

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 27, 2018

Findings Date: February 27, 2018

Project Analyst: Mike McKillip

Team Leader: Fatimah Wilson

Project ID #: J-11410-17

Facility: Clayton Dialysis

FID #: 170420

County: Johnston

Applicant: Total Renal Care of North Carolina, LLC

Project: Develop a new 10-station dialysis facility by relocating six stations from Wilson Dialysis and four stations from Forest Hills Dialysis (Wilson County) and offer home hemodialysis and peritoneal dialysis training and support

### 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 of North Carolina, LLC (TRCNC) d/b/a Clayton Dialysis [**Clayton Dialysis**] proposes to develop a new 10-station dialysis facility by relocating six stations from Wilson Dialysis and four stations from Forest Hills Dialysis (Wilson County). The applicant also proposes to offer home hemodialysis and peritoneal dialysis training and support.

## **Need Determination**

ESRD dialysis station need determinations are published semiannually, in the January and July North Carolina Semiannual Dialysis Report (SDR), by the State Health Coordinating Council and the Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation, Department of Health and Human Services, pursuant to Chapter 14 of the 2017 North Carolina State Medical Facilities Plan (2017 SMFP). The January 2017 SDR is the applicable SDR for applications submitted in 2017 prior to July 1, 2017. The July 2017 SDR is the applicable SDR for applications submitted in 2017 after July 1, 2017.

The July 2017 SDR and the 2017 SMFP provide a county need and facility need methodology for determining the need for new dialysis stations. When the appropriate SDR indicates a dialysis station deficit of 10 or greater in a county and the utilization of each dialysis facility in that county is 80 percent or greater, a county need is generated, otherwise the county need determination is zero. When the county need determination is zero and the facility's reported utilization, in the applicable SDR, is 3.2 patients per station per week or greater, the facility can apply for additional stations at the existing facility pursuant to the facility need methodology. The July 2017 SDR, *Table D: ESRD Dialysis Station Need Determination by Planning Area* projects an 11-station deficit in Johnston County. However, the utilization of dialysis stations in the only existing dialysis facility in Johnston County is less than 80% and the number of patients per station per week is less than 3.2, therefore the county need determination is zero.

The county and facility need methodologies in the January 2017 SDR and the 2017 SMFP are not applicable to this review.

## **Policies**

There are two policies in the 2017 SMFP applicable to this review: Policy ESRD-2: Relocation of Dialysis Stations and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

### **Policy ESRD-2**

Policy ESRD-2 states:

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

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as*

*a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*

*3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant, Clayton Dialysis, filed this application on September 15, 2017 for the review cycle beginning October 1, 2017, based on an 11-station deficit projected in the July 2017 SDR for Johnston County. The applicant proposes to develop a new 10-station dialysis facility in Clayton in Johnston County by relocating six stations from Wilson Dialysis and four stations from Forest Hills Dialysis, both of which are located in Wilson County. Johnston and Wilson are contiguous counties. In Section C.8, page 21, the applicant states that Wilson Dialysis and Forest Hills Dialysis are currently serving residents of Johnston County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

According to Table D of the July 2017 SDR, Wilson County has a projected surplus of 13 dialysis stations. Following the applicant’s proposed relocation of 10 existing stations from the two Wilson County facilities to Johnston County, Wilson County would have a surplus of three dialysis stations ( $13 - 10 = 3$ ). Therefore, the proposal will not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations.

According to Table D of the July 2017 SDR, Johnston County has a projected deficit of 11 dialysis stations. However, on December 12, 2017, Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Selma (FKC Selma) received a Certificate of Need (Project I.D. J-11372-17) to relocate two dialysis stations from FMC Four Oaks (Johnston County), four stations from Johnston Dialysis Center and four dialysis stations from FMC New Hope Dialysis (Wake County) to develop a new 10-station dialysis facility in Selma (Johnston County). Because the project includes the relocation of four existing dialysis from FMC New Hope Dialysis in Wake County to FKC Selma in Johnston County, the 11-station deficit in Johnston County identified in the July 2017 SDR was effectively reduced to a 7-station deficit [ $11 - 4 = 7$ ]. Thus, approval of Clayton Dialysis’s proposal to relocate ten dialysis stations from Wilson County to Johnston County would result in a surplus of three dialysis stations in Johnston County. Therefore, this application is not consistent with Policy ESRD-2.

#### **Policy GEN-4**

Policy GEN-4 states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B.5, pages 11-12, the applicant describes the project's plan to improve energy efficiency and conserve water, including energy efficient lighting, water optimization protocols, sustainable design and building materials, high-performance HVAC systems, and high-efficiency equipment and appliances. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

### **Conclusion**

The applicant does not adequately demonstrate that the application is consistent with Policy ESRD-2.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Written comments and response to comments on the application.
- Information provided during the public hearing.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant does not adequately demonstrate that the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to

which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

Clayton Dialysis proposes to develop a new 10-station dialysis facility by relocating six stations from Wilson Dialysis and four stations from Forest Hills Dialysis (Wilson County). The applicant also proposes to offer home hemodialysis and peritoneal dialysis training and support.

The following tables, summarized from Section A.9, pages 4-5 of the application, show the proposed Clayton Dialysis facility, and the current projects under development which impact the number of dialysis stations at Wilson Dialysis and Forest Hills Dialysis, the two facilities from which the applicant plans to relocate 10 stations to develop the proposed new facility.

