

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: January 24, 2018
Findings Date: January 24, 2018

Project Analyst: Jane Rhoe-Jones
Team Leader: Fatimah Wilson

Project ID #: P-11418-17
Facility: Wallace Dialysis
FID #: 060249
County: Duplin
Applicant: Total Renal Care of North Carolina, LLC
Project: Add one dialysis station to existing facility for a total of 16 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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 (TRC) d/b/a Wallace Dialysis (the applicant) proposes to add one dialysis station to the existing facility for a total of 16 in-center dialysis stations upon project completion.

Need Determination

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of ten dialysis stations in Duplin County; thus, there is no need for additional dialysis stations in the county. 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 Wallace Dialysis in the July 2017 SDR is 3.53 patients per station per week. This utilization rate was calculated based on 53 in-center dialysis patients and 15 certified dialysis stations as of December 31, 2016 (53 patients / 15 stations = 3.5333 patients per station per week). Application of the facility need methodology indicates that at least one additional station is needed for this facility, as illustrated in the following table:

WALLACE DIALYSIS OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/16		88.3%
Certified Stations		15
Pending Stations		0
Total Existing and Pending Stations		15
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR2)		53
In-Center Patients as of 6/30/16 (Jan 2017 SDR) (SDR1)		53
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	0
	Multiply the difference by 2 for the projected net in-center change	0
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.0000
(ii)	Divide the result of Step (i) by 12	0.0000
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.0000
(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	53.0000
(v)	Divide the result of Step (iv) by 3.2 patients per station	16.5625
	and subtract the number of certified and pending stations to determine the number of stations needed	1.5625

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is at least two. 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 one new station and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

Policy GEN-3: Basic Principles, page 33 of the 2017 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.”

The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 9-10 and 4, K-1(g), Section O, page 51 and referenced Exhibit. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality in the delivery of dialysis services.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 10, Section C.3, page 15, Section L, pages 44-48 and Exhibit L-3. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access to dialysis services.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c), page 11 and in Section N.2, page 50. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value for dialysis services.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need for two additional dialysis stations as identified by the applicant. The application is consistent with Policy GEN-3.

Conclusion

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

- The applicant’s use of the facility need methodology in accordance with the July 2017 SDR.
- The applicant’s use of existing policies, historical data, and verifiable sources to provide future projections and demonstrate conformity with Policy GEN-3.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

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

- (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

Total Renal Care of North Carolina, LLC d/b/a Wallace Dialysis proposes to add one dialysis station to the existing facility for a total of 16 in-center dialysis stations upon project completion.

Patient Origin

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

In Section C.8, page 18, the applicant provides the in-center patient origin for Wallace Dialysis as of December 31, 2016, as summarized in the following table:

WALLACE DIALYSIS In-center Patient Origin		
COUNTY	# OF PATIENTS	% OF TOTAL
Duplin	43	81.1%
New Hanover	1	1.9%
Pender	7	13.2%
Sampson	2	3.8%
Total	53	100.0%

In Section C.1, page 13, the applicant identifies the in-center patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table:

WALLACE DIALYSIS Projected In-center Patients				
COUNTY	OPERATING YEAR 1 (CY 2019)		OPERATING YEAR 2 (CY 2020)	
	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL
Duplin	44	81.5%	44	81.5%
New Hanover	1	1.8%	1	1.8%
Pender	7	13.0%	7	13.0%
Sampson	2	3.7%	2	3.7%
Total	54	100.0%	54	100.0%

Note: CY = Calendar Year

See pages 16-17 for the assumptions and methodology used to project in-center patient origin. The applicant proposes to add an additional in-center dialysis station and does not propose any changes to the home therapies program; however, the assumptions and methodology for PD patient origin can be found on page 18 of the application.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section B.2, page 7, the applicant provides a table to show that the application is filed pursuant to the facility need methodology outlined in the 2017 SMFP, utilizing data from the July 2017 SDR. The applicant proposes to add one dialysis station to the existing facility for a total of 16 certified dialysis stations upon project completion.

