

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 1, 2017

Findings Date: June 1, 2017

Project Analyst: Julie Halatek

Team Leader: Fatimah Wilson

Project ID #: A-11316-17

Facility: Graham County Dialysis

FID #: 170126

County: Graham

Applicant: Total Renal Care of North Carolina, LLC

Project: Develop a new five-station dialysis facility pursuant to an adjusted need determination and offer home peritoneal dialysis training and support

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC (TRC-NC) proposes to develop a new five-station dialysis facility, Graham County Dialysis (GCD), pursuant to an adjusted need determination in the 2017 State Medical Facilities Plan (SMFP). The applicant also proposes to offer home peritoneal dialysis (PD) training and support.

Need Determination

Graham County is part of the Cherokee-Clay-Graham Multicounty Planning Area. The 2017 SMFP and the January 2017 Semiannual Dialysis Report (SDR) provide a Dialysis Station Adjusted Need Determination for Graham County. In the 2017 SMFP, Table 14A, on page 379, the adjusted need determination is stated as “*Minimum 5 stations; Maximum as projected*”

in the January 2017 SDR.” In the January 2017 SDR, Table B shows a need for four stations in Graham County and for one station in Clay County. *Table B: ESRD Dialysis Station Need Determinations by Planning Area* in the January 2017 SDR projects a total of 43.1 in-center dialysis patients and 17.1 home patients for the Cherokee-Clay-Graham Planning Area as of June 30, 2017.

On page 379, the 2017 SFMP states the following:

“In response to a petition, the State Health Coordinating Council approved an adjusted need determination for a minimum of five dialysis stations and a maximum projected as needed stations for Graham County in the Semiannual Dialysis Report available prior to the certificate of need application due date. Certificate of Need shall impose a condition requiring the approved applicant to document that it has applied for Medicare certification no later than three (3) years from the effective date on the certificate of need. Graham County will remain in the Cherokee-Graham-Clay service area.”

Policies

Policy GEN-3: Basic Principles on page 33 of the 2017 SMFP is applicable to this review because it is in response to an adjusted need determination. Policy GEN-3 states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 8-9, Section O, page 55, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B, page 9, Section C, pages 17-18, Section L, pages 48-52, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B, page 10, Section F, pages 25-30, Section N, page 54, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

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

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the adjusted need determination in the 2017 SMFP and the January 2017 SDR as well as Policy GEN-3. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

TRC-NC proposes to develop a new five-station dialysis facility, GCD, pursuant to an adjusted need determination in the 2017 SMFP. The applicant also proposes to offer home PD training and support.

Patient Origin

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

GCD will be a new facility in Graham County; therefore, it has no existing patient origin.

In Section C.1, page 14, the applicant provides the projected patient origin for GCD for in-center and PD patients for the first two operating years following completion of the project, as follows:

GCD – Projected Patient Origin – OYs 1 & 2						
County	OY 1 CY 2019		OY 2 CY 2020		County Patients as % of Total	
	In-Center	PD	In-Center	PD	OY1	OY2
Graham	15	4	16	5	95.0%	95.5%
Cherokee	1	0	1	0	5.0%	4.5%
Total	16	4	17	5	100.0%	100.0%

In Section C.1, pages 14-17, the applicant provides the assumptions and data utilized to project patient origin. Exhibit C-1 contains 14 letters of support from existing patients utilizing a TRC-NC facility in nearby counties.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section C.2, page 17, the applicant states the need for the proposed project is a result of an adjusted need determination petition, submitted by commissioners from Graham County, because of concerns about the amount of travel required for Graham County dialysis patients. Exhibit C-1 contains 14 letters of support from in-center patients, indicating they would consider transferring to the proposed dialysis facility. Additionally, Exhibit I-4 contains letters from local government officials and service providers, and the Agency received several letters of support mailed in regarding this project. In supplemental information received May 9, 2017, the applicant provided four additional letters of support from peritoneal dialysis patients living in Graham County, all of which indicated the patients would consider transferring care to the proposed dialysis facility.

