

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 28, 2018

Findings Date: June 28, 2018

Project Analyst: Mike McKillip

Team Leader: Gloria C. Hale

Assistant Chief: Lisa Pittman

Project ID #: P-11491-18

Facility: Wallace Dialysis

FID #: 060249

County: Duplin

Applicant: Total Renal Care of North Carolina, LLC

Project: Add three dialysis stations for a total of 19 dialysis stations upon completion of this project and Project I.D. # P-11418-17 (add one dialysis station for a total 16 stations)

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 d/b/a Wallace Dialysis [**Wallace Dialysis**] proposes to add three dialysis stations to the existing facility for a total of 19 certified dialysis stations upon completion of this project and Project I.D. P-11418-17 (add one dialysis station for a total of 16 stations).

Need Determination

The 2018 State Medical Facilities Plan (2018 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of nine dialysis stations in Duplin County. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. 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 January 2018 SDR is 4.0667 patients per station per week, or 101.67% (4.0667 / 4 patients per station = 1.0167). This utilization rate was calculated based on 61 in-center dialysis patients and 15 certified dialysis stations (61 patients / 15 stations = 4.0667 patients per station per week).

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table:

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/17		101.67%
Certified Stations		15
Pending Stations		1
Total Existing and Pending Stations		16
In-Center Patients as of 6/30/17 (SDR2)		61
In-Center Patients as of 12/31/16 (SDR1)		53
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	8
	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/16	0.3019
(ii)	Divide the result of step (i) by 12	0.0252
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/17 until 12/31/17)	0.1509
(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	70.2075
(v)	Divide the result of step (iv) by 3.2 patients per station	21.9399
	and subtract the number of certified and pending stations to determine the number of stations needed	6

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is six stations. 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 three new stations, therefore the application 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 33 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.”

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4, page 9, Section K.1(g), page 41, Section N.1, page 51, Section O, page 52, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4, page 10, Section C.3, page 15, Section L, pages 45-49, Section N.1, page 51, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4, page 11, Section C.1, pages 13-15, Section F, pages 24-29, Section K, pages 40-44, Section N.1, page 51, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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.

- (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

According to the January 2018 SDR, Wallace Dialysis was certified for 15 stations as of December 1, 2017. On February 27, 2018, the applicant was approved (Project I.D. P-11418-17) to add one dialysis station to the facility for a total of 16 stations. In this application, the applicant proposes to add three dialysis stations to the existing facility for a total of 19 certified dialysis stations at Wallace Dialysis following project completion.

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.”* Thus, the service area is Duplin County. Facilities may serve residents of counties not included in their service area.

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In Section C.1, page 13, the applicant provides the projected patient origin for Wallace Dialysis for in-center (IC), home hemodialysis (HHD) and peritoneal dialysis (PD) patients for the first two years of operation following completion of the project as follows:

County	Operating Year 1 CY2020			Operating Year 2 CY2021			Percent of Total	
	IC	HHD	PD	IC	HHD	PD	OY1	OY2
Duplin	51	0	10	52	0	10	74.4%	74.7%
New Hanover	1	0	0	1	0	0	1.2%	1.2%
Pender	6	0	7	6	0	7	15.9%	15.7%
Sampson	4	0	3	4	0	3	8.5%	8.4%
Total	62	0	20	63	0	20	100.0%	100.0%

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 C, pages 13-14, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. 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 2018 SDR.

On pages 13-14, the applicant states:

- The applicant begins the projections for the future patient population of Wallace Dialysis by using the ending in-center patient census of 61 patients, as of June 30, 2017.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Duplin County which is 0.9% to project the Duplin County patient population forward.
- The applicant does not project an increase in the patient population for New Hanover, Pender and Sampson counties.
- Operating Year 1 (OY1) = Calendar Year (CY) 2020
Operating Year 2 (OY2) = Calendar Year (CY) 2021

Projected Utilization

In Section C, page 14, the applicant provides the methodology used to project in-center patient utilization, as illustrated in the following table,

