

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 3, 2018

Findings Date: December 3, 2018

Project Analyst: Celia C. Inman

Team Leader: Gloria C. Hale

Project ID #: G-11606-18

Facility: Burlington Dialysis

FID #: 956036

County: Alamance

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

Project: Add 3 stations for a total of 16 stations upon completion of this project, Project ID #G-11321-17 (add 4 stations), Project ID #G-11212-16 (relocate 8 stations to Glen Raven [Elon] Dialysis), Project I.D. #G-11289-17 (relocate 4 stations to Mebane Dialysis), and Project I.D. #G-11439-17 (relocate 3 stations to Guilford County Dialysis)

### 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

Renal Treatment Centers - Mid-Atlantic, Inc. (RTC) d/b/a Burlington Dialysis, the applicant, proposes to add three dialysis stations at Burlington Dialysis (BD) for a total of 16 stations upon completion of this project, Project ID #G-11321-17 (add four stations), Project ID #G-11212-16 (relocate eight stations to Glen Raven [Elon] Dialysis), Project I.D. #G-11289-17 (relocate four stations to Mebane Dialysis), and Project I.D. #G-11439-17 (relocate three stations to Guilford County Dialysis).

**Need Determination**

The 2018 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 July 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is a 23 station surplus and therefore no county need determination for Alamance County. However, the applicant is eligible to apply for additional stations in its existing Burlington Dialysis facility based on the facility need methodology because the utilization rate reported for Burlington Dialysis in the July 2018 SDR is 4.08 patients per station per week. This utilization rate was calculated based on 98 in-center dialysis patients and 24 certified dialysis stations as of December 31, 2017 (98 patients / 24 stations = 4.08 patients per station per week). Application of the facility need methodology indicates up to five additional stations are needed for this facility, as calculated by the Project Analyst in the following table.

<b>OCTOBER 1 REVIEW-JULY 2018 SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/17		102.08%
Certified Stations		24
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>24</b>
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2)		98
In-Center Patients as of 6/30/17 (Jan 2018 SDR) (SDR1)		101
<b>Step</b>	<b>Description</b>	<b>Result</b>
(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 6/30/17	-0.059
(ii)	Divide the result of Step (i) by 12	-0.005
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/16 until 12/31/17)	-0.059
(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 (-5.88 + 98 = 92.12)	92.178
(v)	Divide the result of Step (iv) by 3.2 patients per station	28.806
	and subtract the number of certified and pending stations to determine the number of stations needed (-24)	4.81

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 4.81, rounded to five stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add three new stations and, therefore, is consistent with the facility need determination for dialysis stations.

The table above differs from the table provided by the applicant on page 7 of the application, which includes stations the applicant states were certified as of June 2018, but had not

received the certification letter and are not reflected as certified in the July 2018 SDR. The Project Analyst bases the table above on the July 2018 SDR, following the facility need methodology which states the use of the “current” SDR in the methodology. Per proper interpretation of pending stations, the 24 stations in the above table includes the four stations pending addition at Burlington Dialysis in Project ID #G-11321-17; however, the 15 stations pending relocation from Burlington Dialysis are not included in the table above. The 15 stations pending relocation include Project ID #G-11212-16 (relocate eight stations to Glen Raven (Elon) Dialysis), Project I.D. #G-11289-17 (relocate 4 stations to Mebane Dialysis), and Project I.D. #G-11439-17 (relocate 3 stations to Guilford County Dialysis).

### **Policies**

There is one policy in the 2018 SMFP which is applicable to this review: Policy GEN-3: Basic Principles. Policy GEN-3 states:

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

**Promote Safety and Quality** – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 9-10; Section O, page 52; 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 45-48; 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 51. However, the information provided by the applicant is not reasonable and does not adequately support the determination that the applicant’s proposal would maximize healthcare value because the projected utilization is not based upon reasonable and adequately supported assumptions regarding the number of patients to be served.

### **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 does not adequately demonstrate how the projected volumes incorporate maximum healthcare value for the resources expended.

- (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 three dialysis stations at Burlington Dialysis for a total of 16 stations upon completion of this project, Project ID #G-11321-17 (add four stations), Project ID #G-11212-16 (relocate eight stations to Glen Raven [Elon] Dialysis), Project I.D. #G-11289-17 (relocate four stations to Mebane Dialysis), and Project I.D. #G-11439-17 (relocate three stations to Guilford County Dialysis).

