

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: March 27, 2026

Findings Date: March 27, 2026

Project Analyst: Crystal Kearney

Co-Signer: Mike McKillip

Project ID #: J-12727-26

Facility: Garner Dialysis

FID #: 260022

County: Wake

Applicant(s): Total Renal Care of North Carolina, LLC

Project: Develop a new dialysis facility by relocating no more than four dialysis stations from Wake Forest Dialysis and no more than six dialysis stations from Oak City Dialysis for a total of no more than 10 stations upon project completion.

REVIEW CRITERIA

G.S. 131E-183(a): The Department 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.

NA

Total Renal Care of North Carolina, LLC (hereinafter referred to as “the applicant”) proposes to develop a new 10-station dialysis facility, Garner Dialysis, by relocating four stations from Wake Forest Dialysis and six stations from Oak City Dialysis. Both of the facilities from which dialysis stations will be relocated in Wake County. The proposed facility will offer only in-center hemodialysis (ICHHD), upon project completion.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2026 SMFP
- acquire any medical equipment for which there is a need determination in the 2026 SMFP
- offer a new institutional health service for which there are any policies in the 2026 SMFP

Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.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, ... persons [with disabilities], 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, Garner Dialysis, by relocating no more than four dialysis stations from Wake Forest Dialysis and no more than six dialysis stations from Oak City Dialysis.

Patient Origin

On page 107, the 2026 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” The applicant proposes to locate the proposed dialysis facility in Wake County. Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

The proposed project is for a new facility with no historical patient origin data. The following tables, from Section C, page 22, illustrates historical patient origin for calendar year (CY) 2025 for the existing dialysis stations that will be relocated from Wake Forest Dialysis and Oak City Dialysis as part of this proposal.

Wake Forest Dialysis Last Full FY 01/01/2025 to 12/31/2025						
County	IC Patients	% Total	HH Patients	% Total	PD Patients	% Total
Wake	48	73.8%			6	75.00%
Durham	1	1.5%				
Franklin	12	18.5%			2	25.00%
Granville	3	4.6%				
Vance	1	1.5%				
Total	65	100.0%	0	0.00%	8	100.0%

Source: Section C, page 22

Oak City Dialysis Last Full FY 01/01/2025 to 12/31/2025						
County	IC Patients	% Total	HH Patients	% Total	PD Patients	% Total
Wake	81	89.0%	9	81.82%	12	80.00%
Chatham	1	1.1%				
Durham	1	1.1%				
Harnett	1	1.1%				
Johnston	1	1.1%	1	9.09%	2	13.33%
Mecklenburg			1	9.09%		
Moore	1	1.1%				
Warren	1	1.1%				
Wilson					1	6.67%
Other States	4	4.4%				
Total	91	100.0%	11	100.00%	15	100.00%

Source: Section C, page 22

The following table from Section C, page 23, illustrates project patient origin for the proposed facility, Garner Dialysis, for the second full fiscal year(FY) of operation.

Garner Dialysis Second Full FY 01/01/2029 to 12/31/2029						
County	IC Patients	% Total	HH Patients	% Total	PD Patients	%Total
Wake	30.1716	100.0%	0	0.00%	0	0.0%
Total	30.1716	100.0%	0	0.0%	0	0.0%

Source: Section C, page 23

In Section C, pages 23-24, the applicant provides the assumptions and methodology used to project its patient origin, summarized as follows:

- In Exhibit C-3, the applicant provides 29 letters of support signed by 29 in-center patients who receive their dialysis treatments at DaVita-operated facilities in Durham and Wake Counties and who live in Wake County. Each of the letters

indicate that these patients would be willing to transfer their care to the proposed facility upon project completion.

- The applicant provides a table to illustrate the number of patients by county/zip codes of patient residence and the dialysis facility where they are currently being served. All of the patients reside within Wake county.

Patient's Residence County/Zip Code		Downtown Raleigh Dialysis	Oak City Dialysis	Southpoint Dialysis	Wake Forest Dialysis Center	Total
Wake	27529	1				1
Wake	27540			1		1
Wake	27545	2				2
Wake	27591	2				2
Wake	27592		1			1
Wake	27597	2				2
Wake	27603		3			3
Wake	27606		4			4
Wake	27610	4	6		3	13
Total		11	14	1	3	29

- The applicant projects that there will be additional ESRD patients who live in the service area who may want to receive their dialysis treatments at Garner Dialysis.

The applicant's patient origin assumptions are reasonable and adequately supported based on the following:

- The applicant provides patient letters of support that indicate patients residing in Wake and Johnson counties would be willing to transfer their care to the proposed facility.
- The applicant provides ZIP code information that indicates those patients who signed letters of support reside in the 27529 ZIP code and the location of the proposed facility will be in the same 27529 ZIP code.