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Begin with Duplin County patients dialyzing at Wallace Dialysis as of June 30, 2017.	50
Project the Duplin County patient population forward six months to December 31, 2017 using the Five-Year Average Annual Change Rate for Duplin County of 0.9%	$50 \times 1.0045 = 50.225$
Project the Duplin County population forward one year to December 31, 2018 using the Five-Year Average Annual Change Rate for Duplin County of 0.9%.	$50.225 \times 1.009 = 50.67703$
Project the Duplin County population forward one year to December 31, 2019 using the Five-Year Average Annual Change Rate for Duplin County of 0.9%.	$50.67703 \times 1.009 = 51.13312$
Project the Duplin County population forward one year to December 31, 2020 using the Five-Year Average Annual Change Rate for Duplin County of 0.9%.	$51.13312 \times 1.009 = 51.59332$
OY1: Add 11 patients from outside Duplin County. This is the projected census for OY 1.	$51.59332 + 11 = 62.59332$
Project the Duplin County population forward one year to December 31, 2021 using the Five-Year Average Annual Change Rate for Duplin County of 0.9%.	$51.59332 \times 1.009 = 52.05766$
OY2: Add 11 patients from outside Duplin County. This is the projected census for OY 2.	$52.05766 + 11 = 63.05766$

Thus, the applicant projects that Wallace Dialysis will serve a total of 62 in-center patients at the end of OY1 for a utilization rate of 87.5% or 3.3 patients per station per week ($62 \text{ patients} / 19 \text{ stations} = 3.3 / 4 = 0.816$ or 81.6%). The projected utilization of 3.3 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 begins its utilization projection with the existing patients of Wallace Dialysis,
- The applicant grows the Duplin County patient population by the January 2018 SDR Duplin County Five Year AACR and holds the patient population from outside Duplin County constant, and
- The resulting utilization rate at Wallace Dialysis by the end of the first year is above the minimum standard of 3.2 patients per station per week.

Home Therapy Programs

The applicant does not currently provide home hemodialysis (HHD). On page 15, the applicant provides the following table showing its projections of peritoneal dialysis (PD) patients through the first two operating years of the project.

PD Patient Projections	Start Date	# of Patients Start of Year	# of Patients End of Year	Average # of Patients in Year
Interim Period	7/1/2017	17	20	18.5
Current Year	1/1/2018	20	21	20.5
Interim Period	1/1/2019	21	22	21.5
Operating Year 1	1/1/2020	22	23	22.5
Operating Year 2	1/1/2021	23	24	23.5

Source: Table on page 15 of the application.

On page 18, the applicant describes its assumptions as follows:

“Wallace Dialysis had 20 PD patients as of June 30, 2017 based on information included in Table C of the January 2018 SDR. ... The period of growth begins July 1, 2017 and is calculated forward to December 31, 2021. It is reasonable to assume that the Wallace Dialysis home-training program will grow at a rate of at least one patient per year during the period of growth.”

Projected utilization for PD training and support is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section C.3, page 15, the applicant states the facility’s services are available to all residents of the service area without regard to income, race, gender, handicap, age or ability to pay. In Section L.7, page 49, the applicant provides the historical (CY2017) payor mix for Wallace Dialysis, as shown below.

Payment Source	Percent of Total Patients
Medicare/Medicaid	17.4%
Medicare	35.0%
Medicaid	2.5%
Commercial Insurance	11.3%
Medicare / Commercial	23.8%
Misc. (VA)	10.0%
Total	100.0%

As shown in the table above, Wallace Dialysis reports that 78.7% of its patients were Medicare or Medicaid recipients in CY2017. In Section L.1, page 46, the applicant projects the same

percentage of Medicare and Medicaid recipients for Wallace Dialysis in the second operating year of the project. The projected payor mix is reasonable and adequately supported.

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 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

Wallace Dialysis does not propose the reduction, elimination or relocation of a facility or service in the proposed application. 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

Wallace Dialysis proposes to add three dialysis stations to the existing facility for a total of 19 certified dialysis stations upon completion of this project and Project I.D. P-11418-17 (add one dialysis station for a total of 16 stations).

In Section E.1, 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 due to growth in utilization of the facility. Therefore, this alternative was rejected.
- Relocation stations from another facility in Duplin County - The applicant rejected this alternative because relocating stations from Southeastern Dialysis Center-Kenansville *“would negatively impact the patients presently served by this facility, given the scheduling requirements of the patients and physicians.”*

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

- The facility is operating above 80% capacity,
- The applicant’s need projections and the facility need methodology indicate a need for additional stations at the facility,
- Maintaining the status quo does not address the need for additional stations at the facility and would result in higher utilization and potentially restrict patient admissions.
- Relocation of stations from other facilities in Duplin County would negatively impact patients and physicians at those facilities.

