



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

June 7, 2019

Esther Fleming
2321 W. Morehead Street
Charlotte, NC 28208

Disapproval

Project ID #: G-11677-19
Facility: North Burlington Dialysis
Project Description: Add no more than 2 dialysis stations for a total of no more than 20 stations upon completion of this project, Project ID #G-11603-18 (add 2 stations) and Project ID #G-11289-17 (relocate 6 stations)
County: Alamance
FID #: 100785

Last Date to Appeal: July 8, 2019
Required State Agency Findings: Enclosed

Dear Ms. Fleming:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has disapproved the above referenced certificate of need application. This decision was made after review of the application or applications if the review was competitive, consideration of the Certificate of Need Law and regulations promulgated thereunder, the State Medical Facilities Plan, written comments if any, responses to comments if any, and other publicly applicable information.

The applicant or any person aggrieved by this decision may file a petition for a contested case hearing in accordance with N.C. Gen. Stat. §150B, Article 3. This petition must be filed with the Office of Administrative Hearings, 6714 Mail Service Center, Raleigh, North Carolina 27699-6714 within thirty (30) days of the date of this decision. Effective October 1, 2009, OAH requires a filing fee with submittal of petitions for contested cases. Please direct all questions regarding this fee to the OAH Clerk's Office (919-431-3000).

N.C. Gen. Stat. §150B-23 provides that a party filing a petition must also serve a copy of the petition on all parties to the petition. Therefore, if you file a petition for a contested case hearing, you must serve a copy of the petition on the Department of Health and Human Services by mailing a copy of your petition to:

Lisa G. Corbett
Department of Health and Human Services,
Office of Legal Affairs,
Adams Building – Room 154
2001 Mail Service Center
Raleigh, North Carolina, 27699-2001

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 2704 Mail Service Center, Raleigh, NC 27699-2704
www.ncdhhs.gov/dhsr • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

It is requested that a copy of the petition also be served on the Agency.

In accordance with N.C. Gen. Stat. §131E-188(a1), as a condition precedent to proceeding with a contested case hearing on the approval of an applicant for a certificate of need, the petitioner shall deposit a bond with the clerk of superior court where the new institutional health service that is the subject of the petition is proposed to be located. The bond shall be secured by cash or its equivalent in an amount equal to five percent (5%) of the cost of the proposed new institutional health service that is the subject to the petition, but may not be less than five thousand dollars (\$5,000) and may not exceed fifty thousand dollars (\$50,000). Moreover, the applicant who received approval for the new institutional health service that is the subject of the petition may bring an action against a bond filed under this subsection in the superior court of the county where the bond was filed. Upon finding the petition for a contested case was frivolous or filed to delay the applicant, the court may award the applicant part or all of the bond filed.

Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,



Celia C. Inman
Project Analyst



Fatimah Wilson
Team Leader

Enclosure: Required State Agency Findings

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

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

Decision Date: June 7, 2019
Findings Date: June 7, 2019

Project Analyst: Celia C. Inman
Team Leader: Fatimah Wilson

Project ID #: G-11677-19
Facility: North Burlington Dialysis
FID #: 100785
County: Alamance

Applicant: Total Renal Care, Inc.

Project: Add no more than 2 dialysis stations for a total of no more than 20 dialysis stations upon completion of this project, Project ID #G-11603-18 (add 2 stations) and Project ID #G-11289-17 (relocate 6 stations)

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.

NC

Total Renal Care, Inc. d/b/a North Burlington Dialysis (TRC), the applicant, proposes to add two dialysis stations, pursuant to the facility need methodology, for a total of 20 stations at North Burlington Dialysis (NBD) upon completion of this project, Project ID #G-11603-18 (add 2 stations) and Project ID #G-11289-17 (relocate six stations to Mebane Dialysis).

