

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 3, 2019

Findings Date: June 3, 2019

Project Analyst: Gregory F. Yakaboski

Team Leader: Gloria C. Hale

Project ID #: P-11683-19

Facility: Goldsboro Dialysis

FID #: 944654

County: Wayne

Applicant: DVA Renal Healthcare, Inc.

Project: Add no more than 2 dialysis stations for a total of no more than 25 stations upon completion of this project, Project ID #P-11454-18 (relocate 7 stations), and Project ID #P-11596-18 (add six 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. d/b/a Goldsboro Dialysis (the applicant) proposes to add no more than 2 dialysis stations for a total of no more than 25 stations upon completion of this project, Project ID #P-11454-18 (relocate 7 stations), and Project ID #P-11596-18 (add six stations). Goldsboro Dialysis currently offers both a peritoneal dialysis (PD) and a home hemodialysis (HH) program. The parent company of DVA Renal Healthcare, Inc. is DaVita, Inc. (DaVita).

#### **Need Determination**

The 2019 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to

the January 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for Wayne County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Goldsboro Dialysis in the January 2019 SDR is 4.1667 patients per station per week. This utilization rate was calculated based on 100 in-center dialysis patients and 24 certified dialysis stations as of June 30, 2018 (100 patients /24 stations = 4.1667 patients per station per week). Application of the facility need methodology indicates that 2 additional stations are needed for this facility, as illustrated in the following table.

<b>APRIL 1 REVIEW-JANUARY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/18		104.17%
Certified Stations		24
Pending Stations		6
<b>Total Existing and Pending Stations</b>		<b>30</b>
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR2)		100
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR1)		97
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	3
	Multiply the difference by 2 for the projected net in-center change	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/17	0.0619
(ii)	Divide the result of step (i) by 12	0.0052
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/18 until 12/31/18)	0.0309
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	103.0928
(v)	Divide the result of step (iv) by 3.2 patients per station	32.2165
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>2</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 2 stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the January 2019 SDR. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add 2 new stations and, therefore, is consistent with the facility need determination for dialysis stations.

**Policies**

There is one policy in the 2019 SMFP which is applicable to this review: *Policy GEN-3: Basic Principles*, on page 31 of the 2019 SMFP, is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

The applicant addresses *Policy GEN-3* as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 9-10, Section K.1(g), page 42, Section N, page 52, Section O, page 53, and Exhibits O-2 and O-3. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), pages 10-11, Section C.3, page 16, Section L, pages 46-50, Exhibit L-3 and Section N, page 52. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c) and (d), page 11, Section C, pages 13-16, Section F, pages 26-29, Section K, pages 41-44, Section N.1, page 52 and Section R. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

### **Conclusion**

The Agency reviewed the:

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

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

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

C

The applicant proposes to add 2 dialysis stations for a total of no more than 25 stations upon completion of this project, Project ID #P-11454-18 (relocate 7 stations), and Project ID #P-11596-18 (add six stations).

**Patient Origin**

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area is Wayne County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 21 and C.1, page 13, the applicant provides the historical and the projected patient origin for in-center (IC), home hemodialysis (HHD), and peritoneal dialysis (PD) patients, as illustrated in the tables below.

**Goldsboro Dialysis: Historical Patient Origin**

County	DIALYSIS PATIENTS AS OF JUNE 30, 2018		
	IC	HHD	PD
Wayne	96	5	20
Johnston	2	1	2
Lenoir	2	1	4
Sampson	0	2	1
<b>Total</b>	<b>100</b>	<b>9</b>	<b>27</b>

Source: Table on page 21 of the application.

**Goldsboro Dialysis: Projected Patient Origin**

County	Operating Year 1 CY2021			Operating Year 2 CY2022			Percent of Total	
	IC	HHD	PD	IC	HHD	PD	OY1	OY2
Wayne	79	8	23	84	9	24	88.0%	88.6%
Johnston	2	1	2	2	1	2	4.0%	3.8%
Lenoir	2	1	4	2	1	4	5.6%	5.3%
Sampson	0	2	1	0	2	1	2.4%	2.3%
<b>Total</b>	<b>83</b>	<b>12</b>	<b>30</b>	<b>88</b>	<b>13</b>	<b>31</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Table on page 13 of the application.

