

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 11, 2020

Findings Date: May 11, 2020

Project Analyst: Julie M. Faenza

Team Leader: Gloria C. Hale

Project ID #: F-11845-20

Facility: Brookshire Dialysis

FID #: 150477

County: Mecklenburg

Applicant: Renal Treatment Centers – Mid-Atlantic, Inc.

Project: Relocate no more than 1 station from Charlotte Dialysis for a total of no more than 11 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

Renal Treatment Centers – Mid-Atlantic, Inc. (RTC-MA) d/b/a Brookshire Dialysis (Brookshire) proposes to relocate one dialysis station from Charlotte Dialysis for a total of 11 dialysis stations at Brookshire upon project completion. Upon completion of this project and Project I.D. #F-11592-18 (relocate 10 stations to develop Renaissance Park Dialysis), Charlotte Dialysis will have 23 certified dialysis stations.

Need Determination

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. Table 9D on page 170 of the 2020 SMFP does not show a need for additional stations in Mecklenburg County based on the county need methodology. Table 9E on page 172 of the 2020 SMFP does not show a need for additional dialysis stations at Brookshire Dialysis based

on the facility need methodology. This application is a proposal to relocate an existing dialysis station from one facility to another and neither the county need methodology nor the facility need methodology apply. Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2020 SMFP which is applicable to this review. *Policy ESRD-2: Relocation of Dialysis Stations*, on page 20 of the 2020 SMFP, states:

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

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

Both Brookshire and Charlotte Dialysis are in Mecklenburg County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion because the application is consistent with Policy ESRD-2.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and in particular, low income persons, racial and ethnic minorities,

women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to relocate one dialysis station from Charlotte Dialysis for a total of 11 dialysis stations at Brookshire upon project completion.

According to Table 9A on page 135 of the 2020 SMFP, Brookshire does not offer home peritoneal or home hemodialysis training and support. The applicant does not propose to offer home peritoneal or home hemodialysis training and support as part of the current application.

In Section A, page 9, the applicant states its parent company is DaVita, Inc. The applicant uses DaVita, Inc. (DaVita) interchangeably with RTC-MA to refer to itself or its facilities. References to DaVita should be interpreted to mean RTC-MA unless otherwise specified.

Patient Origin

On page 113, the 2020 SMFP defines the service area for dialysis stations as “...the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” Thus, the service area for this facility consists of Mecklenburg County. Facilities may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

Brookshire – Current and Projected Patient Origin				
	Current (12/31/2019)		Projected (OY 2 – CY 2022)	
County	# of Patients	% of Total	# of Patients	% of Total
Mecklenburg	17	94.4%	31	96.9%
Gaston	1	5.6%	1	3.1%
Total	18	100.0%	32	100.0%

Table may not foot due to rounding.

Source: Section C, pages 19-20

In Section C, pages 20-21, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 20-22, the applicant states the facility was certified and began offering services in July 2018 and had a patient population of 16 by December 31, 2018. The applicant states the population increased by two patients – a 12.5 percent increase – between December 31, 2018 and December 31, 2019. The applicant also states 11 patients have signed letters of support stating they would consider transferring care to Brookshire. Each letter of support

states the patient currently dialyzes at Charlotte Dialysis. See Exhibit C.3 for the patient letters of support.

The applicant states it is possible the facility will qualify to apply for additional stations under Condition 1 of the facility need methodology later in the year, but says it is prudent to act sooner rather than later.

On page 22, the applicant states:

“As the center continues to grow, it is important to ensure there are desirable chair times and shifts available to patients. Additionally, physician rounding constraints can and have limited available chairs and shifts in Mecklenburg County over the last several years as patient census growth has outgrown nephrologist capacity. Adding additional chairs on current shifts is an efficient approach to bridging the gap with physician capacity.”

The information is reasonable and adequately supported based on the following:

- Brookshire experienced a 12.5 percent growth in patients during CY 2019.
- The applicant provides letters of support from 11 patients which state the patients will consider transferring care to Brookshire from Charlotte Dialysis.

