

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 20, 2016

Findings Date: December 20, 2016

Project Analyst: Jane Rhoe-Jones

Team Leader: Fatimah Wilson

Project ID #: P-11248-16

Facility: Goldsboro South Dialysis

FID #: 970274

County: Wayne

Applicant: DVA Renal Healthcare, Inc.

Project: Add five stations for a total of 25 stations upon completion of this project and Project ID# P-10365-14 (relocate two stations to Coastal Carolina Dialysis)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

DVA Renal Healthcare, Inc. (DVA) d/b/a Goldsboro South Dialysis (“the applicant”) proposes to add five dialysis stations for a total of 25 stations at Goldsboro South Dialysis upon completion of this project and Project ID# P-10365-14 (relocate two stations to Coastal Carolina Dialysis).

Need Determination

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of two dialysis stations in Wayne County. Therefore, the July 2016 SDR does not

indicate a need for additional stations in Wayne County based on the county need methodology, which states that the county deficit must be 10 or greater to establish a need for additional stations.

However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The applicant is eligible to apply for additional stations because the utilization rate reported for Goldsboro South Dialysis in the July 2016 SDR is 3.9091 patients per station, or 97.73% ($3.9091 / 4 \text{ patients per station} = 0.97727$). This utilization rate was calculated based on 86 in-center dialysis patients and 22 certified dialysis stations ($86 \text{ patients} / 22 \text{ stations} = 3.909 \text{ patients per station}$).

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

GOLDSBORO SOUTH DIALYSIS OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		97.7%
Certified Stations		22
Pending Stations		0
Total Existing and Pending Stations		22
In-Center Patients as of 12/31/15 (July 2016 SDR) (SDR2)		86
In-Center Patients as of 6/30/15 (Jan 2016 SDR) (SDR1)		78
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	8
	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/15	0.2051
(ii)	Divide the result of Step (i) by 12	0.0171
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	0.2051
(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	103.6410
(v)	Divide the result of Step (iv) by 3.2 patients per station	32.3878
	and subtract the number of certified and pending stations to determine the number of stations needed	10.3878

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 10 stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add five new stations, therefore the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2016 SMFP which is applicable to this review, Policy GEN-3: Basic Principles. Policy GEN:3, on page 39 of the 2016 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B-4(a), pages 9-10, Section N.1, page 50 and Section O, page 51, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B-4(b), page 10, Section C, page 16, Section L, pages 44-47, Section N.1, page 50, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B-4(c), page 11, Section F, pages 24-29, and Section N, page 50. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the July 2016 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

- (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 five new stations at Goldsboro South Dialysis, an existing facility located at 1704 Wayne Memorial Drive in Goldsboro. Upon completion of this project and Project I.D. # P-10365-14 (relocate two stations to Coastal Carolina Dialysis), Goldsboro South Dialysis will be certified for a total of 25 dialysis stations.

Patient Origin

On page 369, the 2016 SMFP defines the service area for dialysis services 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 North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Wayne County. Facilities may also serve residents of counties not included in their service area.

In Section C-8, page 19, the applicant identifies the population served as of December 31, 2015, as illustrated below in the table:

GOLDSBORO SOUTH DIALYSIS	
As of December 31, 2015	
County	# In-Center Dialysis Patients
Wayne	79
Lenoir	4
Johnston	2
Wilson	1
TOTAL	86

In Section C.1, page 14, the applicant provides the projected patient origin for Goldsboro South Dialysis for in-center (IC) patients for the first two years of operation following completion of the project as follows:

GOLDSBORO SOUTH DIALYSIS PROJECTED PATIENT ORIGIN by COUNTY				
	OY1 CY2018	OY1 CY2019	Percent of Total OY1	Percent of Total OY2
County	IC	IC		
Wayne	75	78	91.5%	91.8%
Lenoir	4	4	4.9%	4.7%
Johnston	2	2	2.4%	2.4%
Wilson	1	1	1.2%	1.2%
Total	82	85	100.0%	100.0%

The applicant provides the assumptions and methodology used to project patient origin on pages 14-15. The applicant adequately identifies the population to be served.