In Section C, pages 13-16, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C, pages 13-16, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section B.2, page 7, the applicant states the application is filed pursuant to the facility need methodology in the 2019 SMFP utilizing data from the January 2019 SDR.

- The January 2019 SDR shows that Goldsboro Dialysis operated at a utilization rate of 104.17 percent (4.1667 patients per station per week) as of June 30, 2018, and had 100 in-center patients. The applicant states that 96 of the 100 patients were residents of Wayne County with 4 patients residing in other counties.
- The applicant projects the first full operating year of the project will be January 1, 2021 – December 31, 2021 (CY2021) and the second full operating year will be January 1, 2022 – December 31, 2022 (CY2022).
- The applicant begins the projections for the future patient population of Goldsboro Dialysis by using the ending in-center patient census of 96 patients from Wayne County, as of June 30, 2018.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Wayne County which is 5.9%, as published in the January 2019 SDR, to project the Wayne County patient population forward.
- The applicant does not project an increase in the 4 patients who utilize the facility and live in other counties.
- The applicant subtracts the seven dialysis stations to be relocated to Rosewood Dialysis per Project I.D. #P-11451-18 and adds the six dialysis stations approved to be added to the Goldsboro Dialysis facility per Project I.D. #P-11596-18.
- The applicant subtracts the 33 Wayne County IC patients projected to transfer their care to Rosewood Dialysis.

*Projected Utilization*

In Section C, pages 13-16, the applicant provides projected utilization as summarized in the following table.

<b>Goldsboro Dialysis</b>	<b>In-Center Patients</b>
As of June 30, 2018 there were 96 Wayne County IC patients	96
Project the Wayne County IC patients forward six months to December 31, 2018, using one-half the Five Year AACR for Wayne County which is 2.95%.	$96 \times 1.0295 = 98.832$
Project the Wayne County IC patients forward to December 31, 2019, using the Five Year AACR for Wayne County of 5.9%.	$98.832 \times 1.059 = 104.6631$
Subtract the 33 Wayne County IC patients projected to transfer their care to Rosewood Dialysis upon its certification on January 1, 2020.	$104.6631 - 33 = 71$
Project the Wayne County IC patients forward to December 31, 2020, using the Five Year AACR for Wayne County.	$71 \times 1.059 = 75.189$
Project the Wayne County IC patients forward to December 31, 2021, using the Five Year AACR for Wayne County.	$75.89 \times 1.059 = 79.6251$
Add the 4 patients from other counties currently dialyzing at Goldsboro Dialysis. <b>This is the IC patient census at the end of OY1.</b>	$79 + 4 = \mathbf{83}$
Project the Wayne County IC patients forward to December 31, 2022, using the Five Year AACR for Wayne County.	$79.6251 \times 1.059 = 84.3229$
Add the 4 patients from other counties currently dialyzing at Wallace Dialysis. <b>This is the IC patient census at the end of OY2.</b>	$84 + 4 = \mathbf{88}$

The applicant states on page 14 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2021) and OY2 (CY2022) the facility is projected to serve 83 and 88 in-center patients, respectively.

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

- OY1: 3.32 patients per station per week, or 83.0% ( $83 \text{ patients} / 25 \text{ stations} = 3.32 / 4 = 0.83$  or 83.0%).
- OY2: 3.52 patients per station per week, or 88.00% ( $88 \text{ patients} / 25 \text{ stations} = 3.52 / 4 = 0.88$  or 88.00%).

The projected utilization of 3.32 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant starts with the 96 existing Wayne County patients and accounts for the 33 Wayne County IC patients projected to transfer their care to the Rosewood Dialysis facility.

- The Wayne County patients are projected to increase based on 5.9% per year which is the Five Year AACR for Wayne County as reported in Table D of the January 2019 SDR.
- The applicant projects no growth for patients who utilize the facility and live in other counties.
- The utilization rate by the end of OY1 exceeds the minimum standard of 3.2 patients per station per week.

*Home Hemodialysis and Peritoneal Dialysis Utilization*

The applicant currently provides home hemodialysis and peritoneal dialysis. On pages 15-16, the applicant states Goldsboro Dialysis will project its home hemodialysis and peritoneal patient population growth at a rate of one patient per year for each service component beginning on July 1, 2018. On pages 15-16, the applicant provides tables which demonstrate the projected growth in its HHD and PD training and support program. At the end of OY1, CY2021, the applicant projects to serve 13 HHD patients and 31 PD patients and at the end of OY2, CY2022, the applicant projects to serve 14 HHD patients and 32 PD patients.

