

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 31, 2015

Findings Date: July 31, 2015

Project Analyst: Julie Halatek

Team Leader: Fatimah Wilson

Project ID #: A-11013-15

Facility: Smoky Mountain Dialysis Center

FID #: 050254

County: Cherokee

Applicant: Total Renal Care of North Carolina, LLC

Project: Add three dialysis stations for a total of 13 stations upon completion of this project

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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.

C

Total Renal Care of North Carolina, LLC d/b/a Smoky Mountain Dialysis Center (SMDC) proposes to add three dialysis stations for a total of 13 certified dialysis stations upon completion of this project.

Need Determination

Cherokee County is one of three counties in the Cherokee-Clay-Graham Planning Area and the only county in that planning area with a dialysis facility. The 2015 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2015 SDR, the Cherokee-Clay-Graham Planning Area (where SMDC is located) has a deficit of four stations. A deficit of at least 10 stations is required for a county need. However, the applicant

is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate reported for SMDC in the January 2015 SDR is 3.70 patients per station. This utilization rate was calculated based on 37 in-center dialysis patients and 10 certified dialysis stations as of June 30, 2014 (37 patients / 10 stations = 3.70 patients per station). Application of the facility need methodology indicates that up to four additional stations are potentially needed at this facility, as illustrated in the following table:

2015 SMFP Facility Need Methodology		
Required SDR Utilization		80%
SMDC Utilization Rate as of 6/30/2014		92.50%
Certified Stations		10
Pending Stations		0
Total Existing and Pending Stations		10
In-Center Patients as of 6/30/2014 (SDR2, January 2015 SDR)		37
In-Center Patients as of 12/31/2013 (SDR1, July 2014 SDR)		30
Step	Description	
	Difference (SDR2 - SDR1)	7
(i)	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/2013	0.4667
(ii)	Divide the result of Step (i) by 12	0.0389
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/2014 until 12/31/2014) for the January 2015 SDR	0.2333
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	45.6333
(v)	Divide the result of Step (iv) by 3.2 patients per station and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	4.2604

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

Policies

POLICY GEN-3: BASIC PRINCIPLES, on page 38 of the 2015 SMFP, is applicable to this review. 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 its proposal will promote safety and quality in Section I.13(c), pages 6-10; Section II.3, pages 19-20; Section V.2, pages 28-29; Section V.7, page 31; Section VII.3, page 38; Section XI.6(g), pages 57-58; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how its proposal will promote equitable access in Section II.1, page 15; Section V.7, page 31; Section VI, pages 32-36; and referenced exhibits. The applicant states in Sections VI.1(b) and VI.1(c), pages 32-33, that 90.32 percent of its dialysis patients have at least partial coverage through Medicare and/or Medicaid and projects that 90.32 percent of its in-center dialysis treatments will be covered in part by Medicare or Medicaid. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how its proposal will maximize healthcare value for resources expended in Section III.9, pages 24-25, and Sections XI.6(d)-(e) and XI.6(g), pages 57-58. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access, and maximize healthcare value for resources expended in meeting the facility need as identified by the applicant. Therefore, the applicant is consistent with Policy GEN-3.

Conclusion

The applicant adequately demonstrates that the proposal is consistent with POLICY GEN-3: BASIC PRINCIPLES and adequately demonstrates that the application is consistent with the

facility need determination in the January 2015 SDR. 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.

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Total Renal Care of North Carolina, LLC d/b/a Smoky Mountain Dialysis Center proposes to add three dialysis stations to its existing facility for a total of 13 certified dialysis stations upon completion of the proposed project.

Population to be Served

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county where the stations are located, with the exception of 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, in this application, the service area is Cherokee, Clay, and Graham counties. Dialysis facilities may serve residents of counties not included in their service area.

In Section IV.1, page 26, the applicant identifies the patient origin at SMDC as of June 30, 2014, as illustrated in the table below.

