

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 4, 2015

Findings Date: March 4, 2015

Project Analyst: Jane Rhoe-Jones

Assistant Chief: Martha J. Frisone

Project ID #: P-10365-14

Facility: Coastal Carolina Dialysis

FID #: 140466

County: Wayne

Applicant(s): DVA Healthcare Renal Care, Inc.

Project: Develop a new 12-station dialysis facility by relocating 10 stations from Goldsboro Dialysis Center (Wayne County) and two stations from Goldsboro South Dialysis Center (Wayne County) and relocate the existing home training program from Goldsboro Dialysis Center

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

DVA Healthcare Renal Care, Inc. (DVA) d/b/a Coastal Carolina Dialysis, whose parent company is DaVita HealthCare Partners, Inc., proposes to relocate 10 stations from Goldsboro Dialysis Center (Wayne County) and two stations from Goldsboro South Dialysis Center (Wayne County) to develop a new 12-station dialysis facility in Wayne County. The primary site for the new dialysis facility is East Ashe Street at Malloy Street in Goldsboro.

The proposed project requires up-fitting of a building shell and purchasing equipment needed to operate the new facility. Furthermore, the proposed project includes relocating the home training program (home hemodialysis and peritoneal dialysis and support) from Goldsboro Dialysis Center.

### **Need Determination**

The applicant is transferring stations to develop a new facility, therefore, neither the county or facility need methodologies in the 2014 State Medical Facilities Plan (SMFP) are applicable to this review.

### **Policies**

There are two policies in the 2014 SMFP that are applicable to this review: *Policy ESRD-2* on page 32 and *Policy GEN-4* on page 38.

*POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS* states:

*“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of Need applicants proposing to relocate dialysis stations shall:*

- 1. Demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 2. Demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate stations within the host county. See Section I, pages 2-3, Section II.14, page 31, Section II.I, pages 16-28, and Section III.3, pages 34-38. The proposal is consistent with *Policy ESRD-2*.

*POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES* states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceed energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy Gen-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy Gen-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

The proposal is expected to cost more than \$2 million. The applicant provides a written statement describing the project's plan to assure improved energy efficiency and water conservation in Section I.14, pages 11-12, and Section XI.6(d), pages 88-89. The application is consistent with *Policy GEN-4*.

### **Conclusion**

The application is consistent with *Policy ESRD-2* and *Policy GEN-4*. 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

DVA Healthcare Renal Care, Inc. (DVA) d/b/a Coastal Carolina Dialysis, whose parent company is DaVita HealthCare Partners, Inc., proposes to relocate 10 stations from Goldsboro Dialysis Center (Wayne County) and two stations from Goldsboro South Dialysis Center (Wayne County) to develop a new 12-station dialysis facility in Wayne County. Furthermore, the proposed project includes relocating the home training program (home hemodialysis and peritoneal dialysis and support) from Goldsboro Dialysis Center to Coastal Carolina Dialysis. The July 2014 SMFP states that, as of December 31, 2013, Goldsboro

Dialysis Center has 26 certified dialysis stations and Goldsboro South Dialysis Center has 22 certified dialysis stations.

**Population to be Served**

In Section III.3, page 34, the applicant states,

*“This Certificate of Need Application is submitted to provide geographic accessibility of in-center hemodialysis and home dialysis to a patient population located on the eastern side of Goldsboro in Wayne County. DVA Healthcare Renal Care operates two End Stage Renal Disease facilities in Goldsboro. They are the Goldsboro Dialysis Center, located on the north side of Goldsboro and the Goldsboro South Dialysis Center, located on the south side of the city. In doing an analysis of the patients that are served by the two Wayne County facilities, it was determined that the existing facilities are serving a total of at least forty-six (46) patients who live in zip code 27534, which is the eastern side of the city. In order to make travel to dialysis three times a week for these patients more convenient, it was determined that DVA Healthcare Renal Care needs to provide a dialysis center nearer to their homes for better access to their dialysis services and support.*

*It is anticipated that the Goldsboro and Goldsboro South facilities will continue to grow after the relocation of the stations and patients.”*

In Section III.7, page 44, the applicant provides a table, reproduced below, to identify the patient population to be served at the proposed dialysis facility during the first two years of operation following project completion.