<b>Clayton Dialysis</b>		
<b>Stations</b>	<b>Description</b>	<b>Project ID #</b>
0	Total existing certified stations as of the July 2017 SDR	
+10	Stations to be added as part of this project	J-11410-17
10	Total stations upon completion of above projects	
<b>Wilson Dialysis</b>		
<b>Stations</b>	<b>Description</b>	<b>Project ID #</b>
40	Total existing certified stations as of the July 2017 SDR	
-6	Stations to be deleted as part of this project	L-11410-17
-5	Stations previously approved to be deleted	L-11132-16
+5	Stations previously approved to be added	L-11156-16
34	Total stations upon completion of above projects	
<b>Forest Hills Dialysis</b>		
<b>Stations</b>	<b>Description</b>	<b>Project ID #</b>
31	Total existing certified stations as of the July 2017 SDR	
-4	Stations to be deleted as part of this project	L-11410-17
-5	Stations previously approved to be deleted	L-11132-16
+5	Stations previously approved to be added (Certified May 31, 2017)	L-11153-16
+5	Stations previously approved to be added	L-11319-17
32	Total stations upon completion of above projects	

As shown in the table above, upon project completion, Clayton Dialysis will be certified for 10 dialysis stations, Wilson Dialysis will be certified for 34 stations following completion of this project, Project ID# L-11132-16 (Relocate 5 stations from Wilson Dialysis and 5 stations from Forest Hills Dialysis to a new 10-station dialysis facility in Sharpsburg), and Project ID# L-11156-16 (Add 5 dialysis stations), and Forest Hills Dialysis will be certified for 32 stations following completion of this project, Project ID# L-11132-16 (Relocate 5 stations from Wilson Dialysis and 5 stations from Forest Hills Dialysis to a new 10-station dialysis

facility in Sharpsburg), Project ID# L-11153-16 (Add 5 dialysis stations), and Project ID# L-11319-17 (Add 5 dialysis stations).

**Patient Origin**

On page 373 the 2017 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Johnston County. Facilities may serve residents of counties not included in their service area.

In Section C.1, page 13, the applicant provides the projected patient origin for Clayton Dialysis for in-center (IC), home hemodialysis (HHD) and peritoneal dialysis (PD) patients for the first two years of operation following completion of the project as follows:

County	Operating Year 1 FY2020			Operating Year 2 FY2021			Percent of Total	
	IC	HHD	PD	IC	HHD	PD	OY1	OY2
Johnston	11	2	2	12	3	3	40.6%	45.0%
Nash	1	0	0	1	0	0	2.7%	2.5%
Wake	13	0	1	13	0	1	38.8%	35.0%
Wilson	7	0	0	7	0	0	18.9%	17.5%
<b>Total</b>	<b>32</b>	<b>2</b>	<b>3</b>	<b>33</b>	<b>3</b>	<b>4</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant provides the assumptions and methodology used to project patient origin on pages 13-18. The applicant adequately identifies the population to be served.

**Analysis of Need**

In Section C.1, pages 13-18, the applicant describes its need methodology assumptions for projecting utilization of the proposed facility as follows:

1. The applicant projects the first two full operating years of the project will be July 1, 2019 – June 30, 2020 (FY2020) and July 1, 2020 – June 30, 2021 (FY2021).
2. The applicant states that 41 in-center dialysis patients who are currently being treated at existing DaVita dialysis facilities have signed letters indicating they would consider transferring to Clayton Dialysis. Exhibit C-1 contains copies of the 41 letters. In Section C.1, pages 14-15, the applicant provides a description of the patient letters which identifies the existing facility where the patients are being treated, the patient’s county of residence, and number of current patients who signed the letters, which is summarized in the table below:

<b>DaVita Facility</b>	<b>Facility County</b>	<b>County of Patient Residence</b>	<b>Number of Patients</b>
Wilson Dialysis	Wilson	Johnston	3
Wilson Dialysis	Wilson	Wilson	11
Wilson Dialysis	Wilson	Nash	2
Forest Hills Dialysis	Wilson	Johnston	3
Forest Hills Dialysis	Wilson	Wilson	5
Forest Hills Dialysis	Wilson	Nash	2
Wake Forest Dialysis	Wake	Wake	5
Wake Forest Dialysis	Wake	Johnston	2
Durham Dialysis	Durham	Wake	1
Southpoint Dialysis	Durham	Wake	3
Goldsboro Dialysis	Wayne	Johnston	2
Goldsboro South Dialysis	Wayne	Johnston	1
Dialysis Care of Franklin	Franklin	Wake	1
<b>Total</b>			<b>41</b>

- Clayton Dialysis assumes that 32 of the 41 patients identified above will transfer their care to the proposed facility, including all 11 patients who reside in Johnston County, one patient who resides in Nash County, 13 patients who reside in Wake County, and 7 patients who reside in Wilson County. The applicant assumes that the Johnston County patient population will increase by 6.3 percent per year through the first two operating years of the project, and that there will be no increase in patients from the other counties. On pages 15-16, the applicant states,

*“It is reasonable to assume that at least thirty-two (32) of the forty-one (41) in-center patients who signed letters would transfer their care to Clayton Dialysis upon certification of the facility. In order to calculate growth during the first two years of the operation an assumption was made that the eleven (11) patients who live in Johnston County would be projected to transfer their care to Clayton Dialysis; that thirteen (13) patients who live in Wake County would be projected to transfer their care to Clayton Dialysis; and seven (7) patients who live in Wilson County would be projected to transfer their care to Clayton Dialysis. ... The following are the in-center patient projections [shown in the table on page 16] using the 6.3% Average Annual Change Rate for the Past Five Years as indicated in Table D of the July 2017 SDR for the eleven (11) in-center patients living in Johnston County. The period of the growth begins July 1, 2019 and is calculated forward to June 30, 2021. ... No growth calculation were performed for the twenty-one 21 [sic] patients living outside of Johnston County.”*

Projected Utilization

The applicant’s methodology is illustrated in the following table.

