

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 18, 2018

Findings Date: December 18, 2018

Project Analyst: Gregory F. Yakaboski

Team Leader: Gloria Hale

Project ID #: P-11601-18

Facility: Wallace Dialysis

FID #: 060249

County: Duplin

Applicant: Total Renal Care of North Carolina, LLC

Project: Add 2 stations for a total of 18 stations upon completion of this project, Project I.D. # P-11418-17 (add 1 station), Project I.D. # P-11491-18 (add 3 stations), and Project I.D. # P-11546-18 (relocate 3 stations to Warsaw Dialysis)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC (TRC or the applicant), d/b/a Wallace Dialysis proposes to add 2 stations for a total of 18 stations upon completion of this project, Project I.D. # P-11418-17 (add 1 station), Project I.D. # P-11491-18 (add 3 stations), and Project I.D. # P-11546-18 (relocate 3 stations to Warsaw Dialysis). Wallace Dialysis offers a peritoneal dialysis (PD) program however, the facility does not currently offer a home hemodialysis (HH) program. The parent company of TRC is DaVita, Inc. (DaVita).

Need Determination

The 2018 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for Duplin 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 2018 SDR is 4.2 patients per station per week. This utilization rate was calculated based on 63 in-center dialysis patients and 15 certified dialysis stations as of December 31, 2017 (63 patients /15 stations = 4.2 patients per station per week). Application of the facility need methodology indicates that 2 additional stations are needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/17		105.0%
Certified Stations		15
Pending Stations		4
Total Existing and Pending Stations		19
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2)		63
In-Center Patients as of 6/30/17 (Jan 2018 SDR) (SDR1)		61
Step	Description	Result
	Difference (SDR2 - SDR1)	2
(i)	Multiply the difference by 2 for the projected net in-center change	4
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/17	0.0656
(ii)	Divide the result of Step (i) by 12	0.0055
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/16 until 12/31/17)	0.0656
(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	67.1311
(v)	Divide the result of Step (iv) by 3.2 patients per station	20.9785
	and subtract the number of certified and pending stations to determine the number of stations needed	1.9785

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 2 stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2018 SDR. 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 2 new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2018 SMFP which is applicable to this review: *Policy GEN-3: Basic Principles* on page 233 of the 2018 SMFP is applicable to this review because the facility need methodology 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, Section K.1(g), page 40, Section N, page 50, Section O, page 51, and Exhibits O-2 and O-3. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 10, Section C.3, page 16, Section L, pages 44-48, Exhibit L-3 and Section N, page 50. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c) and (d), page 11, Section C, pages 13-16, Section F, pages 24-29, Section K, pages 39-43 and Section N.1, page 50. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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

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

C

TRC proposes to add 2 stations for a total of 18 stations upon completion of this project, Project I.D. # P-11418-17 (add 1 station), Project I.D. # P-11491-18 (add 3 stations), and Project I.D. # P-11546-18 (relocate 3 stations to Warsaw Dialysis). Wallace Dialysis offers a peritoneal dialysis program however, the facility does not currently offer a home hemodialysis program.

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Wallace Dialysis is located in Duplin County. 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 following tables illustrate current and projected patient origin for in-center (IC) patients and PD patients.

Wallace Dialysis: Historical Patient Origin as of December 31, 2017

County	IC Patients	PD Patients
Duplin	51	7
Pender	7	8
Sampson	3	3
New Hanover	1	0
Other States	1	0
Total	63	18

Source: Table on page 19 of the application.

Wallace Dialysis: Projected Patient Origin

County	Operating Year 1 (OY1) [1/1/20 – 12/31/20]		Operating Year 2 (OY2) [1/1/21 – 12/31/21]		County Patients as a % of Total***	
	IC Patients	PD Patients	IC Patients	PD Patients	OY1	OY2
Duplin	49*	10**	50*	11**	71.95%	72.62%
Pender	7	8	7	8	18.29%	17.86%
Sampson	3	3	3	3	7.32%	7.14%
New Hanover	1	0	1	0	1.22%	1.19%
Other States	1	0	1	0	1.22%	1.19%
Total	61*	21	62*	22	100.00%	100.00%

Source: Table on page 13 of the application.