The following table, summarized from page 4 of the application, illustrates the current number of dialysis stations, per the July 2018 SDR and the projected number of dialysis stations upon project completion.

<b>Stations</b>	<b>Description</b>	<b>Project ID #</b>
24	Total existing certified stations as of the July 2018 SDR	
+3	Stations to be added at BD as part of this project	G-11606-18
+4	Stations approved to be added but not yet certified	G-11321-17
-15	Stations approved to be deleted but not yet certified Relocate 8 stations to Glen Raven (Elon) Dialysis Relocate 4 stations to Mebane Dialysis Relocate 3 stations to Guilford County Dialysis	G-11212-16 G-11289-17 G-11439-17
16	Total stations upon completion of proposed project	

As shown in the table above, upon project completion, Burlington Dialysis would be certified for 16 dialysis stations, assuming completion of this project, Project ID #G-11321-17 (add four stations), Project ID #G-11212-16 (relocate eight stations to Glen Raven [Elon] Dialysis), Project ID #G-11289-17 (relocate four stations to Mebane Dialysis), and Project ID #G-11439-17 (relocate three stations to Guilford County Dialysis).

**Patient Origin**

On page 365, the 2018 SMFP defines the service area for dialysis stations as “the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” 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 20, the applicant provides the historical patient origin for Burlington Dialysis patients as of December 31, 2017, which is summarized in the following table:

**Burlington Dialysis Historical Patient Origin  
 As of December 31, 2017**

County	In-Center	Home Hemodialysis	Peritoneal Dialysis
Alamance	82	0	10
Catawba	1	0	0
Guilford	12	0	0
Orange	1	0	0
Randolph	2	0	1
<b>TOTAL</b>	<b>98</b>	<b>0</b>	<b>11</b>

Source: Table on page 20 of the application.

Tables B and C, pages 37 and 52 of the July 2018 SDR, respectively, also show Burlington Dialysis serving 98 in-center (IC), 0 home hemodialysis (HH), and 11 peritoneal (PD) patients, as of December 31, 2017.

In Section C.1, page 13, the applicant provides the projected IC and PD patient origin for Burlington Dialysis for operating year one (OY1) and operating year two (OY2), the first full operating years following project completion, as shown in the following table:

**Burlington Dialysis Projected Patient Origin**

County	First Full FY OY1 1/1/20-12/31/20		Second Full FY OY2 1/1/21-12/31/21		In-Center Patients as a Percent of Total	
	In-Center	Peritoneal	In-Center	Peritoneal	OY1	OY2
Alamance	65	12	68	13	98.7%	98.8%
Catawba	0	0	0	0	0.0%	0.0%
Guilford	0	0	0	0	0.0%	0.0%
Orange	0	0	0	0	0.0%	0.0%
Randolph	0	1	0	1	1.3%	1.2%
<b>Total</b>	<b>65</b>	<b>13</b>	<b>68</b>	<b>14</b>	<b>100.0%</b>	<b>100.0%</b>

Totals may not sum due to rounding  
 The applicant does not propose to serve HH patients.

In Section C, pages 13-16, the applicant provides the assumptions and methodology used to project its patient origin. The assumptions include the addition of stations and the relocation of stations per the effective dates as determined by the approved projects: Project ID #G-11321-17 (add four stations), Project ID #G-11212-16 (relocate eight stations to Glen Raven [Elon] Dialysis), Project ID #G-11289-17 (relocate four stations to Mebane Dialysis), and Project ID #G-11439-17 (relocate three stations to Guilford County Dialysis). The assumptions also include the transfer of patients as determined by the projects, with the exception of Project ID #G-11212-16, which approves the relocation of eight stations and the transfer of 24 Alamance County patients from Burlington Dialysis to Glen Raven Dialysis, effective CY2018.

On page 13, the applicant states that as of December 31, 2017, per the July 2018 SDR, Burlington Dialysis had 98 IC patients, 82 of which were Alamance County residents. The applicant further states that in March of 2018, Project ID #G-11212-16 (relocate 8 stations from Burlington Dialysis to Glen Raven Dialysis) was certified, which per page 14 of the approved Project ID #G-11212-16 application, transfers 24 Alamance County patients from Burlington Dialysis to Glen Raven for treatment. The transfer of patients reduces the Alamance County patients at Burlington Dialysis to 58 effective early 2018; therefore, the applicant's assumptions relative to in-center patient origin are not reasonable or adequately supported.