Projected Utilization – In-Center Patients

In Section C.1, page 14, the applicant provides projected utilization during the first two years of operation following project completion, as illustrated in the table below:

GCD – Projected Patient Origin – OYs 1 & 2						
County	OY 1 CY 2019		OY 2 CY 2020		County Patients as % of Total	
	In-Center	PD	In-Center	PD	OY1	OY2
Graham	15	4	16	5	95.0%	95.5%
Cherokee	1	0	1	0	5.0%	4.5%
Total	16	4	17	5	100.0%	100.0%

In Section C.1, pages 14-16, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below:

- A petition for an adjusted need determination to add a new dialysis facility in Graham County was submitted to the State Health Coordinating Council (SHCC) by Graham County commissioners on July 28, 2016 (see Exhibit C-1). The petition cited transportation

difficulties, both in terms of physical travel as well as cost to the county of transporting patients, and the general difficulty the residents of Graham County have with access to healthcare. The petition was approved and the adjusted need determination is included in the 2017 SMFP and January 2017 SDR.

- The applicant assumes that all 14 of the patients who signed letters indicating a willingness to consider transfer will actually transfer to the proposed facility.
- The project is scheduled for completion on January 1, 2019. OY1 is CY 2019. OY2 is CY 2020.
- The applicant assumes that Graham County patients transferring to the proposed facility will remain part of the Graham County ESRD patient population, and will increase at a rate of 4.2 percent, the Five Year Average Annual Change Rate (AACR) for Graham County as published in the January 2017 SDR. The applicant also assumes that the increase commenced on January 1, 2017. In supplemental information received May 30, 2017, the applicant states:

“All of the patients who live in Graham County who are on dialysis are being treated at facilities operated by DaVita. All of those patients signed letters that they would consider transfer to the proposed Graham Dialysis. Therefore, [the applicant] made the assumption that would be reasonable to use the Five-Year Average Annual Change Rate of 4.2% for Graham County in calculating a projected future Graham County patient population. [The applicant] chose to begin the AACR on January 1, 2017 since it was published in the January 2017 Semiannual Dialysis Report.”

- No growth will be projected for patients living outside of Graham County, but they will be included in the facility census at appropriate times.

In its calculations, the applicant projects the patient population growth for Graham County starting on January 1, 2017, despite the application being submitted on March 15, 2017 and despite providing letters from patients signed as late as March 15, 2017.

In Section C.1, pages 15-16, the applicant provides the calculations used to arrive at the projected in-center patient census for OY1 and OY2 as summarized in the table below.

GCD	In-Center Dialysis
Begin with 14 in-center patients from Graham County, who are projected to transfer to GCD upon facility certification (January 1, 2019), but who are currently dialyzing elsewhere.	14
Graham County patient population is projected forward by one year to December 31, 2017, using the Five Year AACR for Graham County (4.2%).	$14 \times 1.042 = 14.588$
Graham County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR for Graham County (4.2%).	$14.588 \times 1.042 = 15.201$
The patient from Cherokee County is added. This is the beginning patient census for December 31, 2018.	$15.201 + 1 = 16.201$
Graham County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR for Graham County (4.2%).	$15.201 \times 1.042 = 15.839$
The patient from Cherokee County is added. This is the patient census for the end of OY 1 (December 31, 2019).	$15.839 + 1 = 16.839$
Graham County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR for Graham County (4.2%).	$15.839 \times 1.042 = 16.504$
The patient from Cherokee County is added. This is the patient census for the end of OY 2 (December 31, 2020).	$16.504 + 1 = 17.504$

The applicant projects to serve 16 in-center patients on 5 stations, which is 3.2 patients per station per week ($16 \text{ patients} / 5 \text{ stations} = 3.2$), by the end of OY1 and 17 in-center patients on 5 stations, which is 3.4 patients per station per week ($17 \text{ patients} / 5 \text{ stations} = 3.4$), by the end of OY2. This meets the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. Therefore, the applicant adequately demonstrates the need to develop a new five-station dialysis facility.

Projected Utilization-Home PD Patients

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

GCD – PD Patient Projected Utilization – OY1 & OY2		
Operating Year	Beginning Census of PD Patients	Ending Census of PD Patients
CY 2019 (OY1)	4	4
CY 2020 (OY2)	4	5

On page 16, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- In supplemental information received May 9, 2017, the applicant provided letters signed by four PD patients living in Graham County, all of which indicated that the patient would consider transferring to the proposed dialysis facility, if approved.
- The applicant assumes all of the patients who signed letters of support for the proposed facility will transfer their care to GCD upon certification.
- The applicant assumes that the PD patient population will not increase during the first operating year and will increase by one patient during the second operating year.

