ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

Decision Date: November 19, 2018
Findings Date: November 19, 2018

Project Analyst: Julie M. Faenza
Team Leader: Fatimah Wilson

Project ID #: F-11582-18
Facility: FMC Charlotte
FID #: 955947
County: Mecklenburg
Applicant: Bio-Medical Applications of North Carolina, Inc.
Project: Add one dialysis station for a total of 45 dialysis 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) d/b/a FMC Charlotte proposes to add one dialysis station to the existing facility for a total of 45 dialysis stations upon project completion.

Need Determination

The 2018 State Medical Facilities Plan (2018 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 42 dialysis stations in Mecklenburg County. Therefore, the July 2018 SDR does not indicate a need for additional stations in Mecklenburg County based on the county need methodology. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80 percent. The utilization rate

reported for FMC Charlotte in the July 2018 SDR is 3.57 patients per station per week, or 89.21 percent, based on 157 in-center dialysis patients and 44 certified dialysis stations [157 / 44 = 3.57; 3.57 / 4 = 0.8921 or 89.21%].

At the time of the submission of the application (September 17, 2018), BMA had three other projects under development which affected the number of dialysis stations at FMC Charlotte:

- F-11099-15: Relocate six stations to FMC Aldersgate, a new 10-station facility
- F-11306-17: Add seven stations (four were previously certified, leaving three outstanding)
- F-11392-17: Add three stations

Because of the six pending additional stations, and because the six stations being relocated to FMC Aldersgate were not yet certified, the facility need methodology was calculated with 50 pending or approved dialysis stations. Subsequent to submission of the application, but before the end of the review of this application, all three projects listed above were certified – F-11099-15 was certified on October 1, 2018, and F-11306-17 and F-11392-17 were certified on October 2, 2018. If those certifications are taken into account in the calculations of the facility need methodology, the calculations would show 44 stations, and thus the applicant would be eligible for six additional stations in addition to what the facility need methodology calculations show.

Below is a table that illustrates the facility need for additional dialysis stations at FMC Charlotte, based on the number of certified and pending stations as of the date of the submission of this application (September 17, 2018):

OCTOBER 1 REVIEW – JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/17		89.21%
Certified Stations		44
Pending Stations		6
Total Existing and Pending Stations		**50**
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2)		157
In-Center Patients as of 6/30/17 (January 2018 SDR) (SDR1)		154
Step	**Description**	**Result**
(i)	Difference (SDR2 - SDR1)	3
	Multiply the difference by 2 for the projected net in-center change	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/17	0.0390
(ii)	Divide the result of Step (i) by 12	0.0032
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/16 until 12/31/17)	0.0390
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	163.1169
(v)	Divide the result of Step (iv) by 3.2 patients per station	50.9740
	and subtract the number of certified and pending stations to determine the number of stations needed	**1**

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is one station. Step (C) of the facility need methodology states, *"The facility may apply to expand to meet the need established …, up to a maximum of ten stations."* The applicant proposes to add one new station; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2018 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on page 33 of the 2018 SMFP, is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

> *"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."*

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B, pages 9-10; Section K, pages 48-50; Section N, page 59; Section O, pages 61-64; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, page 10; Section C, page 19; Section L, pages 53-57; Section N, page 59; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, page 11; Section C, pages 14-18; Section F, pages 27-34; Section K, pages 48-50; Section N, page 59; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

The applicant adequately demonstrates how its proposal incorporates the concepts of quality, equitable access, and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

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

BMA proposes to add one dialysis station to FMC Charlotte for a total of 45 dialysis stations upon project completion.

As of the date of submission of the application (September 17, 2018), BMA had three outstanding projects that were operational but were not yet certified: F-11099-15 (relocate six stations to FMC Aldersgate); F-11306-17 (add seven stations); and F-11392-17 (add three stations). F-11099-15 was certified as of October 1, 2018, and F-11306-17 and F-11392-17 were certified as of October 2, 2018. There was no net change in the number of stations at FMC Charlotte as a result of these projects being certified.