Need Determination

The 2019 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a 34-station surplus and therefore no county need determination for Alamance County. However, the applicant is eligible to utilize the facility need methodology to determine eligibility to apply for additional stations at the existing facility because the utilization rate reported for North Burlington Dialysis in the January 2019 SDR is 3.27 patients per station per week. This utilization rate was calculated based on 72 in-center dialysis patients and 22 certified dialysis stations as of June 30, 2018 (72 patients / 22 stations = 3.2727 patients per station per week). Application of the facility need methodology indicates zero additional stations are needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW-JANUARY 2019 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/18		81.82%
Certified Stations as of 6/30/18		22
Pending Stations (G-11603-18, certified 1/6/19)		2
Total Existing and Pending Stations		24
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR2)		72
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR1)		75
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	-0.080
(ii)	Divide the result of Step (i) by 12	-0.007
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/18 until 12/31/18)	-0.040
(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	69.120
(v)	Divide the result of Step (iv) by 3.2 patients per station	21.600
	and subtract the number of certified and pending stations to determine the number of stations needed	-2.4

As shown in the table above, based on the January 2019 SDR facility need methodology for dialysis stations, the potential number of stations needed is -2.4 stations or zero additional stations; therefore, there is no need for additional stations based on the facility need methodology pursuant to the January 2019 SDR. Thus, the applicant is not eligible to add stations pursuant to the facility need methodology.

In Section B, page 7, the applicant provides its calculation of the facility need methodology, using erroneous data for what should reflect the number of certified and pending stations,

as of June 30, 2018, per the January 2019 SDR. As a result, the applicant's table erroneously calculates a facility need for up to four additional dialysis stations.

The applicant proposes to add two new stations, which is not consistent with the accurately calculated facility need determination for zero dialysis stations, per the January 2019 SDR. Therefore, the application is not consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2019 SMFP that is applicable to this review, Policy GEN-3: Basic Principles.

Policy GEN-3: Basic Principles, page 31 of the 2019 SMFP, 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 would promote safety and quality in Section B.4(a), pages 9-10; Section O, page 50; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 10; Section L, pages 44-46; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c), page 11; and Section N, page 49. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant failed to adequately demonstrate that the application is consistent with the facility need determination in the January 2019 SDR.

- (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.

NC

The applicant proposes to add two dialysis stations at North Burlington Dialysis, pursuant to the facility need methodology, for a total of 20 stations upon completion of this project, Project ID #G-11603-18 (add 2 stations) and Project ID #G-11289-17 (relocate six stations to Mebane Dialysis).

The following table illustrates the current and projected number of dialysis stations at NBD, based on existing certified stations, as of June 30, 2018, per the January 2019 SDR, pending relocations and additions, and the proposed project.

Stations	Description	Project ID #
22	Total existing certified stations as of the January 2019 SDR	
+2	Stations to be added at NBD as part of this project	G-11677-19
+2	Stations previously approved to be added at NBD but not yet certified (certified January 6, 2019)	G-11603-18
-6	Stations approved to be deleted but not yet certified (Mebane Dialysis)	G-11289-17
20	Total stations upon completion of proposed project	

As shown in the table above, upon project completion, NBD would be certified for 20 dialysis stations, assuming completion of this project, Project ID #G-11603-18 (add 2 stations), and Project ID #G-11289-17 (relocate six stations to Mebane Dialysis).

Patient Origin

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” North Burlington Dialysis is located in Alamance County; thus, the service area for this facility consists of Alamance County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 18, the applicant provides the historical patient origin for North Burlington Dialysis patients as of December 31, 2018, which is summarized in the following table:

**North Burlington Dialysis Historical Patient Origin
 As of December 31, 2018**

County	In-Center	Home Hemodialysis	Peritoneal Dialysis
Alamance	68	0	0
Guilford	2	0	0
Other States	2	0	0
TOTAL	72	0	0

Source: Table on page 18 of the application.

Tables B and C, pages 38 and 53, respectively, of the January 2019 SDR, show the same information as provided above regarding in-center (IC), home hemodialysis (HH), and peritoneal (PD) patients, as of June 30, 2018.

