

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 19, 2018

Findings Date: February 19, 2018

Project Analyst: Celia C. Inman

Assistant Chief: Lisa Pittman

Project ID #: G-11439-17

Facility: Guilford County Dialysis

FID #: 170421

County: Guilford

Applicant: Total Renal Care of North Carolina, LLC

Project: Develop a new 10-station dialysis facility by relocating seven stations from Reidsville Dialysis (Rockingham) and three stations from Burlington Dialysis Center (Alamance)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Total Renal Care of North Carolina, LLC (“TRC” or “the applicant”), d/b/a Guilford County Dialysis (the facility) proposes to develop a new 10-station dialysis facility in Guilford County by relocating seven dialysis stations from Reidsville Dialysis in Rockingham County and three dialysis stations from Burlington Dialysis Center in Alamance County. Both Rockingham and Alamance counties are contiguous to Guilford County. The parent company of TRC is DaVita, Inc. After the relocation of stations, Reidsville Dialysis will have a total of 20 stations (27–7) and Burlington Dialysis Center will have a total of 13 stations, following the completion of this project (relocate 3 stations) and Project ID #s G-

11212-16 (relocate eight stations to Elon Dialysis), G-11289-17 (relocate four stations to Mebane Dialysis), and G-11321-17 (add four stations) [24-3-8-4+4 = 13].

Need Determination

The 2017 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 2017 Semiannual Dialysis Report (SDR), the County Need Methodology shows there is no county need determination for Guilford County. Guilford County Dialysis is not an existing facility, thus is not eligible to apply for stations pursuant to the Facility Need Methodology. Therefore, neither of the two need methodologies in the 2017 SMFP are applicable to the review.

Policies

POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES on page 33 of the 2017 SMFP 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 and less than \$5 million; therefore POLICY GEN-4 is applicable to this review. In Section B.5, pages 12-13, the applicant provides a written statement describing the proposed project’s plan to assure improved energy efficiency and water conservation. The application is consistent with Policy GEN-4.

POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS, on page 27 of the 2017 SMFP of the 2017 SMFP, states:

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

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina 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 proposes to develop a new 10-station dialysis facility in Guilford County by relocating seven stations from Reidsville Dialysis in Rockingham County and three stations from Burlington Dialysis Center in Alamance County; therefore Policy ESRD-2 is applicable to this review. Policy ESRD-2 requires that the facilities losing stations are in counties which are contiguous to Guilford County. Rockingham and Alamance counties are contiguous to Guilford County. Policy ESRD-2 also requires that both Reidsville Dialysis and Burlington Dialysis Center (the facilities losing stations) must currently be serving residents of Guilford County; and that the relocation of the stations does not result in a deficit, or increase an existing deficit of dialysis stations in Rockingham or Alamance counties; or result in a surplus, or increase an existing surplus of dialysis stations in Guilford County.

In Section B.3, page 8, the applicant provides two tables as summarized below:

		Response
(a)	County from which stations will relocate	Rockingham
(b)	County to which stations will relocate	Guilford
(c)	Number of residents of County (row a) who are currently dialyzing in-center at a facility owned by the applicant or a related entity and located in each county from which stations will be relocated	121
(d)	Projected station surplus in the county that will be losing stations (row a) as a result of the proposed project, as reflected in the most recent SDR	16
(e)	Projected station deficit in the county that would gain stations (row b) as a result of the proposed project, as reflected in the most recent SDR	10

		Response
(a)	County from which stations will relocate	Alamance
(b)	County to which stations will relocate	Guilford
(c)	Number of residents of County (row a) who are currently dialyzing in-center at a facility owned by the applicant or a related entity and located in each county from which stations will be relocated	169
(d)	Projected station surplus in the county that will be losing stations (row a) as a result of the proposed project, as reflected in the most recent SDR	27
(e)	Projected station deficit in the county that would gain stations (row b) as a result of the proposed project, as reflected in the most recent SDR	10

Written comments submitted during the 30-day written comment period charge that Reidsville Dialysis does not serve any Guilford County residents. In Section C, page 15, the applicant states:

“Two (2) in-center patients who currently receive their dialysis treatments at Reidsville Dialysis and who lives [sic] in Guilford County have signed a letter indicating they would consider transfer to Guilford County Dialysis.”

Furthermore, Table A of the July 2017 Semi-Annual Dialysis Report (SDR) shows that Reidsville Dialysis was serving two in-center patients who were residents of Guilford County and Burlington Dialysis Center was serving eleven in-center patients who were residents of Guilford County. Table D of the July 2017 SDR shows that Alamance County has a surplus of 27 stations, Rockingham County has a surplus of 16 stations, and Guilford County has a deficit of 10 stations; therefore the relocation of stations will not result in a deficit, or increase an existing deficit of dialysis stations in Rockingham or Alamance counties; or result in a surplus, or increase an existing surplus of dialysis stations in Guilford County. Therefore, the proposal is consistent with POLICY ESRD-2.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,

- remarks at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

- the applicant provides a written statement describing the proposed project's plan to assure improved energy efficiency and water conservation, demonstrating conformity with Policy GEN-4,
- the July 2017 SDR shows Reidsville Dialysis in Rockingham County and Burlington Dialysis Center in Alamance County both serve residents from Guilford County, and
- the applicant demonstrates that the relocation of stations will not result in a deficit, or increase an existing deficit of dialysis stations in the contiguous counties of Rockingham or Alamance counties; or result in a surplus, or increase an existing surplus of dialysis stations in Guilford County.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop a new 10-station dialysis facility in Guilford County by relocating seven stations from Reidsville Dialysis in Rockingham County and three stations from Burlington Dialysis Center in Alamance County. The proposed facility will initially offer in-center and peritoneal dialysis. Home hemodialysis will not be offered upon the initial certification of the proposed facility, and will be referred to Durham West Dialysis for training and support. The applicant plans to add home hemodialysis training and support at some unspecified later date.

