

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 12, 2021

Findings Date: March 12, 2021

Project Analyst: Mike McKillip

Team Leader: Gloria C. Hale

Project ID #: P-12002-20

Facility: Goldsboro South Dialysis

FID #: 970275

County: Wayne

Applicant: DVA Renal Healthcare, Inc.

Project: Relocate no more than 3 dialysis stations pursuant to Policy ESRD-2 from Mt. Olive Dialysis to Goldsboro South Dialysis for a total of no more than 25 stations upon completion of this project and Project I.D. # P-11451-18 (relocate 3 dialysis stations)

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

DVA Renal Healthcare, Inc. (hereinafter referred to as “the applicant” or Goldsboro South Dialysis), proposes to relocate no more than 3 dialysis stations pursuant to Policy ESRD-2 from Mt. Olive Dialysis to Goldsboro South Dialysis for a total of no more than 25 stations upon completion of this project and Project I.D. # P-11451-18 (relocate 3 dialysis stations).

Need Determination

Chapter 9 of the 2020 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 Table 9D, page 169, the county need methodology shows there is no county need determination for additional dialysis stations in Wayne County. The applicant is proposing to relocate existing dialysis stations; therefore, the facility need methodology does not apply to this proposal. Therefore, neither of the two need determination methodologies in the 2020 SMFP apply to this proposal.

Policies

There is one policy in the 2020 SMFP that is applicable to this review: Policy ESRD-2: Relocation of Dialysis Stations.

Policy ESRD-2: Relocation of Dialysis Stations, on page 20 of the 2020 SMFP, states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina State Medical Facilities Plan, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina State Medical Facilities Plan.”*

The applicant proposes to relocate existing dialysis stations within Wayne County, pursuant to Policy ESRD-2. Therefore, the application is consistent with Policy ESRD-2.

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 the application is conforming to this criterion based on the following:

- Neither the county nor facility need methodology is applicable to this review.
 - The applicant adequately demonstrates that the application is consistent with Policy ESRD-2 because the proposal does not change the dialysis station inventory in Wayne County.
- (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

The applicant proposes to relocate no more than 3 dialysis stations pursuant to Policy ESRD-2 from Mt. Olive Dialysis to Goldsboro South Dialysis for a total of no more than 25 stations upon completion of this project and Project I.D. # P-11451-18 (relocate 3 dialysis stations). Mt. Olive Dialysis will be certified for 20 stations upon completion of this project.

The following table, summarized from data on page 7 of the application, shows the projected number of stations at Goldsboro South Dialysis upon project completion.

Goldsboro South Dialysis		
Stations	Description	Project ID #
25	Total existing certified stations in the SMFP in effect on the day the review will begin	
+3	Stations to be added as part of this project	P-12002-20
-3	Stations previously approved to be deleted but not yet certified	P-11451-18
25	Total stations upon completion of proposed project and previously approved projects	

The following table, summarized from information on page 8 of the application, shows the current and projected number of dialysis stations at Mt. Olive Dialysis upon completion of this project.

Mt. Olive Dialysis		
Stations	Description	Project ID #
17	Total existing certified stations in the SMFP in effect on the day the review will begin	
-3	Stations to be deleted as part of this project	P-12002-20
+6	Stations previously approved to be added but not yet certified	P-11683-19 (3) P-11792-19 (3)
20	Total stations upon completion of proposed project and previously approved projects	

Patient Origin

On page 113, the 2020 SMFP defines the service area dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” Both facilities referred to in this application are located in Wayne County. Thus, the service area for this application is Wayne County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 19, the applicant provides the historical in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patient origin for Goldsboro South Dialysis for CY2019, as summarized in the following table:

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Wayne	61	96.8%	0.0		0.0	
Wilson	1	1.6%	0.0		0.0	
Other States	1	1.6%	0.0		0.0	
Total	63	100.0%	0.0	0.0%	0.0	0.0%

In Section C.3, page 20, the applicant provides the projected in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patient origin for Goldsboro South Dialysis for the second full operating year following project completion, January 1, 2023 – December 31, 2023 (CY2023), as summarized in the following table:

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Wayne	78	98.7%	0.0		0.0	
Wilson	1	1.3%	0.0		0.0	
Total	79	100.0%	0.0	0.0%	0.0	0.0%

In Section C.3, pages 20-21, the applicant provides the assumptions and methodology used to project its patient origin. On page 21, the applicant begins with the patient origin for existing in-center dialysis patients for Goldsboro South Dialysis as of July 1, 2020. The applicant’s assumptions are reasonable and adequately supported because

they are based on the historical patient origin for in-center dialysis patients for Goldsboro South Dialysis as of July 1, 2020.