Projected PD utilization is based on reasonable and adequately supported assumptions regarding continued growth at GCD.

Home Hemodialysis

In Section I.1, page 38, the applicant indicates that home hemodialysis training will be provided through Asheville Kidney Center, and Exhibit I-2(a) includes a signed agreement between the applicant and Asheville Kidney Center, which states that Asheville Kidney Center will provide home hemodialysis training and support to any patients at GCD who may wish to use that modality. The applicant does not indicate anywhere else in the application that it plans to offer home hemodialysis training and support.

Access

In Section L.1(a), page 48, the applicant states that GCD, by policy, will make services available to all residents of its service area without qualifications and will “...serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability.” On page 49, the applicant projects the payor mix for the second operating year of the project, and it projects that 83.1 percent of projected patients will have some or all of their services paid for by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the proposed five-station facility, and demonstrates the extent to which all residents, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

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

NA

- (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.

CA

In Section E, page 24, the applicant describes the alternatives it considered prior to submitting this application for the proposed project, which include:

- Maintaining the Status Quo – the applicant states that maintaining the status quo results in the lost chance to provide outpatient dialysis services to Graham County dialysis patients in their home county. Therefore, this is not an effective alternative.

After considering the above alternative, the applicant states that given the adjusted need determination of five stations for Graham County, along with a lack of other providers of dialysis services in Graham County, the proposed project is the most effective alternative to meet the 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.

In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. 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 Graham County Dialysis shall materially comply with all representations made in the certificate of need application and in supplemental information received May 9, 2017, May 10, 2017, and May 30, 2017. In those instances where representations conflict, Total Renal Care of North Carolina, LLC d/b/a Graham County Dialysis shall materially comply with the last made representation.**
- 2. Total Renal Care of North Carolina, LLC d/b/a Graham County Dialysis shall develop and be certified for no more than five dialysis stations upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
- 3. Total Renal Care of North Carolina, LLC d/b/a Graham County Dialysis shall install plumbing and electrical wiring through the walls for no more than five dialysis stations, which shall include any home hemodialysis training or isolation stations.**
- 4. Total Renal Care of North Carolina, LLC d/b/a Graham County Dialysis shall document that it has applied for Medicare certification no later than three (3) years from the effective date on the certificate of need.**
- 5. Total Renal Care of North Carolina, LLC d/b/a Graham County Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to**

the Healthcare Planning and Certificate of Need Section 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

TRC-NC proposes to develop a new five-station dialysis facility, GCD, pursuant to an adjusted need determination in the 2017 SMFP.

Capital and Working Capital Costs

In Section F.1, page 25, the applicant projects \$894,096 in capital costs to develop the proposed project, summarized as follows:

GCD

Construction Contract	\$520,000
Water Treatment Equipment	\$60,000
Other Equipment/Furniture	\$264,096
Architect/Engineering Fees/Expenses	\$50,000
Total	\$894,096

In Section F.10, pages 28-29, the applicant states that it will have \$101,100 in start-up expenses and in Section F.11, page 29, the applicant states it will have six months of initial operating expenses totaling \$411,694. The total estimated working capital for the project is \$512,794.

Availability of Funds

In Section F.2, page 27, and Section F.13, pages 29-30, the applicant states it will finance the capital costs and working capital costs with accumulated reserves. Exhibit F-5 contains letters dated February 17, 2017, from the Chief Accounting Officer of DaVita, Inc., the parent company of TRC-NC, authorizing and committing \$1,406,890 in capital and working costs for the project.

Exhibit F-7 contains the Consolidated Financial Statements for DaVita Healthcare Partners, Inc. for the year ending December 31, 2016. These statements indicate that as of December 31, 2016, it had \$913,187,000 in cash and cash equivalents, \$18,741,257,000 in total assets and \$5,822,999,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

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

Projected Revenues and Operating Expenses		
GCD	Operating Year 1 CY 2019	Operating Year 2 CY 2020
Total Treatments	2,971	3,119
Total Gross Revenues (Charges)	\$963,935	\$1,016,632
Total Net Revenue	\$933,017	\$984,240
Total Operating Expenses (Costs)	\$823,387	\$857,603
Net Income	\$109,630	\$126,637

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

- (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

TRC-NC proposes to develop a new five-station dialysis facility, GCD, pursuant to an adjusted need determination in the 2017 SMFP.