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis services 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 North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 14, the applicant provides the projected patient origin for Guilford County Dialysis for in-center (IC) and peritoneal (PD) patients for operating year one (OY1) and operating year two (OY2) following completion of the proposed project, as shown below:

COUNTY	OY 1 7/1/19-6/30/20			OY 2 7/1/20-6/30/21			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Alamance	12	0	1	12	0	1	36.1%	34.2%
Guilford	15	0	2	16	0	3	47.2%	50.0%
Randolph	3	0	1	3	0	1	11.1%	10.5%
Stokes	2	0	0	2	0	0	5.6%	5.3%
Totals	32	0	4	33	0	5	100.0%	100.0%

The applicant provides the assumptions and methodology used to project patient origin on pages 14-18. Exhibit C-1 contains signed letters from 38 DaVita in-center patients stating an interest in transferring their care to the proposed Guilford County Dialysis. The applicant states that it reasonably expects 32 of the 38 in-center patients will transfer their care to the proposed Guilford County facility. The applicant adequately identifies the population to be served.

Analysis of Need

In Section C-2, page 18, the applicant states that Table D in the July 2017 SDR shows a projected 10-station deficit for Guilford County. The applicant further states that the development of Guilford County Dialysis by DaVita will eliminate the station deficit and provide future dialysis patients with another choice of providers in Guilford County. Guilford County is currently served by two providers of dialysis services.

Written comments received during the 30-day comment period suggest that the approval of either CON Project ID #G-11395-17 or CON Project ID #G-11398-17, submitted for the October 1, 2017 review date would reduce the Guilford County deficit below 10 stations and would thus require the disapproval of this application. That is not the case. Chapter 14 of the State Medical Facilities Plan (SMFP) includes a County Need Methodology and a Facility Need Methodology for determining the need for additional dialysis stations. These need methodologies are mutually exclusive. If a need is generated pursuant to the County Need Methodology, facilities located in that county cannot apply for additional stations pursuant to the Facility Need Methodology. If no need is generated pursuant to the County Need Methodology, then facilities located in that county may apply pursuant to the Facility Need Methodology if utilization was 80% or greater. When reviewing an application filed pursuant to the Facility Need Methodology, the Agency does not consider whether or not there is a deficit or surplus of stations in that county. If the Agency did so, then no applicant proposing additional stations pursuant to the Facility Need Methodology could be approved if the County Need Methodology showed a surplus of stations. This would contradict the intent of the Facility Need Methodology. The same reasoning is true for applications creating new facilities by the relocation of existing stations, pursuant to Policy ESRD-2. Policy ESRD-2 specifically requires that the proposed project be evaluated using the number of stations “as reflected in the most recent North Carolina Semiannual Dialysis

Report.” Therefore, the approval of CON Project ID #G-11395-17 or CON Project ID #G-11398-17 has no bearing on this review.

In Section C-1, pages 14-16, the applicant states that it has identified 38 DaVita in-center patients who have signed letters, dated August 2017 through November 2017, stating an interest in transferring their care to the proposed Guilford County Dialysis, which the patients state will be more convenient for them than where they are currently dialyzing. The applicant provides the patient letters in Exhibit C-1.

The applicant bases the need for this project on the need of those patients who signed letters stating a preference to receive their dialysis services in Guilford County. In Section C.2, page 18, the applicant states:

“The development of Guilford County Dialysis will give these patients the opportunity to receive dialysis services in their home county or in a location in Greensboro that is more convenient for them than where they are currently receiving their dialysis services as indicated in the patient letters.”

Written comments received during the 30-day comment period charge that the patient letters cannot be relied upon because they provide only the zip code and not the county of residence of the patient. In its response to written comments submitted at the public hearing held, the applicant responds to this charge by stating:

“There is no reason why a patient writing a letter of support for TRC’s project should be required to state their home county instead of their home zip code. Because there are more zip codes than counties, the use of a zip code often provides more accurate and detailed information about a patient’s location and area of residence.”

In addition, the written comments charge that some of the same patients signed previous letters of support for other projects, stating a willingness to transfer their care to other proposed dialysis facilities. In its response to written comments, the applicant states that at the time the patients signed any previous letters of support for any other facility, there was no option for DaVita dialysis in Guilford County, further stating:

“To the extent there are letters from a single patient submitted in support of multiple applications, the Agency should recognize that the most recent representation reflects the patient’s current preference and plan. A patient’s earlier support of TRC’s Alamance County facility does not change the fact that the patient currently believes the Guilford facility would be more convenient for them.”

During a 2014 court proceeding, BMA, Inc. v. NCDHHS and TRC, Inc., it was confirmed by the Agency that *“the Agency should pay attention to -- when the patient says they believe that the proposed facility is closer to their house and more convenient, that we should give deference to that. ..., we found that to be very persuasive.”* Therefore, the Project Analyst gives deference to the 38 patient letters submitted in this review and finds them persuasive support for the proposed patient origin and the need that population has for the proposed service in Guilford County.

Projected Utilization-IC Patients

In Section C, pages 14-17, the applicant provides the assumptions and methodology used to project in-center dialysis utilization, as summarized below:

- OY1 is July 1, 2019 – June 30, 2020 (OY1)
- OY2 is July 1, 2020 – June 30, 2021 (OY2)
- 32 of the 38 patients who signed letters (Exhibit C.1) will transfer their care to the proposed Guilford County facility: 15 patients residing in Guilford County, 12 residing in Alamance County, and three and two from Randolph and Stokes counties, respectively.
- In-center Guilford County patient population (15) is projected to grow at 4.7%, the Five Year Average Annual Growth Rate (AAGR) for Guilford County pursuant to Table D in the July 2017 SDR.
- No growth is projected for the 17 in-center patients living outside of Guilford County.