Analysis of Need

In Section C.3, pages 20-21, the applicant describes its need methodology and assumptions for projecting in-center utilization of the facility, summarized as follows:

- The applicant states that it projects patients forward from the July 1, 2020 census data. The applicant states that it assumes the patients from Wayne County dialyzing at Goldsboro South Dialysis on July 1, 2020 will continue to dialyze there and projects no annual growth rate for patient census at the facility through the first two operating years. However, based on letters from eight Mt. Olive Dialysis patients expressing their intention to transfer their care to Goldsboro South Dialysis, the applicant assumes patient census will increase by eight patients on January 1, 2022, when the proposed dialysis stations will be transferred from Mt. Olive Dialysis and certified at Goldsboro South Dialysis.
- The applicant assumes the patient from Wilson County will continue to dialyze at Goldsboro South Dialysis but does not assume any growth in patients from Wilson County.
- The project is scheduled for completion on December 31, 2021. Therefore, Operating Year (OY) 1 is calendar year (CY) 2022, January 1-December 31, 2022 and OY2 is CY2023, January 1-December 31, 2023.

In-Center Projected Utilization

In Section C.3, page 21, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

The applicant begins with the Wayne County in-center patients as of July 1, 2020.	70
The applicant projects the Wayne County in-center patients forward six months to December 31, 2020 assuming no growth.	$70 \times 1.0 = 70$
The applicant projects the Wayne County in-center patients forward one year to December 31, 2021 assuming no growth.	$70 \times 1.0 = 70$
The applicant adds one patient from Wilson County. This is the ending census for December 31, 2021.	$70 + 1 = 71$
The applicant adds eight patients from Mt. Olive Dialysis patients projected to transfer their care to Goldsboro South Dialysis on 1/1/2022. This is the projected beginning census for the project.	$70 + 8 = 78$
The applicant projects the Wayne County in-center patients forward one year to December 31, 2022 assuming no growth.	$78 \times 1.0 = 78$
The applicant adds one patient from Wilson County. This is the projected ending census for Operating Year 1 .	$78 + 1 = 79$
The applicant projects the Wayne County in-center patients forward one year to December 31, 2023 assuming no growth.	$78 \times 1.0 = 78$
The applicant adds one patient from Wilson County. This is the projected ending census for Operating Year 2 .	$78 + 1 = 79$

The applicant projects to serve 79 in-center patients in OY1 and 79 in-center patients in OY2. Thus, the applicant projects that Goldsboro South Dialysis will have a utilization rate of 79% or 3.2 patients per station per week ($79 \text{ patients} / 25 \text{ stations} = 3.2 / 4 = 0.79$ or 79%) in OY1. The projected utilization of 3.2 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 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 the projections with the existing Wayne County Goldsboro South Dialysis patient census as of July 1, 2020.
- The applicant projects the Wayne County patient census at Goldsboro South Dialysis will not increase other than the patients projected to transfer from Mt. Olive Dialysis from whom it has received letters expressing their intention to transfer to Goldsboro South Dialysis. See Exhibit C-3.
- The utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

Access

In Section C.7, page 24, 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.”

We will make every reasonable effort to accommodate all patients, especially those with special needs such as those with disabilities, patients attending school or patients who work. Dialysis services will be provided six days per week with two patient shifts per day to accommodate patient need.

Goldsboro South Dialysis will help uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, disabled persons, elderly and other under-served persons.”

In Section C.7, page 24, the applicant provides the following estimated percentages of dialysis patients for each medically underserved group during the second full fiscal year of operating following completion of the project, as illustrated in the following table.