Analysis of Need

In Section B-2, page 6, the applicant states the need for the proposed project is based on the facility need methodology in the 2016 SMFP utilizing data from the July 2016 SDR, and it proposes to add five dialysis stations to Goldsboro South Dialysis for a total of 25 stations at that facility. The applicant used the following assumptions in Section C.1, pages 14-15 of the application:

- Based on information in the July 2016 SDR, as of December 31, 2015, the utilization rate for Goldsboro South Dialysis was 97.73% or 3.90 patients per station per week. This utilization was based on 86 in-center patients dialyzing on 22 stations. Seventy-nine of the 86 patients were residents of Wayne County.
- The applicant proposed in Project I.D. #P-10365-14 to relocate two stations from Goldsboro South Dialysis to develop Coastal Carolina Dialysis, also in Goldsboro.
- The applicant projects that upon certification of Coastal Carolina Dialysis in January 2018, 14 Wayne County patients currently receiving care at Goldsboro South Dialysis will transfer their care to Coastal Carolina Dialysis.
- The applicant states that Goldsboro South Dialysis facility has experienced a growth rate of 5.3% over the past five years. Wayne County’s Five Year Average Annual Change Rate (AACR) was 3.5%, as published in Table B of the July 2016 Semi-Annual Dialysis Report (SDR). Thus, the applicant assumes a 4.5% growth rate for the facility through the second operating year; which is higher than the county’s but lower than the facility has experienced (see chart of center growth rate on page 15 of the application).
- The applicant projects that after the growth period beginning January 1, 2017 and ending December 31, 2017, Goldsboro South Dialysis will have 93 in-center patients, 86 of whom will be from Wayne County. After subtracting 14 in-center patients who are projected to transfer to Coastal Carolina Dialysis, 72 patients (all from Wayne County) would be dialyzing at Goldsboro South Dialysis.

- The applicant projects Goldsboro South Dialysis will have 82 in-center patients by the end of operating year one for a utilization rate of 82% or 3.28 patients per station per week and 85 in-center patients by the end of operating year two for a utilization rate of 85% or 3.4 patients per station per week.
- OY1 is Calendar Year 2018
- OY2 is Calendar Year 2019

Projected Utilization

The applicant’s methodology is illustrated in the following table.

GOLDSBORO SOUTH DIALYSIS IN-CENTER PATIENT PROJECTIONS					
	Start Date	# SA* Patients x Growth Rate	SA Year End Census + # out of SA existing patients	Total Year End Census	Year End Date
Current Year	1/1/2016	79 x 1.045	82.555 + 7	89.555	12/31/2016
Interim Year	1/1/2017	82.555 x 1.045	86.269 + 7	93.269	12/31/2017
OY1	1/1/2018	86 - 14 = 72 x 1.045	75.24 + 7	82.240	12/31/2018
OY2	1/1/2019	75.24 x 1.045	78.625 + 7	85.625	12/31/2019

*SA = service area = Wayne County

The applicant projects to serve 82 in-center patients or 3.28 patients per station per week (82/25 = 3.28) by the end of Operating Year 1 and 85 in-center patients or 3.4 patients per station per week (85/25 = 3.4) by the end of Operating Year 2 for the proposed 25-station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C.2203(b). The July 2016 SDR indicates that Goldsboro South Dialysis operated at a utilization rate of 97.73 percent (3.9 patients per station) as of December 31, 2015. Based on data reported in the SDR, during the period from June 30, 2015 to December 31, 2015, the in-center census at Wake Forest Dialysis Center increased from 78 to 86 patients, which is an annual rate of growth of 5.5 percent. In this application, the applicant assumes a projected annual rate of growth of 4.5 percent for the in-center patient census at Goldsboro South Dialysis, which exceeds the Wayne County Five Year Average Annual Change Rate (2011-2015) of 3.5%, but is less than Goldsboro South Dialysis’s 5.3% average annual growth rate (page 15 of the application). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section L.1(a), pages 44-45, the applicant states that Goldsboro South Dialysis makes its services available to all persons without qualification, including low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. In Section L.7, page 48, the applicant reports that 87.7% of the in-center patients who received treatments at