<b>COASTAL CAROLINA DIALYSIS Projected Dialysis Patient Origin</b>						
<b>COUNTY</b>	<b>OPERATING YEAR 1 2016</b>		<b>OPERATING YEAR 2 2017</b>		<b>COUNTY PATIENTS AS A PERCENT OF TOTAL</b>	
	<b>IN-CENTER</b>	<b>HOME</b>	<b>IN-CENTER</b>	<b>HOME</b>	<b>YEAR 1</b>	<b>YEAR 2</b>
Wayne	40	28	40	30	75.6%	76.1%
Duplin	0	7	0	7	7.8%	7.6%
Greene	0	1	0	1	1.1%	1.1%
Johnston	0	1	0	1	1.1%	1.1%
Lenoir	0	5	0	5	5.6%	5.4%
Sampson	0	8	0	8	8.8%	8.7%
<b>TOTAL</b>	<b>40</b>	<b>50</b>	<b>40</b>	<b>52</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant adequately identifies the population it proposes to serve.

**Analysis of Need**

In Section III, page 34, the applicant states that it conducted an assessment of its Goldsboro dialysis patients. The applicant determined that there are 46 in-center patients dialyzing at its existing Goldsboro facilities that live in zip code 27534 which means they live on the eastern side of the city, not on the northern side or southern side where the Goldsboro Dialysis and Goldsboro South Dialysis facilities are located, respectively. The applicant states those patients should be afforded the opportunity to receive services at a facility located more conveniently to where they live; which would improve ESRD geographic accessibility for Wayne County residents.

#### In-Center Utilization

In Sections II and III, the applicant projects that the 12-station facility will be utilized at 83% of capacity by the end of the first year of operation ( $40 \text{ patients} / (4 \times 12) = .83$ ). In Section III.7, pages 44-45, the applicant provides the assumptions and methodology used to project utilization, which are summarized below:

- 46 in-center patients (26 from Goldsboro Dialysis and 20 from Goldsboro South Dialysis) have signed letters which indicate they would consider transferring to the proposed Coastal Carolina Dialysis facility. See Exhibit 24 for the letters.
- The applicant assumes that 40 of the 46 in-center patients who signed letters will actually transfer to the new facility.
- Operating Year One is projected to be Calendar Year 2016.
- Operating Year Two is projected to be Calendar Year 2017.
- Coastal Carolina Dialysis is expected to serve 40 in-center patients by the end of Operating Year One based on the assumption that growth will continue at the Wayne County five year average annual change rate, as published in the July 2014 Semiannual Dialysis Report (1.1%).

The applicant's calculations are as follows:

$$\begin{aligned} & \text{"January 1, 2016-December 31, 2016} - 40 \text{ in-center patients} \times 1.011 = 40.44 \\ & \text{January 2, 2017-December 31, 2017} - 40.44 \text{ in-center patients} \times 1.011 = 40.88484 \end{aligned}$$

Projected in-center utilization is based on reasonable and adequately supported assumptions regarding projected growth of dialysis patients at Coastal Carolina Dialysis.

#### Home Training Utilization

On page 46, the applicant provides the assumptions and methodology used to project utilization by home trained patients, which are summarized below:

- It is assumed that all current home trained patients (44) will transfer to the proposed facility.

- Twenty two of the home trained dialysis patients receiving services at Goldsboro Dialysis Center live in Wayne County and have signed letters indicating that they would consider transferring to the proposed facility.
- The five year average annual growth rate for home hemodialysis patients was 27.1%. It is assumed that growth will continue at 15% for the Wayne County patients only.
- The five year average annual growth rate for home peritoneal dialysis patients was 2.8%. It is assumed that growth will continue at this rate for the Wayne County patients only.
- No growth was assumed for the 22 home trained patients who live outside of Wayne County.

Projected utilization is based on reasonable and adequately supported assumptions regarding projected growth of home-trained dialysis patients.

The applicant adequately demonstrates the need the population proposed to be served has for the development of a new dialysis facility in eastern Wayne County.

### **Access**

In Section VI.1, pages 60-65, the applicant describes how underserved persons will have access to services provided by Coastal Carolina Dialysis. On page 60, the applicant states:

*“... The proposed facility, by policy, will make dialysis services available to all patients 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 status.”*

The applicant projects 87% of its patients will be covered by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

### **Conclusion**

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the project and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. 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.