Estimated Percentages of Patients by Group		
a	Low income persons	NA
b	Racial and ethnic minorities	84.1%
c	Women	52.4%
d	Handicapped persons	NA
e	The elderly	57.1%
f	Medicare beneficiaries	76.2%
g	Medicaid recipients	9.5%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

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 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.

- 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.

C

The applicant proposes to relocate no more than 3 dialysis stations pursuant to Policy ESRD-2 from Mt. Olive Dialysis to Goldsboro South Dialysis for a total of no more than 25 stations upon completion of this project and Project I.D. # P-11451-18 (relocate 3 dialysis stations). Mt. Olive Dialysis will be certified for 20 stations upon completion of this project.

In Section D.2, pages 28-29, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 29, the applicant provides a table which shows projected Mt. Olive Dialysis utilization assuming the relocation of 3 stations and the transfer of 8 patients to the Goldsboro South Dialysis facility, which is summarized below:

The applicant begins with 52 in-center patients at Mt. Olive Dialysis as of July 1, 2020, which includes 43 Wayne County residents and 9 patients from outside Wayne County.	52
The applicant projects the Wayne County in-center patients forward six months to December 31, 2020 using one half the Wayne County Five-Year AACR (0.5 X 6.5% = 3.25%).	$43 \times 1.0325 = 44.3975$
The applicant adds 9 patients who reside outside Wayne County. This is the ending census for December 31, 2020.	$44.3975 + 9 = 53.3975$
The applicant projects the Wayne County in-center patients forward one year to December 31, 2021 using the Wayne County Five-Year AACR.	$44.3975 \times 1.065 = 47.2833$
The applicant adds 9 patients who reside outside Wayne County. This is the ending census for December 31, 2021.	$47.2833 + 9 = 56.2833$
The applicant subtracts eight patients from Mt. Olive Dialysis in-center patient census that are projected to transfer their care to Goldsboro South Dialysis on January 1, 2022.	$47.2833 - 8 = 39.2833$
The applicant projects the Wayne County in-center patients forward one year to December 31, 2022 using the Wayne County Five-Year AACR.	$39.2833 \times 1.065 = 41.8367$
The applicant adds 9 patients from outside of Wayne County to the facility's census, for a total year-end census as of December 31, 2022. This is the projected ending census for Operating Year 1 .	$41.8367 + 9 = 50.8367$
The applicant projects the Wayne County in-center patients forward one year to December 31, 2023 using the Wayne County Five-Year AACR.	$41.8367 \times 1.065 = 44.5561$
The applicant adds 9 patients from outside of Wayne County to the facility's census, for a total year-end census as of December 31, 2023. This is the projected ending census for Operating Year 2	$44.5561 + 9 = 53.5561$

As shown in the table above, Mt. Olive Dialysis is projected to have a utilization rate of 2.6 patients per station per week or 64% ($51 \text{ patients} / 20 \text{ stations} = 2.6 / 4 = 0.64$) at the end of the first operating year following the proposed relocation of stations Goldsboro South Dialysis. The applicant states that the population presently served at Mt. Olive Dialysis will continue to have their needs adequately met by the remaining stations.

In Section D.3, page 30, the applicant states the relocation of three stations from Mt. Olive Dialysis to Goldsboro South Dialysis will not have any impact on the access to services by low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, Medicare beneficiaries or Medicaid recipients.

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 following reasons:

- The needs of the population currently using the services to be relocated will be adequately met following project completion.
 - The project will not adversely impact the ability of underserved groups to access these services following project completion.
- (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

The applicant proposes to relocate no more than 3 dialysis stations pursuant to Policy ESRD-2 from Mt. Olive Dialysis to Goldsboro South Dialysis for a total of no more than 25 stations upon completion of this project and Project I.D. # P-11451-18 (relocate 3 dialysis stations).