Analysis of Need

In Section C, pages 24-25, the applicant explains why it believes the population projected to utilize the proposed in-center dialysis services needs the services, summarized as follows:

- **Population Growth.** The applicant reviewed other areas of the county, and it was determined that proposed site in Garner would provide the identified patients convenient access to their dialysis services and support as well as easy access to other healthcare and social services. The applicant states that by relocating the stations from those two Wake County facilities(Wake Forest Dialysis and Oak City Dialysis) will allow for improved access in the identified area of the county, addressing the identified need.

- **Enhance Access to Care.** The applicant states patients dialysis can be a very time-consuming and physically demanding process and sometimes a difference of just a few minutes of travel time can make a significant difference to an individual patient. To make travel to dialysis (three times a week for in-center patients) more convenient for the patients identified in Exhibit C.3, it was determined that DaVita needs to provide a dialysis facility in Garner, in the southern part of Wake County. The applicant states that the twenty-nine in-center patients have indicated an interest in considering transfer to our proposed facility because it will reduce their travel time and/or be more convenient. The applicant states that this could have a positive effect on their quality of life, and also on their ability and willingness to be more compliant with their treatment schedule.

The information is reasonable and adequately supported for all the reasons described above.

Projected Utilization

In Section Q, Form C, page 84, the applicant provides projected utilization for Garner Dialysis, as illustrated in the following table.

	1st Full FY CY 2028	2nd Full FY CY2029
In-Center Patients		
# of Patients at the Beginning of the Year	29.00	29.58
# of Patients at the End of the Year	29.58	30.17
Average # of Patients during the Year	29.29	29.88
# of Treatments /Patients Year	148.20	148.20
Total # of Treatments	4,340.78	4,427.59

In Section Q, page 85-86, the applicant provides the assumptions and methodology used to project utilization, summarized below.

- The applicant states that twenty-nine (29) in-center patients that currently receive dialysis treatments at DaVita-operated facilities in Durham and Wake Counties and who live in Wake County have signed letters indicating they would consider transfer to Garner Dialysis.
- The applicant provided a table that summarized the breakdown of the patients' letters. The applicant proposes that there will be additional ESRD patients that live in the service area who receive dialysis treatments at Garner Dialysis.
- The applicant proposes that at least 29 of the patients who signed letters have been newly diagnosed with End Stage Renal Disease will transfer their care to Garner Dialysis upon project completion.
- The applicant states that the letters of support from patients indicate their willingness to transfer to a new facility is evidence of patient support and commitment.

- The applicant states that the projections for the in-center patients assumes growth at 2%, the Wake County Average Annual Change Rate for the Past Five Years (5- Year AACR) as indicated in Table 9B of the 2026 SMFP.
- The applicant states that the first full FY is projected to be January 1, 2028 to December 31, 2028. The second full FY is projected to be January 1, 2029 to December 31, 2029.
- The applicant states the following in-center patient projections assume growth at 2%, the Wake County Average Annual Change Rate for the Past Five Years (5- Year AACR) as indicated in Table 9B of the 2026 SMFP.
- The applicant states that the first full FY is projected to be January 1, 2028 to December 31, 2028. The second full FY is projected to be January 1, 2029 to December 31, 2029.

	IC Stations	IC Patients
Station count and patient census at the facility as of 01/01/2028	10	29
The facility’s patient census is projected forward a year to 12/31/2028. This is the ending census as of the end of FY1.		$29 \times 1.02 = 29.58$
The facility’s patient census is projected forward a year to 12/31/2029. This is the ending census as of the end of FY2.		$29.58 \times 1.02 = 30.17$

Projected patients for FY1 and FY2 are rounded to the nearest whole number.

Based on the calculations above, by the end of FY1 Garner Dialysis is projected to have:

- 30 patients / 10 certified stations = 3.00 patients / station
- $3.00 / 4 = 0.750$ or 75.0% utilization rate
- For Treatments /Patient/ Year:
 - Assumes patients receive treatment 3 times a week, 52 weeks a year
 - Includes a missed treatment rate of 5% ($3 \times 52 \times 0.95 = 148$)

The projected utilization of 3.0 patients per station per week at the end of FY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NC AC 14C.2203(a).

Projected utilization is reasonable and adequately supported based on the following:

- The applicant’s beginning patient census is based on and supported by letter from patients currently receiving dialysis treatment at the applicant’s existing dialysis facilities who have indicated an interest in transferring to the proposed Garner Dialysis facility.
- The applicant’s projected utilization in the first two years of operation is based on and supported by the 5-Year AACR for Wake County.