FMC Charlotte currently offers both home hemodialysis training (HH) and home peritoneal dialysis training (PD) and plans to continue to offer both HH and PD following completion of the proposed project.

Patient Origin

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

The following table illustrates current and projected patient origin.

FMC Charlotte – Current and Projected Patient Origin								
	Historical (6/30/2018)				Projected (Operating Year 2)			
County	# of IC Patients	# of HH Patients	# of PD Patients	% of Total	# of IC Patients	# of HH Patients	# of PD Patients	% of Total
Mecklenburg	156	27	41	91.4%	161	30	46	92.7%
Cabarrus	0	1	2	1.2%	0	1	2	1.2%
Catawba	1	0	1	0.8%	1	0	1	0.8%
Gaston	1	0	2	1.2%	1	0	2	1.2%
Union	2	2	0	1.6%	2	2	0	1.5%
South Carolina	0	3	3	2.5%	0	3	3	2.3%
Virginia	0	0	1	0.4%	0	0	1	0.4%
Other States	2	0	0	0.8%	0	0	0	0.0%
Total	**162**	**33**	**50**	**100.0%**	**165**	**36**	**55**	**100.0%**

Table may not foot due to rounding.
Source: Section C, pages 14 and 21

In Section C, pages 14-18, 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, pages 18-19, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 18, 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.*
>
> *In this application, BMA has projected a patient population of 250 in-center and home patients to be dialyzing at the FMC Charlotte facility at the end of the first year. Of those, 159 are expected to be in-center patients. Failure to add stations will lead to higher in-center utilization rates at the facility."*

Additionally, in Section B.2, page 7, the applicant demonstrates the need for the proposed project using the facility need methodology. After the submission of the application, when outstanding projects affecting FMC Charlotte were certified, the facility need methodology would show an even greater need.

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

- FMC Charlotte is currently operating at a rate of 3.57 patients per station per day, or 89.21 percent of capacity.

- The applicant demonstrates eligibility to add dialysis stations to its facility via the facility need methodology. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.

- There is an even greater facility need than is reflected in the facility need methodology calculations due to the certification of approved additional stations and relocations.

Projected Utilization

In Section C, pages 14 and 21, the applicant provides historical and projected utilization as illustrated in the following table.

FMC Charlotte – Historical and Projected Utilization								
	Historical (6/30/2018)				Projected (Operating Year 2)			
County	# of IC Patients	# of HH Patients	# of PD Patients	% of Total	# of IC Patients	# of HH Patients	# of PD Patients	% of Total
Mecklenburg	156	27	41	91.4%	161	30	46	92.7%
Cabarrus	0	1	2	1.2%	0	1	2	1.2%
Catawba	1	0	1	0.8%	1	0	1	0.8%
Gaston	1	0	2	1.2%	1	0	2	1.2%
Union	2	2	0	1.6%	2	2	0	1.5%
South Carolina	0	3	3	2.5%	0	3	3	2.3%
Virginia	0	0	1	0.4%	0	0	1	0.4%
Other States	2	0	0	0.8%	0	0	0	0.0%
Total	**162**	**33**	**50**	**100.0%**	**165**	**36**	**55**	**100.0%**

Table may not foot due to rounding.

In Section C.1, pages 14-18, the applicant provides the assumptions and methodology it used to project in-center, HH, and PD patient utilization, which are summarized below.

In-Center

- The applicant begins its utilization projections by using its facility census as of June 30, 2018.

- The applicant assumes that the patient population currently receiving treatment at FMC Charlotte and who currently reside in Mecklenburg County will increase annually at a rate of 3.9 percent, which is the Five Year Average Annual Change Rate (AACR) for Mecklenburg County published in the July 2018 SDR.

- The applicant assumes no population growth for the patients who utilize the facility and live in other counties, South Carolina, and Virginia, but assumes that the patients will continue to dialyze at FMC Charlotte and adds them to the calculations when appropriate.