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

Currently, the applicant is the only provider of dialysis services in the Cherokee-Clay-Graham Multicounty Planning Area. According to the January 2017 SDR, Smoky Mountain Dialysis Center in Cherokee County was serving 37 patients on 13 stations as of June 30, 2016, for a utilization rate 71.15 percent or 2.85 patients per station per week (37 patients / 13 stations = 2.85; $2.85 / 4 = 0.7115$ or 71.15%). According to the January 2017 SDR, Graham County has no dialysis stations and a deficit of four stations and Clay County has no dialysis stations and a deficit of one station. In the 2017 SMFP and January 2017 SDR, there is an adjusted need determination for a minimum of five dialysis stations, to be located in Graham County.

In Section C.1, pages 14-16, the applicant demonstrates that GCD will serve a total of 16 in-center patients at the end of Operating Year One (CY 2019) for a utilization rate of 80 percent or 3.2 patients per station per week (16 patients / 5 stations = 3.2; $3.2 / 4 = .80$ or 80%). The projected utilization of 3.2 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C.2203(b).

The applicant adequately demonstrates the need to develop a new five-station dialysis facility based on the number of in-center patients it proposes to serve. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Graham County. Consequently, the application is conforming to this criterion.

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

C

In Section H.1, page 33, the applicant provides the proposed staffing for the new facility, which includes 5.4 full-time equivalent (FTE) employee positions, summarized as follows:

GCD Proposed Staffing	
Position	Projected # of FTE Positions
Medical Director*	
RN	1.5
Patient Care Technician	1.5
Administrator	0.5
Dietitian	0.2
Social Worker	0.2
Home Training RN	0.3
Admin. Assistant	1.0
Biomed Technician	0.2
Total FTE Positions	5.4

*The Medical Director is a contract position, not an FTE of the facility.

In Section H.3, page 35, the applicant describes its experience and process for recruiting and retaining staff. Section H.7, page 36, contains the applicant's projected direct care staffing hours for the second operating year following project completion.

Exhibit I-3 contains a copy of a letter dated March 13, 2017 from Dr. S. Bryson Fleming, stating that he has agreed to serve as Medical Director of GCD.

The applicant documents the availability of adequate health manpower and management personnel, including a Medical Director, to provide the proposed dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section I.1, page 38, the applicant includes a list of providers of the necessary ancillary and support services and indicates how they are or will be made available. Exhibits I-1 and I-2 contain documentation regarding the availability of laboratory services, home hemodialysis training and support services, numerous services to be provided by Mission Hospital, kidney transplant services, and local transit services. Exhibit I-3 contains a letter from Dr. S. Bryson Fleming agreeing to serve as the Medical Director for the facility. The applicant discusses coordination with the existing health care system in Sections I.3 and I.4, pages 39-40. 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. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (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 construct 1,618 square feet onto the existing building which currently houses the Graham County Department of Public Health [see Exhibit K-4(h) for details of property]. In Section F.1, page 25, the applicant lists the project costs, including \$520,000 for construction costs and \$374,096 in miscellaneous costs including water treatment equipment, furniture, and architect/engineering fees for a total project cost of \$894,096. In Section B.5, pages 11-13, the applicant describes its plans for energy-efficiency and water conservation. Costs and charges are described by the applicant in Section R at the end of the application. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

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. Therefore, the application is conforming to this criterion.

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

C

In Section L.1, pages 48-49, the applicant lists the ways TRC-NC helps provide access to dialysis services for the underserved populations of North Carolina and states its

policy to provide services to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and any other underserved group. In addition, the applicant describes its admission and financial policies in Section L.3, pages 49-51, and provides a copy of its admission policy in Exhibit L-3.

