Charlotte for a total of no more than 28 dialysis stations at BMA North Charlotte upon completion of this project and Project I.D. #F-11243-16 (add 4 stations).**

5. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Mallard Creek shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new 12-station dialysis facility in Charlotte by relocating 12 stations from BMA North Charlotte.

<u>**Capital and Working Capital Costs**</u>

In Section F.1, page 39, the applicant projects $1,850,220 in capital costs to develop the proposed project. The costs are $1,246,298 for construction costs, (RO) water treatment equipment for $225,000, equipment and furniture for $196,543, architect/engineering fees for $112,347, and $68,032 for contingency. The applicant states, on page 42, that

estimated start-up expenses will be $149,488 to cover four weeks of clinical supplies and staff salaries. On page 43, the applicant estimates its initial operating costs to be $1,235,958. Thus, the applicant's total working capital will be $1,388,446 [$1,385,446]. The Project Analyst's correction is in brackets.

**Availability of Funds**

In Section F.2, page 40, the applicant states it will finance the capital costs with accumulated reserves/owner's equity. Exhibit F-1 contains a letter dated July 17, 2017, signed by the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., the parent of BMA, authorizing and committing $1,850,220 in cash reserves for the project. In addition, the letter in Exhibit F-1 states, *"I am also authorized, and authorize any additional funds as may be necessary for start-up costs in the new location."*

Exhibit F-2 contains the Fresenius Medical Care Holdings, Inc. (FMC) and Subsidiaries, Consolidated Financial Statements for the years ending December 31, 2016 and December 31, 2015. These statements indicate that as of December 31, 2016, FMC had $357,899,000 in cash and cash equivalents, $20,135,661,000 in total assets and $10,533,297,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

**Financial Feasibility**

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

**FKC Mallard Creek**

| | OY1<br>1/1/19 – 12/31/19 | OY2<br>1/1/20 – 12/31/20 |
|---|---|---|
| Total Treatments | 5,631 | 5,928 |
| Total Gross Revenues (Charges) | $ 22,456,428 | $ 23,640,864 |
| Total Net Revenue | $ 1,872,112 | $ 1,970,855 |
| Average Net Revenue per Treatment | $ 332 | $ 332 |
| Total Operating Expenses (Costs) | $ 1,858,436 | $ 1,918,317 |
| Average Operating Expense per Treatment | $ 330 | $ 324 |
| Net Income | $ 13,676 | $ 52,537 |

The applicant states, on page 87 of the pro formas, that it calculates the average number of in-center patients for OY1 to be 38.5 patients and rounds down to 38 patients. Similarly for OY2, the average number of in-center patients is 41.5 which is rounded down to 40. The Project Analyst notes that staffing expenses reported on Form A are

higher than those reported in Section H.1, page 50. The highest discrepancies are for the positions of Registered Nurse (RN) and Patient Care Technicians (PCTs). Total salary costs for RNs and PCTs are $11,476 and $16,780 higher, respectively. Nevertheless, the applicant projects a net profit in OY1 and OY2. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, cost and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility is based upon reasonable projections of costs and charges.

**Conclusion**

In summary, the applicant adequately demonstrates the financial feasibility of the project is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to develop a new 12-station dialysis facility in Charlotte by relocating 12 stations from BMA North Charlotte. Both the proposed facility and BMA North Charlotte locations are in Mecklenburg County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. The proposed new facility, FKC Mallard Creek, will be certified for 12 dialysis stations upon completion. BMA North Charlotte will be certified for 28 dialysis stations upon completion of this project and Project I.D. #F-11243-16 (add four stations).