C

The applicant proposes to relocate 10 stations from Goldsboro Dialysis Center and two stations from Goldsboro South Dialysis Center to establish Coastal Carolina Dialysis - a new 12-station dialysis facility in east Goldsboro.

In Section III.6, page 41, the applicant states:

*“The transfer of stations and patients from the Goldsboro Dialysis Center and the Goldsboro South Dialysis Center will have no effect on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other under-served groups and the elderly to obtain needed health care. The discussion below provides information that the transfer of stations and patients will not have a negative effect on the needs of the patient population that is currently being served at the facilities losing stations.”*

Goldsboro Dialysis Center

Goldsboro Dialysis Center is currently certified for 26 dialysis stations and will have 17 stations upon completion of this project (relocate 10 stations), and Project ID# P-10344-14 (add one station).

In Section III.6, page 42, the applicant states:

*“The July 2014 Semiannual Dialysis Report indicates that there were 91 ESRD in-center dialysis patients receiving their treatments at Goldsboro Dialysis Center as of December 31, 2013. The facility has 26 certified stations. The facility utilization rate identified in the SDR was 87.5% as of June 18, 2014. It is projected that ten dialysis stations and 26 current in-center patients from the Goldsboro Dialysis Center will transfer to Coastal Carolina Dialysis.*

*DVA Healthcare Renal Care, Inc. submitted a Certificate of Need application on August 15, 2014 for the expansion of the Goldsboro Dialysis Center by one dialysis station, based on the facility need methodology. It is projected to be certified the same day as Coastal Carolina Dialysis, January 1, 2016. This will increase the number of certified stations to 27 at Goldsboro Dialysis.*

*With 27 in-center patients transferring from Goldsboro Dialysis to Coastal Carolina Dialysis this will leave 65 in-center patients and 17 dialysis stations at Goldsboro Dialysis if we do not take into consideration any patient growth between December 31, 2013 and when the proposed facility is projected to be certified (January 1, 2016).*

*However, we want to ... project the maximum growth that the population of the Goldsboro Dialysis will experience because by doing this we will account for all of the potential growth of that population over the entire period from the data*

*presented in the most recent Semiannual Dialysis Report through the point when the station transfer will occur and the proposed facility opens. We have projected the growth of the entire current patient population at Goldsboro Dialysis by projecting the growth from the date of the most recent data, which is December 31, 2013. Taking into consideration that the Goldsboro [sic] had 91 in-center patients as of December 31, 2013 and that Wayne County had an Average Annual Change Rate for the Past Five Years of 1.1%, we have projected the growth in the patient population from January 1, 2014 to the date [sic] proposed facility is projected to be certified.*

*January 1, 2014-December [sic] 31, 2014 – 91 in-center patients X 1.011 = 92.001*

*January 1, 2015-December [sic] 31, 2015 – 92.001 in-center patients X 1.011 = 93.013011*

*Using the projections above, Goldsboro [sic] would have 93 in-center patients at the point when the proposed facility is projected to be certified on January 1, 2016.*

*With a total of 26 patients and 10 dialysis stations transferring from the Goldsboro Dialysis Center to the proposed facility, this will leave 67 patients and 17 dialysis stations at the Goldsboro Dialysis Center.*

*January 1, 2016-December [sic] 31, 2016 – 67 in-center patients X 1.011 = 67.737*

*January 1, 2017-December [sic] 31, 2017 – 67.737 in-center patients X 1.011 = 68.482107*

*Once the transfer takes place, using the numbers above, the utilization rate at Goldsboro [sic] would be 98.5% in operating year one and 100% in operating year two. Given this projected growth in the in-center patient population, additional Certificate of Need application(s) will be submitted based on facility need as the facility approaches full capacity of stations to ensure that the needs of the facility's patients will continue to be met.*

#### Goldsboro South Dialysis Center

Goldsboro South Dialysis Center is currently certified for 22 dialysis stations and will have 20 stations upon completion of this project (relocate two stations).