GCD is a new facility and has no historical patient payor mix. However, the patients projected to utilize GCD are existing dialysis patients in facilities operated by the applicant. In Section L.1, page 49, the applicant provides the projected payor mix for GCD, and states that the projections are based upon a combination of payor mixes from the existing patients at Smoky Mounty Dialysis in Cherokee County, Cherokee Dialysis in Swain County, and Sylva Dialysis in Jackson County. This payor mix is as follows:

GCD – Historical Combined Payor Mix – Local Facilities			
Payor Type	% Total Patients	% IC Patients	% PD Patients
Medicare	22.5%	23.4%	19.4%
Medicaid	6.9%	6.5%	8.3%
Commercial Insurance	10.0%	8.1%	16.7%
Medicare/Commercial	28.7%	27.4%	33.4%
Medicare/Medicaid	25.0%	28.1%	13.9%
VA	6.9%	6.5%	8.3%
Totals	100.0%	100.0%	100.0%

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

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Graham	22%	51%	13%	21%	7%	22%
Cherokee	27%	51%	8%	21%	15%	22%
Clay	28%	51%	6%	19%	11%	22%
Jackson	18%	51%	19%	24%	9%	25%
Swain	19%	52%	36%	19%	9%	23%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, [2014 Estimate as of December 22, 2015](#).

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

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 provides prevalence data on ESRD Network 6 dialysis patients by age, race, and gender on pages 27-28¹. The

¹http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

ESRD Network 6 service area contract, previously managed by Alliant Healthcare Solutions' Southeastern Kidney Council, was awarded to IPRO in April 2016 and is now called the IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6). IPRO SA Network 6 is still comprised of North Carolina, South Carolina, and Georgia. The 2015 Annual Report, submitted in November 2016 by IPRO differs somewhat from the reports submitted in the past by The Southeastern Kidney Council.

The statistics on number and percent of dialysis patients by age, gender, and race are now shown only in total for Network 6; the statistics are no longer separately shown for North Carolina in the report. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*² percentages for North Carolina and the total Network shows very little variance; therefore the statistics for the total Network 6 are representative of North Carolina's statistics. One would also assume the 2015 percentages for the total Network 6 should also very closely reflect North Carolina percentages by age, gender, and race. The following table shows the North Carolina and total Network data for 2014 as provided by the Southeastern Kidney Council, and compared with the IPRO 2015 Network totals.

Number and Percent of Dialysis Patients by Age, Race, and Gender – 2014 and 2015						
	2014 Patients and Percentages*				2015 Patients and Percentages**	
	NC Patients	NC Percentage	Total Network 6 Patients	Total Network 6 Percentage	Total Network 6 Patients	Total Network 6 Percentage
Age						
0-19	52	0.3%	137	0.3%	137	0.3%
20-34	770	4.8%	2,173	4.9%	2,142	4.7%
35-44	1,547	9.7%	4,385	9.9%	4,493	9.8%
45-54	2,853	17.8%	8,070	18.3%	8,422	18.3%
55-64	4,175	26.1%	11,706	26.5%	12,024	26.1%
65+	6,601	41.3%	17,716	40.1%	18,817	40.9%
Gender						
Female	7,064	44.2%	19,923	45.1%	20,805	45.2%
Male	8,934	55.8%	24,264	54.9%	25,230	54.8%
Race						
African-American	9,855	61.6%	29,191	66.1%	30,092	65.4%
White	5,778	36.1%	14,222	32.2%	15,049	32.7%
Other	365	2.3%	774	1.8%	894	1.9%

*2014 Calendar Year data from the Southeastern Kidney Council Network 6 2014 annual Report at <http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

**2015 Calendar Year data from the IPRO ESRD Network of the South Atlantic at http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian comparing with 85% of Network 6 patients being 45 and over and 69% being non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*). In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older and over 67% were non-Caucasian. (IPRO SA Network 6).

²<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

The applicant demonstrates that it currently provide adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

In Section L.3, page 51, the applicant states that it has no obligations under any federal regulations to provide uncompensated care or community service except those federal requirements of the Rehabilitation Act of 1973 and subsequent amendments. The applicant states that the facility has no Hill-Burton obligations.

In Section L.6, pages 51-52, the applicant states there have been no civil rights complaints filed against any TRC-NC facilities in North Carolina within the past five years. Therefore, the application is conforming to this criterion.