*The applicant applied the incorrect Duplin County Five Year Average Annual Change Rate (AACR) from Table D of the July 2018 SDR to project growth of Duplin County IC patients. The project analyst applied the correct AACR based on clarifying information received from the applicant.

**The applicant projected growth of PD patients for on page 15 of the application, however, the correct projected number of PD patients for OY1 and OY2 were not included in the Table on page 13. The table above reflects the correct projected number of PD patients found on page 15.

***The percentages were corrected based on the corrected number of IC and PD patients.

In Section C, pages 13-15, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section B.2, pages 6-7, the applicant states the application is filed pursuant to the facility need methodology in the 2018 SMFP utilizing data from the January and July 2018 SDRs. The facility need methodology shows a need for two dialysis stations and the proposed project is for two dialysis additional dialysis stations at Wallace Dialysis.

In Section C, pages 13-15, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 13-15, the applicant describes its need methodology assumptions for projecting utilization of the proposed facility as follows:

- The July 2018 SDR shows that Wallace Dialysis operated at a utilization rate of 105.0 percent (4.2 patients per station per week) as of December 31, 2017, and had 63 in-center patients. The applicant states that 51 of the 63 patients were residents of Duplin County with 12 patients residing in other counties.
- The applicant projects the first full operating year of the project will be January 1, 2020 – December 31, 2020 (CY2020) and the second full operating year will be January 1, 2021 – December 31, 2021 (CY2021).

- As of December 31, 2017, Wallace Dialysis had 15 certified dialysis stations. Subsequently three projects have been completed or approved resulting in Wallace Dialysis having 16 dialysis stations as of the filing of this application.
 - * 16 stations: Project ID #P-11418-17 (add one station) was certified on April 21, 2018. (reflected in Table B of the July 2018 SDR)
 - *19 stations: Project ID #P-11491-18 (add three stations), (reflected in the July 2018 SDR as “Decision Pending”.) This project was approved on June 28, 2018 and the Agency issued a certificate of need on July 31, 2018.
 - *16 stations: Project ID # F-11546-18 (transfer three stations to Warsaw Dialysis). This project was approved on October 15, 2018 and the Agency issued a certificate of need on November 15, 2018. As part of this project the applicant projected that three IC patients from Duplin County would transfer their care from Wallace Dialysis to Warsaw Dialysis on January 1, 2020.
- TRC assumes the Duplin County in-center patient population will increase at the Duplin County AACR as set forth in the July 2018 SDR, Table D. Note: The applicant incorrectly stated that the AACR for Duplin County was 3.5% per year. (See page 14 of the application.) The correct Duplin County AACR is 1.4% per year per the July 2018 SDR.
- The applicant projects no growth for patients who utilize the facility and live in other counties.

The information is reasonable and adequately supported because the proposed project is consistent with the facility need methodology.

Projected Utilization

In-Center Patients

The applicant’s projected utilization methodology, based on its stated assumptions and the corrected AACR for Duplin County, is provided on page 14 and is summarized in the following table.

Wallace Dialysis	In-Center Patients
As of January 1, 2018 there were 51 Duplin County IC patients	51
Project the Duplin County IC patients forward to December 31, 2018, using the Five Year AACR for Duplin County of 1.4%.	$51 \times 1.014 = 51.714$
Project the Duplin County IC patients forward to December 31, 2019, using the Five Year AACR for Duplin County.	$51.714 \times 1.014 = 52.438$
Subtract 3 IC Duplin County patients who are projected to transfer their care from Wallace Dialysis to Warsaw Dialysis as of January 1, 2020.	$52 - 3 = 49$
Project the Duplin County IC patients forward to December 31, 2020, using the Five Year AACR for Duplin County	$49 \times 1.014 = 49.686$
Add the 12 patients from other counties currently dialyzing at Wallace Dialysis. This is the IC patient census at the end of OY1.	$49.686 + 12 = \mathbf{61.686}$
Project the Duplin County IC patients forward to December 31, 2021, using the Five Year AACR for Duplin County.	$49.686 \times 1.014 = 50.382$
Add the 12 patients from other counties currently dialyzing at Wallace Dialysis. This is the IC patient census at the end of OY2.	$50.382 + 12 = \mathbf{62.382}$