In Section III.6, page 43, the applicant states:

*“The July 2014 Semiannual Dialysis Report indicates that there were 73 ESRD in-center dialysis patients receiving their treatments at Goldsboro South Dialysis Center as of December 31, 2013. The facility has 22 certified stations. The facility utilization rate identified in the SDR was 82.95% as of June 18, 2014. It is projected that two dialysis stations and 14 current in-center patients from the*

*Goldsboro South Dialysis Center will transfer to Coastal Carolina Dialysis.*

*With 14 in-center patients transferring from Goldsboro [sic] Dialysis to Coastal Carolina Dialysis this will leave 59 in-center patients and 20 dialysis stations at Goldsboro [sic] Dialysis if we do not take into consideration any patient growth between December 31, 2013 and when the proposed facility is projected to be certified (January 1, 2016).*

*However, we want to ... project the maximum growth that the population of the Goldsboro South Dialysis will experience because by doing this we will account for all of the potential growth of that population over the entire period from the data presented in the most recent Semiannual Dialysis Report through the point when the station transfer will occur and Coastal Carolina opens. We have projected the growth of the entire current patient population at Goldsboro South Dialysis by projecting the growth from the date of the most recent data, which is December 31, 2013. Taking into consideration that the Goldsboro South [sic] had 73 in-center patients as of December 31, 2013 and that Wayne County had an Average Annual Change Rate for the Past Five Years of 1.1%, we have projected the growth in the patient population from January 1, 2014 to the date [sic] proposed facility is projected to be certified.*

*January 1, 2014-December [sic] 31, 2014 – 73 in-center patients X 1.011 = 73.803*

*January 1, 2015-December [sic] 31, 2015 – 73.803 in-center patients X 1.011 = 74.614833*

*Using the projections above, Goldsboro [sic] would have 74 in-center patients at the point when the proposed facility is projected to be certified on January 1, 2016.*

*With a total of 14 patients and two dialysis stations transferring from the Goldsboro South Dialysis Center to the Coastal Carolina Dialysis, this will leave 60 patients and 20 dialysis stations at Goldsboro South.*

*January 1, 2016-December [sic] 31, 2016 – 60 in-center patients X 1.011 = 60.66*

*January 1, 2017-December [sic] 31, 2017 – 60.66 in-center patients X 1.011 = 61.3276*

*Once the transfer takes place, using the numbers above, the utilization rate at Goldsboro South would be 75% in operating year one and 76.7% in operating year two. The needs of the facility's patients will continue to be met. If the facility experiences substantial growth in the in-center patient population, additional Certificate of Need application(s) will be submitted based on facility need.”*

## **Conclusion**

The applicant demonstrates that the needs of the population presently served at Goldsboro Dialysis Center and Goldsboro South Dialysis Center; including underserved groups, will be adequately met following relocation of ten stations and two stations, respectively, to Coastal Carolina Dialysis. Therefore, the application is conforming to this criterion.

- (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.

C

In Section III.9, page 50, the applicant states, “*DVA Healthcare Renal Care, Inc. studied appropriate alternatives to this application and concluded that developing a new facility in the east Goldsboro area is the best option.*” The applicant concludes that the proposed project would provide a more convenient option for the 46 in-center patients and 22 home patients currently dialyzing at either Goldsboro Dialysis Center or Goldsboro South Dialysis, and who have signed letters of support and expressing their willingness to consider transferring to Coastal Carolina Dialysis. The applicant assumes that 40 of those patients will actually transfer to the new facility.

The other alternatives that the applicant considered and decided as not being the least costly or most effective alternatives are:

- Maintain status quo: The applicant states that Goldsboro Dialysis and Goldsboro South Dialysis have a combined utilization rate greater than 3.2 patients per station and neither facility has room for expansion.
- Locate the facility in another area of Goldsboro or Wayne County. The applicant states that other areas in the area do not have the patient population to support an additional facility.

On page 51, the applicant describes the cost effective approaches utilized in its dialysis facilities.