In Section C.1, pages 13-14, and summarized below, the applicant provides the assumptions and methodology to support its need to add one station at Wallace Dialysis pursuant to the facility need methodology:

- The applicant notes the facility was dialyzing 53 in-center patients on 15 certified dialysis stations as of December 31, 2016, as reported in the July 2017 SDR, which is a 88.3% utilization rate [$53 / 15 = 3.53$; $3.53 / 4 = 0.8833$].
- The applicant states 43 of those patients are residents of Duplin County, and the remaining 10 patients are residents of New Hanover, Pender and Sampson counties.
- The applicant uses 0.9% as the Duplin County Five Year Average Annual Change Rate (AACR), reported in Table B of the July 2017 SDR to project growth of the Duplin County patient population at the facility.
- The applicant projected no growth in the patient population that resides outside of Duplin County; rather, these patients are added after the Duplin County patient population growth is calculated.

- The applicant states Operating Year one (OY1) is projected to begin January 1, 2019, and Operating Year two (OY2) is projected to begin January 1, 2020. Operating Years are calendar years, as reported by the applicant on page 13.
- The applicant projects growth beginning January 1, 2017 through December 31, 2020.

Projected Utilization

In Section C.1, page 14, the applicant projects the following in-center utilization for Wallace Dialysis, calculating growth of only the Duplin County patients and then adding the out-of-county patients at the end of each year’s growth:

WALLACE DIALYSIS SERVICE AREA CENSUS							
SA Census	START DATE	# SA PTS.	GROWTH RATE (X)	# SA PTS	# PTS FROM OUT OF SA (+)	TOTAL # PTS	DATE
Current Year	1/1/17	43	1.009	43.387	10	53.387	12/31/17
Interim Year	1/1/18	43.387	1.009	43.777	10	53.777	12/31/18
OY 1	1/1/19	43.777	1.009	44.171	10	54.171	12/31/19
OY 2	1/1/20	44.171	1.009	44.569	10	54.569	12/31/19

Note: SA = Service Area.

The applicant rounds down to the nearest whole number and projects to serve 54 in-center patients on 16 stations or 3.37 patients per station per week [54 / 16 = 3.37; 3.37 / 4 = 0.84375] or 84.4% by the end of both OY1 and OY2. The projected utilization of 3.37 patients per station per week for Operating Year One exceeds the minimum of 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b).

The applicant demonstrates that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth in Duplin County.

Access to Services

In Section C.3, page 15, the applicant states that by policy, the proposed services will be available to all persons without regard to race, sex, age or handicap. The applicant further states services will be available to low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, and other persons identified as underserved.

In addition, in Section L.1, page 45, the applicant projects that 94.5% of the total patients who will dialyze at Wallace Dialysis will be covered by Medicare and Medicaid. In Section L.1, page 45, the applicant states that its projected payor mix is based on the payor mix for the last full operating year for Wallace Dialysis. The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to have access to the proposed services.

Conclusion

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

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

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

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

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

NA

TRC does not propose the reduction or elimination of a service in the proposed application, but rather the addition of one dialysis station pursuant to the facility need methodology in the 2017 SMFP, Therefore, Criterion (3a) is not applicable to this review.

- (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.1, page 22, the applicant discusses the alternatives considered prior to submitting this application, summarized as follows:

- Maintain the Status Quo – the applicant states that this alternative was dismissed considering the growth rate at Wallace Dialysis.
- Relocate Dialysis Stations from Another DaVita Facility – The applicant states that there are two existing DaVita facilities in Duplin County. One of those DaVita facilities, Wallace Dialysis is operating over 80% capacity with 53 in-center patients and 15 stations. The other DaVita facility, Southeastern Dialysis Center-Kenansville (SEDC-Kenansville) is operating at 69.1% capacity with 47 in-center patients and 17 stations. However, the applicant states in Section E.1, page 22 and Section G.2, 29, that the SEDC-Kenansville facility operates three days per week and to take stations from that facility would negatively impact its existing patients. Indeed, if the dialysis facility is open one half of the number of days, that a dialysis facility typically operates, then it is reasonable to conclude that the existing stations are utilized at over 100% of functional capacity ($47 / 17 = 2.76$; $2.76 / 2 = 1.382$ or 138.2%). Indeed SEDC-Kenansville is operating at 138% capacity. Thus, this alternative was also dismissed.