The following table, summarized from the application, page 16, illustrates application of the assumptions and the methodology utilized in the applicant’s projections.

Begin July 1, 2019 with 15 Guilford County patients interested in dialyzing at Guilford County Dialysis	15
Project growth forward at 4.7% to June 30, 2020	$15 \times 1.047 = 15.705$
Add 17 patients from outside the county willing to transfer their treatment to the proposed facility. This is the projected ending census for OY1 (June 30, 2020).	$15.705 + 17 = 32.705$
Project the Guilford County patient population forward one year to June 30, 2021.	$15.705 \times 1.047 = 16.443$
Add the 17 patients from outside the county that transferred their treatment to the proposed facility. This is the projected ending census for OY2 (June 30, 2021).	$16.433 + 17 = 33.443$

The applicant states that projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 the facility is projected to serve 32 in-center patients and at the end of OY2 the facility is projected to serve 33 in-center patients.

- OY1: 32 in-center patients = 3.2 patients per station per week, a utilization rate of 80% ($32 \text{ patients} / 10 \text{ stations} = 3.2 / 4 = 0.800$ or 80.0%).
- OY2: 33 in-center patients = 3.3 patients per station per week, a utilization rate of 83% ($33 \text{ patients} / 10 \text{ stations} = 3.3/4 = 0.825$ or 83%).

The projected utilization of 3.2 patients per station per week at the end of OY1 meets the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Therefore, projected utilization for in-center patients is based upon reasonable and adequately supported assumptions regarding the patients to be served at Guilford County Dialysis.

Projected Utilization- PD Patients

The applicant provides projected utilization for its PD patients in Section C.1, pages 17-18, as follows:

Operating Year	Start Date	Beginning Census of PD Patients	Ending Census of PD Patients
Operating Year 1	7/1/19	4	5
Operating Year 2	7/1/20	5	6

On page 17, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- Exhibit C-1 contains four letters of support for the proposed facility from PD patients who currently receive their support at DaVita facilities in Alamance County: two patients are Guilford County residents, one is a resident of Randolph County, and one is a resident of Alamance County. The letters all state that the patient would consider transferring their care to Guilford County Dialysis, if approved, based on the fact that they either lived closer to the proposed new facility or it would be more convenient for them.
- TRC assumes the four patients who signed letters of support for the proposed facility will transfer their care to Guilford County Dialysis upon certification.
- TRC assumes that the PD patients will increase one patient each year.

Written comments received during the 30-day comment period charge that the projected utilization for PD patients was not reasonable, citing Project ID #P-8641-11. However, in Project ID #P-8641-11, the applicant was proposing “two additional stations dedicated to training for peritoneal dialysis and home hemodialysis in addition to the three proposed stations on the treatment floor” for in-center patient dialysis. Therefore in the review of Project ID #P-8641-11, it was necessary for the applicant to demonstrate the need for those additional stations. In this review, as shown in the section above, the applicant has demonstrated the in-center patient need for the proposed 10 station facility, without any consideration of the PD utilization.

The projected PD utilization, based on letters from the transferring patients, is reasonable and adequately supported by the assumptions regarding projected growth at Guilford County Dialysis.

Access

In Section L.1, pages 50-51, the applicant states:

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

...

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

Underserved groups is defined in Criterion (13), as:

“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.”

The 2017 SMFP (page 2) states, *“The SHCC assigns the highest priority to a need methodology that favors providers delivering services to a patient population representative of all payer types in need of those services in the service area.”*

On Page 51, the applicant provides the following projected payor mix for the second operating year.

Projected Payor Mix OY2

Payment Source	Percent of Total Patients	Percent of IC Patients	Percent of HH Patients	Percent of PD Patients
Medicare	25.6%	36.7%	0.0%	16.7%
Medicaid	5.8%	6.5 %	0.0%	0.0%
Commercial Insurance	9.5%	8.8%	0.0%	16.7%
Medicare/Commercial	24.5%	17.2%	0.0%	36.6%
Medicare/Medicaid	30.6%	24.3%	0.0%	30.0%
VA	4.0%	6.5%	0.0%	2.7%
Total	100.0%	100.0%	0.0%	100.0% [102.7%]

As the table above shows, the applicant proposes to deliver services to a patient population representative of all payor types in need of services. The applicant projects that for OY2 (July

1, 2020-June 30, 2021) 84.7% of its IC patients will be Medicare or Medicaid recipients. Guilford County Dialysis will be a new facility and therefore has no historical payor mix upon which to project future payor mix. The applicant states that the projected payor mix is based on DaVita operated facilities in Alamance County, the county of dialysis treatment for 34 of the 38 patients who signed letters stating a willingness to transfer their care to the proposed facility. Of those 34 patients, 18 were Alamance County residents and 13 were Guilford County residents. Thus, the use of the historical DaVita Alamance County payor mix as a proxy for the projected payor mix of the proposed facility in Guilford County is reasonable.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

- the applicant uses Agency accepted methodologies and reasonable assumptions to identify the projected population to be served,
 - the applicant uses Agency accepted methodologies and reasonable assumptions to demonstrate the need the projected patient population has for the proposed services,
 - the applicant provides documentation from patients willing to transfer their care to the facility due to the facility location being closer to their homes or more convenient to access,
 - the projected utilization is based on reasonable and adequately supported assumptions,
 - to the extent that assumptions regarding future performance can be supported by documentation, the applicant provided that documentation, and
 - the applicant demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to develop a new 10-station dialysis facility in Guilford County by relocating seven existing dialysis stations from Rockingham County and three existing stations from Alamance County.

In Section D.1, pages 23-26, the applicant discusses how the needs of dialysis patients at Reidsville Dialysis and Burlington Dialysis Center will continue to be met after the relocation of seven and three stations, respectively, to the proposed Guilford County Dialysis facility. On pages 23-24, the applicant provides the projected utilization at Reidsville Dialysis, based on a 0% growth rate, per the July 2017 SDR's AAGR (-0.002) for Rockingham County. The July 2017 SDR shows 27 certified stations and 72 patients.