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

- the applicant begins with the existing HHD and PD patients, and
- the applicant grows the HHD and PD patients by one patient per year for each service component.

**Access**

In Section C, page 16, the applicant states:

*“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.*

*We will make every reasonable effort to accommodate all patients, especially those with special needs such as the handicapped, 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.*

*Payment will not be required upon admission. Therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly, and other under-served persons.”*

In Section L, page 47, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

**Goldsboro Dialysis Payor Mix  
FY2**

<b>Payor Category</b>	<b>Percent of Total Patients</b>
Medicaid	8.6%
Medicare	21.9%
Medicare/Commercial	31.3%
Medicare/Medicaid	21.1%
VA	5.5%
Commercial Insurance	11.7%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 47 of the application.  
Note: Totals might not foot due to rounding.

The projected payor mix is reasonable and adequately supported.

**Conclusion**

The Agency reviewed the:

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

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

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

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

NA

The applicant does not propose to reduce a service, eliminate a service or relocated a facility. 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 add 2 dialysis stations for a total of no more than 25 stations upon completion of this project, Project ID #P-11454-18 (relocate 7 stations), and Project ID #P-11596-18 (add six stations).

In Section E, page 25, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

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

*Relocate Stations from another DaVita Facility in Wayne County*- The applicant states that while as of June 30, 2018 two of the DaVita facilities in Wayne County are operating at less than 80%, as shown in the January 2019 SDR, relocating stations from either of those two facilities would negatively impact patients currently dialyzing at that facility and therefore this is not the most effective alternative. The two DaVita facilities operating at less than 80% are: Goldsboro South Dialysis and Coastal Plains Dialysis. As of the January 2019 SDR Goldsboro South was operating at 73.0% based on 25 certified stations and 73 IC patients. However, as part of Project I.D.#P-11451-18 (Rosewood Dialysis), three stations are being relocated from Goldsboro South Dialysis. Upon completion of that project, utilizing the data from the January 2019 SDR, Goldsboro South Dialysis would be operating at 82.96% [ $73 \text{ patients} / 22 \text{ stations} = 3.3182/4 = 0.8296$  or 82.96%]. Coastal Plains Dialysis has 12 certified stations. A dialysis facility must have a minimum of 10 dialysis stations. While Coastal Plains Dialysis was only operating at 27.08% as of the January 2019 SDR, per the ESRD data collection forms the number of IC patients dialyzing at Coastal Plains Dialysis increased 69%, or 9 IC patients, from June 30, 2018 to December 31, 2018.

On page 25, the applicant states that its proposal is the most effective alternative because:

- The proposed project will proactively address both the issues of growth and access to the facility.
- Developing a third shift is inconvenient for patients and eliminates patient choice.

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 it believes 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. shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to the facility need determination in the January 2019 SDR, DVA Renal Healthcare, Inc. shall develop no more than two additional dialysis stations for a total of no more than 25 certified stations at Goldsboro Dialysis upon completion of this project, Project ID #P-11454-18 (relocate 7 stations), and Project ID #P-11596-18 (add six stations), which shall include any home hemodialysis training or isolation stations.**
  - 3. DVA Renal Healthcare, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add 2 dialysis stations for a total of no more than 25 stations upon completion of this project, Project ID #P-11454-18 (relocate 7 stations), and Project ID #P-11596-18 (add six stations).

## **Capital and Working Capital Costs**

In Section F.1, page 25, and F.10-F.11, pages 28-29, the applicant states there will be no capital or working capital cost associated with the proposed project.

## **Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section R, Form B, the applicant projects

that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	<b>1<sup>st</sup> Full Fiscal Year</b>	<b>2<sup>nd</sup> Full Fiscal Year</b>
Total Treatments	18,377	19,340
Total Gross Revenues (Charges)	\$6,531,777	\$6,865,834
Total Net Revenue	\$6,342,479	\$6,666,466
Average Net Revenue per Treatment	\$345	\$345
Total Operating Expenses (Costs)	\$4,588,294	\$4,802,255
Average Operating Expense per Treatment	\$250	\$248
Net Income	\$1,754,184	\$1,864,211

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates 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 add 2 dialysis stations for a total of no more than 25 stations upon completion of this project, Project ID #P-11454-18 (relocate 7 stations), and Project ID #P-11596-18 (add six stations).