Projected Utilization

On Form C and the Form C Utilization subsection in Section Q, the applicant provides historical and projected utilization as illustrated in the following table.

Brookshire – Historical and Projected Patient Utilization						
	Historical		Projected			
	12/31/2019		OY 1 (CY 2021)		OY 2 (CY 2022)	
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Mecklenburg	17	94.4%	30	96.8%	31	96.9%
Gaston	1	5.6%	1	3.2%	1	3.1%
Total	18	100.0%	31	100.0%	32	100.0%

In Section C, pages 20-21, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant begins its utilization projections with the patient facility census as of December 31, 2019. On page 20, the applicant states that, as of December 31, 2019, it was serving 17 Mecklenburg County patients and one Gaston County patient.

- The applicant projects growth of the Mecklenburg County patient population at a rate of 4.2 percent, which is the Five Year Average Annual Change Rate (AACR) for Mecklenburg County as published in the 2020 SMFP.
- The applicant assumes the 11 patients who signed letters of support stating they'd consider transferring care to Brookshire will transfer care to Brookshire beginning on January 1, 2021, when the project is projected to offer services.
- All 11 patients who signed letters of support stating they'd consider transferring care to Brookshire are Mecklenburg County residents.
- The applicant assumes no population growth for the Gaston County patient dialyzing at Brookshire but assumes the patient will continue to dialyze at Brookshire and adds them to the calculations when appropriate.
- The project is scheduled to begin offering services on January 1, 2021. OY1 is CY 2021. OY2 is CY 2022.

In Section C, page 21, and the Form C Utilization subsection of Section Q, the applicant provides the calculations used to project the patient census for OY1 and OY2, as summarized in the table below.

Brookshire Projected Utilization	
Starting point of calculations is Mecklenburg County patients dialyzing at Brookshire on December 31, 2019.	17
Mecklenburg County patient population is projected forward by one year to December 31, 2020, using the 4.2% projected AACR.	$17 \times 1.042 = 17.714$
The 11 patients transferring care to Brookshire are added to the projected census on December 31, 2020.	$17.714 + 11 = 28.714$
The Gaston County patient is added. This is the projected census on January 1, 2021 and the starting census for this project.	$28.714 + 1 = 29.714$
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the 4.2% projected AACR.	$28.714 \times 1.042 = 29.920$
The Gaston County patient is added. This is the projected census on December 31, 2021 (OY1).	$29.920 + 1 = 30.920$
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the 4.2% projected AACR.	$29.920 \times 1.042 = 31.177$
The Gaston County patient is added. This is the projected census on December 31, 2022 (OY2).	$31.177 + 1 = 32.177$

The applicant projects to serve 31 patients on 11 stations, which is 2.82 patients per station per week ($31 \text{ patients} / 11 \text{ stations} = 2.82$), by the end of OY1 and 32 patients on 11 stations, which is 2.91 patients per station per week ($32 \text{ patients} / 11 \text{ stations} = 2.91$), by the end of OY2. This exceeds the minimum of 2.8 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

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

- The applicant provides letters of support from 11 patients who state they will consider transferring care to Brookshire.
- The applicant projects future utilization based on historical utilization.
- The applicant uses the Mecklenburg County Five Year AACR as published in the 2020 SMFP to project growth.
- The applicant does not project growth for the Gaston County patient dialyzing at Brookshire.
- The applicant's projected utilization exceeds the minimum of 2.8 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 24, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

We will make every reasonable effort to accommodate all patients, especially those with special needs such as those with disabilities, patients attending school or patients who work. ...

Brookshire Dialysis will help uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, disabled persons, elderly and other under-served persons.”

In Section L, page 49, 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.

Brookshire Projected Payor Mix CY 2022		
Payment Source	# Patients	% Patients
Self-Pay	0	0.0%
Insurance*	5.4	16.7%
Medicare*	25.0	77.8%
Medicaid*	1.8	5.6%
Other	0	0.0%
Total	32	100.0%

Table may not foot due to rounding.