	In-Center
The applicant begins with the facility census of Johnston County in-center residents as of July 1, 2019.	11
The census of Johnston County in-center patients is increased by 6.3% to project the census forward one year to June 30, 2020.	$[11 \times 0.063] + 11 = 11.693$
The applicant adds 21 patients who are projected to originate from Nash, Wake and Wilson counties. This is the projected ending census for Operating Year 1.	$11.693 + 21 = 32.693$
The census of Johnston County in-center patients is increased by 6.3% to project the census forward one year to June 30, 2021.	$[11.693 \times 0.063] + 11.693 = 12.43$
The applicant adds 21 patients who are projected to originate from Nash, Wake and Wilson counties. This is the projected ending census for Operating Year 2.	$12.43 + 21 = 33.43$

The applicant projects to serve 32 in-center patients or 3.2 patients per station per week ( $32/10 = 3.2$ ) by the end of Operating Year 1 and 33 in-center patients or 3.3 patients per station per week ( $33/10 = 3.3$ ) by the end of Operating Year 2 for the proposed 10-station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). In this application, the applicant assumes a projected annual rate of growth of 6.3 percent for the in-center patient census (Johnston County residents only) at Clayton Dialysis, which is equal to the Johnston County Five Year Average Annual Change Rate as published in the July 2017 SDR. Projected in-center utilization is based on reasonable and adequately supported assumptions regarding continued growth.

*Home Hemodialysis (HHD)*

On page 17, the applicant provides the following table showing its projections of home hemodialysis (HHD) patients through the first two operating years of the project.

HHD Patient Projections	Start Date	# of Patients Start of Year	# of Patients End of Year	Average # of Patients in Year
Operating Year 1	7/1/2019	1	2	1.5
Operating Year 2	7/1/2020	2	3	2.5

Source: Table on page 17 of the application.

On page 17, the applicant describes its assumptions as follows:



*“One (1) HHD patient who currently receives their support at Goldsboro Dialysis, a DaVita operated facility in Wayne County and who lives in Johnston County, has signed a letter indicating the new facility will be more convenient for them and they would consider transfer to Clayton Dialysis. This letter can be found in Exhibit C-1. ... It is assumed that the one patient who signed a letter of support for Clayton Dialysis will transfer their care upon certification of the home training program. ... The period of growth begins July 1, 2019 and is calculated forward to June 30, 2021. It is reasonable to assume that the Clayton Dialysis HHD program will grow at a rate of at least one patient per year during the period of growth.”*

### *Peritoneal Dialysis*

On page 18, the applicant provides the following table showing its projections of peritoneal dialysis (PD) patients through the first two operating years of the project.

<b>PD Patient Projections</b>	<b>Start Date</b>	<b># of Patients Start of Year</b>	<b># of Patients End of Year</b>	<b>Average # of Patients in Year</b>
Operating Year 1	7/1/2019	2	3	2.5
Operating Year 2	7/1/2020	3	4	3.5

Source: Table on page 18 of the application.

On page 17, the applicant describes its assumptions as follows:

*“Two (2) PD patient who currently receives their support at Wake Forest Dialysis (1 PD patient) in Wake County and Goldsboro Dialysis (1 PD patient) in Wayne County and who live in Wake and Johnston Counties, have signed a letters indicating that the new facility will be more convenient for them and they would consider transfer to Clayton Dialysis. These letters can be found in Exhibit C-1. ... It is assumed that the two patients who signed letters of support for Clayton Dialysis will transfer their care upon certification of the home training program. ... The period of growth begins July 1, 2019 and is calculated forward to June 30, 2021. It is reasonable to assume that the Clayton Dialysis PD program will grow at a rate of at least one patient per year during the period of growth.”*

Projected utilization for HHD and PD training and support is based on reasonable and adequately supported assumptions regarding continued growth.

### **Access**

In Section L.1(a), pages 52-53, the applicant states that Clayton Dialysis will make its services available to all persons without qualification, including low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. In Section L.1(b), page 53, the applicant projects 87% of its patients will be Medicare or Medicaid recipients. The

applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

### **Conclusion**

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses historical data that is clearly cited and is reasonable to make the assumptions used by the applicant with regard to identifying the population to be served and with regard to demonstrating the need the population projected to be served has for the proposed services.
- The applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need the population projected to be served has for the proposed services.
- The applicant uses historical data to project future access to the services it provides for all residents, including underserved groups.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Written comments and response to comments on the application.
- Information provided during the public hearing.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

### C

Clayton Dialysis proposes to develop a new 10-station dialysis facility by relocating six stations from Wilson Dialysis and four stations from Forest Hills Dialysis (Wilson County). The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon project completion, Clayton Dialysis will be certified for 10 dialysis stations, Wilson Dialysis will be certified for 34 stations following completion of this project, Project ID# L-11132-16 (Relocate 5 stations from Wilson Dialysis and 5 stations from Forest Hills Dialysis to a new 10-station dialysis facility in Sharpsburg), and Project ID# L-11156-16 (Add 5 dialysis stations), and Forest Hills Dialysis will be certified for 32 stations following completion of this project, Project ID# L-11132-16 (Relocate 5 stations from Wilson Dialysis and 5 stations from Forest Hills Dialysis to a new 10-station dialysis

facility in Sharpsburg), Project ID# L-11153-16 (Add 5 dialysis stations), and Project ID# L-11319-17 (Add 5 dialysis stations).

The following table shows the projected relocation of stations from Wilson Dialysis and Forest Hills Dialysis to the proposed Clayton Dialysis facility and identifies the number of patients projected to transfer from those two DaVita facilities to Clayton Dialysis.