Access to Medically Underserved Groups

In Section C, page 27-29, the applicant states

“The facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and socioeconomic groups of patients in need of dialysis.”

In Section C, page 27, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	87.8%
Racial and ethnic minorities	65.4%
Women	40.5%
Persons with Disabilities	100.0%
Persons 65 and older	45.3%
Medicare beneficiaries	75.0%
Medicaid recipients	12.8%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the applicant’s history of providing service to all residents of the service area, including underserved groups who need dialysis services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

The applicant proposes to develop a new 10-station dialysis facility, Garner Dialysis, by relocating no more than four dialysis stations from Wake Forest Dialysis and no more than six dialysis stations from Oak City Dialysis.

In Section D, pages 33-36, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be met following completion of the project.

Wake Forest Dialysis

In Section D, page 33, the applicant provides the following table.

Wake Forest Dialysis Center		
County where the facility is located		Wake
1	Total number of existing , approved, and proposed dialysis stations as of the application deadline	20
2	Number of existing dialysis stations to be reduced , relocated or eliminated in this proposal	4
3	Total number of dialysis stations upon completion of this project and all other projects involving this facility (you should be able to subtract Line 2 from Line 1; if you cannot, explain why not)	16

Source: Section D, page 33

- The applicant states the facility’s December 2025 ESRD Data Collection form showed there were 65 in-center hemodialysis (ICHD) patients at Wake Forest Dialysis Center as of December 31, 2025. In Project ID# J-12556-24, Total Renal Care of North Carolina, LLC is approved to develop Tarheel Place Dialysis in Wake County.
- The applicant states that 48 patients live in the service area, Wake County , and 17 live outside of the service area. There were also 8 peritoneal dialysis (PD) patients.
- The applicant states that the projections for ICHD patients project a 2.0% growth rate for patients who live in Wake County. This is the 5-Year AACR for Wake County as indicated in Table 9B of the 2026 SMFP.
- The applicant does not project any growth for ICHD patients living outside of Wake County.
- The applicant states that in Project ID# J-12556-24, Total Renal Care of North Carolina, LLC is approved to develop Tarheel Place Dialysis in Wake County, with a projected certification date of January 1, 2027 for the project. In its application, DaVita indicated the following:
 - Six (6) stations would be relocated from Wake Forest Dialysis to Tarheel Place Dialysis.
 - Four (4) in-center patients would transfer their care from Wake Forest Dialysis to Tarheel Place Dialysis.

- The applicant states that in Project ID# J-12581-24, Total Renal Care of North Carolina, LLC is approved to add 3 stations. These stations will serve as a backfill for the relocation of stations to Tarheel Place Dialysis.
- It is projected that 3 Wake County ICHD patients will transfer to Garner Dialysis upon the facility’s certification.
- The period of growth begins January 1, 2026 and is calculated forward to December 31, 2029.

In Section D, page 34, the applicant provides a table showing the projected utilization for Wake Forest Dialysis through the first two project years, as summarized below.

	ICHD Stations	ICHD Patients
Wake Forest Dialysis begins with 65 patients dialyzing on 23 stations at the facility as of 01/01/2026.	23	$48 + 17 = 65$
The facility’s Wake County patient census is projected forward a year.		$48 \times 1.020 = 48.960$
The patients from outside Wake County are added to the facility’s census. This is the ending census as of 12/31/2026.		$48.96 + 17 = 65.96$
Tarheel Place Dialysis is projected to be certified on 01/01/2027 <ul style="list-style-type: none"> • Six stations will be relocated (Proj ID# J-12556-24) • Three stations will be added (Proj ID# J-12581-24) • Four Wake County patients are projected to transfer out This is the census for Wake County patients as of 01/01/2027	$23 - 6 + 3 = 20$	$48.96 - 4 = 44.96$
The patients from outside Wake County are added to the facility’s census. This is the station count and in-center census on 01/01/2027.	20	$44.96 + 17 = 61.96$
The facility’s Wake County patient census is projected forward a year.		$44.96 \times 1.020 = 45.859$
The patients from outside Wake County are added to the facility’s census. This is the ending census as of 12/31/2027.		$45.86 + 17 = 62.86$
Garner Dialysis is projected to be certified on 01/01/2028 <ul style="list-style-type: none"> • Four stations will be relocated • Three Wake County patients are projected to transfer out This is the census for Wake County patients as of 01/01/2028	$20 - 4 = 16$	$45.86 - 3 = 42.86$
This is the station count and in-center census on 01/01/2028.	16	$42.86 + 17 = 60.72$
The facility’s Wake County patient census is projected forward a year.		$42.86 \times 1.020 = 43.71638$
The patients from outside Wake County are added to the facility’s census. This is the ending census as of the end of FY1.		$43.72 + 17 = 60.72$
The facility’s Wake County patient census is projected forward a year.		$43.72 \times 1.020 = 44.59071$
The patients from outside Wake County are added to the facility’s census. This is the ending census as of the end of FY2.		$44.59 + 17 = 61.59$

Source: Section D, page 34 of the application

The applicant projects to serve 61 patients on 16 stations, which is 3.81 patients per station per week (61 patients/ 16 stations= 3.81), or $3.81 / 4 = .9531$ or 95.31% utilization rate as of January 1, 2027.