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Wayne County. Facilities may also serve residents of counties not included in their service area.

DaVita operates five of the six dialysis facilities (existing or approved) in Wayne County, as shown below.

Facility Name	Provider	Location	# of Stations	Utilization
Goldsboro Dialysis	DaVita	Goldsboro	24	104.17%
Mt Olive Dialysis	DaVita	Mt Olive	15	98.33%
Goldsboro South Dialysis	DaVita	Goldsboro	25	73.00%
Coastal Plains Dialysis	DaVita	Goldsboro	12	27.08%
Rosewood Dialysis	DaVita	Goldsboro	0	0.00%
RAI Care Centers-Goldsboro	RAI/FMC	Goldsboro	16	103.13%

Source: January 2019 SDR, Table B

Pursuant to Project I.D.#P-11451-18 (Rosewood Dialysis), three stations are being relocated from Goldsboro South Dialysis. Thus, the number of certified stations at Goldsboro South Dialysis will be reduced from 25 to 22. Coastal Plains Dialysis, operating at 27.08%, has only been operational since January 2018. A dialysis facility must have a minimum of 10 dialysis stations, Coastal Plains Dialysis as 12 stations. Per the ESRD data collection forms the number of IC patients dialyzing at Coastal Plains Dialysis increased 69%, or 9 IC patients, over the last six-month period from June 30, 2018 to December 31, 2018.

In Section G, page 32, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wayne County. The applicant states:

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

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

- There is a facility need determination for the proposed two additional dialysis stations as calculated using the methodology in the January 2019 SDR.
- The applicant adequately demonstrates that the proposed two dialysis stations are needed in addition to the existing or approved dialysis facilities in Wayne County.

**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.

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

C

In Section H.1, page 33, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	(CY2018)	2nd Full Fiscal Year (CY2022)
RNs	3.0	4.0
Technician (PCT)	9.0	10.0
Administrator	1.0	1.0
Dietician	1.0	1.0
Social Worker	1.0	1.0
Home Training RN	1.0	1.0
Admin Assistant	1.0	1.0
Biomed Tech	0.5	0.5
<b>TOTAL</b>	<b>17.5</b>	<b>19.5</b>

The assumptions and methodology used to project staffing are provided in Sections H and R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Sections H.3 and H.4, pages 34 and 35, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 34, the applicant identifies the current medical director. In Exhibit I-3, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibits H-2 through H-4, I-1 and I-3, the applicant provides supporting documentation.

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

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support

services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I, page 37, the applicant states that the following ancillary and support services are necessary for the proposed services and explains how each ancillary and support service is made available:

<b>GOLDSBORO DIALYSIS Ancillary and Support Services</b>	
<b>Services</b>	<b>Provider</b>
In-center dialysis/maintenance	On-Site
Self-care training (in-center)	On-Site
Home training Home Hemodialysis Peritoneal Dialysis Accessible follow-up program	On-Site
Psychological counseling	On-Site
Isolation – hepatitis	On-Site
Nutritional counseling	On-Site
Social Work services	On-Site
Acute dialysis in an acute care setting	Wayne Memorial Hospital
Emergency care	Wayne Memorial Hospital
Blood bank services	Wayne Memorial Hospital
Diagnostic and evaluation services	Wayne Memorial Hospital
X-ray services	Wayne Memorial Hospital
Laboratory services	DaVita Laboratory Services
Pediatric nephrology	Wayne Memorial Hospital
Vascular surgery	Wayne Memorial Hospital
Transplantation services	Vidant Medical Center
Vocational rehabilitation & counseling	NC Division of Vocational Rehabilitation Services
Transportation	Wayne County DSS

Source: Table on page 37 of the application.

In Section I, pages 37-39, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-1 and I-3.

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

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose to make more than minor renovations to existing space. Therefore, Criterion (12) is not applicable to this review.

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

C

In Section L, page 50, the applicant provides the historical payor mix during CY2018 for the proposed services, as shown in the table below.