The applicant states on page 14 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2020) and OY2 (CY2021) the facility is projected to serve 61 and 62 in-center patients, respectively.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.39 patients per station per week, or 84.72% ($61 \text{ patients} / 18 \text{ stations} = 3.39 / 4 = 0.8472$ or 84.72%).
- OY2: 3.44 patients per station per week, or 86.11% ($62 \text{ patients} / 18 \text{ stations} = 3.44 / 4 = 0.8611$ or 86.11%).

The projected utilization of 3.39 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant starts with the 51 existing Duplin County patients.
- The Duplin County patients are projected to increase based on the Five Year AACR for Duplin County as reported in Table D of the July 2018 SDR.
- The applicant projects no growth for patients who utilize the facility and live in other counties.

PD Patient Utilization

In Section C.1, page 15, the applicant provides the assumptions and the methodology used to project utilization of PD patients for the first two years of operation following the completion of the project.

- OY 1 is projected to be CY2020; and OY 2 is projected to be CY2021.
- The applicant states it is reasonable to assume that the Wallace Dialysis PD program will grow at a rate of at least one patient per year during the period of growth.
- The applicant projects an increase of one patient per year during the growth period, beginning with 18 PD patient as of January 1, 2018 and reaching 22 patients by the end of OY2.
- The applicant averages the beginning and ending census for the year to reach an average number of patients per year for financial calculations.

The table below summarizes the beginning patient census on January 1, 2020 and its growth through the ending patient census on December 31, 2021, as presented by the applicant on page 15 of the application.

	# Patients, Beginning	# Patients, Ending	Average # Patients
As of January 1, 2018 there were 18 PD patients utilizing Wallace Dialysis. Increase the PD patient census by 1, projecting the PD patients forward one year to December 31, 2018.	18	19	18.5
Project the PD patients forward one year to December 31, 2019 adding 1 PD patient.	19	20	19.5
Project the PD patients forward one year to December 31, 2020 adding 1 PD patient. This is the PD patient census at the end of OY1.	20	21	20.5
Project the PD patients forward one year to December 31, 2021 adding 1 PD patient. This is the PD patient census at the end of OY2.	21	22	21.5

Projected PD patient utilization is reasonable and adequately supported for the following reasons:

- The applicant starts with the 18 existing PD patients utilizing Wallace Dialysis.
- The applicant projects growth at a rate of at least one patient per year during the period of growth.
- The ESRD data collection form for June 30, 2018 states there were 19 PD patients utilizing Wallace Dialysis as of June 30, 2018.

Access

In Section C.3, page 16, the applicant states “By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.” In Section L.1(b), page 45, the applicant projects the

following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

**Projected Payor Mix- Wallace Dialysis
January 1, 2021 to December 31, 2021**

Payor Category	Percent of Total Patients	Percent of IC Patients	Percent of PD Patients
Medicaid	2.5%	1.6%	5.3%
Medicare	35.0%	36.1%	31.6%
Medicare/Medicaid	17.4%	19.7%	10.5%
Medicare/Commercial	23.8%	27.9%	10.5%
Commercial Insurance	11.3%	4.9%	31.6%
VA Insurance	10.0%	9.8%	10.5%
Total	100.0%	100.0%	100.0%

Source: Table, page 45 of the application.

On page 45, the applicant states the projected payor mix is based on the payor mix during the last year of operation. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

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

NA

The applicant does not propose to reduce or eliminate a service, nor does the applicant propose to relocate a facility or service. 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

TRC proposes to add 2 stations for a total of 18 stations upon completion of this project, Project I.D. # P-11418-17 (add 1 station), Project I.D. # P-11491-18 (add 3 stations), and Project I.D. # P-11546-18 (relocate 3 stations to Warsaw Dialysis).