<b>PROPOSED CLAYTON DIALYSIS PROJECT</b>		
<b>Facility</b>	<b>Number of Stations to be Relocated</b>	<b>Number of Patients Transferring</b>
Wilson Dialysis	6	8
Forest Hills Dialysis	4	7
<b>Total Relocated and Transferred</b>	<b>10</b>	<b>15</b>

### Wilson Dialysis

According to the July 2017 Semiannual Dialysis Report (SDR), there were 138 patients dialyzing at Wilson Dialysis and 40 certified dialysis stations for a utilization rate of 86.25%, or 3.45 patients per station per week ( $138/40 = 3.45$ ) as of December 31, 2016. In Section D.1, page 25, the applicant states that 115 of the 138 in-center patients reside in Wilson, and the remaining 23 patients originate from outside Wilson County. In Section C.8, page 21, the applicant provides a table that shows that the remaining 23 patients originated from Edgecombe (2 patients), Johnston (6 patients), Nash (13 patients) and Wayne (2 patients) counties.

The applicant assumes that the number of in-center patients at Wilson Dialysis who reside in Wilson County will increase at a rate of 5.2% per year through the first two operating years of the project based on the Five Year Average Annual Change Rate (AACR) for Wilson County, as reported in Table D of the July 2017 SDR. The applicant assumes that there will be no increase in the number of patients from the other counties. The applicant projects that eight Wilson Dialysis patients, including three who reside in Johnston County and five who reside in Wilson County, will transfer their care to Clayton Dialysis upon certification of that facility on July 1, 2019.

On June 14, 2016, the applicant was approved (Project I.D. # L-11132-16) to relocate five stations from Wilson Dialysis to a new dialysis facility, Sharpsburg Dialysis (Wilson County). Following completion of the project, Wilson Dialysis would be certified for 35 stations ( $40 - 5 = 35$ ). The applicant projects that 17 patients will transfer their care from Wilson Dialysis to Sharpsburg Dialysis upon certification of that facility on January 1, 2018.

On July 19, 2016, the applicant was approved (Project I.D. # L-11156-16) to add five stations to Wilson Dialysis, for a total of 40 certified stations upon completion of that project and Project I.D. # L-11132-16.

In Section D.1, page 26, the applicant calculates the in-center patient census for Wilson Dialysis starting January 1, 2017 through the first two operating years (FY2020 and FY2021), summarized as follows:

<b>Wilson Dialysis</b>	<b>In-Center Patients</b>
Begin with the ESRD patient population of Wilson County, as of December 31, 2016.	115
Project the Wilson County population forward one year to December 31, 2017, using the Five Year AACR for Wilson County.	$115 \times 1.052 = 120.98$
Subtract 17 Wilson County patients projected to transfer their care to Sharpsburg Dialysis.	$120.98 - 17 = 103.98$
Project the Wilson County population forward one year to December 31, 2018, using the Five Year AACR for Wilson County.	$103.98 \times 1.052 = 109.38696$
Add 23 patients from Edgecombe, Johnston, Nash and Wayne counties to calculate the ending census as of December 31, 2018.	$109.386 + 23 = 132.3869$
Project the Wilson County population forward six months to July 1, 2019, using half of the Five Year AACR for Wilson County.	$109.386 \times 1.026 = 112.23$
Add 23 patients from Edgecombe, Johnston, Nash and Wayne counties to calculate the ending census as of June 30, 2019.	$112.23 + 23 = 135.23$
Subtract five Wilson County patients projected to transfer their care to Clayton Dialysis.	$112 - 5 = 107$
Project the Wilson County population forward one year to June 30, 2020 using the Five Year AACR for Wilson County.	$107 \times 1.052 = 112.564$
Subtract 3 Johnston County patients projected to transfer their care to Clayton Dialysis.	$23 - 3 = 20$
Add the 20 remaining patients from Edgecombe, Johnston, Nash and Wayne counties to calculate the ending census as of June 30, 2020. This is ending census for Operating Year 1.	$112.564 + 20 = 132.564$
Project the Wilson County population forward one year to June 30, 2021 using the Five Year AACR for Wilson County.	$112.564 \times 1.052 = 118.417$
Add the 20 remaining patients from Edgecombe, Johnston, Nash and Wayne counties to calculate the ending census as of June 30, 2020. This is the ending census for Operating Year 2.	$118.417 + 20 = 138.417$

Thus, on June 30, 2020, Wilson Dialysis is projected to have 34 ( $40 - 5 + 5 - 6 = 34$ ) certified dialysis stations with a patient population of 133, which is equivalent to a utilization rate of 3.9 patients per station per week ( $133 / 34 = 3.9$ ) or 98% ( $3.9 / 4 = 0.98$ ).

In Section D.1, page 26, the applicant states that the needs of Wilson Dialysis’s patients will continue to be met following the proposed relocation of six stations to Clayton Dialysis, and that it plans to apply for additional stations for Wilson Dialysis based on the facility need methodology when necessary.

Further, in Section D.2, page 28, the applicant states that the proposed relocation of stations will not will not adversely affect the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

The applicant adequately demonstrates that the needs of the populations presently served at Wilson Dialysis will continue to be met following the proposed relocation of dialysis stations

and transfer of patients to Clayton Dialysis, and that access for medically underserved groups will not be negatively impacted.

### Forest Hills Dialysis

According to the July 2017 Semiannual Dialysis Report (SDR), there were 120 patients dialyzing at Forest Hills Dialysis and 31 certified dialysis stations for a utilization rate of 96.77%, or 3.87 patients per station per week ( $120/31 = 3.87$ ) as of December 31, 2016. In Section D.1, page 26, the applicant states that 95 of the 120 in-center patients reside in Wilson, and the remaining 25 patients originate from outside Wilson County. In Section C.8, page 21, the applicant provides a table that shows that the remaining 25 patients originated from Edgecombe (1 patient), Johnston (2 patients), Nash (17 patients), Pitt (1 patient), Wake (1 patient) and Wayne (3 patients) counties.