*Including any managed care plans

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

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

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

C

The applicant proposes to relocate one dialysis station from Charlotte Dialysis for a total of 11 dialysis stations at Brookshire upon project completion.

As of December 31, 2019, Charlotte Dialysis had 34 certified dialysis stations. 10 stations are pending relocation as part of Project I.D. #F-11592-18 (relocate 10 stations to develop Renaissance Park Dialysis). This project proposes to relocate one station to Brookshire. Following completion of this project and Project I.D. #F-11592-18, Charlotte Dialysis will be certified for 23 stations.

In Section D, pages 27-28, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated, or relocated will be adequately met following completion of the project. On pages 27-28, the applicant states that, with the transfer of 11 patients from Charlotte Dialysis to Brookshire upon project completion, and considering population growth of Mecklenburg County patients, Charlotte Dialysis will still have adequate capacity to accommodate its existing patients. The applicant further states it will apply for additional stations as warranted. According to Table 9B of the 2020 SMFP, Charlotte Dialysis has a Facility Station Need Determination of 11 stations.

On Form D and the Form D Utilization subsection in Section Q, the applicant provides projected utilization for Charlotte Dialysis, as shown in the table below.

Charlotte Dialysis – Projected Patient Utilization				
	OY 1 (CY 2021)		OY 2 (CY 2022)	
County	# of Patients	% of Total	# of Patients	% of Total
Mecklenburg	95	92.2%	99	92.5%
Other Counties/States*	8	7.8%	8	7.5%
Total	103	100.0%	107	100.0%

*Includes Gaston, Lenoir, Rutherford, and Wake counties in North Carolina as well as other states.

In Section D, pages 27-28, and in the Form D Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant begins its utilization projections with the patient facility census as of December 31, 2019. On page 27, the applicant states that, as of December 31, 2019, it was serving 98 Mecklenburg County patients and eight patients from other counties and states.
- The applicant projects growth of the Mecklenburg County patient population at a rate of 4.2 percent, which is the Five Year Average Annual Change Rate (AACR) for Mecklenburg County as published in the 2020 SMFP.
- The applicant assumes the 11 patients who signed letters of support stating they'd consider transferring care to Brookshire will transfer care to Brookshire beginning on January 1, 2021, when that project is projected to offer services.
- All 11 patients who signed letters of support stating they'd consider transferring care to Brookshire are Mecklenburg County residents.

- The applicant assumes no population growth for the patients residing outside of Mecklenburg County and dialyzing at Charlotte Dialysis but assumes the patients will continue to dialyze at Charlotte Dialysis and adds them to the calculations when appropriate.
- OY1 for the Brookshire project is CY 2021. OY2 is CY 2022.

In Section D, page 28, and in the Form D Utilization subsection of Section Q, the applicant provides the calculations used to project the patient census for OY1 and OY2 for Charlotte Dialysis, as summarized in the table below.

Charlotte Dialysis Projected Utilization	
Starting point of calculations is Mecklenburg County patients dialyzing at Charlotte Dialysis on December 31, 2019.	98
Mecklenburg County patient population is projected forward by one year to December 31, 2020, using the 4.2% projected AACR.	$98 \times 1.042 = 102.116$
The 11 patients transferring care to Brookshire are subtracted from the Mecklenburg County patient population on December 31, 2020.	$102.116 - 11 = 91.116$
The patients from outside Mecklenburg County are added to the projected census. This is the projected census on January 1, 2021.	$91.116 + 8 = 99.116$
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the 4.2% projected AACR.	$99.116 \times 1.042 = 94.943$
The patients from outside Mecklenburg County are added. This is the projected census on December 31, 2021 (OY1).	$94.943 + 8 = 102.943$
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the 4.2% projected AACR.	$102.943 \times 1.042 = 98.930$
The patients from outside Mecklenburg County are added. This is the projected census on December 31, 2022 (OY2).	$98.930 + 8 = 106.930$

The applicant projects to serve 103 patients on 33 stations, which is 3.12 patients per station per week ($103 \text{ patients} / 33 \text{ stations} = 3.12$), by the end of OY1 and 107 patients on 33 stations, which is 3.24 patients per station per week ($107 \text{ patients} / 33 \text{ stations} = 3.24$), by the end of OY2. 3.12 patients per station per week in OY 1 is a utilization rate of 78 percent and 3.24 patients per station per week in OY 2 is a utilization rate of 81 percent.