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 d/b/a Wallace Dialysis shall materially comply with all representations made in the certificate of need application and any supplemental responses. 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 January 2018 SDR, Total Renal Care of North Carolina, LLC d/b/a Wallace Dialysis shall develop no more than three additional dialysis stations for a total of no more than 19 certified stations at Wallace Dialysis upon completion of this project and Project I.D. P-11418-17 (add one dialysis station), which shall include any home hemodialysis training or isolation stations.**
 3. **Total Renal Care of North Carolina, LLC d/b/a Wallace Dialysis shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations, which shall include any isolation or home hemodialysis training stations.**
 4. **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

Wallace Dialysis proposes to add three dialysis stations to the existing facility for a total of 19 certified dialysis stations upon completion of this project and Project I.D. P-11418-17 (add one dialysis station for a total of 16 stations).

Capital and Working Capital Costs

In Section F.1, pages 24, the applicant projects the total capital cost of the project as shown in the table below.

Dialysis Machines	\$32,000
Equipment/Furniture	\$16,862
Total	\$48,862

In Section R, the applicant provides the assumptions used to project the capital cost.

In Section F.10 and F.11, pages 26-27, the applicant projects that there will be no start-up or initial operating costs associated with the proposed project as Wallace Dialysis is an existing facility.

Availability of Funds

In Section F.2, page 25, the applicant states that the capital cost will be funded as shown in the table below.

Type	DaVita, Inc.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$48,862	\$48,862
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$48,862	\$48,862

* OE = Owner's Equity

In Section F.2, page 25 and Exhibit F-6, the applicant states it will finance the capital costs with the accumulated reserves of DaVita, Inc., which is the parent company for Wallace Dialysis. Exhibit F contains a letter dated March 15, 2018 from the Chief Accounting Officer, authorizing and committing \$48,862 for the capital costs of the project.

Exhibit F-7 also contains a copy of the Securities and Exchange Commission Form 10-K Annual Report for DaVita, Inc. for the year ending December 31, 2016. The report indicates that as of December 31, 2016, DaVita, Inc. had \$913 million in cash and cash equivalents, \$18.7 billion in total assets and \$5.8 billion in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

The applicant provided 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 in the table below.

	Operating Year 1 CY2020	Operating Year 2 CY2021
Total Treatments	12,523	12,523
Total Gross Revenues (Charges)	\$4,382,272	\$4,485,931
Total Net Revenue	\$4,181,049	\$4,281,299
Average Net Revenue per Treatment	\$333.87	\$341.87
Total Operating Expenses (Costs)	\$3,241,398	\$3,310,722
Average Operating Expense per Treatment	\$258.84	\$264.37
Net Income	\$939,651	\$970,576

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
- 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 following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- 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

Wallace Dialysis proposes to add three dialysis stations to the existing facility for a total of 19 certified dialysis stations upon completion of this project and Project I.D. P-11418-17 (add one dialysis station for a total of 16 stations).

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.”* Thus, the service area is Duplin County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, there are currently three operational dialysis facilities in Duplin County, including two operated by the applicant, and one operated by Fresenius Kidney Care (FKC), as shown below.

DUPLIN COUNTY DIALYSIS FACILITIES				
Dialysis Facility (Owner)	Certified Stations 6/30/2017	# In-center Patients 6/30/2017	Percent Utilization 6/30/2017	Patients per Station
RAI-West College-Warsaw (FKC)	16	29	45.31%	1.8125
Southeastern Dialysis Center-Kenansville (DaVita)	17	46	67.65%	2.7059
Wallace Dialysis (DaVita)	15	61	101.67%	4.0667

Source: January 2018 SDR, Table B.

Of the two DaVita facilities, Wallace Dialysis operated with the highest utilization rate of 101.67%.

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

“While adding stations to this facility does increase the number of stations in Duplin County, it serves to meet the need 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 because the applicant adequately demonstrates that the proposed addition of three dialysis stations at Wallace Dialysis is needed in addition to the existing or approved dialysis stations.

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.

- (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 current and projected staffing for the proposed services, as illustrated in the following table.

POSITION	CURRENT # FTES	PROJECTED # FTES OY2
Registered Nurse	2.00	3.00
Technician (PCT)	6.00	8.00
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 Technician	1.00	1.00
Total	14.00	17.00

The assumptions and methodology used to project staffing are provided in Sections H and R. 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, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit I, the applicant provides a letter from the medical director indicating his interest in continuing to serve as the medical director of Wallace Dialysis. In Exhibit H, the applicant provides supporting documentation.