After considering the above alternatives, the applicant states that applying for one additional station at Wallace Dialysis pursuant to the facility need methodology is the most effective alternative to meet the identified need for additional stations to serve the dialysis patients in Duplin County who dialyze at that facility.

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

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

- The applicant uses reasonable and adequately supported assumptions to project utilization.
- The data cited is reasonable to use to support the assumptions of the applicant with regard to the least costly or most effective alternative for development of the proposed project.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

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 Wallace Dialysis shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the July 2017 SDR, Total Renal Care of North Carolina, LLC d/b/a Wallace Dialysis shall develop no more than one additional dialysis station for a total of no more than 16 certified 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 Wallace Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add one dialysis station to the existing facility for a total of 16 dialysis stations upon project completion.

Capital and Working Capital Costs

In Section F.1, page 23, the applicant projects no capital costs for the proposed additional station. In Section F.10, pages 25-26, the applicant states that there are no projected start-up expenses or initial operating expenses because it is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 24, the applicant states no capital costs and working capital costs for the proposed project. The applicant states in its Exhibit List that Exhibit F-5 contains a capital funds availability letter; although it does not contain the letter.

Exhibit F-7 contains the Consolidated Financial Statements for the year ending December 31, 2016. The statements indicate that as of December 31, 2016, it had a consolidated total of \$913,187,000 in cash and cash equivalents, \$18,741,257 in total assets and \$16,044,812 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for capital needs of the project, if needed.

Financial Feasibility

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

WALLACE DIALYSIS CENTER		
	Operating Year 1	Operating Year 2
Total Treatments (adjusted for missed treatments)	7,929	8,003
Total Gross Revenues (Charges)	\$3,021,946	\$3,096,815
Total Net Revenue	\$2,912,050	2,984,569
Total Operating Expenses (Costs)	\$2,478,115	\$2,532,272
Net Income	\$433,935	\$452,297

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.

Conclusion

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

- The applicant uses reasonable and adequately supported assumptions to project utilization.
- Historical data is used to provide future projections of costs and charges and demonstrate financial feasibility of the project.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

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

- (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

Total Renal Care of North Carolina, LLC d/b/a Wallace Dialysis proposes to add one dialysis station to the existing facility for a total of 16 in-center stations upon project completion.

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

The applicant currently operates two of three dialysis facilities in Duplin County. See the following table, which lists those facilities and their utilization:

DUPLIN COUNTY DIALYSIS FACILITIES					
as of December 31, 2016					
FACILITY NAME	OWNER	# PATIENTS	LOCATION	# CERTIFIED STATIONS	% UTILIZATION
Wallace Dialysis	TRC	53	Wallace	15	88.33%
SEDC-Kenansville	TRC	47	Kenansville	17	69.12%
RAI-West College	FKC	25	Warsaw	16	39.06%

Source: July 2017 SDR, Table B, Application - Section G, page 29

In Section G, page 29, the applicant states that transferring stations from SEDC-Kenansville in Duplin County would negatively impact the patients who currently dialyze at that facility. The applicant states that there are two existing DaVita facilities in Duplin County. One of those DaVita facilities, Wallace Dialysis is operating over 80% capacity with 53 in-center patients and 15 stations. The other DaVita facility, Southeastern Dialysis Center-Kenansville (SEDC-Kenansville) is operating at 69.1% capacity with 47 in-center patients and 17 stations. However, the applicant states in Section E.1, page 22 and Section G.2, 29, that the SEDC-Kenansville facility operates three days per week and to take stations from that facility would negatively impact its existing patients. Indeed, if the dialysis facility is open one half of the number of days, that a dialysis facility typically operates, then it is reasonable to conclude that the existing stations are utilized at over 100% of functional capacity ($47 / 17 = 2.76$; $2.76 / 2 = 1.382$ or 138.2%). Indeed SEDC-Kenansville is operating at 138% capacity. Furthermore, the applicant states that while it does propose to increase the inventory of dialysis stations in Duplin County, the increase serves to satisfy needed capacity at the particular facility, rather than duplicate any existing or approved services in the county.