In Section E, page 23, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo- The applicant states that maintaining the status quo is not an effective alternative because of the growth rate at the facility.

Relocate Stations from another DaVita Facility in Duplin County- At the time this application was submitted DaVita had one other dialysis facility in Duplin County, Southeastern Dialysis Center-Kenansville (SEDC-Kenansville). The applicant rejected relocating stations from SEDC-Kenansville because relocating stations “*would negatively impact the patients presently served by this facility, given the scheduling requirements of the patients and physicians.*” Furthermore, on October 15, 2018, the applicant was approved to relocate seven dialysis stations from SEDC-Kenansville as part of the project to develop a new dialysis facility, Warsaw Dialysis, in Duplin County (See Project ID# P-11546-18). The Agency issued a certificate of need for Project ID# P-11546-18 on November 15, 2018. Per the July 2018 SDR, Southeastern Dialysis Center-Kenansville had 17 certified dialysis stations. Upon completion of Project ID# P-11546-18, SEDC-Kenansville will only have 10 certified dialysis stations. Per Chapter 14 of the 2018 SMFP, a dialysis facility cannot have less than 10 dialysis stations, therefore, relocating stations from the other existing DaVita dialysis facility (SEDC-Kenansville) in Duplin County is not a feasible option.

On page 23, the applicant states that its proposal is the most effective alternative because the proposed project will address both the issues of growth and access to the facility. Developing a third shift is inconvenient for patients and if a facility is at its maximum capacity that eliminates patient choice.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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

- 1. Total Renal Care of North Carolina, LLC shall materially comply with all representations made in the certificate of need application and any clarifying information. In the event that representations conflict, Total Renal Care of North Carolina, LLC shall materially comply with the last made representation.**
 - 2. Pursuant to the facility need determination in the July 2018 SDR, Total Renal Care of North Carolina, LLC shall develop no more than two additional dialysis stations for a total of no more than 18 certified stations at Wallace Dialysis upon completion of this project and Project I.D. # P-11418-17 (add 1 station), Project I.D. # P-11491-18 (add 3 stations), and Project I.D. # P-11546-18 (relocate 3 stations to Warsaw Dialysis), which shall include any home hemodialysis training or isolation stations.**
 - 3. Total Renal Care of North Carolina, LLC 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

TRC proposes to add 2 stations for a total of 18 stations upon completion of this project, Project I.D. # P-11418-17 (add 1 station), Project I.D. # P-11491-18 (add 3 stations), and Project I.D. # P-11546-18 (relocate 3 stations to Warsaw Dialysis).

Capital and Working Capital Costs

In Section F, pages 24 and 26-27, the applicant states that the proposed project will not involve any capital expenditures, start-up or initial operating expenses because Wallace Dialysis is an existing facility.

Financial Feasibility

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

	1 st Full Fiscal Year	2 nd Full Fiscal Year
Total Treatments	12,449	12,819
Total Gross Revenues (Charges)	\$4,281,641	\$4,425,552
Total Net Revenue	\$4,080,972	\$4,219,030
Average Net Revenue per Treatment	\$328	\$329
Total Operating Expenses (Costs)	\$3,192,906	\$3,288,417
Average Operating Expense per Treatment	\$256	\$257
Net Income	\$888,065	\$930,613

The Project Analyst notes that the applicant’s pro forma financial statements are based, in part, on a projected number of in-center patient treatments calculated from using an incorrect Five Year AACR. However, the difference in the projected number of treatments is not large enough to result in a significant decrease in net income.

Therefore, 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

TRC proposes to add 2 stations for a total of 18 stations upon completion of this project, Project I.D. # P-11418-17 (add 1 station), Project I.D. # P-11491-18 (add 3 stations), and Project I.D. # P-11546-18 (relocate 3 stations to Warsaw Dialysis).

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Wallace

Dialysis is located in Duplin County. Thus, the service area for this facility consists of Duplin County. Facilities may also serve residents of counties not included in their service area.

DaVita operates three of the four dialysis facilities in Duplin County, as shown in the table below.