SMDC	
Patient Population as of June 30, 2014	
County/State	In-Center Patients
Cherokee	21
Clay	6
Graham	4
Macon	1
Georgia	3
Tennessee	2
TOTAL	37

In Section III.7, page 23, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table.

SMDC Projected Patient Origin				
County/State	OY 1 – 2016		OY 2 – 2017	
	In-Center Patients	In-Center Patients	OY 1	OY 2
Cherokee	26	28	61.9%	63.7%
Clay	6	6	14.3%	13.6%
Graham	4	4	9.5%	9.1%
Macon	1	1	2.4%	2.3%
Georgia	3	3	7.1%	6.8%
Tennessee	2	2	4.8%	4.5%
TOTAL	42	44	100.0%	100.0%

The applicant adequately identifies the population to be served.

Need Analysis

The applicant states that need for the proposed expansion is based on the following factors:

- SMDC is experiencing growth and expanding the facility will help meet the growing demand for dialysis services. See page 24 of the application.
- The applicant projects that SMDC will have 42 in-center patients at the end of Operating Year One (ending December 31, 2016), which is a utilization rate of 80.75 percent. See page 24 of the application.

Projected Utilization

In Section III.7, page 23, the applicant provides projected utilization of the expanded facility for Operating Years One and Two, as shown in the table below:

SMDC Projected Utilization – Operating Years One and Two				
County/State	OY 1 – 2016		OY 2 – 2017	
	In-Center Patients	In-Center Patients	OY 1	OY 2
Cherokee	26	28	61.9%	63.7%
Clay	6	6	14.3%	13.6%
Graham	4	4	9.5%	9.1%
Macon	1	1	2.4%	2.3%
Georgia	3	3	7.1%	6.8%
Tennessee	2	2	4.8%	4.5%
TOTAL	42	44	100.0%	100.0%

As shown in the table above, at the end of Operating Year 1, the applicant projects to serve 42 in-center dialysis patients on 13 certified dialysis stations, or 3.23 patients per station per week, which is a utilization rate of 80.75 percent [42 / 13 = 3.23; 3.23 / 4 = 0.8075 or 80.75%]. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

Assumptions and Methodology Used

In Section III.7, pages 23-24, the applicant states it uses the following assumptions to project utilization:

- As of June 30, 2014, SMDC had 37 in-center patients; 21 patients were residents of Cherokee County and the remaining 16 patients were residents of Clay, Graham, and Macon counties, as well as Georgia and Tennessee.
- The Average Annual Change Rate for Cherokee County, as published in Table B of the January 2015 SDR, is 9.3 percent.
- No growth calculations were performed for patients living outside of Cherokee County.
- Operating Year One = Calendar Year 2016.
- Operating Year Two = Calendar Year 2017.
- The applicant projects that the Cherokee County in-center patient population at SMDC will continue to grow at the published 9.3 percent Average Annual Change Rate.
- The number of patients calculated with the methodology is rounded down to the nearest whole number.

The applicant calculated growth starting on June 30, 2014 with 21 patients from Cherokee County. In Section III.7, pages 23-24, the applicant states the following regarding its calculations to project utilization by Cherokee County patients:

“June 30, 2014–December 31, 2014 – 21 patients X 1.0465 = 21.9765

January 1, 2015–December 31, 2015 – 21.9765 patients X 1.093 = 24.0203145

January 1, 2016–December 31, 2016 – 24.0203145 patients X 1.093 = 26.2542037

January 1, 2017–December 31, 2017 – 26.2542037 patients X 1.093 = 28.6958447”

By the end of Operating Year One, the applicant projects to serve 42 in-center patients (26 from Cherokee County and 16 from surrounding counties and states) dialyzing on 13 stations for a utilization rate of 80.75 percent or 3.23 patients per station [$42 / 13 = 3.23 / 4.0 = 0.8075$ or 80.75%]. The applicant projects 44 in-center patients (28 from Cherokee County and 16 from surrounding counties and states) will be dialyzing on 13 stations at the end of Operating Year Two for a utilization rate of 84.5 percent or 3.38 patients per station [$44 / 13 = 3.38 / 4.0 = 0.845$ or 84.5%], which exceeds the 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and adequately supported assumptions. The applicant adequately demonstrates the need the population to be served has for three additional dialysis stations at the SMDC facility.