In Section C.1, pages 13-14, the applicant provides reasonable projections for the in-center patient population it proposes to serve at Wallace Dialysis. The applicant's growth projections are based on the 0.9% Duplin County Five Year AACR as published in the July 2017 SDR.

The applicant adequately demonstrates the need to add one station to the existing facility. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference.

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

- The applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need for the proposed services.
- The applicant provides adequate documentation that the proposed services will not result in the unnecessary duplication of existing or approved health service capabilities or facilities.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

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

- (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 30, the applicant provides the current staffing for the facility and the projected staffing following the addition of one dialysis station. The following table illustrates current and projected staffing at Wallace Dialysis:

WALLACE DIALYSIS FACILITY STAFFING	
POSITION	CURRENT & PROJECTED FTEs
Registered Nurse	2.0
Patient Care Technician	6.0
Administrator	1.0
Dietician	1.0
Social Worker	1.0
Home Training RN	0.5
Administrative Assistant	1.0
Biomedical Technician	0.5
Total	13.0

As shown in the table above, the applicant does not propose to add any full-time equivalent (FTE) positions upon project completion. In Section H.2, page 31, the applicant states that the Medical Director for Wallace Dialysis is Dr. Brian Donner. In Exhibit I-3, the applicant provides a letter signed by Dr. Donner, dated August 15, 2017, confirming his commitment

to continue to serve as Medical Director. In Section H.3, page 31, the applicant describes its method for recruiting and retaining staff at the facility.

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

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

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

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

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

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

C

In Section I, page 34-36, the applicant includes a list of providers of the necessary ancillary and support services provided for the patients who dialyze at Wallace Dialysis. The applicant provides documentation regarding coordination with the existing health care system in Exhibits I-1 and I-3, including letters from DaVita Laboratory Services, Inc., the medical director for Wallace Dialysis and several nephrologists. The information in Section I and Exhibits I-1 and I-3 is reasonable and adequately supported.

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

- The applicant provides appropriate and credible documentation of the availability of necessary ancillary and support services for the provision of the proposed dialysis services.

- The applicant provides credible documentation of ongoing coordination with the existing health care system.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

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

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction

project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose to construct any new space, but proposes to make minor modifications to existing space by installing plumbing and electrical wiring through the walls for one dialysis station. Therefore, Criterion (12) is not applicable to this review.

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

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.7, page 48, the applicant reports that over 94% of the total patient revenue received for treatments at Wallace Dialysis was from Medicare and Medicaid in CY 2016. The table below shows the facility's historical payor sources.

WALLACE DIALYSIS CY2016	
Payor Source	Percent of Total Revenue
Medicare	21.9%
Medicaid	6.8%
Commercial Insurance	4.1%
Medicare / Commercial	41.1%
Medicare / Medicaid	24.7%
VA	1.4%
Total	100.00%

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 Duplin County, the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Duplin	17%	51%	48%	25%	12%	21%
Statewide	16%	51%	37%	16%	10%	13%

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

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

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

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

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

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

- The applicant's historical payor mix is adequate documentation that it currently provides services to medically underserved populations.
- The applicant's historical payor mix is adequate documentation of the extent to which medically underserved populations utilize the applicant's existing services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

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

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

²http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

- (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 applicants;

C

In Section L.3(d) page 47, the applicant states,

“Wallace Dialysis has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993. The facility has no obligation under the Hill Burton Act.”

In Section L.6, page 47, the applicant states that there have been no civil rights equal access complaints filed within the last five years against the existing facility or any facilities owned by the parent corporation.

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

The applicant provides credible information about its lack of obligation to provide any uncompensated care or community service under any federal regulations.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

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

- (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(b), page 45, the applicant states that the projected payor mix is based on historical payor mix for the facility for the last full operating year, illustrated as follows:

WALLACE DIALYSIS Projected Payor Mix OY2 (CY 2020)	
Payor Source	Percent of Total Revenue
Medicare	21.9%
Medicaid	6.8%
Commercial Insurance	4.1%
Medicare / Commercial	41.1%
Medicare / Medicaid	24.7%
VA	1.4%
Total	100.00%

The applicant projects that 94.5% of its patients will be covered by Medicare and Medicaid.