Projected utilization is reasonable and adequately supported based on the following:

- The applicant projects growth of the Wake County patient population using a 2% growth rate, which is consistent within 5-Year AACR for Wake County in the 2026 SMFP.
- The applicant’s projections are based on the historical patient census and adjusted for the projected transfer of stations and patients in previously approved projects.

Oak City Dialysis

In Section D, page 34, applicant provides a table showing the number of dialysis stations at Oak City Dialysis as summarized below.

Oak City Dialysis		
County where the facility is located		Wake
1	Total number of existing approved, and proposed dialysis stations as of the application deadline	28
2	Number of existing dialysis stations to be reduced, relocated or eliminated in this proposal	6
3	Total number of dialysis stations upon completion of this project and all other projects involving this facility (you should be able to subtract Line 2 from Line 1; if you cannot, explain why not)	22

- The applicant states the facility’s December 2025 ESRD Data Collection form showed there were 91 in-center hemodialysis (ICHD) patients at Oak City Dialysis as of December 31, 2025.
- The applicant states that of the 91 patients, 81 lived in Wake County, and 10 lived outside of the service area. There were also 12 HHD patients and 16 PD patients.

Projected utilization is reasonable and adequately supported based on the following:

The applicant states that the projections for ICHD patients assume a 2.0% growth rate for patients who live in Wake County. This is the 5YAACR for Wake County as indicated in Table 9B of the 2026 SMFP. The projections assume no growth rate for ICHD patients living outside of Wake County.

The applicant states that in Project ID# J-12556-24, Total Renal Care of North Carolina, LLC is approved to develop Tarheel Place Dialysis in Wake County, with a projected certification date of January 1, 2027 for the project. In its application, DaVita indicated the following:

- Four (4) stations would be relocated from Oak City Dialysis to Tarheel Place Dialysis
- Twenty-one (21) in-center patients would transfer their care from Oak City Dialysis to Tarheel Place Dialysis
- The applicant states that it is projected that 14 Wake County ICHD patients will transfer to Garner Dialysis upon the facility's certification.
- The applicant states that the period of growth begins January 1, 2026 and is calculated forward to December 31, 2029:

In Section D, page 35, the applicant provides a table showing the number of dialysis stations at Oak City Dialysis as summarized below.

	ICHD Stations	ICHD Patients
Oak City Dialysis begins with 91 patients dialyzing on 32 stations at the facility as of 01/01/2026.	32	$81 + 10 = 91$
The facility's Wake County patient census is projected forward a year.		$81 \times 1.020 = 82.620$
The patients from outside Wake County are added to the facility's census. This is the ending census as of 12/31/2026.		$82.62 + 10 = 92.62$
Tarheel Place Dialysis is projected to be certified on 01/01/2027 <ul style="list-style-type: none"> • 4 stations will be relocated (Proj ID# J-12556-24) • 21 Wake County patients are projected to transfer out This is the census for Wake County patients as of 01/01/2027	$32 - 4 + = 28$	$82.62 - 21 = 61.62$
The patients from outside Wake County are added to the facility's census. This is the station count and in-center census on 01/01/2027.	28	$61.62 + 10 = 71.62$
The facility's Wake County patient census is projected forward a year.		$61.62 \times 1.020 = 62.852$
The patients from outside Wake County are added to the facility's census. This is the ending census as of 12/31/2027.		$62.85 + 10 = 72.85$
Garner Dialysis is projected to be certified on 01/01/2028 <ul style="list-style-type: none"> • 6 stations will be relocated • 14 Wake County patients are projected to transfer out This is the census for Wake County patients as of 01/01/2028	$28 - 6 = 22$	$62.85 - 14 = 48.85$
This is the station count and in-center census on 01/01/2028.	22	$48.85 + 10 = 58.85$
The facility's Wake County patient census is projected forward a year.		$48.85 \times 1.020 = 49.829$
The patients from outside Wake County are added to the facility's census. This is the ending census as of the end of FY1.		$49.83 + 10 = 59.83$
The facility's Wake County patient census is projected forward a year.		$49.83 \times 1.020 = 50.826$
The patients from outside Wake County are added to the facility's census. This is the ending census as of the end of FY2.		$50.83 + 10 = 60.83$

The applicant states that by the end of OY1 Oak city Dialysis is projected to have:

- 60 patients / 22 certified stations = 2.727 patients / station
- $2.73 / 4 = .68181$ or 68.18% utilization rate

On page 35, the applicant states that the applicant will submit additional Certificate of Need applications based on facility needs as the facility approaches full capacity of stations to ensure that the needs of the facility's patients will continue to be met.