Access to Services

In Sections VI.1(b) and VI.1(c), pages 32-33, the applicant provides the current and projected payor mix for the proposed services at SMDC, as shown in the table below. The applicant projects no change from the current payor mix upon project completion:

SMDC Current / Projected* Payor Mix	
Payor Source	% Gross Revenue In-Center Patients
Medicare	22.58%
Medicaid	9.68%
Medicare/Medicaid	22.58%
Commercial Insurance	6.45%
VA	3.23%
Medicare/Commercial	35.48%
Total	100.00%

*In Section VI.1(c), page 33, the table provided by the applicant appears to have an error where the percent of gross revenue by payor source is transposed down by one line. Based on the information provided in Section VI and throughout the application, the Project Analyst assumes that the table on page 33 should be identical to the table in Section VI.1(b) on page 32.

The applicant adequately demonstrates 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 proposed services.

Conclusion

In summary, the applicant adequately:

- Identifies the population it proposes to serve.
- Adequately demonstrates the need this population has for the proposed services.
- Demonstrates 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 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 III.9, pages 24-25, the applicant states the only alternative considered was to maintain the status quo. The applicant states: *“This alternative was dismissed since the facility is experiencing growth.”* Thus, the applicant concluded that the project as proposed was the most effective alternative to meet the need.

The applicant adequately demonstrates the need for three additional dialysis stations based on the facility’s projected utilization. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable. An application that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the need. Consequently, 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 Smoky Mountain Dialysis Center shall materially comply with all representations made in the certificate of need application.**
- 2. Total Renal Care of North Carolina, LLC d/b/a Smoky Mountain Dialysis Center shall develop no more than three additional stations for a total of no more than 13 certified stations upon completion of this project, which shall include any home hemodialysis or isolation stations.**
- 3. Total Renal Care of North Carolina, LLC d/b/a Smoky Mountain Dialysis Center shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations for a total of no more than 13 dialysis stations upon completion of this project, which shall include any home hemodialysis or isolation stations.**
- 4. Total Renal Care of North Carolina, LLC d/b/a Smoky Mountain Dialysis Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1(b), page 41, the applicant projects a capital cost of \$34,756 for the proposed project. In Section IX.1(a), page 46, the applicant states there will be no start-up or initial operating expenses associated with the proposed project because it is an existing facility.

In Section VIII.2, page 42, and Section VIII.5, page 44, the applicant states the entire capital cost of the project will be funded with accumulated reserves of DaVita HealthCare Partners, Inc. Exhibit 18 contains a letter dated March 10, 2015, signed by the Vice President of Tax for both DaVita HealthCare Partners, Inc., and Total Renal Care, Inc., which states that DaVita HealthCare Partners, Inc. is authorizing the use of \$34,756 from cash reserves to add three stations to SMDC.

In Exhibit 19, the applicant provides the audited financial statements for DaVita HealthCare Partners, Inc. for the years ending December 31, 2014 and December 31, 2013. As of December 31, 2014, DaVita HealthCare Partners, Inc. had \$965,241,000 in cash and cash equivalents, \$17,942,715,000 in total assets, and \$5,360,311,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In Section X.1, page 47, the applicant provides the allowable charges per treatment for each payor source for SMDC as follows:

SMDC	
Payor Source	Allowable Charge Per Treatment
Medicare	\$239.43
Medicaid	\$143.00
Medicare/Medicaid	\$239.43
Commercial Insurance	\$1,275.00
VA	\$193.00
Medicare/Commercial	\$239.43

The applicant provides, on page 47, a series of statements to further explain its assumptions for revenue calculations, which are summarized below.