At the end of OY1, after the relocation of seven stations and the transfer of two patients, Reidsville Dialysis is projected to have a census of 70 patients dialyzing on 20 stations for a utilization rate of 87.5% ($70 / 20 = 3.5 / 4 = 0.875$). The applicant states:

“Given the number of stations available with the in-center patient population, the needs of the facility’s patients will continue to be met. Additional Certificate of Need application(s) will be submitted based on facility need.”

Written comments submitted during the 30-day written comment period suggest that the applicant should have used the Reidsville Dialysis’ facility growth rate since 2014 to project utilization at Reidsville Dialysis, rather than the July 2017 SDR’s AAGR for Rockingham County. However, use of the SDR’s published county AAGR is a common assumption used by applicants in ESRD applications and is considered by the Project Analyst to be reasonable in this case. Furthermore, as the applicant states above, the applicant can apply for additional stations at Reidsville Dialysis based on facility need when the facility needs more stations.

On pages 24-26, the applicant provides the projected utilization at Burlington Dialysis Center for Alamance County residents based on a 4.1% growth rate, per the July 2017 SDR’s AAGR for Alamance County. A 0% growth rate is used for patients residing outside of Alamance County. The July 2017 SDR shows 24 certified stations and 96 in-center patients, which is a utilization rate of 100%. Of the 96 in-center patients, 79 are from Alamance County. The following CON decisions impact the number of stations and number of patients at Burlington Dialysis Center:

- Project ID #G-11212-16 relocates eight stations and transfers 31 in-center patients from Burlington Dialysis Center to Elon Dialysis,
- Project ID #G-11289-17 relocates four stations and transfers 17 in-center patients from Burlington Dialysis Center to Mebane Dialysis ($16 - 4 = 12$ stations, $65 - 17 = 48$ patients),
- Project ID #G-11321-17 adds four dialysis stations for a total of 16 stations, and

- The approval of this application would relocate three stations from Burlington Dialysis Center, leaving the facility with a total of 13 stations and 41 patients at the end of OY2, as summarized below.

TRC projects 79 in-center patients, all of whom reside in Alamance County as of January 1, 2017.	79
TRC projects this patient population forward one year to December 31, 2017, using the 4.1% AAGR.	$1.041 \times 79 = 82.239$
TRC then adds the 17 in-center patients who are not residents of Alamance County. This is the projected ending census for 2017.	$65.78 + 17 = 99.239$
TRC relocates eight stations and transfers 31 Alamance County patients (G-11212-16) for a total of 16 stations and 51 Alamance county patients.	$82 - 31 = 51$
TRC projects the Alamance County patient population forward one year to December 31, 2018, using the 4.1% AAGR.	$1.041 \times 51 = 53.091$
TRC then adds the 17 in-center patients who are not residents of Alamance County. This is the projected ending census for CY2018.	$53.091 + 17 = 70.091$
TRC relocates four stations and transfers 17 patients (G-11289-17) and adds four stations (G-11321-17) for a total of 16 stations and 36 Alamance County patients.	$53 - 17 = 36$
TRC projects the Alamance County patient population forward six months to June 30, 2019 using the 4.1% AAGR / 12 months x 6 months (2.05%).	$1.0205 \times 36 = 36.738$
TRC then adds the 17 in-center patients who are not residents of Alamance County. This is the projected census to begin OY1 with at July 1, 2019.	$36.738 + 17 = 53.738$
TRC projects the Alamance County patient population (rounded down) forward one year to the end of OY1 (June 30, 2020) using the 4.1% AAGR.	$1.041 \times 36 = 37.476$
During the first operating year, TRC will relocate three dialysis stations and transfer 15 non-Alamance County patients to Guilford County Dialysis. TRC adds the two in-center patients (17-15) who are not residents of Alamance County for a total of 13 (16-3) stations and 39 patients at the end of OY1.	$37.476 + 2 = 39.476$
TRC projects the Alamance County patient population (rounded down) forward one year to the end of OY2 (June 30, 2021) using the 4.1% AAGR.	$1.041 \times 37.476 = 39.013$
TRC then adds the two in-center patients who are not residents of Alamance County. This is the projected ending census for Operating Year 2 with 13 stations and 41 patients (rounded down).	$39.013 + 2 = 41.013$

At the end of OY1, Burlington Dialysis Center is projected to have a census of 39 patients dialyzing on 13 stations for a utilization rate of 75% ($39 / 13 = 3.00 / 4 = 0.75$). At the end of OY2, Burlington Dialysis Center is projected to have a census of 41 patients dialyzing on 13 stations for a utilization rate of 79% ($41 / 13 = 3.15 / 4 = 0.79$). The applicant states:

“Given the number of stations available with the in-center patient population, the needs of the facility’s patients will continue to be met. Additional Certificate of Need

application(s) will be submitted based on facility need as the facility approaches full capacity of stations, if necessary.”

In Section D, page 26, the applicant states:

“The transfer [relocation] of stations from Reidsville Dialysis and Burlington Dialysis will have no effect on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other under-served group [sic] and the elderly to obtain needed health care.”

The applicant further states (page 26) that both facilities losing stations, by policy, will continue to make dialysis services available to “*all residents in its service area without qualification*”, serving patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability. The applicant further states that both facilities will continue to help uninsured/underinsured patients with identifying and applying for financial assistance, making services available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.