### **Analysis of Need**

The applicant proposes to add three dialysis stations, pursuant to the facility need methodology, at Burlington Dialysis for a total of 16 stations upon completion of this project, Project ID #G-11321-17 (add four stations), Project ID #G-11212-16 (relocate eight stations to Glen Raven [Elon] Dialysis), Project ID #G-11289-17 (relocate four stations to Mebane Dialysis), and Project ID #G-11439-17 (relocate three stations to Guilford County Dialysis).

In Section C.2, page 16, the applicant states that the facility need methodology table in Section B.2, page 7, outlines the need the in-center patient population to be served has for the proposed three-station expansion. However, the applicant's table on page 7 incorrectly identifies a total of 20 certified stations, rather than the 24 stations shown as of December 31, 2017 in the July 2018 SDR.

The applicant uses the following assumptions to support its need and projected utilization, as discussed in Section C.7, pages 17-20:

1. The applicant projects OY1 of the project will be January 1, 2020 – December 31, 2020 (CY2020) and OY2 will be January 1, 2021 – December 31, 2021 (CY2021).
2. Per the July 2018 SDR, as of December 31, 2017, Burlington Dialysis was providing dialysis treatment for 98 in-center patients on 24 stations at a utilization rate of 102.08%. Of the 98 total patients, 82 patients lived in Alamance County.

3. Project ID #G-11212-16 relocates eight stations from Burlington Dialysis to Glen Raven [Elon] Dialysis. (Not included in the applicant's assumption is the fact that per the approved project, 24 Burlington Dialysis patients will transfer their care to Glen Raven [Elon] Dialysis, effective January 1, 2018.)
4. Project ID #G-11321-17 adds four stations to Burlington Dialysis.
5. Project ID #G-11289-17 approves the development of Mebane Dialysis and includes the relocation of four stations and transfer of patients from Burlington Dialysis. The approved application projects that 17 in-center patients (16 of which are Alamance County residents and 1 is a non-Alamance County resident) will transfer their care from Burlington Dialysis to Mebane Dialysis upon its projected certification date of January 1, 2019.
6. Project ID #G-11439-17 (the applicant erroneously identified the project as G-11412-17, which was a withdrawn application) approves the development of Guilford County Dialysis and includes the relocation of three stations from Burlington Dialysis. The application projects that 23 [24] in-center patients (nine of which are Alamance County residents and 15 are non-Alamance County residents) will transfer their care from Burlington Dialysis to Guilford County Dialysis upon its projected certification date of January 1, 2019. Project ID #G-11439-17 is currently under appeal.
7. 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.

However, the information provided is not reasonable or adequately supported because the applicant does not reduce the patient census by the 24 patients who are transferring from Burlington Dialysis to Glen Raven [Elon] Dialysis, effective January 1, 2018, per Project ID #G-11212-16.

### Projected Utilization

#### *In-Center Patient Utilization*

In Section C.7, page 19, the applicant projects an average in-center patient utilization of 63.5 and 66.45 for OY1 and OY2, respectively, and provides the calculation table. However, the projections, as provided by the applicant on page 19, fail to deduct the 24 Alamance County patients transferring to Glen Raven [Elon] effective January 2018, per Project ID #G-11212-16. The applicant begins its patient census calculation at 82 Alamance County patients, instead of the correct number of 58 ( $82 - 24 = 58$ ) Alamance County patients.

The following table illustrates the applicant's methodology and assumptions, applying the relocation of stations and transfer of patients as described in the applicable approved projects listed in the assumptions above.