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 the proposal is the least costly or most effective alternative to meet the identified need for a dialysis facility located in Goldsboro, in eastern Wayne County. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. DVA Healthcare Renal Care, Inc. d/b/a Coastal Carolina Dialysis shall materially comply with all representations made in the certificate of need application.**

2. **DVA Healthcare Renal Care, Inc. d/b/a Coastal Carolina Dialysis shall relocate and operate no more than twelve dialysis stations at Coastal Carolina Dialysis, which shall include any home hemodialysis training or isolation stations.**
  3. **DVA Healthcare Renal Care, Inc. d/b/a Coastal Carolina Dialysis shall install plumbing and electrical wiring through the walls for no more than twelve dialysis stations, which shall include any home hemodialysis training or isolation stations.**
  4. **After certification of the 12 relocated dialysis stations at Coastal Carolina Dialysis, DVA Healthcare Renal Care, Inc. d/b/a Goldsboro Dialysis Center shall take steps to decertify 10 dialysis stations for a total of no more than 17 certified stations at Goldsboro Dialysis Center upon completion of this project (relocate 10 stations) and Project ID# P-10344-14 (add one station).**
  5. **After certification of the 12 relocated dialysis stations at Coastal Carolina Dialysis, DVA Healthcare Renal Care, Inc. d/b/a Goldsboro South Dialysis Center shall take steps to decertify two dialysis stations for a total of no more than 20 certified stations at Goldsboro South Dialysis Center.**
  6. **DVA Healthcare Renal Care, Inc. d/b/a Coastal Carolina 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

In Section VIII.1, pages 70-72, the applicant projects that the total capital cost of the project will be \$2,205,342 which includes \$1,640,500 for construction, \$125,000 for dialysis machines, \$116,025 for water treatment equipment, \$231,067 for equipment/furniture, \$6,890 for architect/engineering fees, \$18,955 for dialysis chairs, \$7,905 for a scale, \$31,500 for a television system, and \$27,500 for a patient computer system.

In Section IX.3, page 75, the applicant projects that the total working capital (start-up and initial operating expenses) associated with the proposed project will be \$2,020,427, as follows:

▪ Start-up Expenses	\$ 245,482
▪ Initial Operating Expenses	<u>\$1774,945</u>
<b>Total Working Capital</b>	<b>\$2,020,427</b>

In Section VIII.2-3, page 72, and Section IX.4, page 76, the applicant states that the capital and working capital needs of the project will be funded from cash reserves of DaVita Healthcare Partners Inc., the parent company of DVA Healthcare Renal Care, Inc.

Exhibit 29 contains a letter dated November 12, 2014 from the Vice President of Tax, DaVita Healthcare Partners, which states:

*“I am the Vice President of Tax at DaVita HealthCare Partners, Inc., the parent and 100% owner of DVA Healthcare Renal Care, Inc.*

*... I am writing this letter ... to confirm DaVita’s commitment of \$2,205,342, for the capital expenditures associated with this project; a commitment of \$245,482, for its start-up expenses; and a further commitment of \$1,774,945 in working capital. ...*

*DaVita Healthcare Partners has committed cash reserves in the total sum of \$4,225,769, for the capital costs, start-up costs and working capital for this project. ... ”*

Exhibit 30 contains the audited financial statements for DaVita Healthcare Partners, Inc. for the fiscal year ended December 31, 2013. As of December 31, 2013, DaVita Healthcare Partners, Inc. had \$946,249,000 in cash and cash equivalents, \$17,098,877,000 in total assets and \$4,605,541,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

In Section X.1, page 77, the applicant provides the allowable charges per treatment for each payment source, as illustrated below in the table.

<b>COASTAL CAROLINA DIALYSIS</b>	
<b>Payor</b>	<b>Charge Per Treatment</b>
Medicare	\$239.02
Medicaid	\$143.00
Medicare/Medicaid	\$239.02
Commercial Insurance	\$1,275.00
VA	\$193.00
Medicare/Commercial	\$239.02

The applicant projects revenues in Section X.2, page 78, and operating expenses in Section X.4, page 82, as illustrated below in the table:

<b>COASTAL CAROLINA DIALYSIS</b>		
	<b>Operating Year 1</b>	<b>Operating Year 2</b>
Total Net Revenue	\$4,306,811	\$4,431,839

Total Operating Costs	\$3,549,890	\$3,648,278
<b>Net Profit</b>	<b>\$756,920</b>	<b>\$783,561</b>

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the proformas, including the number of projected treatments, are reasonable and adequately supported. In Section VII.1, page 66 and Section X.5, page 82, the applicant provides projected staffing and salaries. See Section X of the application for the applicant's assumptions. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and charges. 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