Conclusion

The applicant demonstrates that the needs of the population presently served at the both facilities losing stations will continue to be adequately met following the proposed relocation of seven dialysis stations from Reidsville Dialysis and three stations from Burlington Dialysis Center to Guilford County Dialysis and that access for medically underserved groups would not be negatively impacted.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

- the applicant adequately demonstrates that the needs of the population presently served will be adequately met after the proposed relocation of stations and transfer of patients,
- the applicant provides documentation from patients willing to transfer their care to the facility due to the facility location being closer to their homes or more convenient to access,
- the applicant uses reasonable and adequately supported assumptions to project utilization for the remaining population and services,

- the applicant adequately demonstrates the effect of the relocation of stations on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed healthcare , and
 - the applicant operates under a policy of serving all residents in the service area without qualification.
- (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.

C

In Section E-1, pages 27-28, the applicant discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo – the applicant states that this is not a satisfactory alternative because the applicant wants to serve patients who live in Guilford County, offer Guilford County patients another choice of provider and offer DaVita patients the opportunity to dialyze in the greater Greensboro area.
2. Locate a Facility in Another Area of Johnston [“*Guilford*”] County- the applicant states that the selected site will allow the applicant to provide better geographic access to the patient population identified and reflected in the patient letters. The primary site is located near the population high growth area of the county.

After considering these alternatives, the applicant states the most effective alternative is to develop the facility as proposed; thereby offering the ESRD patients in Guilford County another choice of provider and the opportunity to dialyze with “*the national provider with the best clinical outcomes as indicated by the Centers for Medicare and Medicaid Services.*” The applicant states that the proposed project is the most effective alternative to meet its identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

- the applicant uses reasonable and adequately supported assumptions to project utilization, and
- the data cited is reasonable to support the assumptions made with regard to the most effective alternative for development of the proposed project.

Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC d/b/a Guilford County Dialysis shall materially comply with all representations made in the certificate of need application.**
 - 2. Total Renal Care of North Carolina, LLC d/b/a Guilford County Dialysis shall relocate no more than seven dialysis stations from Reidsville Dialysis and no more than three dialysis stations from Burlington Dialysis Center for a total of no more than 10 dialysis stations at Guilford County Dialysis.**
 - 3. Total Renal Care of North Carolina, LLC d/b/a Guilford County Dialysis shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 - 4. Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify seven dialysis stations at Reidsville Dialysis in Rockingham County for a total of no more than 20 dialysis stations at Reidsville Dialysis upon project completion.**
 - 5. Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify three dialysis stations at Burlington Dialysis Center in Alamance County for a total of no more than 13 dialysis stations at Burlington Dialysis Center upon completion of this project and Project ID #G-11321-17 (Add 4 dialysis stations for a total of 16 stations upon completion of this project, Project ID #G-11212-16 (relocate 8 stations), and Project ID #G-11289-17 (relocate 4 stations).**
 - 6. Total Renal Care of North Carolina, LLC d/b/a Guilford County Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new 10-station dialysis facility in Guilford County by relocating 10 existing dialysis stations: seven from Reidsville Dialysis in Rockingham County and three from Burlington Dialysis Center in Alamance County.

Capital and Working Capital Costs

In Section F.1, pages 29-30, the applicant states that the capital costs for the project will total \$2,081,124 and provides a table with the estimated capital costs on page 29, as summarized below.

Projected Capital Costs

		Total Costs
Total Construction		\$ 1,266,840
Miscellaneous Costs		
Machines	\$165,360	
Water Treatment Equipment	\$154,860	
Other Equipment/Furniture	\$377,137	
Architect/engineering Fees	\$99,700	
Consultant Fees	\$17,191	
		\$814,284
Total Miscellaneous		[\$ 814,248]
Total Capital Costs		\$2,081,124 [\$2,081,088]

The applicant incorrectly summed the miscellaneous costs. The correct totals are provided in [brackets]. The difference is insignificant and irrelevant.

In Section F.10 and F.11, pages 31-32, respectively, the applicant states that estimated start-up expenses are \$191,283 and initial operating expenses are \$809,223 for total working capital needs for the proposed project of \$1,000,506.

Availability of Funds

In Section F.5, page 30, the applicant refers to Exhibit F-5 for the response as to how the project will be financed. In Exhibit F-5, the applicant provides a letter dated November 15, 2017, from the Chief Accounting Officer of the parent company, DaVita Inc., authorizing the project and committing DaVita cash reserves for the development of the project. The letter in Exhibit F-5 gives authorization and commits cash reserves of \$3,081,630 to develop the new 10-station facility in Greensboro.

In Section F.7, page 31, in reference to providing the most recent financial report, the applicant states:

“Corporate financial statements serve as Exhibit F-7. These statements include a copy of the United States Securities and Exchange Commission Form 10-K for the fiscal year ended December 31, 2016”.

Exhibit F-7 contains DaVita’s Form 10-K for the fiscal year ended December 31, 2016, showing consolidated totals of \$913,187,000 in cash and cash equivalents, \$18,741,257,000 in total assets and \$4,849,741,000 in total equity.

Therefore, the applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.

Financial Feasibility

In the projected revenue and expense statement (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.

Guilford County Dialysis Revenue and Expenses		
	OY1 (CY2019)	OY2 (CY2020)
In-Center Treatments	4,742	4,817
PD Treatments	667	815
Total Treatments	5,409	5,632
Gross Patient Revenue	\$1,762,879	\$1,846,245
Deductions from Gross Revenue	\$85,383	\$87,779
Net Patient Revenue	\$1,677,496	\$1,758,466
Operating Expenses	\$1,618,445	\$1,672,912
Net Income	\$59,051	\$85,555

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

- the applicant projects utilization based on reasonable assumptions,
 - the applicant uses historical DaVita data for future projections of costs and charges and to demonstrate financial feasibility of the project, and
 - the applicant provides adequate documentation of sufficient funding for the capital and operating needs of the project.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to develop a new 10-station dialysis facility in Guilford County by relocating 10 existing dialysis stations: seven from Reidsville Dialysis in Rockingham County and three from Burlington Dialysis Center in Alamance 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.”* The facility is located in Guilford County; thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

According to the July 2017 SDR, there are seven operational dialysis facilities in Guilford County, as follows:

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA of Greensboro (FMC)	56	79.91%	3.1964
BMA of South Greensboro (FMC)*	59	77.12%	3.0847
BMA of Southwest Greensboro (FMC)**	33	85.61%	3.4242
FMC of East Greensboro (FMC)	39	85.26%	3.4103
Fresenius Kidney Care Garber-Olin (FMC Proposed new site)	0	0.00%	0.0000
FMC High Point (FMC Proposed Site)	0	0.00%	0.0000
High Point Kidney Center (WFUHS)***	40	93.75%	3.7500
Northwest Greensboro Kidney Center (FMC)	33	81.06%	3.2424
Triad Dialysis Center (WFUHS)	27	77.78%	3.1111

Source: July 2017 SDR, Table B.