Access to Medically Underserved Groups

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use dialysis services at Wake Forest Dialysis and Oak City Dialysis will be adequately met following completion of the project for the following reasons:

- The applicant states that the relocation of stations from Wake Forest Dialysis and Oak City Dialysis will have no effect on the ability of low-income persons, racial and ethnic minorities, women, disabled persons, and other under-served group and the elderly to obtain need health care.
- The applicant states that Wake Forest Dialysis and Oak City Dialysis by policy will continue to make dialysis services available to all residents its service area without qualifications.
- The applicant states that Wake Forest Dialysis and Oak City Dialysis will continue to assist uninsured/underinsured patients with identifying and applying for financial assistance: therefore, services are available to all patients including low- income persons, racial and ethnic minorities, women, disabled persons, elderly and other underserved persons.

The applicant adequately demonstrates the needs of medically underserved groups will be adequately met following completion of the project based on applicant history of providing care to these groups.

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

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.

- (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.

The applicant proposes to develop a new 10-station dialysis facility, Garner Dialysis, by relocating no more than four dialysis stations from Wake Forest Dialysis and no more than six dialysis stations from Oak City Dialysis.

In Section E, page 39, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- **Maintain the Status Quo.** The applicant states maintaining the status quo does not serve to meet the needs of a growing in-center patient population served by DaVita in Wake County, specifically in the identified region of the service area.
- **Locating a facility in another area of Wake County.** The applicant states that the site proposed for the new facility was selected because it will allow us to provide better geographic access to the patient population identified and reflected in the patient letters at C-3. The applicant states that a facility located in another area of Wake County would not address the needs of the patients identified.

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

- The applicant states that its proposal is the most effective alternative because a facility located in another area of Wake County would not address the need of the patients identified.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

1. **Total Renal Care of North Carolina, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**

- 2. The certificate holder shall develop a new 10-station dialysis facility, Garner Dialysis, by relocating no more than four dialysis stations from Wake Forest Dialysis and no more than six dialysis stations from Oak City Dialysis.**
 - 3. Upon completion of the proposed project, the certificate holder shall take the necessary steps to decertify four stations at Wake Forest Dialysis for a total of no more than 16 in-center stations upon completion of the project.**
 - 4. Upon completion of the proposed project, the certificate holder shall take the necessary steps to decertify six stations at Oak City Dialysis for a total of no more than 22 in-center stations upon completion of the project.**
 - 5. Progress Reports**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on August 1, 2026.**
 - 6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein for 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, Garner Dialysis, by relocating no more than four dialysis stations from Wake Forest Dialysis and no more than six dialysis stations from Oak City Dialysis.

Capital and Working Capital Costs

In Section Q, Form F.1a page 91, the applicant projects the total capital cost of the project, as shown in the table below.

Site Preparation	\$37,565
Construction/Renovation Contract(s)	\$1,946,661
Architect/Engineering Fees	495,620
Medical Equipment	\$183,790
Non-Medical Equipment	\$514,792
Furniture	\$92,705
Interest during Construction	\$77,501
Total Capital Cost	\$2,948,634

In Section Q, page 92, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant states that the Team Genesis Project Management is DaVita's team of Project Managers throughout the nation working with Real Estate, Operations, Teammates, Architects, Contractors and Procurement providing due diligence, design, construction documents, permits, construction and equipment/fixtures for DeNovo's, relocations, expansions and major renovation projects. The Project Manager for North Carolina partnered with Finance to develop the capital cost for this project.
- The applicant states that they use a corporate model and regional database along with inputs from operations and the regional Real Estate team to ensure project costs are reasonable. For this project, those inputs include a ground up design for a facility that will support at least 10 dialysis stations.

In Section F, pages 42-43, the applicant projects that start-up costs will be \$191,565 and initial operating expenses will be \$603,984 for a total working capital of \$795,549. On page 43, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant states that prior to opening, start-up expenses will include purchasing an inventory of consumable supplies as well as staff labor and training in the timeframe between the completion of leasehold improvements and certification.
- The staffing expenses will consist of salaries and benefits for a three-month period. The amount of staff training expenses will be less if any of the teammates facilities in the region transfer to the new facility. It is anticipated that some of the teammates will transfer. The applicant states that it is not known how many will be transferred and how many new hires will be required.