Goldsboro South Dialysis had some or all of their services paid for by Medicare or Medicaid in CY2015. In Section L.1, page 45, the applicant projects 87.7% of its patients will be Medicare or Medicaid recipients; no change from its current payor mix. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for five additional stations at Goldsboro South Dialysis, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (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

- (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

In Section E-1, page 23, the applicant discusses the three alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo - the applicant states that this option would not support the growth rate at the facility.
2. Relocate stations from another DaVita facility - the applicant states that relocating stations from the one facility in the county that is operating at less than 80% would negatively impact the patients who receive dialysis there, because the patient population at that facility is growing.
3. Apply to add five stations – the applicant states the five-station expansion would help to meet the growing demand for dialysis services at Goldsboro South Dialysis.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **DVA Renal Healthcare, Inc. d/b/a Goldsboro South Dialysis shall materially comply with all representations made in the certificate of need application.**
 2. **DVA Renal Healthcare, Inc. d/b/a Goldsboro South Dialysis shall add no more than five dialysis stations at Goldsboro South Dialysis for a total of no more than 25 certified dialysis stations upon completion of this project and Project ID# P-10365-14 (relocate two stations to Coastal Carolina Dialysis), which shall include any include any home hemodialysis training or isolation stations.**
 3. **DVA Renal Healthcare, Inc. d/b/a Goldsboro South Dialysis shall install plumbing and electrical wiring through the walls for no more than 25 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 4. **DVA Renal Healthcare, Inc. d/b/a Goldsboro South Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add five dialysis stations to Goldsboro South Dialysis, for a total of 25 dialysis stations at Wilson Dialysis upon completion of this project and Project ID# P-10365-14 (relocate two stations to Coastal Carolina Dialysis).

Capital and Working Capital Costs

In the table in Section F-1, page 24, the applicant states the capital costs associated with the proposed project as \$2,902,861. Additionally, in Section F-10, pages 26-27, the applicant states that there are no working capital needs as Goldsboro South Dialysis is an existing facility.

Availability of Funds

In Section F.2, page 25, the applicant states it will finance the capital costs with accumulated reserves/owner's equity of DVA Renal Healthcare, Inc.

Exhibit F-5 contains a letter dated September 12, 2016, from the Chief Accounting Officer of DaVita, the parent company of DVA Renal Healthcare, Inc., which authorizes and commits cash reserves for the project capital costs of \$2,902,861, as well as, "*any other funds that are necessary for development of this project.*" Exhibit F-7 contains the Consolidated Financial Statements for DaVita Healthcare Partners, Inc. which indicates that it had \$965,241 million in cash and cash equivalents as of December 31, 2014, \$17.9 billion in total assets and \$6.1 billion in net assets (total assets less total liabilities). However, the applicant does have 2015 data available and in clarifying information submitted December 15, 2016, states that DaVita

Healthcare Partners, Inc. had \$1.5 billion in cash and cash equivalents, \$18.5 billion in total assets and \$5.9 billion in net assets as of December 31, 2015. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

The applicant projects revenues and expenses and provides assumptions in Section R, Form B, as summarized below in the table:

GOLDSBORO SOUTH DIALYSIS		
Revenue and Expenses		
	CY2018	CY2019
Total Treatments	11,930	12,375
Total Charges	\$3,466,061	\$3,595,300
Total Net Revenue	\$3,330,269	\$3,454,439
Total Operating Expenses	\$3,091,687	\$3,199,259
Net Income	\$ 238,582	\$ 255,180

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used by the applicant in preparation of the pro forma financial statements including projected utilization, costs and charges are reasonable. See the financial section 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. 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.

Conclusion

In summary, the applicant adequately demonstrates the financial feasibility of the project is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. Therefore, the application is conforming to this criterion.