* Project ID #G-11055-15 approved the relocation of 10 stations from BMA of South Greensboro to develop FMC High Point in Guilford County, leaving a total of 49 stations at BMA of South Greensboro upon project completion.

**BMA of Southwest Greensboro was approved to relocate four stations to Northwest Greensboro Kidney Center in Project ID #G-11287-17. This certificate of need was relinquished by the applicant on September 5, 2017.

*** Approved to relocate 10 stations to North Randolph Dialysis Center in Randolph County in Project ID #G-10262-14, leaving a total of 32 stations at High Point Kidney Center upon project completion.

Fresenius related entities own and operate seven of the nine existing and proposed dialysis facilities in Guilford County. The other two facilities are owned and operated by Wake Forest University Health Sciences.

In Section G of the application, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis facilities in Guilford County.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

The applicant adequately demonstrates its proposal would not result in an unnecessary duplication of existing or approved dialysis services in Guilford County based on the following analysis:

- the applicant uses Agency accepted methodologies and reasonable assumptions to identify the projected population to be served,
- the applicant uses Agency accepted methodologies and reasonable assumptions to demonstrate the need for the population has for the proposed services,

- the applicant provides documentation from patients willing to transfer their care to the facility due to the facility location being closer to their homes or more convenient to access, and
- the projected utilization is based on reasonable and adequately supported assumptions.

Consequently, the applicant adequately demonstrates 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, page 36, the applicant provides a table, as summarized below, to illustrate the projected staffing in full time equivalent (FTE) positions for Guilford County Dialysis. The applicant states the Medical Director will not be employed by the facility; thus it is not reflected on the staffing chart below.

GUILFORD COUNTY DIALYSIS			
POSITION	PROJECTED FTE POSITIONS	OY2 PROJECTED ANNUAL SALARY	OY2 TOTAL PROJECTED SALARY
Registered Nurse	2.00	\$72,120	\$144,240
Technician (Patient Care)	4.00	\$27,318	\$109,273
Administrator	1.00	\$81,955	\$81,955
Dietician	0.50	\$60,100	\$30,050
Social Worker	0.50	\$60,100	\$30,050
Home Training RN	0.50	\$72,120	\$36,060
Administrative Assistant	1.00	\$28,957	\$28,957
Bio-med Technician	0.30	\$44,802	\$13,441
Total	9.80		

As illustrated in the table above, the applicant projects a total of 9.8 FTE positions at the proposed facility. In Section H.7, page 39, the applicant provides the projected direct care staff hours for OY2.

In Section I-3, page 41, the applicant identifies Harmeet Singh, M.D. as the Medical Director of the proposed facility. Exhibit I-3 contains a copy of an August 22, 2017 letter signed by Dr. Singh, supporting the establishment of a 10-station DaVita ESRD facility at the proposed location and confirming his commitment to serve as Medical Director. Though the letter was also submitted in the withdrawn application from Project ID #G-11412-17, proposing a 10-station facility at the same proposed location, the Project Analyst has no reason to doubt that Dr. Singh would have signed a new letter for this project, if needed. In fact, Dr. Singh spoke in support of this project at the public hearing. Likewise for some of the other support letters provided in Exhibit I, which are copies of the letters submitted in

the withdrawn Project ID #G-11412-17. Because both projects propose the establishment of a new 10-station DaVita ESRD facility at the same location, the Project Analyst determined that accepting the letters as support for the project in this review is reasonable.

In Section H.3, pages 37-38, the applicant states that the facility administrator sources candidates to fill the positions by utilizing the DaVita Teammate Recruiter, the Teammate Referral Program, or the Student Internship Program. The applicant further states that DaVita offers a wide range of teammate benefits and maintains a competitive salary structure in order to attract qualified teammates.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis services.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

- the applicant demonstrates the availability of adequate health manpower and management personnel for the provision of the proposed dialysis services,
 - the applicant provides appropriate and reasonable documentation of support from the proposed Medical Director for the facility, and other physicians, and
 - the applicant demonstrates the availability of other resources, including methods of recruitment and documentation of staff training, necessary for the provision of the proposed dialysis services.
- (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 40, the applicant identifies the necessary ancillary and support services and indicates how they will be made available. The table states that acute dialysis in an acute care setting, emergency care, blood bank services, diagnostic/evaluation, and X-ray will be referred to Cone Health. The applicant discusses coordination with the existing health care system on pages 40-42. Exhibit I-2 includes a letter from Cone Health documenting intent to provide services for the patients at the proposed facility. Exhibit I.1 contains an agreement with DaVita Laboratory Services, Inc. for lab services. Exhibit I.2 contains transplant services agreements provided by Vidant Health and UNC Hospitals. 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.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

- the applicant provides agreements for the provision of necessary ancillary services required for the provision of the proposed services,
 - the applicant provides agreements for the referral and transfer of dialysis patients for inpatient hospital services and transplant services, and
 - the applicant identifies relationships with the medical community, including physicians and hospitals.
- (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.

- (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.