DVA Healthcare Renal Care, Inc. (DVA) d/b/a Coastal Carolina Dialysis, whose parent company is DaVita HealthCare Partners, Inc., proposes to relocate 10 stations from Goldsboro Dialysis Center (Wayne County) and two stations from Goldsboro South Dialysis Center (Wayne County) to develop a new 12-station dialysis facility in Wayne County. Furthermore, the proposed project includes relocating the home training program (home hemodialysis and peritoneal dialysis and support) from Goldsboro Dialysis Center to Coastal Carolina Dialysis. The applicant adequately demonstrates the need for the new dialysis facility based on the number of in-center patients it proposes to serve. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

There are four existing dialysis facilities located in Wayne County; three in Goldsboro and one in Mt. Olive. Of the four facilities, the applicant or a related entity owns three, two of which are located in Goldsboro (Goldsboro Dialysis Center and Goldsboro South Dialysis Center) and the third is located in Mt. Olive (Mt. Olive Dialysis). The third facility in Goldsboro is owned by Fresenius Medical Care (RAI Care Centers).

The following table identifies the existing dialysis facilities located in Wayne County as reported in Table A of the July 2014 SDR.

WAYNE COUNTY DIALYSIS FACILITIES						
Facility	Existing, Approved and Proposed	Approved/Relocate	# of In-center patients	Utilization Rate as of 6/30/13	Address	**Distance to Proposed Facility
Coastal Carolina Dialysis* (proposed)	0	na	na	na	Ashe St @ Malloy St Goldsboro	NA
Goldsboro Dialysis* (existing)	26	1/10	91	87.50%	2609 Hospital Rd Goldsboro	4.9-4.7 miles 8-9 minutes
Goldsboro South* (existing)	22	0/2	73	82.95%	1704 Wayne Memorial Dr Goldsboro	4.3-4.1 miles 6-7 minutes
RAI Care Centers (existing)	16	0	24	37.50%	2403 Wayne Memorial Dr Goldsboro	4.1-4.4 miles 6-7 minutes
Mt Olive Dialysis* (existing)	15	0	40	66.67%	105 Michael Martin Dr Mt Olive	13.3-13.5 miles 18-19 minutes

\*DaVita facilities. \*Source: July 2014 SDR. \*\*<sup>1</sup><http://www.mapquest.com>

As shown in the table above, two of the three existing facilities in Goldsboro have a utilization rate above 70%. The Mt. Olive and RAI Care Center facilities have a utilization rate less than 70%. The four existing facilities in Wayne County are within fifteen miles of the proposed facility and less than 25 minutes. The facility located in Mt. Olive has the longest distance and travel time.

Table B of the July 2014 SDR identifies a surplus of 10 dialysis stations in Wayne County. However, the applicant, per *Policy EDRD-2* is not proposing to increase stations in the host county. Rather, the applicant proposes to relocate existing stations within the host county to improve geographic access for its existing patients.

The applicant adequately demonstrates the need to develop a new 12-station dialysis center in Goldsboro based on the number of Wayne County patients currently traveling to Goldsboro Dialysis or Goldsboro South Dialysis for dialysis services who live in the 27534 zip code, the absence of any existing or approved dialysis facilities located in the 27534 zip code, and the

projected number of in-center patients to be served. Exhibit 24 contains 46 letters from in-center patients and 22 letters from home dialysis patients currently receiving services at either Goldsboro Dialysis Center or Goldsboro South Dialysis Center who express a willingness to consider transferring to the proposed Coastal Carolina Dialysis facility.

Consequently, the applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities in Wayne County. Therefore, 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 VII.1, page 66, the applicant provides projected staffing for Coastal Carolina Dialysis, as illustrated in the following table:

<b>COASTAL CAROLINA DIALYSIS Full-Time Equivalent (FTE) Positions</b>	
RN	1.5
HTRN	3.0
PCT	4.5
Bio-Med Tech	0.3
Admin.	1.0
Dietician	0.5
Social Worker	0.5
Unit Secretary	2.0
Reuse	1.0
<b>Total FTEs</b>	<b>14.3</b>

The applicant projects a total of 14.3 FTE positions and states on page 67 that some teammates will transfer from Goldsboro Dialysis Center and Goldsboro South Dialysis Center to Coastal Carolina Dialysis. The applicant also states expecting no difficulty in recruiting staff for the remaining positions. In Section V.4, page 58 and Section VII.2, page 67, the applicant identifies the Medical Director for Coastal Carolina Dialysis as Dr. Robert Dunmire. In Exhibit 23, the applicant provides a letter from Dr. Dunmire indicating his willingness to serve as Medical Director of the facility. Additionally, in Section VII.10, page 69, the applicant states Coastal Carolina Dialysis will operate two shifts, six days a week from 6:00 a.m. to 4:00 p.m.