Duplin County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
RAI-West College-Warsaw (Fresenius Medical Care)	16	42.19%	1.6875
SEDC-Kenansville (DaVita)*	17	64.71%	2.5882
Wallace Dialysis (DaVita)**	15	105.00%	4.2000
Warsaw Dialysis (DaVita)***	0	0.00%	0.0000

Source: July 2018 SDR, Table B.

*SEDC- Kenansville will have 10 stations upon completion of Project ID# P-11546-18 [Develop a new 10-station facility and home training program by relocating 7 stations from Southeastern Dialysis Center-Kenansville and 3 stations from Wallace Dialysis.]

**Wallace Dialysis will have 16 stations upon completion of Project I.D. # P-11418-17 (add 1 station), Project I.D. # P-11491-18 (add 3 stations), and Project I.D. # P-11546-18 (relocate 3 stations to Warsaw Dialysis).

***Warsaw Dialysis is a new facility approved on October 15, 2018 per Project ID# P-11546-18 [Develop a new 10-station facility and home training program by relocating 7 stations from Southeastern Dialysis Center-Kenansville and 3 stations from Wallace Dialysis.] A certificate of need was issued on November 15, 2018

In Section G.2, page 30, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Duplin County. The applicant states:

“While adding stations at this facility does increase the number of stations in Duplin County, it serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed addition of two dialysis stations at Wallace Dialysis is needed in addition to the existing stations.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

C

In Section H.1, page 31, the applicant provides the current and projected staffing for proposed services as illustrated in the following table.

Position	Current FTEs	2nd Full Fiscal Year FTEs
RN	2.00	3.00
Technician (PCT)	6.00	7.00
Administrator	1.00	1.00
Dietitian	1.00	1.00
Social Worker	1.00	1.00
Home Training RN	1.00	1.00
Admin Assistant	1.00	1.00
Biomed Tech	1.00	1.00
TOTAL	14.00	16.00

Source: Table on page 31 of the application.

In addition, the applicant provides projected direct care staff in OY 2 in Section H.7, page 34.

The assumptions and methodology used to project staffing are provided in Section H.1-2, pages 31-32 and Section H.6-7, page 34. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Sections H.3 and H.4, pages 32-33, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibits H-2, H-3 and H-4, the applicant provides supporting documentation. In Section I.3, page 36, the applicant identifies the medical director. In Exhibit I, the applicant provides a letter from the current medical director indicating an interest in continuing to serve as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section I.1, page 35, the applicant identifies the ancillary and support services necessary for the proposed services, as shown in the table below.

WALLACE DIALYSIS Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	Wallace Dialysis
Self-care training (in-center)	Wallace Dialysis
Home training	New River Dialysis Wallace Dialysis Wallace Dialysis
HH	
PD	
Accessible follow-up program	
Psychological counseling	Wallace Dialysis
Isolation – hepatitis	Wallace Dialysis
Nutritional counseling	Wallace Dialysis
Social Work services	Wallace Dialysis
Acute dialysis in an acute care setting	Duplin General Hospital
Emergency care	Duplin General Hospital
Blood bank services	Duplin General Hospital
Diagnostic and evaluation services	Duplin General Hospital
X-ray services	Duplin General Hospital
Laboratory services	DaVita Laboratory Services
Pediatric nephrology	Duplin General Hospital
Vascular surgery	Duplin General Hospital
Transplantation services	Vidant Medical Center
Vocational rehabilitation & counseling	NC DHHS Div of Vocational Rehab Services
Transportation	Duplin County Transportation Department

On page 35, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.

In Section I, pages 36-37, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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:
- would be available under a contract of at least 5 years duration;
 - would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - would cost no more than if the services were provided by the HMO; and
 - 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 nor renovate any existing space. 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 provides the historical payor mix during calendar year 2017 at Wallace Dialysis for the proposed services, as shown in the table below.

**Historical Payor Mix- Wallace Dialysis
CY2017**

Payor Category	Wallace Dialysis Percent of Total Treatments
Medicaid	2.5%
Medicare	35.0%
Medicare/Medicaid	17.4%
Medicare/Commercial	23.8%
Commercial Insurance	11.3%
VA Insurance	10.0%
Total	100.0%

Source: Table, page 48 of the application.

