

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 17, 2021

Findings Date: March 17, 2021

Project Analyst: Mike McKillip

Team Leader: Gloria C. Hale

Project ID #: P-12003-20

Facility: Wayne County Home Training

FID #: 200899

County: Wayne

Applicant: Swanville Dialysis, LLC

Project: Develop a new dialysis facility in Goldsboro dedicated to providing home peritoneal dialysis training and support services

### 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.

NA

Swanville Dialysis, LLC, (hereinafter referred to as “the applicant” or Swanville Dialysis), proposes to develop a new dialysis facility in Goldsboro dedicated to peritoneal dialysis training and support services. The applicant does not propose to include any certified in-center stations or home hemodialysis stations as part of the proposed project.

The applicant does not propose to add stations via either the facility need methodology, or the county need methodology published in the 2020 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

The applicant does not propose to:

- Develop any beds or services for which there is a need determination in the 2020 SMFP. The 2020 SMFP does not provide a need methodology for determining the need for kidney disease treatment centers dedicated to providing home PD services.
- Acquire any medical equipment for which there is a need determination in the 2020 SMFP.
- Offer a new institutional health service for which there are any applicable policies in the 2020 SMFP. Policy GEN-3 is not applicable to this review because the applicant does not propose to develop or offer a new institutional health service for which there is a need determination in the 2020 SMFP. Policy GEN-4 is not applicable to this review because the proposed capital cost for the project is less than the \$2 million dollars required for Policy GEN-4 to be applicable.

Therefore, Criterion (1) is not applicable to this review.

- (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 develop a new dialysis facility in Goldsboro dedicated to peritoneal dialysis training and support services. The applicant, Swanville Dialysis, LLC, is a subsidiary of DaVita, Inc., which is the parent corporation for the applicant. In Section C.4, pages 19-20, the applicant states,

*“The proposed project will be a new kidney disease treatment center dedicated exclusively to home peritoneal dialysis training and support services and will be developed in the same building as the recently certified Rosewood Dialysis. Home PD services were proposed in the Rosewood Dialysis application because DaVita wanted to create greater capacity for future growth in Wayne County. ... As detailed in Section C, Question 3, the data indicate that the home PD patient population is growing, both generally speaking and specifically in Wayne County. ... While there are no deficiencies in facility-related quality of care metrics at Goldsboro Dialysis, the condition and footprint of the facility’s physical plant limit the applicant’s ability to cost-effectively renovate and expand the PD training and support areas. The other DaVita-owned Wayne County facility serving PD patients, Coastal Plains Dialysis, has been open less*

*than three years and has already seen robust growth in its home PD program growing from zero patients in January 2018 to 19 patients at the end of 2019. Developing Wayne County Home Training would help to meet the needs of a growing home PD patient population in Wayne County, including the patients projected to be served by Wayne County Home Training - the 10 DaVita patients identified to be on the waiting list on December 31, 2022.”*

### **Patient Origin**

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.*” The facility referred to in this application is 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.

This proposal is to develop a new dialysis facility, Wayne County Home Training, dedicated to peritoneal dialysis training and support services; therefore, there is no historical utilization data.

In Section C.3, page 17, the applicant provides the projected home hemodialysis (HH) and peritoneal dialysis (PD) patient origin for Wayne County Home Training for the second full operating year following project completion, January 1, 2024 – December 31, 2024 (CY2024), as summarized in the following table:

County	Home Hemodialysis		Peritoneal Dialysis	
	HH Patients	% of Total	PD Patients	% of Total
Wayne	0	0%	12	100%
<b>Total</b>	<b>0</b>	<b>0%</b>	<b>12</b>	<b>100%</b>

In Section C.3, pages 17-19, the applicant provides the assumptions and methodology used to project its patient origin. On page 19, the applicant begins with the patient origin for existing peritoneal dialysis patients for Wayne County as of December 31, 2019. The applicant’s assumptions are reasonable and adequately supported because they are based on the historical patient origin for peritoneal dialysis patients as of December 31, 2019.