On page 373, the 2017 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."* The proposed new facility, FKC Mallard Creek, is located in Mecklenburg County; thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

According to the July 2017 SDR, there are 23 dialysis facilities in Mecklenburg County, 18 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the July 2017 SDR, is provided below:

**Mecklenburg County Dialysis Facilities**
**Certified Stations and Utilization as of December 31, 2016**

| Dialysis Facility | Owner | Location | Number of Certified Stations | Utilization |
|---|---|---|---|---|
| BMA Beatties Ford | BMA | Charlotte | 32 | 98.44% |
| BMA Nations Ford | BMA | Charlotte | 28 | 93.75% |
| BMA of East Charlotte | BMA | Charlotte | 25 | 92.00% |
| BMA of North Charlotte | BMA | Charlotte | 36 | 102.78% |
| BMA West Charlotte | BMA | Charlotte | 29 | 86.21% |
| Brookshire Dialysis | DaVita | Charlotte | 0 | 0.00% |
| Carolinas Medical Center | CMC | Charlotte | 9 | 27.78% |
| Charlotte Dialysis | DaVita | Charlotte | 36 | 84.72% |
| Charlotte East Dialysis | DaVita | Charlotte | 34 | 88.24% |
| DSI Charlotte Latrobe Dialysis | DSI | Charlotte | 24 | 69.79% |
| DSI Glenwater Dialysis | DSI | Charlotte | 42 | 77.38% |
| FMC Charlotte | BMA | Charlotte | 43 | 90.70% |
| FMC Matthews | BMA | Matthews | 21 | 111.90% |
| FKC Southeast Mecklenburg County** | BMA | Charlotte | 0 | 0.00% |
| FMC Regal Oaks* | BMA | Charlotte | 0 | 0.00% |
| FMC Aldersgate* | BMA | Charlotte | 0 | 0.00% |
| Fresenius Medical Care Southwest Charlotte*** | BMA | Charlotte | 10 | 40.00% |
| Huntersville Dialysis | DaVita | Huntersville | 10 | 92.50% |
| Mint Hill Dialysis | DaVita | Mint Hill | 16 | 96.88% |
| North Charlotte Dialysis Center | DaVita | Charlotte | 41 | 74.39% |
| South Charlotte Dialysis | DaVita | Charlotte | 22 | 86.36% |
| South Charlotte Dialysis* | DaVita | Charlotte | 0 | 0.00% |
| Sugar Creek Dialysis* | DaVita | Charlotte | 0 | 0.00% |

Source: July 2017 SDR, Table B.
* Facility under development.
** FKC Southeast Mecklenburg County is a new facility under development, however it is erroneously named FMC of Southwest Charlotte in the July 2017 SDR, Table B. In addition, the FID# should be 160337.
*** FMC Southwest Charlotte is an existing facility, however the FID# is erroneous as listed in the July 2017 SDR, Table B. The FID# should be 120485.

As illustrated above, BMA owns eight of the 17 operational dialysis facilities in Mecklenburg County. As shown in the table above, seven of BMA's eight operational dialysis facilities are operating above 80% utilization (3.2 patients per station per week) and six of those are operating above 90% utilization. Five dialysis facilities are operating below 80% utilization, including one BMA facility, two DSI facilities, a CMC facility, and one DaVita facility.

According to Table D in the July 2017 SDR, there is a surplus of fourteen dialysis stations in Mecklenburg County. However, the applicant is not increasing the number of dialysis stations in Mecklenburg County, rather it is proposing to relocate 12 existing Mecklenburg County dialysis stations to develop a new facility that is closer to patients living in the area where the new facility will be located.

In Section C.1, page 20, the applicant demonstrates that FKC Mallard Creek will serve a total of 39 in-center patients on 12 stations at the end of OY1, which is 3.25 patients per station per week, or a utilization rate of 81.25% (39 / 12 = 3.25; 3.25 / 4 = 0.8125 ). The applicant provides documentation in Exhibit C-1 from 35 Mecklenburg County in-center patients dialyzing at BMA facilities indicating their willingness to consider transferring to FKC Mallard Creek because its location would be more convenient. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

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

C

In Section H.1, page 50, the applicant provides the projected staffing for FKC Mallard Creek in OY2 by full-time equivalent (FTE) positions, as shown in the table below:

| **FKC Mallard Creek Proposed FTE Positions OY2** | |
|---|---|
| **Position** | **Total FTEs** |
| Registered Nurse | 2.00 |
| Patient Care Technician | 6.00 |
| Clinical Manager | 1.00 |
| Administrator | 0.15 |
| Dietitian | 0.50 |
| Social Worker | 0.50 |
| Chief Tech | 0.15 |
| Equipment Tech | 0.60 |
| In-Service | 0.15 |
| Clerical | 0.80 |
| **Total FTEs** | **11.85** |

Note: The Medical Director is an independent contractor, not an employee.