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
- 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.

- (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 provides a list of the necessary ancillary and support services, as illustrated below.

Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	Wallace Dialysis
Self-care training (in-center)	Wallace Dialysis
Home training:	
Home hemodialysis	New River Dialysis
Peritoneal dialysis	Wallace Dialysis
Accessible follow-up program	Wallace Dialysis
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 Division of Vocational Rehab
Transportation	Duplin County Transportation Dept.

In Section I.3, pages 36-37, and Section I.4, page 37, the applicant describes its existing and proposed relationships with other local health care and social services providers. The applicant 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
- 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.

- (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

In Section K.2, page 41, the applicant indicates that the project does not involve any new construction or renovation of 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 49, the applicant provides the historical (CY2017) payor mix for Wallace Dialysis, as shown below.

Payment Source	Percent of Total Patients
Medicare/Medicaid	17.4%
Medicare	35.0%
Medicaid	2.5%
Commercial Insurance	11.3%
Medicare / Commercial	23.8%
Misc. (VA)	10.0%
Total	100.0%

As shown in the table above, Wallace Dialysis reports that 78.7% of its patients were Medicare or Medicaid recipients in CY2017.

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**
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 SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28¹. 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). However, a direct comparison to the applicant’s current payor mix would be of little value because the population data by age, race, or gender does not include information on the

¹http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

number of elderly, minorities, women or handicapped persons utilizing health services.

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and 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, page 48, 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.”

In Section L.6, page 48 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.

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.

- (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.3, page 46, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation (CY2021) following completion of the project, as shown in the table below.

Payment Source	Percent of Total Patients
Medicare/Medicaid	17.4%
Medicare	35.0%
Medicaid	2.5%
Commercial Insurance	11.3%
Medicare / Commercial	23.8%
Misc. (VA)	10.0%
Total	100.0%

As shown in the table above, during the second full fiscal year of operation, the applicant projects to provide 78.7% of its services to Medicare patients (includes Medicare, Medicare/Medicaid and Medicare/Commercial) and 2.5% to Medicaid patients.

On page 46, the applicant states the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project is based on the facility's historical (CY2017) experience. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization at Wallace Dialysis.

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.

- (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 48, 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
- 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.

- (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 50, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.

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 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

Wallace Dialysis proposes to add three dialysis stations to the existing facility for a total of 19 certified dialysis stations upon completion of this project and Project I.D. P-11418-17 (add one dialysis station for a total of 16 stations).

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.*” Thus, the service area is Duplin County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, there are currently three operational dialysis facilities in Duplin County, including two operated by the applicant, and one operated by Fresenius Kidney Care (FKC), as shown below.

DUPLIN COUNTY DIALYSIS FACILITIES				
Dialysis Facility (Owner)	Certified Stations 6/30/2017	# In-center Patients 6/30/2017	Percent Utilization 6/30/2017	Patients per Station
RAI-West College-Warsaw (FKC)	16	29	45.31%	1.8125
Southeastern Dialysis Center-Kenansville (DaVita)	17	46	67.65%	2.7059
Wallace Dialysis (DaVita)	15	61	101.67%	4.0667

Source: January 2018 SDR, Table B.

In Section N.1, page 51, 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 51, the applicant states:

“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 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 B.4, pages 9-10, the applicant discusses the methods it uses to ensure and maintain quality. In Exhibit O, the applicant lists two dialysis facilities in the state owned by DaVita, Southeastern Dialysis Center – Wilmington and Goldsboro South Dialysis, that were cited during the 18 months immediately preceding the submittal of the application for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant provides documentation regarding the deficiencies and subsequent compliance with CMS Conditions for Coverage for Goldsboro South Dialysis in Exhibit O of the application. The applicant provided documentation regarding the deficiencies and subsequent compliance with CMS Conditions for Coverage for Southeastern Dialysis Center-Wilmington in response to a request by the Agency for additional information. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care 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

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.

.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, pages 13-14, the applicant demonstrates that Wallace Dialysis will serve a total of 62 in-center patients at the end of OY1 for a utilization rate of 81.6% or 3.3 patients per station per week ($62 \text{ patients} / 19 \text{ stations} = 3.3 / 4 = 0.816$ or 81.6%). 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.