In Project I.D. #F-11592-18, the applicant projected to relocate 10 stations from Charlotte Dialysis to develop Renaissance Park Dialysis. The applicant also projected that 32 patients would transfer care from Charlotte Dialysis to Renaissance Park Dialysis. The applicant does not include the projections related to developing Renaissance Park Dialysis in this application. However, according to Agency records, Project I.D. #F-11592-18's most recent timetable projected to offer services beginning on December 31, 2021, or the beginning of OY 2 of this project. Additionally, according to the progress report submitted by the applicant on April 1, 2020, DaVita is prioritizing completion of its projects further along in development so as to care for medically fragile patients experiencing COVID-19 or complications from COVID-19 in appropriate settings separately from the rest of the dialysis patients, and this project's development has been put on hold for the foreseeable future due to the current COVID-19 international pandemic.

The Project Analyst did an analysis of projected utilization at Charlotte Dialysis based on the assumptions and projections from Project I.D. #F-11592-18, the current timetable for Project I.D. #F-11592-18, and the assumptions and methodology in this application. The assumptions, methodology, and projections are below.

- The applicant begins its utilization projections with the patient facility census as of December 31, 2019. On page 27, the applicant states that, as of December 31, 2019, it was serving 98 Mecklenburg County patients and eight patients from other counties and states.
- The applicant projects growth of the Mecklenburg County patient population at a rate of 4.2 percent, which is the Five Year Average Annual Change Rate (AACR) for Mecklenburg County as published in the 2020 SMFP.
- The applicant assumes the 11 patients who signed letters of support stating they'd consider transferring care to Brookshire will transfer care to Brookshire beginning on January 1, 2021, when that project is projected to offer services.
- All 11 patients who signed letters of support stating they'd consider transferring care to Brookshire are Mecklenburg County residents.
- 32 patients from Charlotte Dialysis who signed letters of support stating they'd consider transferring care to Renaissance Park Dialysis will transfer care to Renaissance Park Dialysis beginning on January 1, 2022, when that project is projected to offer services.
- All 32 patients who signed letters of support stating they'd consider transferring care to Renaissance Park Dialysis are Mecklenburg County residents.
- The applicant assumes no population growth for the patients residing outside of Mecklenburg County and dialyzing at Charlotte Dialysis but assumes the patients will continue to dialyze at Charlotte Dialysis and adds them to the calculations when appropriate.
- OY1 for the Brookshire project is CY 2021. OY2 is CY 2022.

The Project Analyst's updated assumptions and calculations are shown in the table below.

Charlotte Dialysis Projected Utilization – Updated by Project Analyst	
Starting point of calculations is Mecklenburg County patients dialyzing at Charlotte Dialysis on December 31, 2019.	98
Mecklenburg County patient population is projected forward by one year to December 31, 2020, using the 4.2% projected AACR.	$98 \times 1.042 = 102.116$
The 11 patients transferring care to Brookshire are subtracted from the Mecklenburg County patient population on December 31, 2020.	$102.116 - 11 = 91.116$
The patients from outside Mecklenburg County are added to the projected census. This is the projected census on January 1, 2021.	$91.116 + 8 = 99.116$
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the 4.2% projected AACR.	$91.116 \times 1.042 = 94.943$
The patients from outside Mecklenburg County are added. This is the projected census on December 31, 2021 (OY1).	$94.943 + 8 = 102.943$
The 32 patients transferring care to Renaissance Park Dialysis are subtracted from the Mecklenburg County patient population on January 1, 2022.	$94.943 - 32 = 62.943$
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the 4.2% projected AACR.	$62.943 \times 1.042 = 65.587$
The patients from outside Mecklenburg County are added. This is the projected census on December 31, 2022 (OY2).	$65.587 + 8 = 73.587$