- (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

In Section K.2, page 46, the applicant states that the facility will have 5,341 square feet of treatment area, which includes isolation space. The applicant provides a proto-type ESRD facility line drawing in Exhibit K. The drawing depicts a facility, with ten dialysis stations, including isolation dialysis stations. In Section K, page 45, the applicant states that the rooms shown on the drawing as H.T. offices will be PD training rooms. In Section F.1, page 29, the applicant provides the proposed costs, including \$1,266,840 for construction and \$814,284 [\$814,248] in miscellaneous costs, including dialysis machines, water treatment equipment, furniture, architect/engineering fees, and consultant fees for a total project cost of \$2,081,124 [\$2,081,088]. In Section K.1 (c) and (d), page 45, the applicant addresses energy-efficiency, including water conservation.

Costs and charges are described by the applicant in Section F, pages 29-34, and in Section R proforma financial statements.

Written comments submitted during the 30-day comment period suggest that the size of the facility is far beyond the minimum requirement of square footage in construction guidelines and therefore the applicant is proposing to develop a space much larger than is necessary for

the proposed dialysis facility, which could lead to excessive costs of construction. In its response to written comments submitted at the public hearing, the applicant states:

“TRC intends to make its facility generous and spacious for its patients ... The guidelines provide no suggestion that there should be a maximum number of square feet per station.”

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans and that the construction cost will not unduly increase costs and charges for health services.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

- the applicant adequately documents construction costs related to the development of the proposed project, and
 - the applicant demonstrates that energy saving features have been incorporated in to the construction plans and that the construction costs will not unduly increase cost and charges for health services.
- (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

Guilford County Dialysis would be a new facility, thus, it has no historical payor mix. However, the applicant provides the historical payor mix for the two facilities from which the applicant proposes to relocate stations in Section L.7, page 54.

**Reidsville Dialysis
 Historical Payor Mix CY 2016**

Payment Source	Percent of Total Patients	Percent of IC Patients	Percent of PD Patients
Medicare	37.3%	38.3%	0.0%
Medicaid	6.0%	6.2%	0.0%
Commercial Insurance	8.4%	8.6%	0.0%
Medicare / Commercial	25.3%	24.7%	50.0%
Medicare / Medicaid	18.2%	17.3%	50.0%
VA	4.8%	4.9%	0.0%
Total	100.0%	100.0%	100.0%

**Burlington Dialysis Center
 Historical Payor Mix CY 2016**

Payment Source	Percent of Total Patients	Percent of IC Patients	Percent of PD Patients
Medicare	32.5%	34.6%	0.0%
Medicaid	4.8%	5.1%	0.0%
Commercial Insurance	9.6%	10.3%	0.0%
Medicare / Commercial	29.0%	28.2%	40.0%
Medicare / Medicaid	18.1%	15.4%	60.0%
VA	6.0%	6.4%	0.0%
Total	100.0%	100.0%	100.0%

As shown in the tables above, the applicant reports that 86.5% of the in-center patients at Reidsville Dialysis and 83.3% of the in-center patients at Burlington Dialysis Center had some or all of their services paid for by Medicare or Medicaid in CY 2016.

However, the payor mix provided by the applicant for Burlington Dialysis Center was the exact same as that provided by the applicant for Dialysis Care of Rockingham County in its withdrawn application for Project ID #G-11412-17. Therefore, the Project Analyst researched the public records on file at the Agency for Burlington Dialysis Center CON projects and found that in Section L.1, page 49 of the application Project ID #G-11321-17 and in Section L.7 of the withdrawn application for Project ID #G-11409-17, the applicant provided the payor mix for Burlington Dialysis Center in each application, as shown below.

**Burlington Dialysis Center
Historical Payor Mix CY 2016**

Payment Source	Percent of Total Patients	Percent of IC Patients	Percent of PD Patients
Medicare	29.3%	30.7%	18.2%
Medicaid	4.0%	4.5%	0.0%
Commercial Insurance	10.1%	6.8%	36.3%
Medicare / Commercial	26.3%	25.1%	36.4%
Medicare / Medicaid	21.2%	22.7%	9.1%
VA	9.1%	10.2%	0.0%
Total	100.0%	100.0%	100.0%

Based on the information on file with the Agency and reflected in the table above, Burlington Dialysis Center has different percentages for the individual payment sources than the ones presented on page 54 of the application. However, the total percent of the in-center patients who had some or all of their services paid for by Medicare or Medicaid in CY 2016, remained 83%. Therefore, though the applicant inadvertently failed to include the proper table in the application, the outcome does not change; therefore the percentage quoted appears reasonable and is adequately supported.

The IPRO ESRD Network of the South Atlantic (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, and is representative of North Carolina patient profiles.

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

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

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

- the proposed facility is a new facility and has no history,
 - the applicant adequately demonstrates the extent to which medically underserved populations currently use DaVita's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved.
- (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

The applicant is proposing a new facility. In Section L.3, page 53, the applicant states that it 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.7, page 54, the applicant provides two DaVita facilities' historical payor mixes, showing services provided to 83% Medicare/Medicaid patients.

In Section L.6, page 54, the applicant states, "*There have been no civil rights equal access complaints filed within the last five years.*"

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

- application,
 - exhibits to the application,
 - written comments,
 - remarks at the public hearing,
 - responses to comments, and
 - information 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(a), page 50, the applicant states:

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

In Section L of the application, the applicant provides the information required by this criterion. The following table illustrates the projected payor mix during the second full fiscal year.

Projected Payor Mix OY2

Payment Source	Percent of Total Patients	Percent of IC Patients	Percent of HH Patients	Percent of PD Patients
Medicare	25.6%	36.7%	0.0%	16.7%
Medicaid	5.8%	6.5 %	0.0%	0.0%
Commercial Insurance	9.5%	8.8%	0.0%	16.7%
Medicare/Commercial	24.5%	17.2%	0.0%	36.6%
Medicare/Medicaid	30.6%	24.3%	0.0%	30.0%
VA	4.0%	6.5%	0.0%	2.7%
Total	100.0%	100.0%	0.0%	100.0% [102.7%]

The applicant states on page 51, that projected payor mix is based on the historical patient payment received by DaVita operated facilities in Alamance County. The applicant states that Alamance County payor mix was chosen as a proxy because a significant number of DaVita in-center and PD patients dialyze in Alamance County, have signed letters indicating a willingness to transfer their care to the proposed facility, and Alamance County is contiguous to Guilford County.