- (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 five stations to Goldsboro South Dialysis for a total of 25 certified dialysis stations at Goldsboro South Dialysis upon completion of this project and Project ID# P-10365-14 (relocate two stations to Coastal Carolina Dialysis).

On page 369, the 2016 SMFP defines the service area for dialysis services 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 North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Wayne County. Facilities may also serve residents of counties not included in their service area.

The July 2016 SDR indicates there are four existing dialysis facilities and one approved new dialysis facility in Wayne County, as follows:

WAYNE COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of DECEMBER 31, 2015						
Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Goldsboro South Dialysis	DaVita	86	Goldsboro	22	-2	97.73%
Goldsboro Dialysis	DaVita	101	Goldsboro	27	-10	93.52%
Mt. Olive Dialysis	DaVita	45	Mt. Olive	15	0	75%
Coastal Carolina Dialysis	DaVita	0	Goldsboro	0	12	0.00%
RAI Care Centers-Goldsboro	RAI	30	Goldsboro	16	0	46.88%

As illustrated above, three of the four existing facilities are owned and operated by the applicant and have a utilization rate of 75% or above. However, one of the operational dialysis facilities, owned and operated by RAI, and also located in Goldsboro, is not well utilized. A new facility owned by the applicant has been approved but is not yet operational.

In Section G.2, page 30, the applicant states,

“... Because this application utilizes the Facility Need Methodology and addresses the specific needs of patients who chose to receive service from DaVita, we will focus on these 4 facilities for the purposes of examining possible duplication of services.

Coastal Carolina Dialysis is still under development and, as discussed in Section E, relocating stations from Mt Olive Dialysis would negatively impact patients and operations at the facility. ... While adding stations at this facility does increase the number of stations in Wayne County, it serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved serves in the area.”

In Section C-1, page 14, the applicant identifies the patient population it proposes to serve during the first two years of operation following completion of this project and Project ID# P-10365-14 (relocate two stations to Coastal Carolina Dialysis), as illustrated below in the table:

GOLDSBORO SOUTH DIALYSIS Projected Utilization				
County	OY1 2018	OY2 2019	County Patients as Percent of Total	
	In- Center Patients	In- Center Patients	OY1	OY2
Wayne	75	78	91.5%	91.8%
Lenoir	4	4	4.9%	4.7%
Johnston	2	2	2.4%	2.4%
Wilson	1	1	1.2%	1.2%
TOTAL	82	85	100.0%	100.0%

As shown in the previous table, at the end of OY1 2018, the applicant is projecting an in-center patient census of 82 patients, for a utilization rate of 82.0% or 3.28 patients per station per week ($82 \text{ patients} / 25 \text{ stations} = 3.28/4 = 0.82$ or 82.0%). At the end of OY2 2019, the applicant is projecting an in-center patient census of 85 patients for a utilization rate of 85.0% or 3.4 patients per station per week ($85 \text{ patients} / 25 \text{ stations} = 3.4/4 = 0.85$ or 85.0%). The projected utilization of 3.2 patients per station per week for OY1 meets the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b). The applicant adequately demonstrates that projected utilization is based on growth of in-center patients at the facility.

The applicant adequately demonstrates the need to add five stations to the Goldsboro South Dialysis facility based on the number of in-center patients it proposes to serve. The discussion of analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Wayne County. Consequently, the application is conforming to this criterion.

- (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, page 31, the applicant provides a table as illustrated below, with the current and projected staffing in full time equivalents (FTEs) for Goldsboro South Dialysis. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart.

GOLDSBORO SOUTH DIALYSIS			
POSITION	CURRENT # FTEs	# FTEs TO BE ADDED	PROJECTED # FTEs
Registered Nurse	3.0	1.0	4.0
Technician (Patient Care)	9.0	1.0	10.0
Administrator	1.0	1.0	2.0
Dietician	1.0	-	1.0
Social Worker	1.0	-	1.0
Administrative Assistant	1.0	-	1.0
Bio-med Technician	.5	-	.5
Total	16.5	3.0	19.5

As illustrated in the table above, the applicant projects an increase of 3.0 FTEs in the total number of FTE positions at Goldsboro South Dialysis.