- The initial operating expenses are calculated to be approximately 50% of the annual budget of OY1.

Availability of Funds

In Section F, page 45, the applicant states that the capital cost will be funded by accumulated reserves. Exhibit F-2c contains a letter dated December 29, 2025, from the Chief Accounting Officer of DaVita Inc. committing \$3,744,183 for the capital cost, start-up and initial operating expenses for the proposed project. DaVita Inc. is the parent company and 100% owner of Total Renal Care, Inc., which owns 85% of the ownership interests in Total Renal Care of North Carolina, LLC. In Exhibit F-2 In Exhibit F.2, the applicant provides a balance sheets for DaVita, Inc., which shows the December 2023 and 2024, DaVita inc., had adequate cash and assets to finance the capital and working capital costs of the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the documentation in Exhibit F.2 of the application.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, page 92, the applicant projects that revenues will exceed operating expenses in the first two full fiscal years following completion of the project, as shown in the table below.

	1st Full Fiscal Year	2nd Full Fiscal Year
Total # of Treatments	4,341	4,428
Total Gross Revenues	\$1,543,787	\$1,574,662
Total Net Revenue	\$1,539,579	\$1,570,370
Average Net Revenue per Treatment	\$356	\$356
Total Operating Costs	\$1,207,969	\$1,234,331
Average Operating Expense per Treatment	\$355	\$355
Net Income	\$331,610	\$336,039

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Form F.2, F.3, and F.4 in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant adequately explains the assumptions used to project revenue, such as projected reimbursement rates and operating costs, such as salaries.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
 - 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 revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to develop a new 10-station dialysis facility, Garner Dialysis, by relocating no more than four dialysis stations from Wake Forest Dialysis and no more than six dialysis stations from Oak City Dialysis.

On page 107, the 2026 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Wake County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on pages 124-125 of the 2026 SMFP, there are 21 existing or approved dialysis facilities in Wake County as shown in the following table:

Wake County			
Facility	Certified Stations 12/31/2024	# of In-Center Patients 12/31/2024	Utilization Rate 12/31/2024
BMA of Fuquay Varina Kidney Center	29	93	80.17%
BMA of Raleigh Dialysis	50	120	60.00%
Cary Kidney Center	29	84	72.41%
Downtown Raleigh Dialysis	0	18	0.00%
FMC Eastern Wake	15	60	100.00%
FMC Morrisville	13	45	86.54%
FMC New Hope Dialysis	36	116	80.56%
FMC Northern Wake	20	57	71.25%
FMC Wake Dialysis Clinic	50	150	75.00%
Fresenius Kidney Care Holly Springs	10	36	90.00%
Fresenius Kidney Care Knightdale	0	0	0.00%
Fresenius Medical Care Apex	20	66	82.50%
Fresenius Medical Care Central Raleigh	19	50	65.79%
Fresenius Medical Care Millbrook	17	63	92.65%
Fresenius Medical Care Rock Quarry	0	0	0.00%
Fresenius Medical Care White Oak	20	72	90.00%
Oak City Dialysis	32	78	60.94%
Southwest Wake County Dialysis	30	105	87.50%
Tarheel Place Dialysis	0	0	0.00%
Wake Forest Dialysis Center	21	81	96.43%
Zebulon Kidney Center	30	79	65.83%

Source: Table 9A of the 2026 SMFP, pages 124-125.

In Section G, page 49, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved services in Wake County. The applicant states:

“This certificate of need application does not propose to increase the number of stations in Wake County. Transferring a total of ten stations from Wake Forest Dialysis Center and Oak City Dialysis will create a new facility at a different location to better serve patients identified, but it will not result in the duplication of existing services.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The proposal would not result in an increase in the number of certified dialysis stations in Wake County.
- The applicant adequately demonstrates that the proposed relocation of existing certified dialysis stations is needed.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop a new 10-station dialysis facility, Garner Dialysis, by relocating no more than four dialysis stations from Wake Forest Dialysis and no more than six dialysis stations from Oak City Dialysis.