- Two patients from states other than South Carolina and Virginia were dialyzing in-center at FMC Charlotte on June 30, 2018. The applicant assumes that they are transient patients who will not continue to dialyze at FMC Charlotte in the future.

- In its application for FMC Aldersgate (Project I.D. #F-11099-15), the applicant projected that 10 patients residing in Mecklenburg County and dialyzing at FMC Charlotte would transfer care to FMC Aldersgate, and the applicant subtracts the 10 patients projected to transfer from the calculations on December 31, 2018 (FMC Aldersgate was certified on October 1, 2018).

- In its application for FKC Southeast Mecklenburg County (Project I.D. #F-11207-16), the applicant projected that one patient residing in Mecklenburg County and dialyzing at FMC Charlotte would transfer care to FKC Southeast Mecklenburg County, and the applicant subtracts the one patient projected to transfer from the calculations on December 31, 2019 (when FKC Southeast Mecklenburg County is projected to be certified).

- In its application for FKC Mallard Creek (Project I.D. #F-11375-17), the applicant projected that four patients residing in Mecklenburg County and dialyzing at FMC Charlotte would transfer care to FKC Mallard Creek, and the applicant subtracts the four patients projected to transfer from the calculations on December 31, 2019 (when FKC Mallard Creek is projected to be certified).

- The project is scheduled for completion on December 31, 2019. OY1 is CY 2020. OY2 is CY 2021.

In Section C, page 16, the applicant provides the calculations used to arrive at the projected in-center patient census for OY1 and OY2 as summarized in the table below.

FMC Charlotte In-Center Projections	
Starting point of calculations is Mecklenburg County patients dialyzing in-center at FMC Charlotte on June 30, 2018.	156
Mecklenburg County patient population is projected forward by six months to December 31, 2018, using one half of the Five Year AACR (3.9%).	156* X 1.0195 = 159
10 Mecklenburg County patients, projected to transfer care to FMC Aldersgate, are subtracted from the projected patient population.	159 – 10 = 149
Mecklenburg County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (3.9%).	149 X 1.039 = 154.9
One Mecklenburg County patient, projected to transfer care to FKC Southeast Mecklenburg County, is subtracted from the projected patient population.	154.9 – 1 = 153.9
Four Mecklenburg County patients, projected to transfer care to FKC Mallard Creek, are subtracted from the projected patient population.	153.9 – 4 = 149.9
The patients from other counties are added. This is the projected census on December 31, 2019 and the starting census for this project.	149.9 + 4 = 153.9
Mecklenburg County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (3.9%).	149.9 X 1.039 = 155.7
The patients from other counties are added. This is the projected census on December 31, 2020 (OY1).	155.7 + 4 = 159.7
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (3.9%).	155.7 X 1.039 = 161.8
The patients from other counties are added. This is the projected census on December 31, 2021 (OY2).	161.8 + 4 = 165.8

*On page 16, there is a typo in this spot – the application lists the number of patients as 149. The calculations are correct when 156 patients are used.

The applicant rounds down and projects to serve 159 in-center patients on 45 stations, which is 3.53 patients per station per week (159 patients / 45 stations = 3.53), by the end of OY1 and 165 in-center patients on 45 stations, which is 3.67 patients per station per week (165 patients / 45 stations = 3.67), 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).

Home Hemodialysis Patients

- The applicant begins its utilization projections by using its HH patient census as of June 30, 2018.

- As discussed above under in-center patient utilization, the applicant projects that the Mecklenburg County HH population will grow at the Five Year AACR for Mecklenburg County published in the July 2018 SDR (3.9 percent).

- The applicant assumes no population growth for the patients who utilize HH services at FMC Charlotte and live in other counties or states, but adds the patients to the calculations when appropriate.

- The project is scheduled for completion on December 31, 2019. OY1 is CY 2020. OY2 is CY 2021.