In this analysis, the applicant projects to serve 103 patients on 33 stations, which is 3.12 patients per station per week ($103 \text{ patients} / 33 \text{ stations} = 3.12$), by the end of OY1 and 74 patients on 23 stations, which is 3.22 patients per station per week ($74 \text{ patients} / 23 \text{ stations} = 3.22$), by the end of OY2. 3.12 patients per station per week in OY 1 is a utilization rate of 78 percent and 3.22 patients per station per week in OY 2 is a utilization rate of 80.5 percent.

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

- The applicant provides letters of support from 11 patients who state they will consider transferring care to Brookshire.
- The applicant projects future utilization based on historical utilization.
- The applicant uses the Mecklenburg County Five Year AACR as published in the 2020 SMFP to project growth.
- The applicant does not project growth for patients dialyzing at Charlotte Dialysis who live outside of Mecklenburg County.
- The applicant’s projections still allow for adequate capacity for existing patients when its projections from Project I.D. #F-11592-18 are included in projecting utilization at Charlotte Dialysis.

In Section D, page 29, the applicant states:

“The relocation of stations from Charlotte Dialysis will have no effect on the ability of low income persons, racial and ethnic minorities, women, disabled persons, and other under-served group and the elderly to obtain needed health care.

Charlotte Dialysis by policy, will continue to make dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability.

Charlotte Dialysis will continue to assist uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, disabled persons, elderly and other under-served persons.”

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated, or relocated will be adequately met following project completion.
 - The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion.
- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to relocate one dialysis station from Charlotte Dialysis for a total of 11 dialysis stations at Brookshire upon project completion.

In Section E, pages 30-31, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo: the applicant states maintaining the status quo would not allow optimal alignment of stations with minimal impact on the facility losing the station; therefore, this is not an effective alternative.

- Relocate More Than One Station: the applicant states there is not a demonstrable need to relocate more than one station; therefore, this is not an effective alternative.
- Relocate Stations from Another DaVita Facility: the applicant states that, except for Charlotte East Dialysis, every other DaVita facility in Mecklenburg County is either new, close to capacity, or already involved in projects to relocate existing stations; therefore, this is not an effective alternative.

On page 30, the applicant states its proposal is the most effective alternative because it optimizes station alignment, avoids negative impacts on the facility losing the station, and of the options for facilities from which to relocate stations, the station will be relocated from the appropriate facility closest to Brookshire.

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

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

Conclusion

The Agency reviewed the:

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

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

- 1. Renal Treatment Centers – Mid-Atlantic, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, Renal Treatment Centers – Mid-Atlantic, Inc. shall relocate no more than one station from Charlotte Dialysis to Brookshire Dialysis for a total of no more than 11 stations at Brookshire Dialysis.**
- 3. Renal Treatment Centers – Mid-Atlantic, Inc. shall take the necessary steps to decertify one station at Charlotte Dialysis for a total of no more than 23 stations upon completion of this project and Project I.D. #F-11592-18 (relocate 10 stations to develop Renaissance Park Dialysis).**

4. Renal Treatment Centers – Mid-Atlantic, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

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

C

The applicant proposes to relocate one dialysis station from Charlotte Dialysis for a total of 11 dialysis stations at Brookshire upon project completion.

Capital and Working Capital Costs

On Form F.1a in Section Q, the applicant projects a total capital cost of \$19,548, to be used for medical equipment, non-medical equipment, and furniture. In Section Q, the applicant provides the assumptions used to project the capital cost. In Section F, page 34, the applicant states there are no projected start-up expenses or initial operating expenses because Brookshire is an existing and operational facility.