In Section H-7, page 34, the applicant provides the projected direct care staff for Goldsboro South Dialysis in Operating Year 2, as shown below in the table:

GOLDSBORO SOUTH DIALYSIS					
DIRECT CARE POSITIONS	# FTEs	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	4.0	2,080	8,320	3,120	2.7
Patient Care Tech	10.0	2,080	20,800	3,120	6.7
Total	14.0	2,080	29,120	3,120	9.3

In Section I-3(a), page 37, the applicant identifies Dr. Ajay Shreenath, as the Medical Director of the facility. In Exhibit I-3, the applicant provides a copy of an August 2016 letter signed by Dr. Shreenath of Carolina Nephrology, supporting the project and confirming his continued commitment to serve as Medical Director. In Section H-3, pages 32-33, the applicant states that vacant staff positions are filled by one or more of the following: the DaVita Teammate Recruiter, Teammate Referral Program and/or Student Internship Program.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section I-1, page 35, the applicant lists the providers of the necessary ancillary and support services to be provided at the existing facility. The applicant discusses coordination with the existing health care system on pages 36-37. Exhibits I-1, and I-3 contain documents from DaVita, DaVita Laboratory Services, Inc., and Dr. Shreenath (Medical Director), respectively,

documenting availability of the necessary ancillary and support services. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information in Section I and corresponding exhibits is reasonable and supports a finding of conformity 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

- (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

- (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 renovate and expand the existing facility from 3,227 square feet to 5,959 square feet. The applicant provides a line drawing of the facility with the proposed additional stations in Exhibit K. In Section F.1, page 24, the applicant lists the project costs, including \$1,715,000 for construction, \$1,187,861 in miscellaneous costs including water treatment equipment, furniture, architect/engineering fees, and a contingency for a total project cost of \$2,902,861. In Section K.1, pages 39-40, the applicant describes its plans for energy-efficiency and water conservation. Costs and charges are described by the applicant in Section R

of the application. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (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-1, pages 44-45, the applicant states, “*Goldsboro South Dialysis, by policy, makes dialysis services available to all residents in its service area. ... Goldsboro South Dialysis helps 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, handicapped persons, elderly and other under-served persons.*”

In addition, on pages 45-47, the applicant discusses its financial policies to help the above named classifications of persons. In Section L-7, page 48, the applicant states that Medicare/Medicaid represented 87.7% of all dialysis services provided at Goldsboro South Dialysis in calendar year 2015. The following table illustrates the historical payor sources for Goldsboro South Dialysis:

GOLDSBORO SOUTH DIALYSIS HISTORICAL PAYOR MIX	
PAYOR TYPE	PERCENT OF TOTAL IN-CENTER PATIENTS
Medicare	24.7%
Medicaid	9.0%
Commercial Insurance	6.7%
Medicare/ Commercial	29.3%
Medicare/Medicaid	24.7%
VA	5.6%
Total	100.0%

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 & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Wayne	15%	51%	46%	23%	12%	18%
Lenoir	18%	52%	50%	22%	17%	19%
Johnston	12%	51%	31%	15%	10%	19%
Wilson	16%	53%	52%	24%	11%	20%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015. *Excludes "White alone" who are "not Hispanic or Latino" **"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The *Southeastern Kidney Council Network 6 Inc. Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

Source: <http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).

The applicant demonstrates that it currently provides adequate access to medically underserved populations. 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;

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In Section L-3(d), page 47, the applicant states:

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

In Section L-6, page 47, the applicant states, *“There have been no civil rights equal access filed within the last five years.”*

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 C-3, page 16, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. ...

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-3(c), page 47, the applicant states:

“Goldsboro South Dialysis makes no effort to categorize patients into groups according to their financial ability to obtain medical care. Physicians identify the patients in need of dialysis services and only then will a financial counselor and/or social worker evaluate their medical insurance and financial status.”