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Duplin	18%	51%	49%	21%	13%	20%
Pender	18%	50%	25%	15%	13%	13%
Sampson	17%	51%	49%	20%	14%	19%
New Hanover	17%	52%	23%	17%	9%	11%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217> Latest Data 7/1/17 as of 7/17/18

* Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. 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., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

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

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities

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

and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.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 during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.1(b), page 45, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

**Projected Payor Mix- Wallace Dialysis
1/1/21 to 12/31/21**

Payor Category	Percent of Total Treatments
Medicaid	2.5%
Medicare	35.0%
Medicare/Medicaid	17.4%
Medicare/Commercial	23.8%
Commercial Insurance	11.3%
VA Insurance	10.0%
Total	100.0%

Source: Table, page 45 of the application.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 76.2% of total services will be provided to Medicare patients (includes Medicare/Medicaid) and 2.5% to Medicaid patients.

On page 45, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based “*on the sources of patient payment that have been received by existing facility in the last full operating year.*”

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes 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 adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 49, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

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

C

TRC proposes to add 2 stations for a total of 18 stations upon completion of this project, Project I.D. # P-11418-17 (add 1 station), Project I.D. # P-11491-18 (add 3 stations), and Project I.D. # P-11546-18 (relocate 3 stations to Warsaw Dialysis).

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Wallace Dialysis is located in Duplin County. Thus, the service area for this facility consists of Duplin County. Facilities may also serve residents of counties not included in their service area.

DaVita operates three of the four dialysis facilities in Duplin County, as shown in the table below.

Duplin County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
RAI-West College-Warsaw (Fresenius Medical Care)	16	42.19%	1.6875
SEDC-Kenansville (DaVita)*	17	64.71%	2.5882
Wallace Dialysis (DaVita)**	15	105.00%	4.2000
Warsaw Dialysis (DaVita)***	0	0.00%	0.0000

Source: July 2018 SDR, Table B.

*SEDC- Kenansville will have 10 stations upon completion of Project ID# P-11546-18 [Develop a new 10-station facility and home training program by relocating 7 stations from Southeastern Dialysis Center-Kenansville and 3 stations from Wallace Dialysis.]

**Wallace Dialysis will have 16 stations upon completion of Project I.D. # P-11418-17 (add 1 station), Project I.D. # P-11491-18 (add 3 stations), and Project I.D. # P-11546-18 (relocate 3 stations to Warsaw Dialysis).

***Warsaw Dialysis is a new facility approved on October 15, 2018 per Project ID# P-11546-18 [Develop a new 10-station facility and home training program by relocating 7 stations from Southeastern Dialysis Center-Kenansville and 3 stations from Wallace Dialysis.] A certificate of need was issued on November 15, 2018

In Section N, page 50, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 50, the applicant states:

“The expansion of Wallace Dialysis will have no effect on competition in Duplin County. ... 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 others involved in the dialysis process to receive services.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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

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

C

In Section A, page 5, the applicant states DaVita operates more than 85 dialysis facilities in North Carolina. Exhibit A-11 contains a list of the DaVita dialysis facilities located in North Carolina.

In Section O, page 51, and Exhibit O-3 the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two of these facilities: Southeastern Dialysis Center-Wilmington and Goldsboro South Dialysis. The applicant states that all of the problems have been corrected and that Southeastern Dialysis Center-Wilmington was back in compliance as of March 21, 2018 and that Goldsboro South Dialysis was back in compliance as of November 20, 2017. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (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

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- The applicant is not proposing to establish a new End Stage Renal Disease 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 C, pages 13-15, the applicant demonstrates that Wallace Dialysis will serve 61 in-center patients at the end of OY1 (CY2020) for a utilization rate of 84.72% or 3.39 patients per station per week (61 patients / 18 stations = 3.39 / 4 = 0.8472 or 84.72%). 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- In Section C, pages 13-15, the applicant provides the assumptions and methodology used to project utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.