In Section C.1, page 13, the applicant provides the projected IC patient origin for NBD for the first two years of operation following completion, as shown in the following table:

North Burlington Dialysis Projected In-Center Patient Origin

COUNTY	OY 1 CY2021	OY 2 CY2022	PERCENT OF TOTAL	
			OY 1	OY 2
Alamance	60	63	93.8%	94.0%
Guilford	2	2	3.1%	3.0%
Other States	2	2	3.1%	3.0%
Total	64	67	100.0%	100.0%

In Section C, pages 13-14, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported; therefore, the applicant adequately identifies the population to be served.

Analysis of Need

In Section C.2, page 15, the applicant attempts to explain why it believes the population projected to utilize the proposed services needs the proposed services, stating:

“Section B-2 clearly outlines the need that the population to [sic] served, the in-center patients of North Burlington Dialysis, has for the two-station expansion proposed in this application.”

However, in Section B.2, page 7, the applicant provides its calculation of the facility need methodology, showing an erroneous need for four additional dialysis stations. Correctly utilizing the data from the January 2019 SDR, including the two pending stations on December 3, 2018 from Project ID #G-11603-18, which was conditionally approved November 16, 2018 and certified January 6, 2019, the facility need methodology results in a need for zero (-2.4) additional dialysis stations, as calculated by the Project Analyst in Criterion (1). The discussion regarding facility need in Criterion (1) is incorporated herein by reference.

The information provided by the applicant is not reasonable and not adequately supported for the following reasons:

- the facility need table calculated by the applicant includes erroneous data and yields an erroneous result, and
- the facility need methodology using the January 2019 SDR data results in a need determination for zero additional dialysis stations.

Projected Utilization

In Section C.7, pages 16-17, the applicant provides the assumptions and methodology used to project utilization. The assumptions are summarized below.

1. The January 2019 SDR shows that North Burlington Dialysis operated at a utilization rate of 81.82% (3.27 patients per station) as of June 30, 2018 and had 72 in-center patients. The applicant states that 68 of the 72 patients were residents of Alamance County.
2. The applicant projects the first full operating year (OY1) of the project will be January 1, 2021 – December 31, 2021 (CY2021) and the second full operating year (OY2) will be January 1, 2022 – December 31, 2022 (CY2022).
3. Project ID #G-11289-17 approved the development of Mebane Dialysis in Alamance County via relocation of 10 stations; four from Burlington Dialysis and six from North Burlington Dialysis. The applicant projects that 16 in-center patients will transfer their care from North Burlington Dialysis to Mebane Dialysis upon the stations' certification which was September 26, 2018.

4. North Burlington Dialysis assumes the Alamance County in-center patient population utilizing the facility will increase at the Alamance County Average Annual Change Rate (AACR) of 4.7 percent per year. On pages 16-17, the applicant states,

“The following are the in-center patient projections using the 4.7% Average Annual Change Rate for the Past Five Years as indicated in Table D of the January 2019 SDR for the 68 in-center patients living in Alamance County. The period of growth begins July 1, 2018 and is calculated forward to December 31, 2022. No growth calculations were performed for the patient living outside of Alamance County.

Based on the calculations below, North Burlington Dialysis is projected to have at least 64 in-center patients by the end of operating year 1 for a utilization rate of 80.0% or 3.20 patients per station and at least 67 in-center patients by the end of operating year 2 for a utilization rate of 83.8% or 3.35 patients per station.”

The applicant’s utilization methodology, based on its stated assumptions, is provided on page 17 and is summarized in the following table.