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

FMC Charlotte HH Patients	
Starting point of calculations is Mecklenburg County HH patients dialyzing at FMC Charlotte on June 30, 2018.	27
Mecklenburg County patient population is projected forward by six months to December 31, 2018, using one half of the Five Year AACR (3.9%).	27 X 1.0195* = 27.5
Mecklenburg County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (3.9%).	27.5 X 1.039 = 28.6
The patients from other counties and states are added. This is the projected census on December 31, 2019 and the starting census for this project.	28.6 + 6 = 34.6
Mecklenburg County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (3.9%).	28.6 X 1.039 = 29.7
The patients from other counties and states are added. This is the projected census on December 31, 2020 (OY1).	29.7 + 6 = 35.7
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (3.9%).	29.7 X 1.039 = 30.9
The patients from other counties and states are added. This is the projected census on December 31, 2021 (OY2).	30.9 + 6 = 36.9

*On page 17, there is a typo in this spot – the application appears to multiply the June 30, 2018 patient population by the full AACR instead of one half of it. The calculations are correct when one half of the AACR is used.

Home Peritoneal Dialysis Patients

- The applicant begins its utilization projections by using its PD patient census as of June 30, 2018.

- As discussed above under in-center patient utilization, the applicant projects that the Mecklenburg County PD population will grow at the Five Year AACR for Mecklenburg County published in the July 2018 SDR (3.9 percent).

- The applicant assumes no population growth for the patients who utilize PD services at FMC Charlotte and live in other counties or states, but adds the patients to the calculations when appropriate.

- The project is scheduled for completion on December 31, 2019. OY1 is CY 2020. OY2 is CY 2021.

In Section C, page 18, the applicant provides the calculations it uses to arrive at the projected PD patient census for OY1 and OY2 as summarized in the table below.

FMC Charlotte PD Patients	
Starting point of calculations is Mecklenburg County PD patients dialyzing at FMC Charlotte on June 30, 2018.	41
Mecklenburg County patient population is projected forward by six months to December 31, 2018, using one half of the Five Year AACR (3.9%).	41 X 1.0195* = 41.8
Mecklenburg County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (3.9%).	41.8 X 1.039 = 43.4
The patients from other counties and states are added. This is the projected census on December 31, 2019 and the starting census for this project.	43.4 + 9 = 52.4
Mecklenburg County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (3.9%).	43.4 X 1.039 = 45.1
The patients from other counties and states are added. This is the projected census on December 31, 2020 (OY1).	45.1 + 9 = 54.1
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (3.9%).	45.1 X 1.039 = 46.9
The patients from other counties and states are added. This is the projected census on December 31, 2021 (OY2).	46.9 + 9 = 55.9

*On page 18, there is a typo in this spot – the application appears to multiply the June 30, 2018 patient population by the full AACR instead of one half of it. The calculations are correct when one half of the AACR is used.

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

- The July 2018 SDR states that FMC Charlotte's utilization was 3.57 patients per station per week (a utilization rate of 89.21 percent) as of December 31, 2017.

- The applicant projects future utilization based on historical utilization.

- The applicant uses the Five Year AACR for Mecklenburg County as published in the July 2018 SDR to project growth of Mecklenburg County residents.

- The applicant reasonably accounts for projected patient utilization by related projects under development.

- The applicant does not project growth for its patients who do not reside in Mecklenburg County.

- 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 19, 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 54, 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.

FMC Charlotte Projected Payor Mix CY 2021

Payment Source	% Total Patients	% In-Center Patients	% HH Patients	% PD Patients
Self-Pay/Indigent/Charity	2.88%	5.45%	2.62%	2.62%
Medicare	62.95%	69.00%	56.93%	56.93%
Medicaid	5.04%	8.58%	2.79%	2.79%
Commercial Insurance	21.22%	6.89%	34.79%	34.79%
Medicare/Commercial	6.12%	7.13%	2.82%	2.82%
Misc. (including VA)	1.80%	2.95%	0.05%	0.05%
Total	**100.00%**	**100.00%**	**100.00%**	**100.00%**

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

NA

The applicant does not propose to reduce a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

(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

BMA proposes to add one dialysis station to FMC Charlotte for a total of 45 dialysis stations upon project completion.