The applicant adequately documents the availability of resources, including health manpower and management personnel, for 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 V.1, page 56, the applicant lists the providers of the necessary ancillary and support services. Exhibits 8-9 and 17 contain documentation on service agreements. Exhibit 24 contains letters of support from area healthcare providers and the local community. The applicant adequately demonstrates that necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing healthcare system. Therefore, 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

- (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

In Section XI, pages 85-87, the applicant discusses the primary and secondary sites being considered for the proposed facility. The applicant states that DVA plans to enter a leasehold agreement for the proposed facility. The applicant states the primary site is 2.63 acres and is located on East Ash Street at Malloy Street in Goldsboro and is zoned for dialysis facility use (See Exhibit 12). The secondary site is 2.70 acres located on North Berkeley Boulevard and Caudill Avenue in the 27534 zip code and is also zoned for dialysis facility use. See Exhibit 32 for a map of the proposed sites. The applicant further states on pages 86 and 87, that both sites are conveniently located for its patients.

In Section XI.6(h), page 91 and Exhibit 33, the applicant states the facility will be 10,500 square feet. In Section XI.6(a), page 88, the applicant states that each dialysis station will occupy 174 square feet. In Section VIII.1, page 71, the applicant projects the construction upfit cost will be \$1,640,500 and architect and engineering fees will be \$6,890, which is a total of \$1,647,390. Thus, per square feet cost is projected to be \$156.89 ( $\$1,647,390/10,500 = \$156.89$ ). The following table illustrates the square footage breakdown as provided by the applicant in Section XI.6(h), page 91:

<b>COASTAL CAROLINA DIALYSIS</b>	
<b>Facility Area</b>	<b>Estimated Total Sq. Ft.</b>
<b>Ancillary Areas:</b>	
Administration/Offices/Reception/Elevator Lobby	409
Public Lobby	920
Mechanical Equipment	117
Biomedical	125
General Storage/Medical Records	868
Exam/Treatment & Medical Offices	1,117
Staff Lounge & Lockers	1,029
RO	840
Other: Handicap baths, dock and walkways	414
<b>Sub-Total Support</b>	<b>5,839</b>
<b>Treatment Areas:</b>	
Nurses Station	240
Dialysis Stations	2,095
Isolation Room(s)	121
Other: Walkways, Lab, Storage	152
<b>Sub-Total Treatment</b>	<b>2,608</b>
<b>Corridors/Walls</b>	<b>2,053</b>
<b>Total Square Feet</b>	<b>10,500</b>

In Section XI.6(d), page 89, the applicant states the facility will be constructed with energy-efficient glass, mechanically operated access doors and energy-efficient heating, ventilation and air conditioning (HVAC).

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy savings features have been incorporated into the construction plans, and that the construction costs will not unduly increase costs and charges for health services. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. 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 VI.1(b), pages 60 and 61, the applicant reports the payor mix for Goldsboro Dialysis and Goldsboro South Dialysis, respectively. The applicant reports that 87.8% of the in-center patients who received treatments at Goldsboro Dialysis and 86.2% 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 the past year. The tables below illustrate the historical payment source for these existing facilities:

<b>GOLDSBORO DIALYSIS CENTER 2013 IN-CENTER PAYOR MIX</b>	
<b>PAYOR</b>	<b>PERCENTAGE</b>
Medicare	19.4%
Medicaid	11.2%
Medicare/ Medicaid	28.6%
Commercial Insurance	7.1%
VA	5.1%
Medicare/Commercial	28.6%
<b>Total</b>	<b>100.0%</b>

<b>GOLDSBORO SOUTH DIALYSIS CENTER 2013 IN-CENTER PAYOR MIX</b>	
<b>PAYOR</b>	<b>PERCENTAGE</b>
Medicare	15.0%
Medicaid	6.3%
Medicare/ Medicaid	36.2%
Commercial Insurance	12.5%
VA	1.3%
Medicare/Commercial	28.7%
<b>Total</b>	<b>100.0%</b>

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Wayne, Duplin, Greene, Johnston, Lenoir, Sampson, and Wilson counties and statewide.