### **Analysis of Need**

In Section C.3, pages 17-18, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below:

- The historical growth rates for home dialysis therapies are significantly higher than the growth rates for in-center dialysis nationally and in North Carolina generally, and in Wayne County specifically.
- Home dialysis treatments allow greater scheduling flexibility and avoid travel time and expense for patients.
- Physicians are referring greater numbers of patients to home therapies.

The information is reasonable and adequately supported because the applicant demonstrates that home dialysis services are increasingly preferred by both patients and referring physicians and are experiencing increasing rates of utilization.

### **Projected Utilization**

#### *Peritoneal Dialysis Projected Utilization*

In Section C.3, pages 18-19, the applicant describes its need methodology and assumptions for projected utilization for the proposed facility summarized as follows:

*“The projections that follow assume that Wayne County DaVita-owned facilities will continue to serve at least 75% of the Wayne County PD patients. ... Swanville Dialysis, LLC projects that when the facility opens on January 1, 2023, one third of DaVita’s Wayne County PD patients will be on the waiting list for admission to Wayne County Home Training, the third DaVita-owned facility in the county serving home PD patients. ... It is anticipated that there will be additional ESRD patients who live in the service area who may want to receive their dialysis training and support at Wayne County Home Training. In addition to patients who are new to dialysis choosing home PD from the outset, some patients who have been dialyzing in-center may choose to change modalities.”*

The applicant states Operating Year One is projected to begin January 1, 2023 and end on December 31, 2023. Operating Year Two is projected to begin January 1, 2024 and end on December 31, 2024. The table below summarizes the beginning patient census for peritoneal dialysis (PD) patients on December 31, 2019 and their growth through the ending patient census on December 31, 2024.

Wayne County Home Training	PD Patients
The applicant begins with the total Wayne County PD patient population as of December 31, 2019.	31
The applicant projects the Wayne County PD patient population forward one year to December 31, 2020 based on the Wayne County Five Year Average Annual Change Rate (AACR) for PD patients of 9.34%.	$31 \times 1.0934 = 33.895$
The applicant projects the Wayne County PD patient population forward one year to December 31, 2021 based on the Wayne County Five Year AACR for PD patients of 9.34%.	$33.895 \times 1.0934 = 37.061$
The applicant projects the Wayne County PD patient population forward one year to December 31, 2022 based on the Wayne County Five Year AACR for PD patients of 9.34%.	$37.061 \times 1.0934 = 40.523$
The applicant projects that 75% of the total Wayne County PD patient population will be DaVita patients as of December 31, 2022.	$0.75 \times 40.523 = 30.392$
The applicant projects that one third of DaVita's Wayne County PD patient population will be on the DaVita home training waiting list as of December 31, 2022.	$1/3 \times 30.392 = 10.13$
The applicant projects the Wayne County Home Training facility will be certified on January 1, 2023 and will begin operation with those ten patients from the DaVita Wayne County home training waiting list.	10
The applicant projects the Wayne County Home Training PD patient census forward one year to December 31, 2023 based on the Wayne County Five Year AACR for PD patients of 9.34%. This is the projected ending census for <b>Operating Year 1</b> .	$10 \times 1.0934 = 10.934$
The applicant projects the Wayne County Home Training PD patient census forward one year to December 31, 2024 based on the Wayne County Five Year AACR for PD patients of 9.34%. This is the projected ending census for <b>Operating Year 2</b> .	$10.934 \times 1.0934 = 11.9552$

As the table above shows, the applicant projects 12 peritoneal dialysis patients by the end of the second operating year.

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

- The applicant bases the utilization projections on the Wayne County PD patient population as of December 31, 2019.
- The applicant projects the growth of the Wayne County patient census using the Wayne County Five-Year AACR for PD patients of 9.34%.
- The applicant assumes that 75% of PD patients will be DaVita patients, which is consistent with the applicant's historical share of those patients.

**Access**

In Section C.7, page 21, 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 training and support services will be provided five days per week with monthly clinic days for physician follow-up to accommodate patient need.*

*Wayne County Home Training 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 underserved persons.”*

In Section C.7, page 22, the applicant provides the following estimated percentages of dialysis patients for each medically underserved group during the second full fiscal year of operation following completion of the project, as summarized in the following table.