In Section L-1(b), page 46, the applicant reports that it expects 87.7% of the in-center patients who receive treatments at Goldsboro South Dialysis to have all or part of their services paid for by Medicare and Medicaid, as indicated below in the table.

GOLDSBORO SOUTH DIALYSIS PROJECT YEAR 2 PAYOR MIX	
PAYOR TYPE	PERCENT OF TOTAL IN-CENTER PATIENTS
Medicare	24.7%
Medicaid	9.0%
Commercial Insurance	6.7%
Medicare/ Commercial	29.3%
Medicare/Medicaid	24.7%
VA	5.6%
Total	100.0%

On page 45, the applicant states the projected payor mix for Goldsboro South Dialysis will remain the same as its historical payor mix.

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section L-4, page 47, the applicant states:

“Patients with End Stage Renal Disease have access to dialysis services upon referral by a nephrologist with privileges at Goldsboro South Dialysis. ... Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies, found at Exhibit L-3. ...”

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section M-1, page 50, the applicant states that Goldsboro South Dialysis has been offered as a clinical training site for student nurses attending James Sprunt Community College in Kenansville.

Exhibit M-2 contains a copy of the student training agreement with James Sprunt Community College. The information provided in Section M and referenced exhibits is reasonable and supports a finding of conformity 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.

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The applicant proposes to add five stations to Goldsboro South Dialysis for a total of 25 certified dialysis stations at Goldsboro South Dialysis upon completion of this project and Project ID# P-10365-14 (relocate two stations to Coastal Carolina Dialysis).

On page 369, the 2016 SMFP defines the service area for dialysis services 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 North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Wayne County. Facilities may also serve residents of counties not included in their service area.

The July 2016 SDR indicates there are four existing dialysis facilities and one approved new dialysis facility in Wayne County, as follows:

WAYNE COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of DECEMBER 31, 2015						
Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Goldsboro South Dialysis	DaVita	86	Goldsboro	22	-2	97.73%
Goldsboro Dialysis	DaVita	101	Goldsboro	27	-10	93.52%
Mt. Olive Dialysis	DaVita	45	Mt. Olive	15	0	75%
Coastal Carolina Dialysis	DaVita	0	Goldsboro	0	12	0.00%
RAI Care Centers-Goldsboro	RAI	30	Goldsboro	16	0	46.88%

As illustrated above, three of the four existing facilities are owned and operated by the applicant and have a utilization rate of 75% or above. However, one of the operational dialysis facilities, owned and operated by RAI, and also located in Goldsboro, is not well utilized. A new facility owned by the applicant has been approved but is not yet operational.

In Section N-1, page 50, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states:

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

The expansion of Goldsboro South Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services.”

See also Sections B, C, D, F, G, L and P where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the sections referenced above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicant adequately demonstrates that Goldsboro South Dialysis will continue to provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that Goldsboro South Dialysis will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

In Section B-4(a), pages 9-10, the applicant discusses the methods it uses to ensure and maintain quality. In Exhibit O-3, the applicant provides a listing below of four dialysis facilities that were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application:

DVA Quality Care			
Facility	Survey Date	Back in Compliance	
Southeastern Dialysis Center-Kenansville	3/22/2016	Yes	6/10/2016
Durham Dialysis	3/22/2016	Yes	5/31/2016
Marshville Dialysis	2/29/2016	Yes	4/15/2016
Durham West Dialysis	10/7/2015*	Yes	9/30/2015

*Back in compliance prior to survey on 10/7/2015

Based on a review of the information in the application and publicly available information, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

10 NCAC 14C.2203 PERFORMANCE STANDARDS

.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- This application is to add stations and does not propose a new facility.

.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section C-1, pages 14-16, the applicant documents the need for the project and demonstrates that it will serve a total of 82 in-center patients on 25 stations at the end of the first operating year, which is 3.28 patients per station per week, or a utilization rate of 82.0%. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

.2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-C- In Section B.2, page 7 and Section C.1, pages 14-16, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.