	<b>Stations</b>	<b>Alamance County In-Center Patients</b>
Burlington Dialysis beginning number of stations and census of Alamance County in-center patients as of December 31, 2017.	24	82
G-11212-16 approves the relocation of 8 stations and the transfer of 24 patients from BD to Glen Raven, as of January 1, 2018.	$24 - 8 = 16$	$82 - 24 = 58$
G-11321-17 approves the addition of 4 stations at BD.	$16 + 4 = 20$	58
The census of Alamance County in-center patients is increased by 4.7% to project the census forward one year to December 31, 2018.	20	$58 \times 1.047 = 60.726$
G-11289-17 approves the relocation of 4 stations and the transfer of 17 patients (16 Alamance County residents and one Orange County resident) from BD to Mebane Dialysis, as of January 1, 2019	$20 - 4 = 16$	$60.726 - 16 = 44.726$
G-11439-17 approves the relocation of 3 stations and the transfer of 23 patients (9 Alamance County residents and 15 non-Alamance residents) from BD to Guilford County Dialysis, as of January 1, 2019.	$16 - 3 = 13$	$44.726 - 9 = 35.726$
At this point, Burlington Dialysis has 13 stations and has transferred 49 Alamance County patients and all 16 non-Alamance County patients from BD to the Glen Raven, Mebane and Guilford County facilities.	13	35.726
The census of Alamance in-center patients is increased by 4.7% to project the census forward one year to December 31, 2019.	13	$35.726 \times 1.047 = 37.405$
G-11606-18 approves the addition of 3 stations. The census of Alamance in-center patients is increased by 4.7% to project the census forward one year to December 31, 2020. End of OY1, CY2020	16	$37.405 \times 1.047 = 39.163$
The census of Alamance in-center patients is increased by 4.7% to project the census forward one year to December 31, 2021. End of OY2, CY2021	16	$39.163 \times 1.047 = 41.004$

Using the applicant's methodology and applying the applicant's assumptions properly, results in the applicant projecting to serve 39 in-center patients or 2.4 patients per station per week ( $39/16 = 2.44$ ) at a utilization rate of 61% ( $2.44 / 4 = 0.610$ ) by the end of Operating Year 1 and 41 in-center patients or 2.6 patients per station per week ( $41/16 = 2.56$ ) by the end of Operating Year 2 for the proposed 16-station facility. This does not meet 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).

Therefore, projected utilization for in-center dialysis patients at Burlington Dialysis is not reasonable and is not adequately supported because the applicant fails to consider the transfer of patients approved in Project ID #G-11212-16 to relocate eight stations and transfer 24 Alamance County patients' care to Glen Raven [Elon], effective January 2018.

*Peritoneal Dialysis Patient Utilization*

In Section C.7, pages 19-20, the applicant projects Burlington Dialysis will have 12 and 13 PD patients at the end of OY1 and OY2, respectively, based on the following assumptions:

1. OY1 = CY2020 and OY2 = CY2021.
2. Beginning PD patient census is 11, per Table C of the July 2018 SDR.
3. The growth rate = one patient per year. The applicant states this growth rate is reasonable.
4. Two PD patients (one from Alamance County and one from Randolph County) will transfer their care to Guilford County Dialysis, effective January 1, 2019.

The table from page 20 of the application and shown below summarizes the beginning and ending PD patient census, along with the average number of PD patients per year.

	<b># Patients, Beginning</b>	<b># Patients, Ending</b>	<b>Average # Patients</b>
January 1, 2018	11	12	11.5
Interim Period, January 1, 2019- December 31, 2019	12-2=10	11	10.5
OY1 CY2020, January 1, 2020-December 31, 2020	11	12	11.5
OY2 CY2021, January 1, 2021-December 31, 2021	12	13	12.5

Projected utilization for PD patients at Burlington Dialysis is reasonable and adequately supported for the following reasons:

- According to the July 2018 SDR, Table C, there are 11 PD patients at Burlington Dialysis, as of December 31, 2017.
- The applicant includes the transfer of two PD patients to Guilford County Dialysis, as of January 1, 2019, per Project ID #G-11439-17.
- According to the January and July 2018 SDRs, Table D, the PD patient census in Alamance County has increased by one patient per year.