	In-Center
The applicant begins with the facility census of Alamance County in-center patients as of July 1, 2018.	68
The census of Alamance County in-center patients is increased by 2.35% to project the census forward six months to December 31, 2018. (4.70%/12*6 = 2.35%)	$68 \times 1.0235 = 69.598$
The applicant subtracts 16 patients who are projected to transfer to Mebane Dialysis as of January 1, 2019.	$69 - 16 = 53$
The census of Alamance in-center patients is increased by 4.7% to project the census forward one year to December 31, 2019.	$53 \times 1.047 = 55.491$
The census of Alamance in-center patients is increased by 4.7% to project the census forward one year to December 31, 2020.	$55.491 \times 1.047 = 58.099$
The census of Alamance in-center patients is increased by 4.7% to project the census forward one year to December 31, 2021.	$58.099 \times 1.047 = 60.8297$
The applicant adds the four patients from outside Alamance County. This is the projected ending census for Operating Year 1 (CY2021).	$60.8297 + 4 = 64.8297$
The census of Alamance in-center patients is increased by 4.7% to project the census forward one year to December 31, 2022.	$60.8297 \times 1.047 = 63.6887$
The applicant adds the one patient from outside Alamance County. This is the projected ending census for Operating Year 2 (CY2022).	$63.6887 + 4 = 67.6887$

The applicant rounds patient numbers down.

The applicant projects to serve 64 in-center patients or 3.2 patients per station per week ($64/20 = 3.2$) by the end of Operating Year 1 and 67 in-center patients or 3.4 patients per station per week ($67/20 = 3.35$) by the end of Operating Year 2 for the proposed 20-station

facility. This satisfies the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Projected utilization for in-center dialysis patients at North Burlington is reasonable and adequately supported for the following reasons:

- North Burlington Dialysis is currently operating at 81.82% capacity.
- The projection of the future utilization of services is based upon the facility’s historical patient utilization, adjusted for all approved relocation of stations and transfer of patients.
- The growth projections are based on an assumption that the Alamance County dialysis patient census will increase annually by 1.47%, which is consistent with the 4.7% five-year AACR for Alamance County, reported in the January 2019 SDR, Table D.

Access

In Section C.3, page 15, 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.

...

Payment will not be required upon admission. Therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped person, elderly and other under-served persons.”

The applicant projects payor mix for the second operating year following completion of the project in Section L.1(b), page 44, by percent, as summarized below:

**Projected Payor Mix
 OY2**

Payor Source	Total Patients	In-center Patients	HH Patients	PD Patients
Private Pay	0.0%	0.0%	0.0%	0.0%
Medicare	26.6%	26.6%	0.0%	0.0%
Medicaid	10.9%	10.9%	0.0%	0.0%
Commercial Insurance	6.3%	6.3%	0.0%	0.0%
Medicare / Commercial	15.6%	15.6%	0.0%	0.0%
Medicare / Medicaid	34.4%	34.4%	0.0%	0.0%
VA	6.3%	6.3%	0.0%	0.0%
Other	0.0%	0.0%	0.0%	0.0%
Total	100.0%	100.0%	0.0%	0.0%

Totals may not sum due to rounding

In Section L.1(b), page 44, the applicant states that the projected payor mix is based upon the the patient payments received by the existing facility during the last full operating year. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes:

- The applicant adequately identifies the population to be served.
- 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.

However, based on the facility need methodology in the January 2019 SDR, the applicant is not eligible to apply for additional stations at NBD; therefore, the applicant failed to demonstrate the need that the proposed population has for the proposed services. The discussion related to the facility need determination in Criterion (1) is incorporated herein by reference. Thus, the Agency concludes that the application is not conforming to this criterion.

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

NA

The applicant does not propose a reduction or elimination of a service, or the relocation of a facility or a 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.

NC

The applicant proposes to add two dialysis stations at NBD, pursuant to the facility need methodology, for a total of 20 stations upon completion of this project, Project ID #G-

11603-18 (add 2 stations) and Project ID #G-11289-17 (relocate six stations to Mebane Dialysis).

In Section E, page 21, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application. The alternatives considered were:

- Maintain status quo – the applicant states that this alternative was dismissed given the growth rate at the facility.
- Relocate stations from another DaVita Facility – the applicant states that relocating stations from Burlington Dialysis or Alamance County Dialysis would negatively impact the patients presently served by those facilities.
- Apply for two stations based on the facility need methodology – the applicant states this alternative meets the growing demand for services at NBD.