The applicant assumes that the number of in-center patients at Forest Hills Dialysis who reside in Wilson County will increase at a rate of 5.2% per year through the first two operating years of the project based on the Five Year Average Annual Change Rate (AACR) for Wilson County, as reported in Table D of the July 2017 SDR. The applicant assumes that there will be no increase in the number of patients from the other counties. The applicant projects that seven Forest Hills Dialysis patients, including four who reside in Johnston County, one who resides in Nash County and two who reside in Wilson County, will transfer their care to Clayton Dialysis upon certification of that facility on July 1, 2019.

On June 14, 2016, the applicant was approved (Project I.D. # L-11132-16) to relocate five stations from Forest Hills Dialysis to a new dialysis facility, Sharpsburg Dialysis (Wilson County). The applicant projects that 9 patients will transfer their care from Forest Hills to Sharpsburg Dialysis upon certification of that facility on January 1, 2018.

On July 15, 2016, the applicant was approved (Project I.D. # L-11153-16) to add five stations to Forest Hills Dialysis, for a total of 36 certified stations upon completion of the project. The five additional stations were certified effective May 31, 2017.

On June 9, 2017, the applicant was approved (Project I.D. # L-11319-17) to add five stations to Forest Hills Dialysis, for a total of 36 certified stations upon completion of that project, Project I.D. L-11132-16 (Relocate five stations) and Project I.D. # L-11153-16 (Add five stations).

In Section D.1, page 26, the applicant calculates the in-center patient census for Forest Hills Dialysis starting January 1, 2017 through the first two operating years (FY2020 and FY2021), summarized as follows:

<b>Forest Hills Dialysis</b>	<b>In-Center Patients</b>
Begin with the ESRD patient population of Wilson County, as of December 31, 2016.	95
Project the Wilson County population forward one year to December 31, 2017, using the Five Year AACR for Wilson County.	$95 \times 1.052 = 99.94$
Add 25 patients from Edgecombe, Johnston, Nash, Pitt, Wake and Wayne counties to calculate the ending census as of December 31, 2017.	$99.94 + 25 = 124.94$
Subtract 9 Wilson County patients projected to transfer their care to Sharpsburg Dialysis.	$99.94 - 9 = 90.94$
Project the remaining Wilson County population forward one year to December 31, 2018, using the Five Year AACR for Wilson County.	$90.94 \times 1.052 = 95.66888$
Add 25 patients from Edgecombe, Johnston, Nash, Pitt, Wake and Wayne counties to calculate the ending census as of December 31, 2018.	$95.66888 + 25 = 120.6688$
Project the Wilson County population forward six months to July 1, 2019, using half of the Five Year AACR for Wilson County.	$95.6688 \times 1.026 = 98.1561$
Add 25 patients from Edgecombe, Johnston, Nash, Pitt, Wake and Wayne counties to calculate the ending census as of June 30, 2019.	$98.1561 + 25 = 123.1561$
Subtract two Wilson County patients projected to transfer their care to Clayton Dialysis.	$98 - 2 = 96$
Project the Wilson County population forward one year to June 30, 2020 using the Five Year AACR for Wilson County.	$96 \times 1.052 = 100.992$
Subtract four Johnston County and one Nash County patient projected to transfer their care to Clayton Dialysis.	$25 - 5 = 20$
Add the 20 remaining patients from Edgecombe, Johnston, Nash, Pitt, Wake and Wayne counties to calculate the ending census as of June 30, 2020. This is ending census for Operating Year 1.	$100.992 + 20 = 120.992$
Project the Wilson County population forward one year to June 30, 2021 using the Five Year AACR for Wilson County.	$100.992 \times 1.052 = 106.243$
Add the 20 remaining patients from Edgecombe, Johnston, Nash, Pitt, Wake and Wayne counties to calculate the ending census as of June 30, 2020. This is the ending census for Operating Year 2.	$106.243 + 20 = 126.243$

Thus, on June 30, 2020, Forest Hills Dialysis is projected to have 32 ( $31 + 5 + 5 - 5 - 4 = 32$ ) certified dialysis stations with a patient population of 121, which is equivalent to a utilization rate of 3.8 patients per station per week ( $121 / 32 = 3.8$ ) or 95% ( $3.8/4 = 0.95$ ).

In Section D.1, page 28, the applicant states that the needs of Forest Hills Dialysis’s patients will continue to be met following the proposed relocation of four stations to Clayton Dialysis, and that it plans to apply for additional stations for Forest Hills Dialysis based on the facility need determination methodology when necessary.

Further, in Section D.2, page 28, the applicant states that the proposed relocation of stations will not will not adversely affect the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses historical data that is clearly cited and is reasonable to use to make the assumptions used by the applicant with regard to demonstrating that the needs of the population presently served will be met adequately by the proposed relocations.
- The applicant provides historical data to support its projections that the proposed relocations will not adversely affect the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to access the services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Written comments and response to comments on the application.
- Information provided during the public hearing.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

NC

In Section E.1, page 29, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative due to the fact that it does not address the projected station deficit of 11 stations identified in the July 2017 SDR nor does it offer residents of Johnston County the choice of another provider of dialysis services.
- Another Location – The applicant states it considered locating the facility elsewhere in Johnston County but rejected that alternative because the Clayton location provides better access to current DaVita dialysis patients who wrote letters expressing their interest in transferring and because Clayton is a high-growth area of Johnston County.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

However, on December 12, 2017, Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Selma (FKC Selma) received a Certificate of Need (Project I.D. J-11372-17) to relocate two dialysis stations from FMC Four Oaks (Johnston County), four stations from Johnston Dialysis Center and four dialysis stations from FMC New Hope Dialysis (Wake County) to develop a new 10-station dialysis facility in Selma (Johnston

County). Because the project includes the relocation of four existing dialysis from FMC New Hope Dialysis in Wake County to FKC Selma in Johnston County, the 11-station deficit in Johnston County identified in the July 2017 SDR was effectively reduced to a 7-station deficit [ $11 - 4 = 7$ ]. Thus, approval of TRCNC's proposal to relocate ten dialysis stations from Wilson County to Johnston County would result in a surplus of three dialysis stations in Johnston County.