Estimated Percentages of Patients by Group		
a	Low income persons	NA
b	Racial and ethnic minorities	35.7%
c	Women	50.0%
d	Handicapped persons	NA
e	The elderly	35.7%
f	Medicare beneficiaries	75.0%
g	Medicaid recipients	14.3%

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 and adequately supports its assumptions.

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

NA

The applicant does not propose a reduction, elimination or relocation of a facility or service; therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to develop a new dialysis facility in Goldsboro dedicated to peritoneal dialysis training and support services.

In Section E.2, page 27, 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 meet the growing need for PD training and support services for Wayne County dialysis patients.
- *Develop the facility in a different location* – The applicant states that developing the facility in a different location is not an effective alternative because the program can be developed more cost-effectively in the same building that will accommodate the recently approved Rosewood Dialysis facility.

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. Swanville Dialysis, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
  - 2. The certificate holder shall establish a freestanding home dialysis training and support program exclusively for peritoneal dialysis patients, with no home hemodialysis stations.**
  - 3. 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.**
  - 4. 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 develop a new dialysis facility in Goldsboro dedicated to peritoneal dialysis training and support services.

**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.

<b>Projected Capital Costs</b>	
	<b>Total Costs</b>
Construction Costs	\$212,728
Architect/Engineering Fees	\$26,224
Nonmedical Equipment	\$45,811
Furniture	\$88,928
Interest during construction	\$1,417
<b>Total Capital Costs</b>	<b>\$375,109</b>

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 Section Q, Form F.1a of the application.

In Section F, pages 29-30, the applicant projects that start-up costs will be \$43,453 and initial operating expenses will be \$161,529 for a total working capital of \$204,982. On page 30, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the information regarding projected start-up costs and initial operating expenses provided on page 30 of the application.

**Availability of Funds**

In Section F, pages 28 and 30, the applicant states that the capital and working capital cost, respectively, will be funded by DaVita, Inc. as shown in the tables below.

**Sources of Capital Financing**

<b>Type</b>	<b>DaVita, Inc.</b>
Loans	
Accumulated reserves or OE *	\$375,109
Bonds	
Other (Specify)	
<b>Total Financing</b>	<b>\$375,109</b>

\* OE = Owner's Equity

**Sources of Working Capital Financing**

<b>Type</b>	<b>DaVita, Inc.</b>
Loans	
Accumulated reserves or OE *	\$204,982
Bonds	
Other (Specify)	
<b>Total Financing</b>	<b>\$204,982</b>

\* OE = Owner's Equity

In Exhibit F, the applicant provides a letter dated November 14, 2020, from the Chief Accounting Officer for DaVita Kidney Care documenting its commitment to fund the capital and working capital costs of the project. Exhibit F 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 and working capital needs of the project based on the documentation provided in Section F and Exhibit F, 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.

<b>Wayne County Home Training Revenue and Expenses</b>		
	<b>CY2023</b>	<b>CY2024</b>
Treatments	1,551	1,696
Gross Patient Revenue	\$543,754	\$594,541
Net Patient Revenue	\$519,617	\$568,150
Average Net Revenue per Treatment	\$335	\$335
Total Operating Expenses	\$323,058	\$338,831
Average Operating Expense per Treatment	\$208	\$200
Net Income	\$196,559	\$229,319

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 and working capital costs are based on reasonable and adequately supported assumptions.
  - The applicant adequately demonstrates availability of sufficient funds for the capital and working 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 develop a new dialysis facility in Goldsboro dedicated to peritoneal dialysis training and support services.

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.”* The facility referred to in this application is 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 33 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 33.

In Section G.2, page 33, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wayne County. The applicant states:

*“As of December 31, 2018, there were six dialysis facilities in Wayne County with a total of 92 certified stations. The proposed new facility will be dedicated exclusively to home peritoneal dialysis training and support services and will not include any dialysis stations. This certificate of need application does not propose to increase the number of dialysis stations in Wayne County.”*

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 home training facility is needed in addition to the in-center dialysis 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 develop a new dialysis facility in Goldsboro dedicated to peritoneal dialysis training and support services.