**Access**

In Section C.3, page 16, 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 persons, 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 46, by percent, as summarized below:

**Projected Payor Mix  
 OY2**

<b>Payor Source</b>	<b>Total Patients</b>	<b>In-center Patients</b>	<b>HH Patients</b>	<b>PD Patients</b>
Private Pay	0.0%	0.0%	0.0%	0.0%
Medicare	26.3%	27.3%	0.0%	18.2%
Medicaid	5.1%	5.7%	0.0%	0.0%
Commercial Insurance	11.1%	8.0%	0.0%	36.4%
Medicare / Commercial	26.3%	25.0%	0.0%	36.4%
Medicare / Medicaid	22.2%	23.9%	0.0%	9.1%
VA	9.1%	10.2%	0.0%	0.0%
Other	0.0%	0.0%	0.0%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>0.0%</b>	<b>100.0%</b>

Totals may not sum due to rounding

In Section L.1(b), page 46, 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 that the application is not conforming to this criterion for the following reasons:

- The applicant does not adequately identify the population to be served.
- The applicant does not adequately demonstrate why the population to be served needs the services proposed in this application.
- Projected utilization is not based on reasonable and adequately supported assumptions.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income

persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The application under review 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 three dialysis stations at Burlington Dialysis for a total of 16 stations upon completion of this project, Project ID #G-11321-17 (add four stations), Project ID #G-11212-16 (relocate eight stations to Glen Raven [Elon] Dialysis), Project I.D. #G-11289-17 (relocate four stations to Mebane Dialysis), and Project I.D. #G-11439-17 (relocate three stations to Guilford County Dialysis).

In Section E, page 24, the applicant describes the alternatives considered and discusses why each alternative is either more costly or less effective than the alternative proposed in this application to meet the identified need. 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 other DaVita facilities in Alamance County would negatively impact the patients presently served by those facilities.
- Apply for three stations based on the facility need methodology – the applicant states this alternative meets the growing demand for services at Burlington Dialysis.

On page 24, 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 does not adequately identify the population to be served or demonstrate the need the population to be served has for the services proposed in this application.

- Projected utilization is not based upon reasonable and adequately supported assumptions.
- The applicant 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,
- 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 all 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.

NC

The applicant proposes to add three dialysis stations at Burlington Dialysis for a total of 16 stations upon completion of this project, Project ID #G-11321-17 (add four stations), Project ID #G-11212-16 (relocate eight stations to Glen Raven [Elon] Dialysis), Project I.D. #G-11289-17 (relocate four stations to Mebane Dialysis), and Project I.D. #G-11439-17 (relocate three stations to Guilford County Dialysis).

### **Capital and Working Capital Costs**

In Section F.1, page 25, the applicant shows that it will not incur any capital costs to develop this project. In Sections F.10-F.12, pages 27-28, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project because Burlington Dialysis 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.

<b>Burlington Dialysis Revenue and Expenses</b>		
	<b>OY1 (CY2020)</b>	<b>OY2 (CY2021)</b>
In-Center Patient	63.5	66.5
PD Patients	11.5	12.5
In-Center Treatments	9,411	9,855
PD Treatments	1,704	1,853
Gross Patient Revenue (IC and PD)	\$ 3,908,787	\$ 4,134,281
Medicare Adjustment from Gross	\$132,566	\$139,386
Net Patient Revenue (IC and PD)	\$ 3,776,220	\$ 3,994,895
Average Net Revenue per IC and PD Patient	\$50,350	\$50,568
Total Operating Expenses (IC and PD)	\$2,895,047	\$3,036,068
Average Operating Expense per IC and PD Patient	\$38,601	\$38,431
Net Income	\$ 881,174	\$ 958,826

Totals may not sum due to rounding

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

However, because the applicant over-projects patient utilization, revenues and expenses are not reasonable. In-center patients were over-projected by 25 (63.5 – 38.28) and 26 (66.5 - 40.08) average patients in OY1 and OY2, respectively. Assuming the applicant’s average net revenue per patient of \$50,350 for OY1 and \$50,568 for OY2, projected net revenue would be reduced by \$1.2 and \$1.3 million in OY1 and OY2, respectively, calling into question the financial feasibility of the project. 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.

The assumptions used by the applicant in preparation of the pro forma financial statements are not reasonable and adequately supported for the following reasons:

- Projected utilization is questionable. It is not based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- Since projected revenues and expenses are based at least in part on projected utilization, projected revenues and expenses are questionable.

**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 all the reasons stated above.

- (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 three dialysis stations at Burlington Dialysis for a total of 16 stations upon completion of this project, Project ID #G-11321-17 (add four stations), Project ID #G-11212-16 (relocate eight stations to Glen Raven [Elon] Dialysis), Project I.D. #G-11289-17 (relocate four stations to Mebane Dialysis), and Project I.D. #G-11439-17 (relocate three stations to Guilford County Dialysis).