Furthermore, this application is not conforming to all other applicable statutory review criteria, and thus, is not approvable. See Criteria (1), (6), and (18a). A project that cannot be approved cannot be an effective alternative.

The information in the application regarding which alternative is the least costly or most effective is not reasonable and adequately supported for the following reasons:

- The applicant fails to consider the effect of the Agency's prior approval of the FKC Selma project on the dialysis station deficit in Johnston County identified in the July 2017 SDR.
- The applicant proposes a project that would result in the surplus of dialysis stations in Johnston County.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Written comments and response to comments on the application.
- Information provided during the public hearing.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant does not adequately demonstrate that the application is conforming to this criterion.

- (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

Clayton Dialysis proposes to develop a new 10-station dialysis facility by relocating six stations from Wilson Dialysis and four stations from Forest Hills Dialysis (Wilson County).

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

In Section F.1, page 30, the applicant projects \$2,081,682 in capital costs, including \$1,266,840 for the construction contract, \$165,360 for dialysis machines, \$154,860 for water treatment equipment, \$377,731 for other equipment and furniture and \$116,891 in other costs. In Section F.10, pages 32-33, the applicant states that it projects \$191,283 in start-up



expenses and \$820,403 in initial operating expenses for the new facility, for total estimated working capital of \$1,011,686.

### **Availability of Funds**

In Section F.2, page 31, the applicant states it will finance the capital costs with the accumulated reserves of DaVita, Inc., which is the parent company for Clayton Dialysis. In Section F.13, page 34, the applicant states it will also finance the working capital costs with cash reserves. Exhibit F-5 contains a letter dated September 15, 2017 from the Chief Accounting Officer, authorizing and committing \$3,093,368 for the capital and working capital costs of the project.

Exhibit F-7 contains a copy of the Securities and Exchange Commission Form 10-K Annual Report for DaVita, Inc. for the year ending December 31, 2016. The report indicates that as of December 31, 2016, DaVita, Inc. had \$550 million in cash and cash equivalents, \$14.1 billion in total assets and \$4.9 billion in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

### **Financial Feasibility**

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

	<b>Operating Year 1 FY2020</b>	<b>Operating Year 2 FY2021</b>
Total Treatments*	5,335	5,707
Total Gross Revenues (Charges)	\$1,708,253	\$1,839,163
Total Net Revenue	\$1,645,034	\$1,772,074
Total Operating Expenses (Costs)	\$1,640,806	\$1,716,607
<b>Net Income</b>	<b>\$4,227</b>	<b>\$55,467</b>

\*Includes in-center, home hemodialysis and peritoneal dialysis treatments.

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. The applicant adequately demonstrates sufficient funds for the capital and working capital needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

### **Conclusion**

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion. This determination is based on a review of the information in the application, including any exhibits.

- (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

Clayton Dialysis proposes to develop a new 10-station dialysis facility in Johnston County by relocating six stations from Wilson Dialysis and four stations from Forest Hills Dialysis (Wilson County).

On page 373 the 2017 SMFP defines the service area for dialysis stations as *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Johnston County. Facilities may serve residents of counties not included in their service area.

Bio-Medical Applications of North Carolina, Inc. (BMA) operates three dialysis centers in Johnston County. Also, on December 12 2017, the Agency issued a Certificate of Need to BMA for Project I.D. # J-11372-17, to develop a new 10-station dialysis facility in Selma (Johnston County) by relocating two dialysis stations from FMC Four Oaks, four stations from Johnston Dialysis Center and four dialysis stations from FMC New Hope Dialysis. The applicant, DaVita, does not currently have any existing or approved dialysis facilities in Johnston County. The existing and approved Johnston County dialysis facilities are shown below:

**Johnston County Dialysis Facilities**

Dialysis Facility	Certified Stations 12/31/16	CON Issued Not Certified	% Utilization	Patients Per Station
FMC Four Oaks (BMA)	22	0	65.91%	2.6
FMC Stallings Station (BMA)	24	0	81.25%	3.3
BMA Johnston	25	6	94.00%	3.8
FKC Selma (BMA)*	0	10	NA	NA

Source: July 2017 SDR, Table B.

\*Received Certificate of Need on December 12, 2017.

As shown in the table above, two of the three operational Johnston County dialysis facilities were operating above 80% utilization (3.2 patients per station) as of December 31, 2016.

The applicant proposes to develop a new 10-station dialysis facility in Clayton in Johnston County by relocating six stations from Wilson Dialysis and four stations from Forest Hills

Dialysis, both of which are located in Wilson County. Johnston and Wilson are contiguous counties. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

Subsequent to the submission of this application, on December 12, 2017, Bio-Medical Applications of North Carolina, Inc. d/b/a FKC Selma (Project I.D. # J-11372-17) received a Certificate of Need to relocate two dialysis stations from FMC Four Oaks (Johnston County), four stations from Johnston Dialysis Center and four dialysis stations from FMC New Hope Dialysis (Wake County) to develop a new 10-station dialysis facility in Selma (Johnston County). Because the project includes the relocation of four existing dialysis from FMC New Hope Dialysis in Wake County to FKC Selma in Johnston County, the 11-station deficit in Johnston County identified in the July 2017 SDR was effectively reduced to a 7-station deficit [ $11 - 4 = 7$ ]. Thus, approval of Clayton Dialysis's proposal to relocate ten dialysis stations from Wilson County to Johnston County would result in a surplus of three dialysis stations in Johnston County.