- The Medicare reimbursement amount for the facility is 80 percent of the allowable charge of \$239.43, or \$191.54.
- The Center for Medicare and Medicaid Services has recommended no change in the reimbursement rate for the next two years but will provide guidance at a later date.

Because there has not been a decision on any future reimbursement rates, the Medicare rate of \$239.43 as documented in the Federal Register dated November 6, 2014 is used for future calculations.

- The Medicare rate of \$239.43 includes an 80 percent reimbursement rate of \$191.54 and a 20 percent patient responsibility of \$47.89. Because the applicant can't predict which Medicare-only patients will have that 20 percent written off because of a lack of ability to pay, the applicant does not include the 20 percent patient responsibility for Medicare-only patients to take a conservative approach to revenue calculations.
- The Commercial Insurance rate listed is the average amount of reimbursement received after any deductions are taken for contractual allowances.

In Sections X.2, page 48, and X.4, page 51, the applicant projects revenues and expenses for SMDC as follows:

SMDC Revenue/Expenses/Profit		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$1,729,219	\$1,813,537
Total Expenses	\$1,620,932	\$1,686,482
Net Profit	\$108,287	\$127,055

The applicant projects that revenue will exceed operating expenses in each of the first two operating years of the project. Projected charges, reimbursement rates, and contractual adjustments are reasonable and adequately supported. See Section X, pages 47-52, for the applicant's assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and operating expenses of the project, and that the financial feasibility of the proposal is based on reasonable projections of revenues and operating expenses. 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

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county where the stations are located, with the exception of 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, in this application, the service area is Cherokee, Clay, and Graham counties. Dialysis facilities may serve residents of counties not included in their service area.

Total Renal Care of North Carolina, LLC d/b/a Smoky Mountain Dialysis Center (SMDC) proposes to add three dialysis stations for a total of 13 certified dialysis stations upon completion of this project.

The applicant proposes to add three dialysis stations to its existing facility for a total of 13 certified dialysis stations upon completion of the proposed project. According to the January 2015 SDR, the Cherokee-Clay-Graham Planning Area (where SMDC is located) has a deficit of four stations. In this application, the applicant is applying for additional stations based on the facility need methodology.

The applicant operates the only existing dialysis facility located in the Cherokee-Clay-Graham Planning Area and there are no other approved facilities. As of June 30, 2014, SMDC was serving 37 patients weekly on 10 stations, which is 3.70 patients per station or 92.5 percent of capacity ($37 \text{ patients} / 10 \text{ stations} = 3.7$; $3.7 / 4 = 0.925$ or 92.5%). At the end of Operating Year One, SMDC projects that it will be serving 42 patients weekly on 13 stations, which is 3.23 in-center patients per station or 80.75 percent of capacity ($42 \text{ patients} / 13 \text{ stations} = 3.23$; $3.23 / 4 = 0.8075$ or 80.75%). This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates the need for three additional stations based on the number of in-center patients it currently serves and proposes to serve. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates the proposed project would not result in the unnecessary duplication of existing or approved dialysis services or facilities in the Cherokee-Clay-Graham Planning Area. 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.

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The following table illustrates current and projected staffing for SMDC, as provided by the applicant in Section VII.1, page 37:

SMDC			
Full-Time Equivalent (FTE) Positions			
Position	Current	Additional	Total
RN	2.0	0.0	2.0
Patient Care Technician	0.0	0.0	0.0
Bio-Med Technician	4.0	1.0	5.0
Medical Director*	0.5	0.0	0.5
Administrative	0.0	0.0	0.0
Dietician	1.0	0.0	1.0
Social Worker	0.5	0.0	0.5
Unit Secretary	0.5	0.0	0.5
Reuse	1.0	0.0	1.0
Total FTEs	9.5	1.0	10.5

*The applicant states on page 37 that the Medical Director is not an employee of the facility. There is a contract between the facility and the Medical Director for \$50,000 per year to carry out the responsibilities of Medical Director.