Availability of Funds

In Section F, page 32, the applicant states it will fund the capital cost of the proposed project with accumulated reserves. Exhibit F-2 contains a letter from the applicant on behalf of the Chief Accounting Officer of DaVita, Inc., authorizing the use of accumulated reserves for the capital needs and any other needs of the project. Exhibit F-2 also contains a Form 10-K Consolidated Financial Statement from DaVita, Inc., which showed that as of December 31, 2018, DaVita, Inc. had adequate cash and assets to fund the capital and working capital costs 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. On Form F.2 in Section Q, 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		
Brookshire	Operating Year 1 CY 2021	Operating Year 2 CY 2022
Total Treatments	4,493	4,675
Total Gross Revenues (Charges)	\$1,892,043	\$1,968,888
Total Net Revenue	\$1,768,936	\$1,840,780
Average Net Revenue per Treatment	\$394	\$394
Total Operating Expenses (Costs)	\$1,483,930	\$1,525,660
Average Operating Expense per Treatment	\$330	\$326
Net Income/Profit	\$285,005	\$315,120

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

The applicant proposes to relocate one dialysis station from Charlotte Dialysis for a total of 11 dialysis stations at Brookshire upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “...the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and

Avery, Mitchell, and Yancey counties.” Thus, the service area for this facility consists of Mecklenburg County. Facilities may serve residents of counties not included in their service area.

There are 27 existing and approved facilities which provide dialysis and/or dialysis home training and support in Mecklenburg County, 23 of which are operational. Information on all 27 of these dialysis facilities is provided below:

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Brookshire Dialysis	DaVita	Charlotte	10	40.00%
Charlotte Dialysis	DaVita	Charlotte	34	81.62%
Charlotte East Dialysis	DaVita	Charlotte	34	80.15%
Huntersville Dialysis	DaVita	Huntersville	14	92.86%
Mint Hill Dialysis	DaVita	Mint Hill	22	55.68%
Mountain Island Lake Dialysis*	DaVita	Charlotte	0	0.00%
North Charlotte Dialysis Center	DaVita	Charlotte	36	72.92%
Renaissance Park Dialysis*	DaVita	Charlotte	0	0.00%
South Charlotte Dialysis**	DaVita	Charlotte	23	85.87%
South Charlotte Dialysis**	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis	DaVita	Charlotte	10	50.00%
BMA Beatties Ford	BMA	Charlotte	32	95.31%
BMA Nations Ford	BMA	Charlotte	28	79.46%
BMA of East Charlotte	BMA	Charlotte	26	89.42%
Carolinas Medical Center	CMC	Charlotte	9	33.33%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	67.71%
DSI Glenwater Dialysis	DSI	Charlotte	42	74.40%
BMA West Charlotte	BMA	Charlotte	29	87.93%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
FKC Regal Oaks	BMA	Charlotte	12	93.75%
FKC Southeast Charlotte*	BMA	Pineville	0	0.00%
FMC Aldersgate	BMA	Charlotte	10	27.50%
FMC Charlotte	BMA	Charlotte	44	89.20%
FMC Matthews	BMA	Matthews	21	114.29%
FMC of North Charlotte	BMA	Charlotte	40	96.88%
FMC Southwest Charlotte	BMA	Charlotte	13	92.31%
INS Charlotte***	BMA	Charlotte	0	0.00%
INS Huntersville***	BMA	Huntersville	0	0.00%

Source: Table 9B, Chapter 9, 2020 SMFP; Agency records

*Facility under development or which was not operational at the time of data collection for the 2020 SMFP.

**Per Project I.D. #F-11323-17, this facility is being relocated to a new location; the 2020 SMFP lists both the existing operational facility and the replacement facility.

***Facility which is dedicated exclusively to providing HH and PD training and support.

In Section G, page 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 that it is proposing to relocate one station and no stations are being added to Mecklenburg County.

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area because the proposal will not increase the number of dialysis stations in Mecklenburg County.