The applicant does not adequately demonstrate that relocating ten stations from Wilson County to Johnston County will not result in the unnecessary duplication of existing and approved in-center dialysis stations in Johnston County.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Written comments and response to comments on the application.
- Information provided during the public hearing.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant does not adequately demonstrate that the application is conforming to this criterion.

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

## C

In Section H.1, page 37, the applicant provides the projected staffing for Clayton Dialysis in the second operating year (FY2021) by full-time equivalent (FTE) positions, as shown below in the table:

<b>Clayton Dialysis Projected Staffing FY2021</b>	
<b>Position</b>	<b>Total FTE Positions</b>
Medical Director	NA*
Registered Nurse	2.0
Technician	4.0
Administrator	1.0
Dietitian	0.5
Social Worker	0.5
Home Training RN	0.5
Administrative Assistant	1.0
Biomed Technician	0.3
<b>Total FTEs</b>	<b>9.8</b>

\*Medical Director is an independent contractor, not an employee.

In Section H.3, pages 38-39, the applicant describes its experience and process for recruiting and retaining staff. In Section H.6, page 40, the applicant provides a table showing the proposed hours of operation. In Section H.7, page 40, the applicant provides a table showing the direct care staffing hours and FTEs. Exhibit I-5 contains a letter from Anwar D. Al-Haidary, M.D., expressing his interest in serving as the 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 information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides appropriate documentation of the availability of adequate health manpower and management personnel for the provision of the proposed dialysis services.
- The applicant provides appropriate and credible documentation of support from the identified Medical Director.
- The applicant documents the availability of other resources, including methods of recruitment and documentation of staff training, necessary for the provision of the proposed dialysis services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Written comments and response to comments on the application.
- Information provided during the public hearing.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

In Section I.1, page 41, the applicant includes a list of providers of the necessary ancillary and support services. The table states that acute dialysis in an acute care setting, blood bank services, diagnostic/evaluation, and X-ray will be referred to Johnston UNC HealthCare. Exhibit I-2(a) is a letter of support from the Johnston UNC Health Care President and CEO confirming its willingness to provide those services to Clayton Dialysis patients. Exhibit I-2(b) contains a letter from Vidant Health agreeing to enter in to an agreement with Clayton Dialysis to provide its patients with transplant services. The applicant discusses the project's coordination with the existing health care system in Sections I.3 and I.4, pages 42-44.

**Conclusion**

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides appropriate and credible documentation of the availability of necessary ancillary and support services for the provision of the proposed dialysis services.
- The applicant provides credible documentation of ongoing coordination with the existing health care system.
- The applicant identifies nephrologists in the area who have agreed to provide medical coverage to the facility.

Therefore, the applicant adequately demonstrates 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.

C

Clayton Dialysis proposes to develop a new 10-station dialysis facility in Johnston County by relocating six stations from Wilson Dialysis and four stations from Forest Hills Dialysis (Wilson County). The proposed facility will be developed in 5,121 square feet of leased space in an existing building located at 2196 Highway 42 in Clayton. The applicant provides the proposed facility's line drawings in Exhibit K-1(a). The drawing depicts a facility with nine main floor dialysis stations and one isolation ("*private treatment*") dialysis station, for a total of 10 stations. In Section K.1, page 46, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant's line drawing of the facility shows adequate space for the ten proposed dialysis stations.

- The applicant describes the energy saving features that have been incorporated into the construction plan.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Written comments and response to comments on the application.
- Information provided during the public hearing.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

In Section L.7, page 56, the applicant reports that 87% of the patients who received treatments at Wilson Dialysis and 86% of the patients who received treatments at Forest Hills Dialysis had some or all of their services paid for by Medicare or Medicaid in CY2016. The table below shows the historical (CY2016) payment source for the two Wilson County DaVita facilities:

<b>Payment Source</b>	<b>Wilson Dialysis Patients as Percent of Total</b>	<b>Forest Hills Patients as Percent of Total</b>
Medicare	25.3%	26.3%
Medicaid	6.1%	5.1%
Commercial Insurance	10.0%	8.5%
Medicare/Commercial Insurance	28.0%	17.8%
Medicare/Medicaid	27.1%	37.2%
VA	3.5%	5.1%
<b>Total</b>	<b>100.0%</b>	<b>100.00%</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**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Johnston	13%	51%	31%	13%	10%	14%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

\*Excludes "White alone" who are "not Hispanic or Latino"

\*\*"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

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

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

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant’s historical payor mix is adequate documentation of the extent to which medically underserved populations utilize the applicant’s existing services reasons:

The application is conforming to this criterion based on a review of the:

- Information in the application, including any exhibits.
- Written comments and response to comments on the application.
- Information provided during the public hearing.

<sup>1</sup><http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

<sup>2</sup>[http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015\\_NW-6\\_Annual-Report\\_Final-11-29-2016.pdf](http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf)



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

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section L.3, page 55, the applicant states:

*“Clayton 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.”*

In Section L.6, page 55, the applicant states there have been no civil rights access complaints filed within the last five years.