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 CY2023	PROJECTED FTE POSITIONS CY2024
Administrator	0.30	0.30
Home Training Nurse	0.50	0.50
Dietician	0.25	0.25
Social Worker	0.25	0.25
Administrative/Business Office	0.33	0.33
Biomedical Technician	0.25	0.25
<b>Total</b>	<b>1.88</b>	<b>1.88</b>

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 34-35, 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 34-35, 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.

C

The applicant proposes to develop a new dialysis facility in Goldsboro dedicated to peritoneal dialysis training and support services.

### **Ancillary and Support Services**

In Section I.1, the applicant identifies the necessary ancillary and support services for the proposed services. On page 36, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I. 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, as described above.

### **Coordination**

In Section I.2, page 37, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the information provided in Section I.2 and Exhibit I, 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.

C

The applicant proposes to develop a new dialysis facility in Goldsboro dedicated to peritoneal dialysis training and support services.

In Section K.1, page 39, the applicant states that the project involves renovation of 3,200 square feet of leased space. Line drawings are provided in Exhibit K-2.

On pages 41-42, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K. The site appears to be suitable for the proposed facility based on the applicant's representations and supporting documentation.

In Section K.3, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the information and representations made by the applicant on pages 39-40 of the application.

In Section K.3, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the information and representations made by the applicant on page 40 of the application.

On pages 40-41, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

**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.

- (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;

NA

The applicant proposes to develop a new dialysis facility in Goldsboro dedicated to peritoneal dialysis training and support services. This will be a new facility and therefore has no history.

- (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;

NA

The applicant proposes to develop a new dialysis facility in Goldsboro dedicated to peritoneal dialysis training and support services. This will be a new facility and therefore has no history.

- (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 45, 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.

**Projected Payor Mix CY2024**

Payment Source	Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total
Insurance*	0	0.0%	1.3	10.7%
Medicare*	0	0.0%	9.0	75.0%
Medicaid*	0	0.0%	1.7	14.3%
<b>Total</b>	<b>0</b>	<b>0.0%</b>	<b>18.06</b>	<b>100.0%</b>

Totals may not sum due to rounding

\*Including any managed care plans

On page 45, 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 proposed patient payor mix is

based on the historical payor mix for DaVita's existing Wayne County PD patients.

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 45, 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 develop a new dialysis facility in Goldsboro dedicated to peritoneal dialysis training and support services.

In Section M., 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 47, 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 develop a new dialysis facility in Goldsboro dedicated to peritoneal dialysis training and support services.

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.*” The facility referred to in this application is 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 33 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 33.

Regarding the expected effects of the proposal on competition in the service area, in Section N.1, page 48, the applicant states:

*“The development of Wayne County Home Training will have no effect on any dialysis facilities located in Wayne County. DaVita operates five of the six facilities in the county. ... The proposed facility will not have an adverse effect on competition since the projected patients will already be served by DaVita and will be transferring their care from one DaVita facility to another DaVita facility. ... The bottom line is Wayne County Home Training will enhance accessibility and/or convenience 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. 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.”*

Regarding the impact of the proposal on cost effectiveness, quality and access, in Section N.2, page 48, the applicant states:

*“As discussed in Section O, DaVita is committed to providing quality care to the ESRD population and, by policy, works to make every reasonable effort to accommodate all of its patients. The development of Wayne County Home Training 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.

### C

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 52, 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.

NA

The applicant proposes to develop a new kidney disease treatment center dedicated to providing home training and support services for peritoneal dialysis patients. The applicant does not propose to include any certified in-center stations as a part of the proposed project. The Criteria and Standards for End Stage Renal Disease Services, promulgated in 10A NCAC 14C .2200, are not applicable to this review due to a declaratory ruling issued by the Agency on October 10, 2018, which exempts the Criteria and Standards from applying to proposals to develop or expand facilities exclusively serving home hemodialysis and peritoneal dialysis patients.