As shown in the above table, the applicant proposes to employ a total of 10.5 full-time equivalent positions to staff SMDC upon completion of the proposed project. In Section V.4(c), page 30, the applicant states that Dr. Matthew Volk will continue to serve as medical director of the facility. Exhibit 13 contains a letter from Dr. Volk stating his support for the expansion of SMDC.

In Section VII.10, page 40, the applicant provides the following table showing the projected number of direct care staff for each shift offered at SMDC after the addition of the three dialysis stations.

SMDC Direct Care Staff Per Shift							
	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6am to 11am	4	4	4	4	4	4
Afternoon	11am to 4pm	4	4	4	4	4	4

The applicant documents the availability of adequate health manpower and management personnel, including the medical director, for the provision of 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.

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In Section V.1, page 28, the applicant lists the providers of the necessary ancillary and support services. See Exhibits 9, 10, and 12 for documentation of service agreements. The applicant discusses coordination with the existing health care system on pages 30-31, stating that it has been providing dialysis services to many of the patients residing in Cherokee

County at SMDC, and that “...over the years [it has] *established relationships with other agencies in Cherokee County and surrounding counties.*” The applicant adequately demonstrates the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing healthcare 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.

NA

- (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 VI.1(b), page 32, the applicant reports that 90.32 percent of the patients who received treatments at SMDC had some or all of their services paid for by Medicare and/or Medicaid in the past year. The table below illustrates the current payor mix for the facility:

SMDC Current Payor Mix	
Payor Source	% Gross Revenue In-Center Patients
Medicare	22.58%
Medicaid	9.68%
Medicare/Medicaid	22.58%
Commercial Insurance	6.45%
VA	3.23%
Medicare/Commercial	35.48%
Total	100.00%

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for the Cherokee-Clay-Graham Planning Area and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population*	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population*	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center)*
Cherokee County	19.9%	9.6%	19.4%
Clay County	18.1%	8.9%	20.6%
Graham County	23.3%	11.7%	19.9%
Statewide	16.5%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, is not available.

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of

age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).¹

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race, or gender. But it does not include information on the number of elderly, handicapped, minorities, or women utilizing health services.

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, incl. not specified	365	2.3%

Source: Southeastern Kidney Council Network 6 Inc. 2014 Annual Report.²

The applicant demonstrates that it currently provides 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;

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¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

²<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

Recipients of Hill-Burton funds were required to provide uncompensated care, community service, and access by minorities and handicapped persons. In Section VI.1(f), page 34, the applicant states that SMDC has no obligations under any applicable federal regulation to fulfill.

In Section VI.6(a), page 36, the applicant states there have been no patient civil rights access complaints filed in the last 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 VI.1(c), page 33, the applicant provides the projected payor mix for the proposed services at SMDC as shown in the table below:

SMDC Projected* Payor Mix	
Payor Source	% Patients
Medicare	22.58%
Medicaid	9.68%
Medicare/Medicaid	22.58%
Commercial Insurance	6.45%
VA	3.23%
Medicare/Commercial	35.48%
Total	100.00%

*In Section VI.1(c), page 33, the table provided by the applicant appears to have an error where the percent of gross revenue by payor source is transposed down by one line. Based on the information provided in Section VI and throughout the application, the Project Analyst assumes that the table on page 33 should be identical to the table in Section VI.1(b) on page 32.