In Section E, page 25, 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 that maintaining the status quo would lead to higher utilization rates and potentially restrict patient admissions. Therefore, this is not an effective alternative.

- Relocate Stations From Another Mecklenburg County Facility: the applicant states that all but one of its facilities in Mecklenburg County are operating above 80 percent, and the one facility with utilization below 80 percent has had increasing utilization. Therefore, this is not an effective alternative.

On page 25, the applicant states that its proposal is the most effective alternative because the facility need methodology shows a need for an additional station, which will have a small

capital expenditure, and is necessary to meet the need for dialysis patients in Mecklenburg County.

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

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

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte shall materially comply with all representations made in the certificate of need application.**

2. **Pursuant to the facility need determination in the July 2018 SDR, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte shall develop no more than one additional dialysis station for a total of no more than 45 certified stations upon project completion, which shall include any home hemodialysis training or isolation stations.**

3. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte 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

BMA proposes to add one dialysis station to FMC Charlotte for a total of 45 dialysis stations upon project completion.

Capital and Working Capital Costs

In Section F.1, page 27, the applicant projects the total capital cost to be $3,750, with $3,000 to be used for landscaping and $750 for water treatment equipment. In Sections F.10 and F.11, page 30, the applicant states that there are no projected start-up expenses or initial operating expenses because it is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 28, the applicant states that it will fund the entire capital cost of the proposed project with accumulated reserves. Exhibit F-1 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. Exhibit F-2 contains a Form 10-K Consolidated Financial Statement from Fresenius Medical Care Holdings, Inc., which showed that as of December 31, 2017, Fresenius Medical Care Holdings, Inc. had adequate cash and assets to fund the capital cost of the proposed project.

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 B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

Projected Revenues and Operating Expenses		
FMC Charlotte	**Operating Year 1 CY 2020**	**Operating Year 2 CY 2021**
Total Treatments	36,160	37,494
Total Gross Revenues (Charges)	$144,206,080	$149,526,072
Total Net Revenue	$13,192,285	$14,765,434
Average Net Revenue per Treatment	$365	$394
Total Operating Expenses (Costs)	$12,596,374	$12,972,069
Average Operating Expense per Treatment	$348	$346
Net Income/Profit	**$595,911**	**$1,793,366**

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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 following reasons:

- The applicant adequately demonstrates that the capital cost is based on reasonable and adequately supported assumptions.

- The applicant adequately demonstrates availability of sufficient funds for the 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

BMA proposes to add one dialysis station to FMC Charlotte for a total of 45 dialysis stations upon project completion.

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

According to Table B of the July 2018 SDR, there are 23 facilities which provide dialysis in Mecklenburg County, 17 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the July 2018 SDR, is provided below:

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2017				
Dialysis Facility	**Owner**	**Location**	**# of Certified Stations**	**Utilization**
BMA Beatties Ford	BMA	Charlotte	32	89.84%
BMA Nations Ford	BMA	Charlotte	28	91.96%
BMA of East Charlotte	BMA	Charlotte	26	88.46%
BMA of North Charlotte	BMA	Charlotte	40	98.75%
BMA West Charlotte	BMA	Charlotte	29	87.93%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
FKC Regal Oaks	BMA	Charlotte	12	43.75%
FKC Southeast Charlotte*	BMA	Charlotte	0	0.00%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
FMC Charlotte	BMA	Charlotte	44	89.20%
FMC Matthews	BMA	Matthews	21	115.48%
FMC Southwest Charlotte	BMA	Charlotte	13	84.62%
Brookshire Dialysis*	DaVita	Charlotte	0	0.00%
Carolinas Medical Center	CMC	Charlotte	9	25.00%
Charlotte Dialysis	DaVita	Charlotte	36	86.11%
Charlotte East Dialysis	DaVita	Charlotte	34	90.44%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	69.79%
DSI Glenwater Dialysis	DSI	Charlotte	42	75.00%
Huntersville Dialysis	DaVita	Huntersville	14	83.93%
Mint Hill Dialysis	DaVita	Mint Hill	16	84.38%
North Charlotte Dialysis Center	DaVita	Charlotte	37	68.24%
South Charlotte Dialysis**	DaVita	Charlotte	23	83.70%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis*	DaVita	Charlotte	0	0.00%

Source: July 2018 SDR, Table B.
* Facility under development.
**Per Project I.D. #F-11323-17, this facility is being relocated to a new location.