The application is conforming to this criterion based on a review of:

- Information in the application, including any exhibits.
  - Written comments and response to comments on the application.
  - Information provided during the public hearing.
  - Information which was publicly available during the review and used by the Agency.
- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L.1, page 53, the applicant projects that 89% of the patients who will receive treatments at Clayton Dialysis in the second operating year (FY2021) will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected Year 2 payment source for the facility for patients:

<b>Payment Source</b>	<b>Total Patients by Percent of Total</b>
Medicare	25.6%
Medicaid	5.8%
Commercial Insurance	9.5%
Medicare/Commercial Insurance	24.5%
Medicare/Medicaid	30.6%
VA	4.0%
<b>Total</b>	<b>100.00%</b>

In Section L.1, page 53, the applicant provides the assumptions used to project payor mix. The applicant's projected payment sources are consistent with the facility's historical (CY2016) payment sources as reported by the applicant in Section L.7, page 55.

The applicant is conforming to this criterion based on a review of:

- Information in the application, including any exhibits.
- Written comments and response to comments on the application.
- Information provided during the public hearing.
- Information which was publicly available during the review and used by the Agency.

- (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 55, and Exhibit L-3, the applicant describes the range of means by which a person will have access to the dialysis services at Clayton Dialysis, which requires referral from a nephrologist. Therefore, the application is conforming to this criterion.

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

C

In Section M.1, page 57 the applicant states that Clayton Dialysis has offered to establish a relationship with a local health professional training program. Exhibit M-2 contains a copy of correspondence to an area health professional training program expressing an interest on the part of the applicant to offer the facility as clinical training site. 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

Clayton Dialysis proposes to develop a new 10-station dialysis facility in Johnston County by relocating six stations from Wilson Dialysis and four stations from Forest Hills Dialysis (Wilson County).

On page 373 the 2017 SMFP defines the service area for dialysis stations as *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Johnston County. Facilities may serve residents of counties not included in their service area.

Bio-Medical Applications of North Carolina, Inc. (BMA) operates three dialysis centers in Johnston County. Also, on December 12 2017, the Agency issued a Certificate of Need to BMA for Project I.D. # J-11372-17, to develop a new 10-station dialysis facility in Selma (Johnston County) by relocating two dialysis stations from FMC Four Oaks, four stations from Johnston Dialysis Center and four dialysis stations from FMC New Hope Dialysis. The applicant, DaVita, does not currently have any existing or approved dialysis facilities in Johnston County. The existing and approved Johnston County dialysis facilities are shown below:

**Johnston County Dialysis Facilities**

Dialysis Facility	Certified Stations 12/31/16	CON Issued Not Certified	% Utilization	Patients Per Station
FMC Four Oaks (BMA)	22	0	65.91%	2.6
FMC Stallings Station (BMA)	24	0	81.25%	3.3
BMA Johnston	25	6	94.00%	3.8
FKC Selma (BMA)	0	10	NA	NA

Source: July 2017 SDR, Table B.

\*Received Certificate of Need on December 12, 2017.

As shown in the table above, two of the three operational Johnston County dialysis facilities were operating above 80% utilization (3.2 patients per station) as of December 31, 2016.

In Section N.1, page 58, the applicant 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 development of Clayton Dialysis will have no effect on any dialysis facilities located in Johnston County or in counties contiguous to it. This certificate of need application is being submitted in response to a projected station deficit of eleven stations in Johnston County as indicated in the July 2017 Semiannual Dialysis Report in Table D. The projected station deficit in Johnston County indicates that there is a need for additional dialysis stations. Since there is only one provider in the county at present this is a great opportunity for patients, referring hospitals and physicians to have a choice of providers.”*

However, the applicant does not adequately demonstrate that the proposal will have a positive impact on the cost-effectiveness of dialysis services in Johnston County. This determination is based on the information in the application and the following analysis:

- The January 2017 SDR, *Table D: ESRD Dialysis Station Need Determination by Planning Area* projects a 11-station deficit in Johnston County;
- On September 15, 2017, Clayton Dialysis filed this application proposing to develop a new 10-station dialysis facility in Johnston County by relocating ten stations from Wilson County to Johnston County. The review cycle began October 1, 2017;
- On July 17, 2017, two months earlier, Bio-Medical Applications of North Carolina Inc. d/b/a FKC Selma had filed an application proposing to develop a new 10-station dialysis facility in Johnston County by relocating four stations from Wake County to Franklin County and six stations from within Johnston County. The review cycle began August 1, 2017;
- FKC Selma’s application was approved on December 12, 2017, effectively reducing the 11-station deficit in Johnston County identified in the July 2017 SDR to a 7-station deficit;
- Approval of Clayton Dialysis’s proposal would create a surplus of three dialysis stations in Johnston County;
- Approval of only a portion of Clayton Dialysis’s application (i.e., the relocation seven stations from Wilson County to Johnston County) would not be consistent with the Performance Standards for dialysis facilities, as promulgated in 10A NCAC 14C .2203(a), which requires an applicant to *“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...”*

- Clayton Dialysis does not adequately demonstrate how any enhanced competition will have a positive impact on the cost effectiveness of dialysis services in Johnston County.

Consequently, the application is nonconforming to this criterion.

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

C

In Section B.4, pages 8-9, the applicant discusses the methods it uses to ensure and maintain quality. In Exhibit O-3, the applicant lists two dialysis facilities in the state owned by DaVita, Southeastern Dialysis Center – Kenansville and Durham Dialysis, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant provides documentation regarding the deficiencies and subsequent compliance with CMS Conditions for Coverage in Exhibit O-3. The applicant states, on page 59, that both facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision.

The applicant provides sufficient evidence that quality of 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.

C

The application is 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.*

- C- In Section C.1, page 13, the applicant projects to serve 32 in-center patients by the end of Operating Year 1, which is 3.2 patients per station ( $32 / 10 = 3.2$ ). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
  
- .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.*
  
- NA- The applicant is not proposing to increase the number of dialysis stations in an existing facility or one that was not operational prior to the beginning of the review period.
  
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
  
- C- In Section C.1, pages 13-18, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.