In Section E.2, page 31, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the identified need. The alternatives considered were:

- *Maintain the Status Quo* - The applicant states that maintaining the status quo is not an effective alternative because it would not optimize utilization of existing in-center dialysis services in Wayne County.
- *Relocate more than three stations* – The applicant states that relocating more than three stations is not cost-effective because the Goldsboro South Dialysis facility does not have adequate capacity to accommodate more than three stations without renovations.
- *Relocate stations from another facility* – The applicant states that relocating stations from another facility is not an effective alternative because two of the facilities, Coastal Plains Dialysis and Rosewood Dialysis, are new and the remaining facility, Goldsboro Dialysis, is highly utilized.

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 application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why they believe the proposed project is the most effective alternative.

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. Therefore, the application is approved subject to the following conditions:

- 1. DVA Renal Healthcare, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, the certificate holder shall relocate no more than three stations from Mt. Olive Dialysis to Goldsboro South Dialysis for a total of no more than 25 in-center and home hemodialysis stations at Goldsboro South Dialysis upon completion of the project.**
- 3. Upon completion of this project, the certificate holder shall take the necessary steps to decertify three stations at Mt. Olive Dialysis for a total of no more than 20 in-center and home hemodialysis stations upon completion of the project.**
- 5. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on September 1, 2021. The second progress report shall be due on January 1, 2022 and so forth.**
- 6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

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

C

The applicant proposes to relocate no more than 3 dialysis stations pursuant to Policy ESRD-2 from Mt. Olive Dialysis to Goldsboro South Dialysis for a total of no more than 25 stations upon completion of this project and Project I.D. # P-11451-18 (relocate 3 dialysis stations).

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, the applicant projects the total capital cost for the project as summarized below.

Projected Capital Costs	
	Total Costs
Medical Equipment	\$44,550
Nonmedical Equipment	\$9,321
Furniture	\$4,200
Total Capital Costs	\$58,071

In Section F, page 34, the applicant states there will be no working capital costs because Goldsboro South Dialysis is an operational facility.

In Section Q, Form F.1a, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the information on projected capital costs provided by the applicant in Form F.1a of the application.

Availability of Funds

In Section F, page 32, the applicant states that the capital costs will be funded by DaVita, Inc., the parent corporation for the applicant, as shown in the table below.

Sources of Capital Financing

Type	DaVita, Inc.
Loans	
Accumulated reserves or OE *	\$58,071
Bonds	
Other (Specify)	
Total Financing	\$58,071

* OE = Owner's Equity

In Exhibit F-2, the applicant provides a letter dated November 11, 2020, from the Chief Accounting Officer for DaVita Kidney Care documenting its commitment to fund the capital costs of the project. Exhibit F-2 also contains a copy of Form 10-K for DaVita, Inc. indicating that the applicant had \$1.1 billion in cash and cash equivalents as of December 31, 2019.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the documentation provided in Section F and Exhibit F-2, as described above.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of this project. In Section Q, Forms F.2 and F.4, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as summarized in the table below.

Goldsboro South Dialysis Revenue and Expenses		
	CY2022	CY2023
Treatments	11,708	11,708
Gross Patient Revenue	\$3,810,053	\$3,810,053
Net Patient Revenue	\$3,629,284	\$3,629,284
Average Net Revenue per Treatment	\$310	\$310
Total Operating Expenses	\$2,357,365	\$2,386,420
Average Operating Expense per Treatment	\$201	\$204
Net Income	\$1,271,919	\$1,242,864

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which 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 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

The applicant proposes to relocate no more than 3 dialysis stations pursuant to Policy ESRD-2 from Mt. Olive Dialysis to Goldsboro South Dialysis for a total of no more than 25 stations upon completion of this project and Project I.D. # P-11451-18 (relocate 3 dialysis stations).

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” Both facilities referred to in this application are located in Wayne County. Thus, the service area for this application is Wayne County. Facilities may serve residents of counties not included in their service area.