In Section Q, on Form H, page 99, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	1st Full FY CY2028	2nd Full FY CY2029
Administrator	1.00	1.00
Registered Nurses (RN)	1.25	1.25
Licensed Practical Nurses (LPN)	0.00	0.00
Home Training Nurse	0.00	0.00
Technicians (PCT)	3.75	3.75
Medical Records	0.00	0.00
Dietician	0.50	0.50
Social Worker	0.50	0.50
Housekeeping	0.00	0.00
Maintenance	0.00	0.00
Administration/Business Office	0.50	0.50
Other (Describe) Biomedical Tech	0.50	0.50
Total	8.00	8.00

The assumptions and methodology used to project staffing are provided in Section Q, page 100. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 in Section Q. In Section H, pages 51-52, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant projects sufficient operating expenses for the staff proposed by the applicant.
- The applicant describes the methods it uses to attract qualified staff which will enable the facility to maintain staff levels.
- The applicant describes the required qualifications for staff, continuing education, and other training programs.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop a new 10-station dialysis facility, Garner Dialysis, by relocating no more than four dialysis stations from Wake Forest Dialysis and no more than six dialysis stations from Oak City Dialysis.

Ancillary and Support Services

In Section I, page 54, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 55-56, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I, page 56, the applicant describes its existing and proposed relationships with several healthcare providers and social service agencies in the county. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system because the applicant has existing relationships with healthcare providers and social service providers in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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

- (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

The applicant proposes to develop a new 10-station dialysis facility, Garner Dialysis, by relocating no more than four dialysis stations from Wake Forest Dialysis and no more than six dialysis stations from Oak City Dialysis.

In Section K, page 61, the applicant states that the project involves renovating approximately 6,750 square feet of existing space. Line drawings are provided in Exhibit K-2 .

On pages 63-64, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. The site appears to be suitable for the proposed dialysis facility based on the applicant's representations.

In Section K, pages 61-62, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on DaVita's development department implements several strategies relative to the design and construction of new facilities that work to maximize energy efficiency, water conservation and sustainability.

On page 62, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states that the costs and charges to the public for the proposed services are not expected to be unduly increased by the proposed project given that the majority of patients served by the facility are covered by Medicare and/or Medicaid.
- The applicant states that the capital expenditures for the proposed project are not costs that can be passed along to the public

On pages 62-63, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit k.3.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

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

(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 ... persons [with disabilities], 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, pages 66-67, the applicant provides the historical payor mix during CY2025 for its existing services at Wake Forest Dialysis and Oak City Dialysis, as shown in the table below.

Payor Source	Wake Forest Dialysis Center CY2025					
	In-center Dialysis		Home Hemodialysis **		Peritoneal Dialysis **	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Insurance*	5	7.7%	0	0.0%	2	25.0%
Medicare*	53	81.5%	0	0.0%	5	62.5%
Medicaid*	5	7.7%	0	0.0%	1	12.5%
Other-VA	2	3.1%	0	0.0%	0	0.0%
Total	65	100.0%	0	0.0%	8	100.0%

*Including any managed care plans

** This is not the number of patients trained in a year. Provide the total number of patients performing their hemodialysis or peritoneal dialysis in a location other than the dialysis facility.

Payor Source	Oak City Dialysis CY2025					
	In-center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Insurance*	12	13.2%	6	54.5%	8	53.3%
Medicare*	64	70.3%	4	36.4%	4	26.7%
Medicaid*	15	16.5%	1	9.1%	3	20.0%
Other-VA	0	0.0%	0	0.0%	0	0.0%
Total	91	100.0%	11	100.0%	15	100.0%

*Including any managed care plans

** This is not the number of patients trained in a year. Provide the total number of patients performing their hemodialysis or peritoneal dialysis in a location other than the dialysis facility.

In Section L, pages 67-68, the applicant provides the following comparison.

Wake Forest Dialysis Center	Last Full FY Submission of the Application	
	Percentage of Total Patients Served	Percentage of the Population of the Service Area
Female	36.4%	51.0%
Male	63.6%	49.0%
Unknown	0.0%	0.0%
64 and Younger	43.8%	86.3%
65 and Older	56.3%	13.7%
American Indian	0.0%	0.9%
Asian	1.6%	10.2%
Black or African American	62.9%	20.3%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	33.9%	65.5%
Other Race	1.6%	3.0%
Declined/ Unavailable	NA	NA

Source: Section L, page 67

Oak City Dialysis	Last Full FY Submission of the Application	
	Percentage of Total Patients Served	Percentage of the Population of the Service Area
Female	43.3%	51.0%
Male	56.7%	49.0%
Unknown	0.0%	0.0%
64 and Younger	61.9%	86.3%
65 and Older	38.1%	13.7%
American Indian	0.0%	0.9%
Asian	3.1%	10.2%
Black or African American	60.8%	20.3%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	35.1%	65.5%
Other Race	1.0%	3.0%
Declined/ Unavailable	NA	NA

Source: Section L, page 68

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 68, the applicant states it has no such obligation.