On page 21, the applicant states that the project as proposed is the most effective alternative because it ensures that the facility will proactively address the issues of growth and access at the facility. The applicant further states:

“As calculated in Section B-2, there is a need for additional stations. ... We are committed to ensuring that all patients referred by our admitting nephrologists have convenient access to the facility and the chosen alternative does that effectively.”

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The applicant failed to adequately demonstrate that the application is consistent with the facility need methodology in the January 2019 SDR. See the discussion related to the facility need methodology in Criterion (1) which is incorporated herein by reference.
- The application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above. Therefore, the application is denied.

- (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 add two dialysis stations at NBD for a total of 20 stations upon completion of this project, Project ID #G-11603-18 (add 2 stations) and Project ID #G-11289-17 (relocate six stations to Mebane Dialysis).

Capital and Working Capital Costs

In Section F.1, page 22, the applicant shows that it will not incur any capital costs to develop this project. In Sections F.10-F.12, pages 24-25, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project, because NBD is an existing facility.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Section R, 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.

North Burlington Dialysis Revenue and Expenses		
	OY1 (CY2021)	OY2 (CY2022)
In-Center Patient	63	65.5
In-Center Treatments	9,337	9,707
Gross Patient Revenue	\$2,685,639	\$2,791,704
Medicare Adjustment from Gross	\$116,741	\$121,352
Net Patient Revenue	\$2,568,898	\$2,670,352
Average Net Revenue per Patient	\$40,776	\$40,769
Total Operating Expenses	\$2,515,494	\$2,605,876
Average Operating Expense per Patient	\$39,928	\$39,784
Net Income	\$53,403	\$64,476

Totals may not sum due to rounding

The applicant averages beginning and ending patient censuses for # of patients to calculate OY1 and OY2 revenues.

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, and
- exhibits to the application.

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

NC

The applicant proposes to add two dialysis stations at NBD for a total of 20 stations upon completion of this project, Project ID #G-11603-18 (add 2 stations) and Project ID #G-11289-17 (relocate six stations to Mebane Dialysis).

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” North Burlington Dialysis is located in Alamance County; thus, the service area for this facility consists of Alamance County. Facilities may also serve residents of counties not included in their service area.

DaVita, the parent company for the applicant, is one of two providers of dialysis services in Alamance County. According to the January 2019 SDR, Alamance County has the following dialysis facilities.

Alamance County Dialysis Facilities

Dialysis Facilities	Certified Stations 6/30/2018	CON Issued Not Certified	Percent Utilization	Patients Per Station
Alamance County Dialysis (DaVita)	10	0	80.00%	3.20
BMA Burlington (BMA)	45	-3	48.89%	1.96
Burlington Dialysis (DaVita)	20	0	93.75%	3.75
Carolina Dialysis-Mebane (BMA)	20	7	87.50%	3.50
Glen Raven (Elon) Dialysis (DaVita)	10	0	40.00%	1.60
Mebane Dialysis (DaVita) New Site	10	0	NA	NA
North Burlington Dialysis (DaVita)	22	0	81.82%	3.27

Source: January 2019 SDR, Table B.

In Section G, page 28, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Alamance County. The applicant states that the applicant addresses the specific needs of patients who chose to receive service from DaVita. The applicant further states:

“In Section B-2 and Section C of this application, we demonstrate the need that North Burlington Dialysis has for adding stations. While adding stations at this facility does increase the number of stations in Alamance County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”

However, the applicant fails to adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- the facility need table calculated by the applicant includes erroneous data and yields an erroneous result, and
- the facility need methodology using the January 2019 SDR data results in a need determination for zero additional dialysis stations.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above.

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

C

In Section H.1, page 29, the applicant provides current and projected OY2 staffing for the proposed services in full-time equivalent (FTE) positions, as summarized in the following table.