The applicant operates all of the dialysis centers in Wayne County except RAI Care Centers-Goldsboro. Utilization of all six Wayne County dialysis centers is shown in the following table from the 2020 SMFP, Table 9B, and page 37 of the application:

Wayne County Dialysis Facilities

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/18	# IN-CENTER PATIENTS	% UTILIZATION	PATIENTS PER STATION PER WEEK
Coastal Plains Dialysis	12	22	45.83%	1.83
Goldsboro Dialysis	24	98	102.08%	4.08
Goldsboro South Dialysis	25	68	68.00%	2.72
Mt Olive Dialysis	15	64	106.67%	4.27
RAI Care Centers – Goldsboro	16	64	100.00%	4.00
Rosewood Dialysis	0	0	0.00%	0.00

Source: 2020 SMFP, Table 9B, application page 37.

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The proposal would not result in a surplus of stations or increase an existing surplus of stations in Wayne County.
- The applicant adequately demonstrates that the proposed relocation of the three stations to Goldsboro South Dialysis is needed in addition to the operational facilities in Wayne County.

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

The applicant proposes to relocate no more than 3 dialysis stations pursuant to Policy ESRD-2 from Mt. Olive Dialysis to Goldsboro South Dialysis for a total of no more than 25 stations upon completion of this project and Project I.D. # P-11451-18 (relocate 3 dialysis stations).

In Section Q, Form H, the applicant provides the projected staffing in full-time equivalent (FTE) positions for the first and second full operating years of the proposed services, as summarized in the following table.

POSITION	PROJECTED FTE POSITIONS CY2022	PROJECTED FTE POSITIONS CY2023
Administrator	1.00	1.00
Registered Nurse	3.25	3.25
Technicians (PCT)	9.50	9.50
Dietitian	1.00	1.00
Social Worker	1.00	1.00
Administration/Business Office	1.00	1.00
Biomedical Technician	0.50	0.50
Total	17.25	17.25

Source: Section Q, Form H

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section Q. In Section H, pages 38-39, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the information provided in Section H, pages 38-39, and in Section Q, Form H, as described above.

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.

The applicant proposes to relocate no more than 3 dialysis stations pursuant to Policy ESRD-2 from Mt. Olive Dialysis to Goldsboro South Dialysis for a total of no more than 25 stations upon completion of this project and Project I.D. # P-11451-18 (relocate 3 dialysis stations).

Ancillary and Support Services

In Section I.1, the applicant identifies the necessary ancillary and support services for the proposed services. On page 40, and Exhibit I-1, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the information provided in Section I.1 and Exhibit I.1, as described above.

Coordination

In Section I.2, pages 40-41, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the information provided in Section I.2, as described above.

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 all the reasons described above.

- (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.1, page 43, the applicant states that the project will not involve 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

The applicant proposes to relocate no more than 3 dialysis stations pursuant to Policy ESRD-2 from Mt. Olive Dialysis to Goldsboro South Dialysis for a total of no more than 25 stations upon completion of this project and Project I.D. # P-11451-18 (relocate 3 dialysis stations). In Section L.1, page 47, the applicant provides Goldsboro South Dialysis’s historical payor mix for CY2019, as shown in the table below.

Payor Source	Percent of Total
Self Pay	1.6%
Insurance*	7.9%
Medicare*	76.2%
Medicaid*	9.5%
VA	4.8%
Total	100.0%

Totals may not sum due to rounding
 *Including any managed care plans

In Section L.1(a), page 46, the applicant provides comparison of the demographical information on Goldsboro South Dialysis patients and the service area patients during the last full operating year, as summarized below.

	Percentage of Total Goldsboro South Dialysis Patients Served during the Last Full OY	Percentage of the Population of the Service Area Where the Stations are Located*
Female	52.4%	51.3%
Male	47.6%	48.7%
Unknown	0.0%	0.0%
64 and Younger	42.9%	83.1%
65 and Older	57.1%	16.9%
American Indian	0.0%	0.9%
Asian	0.0%	1.3%
Black or African-American	76.2%	32.4%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	15.9%	62.8%
Other Race	7.9%	2.5%
Declined / Unavailable	0.0%	0.0%

* The percentages can be found online using the United States Census Bureau’s QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

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 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.2(a), page 48, the applicant states that the facility is not obligated to provide uncompensated care, community service, or access by minorities and persons with disabilities.

In Section L.2, page 48, the applicant states there have been no civil rights access complaints filed against Mt. Olive Dialysis or Goldsboro South Dialysis within the last five years.