In Exhibit I.5, the applicant provides a letter from Dr. George Hart, dated May 31, 2017, indicating his support for the project and his willingness to serve as Medical Director of the facility. In Section H.3, page 51, the applicant states it does not anticipate any difficulties in filling staff positions as it provides a range of benefits and competitive salaries to attract qualified staff. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section I.1, page 54, the applicant lists the providers of the necessary ancillary and support services for the proposed project. Exhibit I-3 includes a letter of support from Carolinas HealthCare System (CHS) affirming a willingness to provide those services to FKC Mallard Creek patients. Exhibit I-3 contains a letter from CHS indicating their willingness to enter into an affiliation agreement with FKC Mallard Creek to provide various services, including acute dialysis, x-ray, and surgical services, among others. In addition, in Exhibit I-4, a letter is provided from CHS indicating their intention to enter into a Transplant Agreement with FKC Mallard Creek. Lastly, in Exhibit I-2 the applicant provides a copy of an extension of a Laboratory Services Agreement with Spectra Laboratories to provide lab services for Fresenius-related dialysis centers. The applicant discusses coordination with the existing health care system in Sections I.3 and I.4, pages 56-57, and includes a listing of 31 nephrologists in the area whom Fresenius has been working with over the years in Mecklenburg County. The applicant states, on page 56, that it has forged relationships over the years with physicians, local hospitals, and other health professionals in the community. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

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

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

NA

(11) Repealed effective July 1, 1987.

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

C

In Section K.2, page 61, the applicant states that the proposed facility will have 2,944 square feet of treatment area, which includes isolation space. The applicant provides the line drawings for the proposed facility in Exhibit K-1. In Section F.1, page 39, the applicant provides the proposed costs, including $1,248,298 for construction, $225,000 for water treatment equipment, $196,543 for other equipment and furniture, $112,347 for architect/engineering fees, and $68,032 for contingency for a total project cost of $1,850,220. In Section K.1, pages 59-60, the applicant describes its plans for energy-efficiency, including water conservation, summarized as follows:

- The building's exterior envelope, including roofing, wall, and glass systems will meet current requirements for energy conservation.
- The HVAC system operating efficiency *"will equal current industry standards for high seasonal efficiency."* In addition, the system will be controlled via 7 day/24 hour set back time clock and maintained and serviced quarterly.
- The facility will use energy efficient exit signs, water flow restrictors at sink faucets, water conserving flush toilets, optical sensor water switches, and on-demand tank-less water heaters will be used for energy and water conservation.
- LED recessed can lights will be used to reduce wattage and energy costs.

- The water treatment system will allow for a percentage of the concentrate water to be re-circulated into the supply feed water, thus lowering water discharge quantity; and will use three-phase electric motors which run cooler and use less amperage.

Costs and charges are described by the applicant in Section F, pages 38-47, and in Section R pro forma financial statements. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

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

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

C

FKC Mallard Creek is not an existing facility; thus, it has no historical payor mix. However, in Section L.7, page 70, the applicant provides the payor mix for BMA North Charlotte for CY2016. The historical payor mix is illustrated as follows:

**BMA North Charlotte**

| Payor Source | Percentage of In-Center Patients |
|---|---|
| Self Pay/Indigent/ Charity | 4.68% |
| Medicare | 59.19% |
| Medicaid | 12.21% |
| Commercial Insurance | 10.74% |
| Medicare/Commercial | 11.54% |
| Miscellaneous, including VA | 1.64% |
| **Total** | **100.0%** |