On page 365, the 2018 SMFP defines the service area for dialysis stations as “the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Burlington Dialysis is proposed to be 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 July 2018 SDR, Alamance County has the following dialysis facilities.

**Alamance County Dialysis Facilities**

<b>Dialysis Facilities</b>	<b>Certified Stations 12/31/2017</b>	<b>CON Issued Not Certified</b>	<b>Percent Utilization</b>	<b>Patients Per Station</b>
Alamance County Dialysis (DaVita)	10	0	112.50%	4.5
BMA Burlington (BMA)	45	-3	54.44%	2.1
Burlington Dialysis (DaVita)	24	-8	102.08%	4.1
Carolina Dialysis-Mebane (BMA)	20	7	87.50%	3.5
Glen Raven [Elon] Dialysis (DaVita)	0	10	NA	NA
Mebane Dialysis (DaVita)	0	10	NA	NA
North Burlington Dialysis (DaVita)	22	-6	85.23%	3.4

Source: July 2018 SDR, Table B.

In Section G, page 31, 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 application utilizes the facility need methodology and 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 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 does not 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 applicant does not adequately identify the population to be served or demonstrate the need the proposed population has for the stations.
- Projected utilization is not based on reasonable and adequately supported assumptions.

### **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

The applicant proposes to add three dialysis stations at Burlington Dialysis for a total of 16 stations upon completion of this project, Project ID #G-11321-17 (add four stations), Project ID #G-11212-16 (relocate eight stations to Glen Raven [Elon] Dialysis), Project I.D. #G-11289-17 (relocate four stations to Mebane Dialysis), and Project I.D. #G-11439-17 (relocate three stations to Guilford County Dialysis).

In Section H.1, page 32, the applicant provides current and projected OY2 staffing for the proposed services as summarized in the following table.

<b>POSITION</b>	<b>Current FTE Positions</b>	<b>OY2 PROJECTED FTE POSITIONS</b>
RN	3.0	3.0
LPN	0.0	0.0
Technician (Patient Care)	9.0	7.0
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	0.5	0.5
Administrative Assistant	1.0	1.0
Bio-med Technician	0.5	0.5
<b>Total</b>	<b>17.0</b>	<b>15.0</b>

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 33-34, the applicant describes the methods used to recruit or fill new positions and DaVita's existing training and continuing education programs. The Medical Director is a contract service, not an FTE position. Exhibit H contains DaVita training documentation. In Section H.2, page 33, and Section I.3, page 37, the applicant identifies the Medical Director. In Exhibit I-3, the applicant provides a letter from Munsoor Lateef, 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

The applicant proposes to add three dialysis stations at Burlington Dialysis for a total of 16 stations upon completion of this project, Project ID #G-11321-17 (add four stations), Project ID #G-11212-16 (relocate eight stations to Glen Raven [Elon] Dialysis), Project I.D. #G-11289-17 (relocate four stations to Mebane Dialysis), and Project I.D. #G-11439-17 (relocate three stations to Guilford County Dialysis).

In Section I-1, page 36, the applicant identifies the necessary ancillary and support services and explains how they will be made available. The applicant provides a table on page 36, as summarized below.

**Burlington Dialysis  
 Ancillary and Support Services**

<b>Services</b>	<b>Provider</b>
(a) In-center dialysis/maintenance	Available on Premises
(b) Self-care training (performed in-center)	Available on Premises
(c) Home training	
(1) Hemodialysis	Available on Premises
(2) Peritoneal dialysis	Available on Premises
(3) Accessible follow-up program	Available on Premises
(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 37-38, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation for some services 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 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.7, page 49, the applicant reports that 82% of the IC patients who received treatments at Burlington Dialysis had some or all of their services paid for by Medicare or Medicaid in CY2017. The table below shows the historical (CY2017) payment source for the facility:

<b>Payor Source</b>	<b>Total Patients</b>	<b>In-center Patients</b>	<b>HH Patients</b>	<b>PD Patients</b>
Private Pay	0.0%	0.0%	0.0%	0.0%
Medicare	26.3%	27.3%	0.0%	18.2%
Medicaid	5.1%	5.7%	0.0%	0.0%
Commercial Insurance	11.1%	8.0%	0.0%	36.4%
Medicare / Commercial	26.3%	25.0%	0.0%	36.4%
Medicare / Medicaid	22.2%	23.9%	0.0%	9.1%
VA	9.1%	10.2%	0.0%	0.0%
Other	0.0%	0.0%	0.0%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>0.0%</b>	<b>100.0%</b>

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 25-26<sup>1</sup>) 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

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<sup>1</sup><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 48, the applicant states:

*“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 48, the applicant states that there have been no civil rights access complaints filed against any similar facilities owned by the applicant or a related entity 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 46, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as summarized in the table below.