As shown in the table above, the applicant projects that 90.32 percent of in-center patients will have some or all of their services paid for by Medicare or Medicaid. The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. 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 VI.5(b), page 35, the applicant describes the range of means by which patients will have access to the proposed services. The information provided in Section

VI.5(b) is reasonable and credible and supports a finding of conformity with 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 V.3, page 41, the applicant states it has an established Student Training Agreement with Southwestern Community College. Exhibit 12 contains a copy of the Student Training Agreement. The information provided in Section V.3 and Exhibit 12 is reasonable and supports a finding of conformity 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

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county where the stations are located, with the exception of 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, in this application, the service area is Cherokee, Clay, and Graham counties. Dialysis facilities may serve residents of counties not included in their service area.

Total Renal Care of North Carolina, LLC d/b/a Smoky Mountain Dialysis Center (SMDC) proposes to add three dialysis stations for a total of 13 certified dialysis stations upon completion of this project.

The applicant proposes to add three dialysis stations to its existing facility for a total of 13 certified dialysis stations upon completion of the proposed project. According to the January 2015 SDR, the Cherokee-Clay-Graham Planning Area (where SMDC is located) has a deficit of four stations. In this application, the applicant is applying for additional stations based on the facility need methodology.

The applicant operates the only existing dialysis facility located in the Cherokee-Clay-Graham Planning Area and there are no other approved facilities. As of June 30, 2014, SMDC was serving 37 patients weekly on 10 stations, which is 3.70 patients per station or 92.5 percent of capacity ($37 \text{ patients} / 10 \text{ stations} = 3.7$; $3.7 / 4 = 0.925$ or 92.5%). At the end of Operating Year One, SMDC projects that it will be serving 42 patients weekly on 13 stations, which is 3.23 in-center patients per station or 80.75 percent of capacity ($42 \text{ patients} / 13 \text{ stations} = 3.23$; $3.23 / 4 = 0.8075$ or 80.75%). This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates the need to add three dialysis stations to SMDC and that it would not result in an unnecessary duplication. The discussions regarding analysis of need and unnecessary duplication found in Criteria (3) and (6), respectively, are incorporated herein by reference.

In Section V.7, page 31, the applicant discusses how any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality, and access to the proposed services. The applicant states:

“The proposed expansion of the facility is an effort to provide dialysis services to this community and is not intended to be a competitive venture. The bottom line is that patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs. The Smoky Mountain Dialysis Center provides access to all qualified Nephrologists to admit his or her patients.”

See also Sections II, III, V, VI, and VII where the applicant discusses the impact of the project on cost-effectiveness, quality, and access.

The information provided by the applicant in those sections is reasonable and adequately demonstrates that any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality, and access to the proposed dialysis 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 it will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates it will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1) and (13) are 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 Section I.13 and referenced exhibits, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The 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 proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

- (a) *An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:*
 - (1) *Utilization rates;*
 - C- In Section II.1, page 11 and Section III.7, page 23, the applicant states that SMDC had 37 in-center patients dialyzing on 10 certified stations for a utilization rate of 92.5%.

(2) *Mortality rates;*

-C- In Section IV.2, page 26, the applicant reports 2012, 2013, and 2014 facility mortality rates of 16.33 percent, 15.09 percent, and 17.24 percent, respectively.

(3) *The number of patients that are home trained and the number of patients on home dialysis;*

-C- In Section IV.3, page 26, the applicant states that home training is provided by Asheville Kidney Center pursuant to an agreement between the two facilities.

(4) *The number of transplants performed or referred;*

-C- In Section IV.4, page 27, the applicant states SMDC referred 10 patients for transplant evaluation in 2014. SMDC had no patients receive a transplant in 2014.

(5) *The number of patients currently on the transplant waiting list;*

-C- In Section IV.5, page 27, the applicant states SMDC has two patients on the transplant waiting list.

(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

-C- In Section IV.6, page 27, the applicant reports a total of 33 hospital admissions in 2014; 27 (81.8 percent) were non-dialysis related and six (18.2 percent) were dialysis related.

(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*

-C- In Section IV.7, page 27, the applicant reports that as of December 31, 2014, there were no patients with AIDS and no patients with hepatitis B. No patients converted to infectious status in 2014.