In Section G, pages 36-38, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Mecklenburg County. The applicant states:

> *"Mecklenburg County has the largest ESRD patient population of any county in North Carolina. The July 2018 SDR reports that as of December 31, 2017 there were 1,710 dialysis patients residing in Mecklenburg County. This is equiavlent* [sic] *to 9.48% of the total ESRD patient population of NC.*
>
> …
>
> *…three of the BMA facilities* [in Mecklenburg County] *were operating below the 80% threshold as of June 30, 2018. The three BMA facilities below 80% were operating above 70%. Furthermore, BMA was serving a total of 15 more patients for this period. Overall utilization rates increased from 3.63 patients per station as of December 31, 2017 to 3.69 patients per station as of June 30, 2018. The ESRD census of Mecklenburg County is increasing. The number of patients choosing to dialyze with BMA is*

increasing. BMA suggests additional stations are needed within Mecklenburg County and will continue to be needed."

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:

- There is a facility need determination, as calculated using the methodology in the July 2018 SDR, for the proposed dialysis station.

- The applicant adequately demonstrates that the proposed dialysis station is needed in addition to the existing or approved dialysis 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

In Section H, page 39, the applicant provides information about current and projected staffing for the proposed services. The applicant does not project to change its current staffing levels upon project completion.

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H, page 40, the applicant describes the methods it uses to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 44, the applicant identifies the current medical director. In Exhibit I-5, the applicant provides a letter from the current medical director indicating his intent to continue serving 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, page 43, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

FMC Charlotte – Ancillary and Support Services	
Services	**Provider**
In-center dialysis/maintenance	On site
Self-care training (in-center)	On site
Home training HH PD Accessible follow-up program	 On site On site On site
Psychological counseling	Referral to CMC Randolph Road
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	Carolinas Medical Center
Emergency care	Crash cart on site/staff trained; ambulance transport to CMC
Blood bank services	Carolinas Medical Center
Diagnostic and evaluation services	Carolinas Medical Center
X-ray services	Carolinas Medical Center
Laboratory services	Spectra
Pediatric nephrology	Carolinas Medical Center
Vascular surgery	CMC; Sanger Heart & Vascular; MNA Vascular Access Center
Transplantation services	Carolinas Medical Center
Vocational rehabilitation & counseling	NC DHHS Vocational Rehab Services
Transportation	Charlotte Area Transportation (CATS); A-1 Wheelchair Transport, or area taxi services

The applicant provides supporting documentation in Exhibits I-2 through I-4.

In Section I, pages 45-46, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-5.

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.

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

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

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

C

In Section L, page 57, the applicant provides the historical payor mix during CY 2017 for its existing services, as shown in the table below.

FMC Charlotte Historical Payor Mix CY 2017	
Payment Source	**% Total Patients**
Self-Pay/Indigent/Charity	3.72%
Medicare	64.03%
Medicaid	5.70%
Commercial Insurance	18.71%
Medicare/Commercial	5.68%
Misc. (including VA)	2.17%
Total	**100.00%**

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant’s service area.

Percent of Population						
County	**% 65+**	**% Female**	**% Racial & Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
Mecklenburg	11%	52%	53%	12%	6%	12%
Statewide	16%	51%	37%	15%	10%	12%

Source: http://www.census.gov/quickfacts/table; Latest Data 7/1/17 as of 7/17/18
*Excludes *"White alone"* who are *"not Hispanic or Latino"*
***""Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable…The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."*

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26[1]) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

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 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;

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, pages 55-56, that it has no obligation by any of its facilities to provide uncompensated care or community service under any federal regulations.