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**** |
| | **2016 Estimate** | **2016 Estimate** | **2016 Estimate** | **2015 Estimate** | **2011-2015** | **2015 Estimate** |
| Mecklenburg | 11% | 52% | 52% | 14% | 6% | 13% |
| Statewide | 16% | 51% | 37% | 16% | 10% | 13% |

http://www.census.gov/quickfacts/table Latest Data 7/1/16 as of 8/22/17
*Excludes *"White alone"* who are *"not Hispanic or Latino"*
***"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable…The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."*

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*[1] percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28[2]. In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

The applicant adequately demonstrates that it currently provides access to medically underserved populations. Therefore, the application is conforming to this criterion.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal

[1] http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf
[2] http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L.3(e), page 68, 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 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 69, the applicant states that no civil rights complaints have been lodged against any BMA North Carolina facilities in the past five years.

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 67, the applicant provides the projected payor mix for the proposed services at FKC Mallard Creek as shown in the table below:

**Projected Payor Mix, OY2**
**1/1/20-12/31/20**

| Payor Source | Percentage |
|---|---|
| Self Pay/Indigent/Charity | 4.68% |
| Medicare | 59.19% |
| Medicaid | 12.21% |
| Commercial Insurance | 10.74% |
| Medicare/Commercial | 11.54% |
| Miscellaneous, including VA | 1.64% |
| **Total** | **100.00%** |

Note: Totals may not foot due to rounding.

As shown in the table above, the applicant projects that over 82% of in-center patients will have some or all of their services paid for by Medicare or Medicaid. In Section L.1, page 67, the applicant states that the projected payor mix is based upon the current payor mix of BMA North Charlotte. The applicant adequately demonstrates that medically underserved populations would have access to the proposed services. Therefore, the application is conforming to this criterion.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L.4, page 69, the applicant states that nephrologists who have received medical staff privileges will admit patients to the facility and that any nephrologist may apply for privileges. Further, nephrologists with medical staff privileges will receive referrals from other physicians or hospital emergency rooms.

The applicant adequately demonstrates that FKC Mallard Creek will provide a range of means by which a person can access its services. Therefore, the application is conforming to this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M.1, page 71, the applicant states that health related education programs will be welcomed at the facility. Exhibit M-1 includes a letter from the applicant to the Central Piedmont Community College, dated July 17, 2017, inviting the school to include FKC Mallard Creek in its clinical rotations for its nursing students. The information

provided is reasonable and supports a determination that the application is conforming to this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

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

C

The applicant proposes to develop a new 12-station dialysis facility in Charlotte by relocating 12 stations from BMA North Charlotte. Both facility locations are in Mecklenburg County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. FKC Mallard Creek will be certified for 12 stations upon completion of the project and BMA North Charlotte will be certified for 28 dialysis stations upon completion of this project and Project I.D. #F-11243-16 (add four stations).

On page 373, the 2017 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."* The proposed new facility, FKC Mallard Creek, is located in Mecklenburg County; thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

According to the July 2017 SDR, there are 23 dialysis facilities in Mecklenburg County, 17 of which are operational, summarized as follows:

**Mecklenburg County Dialysis Facilities**
**Certified Stations and Utilization as of December 31, 2016**

| Dialysis Facility | Owner | Location | Number of Certified Stations | Utilization |
|---|---|---|---|---|
| BMA Beatties Ford | BMA | Charlotte | 32 | 98.44% |
| BMA Nations Ford | BMA | Charlotte | 28 | 93.75% |
| BMA of East Charlotte | BMA | Charlotte | 25 | 92.00% |
| BMA of North Charlotte | BMA | Charlotte | 36 | 102.78% |
| BMA West Charlotte | BMA | Charlotte | 29 | 86.21% |
| Brookshire Dialysis | DaVita | Charlotte | 0 | 0.00% |
| Carolinas Medical Center | CMC | Charlotte | 9 | 27.78% |
| Charlotte Dialysis | DaVita | Charlotte | 36 | 84.72% |
| Charlotte East Dialysis | DaVita | Charlotte | 34 | 88.24% |
| DSI Charlotte Latrobe Dialysis | DSI | Charlotte | 24 | 69.79% |
| DSI Glenwater Dialysis | DSI | Charlotte | 42 | 77.38% |
| FMC Charlotte | BMA | Charlotte | 43 | 90.70% |
| FMC Matthews | BMA | Matthews | 21 | 111.90% |
| FKC Southeast Mecklenburg County** | BMA | Charlotte | 0 | 0.00% |
| FMC Regal Oaks* | BMA | Charlotte | 0 | 0.00% |
| FMC Aldersgate* | BMA | Charlotte | 0 | 0.00% |
| Fresenius Medical Care Southwest Charlotte*** | BMA | Charlotte | 10 | 40.00% |
| Huntersville Dialysis | DaVita | Huntersville | 10 | 92.50% |
| Mint Hill Dialysis | DaVita | Mint Hill | 16 | 96.88% |
| North Charlotte Dialysis Center | DaVita | Charlotte | 41 | 74.39% |
| South Charlotte Dialysis | DaVita | Charlotte | 22 | 86.36% |
| South Charlotte Dialysis* | DaVita | Charlotte | 0 | 0.00% |
| Sugar Creek Dialysis* | DaVita | Charlotte | 0 | 0.00% |

As illustrated above, BMA owns eight of the 17 operational dialysis facilities in Mecklenburg County. Seven of BMA's eight operational dialysis facilities are operating above 80% utilization (3.2 patients per station per week) and six of those are operating above 90% utilization. Five dialysis facilities are operating below 80% utilization, including one BMA facility, two DSI facilities, a CMC facility, and one DaVita facility.

According to Table D in the July 2017 SDR, there is a surplus of fourteen dialysis stations in Mecklenburg County. However, the applicant is not increasing the number of dialysis stations in Mecklenburg County, rather it is proposing to relocate 12 existing Mecklenburg County dialysis stations to develop a new facility that is closer to patients living in the area where the new facility will be located.

In Section N.1, page 72, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states that it proposes to serve patients at the new facility that are already being served at other BMA locations and that this patient population is expected to increase consistent with the Mecklenburg County Five Year AACR published in the July 2017 SDR. In addition, the applicant states it will benefit from the collaborative efforts of very qualified nephrologists and will be compelled to operate efficiently due to fixed reimbursement rates received from Medicare and Medicaid. The applicant further states,

> *"BMA does not expect this proposal to have effect on the competitive climate in Mecklenburg County.*

See also Sections B, C, F, K, L, N and O where the applicant discusses the impact of the project on cost-effectiveness, quality and access to the proposed services.

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

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

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Exhibit A-4, the applicant provides a listing of the Fresenius-related owned and operated ESRD facilities in North Carolina. In Section O.3, pages 76-77, and Exhibits O-3 and O-4, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation during the 18 month look-back period. Two BMA facilities had immediate jeopardy citations: RAI West College-Warsaw and BMA East Rocky Mount. Based on a review of all Fresenius-related applications submitted during the review cycle, the Project Analyst notes that there were inconsistencies in the statements made regarding the ESRD facilities that did not operate in compliance with Medicare conditions of participation during the 18 month look-back period. However, in this application, in Exhibits O-3 and O-4, the applicant provides copies of correspondence from Licensure and the Centers for Medicare and Medicaid Services that state that both RAI West College-Warsaw and BMA East Rocky Mount are now back in compliance. Moreover, on page 77, the applicant states that both of these facilities were back in full compliance with all CMS Guidelines upon the submittal of the application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

**10A NCAC 14C .2203 PERFORMANCE STANDARDS**

*(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-C- In Section C.1, pages 18-20, the applicant documents the need for the project and demonstrates that it will serve a total of 39 in-center patients on 12 stations at the end of the first operating year, which is 3.25 patients per station per week, or a utilization rate of 81.25% (39 patients / 12 stations = 3.25; 3.25 / 4 = 0.8125). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-NA- The applicant is seeking to develop a new 12-station dialysis facility.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section C.1, pages 18-20. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.