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.3, page 48, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**Goldsboro South Dialysis
Projected Payor Mix CY2023**

Payor Source	Percent of Total
Self Pay	1.6%
Insurance*	7.9%
Medicare*	76.2%
Medicaid*	9.5%
VA	4.8%
Total	100.0%

Totals may not sum due to rounding
*Including any managed care plans

As shown in the table above, during the second full calendar year of operation, the applicant projects that 1.6% of the in-center dialysis patients will be self-pay patients and 86% will have all or part of their services paid for by Medicare or Medicaid.

On page 49, the applicant provides the assumptions and methodology used to project payor mix during the first and second fiscal full years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the applicant's projected patient payor mix is based on the historical payor mix for Goldsboro South Dialysis.

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.5, page 49, 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

The applicant proposes to relocate no more than 3 dialysis stations pursuant to Policy ESRD-2 from Mt. Olive Dialysis to Goldsboro South Dialysis for a total of no more than 25 stations upon completion of this project and Project I.D. # P-11451-18 (relocate 3 dialysis stations).

In Section M, 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-2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the information provided in Section M, page 50, and Exhibit M-2, as described above.

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 all the reasons described above.

- (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

The applicant proposes to relocate no more than 3 dialysis stations pursuant to Policy ESRD-2 from Mt. Olive Dialysis to Goldsboro South Dialysis for a total of no more than 25 stations upon completion of this project and Project I.D. # P-11451-18 (relocate 3 dialysis stations).

On page 113, the 2020 SMFP defines the service area for dialysis stations as “the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.” Both facilities referred to in this application are located in Wayne County. Thus, the service area for this application is Wayne County. Facilities may serve residents of counties not included in their service area.

The applicant operates all of the dialysis centers in Wayne County except RAI Care Centers-Goldsboro. Utilization of all six Wayne County dialysis centers is shown in the following table from the 2020 SMFP, Table 9B, and page 37 of the application:

Wayne County Dialysis Facilities

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/18	# IN-CENTER PATIENTS	% UTILIZATION	# PTS. / STATION PER WEEK
Coastal Plains Dialysis	12	22	45.83%	1.83
Goldsboro Dialysis	24	98	102.08%	4.08
Goldsboro South Dialysis	25	68	68.00%	2.72
Mt Olive Dialysis	15	64	106.67%	4.27
RAI Care Centers – Goldsboro	16	64	100.00%	4.00
Rosewood Dialysis	0	0	0.00%	0.00

Source: 2020 SMFP, Table 9B, application page 37.

Regarding the expected effects of the proposal on competition in the service area, in Section N.1, page 51, the applicant states:

“The relocation of three stations to Goldsboro South Dialysis will have no effect on competition in Wayne County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita.”

Regarding the impact of the proposal on cost effectiveness, quality and access, in Section N.2, page 51, the applicant states:

“As discussed in Section B, DaVita is committed to providing quality care to the ESRD population and, by policy, works to every reasonable effort to

accommodate all of its patients. The relocation to Goldsboro South Dialysis will enhance accessibility to dialysis for current and projected 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. Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs.”

See also Sections C, F, K, L, O and Q of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

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 based on all the reasons described 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.

In Section Q, Form A, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by DaVita, Inc. or a related entity.

In Section O.2, page 53, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred in any DaVita-related facility. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all DaVita and related facilities, the applicant provides 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

The application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

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 kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.
- NA- The applicant is not proposing to establish a new kidney disease treatment center or dialysis facility.
- (b) An applicant proposing to increase the number of dialysis stations in:
- (1) an existing dialysis facility; or

- (2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

- C- In Section C.3, pages 20-21, the applicant projects 79 in-center patients will be served by the Goldsboro South Dialysis facility by the end of the first operating year, CY2022, for a utilization rate of 3.2 patients per station per week or 79% ($79 \text{ patients} / 25 \text{ stations} = 3.2 \text{ patients per station} / 4 = 0.79$). The projected utilization of 3.2 patients per station per week exceeds the 2.8 in-center patients per station threshold required in this Rule. 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.3, pages 20-21, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.