In Section L, page 56, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and 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 54, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

FMC Charlotte Projected Payor Mix CY 2021				
Payment Source	**% Total Patients**	**% In-Center Patients**	**% HH Patients**	**% PD Patients**
Self-Pay/Indigent/Charity	2.88%	5.45%	2.62%	2.62%
Medicare	62.95%	69.00%	56.93%	56.93%
Medicaid	5.04%	8.58%	2.79%	2.79%
Commercial Insurance	21.22%	6.89%	34.79%	34.79%
Medicare/Commercial	6.12%	7.13%	2.82%	2.82%
Misc. (including VA)	1.80%	2.95%	0.05%	0.05%
Total	**100.00%**	**100.00%**	**100.00%**	**100.00%**

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.88 percent of total services will be provided to self-pay, indigent, and charity care patients; 69.07 percent to patients who will have some or all of their care paid for by Medicare, and 5.04 percent to Medicaid patients.

On page 54, 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 on the historical payor mix.

- Projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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-1.

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

BMA proposes to add one dialysis station to FMC Charlotte for a total of 45 dialysis stations upon project completion.

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

According to Table B of the July 2018 SDR, there are 23 facilities which provide dialysis in Mecklenburg County, 17 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the July 2018 SDR, is provided below:

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2017				
Dialysis Facility	**Owner**	**Location**	**# of Certified Stations**	**Utilization**
BMA Beatties Ford	BMA	Charlotte	32	89.84%
BMA Nations Ford	BMA	Charlotte	28	91.96%
BMA of East Charlotte	BMA	Charlotte	26	88.46%
BMA of North Charlotte	BMA	Charlotte	40	98.75%
BMA West Charlotte	BMA	Charlotte	29	87.93%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
FKC Regal Oaks	BMA	Charlotte	12	43.75%
FKC Southeast Charlotte*	BMA	Charlotte	0	0.00%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
FMC Charlotte	BMA	Charlotte	44	89.20%
FMC Matthews	BMA	Matthews	21	115.48%
FMC Southwest Charlotte	BMA	Charlotte	13	84.62%
Brookshire Dialysis*	DaVita	Charlotte	0	0.00%
Carolinas Medical Center	CMC	Charlotte	9	25.00%
Charlotte Dialysis	DaVita	Charlotte	36	86.11%
Charlotte East Dialysis	DaVita	Charlotte	34	90.44%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	69.79%
DSI Glenwater Dialysis	DSI	Charlotte	42	75.00%
Huntersville Dialysis	DaVita	Huntersville	14	83.93%
Mint Hill Dialysis	DaVita	Mint Hill	16	84.38%
North Charlotte Dialysis Center	DaVita	Charlotte	37	68.24%
South Charlotte Dialysis**	DaVita	Charlotte	23	83.70%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis*	DaVita	Charlotte	0	0.00%

Source: July 2018 SDR, Table B.
* Facility under development.
**Per Project I.D. #F-11323-17, this facility is being relocated to a new location.

In Section N, page 59, 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:

> *"BMA does not expect this proposal to have effect on the competitive climate in Mecklenburg County. BMA does not project to serve dialysis patients currently being served by another provider. …*
>
> *…*
>
> *BMA 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."*

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

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits).

- Quality services will be provided (see Section O of the application and any exhibits).

- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion

The Agency reviewed the:

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

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

(19) Repealed effective July 1, 1987.

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

C

In Exhibit A-4, 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 114 dialysis facilities located in North Carolina.

In Section O, page 62, 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 114 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.

-NA- FMC Charlotte is an existing facility. Therefore, this Rule is not applicable to this review.

(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 14, the applicant projects that FMC Charlotte will serve 159 patients on 45 stations, or a rate of 3.53 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 14-18, 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.