Conclusion

The Agency reviewed the:

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

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

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

C

On Form H in Section Q, the applicant provides current and projected staffing for the proposed services, as illustrated in the following table.

Brookshire Current and Projected Staffing			
	Current	To Be Added	Total
Administrator	1.0	0.0	1.0
Registered Nurses	2.0	0.0	2.0
Patient Care Technicians	4.0	1.0	5.0
Dietician	0.5	0.0	0.5
Social Worker	0.5	0.0	0.5
Administration/Office	0.5	0.0	0.5
Biomed Technician	0.5	0.0	0.5
TOTAL	9.0	1.0	10.0

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, pages 39-40, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibits H-2 and H-3. In Section H, page 40, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the current medical director expressing support for the proposed project and stating his interest in continuing to serve as medical director for the proposed services.

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 41, the applicant states the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

Brookshire – Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	On site
Self-care training (in-center)	On site
Home training	
HH	Charlotte East Dialysis
PD	Charlotte East Dialysis
Accessible follow-up program	Charlotte East Dialysis
Psychological counseling	On site (by registered nurse)
Isolation – hepatitis	On site
Nutritional counseling	On site (by registered dietician)
Social Work services	On site (by MSW)
Acute dialysis in an acute care setting	Carolinas Medical Center
Emergency care	Carolinas Medical Center
Blood bank services	Carolinas Medical Center
Diagnostic and evaluation services	Carolinas Medical Center
X-ray services	Carolinas Medical Center
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	Carolinas Medical Center
Vascular surgery	Carolinas Medical Center
Transplantation services	Carolinas Medical Center
Vocational rehabilitation & counseling	NC DHHS Vocational Rehab Services
Transportation	Mecklenburg Transportation System

The applicant provides supporting documentation in Exhibit I-1.

In Section I, page 42, the applicant describes its existing relationships with other local health care and social service providers.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

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 48, the applicant provides the historical payor mix during CY 2019 for its existing services at Brookshire and Charlotte Dialysis, as shown in the table below.

Historical Payor Mix CY 2019				
	Brookshire		Charlotte Dialysis	
Payment Source	# Patients	% Patients	# Patients	% Patients
Self-Pay	0	0.0%	3.0	2.8%
Insurance*	3.0	16.7%	9.0	8.5%
Medicare*	14.0	77.8%	82.0	77.4%
Medicaid*	1.0	5.6%	11.0	10.4%
Other	0	0.0%	1.0	0.9%
Total	18.0	100.0%	106.0	100.0%

*Including any managed care plans

In Section L, pages 47-48, the applicant provides the following comparison.

	% of Patients Served During CY 2019		Percentage of the Population of Mecklenburg County
	Brookshire	Charlotte Dialysis	
Female	66.7%	47.5%	51.9%
Male	33.3%	52.5%	39.1%
Unknown	0.0%	0.0%	0.0%
64 and Younger	72.2%	60.6%	89.8%
65 and Older	27.8%	39.4%	11.2%
American Indian	0.0%	1.0%	0.8%
Asian	0.0%	1.0%	6.4%
Black or African-American	94.4%	83.8%	32.9%
Native Hawaiian or Pacific Islander	0.0%	0.0%	0.1%
White or Caucasian	0.0%	0.0%	57.5%
Other Race	5.6%	4.0%	2.4%
Declined / Unavailable	0.0%	10.1%	0.0%

Sources: RTC-MA Internal Data, US Census Bureau

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 49, that Brookshire has no obligation to provide uncompensated care or community service under any federal regulations.

In Section L, page 49, the applicant states that during the last five years no patient civil rights access complaints have been filed against either Brookshire or Charlotte Dialysis.

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 49, 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.

Brookshire Projected Payor Mix CY 2022		
Payment Source	# Patients	% Patients
Self-Pay	0	0.0%
Insurance*	5.4	16.7%
Medicare*	25.0	77.8%
Medicaid*	1.8	5.6%
Other	0	0.0%
Total	32	100.0%

Table may not foot due to rounding.