POSITION	Current FTE Positions	OY2 PROJECTED FTE POSITIONS
RN	3.0	3.0
LPN	0.0	0.0
Technician (Patient Care)	7.0	8.0
Medical Records	0.0	0.0
Administrator	1.0	1.0
Dietician	1.0	1.0
Social Worker	1.0	1.0
Home Training RN	0.0	0.0
Administrative Assistant	1.0	1.0
Bio-med Technician	0.5	0.5
Total	14.5	15.5

Source: Sections H and R of the application.

The assumptions and methodology used to project staffing are provided in Sections H and R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section R. In Section H, pages 30-31, the applicant describes the methods used to recruit or fill new positions and DaVita's existing training and continuing education programs. Exhibit H contains DaVita training documentation. The Medical Director is a contract service, not an FTE position. In Section H.2, page 30, and Section I.3, page 34, the applicant identifies the Medical Director. In Exhibit I-3, the applicant provides a letter from Harmeet Singh, M.D., indicating a commitment to continue to serve as Medical Director for the facility.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section I, pages 33-35, the applicant identifies the necessary ancillary and support services and explains how they will be made available. The applicant provides a table on page 33, as summarized below.

**North Burlington Dialysis
 Ancillary and Support Services**

Services	Provider
(a) In-center dialysis/maintenance	Available on Premises
(b) Self-care training (performed in-center)	Available on Premises
(c) Home training	
(1) Hemodialysis	Alamance County Dialysis
(2) Peritoneal dialysis	Alamance County Dialysis
(3) Accessible follow-up program	Alamance County Dialysis
(d) Psychological counseling	Available on Premises
(e) Isolation-hepatitis	Available on Premises
(f) Nutritional counseling	Available on Premises
(g) Social work services	Available on Premises
(h) Acute dialysis in an acute care setting	Alamance Regional Medical Center
(i) Emergency care	Alamance Regional Medical Center
(j) Blood bank services	Alamance Regional Medical Center
(k) Diagnostic and evaluation services	Alamance Regional Medical Center
(l) X-ray services	Alamance Regional Medical Center
(m) Laboratory services	DaVita Laboratory Services, Inc.
(n) Pediatric nephrology	Alamance Regional Medical Center
(o) Vascular surgery	Alamance Regional Medical Center
(p) Transplantation services	UNC Health Care
(q) Vocational rehabilitation counseling & services	NC Division of Vocational Rehabilitation Services
(r) Transportation	Alamance County DSS

In Section I, pages 34-35, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.

The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- application, and
- 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 project does not require any construction or renovation; 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.7, page 47, the applicant provides the historical (CY2018) payment source for the patients dialyzing at NBD, as shown below.

Payment Source	In-center and Total Patients by Percent of Total
Medicare	26.6%
Medicaid	10.9%
Commercial Insurance	6.3%
Medicare/Commercial	15.6%
Medicare/Medicaid	34.4%
VA	6.3%
Total	100.00%

Totals may not sum due to rounding

The table above shows that 88% of the patients who received treatments at NBD had some or all of their services paid for by Medicare or Medicaid in CY2018.

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Alamance	17%	52%	36%	16%	10%	14%
Statewide	16%	51%	37%	15%	10%	12%

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

* Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

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

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information 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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3(d), page 46, the applicant states:

“North Burlington Dialysis has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993. The facility has no obligation under the Hill Burton Act.”

In Section L.6, page 46, the applicant states that there have been no civil rights access complaints filed against facilities owned by the applicant or the parent company and located in North Carolina within the last five years.

The Agency reviewed the:

- application, and
- 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.1(b), page 44, the applicant projects the following payor mix for the proposed services during the second full calendar year of operation following completion of the project, as summarized in the table below.