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

C

In Section L.1, page 49, the applicant provides the projected payor mix for the proposed project for the second operating year (CY 2020). The applicant states on page 49 that the projections are based upon a combination of payor mixes from the existing patients at Smoky MOUNTY Dialysis in Cherokee County, Cherokee Dialysis in Swain County, and Sylva Dialysis in Jackson County. The projected payor mix is illustrated as follows:

GCD – Historical Combined Payor Mix – Local Facilities			
Payor Type	% Total Patients	% IC Patients	% PD Patients
Medicare	22.5%	23.4%	19.4%
Medicaid	6.9%	6.5%	8.3%
Commercial Insurance	10.0%	8.1%	16.7%
Medicare/Commercial	28.7%	27.4%	33.4%
Medicare/Medicaid	25.0%	28.1%	13.9%
VA	6.9%	6.5%	8.3%
Totals	100.0%	100.0%	100.0%

As illustrated in the table above, the applicant projects that 83.1 percent of all of the patients receiving dialysis services at GCD in the second year of operation will have some or all of their services paid for by Medicare or Medicaid. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at GCD. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, page 51, the applicant describes the range of means by which a person will have access to the dialysis services at GCD. The applicant states that nephrologists with medical staff privileges will admit patients to the facility for dialysis. Referrals to these nephrologists may come from patients themselves, family, or friends. In Exhibit I-3, the applicant provides a letter signed by Dr. S. Bryson Fleming of Mountain Kidney & Hypertension Associates in Asheville, indicating his willingness to serve as Medical Director. Exhibit I-3 also contains letters of support from local nephrologists who state they plan to refer patients to GCD. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. 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 53, the applicant states it has offered the facility as a clinical learning site to nursing students at Tri-County Community College. Exhibit M-1 contains a letter from the applicant to Tri-County Community College's Department of Nursing, inviting the school to do clinical rotations for nursing students at its proposed facility. The information provided is reasonable and adequately supports a determination 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

TRC-NC proposes to develop a new five-station dialysis facility, GCD, pursuant to an adjusted need determination in the 2017 SMFP.

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

Currently, the applicant is the only provider of dialysis services in the Cherokee-Clay-Graham Multicounty Planning Area. According to the January 2017 SDR, Smoky Mountain Dialysis Center in Cherokee County was serving 37 patients on 13 stations as of June 30, 2016, for a utilization rate 71.15 percent or 2.85 patients per station per week (37 patients / 13 stations = 2.85; $2.85 / 4 = 0.7115$ or 71.15%). According to the January 2017 SDR, Graham County has no dialysis stations and a deficit of four stations and Clay County has no dialysis stations and a deficit of one station. In the 2017 SMFP and January 2017 SDR, there is an adjusted need determination for a minimum of five dialysis stations, to be located in Graham County.

In Section N.1, page 54, the applicant discusses how any enhanced competition will have a positive impact on cost-effectiveness, quality, and access to the proposed services. The applicant states:

“This certificate of need application is being submitted in response to a need determination for five dialysis stations in Graham County as indicated in the January 2017 Semiannual Dialysis Report in Table C. This is a great opportunity for patients since there is not a dialysis facility Graham County [sic].

The bottom line is Graham 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 [sic] involved in the dialysis process to receive services.”

See also Sections B, C, E, F, G, H, and L where the applicant discusses the impact of the project on cost-effectiveness, quality, and access.

The information in the application is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality, and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that it will continue to provide quality services. The discussion regarding quality found in Criteria (1), (3), and (20) is incorporated herein by reference.

- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1), (3), and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

In Exhibit O-3, the applicant identifies four of its 70+ North Carolina facilities (Southeastern Dialysis Center – Kenansville, Durham Dialysis, Marshville Dialysis, and Durham West Dialysis) as having been cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant states that all four facilities are back in full compliance with CMS Guidelines as of the date of submission of this application and provides copies of letters to each facility from the Agency’s Acute and Home Care Licensure and Certification Section that state each facility is back in compliance. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

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

C

The 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.

10 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.1, pages 15-16, the applicant adequately demonstrates that GCD will serve at least 16 in-center patients on 5 dialysis stations at the end of the first operating year, which is 3.2 patients per station per week, or a utilization rate of 80.0 percent ($16 / 5 = 3.2$; $3.2 / 4 = 0.80$ or 80.0%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.
- (b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- NA- The applicant is seeking to develop a new five-station dialysis facility.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 14-17, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.