*Including any managed care plans

As shown in the table above, during the applicant's second full fiscal year following project completion, the applicant projects to provide 77.8 percent of services to Medicare patients and 5.6 percent of services to Medicaid patients.

On page 50, 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 50, 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 51, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

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

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

C

The applicant proposes to relocate one dialysis station from Charlotte Dialysis for a total of 11 dialysis stations at Brookshire upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Mecklenburg County. Facilities may serve residents of counties not included in their service area.

There are 27 existing and approved facilities which provide dialysis and/or dialysis home training and support in Mecklenburg County, 23 of which are operational. Information on all 27 of these dialysis facilities is provided below:

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Brookshire Dialysis	DaVita	Charlotte	10	40.00%
Charlotte Dialysis	DaVita	Charlotte	34	81.62%
Charlotte East Dialysis	DaVita	Charlotte	34	80.15%
Huntersville Dialysis	DaVita	Huntersville	14	92.86%
Mint Hill Dialysis	DaVita	Mint Hill	22	55.68%
Mountain Island Lake Dialysis*	DaVita	Charlotte	0	0.00%
North Charlotte Dialysis Center	DaVita	Charlotte	36	72.92%
Renaissance Park Dialysis*	DaVita	Charlotte	0	0.00%
South Charlotte Dialysis**	DaVita	Charlotte	23	85.87%
South Charlotte Dialysis**	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis	DaVita	Charlotte	10	50.00%
BMA Beatties Ford	BMA	Charlotte	32	95.31%
BMA Nations Ford	BMA	Charlotte	28	79.46%
BMA of East Charlotte	BMA	Charlotte	26	89.42%
Carolinas Medical Center	CMC	Charlotte	9	33.33%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	67.71%
DSI Glenwater Dialysis	DSI	Charlotte	42	74.40%
BMA West Charlotte	BMA	Charlotte	29	87.93%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
FKC Regal Oaks	BMA	Charlotte	12	93.75%
FKC Southeast Charlotte*	BMA	Pineville	0	0.00%
FMC Aldersgate	BMA	Charlotte	10	27.50%
FMC Charlotte	BMA	Charlotte	44	89.20%
FMC Matthews	BMA	Matthews	21	114.29%
FMC of North Charlotte	BMA	Charlotte	40	96.88%
FMC Southwest Charlotte	BMA	Charlotte	13	92.31%
INS Charlotte***	BMA	Charlotte	0	0.00%
INS Huntersville***	BMA	Huntersville	0	0.00%

Source: Table 9B, Chapter 9, 2020 SMFP; Agency records

*Facility under development or which was not operational at the time of data collection for the 2020 SMFP.

**Per Project I.D. #F-11323-17, this facility is being relocated to a new location; the 2020 SMFP lists both the existing operational facility and the replacement facility.

***Facility which is dedicated exclusively to providing HH and PD training and support.

In Section N, page 52, 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. The applicant states:

“..., DaVita is committed to providing quality care to the ESRD population and, by policy, works to every reasonable effort to accommodate all of its patients. The relocation of one station to Brookshire will enhance accessibility to dialysis for current and projected patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the

dialysis process to receive services. Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs.”

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on:

- Cost-effectiveness (see Sections C, F, N, and Q of the application and any exhibits)
- Quality (see Sections C, N, and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L, and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

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

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

On Form A in Section Q, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 110 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, pages 54-55, the applicant states that, during the 18 months immediately preceding the submittal of the application, an incident resulting in an Immediate Jeopardy violation occurred in one of these facilities. The applicant states that all the problems have been corrected and the facility is back in compliance. Supporting documentation is provided in Exhibit O-2. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 110 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, including Temporary Rule 10A NCAC 14C .2203, 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 kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.*

-NA- Brookshire 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:*
- (1) *an existing dialysis facility; or*
 - (2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;*

shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

-C- In Section C, page 21, and on Form C in Section Q, the applicant projects that Brookshire will serve 31 patients on 11 stations, or a rate of 2.82 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 20-21, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.