(b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*

(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will*

provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.

-NA- SMDC is an existing facility.

(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) *composition of the assessment/evaluation team at the transplant center,*
- (C) *method for periodic re-evaluation,*
- (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
- (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- SMDC is an existing facility.

(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- SMDC is an existing facility.

(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- Exhibit 8 contains a copy of written policies and procedures for back up for electrical service in the event of a power outage.

(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-NA- SMDC is an existing facility.

- (6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- See Section II.1, pages 11-18; Section VII.2, page 37, Section XI.6(g), pages 57-58, and Exhibits 1, 23, and 24 for documentation of conformity with the applicable laws and regulations.
- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- In Section III.7, page 23, SMDC provides projected patient origin based on historical experience for the first two years of operation following completion of the project, as presented in the following table:

SMDC Projected Patient Origin						
County/State	OY 1 – 2016		OY 2 – 2017		County/State Patients as a % of Total	
	In-Center Patients	In-Center Patients	OY 1	OY 2	OY 1	OY 2
Cherokee	26	28	61.9%	63.7%		
Clay	6	6	14.3%	13.6%		
Graham	4	4	9.5%	9.1%		
Macon	1	1	2.4%	2.3%		
Georgia	3	3	7.1%	6.8%		
Tennessee	2	2	4.8%	4.5%		
TOTAL	42	44	100.0%	100.0%		

The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

- (8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- SMDC is an existing facility.
- (9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*
- C- In Section II.1, page 15, the applicant states:

“Total Renal Care of North Carolina, LLC d/b/a Smoky Mountain Dialysis Center will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for

dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- SMDC is an existing facility.

(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.*

-C- In Section III.7, pages 23-24, the applicant projects to serve 42 in-center patients by the end of Operating Year One, which is 3.23 patients per station ($42 / 13 = 3.23$). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section II.1, pages 11-14, and Section III.7, pages 23-24.

10A NCAC 14C .2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

(1) *diagnostic and evaluation services;*

-C- These services are provided by Mission Hospital. See Section V.1, page 28.

(2) *maintenance dialysis;*

-C- These services are provided by SMDC. See Section V.1, page 28.

(3) *accessible self-care training;*

-C- These services are provided by Asheville Kidney Center. See Section V.1, page 28.

- (4) *accessible follow-up program for support of patients dialyzing at home;*
-C- These services are provided by Asheville Kidney Center. See Section V.1, page 28.
- (5) *x-ray services;*
-C- These services are provided by Mission Hospital. See Section V.1, page 28.
- (6) *laboratory services;*
-C- These services are provided by Dialysis Laboratories. See Section V.1, page 28.
- (7) *blood bank services;*
-C- These services are provided by Mission Hospital. See Section V.1, page 28.
- (8) *emergency care;*
-C- These services are provided by Mission Hospital. See Section V.1, page 28.
- (9) *acute dialysis in an acute care setting;*
-C- These services are provided by Mission Hospital. See Section V.1, page 28.
- (10) *vascular surgery for dialysis treatment patients;*
-C- These services are provided by Mission Hospital. See Section V.1, page 28.
- (11) *transplantation services;*
-C- These services are provided by Piedmont Hospital. See Section V.1, page 28.
- (12) *vocational rehabilitation counseling and services; and*
-C- These services are provided by Vocational Rehabilitation. See Section V.1, page 28.
- (13) *transportation.*
-C- This service is provided by Smoky Mountain Public Transportation Authority. See Section V.1, page 28.

10A NCAC 14C .2205 STAFFING AND STAFF TRAINING

- (a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100 [494].*

- C- In Section VII.1, page 37, the applicant provides the proposed staffing after completion of the proposed project. In Section VII.2, pages 37-38, the applicant states that staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.
- (b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
- C- See Section VII.5, page 39, and Exhibits 17 and 24 for documentation of ongoing training for staff at SMDC.