**Goldsboro Dialysis Payor Mix  
CY2018**

Payor Category	Percent of Total Patients
Medicaid	8.6%
Medicare	21.9%
Medicare/Commercial	31.3%
Medicare/Medicaid	21.1%
VA	5.5%
Commercial Insurance	11.7%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 50 of the application.  
Note: Totals might not foot due to rounding.

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Wayne	16%	51%	47%	21%	13%	15%
Johnston	13%	51%	32%	13%	10%	13%
Lenoir	19%	52%	51%	21%	19%	14%
Sampson	17%	51%	49%	20%	14%	19%
Statewide	16%	51%	37%	15%	10%	12%

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

\* Excludes "White alone, not Hispanic or Latino"

\*\* "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent



*differences between geographies statistically indistinguishable...The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable.”*

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

The IPRO SA Network 6 2016 Annual Report (pages 25-26<sup>1</sup>) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

The Agency reviewed the:

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

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3 (d), page 49, the applicant states

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

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

In Section L.6, page 49, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 47, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

**Goldsboro Dialysis Payor Mix  
FY2**

<b>Payor Category</b>	<b>Percent of Total Patients</b>
Medicaid	8.6%
Medicare	21.9%
Medicare/Commercial	31.3%
Medicare/Medicaid	21.1%
VA	5.5%
Commercial Insurance	11.7%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 47 of the application.

Note: Totals might not foot due to rounding.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 53.2% of total services will be provided to Medicare patients (including Medicare/Commercial), 8.6% to Medicaid patients and 21.1% to Medicare/Medicaid patients.

On page 47, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the applicant's proposed patient origin is comparable to its historical patient origin.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L.4, page 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

In Section M, page 51, 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.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.  
(16) Repealed effective July 1, 1987.  
(17) Repealed effective July 1, 1987.

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

C

The applicant proposes to add 2 dialysis stations for a total of no more than 25 stations upon completion of this project, Project ID #P-11454-18 (relocate 7 stations), and Project ID #P-11596-18 (add six stations).

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area is Wayne County. Facilities may also serve residents of counties not included in their service area.

DaVita operates five of the six dialysis facilities (existing or approved) in Wayne County, as shown below.

<b>Facility Name</b>	<b>Provider</b>	<b>Location</b>	<b># of Stations</b>	<b>Utilization</b>
Goldsboro Dialysis	DaVita	Goldsboro	24	104.17%
Mt Olive Dialysis	DaVita	Mt Olive	15	98.33%
Goldsboro South Dialysis	DaVita	Goldsboro	25	73.00%
Coastal Plains Dialysis	DaVita	Goldsboro	12	27.08%
Rosewood Dialysis	DaVita	Goldsboro	0	0.00%
RAI Care Centers-Goldsboro	RAI/FMC	Goldsboro	16	103.13%

Source: January 2019 SDR, Table B

In Section N, page 52, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 52, the applicant states:

*“The expansion of Goldsboro Dialysis will have no effect on competition in Wayne County. ... This project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DVA Renal Healthcare, Inc.”*

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

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

### **Conclusion**

The Agency reviewed the:

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

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

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

### C

In Section A.11, page 5, the applicant states DaVita Inc. owns and operates over 85 dialysis facilities in North Carolina. In Exhibit A-11, the applicant provides a list of those facilities.

In Section O.3, page 53, and Exhibit O-3, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two of these facilities, Southeastern Dialysis Center-Wilmington and Goldsboro South Dialysis. The applicant provides documentation regarding the deficiencies and subsequent measures taken by those facilities to ensure compliance with CMS Conditions for Coverage in Exhibit O-3. The applicant states that all of the problems have been corrected and that Southeastern Dialysis Center-Wilmington was back in compliance as of March 21, 2018 and that Goldsboro South Dialysis was back in compliance as of November 20, 2017. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic

medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below.

**10 NCAC 14C .2203 PERFORMANCE STANDARDS**

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

-NA- The applicant is not proposing to establish a new ESRD facility.

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

-C- In Section C, pages 13 - 16, the applicant demonstrates that Goldsboro Dialysis will serve a total of 83 in-center patients at the end of OY1 (CY 2021) for a utilization rate of 83.0% or 3.32 patients per station per week (83 patients / 25 stations = 3.32/ 4 = 0.83 or 83.0%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 13-16, the applicant provides the assumptions and methodology used to project utilization of the facility.