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

- application,
 - exhibits to the application,
 - written comments,
 - remarks at the public hearing,
 - responses to comments, and
 - information 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 53, the applicant states:

“Patients with End Stage Renal Disease have access to dialysis services upon referral by a Nephrologist with privileges at Guilford County Dialysis. ... Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies, found at Exhibit L-3. ...”

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 55, the applicant states that Guilford County Dialysis has been offered as a clinical training site for nursing students attending Guilford Technical Community College. Exhibit M-2 contains a copy of the letter sent to the President of Guilford Technical Community College, offering the proposed facility as a clinical training site.

The applicant demonstrates it will accommodate the needs of health professional training programs in the area. Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to develop a new 10-station dialysis facility in Guilford County by relocating 10 existing dialysis stations: seven from Reidsville Dialysis in Rockingham County and three from Burlington Dialysis Center in Alamance 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.” The facility is located in Guilford County; thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

According to the July 2017 SDR, there are seven operational dialysis facilities in Guilford County, as follows:

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA of Greensboro (FMC)	56	79.91%	3.1964
BMA of South Greensboro (FMC)*	59	77.12%	3.0847
BMA of Southwest Greensboro (FMC)**	33	85.61%	3.4242
FMC of East Greensboro (FMC)	39	85.26%	3.4103
Fresenius Kidney Care Garber-Olin (FMC Proposed new site)	0	0.00%	0.0000
FMC High Point (FMC Proposed Site)	0	0.00%	0.0000
High Point Kidney Center (WFUHS)***	40	93.75%	3.7500
Northwest Greensboro Kidney Center (FMC)	33	81.06%	3.2424
Triad Dialysis Center (WFUHS)	27	77.78%	3.1111

Source: July 2017 SDR, Table B.

* Project ID #G-11055-15 approved the relocation of 10 stations from BMA of South Greensboro to develop FMC High Point in Guilford County, leaving a total of 49 stations at BMA of South Greensboro upon project completion.

**BMA of Southwest Greensboro was approved to relocate four stations to Northwest Greensboro Kidney Center in Project ID #G-11287-17. This certificate of need was relinquished by the applicant on September 5, 2017.

*** Approved to relocate 10 stations to North Randolph Dialysis Center in Randolph County in Project ID #G-10262-14, leaving a total of 32 stations at High Point Kidney Center upon project completion.

Fresenius related entities own and operate seven of the nine existing and proposed dialysis facilities in Guilford County. The other two facilities are owned and operated by Wake Forest University Health Sciences.

According to Table D in the July 2017 SDR, there is a deficit of ten dialysis stations in Guilford County. The county need methodology, as discussed on page 376 of the 2017 SMFP, requires a deficit of 10 stations or greater and the utilization of all facilities in the county to be 80% or greater to identify a county need for an additional facility. Therefore, based on the utilizations in the July 2017 SDR for Guilford County facilities, as shown above, the deficit does not result in a county need determination.

In Section C, pages 14-18, the applicant projects a utilization of 3.2 patients per station per week at the end of OY1, which meets the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

In Section N of the application, 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 cost-effectiveness, quality and access to the proposed services. The applicant states:

“The development of Guilford County Dialysis will have no effect on any dialysis facilities located in Guilford County or in counties contiguous to it. This certificate of need application is being submitted in response to a projected station deficit of ten stations in Guilford County as indicated in the July 2017 Semiannual Dialysis report in Table D. The projected station deficit in Guilford County indicates that there is a need for additional dialysis stations.”

The applicant further states that though there are two providers in Guilford County, the “greater Greensboro” area has only one provider; therefore, the project is an opportunity for patients, referring hospitals and physicians to have a choice of providers. The applicant states:

“The bottom line is Guilford County 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 other involved in the dialysis process to receive services. Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs.”

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

The application is conforming to this criterion for the following reasons:

- the applicant adequately demonstrates the need for the proposal and that it is a cost-effective alternative,
- the applicant adequately demonstrates that it will provide quality services, and
- the applicant adequately demonstrates that it will provide access to medically underserved groups.

(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 9-10, the applicant discusses the methods it uses to ensure and maintain quality. In Section O.3, page 57 and Exhibit O-3, the applicant discusses the DaVita-owned facilities that did not operate in compliance with the Medicare conditions of participation during the 18 month look-back period from May 1, 2016 through the date of application submission.

In Section A.11, page 6, the applicant states that DaVita operates 70 dialysis facilities located in North Carolina. Exhibit O-3 shows that of the 70 facilities, only the one listed below was not in compliance with Medicare Conditions of Participation during the 18 months prior to submission of the application.

DaVita Quality Care		
Facility	Survey Date	Back in Compliance
Goldsboro South Dialysis	10/26/2017	No – The Plan of Correction was submitted 11/6/2017*

*The applicant states that it expects the facility will be found to be back in compliance and that the Immediate Jeopardy (IJ) status will be removed on or about November 24, 2017.

The applicant provides 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.

C

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

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-C- In Section C, pages 14-18, the applicant projects a utilization of 3.2 patients per station per week at the end of OY1. Furthermore, the applicant adequately demonstrates the need that the proposed population has for the services to be developed in Guilford County, and that the projected utilization is based on reasonable and adequately supported assumptions.

(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 does not propose to increase the number of dialysis stations in an existing facility.

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

-C- In Section C, pages 14-18, the applicant provides the assumptions and methodology used to project utilization of the facility.