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant's projected payor mix adequately demonstrates that medically underserved populations will have adequate access to the proposed services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

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

- (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 47, the applicant states that patients will have access to the facility for dialysis services upon referral from a Nephrologist with admitting privileges at the facility. Patients who contact the facility directly or indirectly will be referred to "*a qualified nephrologist for evaluation and subsequent admission if it were found to be medically necessary.*" In Exhibit I-3, the applicant provides letters of support from area Nephrologists who indicate they have referred patients to the facility for dialysis and will continue to do so following the addition of one station.

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to the proposed services.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant adequately demonstrates that the facility will provide a range of means by which a person can access the services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

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

- (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 49, the applicant states that it has offered Wallace Dialysis as a clinical training site for student nurses at James Sprunt Community College. A copy of the student training agreement with the college, dated March 10, 2009, is included as Exhibit M-2.

The information provided in Section M.1 and Exhibit M-2 is reasonable and adequately supports a finding of conformity with this criterion.

The information provided is reasonable and adequately supported. This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

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

- (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.

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Total Renal Care of North Carolina, LLC d/b/a Wallace Dialysis proposes to add one dialysis station to the existing facility for a total of 16 in-center dialysis stations upon project completion.

On page 373, the 2017 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Duplin County. Facilities may also serve residents of counties not included in their service area.

The July 2017 SDR indicates there are three dialysis facilities in Duplin County, and the applicant currently operates two of the three. See the following table, which lists those facilities and their utilization:

DUPLIN COUNTY DIALYSIS FACILITIES as of December 31, 2016					
FACILITY NAME	OWNER	# PATIENTS	LOCATION	# CERTIFIED STATIONS	% UTILIZATION
Wallace Dialysis	TRC	53	Wallace	15	88.33%
SEDC-Kenansville	TRC	47	Kenansville	17	69.12%
RAI-West College	FKC	25	Warsaw	16	39.06%

Source: July 2017 SDR, Table B, Application - Section G, page 29

As shown in the table above, the applicant, TRC owns two of the current dialysis facilities and Fresenius owns one. The Fresenius facility and the second TRC facility are operating at less than 70% utilization. Based on the most recent SDR, Wallace Dialysis was operating above 80% (3.2 patients per station).

In Section N.1, page 50, the applicant discusses how this project is not expected to have any impact on competition. The applicant states the following as the project relates to cost-effectiveness, quality and access,

“The expansion of Wallace Dialysis will have no effect on competition in Duplin County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider ..., this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by Total Renal Care of North Carolina, LLC.

The expansion of Wallace Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it

will make it easier for patients, family members, and other involved in the dialysis process to receive services.”

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 applicant adequately demonstrates that it will continue to provide quality services.
- The applicant demonstrates that it will continue to provide access to medically underserved populations.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

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

- (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

DaVita currently operates more than 70 dialysis facilities in North Carolina. In Section O and Exhibit 0-3, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation during the 18-month look-back period. Two facilities, SEDC-Kenansville and Durham Dialysis were cited for deficiencies, but are back in compliance now. 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 information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides adequate and credible documentation of its current policies with regard to providing quality care.
- The applicant provides accurate information regarding past deficiencies and how those deficiencies were addressed.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

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

(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

.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- Wallace Dialysis is an existing facility and the applicant is not proposing to establish a new end stage renal disease facility.

.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section C.1, pages 13-14, the applicant demonstrates that Wallace Dialysis will serve a total of 54 in-center patients at the end of Operating Years One and Two for a utilization rate of 84% or 3.3 patients per station (54 patients / 16 stations = 3.37 / 4

= .8437 or 84%). The projected utilization of 3.3 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

.2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-C- In Section C.1, pages 13-14, 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. The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides adequate and credible documentation that it meets the performance standard required by this Rule.
- The applicant provides all documentation of its assumptions and methodology required by this Rule.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

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