In Section L, page 68, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights equal

access complaints have been filed against Wake Forest Dialysis Center or Oak City Dialysis.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 69, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Garner Dialysis Projected Payor Mix CY2029		
	IC	
Payor Source	# Patients	% Patients
Insurance*	3.29	10.9%
Medicare*	22.63	75.0%
Medicaid*	3.87	12.8%
Other-VA	0.39	1.3%
Total	30.17	100.0%

*Including any managed care plans
Source: Section L, page 69

As shown in the table above, during the second full fiscal year of operation, the applicant projects 75.0% of the services will be provided to Medicare patients and 12.8% to Medicaid patients.

On page 69, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical experience of the two dialysis facilities from which the dialysis stations will be relocated.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, page 70, the applicant adequately describes the range of means by which patients will have access to the proposed services and provides supporting documentation in Exhibit L-5.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop a new 10-station dialysis facility, Garner Dialysis, by relocating no more than four dialysis stations from Wake Forest Dialysis and no more than six dialysis stations from Oak City Dialysis.

In Section M, page 72, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the applicant provides a copy of a letter sent to Wake Technical Community College offering the facility as a training site for nursing students.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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, Garner Dialysis, by relocating no more than six dialysis stations from Wake Forest Dialysis and no more than four dialysis stations from Oak City Dialysis.

On page 107, the 2026 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Wake County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on pages 124-125 of the 2026 SMFP, there are 21 existing or approved dialysis facilities in Wake County as shown in the following table:

Wake County			
Facility	Certified Stations 12/31/2024	# of In-Center Patients 12/31/2024	Utilization Rate 12/31/2024
BMA of Fuquay Varina Kidney Center	29	93	80.17%
BMA of Raleigh Dialysis	50	120	60.00%
Cary Kidney Center	29	84	72.41%
Downtown Raleigh Dialysis	0	18	0.00%
FMC Eastern Wake	15	60	100.00%
FMC Morrisville	13	45	86.54%
FMC New Hope Dialysis	36	116	80.56%
FMC Northern Wake	20	57	71.25%
FMC Wake Dialysis Clinic	50	150	75.00%
Fresenius Kidney Care Holly Springs	10	36	90.00%
Fresenius Kidney Care Knightdale	0	0	0.00%
Fresenius Medical Care Apex	20	66	82.50%
Fresenius Medical Care Central Raleigh	19	50	65.79%
Fresenius Medical Care Millbrook	17	63	92.65%
Fresenius Medical Care Rock Quarry	0	0	0.00%
Fresenius Medical Care White Oak	20	72	90.00%
Oak City Dialysis	32	78	60.94%
Southwest Wake County Dialysis	30	105	87.50%
Tarheel Place Dialysis	0	0	0.00%
Wake Forest Dialysis Center	21	81	96.43%
Zebulon Kidney Center	30	79	65.83%

Source: Table 9A of the Proposed 2026 SMFP, pages 124-125

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 74, the applicant states:

“The proposed facility will not have an adverse effect on competition since the patients already being served by DaVita will be transferring their care from one DaVita facility to another DaVita facility, which will be more convenient for the patients who have indicated this in the letters they signed.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 74, the applicant states:

“The development of Garner Dialysis will enhance accessibility to dialysis for current and projected patients and, by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services.”

See also Sections C, F, H, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 74, the applicant states:

“DaVita is committed to providing quality care to the ESRD population and, by policy, works to make every reasonable effort to accommodate all of its patients.”

See also Sections B and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 74, the applicant states:

“...the facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and, by policy, works to make every reasonable effort to accommodate all of its patients.”

See also Section C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

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

C

In Section Q, Form O, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 108 of this type of facility located in North Carolina.

In Section O, page 78, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 108 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (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.

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new dialysis facility for in-center hemodialysis services shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first full fiscal year of operation following certification of the facility. An applicant may document the need for fewer than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for fewer than 10 stations.*

- C- In Section C, page 24, the applicant projects 30 in-center patients will be served by the proposed facility by the end of the first operating year, FY2028 for utilization rate of 3.00 patients per station per week or 75.0% (30 patients / 10 stations = 3.0 patients per station / 4 = 0.750). the projected utilization of 3.00

patients per station per week exceeds the 2.8 in-center patients per station threshold required by this rule.

(b) *An applicant proposing to increase the number of in-center dialysis stations in:*

(1) *an existing dialysis facility; or*

(2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first full fiscal year of operation following certification of the additional stations.*

-NA- The applicant is proposing to establish a new ESRD facility.

(c) *An applicant proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.*

-NA- The applicant does not propose to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis. Therefore, this Rule does not apply.

(d) *An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the additional stations.*

-NA- The applicant is not proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training.

(e) *The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.”*

-C- In Section C, page 23, and Section Q, pages 85-86, the applicant provides the assumption and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.