**Projected Payor Mix
OY2**

Payor Source	Total Patients	In-center Patients	HH Patients	PD Patients
Private Pay	0.0%	0.0%	0.0%	0.0%
Medicare	26.6%	26.6%	0.0%	0.0%
Medicaid	10.9%	10.9%	0.0%	0.0%
Commercial Insurance	6.3%	6.3%	0.0%	0.0%
Medicare / Commercial	15.6%	15.6%	0.0%	0.0%
Medicare / Medicaid	34.4%	34.4%	0.0%	0.0%
VA	6.3%	6.3%	0.0%	0.0%
Other	0.0%	0.0%	0.0%	0.0%
Total	100.0%	100.0%	0.0%	0.0%

Totals may not sum due to rounding

As shown in the table above, during the second full calendar year of operation, the applicant projects that 87.5% of the total dialysis patients will have all or part of their services paid for by Medicare and/or Medicaid.

On page 44, the applicant states that the projected payor mix is based on the sources of patient payments that have been received by the existing facility in the last full operating year. The projected payor mix is reasonable and adequately supported for the following reasons:

- the applicant bases the projected payor mix on the facility's historical payor mix, and
- the applicant's proposed patient origin is based on historical patient origin of the facility.

The Agency reviewed the:

- application, and
- 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.4, page 46, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application, and
- 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 48, 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.

The Agency reviewed the:

- application, and
- 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 add two dialysis stations at NBD for a total of 20 stations upon completion of this project, Project ID #G-11603-18 (add 2 stations) and Project ID #G-11289-17 (relocate six stations to Mebane Dialysis).

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-*

Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” North Burlington Dialysis is located in Alamance County; thus, the service area for this facility consists of Alamance County. Facilities may also serve residents of counties not included in their service area.

DaVita is one of two providers of dialysis services in Alamance County. According to the January 2019 SDR, Alamance County has the following dialysis facilities.

Alamance County Dialysis Facilities

Dialysis Facilities	Certified Stations 6/30/2018	CON Issued Not Certified	Percent Utilization	Patients Per Station
Alamance County Dialysis (DaVita)	10	0	80.00%	3.20
BMA Burlington (BMA)	45	-3	48.89%	1.96
Burlington Dialysis (DaVita)	20	0	93.75%	3.75
Carolina Dialysis-Mebane (BMA)	20	7	87.50%	3.50
Glen Raven (Elon) Dialysis (DaVita)	10	0	40.00%	1.60
Mebane Dialysis (DaVita) New Site	10	0	NA	NA
North Burlington Dialysis (DaVita)	22	0	81.82%	3.27

Source: January 2019 SDR, Table B.

In Section N, page 49, 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:

“The expansion of North Burlington dialysis will have no effect on competition in Alamance County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by Total Renal Care, Inc.

The expansion of North Burlington Dialysis will enhance accessibility to dialysis for our 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.”

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 B, F, and R of the application and any exhibits),

- quality services will be provided (see Sections B and O of the application and any exhibits), and
- access will be provided to underserved groups (see Sections B and L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

C

In Section A.11, page 5, the applicant states that DaVita operates over 90 dialysis facilities located in North Carolina. Exhibit A-11 contains a list of 106 dialysis facilities, including facilities not yet certified and facilities providing at home services.

In Section O, page 50, the applicant refers to Exhibit O-3, which shows that during the 18-month look-back period immediately preceding the submittal of the application, incidents related to quality of care occurred in two of these DaVita facilities. On page 50, the applicant states that both facilities were back in compliance at the time of application submittal. After reviewing and considering information provided by the applicant and considering the quality of care provided at the over 90 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

The application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- The applicant is not proposing to establish a new ESRD facility.

(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.7, page 17, the applicant provides the calculations used to arrive at the projected in-center patient census for the first two years of operation following the completion of the project.

The methodology used by the applicant achieves a projection of 64 in-center patients by the end of the first operating year, OY1, for a utilization rate of 3.2 patients per station per week or 80.0% ($64 \text{ patients} / 20 \text{ stations} = 3.2 \text{ patients per station} / 4 = 0.80$). The projected utilization of 3.2 patients per station per week for OY1 satisfies the 3.2 in-center patients per station threshold as required. The discussion on projected utilization 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.7, pages 16-17, respectively, the applicants provide the assumptions and methodology used to project utilization of the facility.