**Projected Payor Mix  
 OY2**

<b>Payor Source</b>	<b>Total Patients</b>	<b>In-center Patients</b>	<b>HH Patients</b>	<b>PD Patients</b>
Private Pay	0.0%	0.0%	0.0%	0.0%
Medicare	26.3%	27.3%	0.0%	18.2%
Medicaid	5.1%	5.7%	0.0%	0.0%
Commercial Insurance	11.1%	8.0%	0.0%	36.4%
Medicare / Commercial	26.3%	25.0%	0.0%	36.4%
Medicare / Medicaid	22.2%	23.9%	0.0%	9.1%
VA	9.1%	10.2%	0.0%	0.0%
Other	0.0%	0.0%	0.0%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>0.0%</b>	<b>100.0%</b>

Totals may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 80% of the total dialysis patients will have all or part of their services paid for by Medicare and/or Medicaid.

On page 46, 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 48, 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 50, 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.

### NC

The applicant proposes to add three dialysis stations at Burlington Dialysis for a total of 16 stations upon completion of this project, Project ID #G-11321-17 (add four stations), Project ID #G-11212-16 (relocate eight stations to Glen Raven [Elon] Dialysis), Project I.D. #G-11289-17 (relocate four stations to Mebane Dialysis), and Project I.D. #G-11439-17 (relocate three stations to Guilford County Dialysis).

On page 365, the 2018 SMFP defines the service area for dialysis stations as “the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Burlington Dialysis is proposed to be 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 July 2018 SDR, Alamance County has the following dialysis facilities.

**Alamance County Dialysis Facilities**

<b>Dialysis Facilities</b>	<b>Certified Stations 12/31/2017</b>	<b>CON Issued Not Certified</b>	<b>Percent Utilization</b>	<b>Patients Per Station</b>
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BMA Burlington (BMA)	45	-3	54.44%	2.1
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Carolina Dialysis-Mebane (BMA)	20	7	87.50%	3.5
Glen Raven (Elon) Dialysis (DaVita)	0	10	NA	NA
Mebane Dialysis (DaVita)	0	10	NA	NA
North Burlington Dialysis (DaVita)	22	-6	85.23%	3.4

Source: July 2018 SDR, Table B.

In Section N, page 51, 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 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 Renal Treatment Centers-Mid-Atlantic, Inc.*

*The expansion of 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.”*

However, the applicant does not adequately describe the expected effects of the proposed services on competition in the service area and does not adequately demonstrate the cost-effectiveness of the proposal. (See the discussions regarding need and projected utilization in

Criterion (3) and duplication of services in Criterion (6), which are 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 not conforming to this criterion for all 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 85 dialysis facilities located in North Carolina. Exhibit A-11 contains a list of the facilities.

In Section O, page 52, 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 52, 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 all 85 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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 applicants provide sufficient evidence that quality care has been provided in the past.

- (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.

NC

The application is not 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**

The application is not conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

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

*.2203(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- Burlington Dialysis is an existing facility.

*.2203(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.*

-NC- In Section C.1, page 19, the applicant projects to serve 65 in-center patients by the end of Operating Year 1, which is 4.06 ( $65 / 16 = 4.06$ ) patients per station per week. However, the applicant does not properly apply the assumptions related to the previously approved transfer of patients in Project ID #G-11212-16, which reduces the beginning census at Burlington Dialysis by 24 patients, resulting in the OY1 utilization of only 39 in-center patients or 2.4 ( $39/16 = 2.44$ ) patients per station per week, below the required 3.2 patients per station per week. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

.2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section C.1, pages 17-20, the applicant provides the assumptions and methodology used to project utilization of the facility; however, the applicant fails to properly apply the assumptions and methodology. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.