<b>COUNTY</b>	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Wayne	20.2%	8.3%	20.3%
Duplin	21.6%	9.8%	20.2%
Greene	21.1%	7.6%	24.6%
Johnston	17.5%	6.7%	20.0%
Lenoir	24.6%	11.0%	21.1%
Sampson	25.4%	10.1%	24.0%
Wilson	21.9%	9.0%	21.9%
Statewide	16.5%	6.7%	19.7%

\*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/21/2013, page 99*).<sup>1</sup>

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. However, a direct comparison to the

<sup>1</sup><http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

applicant's current payor mix would be of little value. The population data by age, race or gender do not include information on the number of elderly, handicapped, minorities or women utilizing health services.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides national statistics for FY 2011:

*"The December 31, 2011 prevalent population included 430,273 patients on dialysis ...."*<sup>2</sup> (p. 216)

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender and race, which show that 65.4% were white, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American. (p.216) Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 216). The report further states:

*"In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant."* (p. 216)

The *2013 USRDS Annual Data Report* provides 2011 ESRD spending by payor, as follows:

<b>ESRD Spending by Payor</b>		
<b>Payor</b>	<b>Spending in Billions</b>	<b>% of Total Spending</b>
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
<b>Total</b>	<b>\$49.2</b>	<b>100.0%</b>

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

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<sup>2</sup> [www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2013</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
<b>Gender</b>		
Female	6,845	44.5%
Male	8,544	55.5%
<b>Race</b>		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.<sup>3</sup>

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;

C

In Section VI.1(f), page 63, the applicant states,

*“The proposed facility will have 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 proposed facility will have no obligation under the Hill Burton Act.”*

In Section VI.6(a), page 65, the applicant states, *“There have been no civil rights access complaints filed within the last five years.”*

Therefore, the application is conforming to this criterion.

<sup>3</sup><http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

- (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 VI.1(c), page 61, the applicant provides the projected payor mix for the proposed in-center services at the new facility as follows:

<b>COASTAL CAROLINA DIALYSIS PROJECTED PAYOR MIX</b>	
<b>SOURCE OF PAYMENT</b>	<b>PERCENTAGE</b>
Medicare	17.4%
Medicaid	9.0%
Medicare/Medicaid	31.9%
Commercial Insurance	9.6%
VA	3.4%
Medicare/Commercial	28.7%
<b>Total</b>	<b>100.0%</b>

The applicant projects the payor mix for in-center dialysis services at Coastal Carolina Dialysis will be a consolidated in-center payor mix from the payor mixes of Goldsboro Dialysis Center and Goldsboro South Dialysis Center. The applicant projects that 87% of in-center patients at Coastal Carolina Dialysis will have their services paid for by Medicare and Medicaid.

In Section VI.1(a), page 60, the applicant states,

*“The proposed facility will not require payment upon admission to its services; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”*

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 VI.5, page 64, the applicant states that:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral by a Nephrologist with privileges at the proposed facility. These referrals most commonly come from primary care physicians or specialty physicians in Wayne or neighboring counties. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact the facility directly or indirectly, the patient will be referred to a qualified Nephrologist for evaluation and subsequent admission if it were found to be medically necessary. Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies which comprise **Exhibit 25**. [Emphasis in original.] The patient, again, will be referred to a qualified Nephrologist for final evaluation and then admission based on the doctor’s orders.”*

The applicant adequately demonstrates that it will provide a range of means by which a person can access 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 V.3, page 57, the applicant states,

*“The proposed facility will be offered as a clinical training site for nursing students at the local community colleges.”*

Exhibit 22 contains a letter from the DaVita Director of Healthcare Planning to the President of Wayne Community College in Goldsboro, offering Coastal Carolina Dialysis Center as a clinical training site for student nurses.

The information provided in Section V.3 is reasonable and credible for a new facility 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.

C

DVA Healthcare Renal Care, Inc. (DVA) d/b/a Coastal Carolina Dialysis, whose parent company is DaVita HealthCare Partners, Inc., proposes to relocate 10 stations from Goldsboro Dialysis Center (Wayne County) and two stations from Goldsboro South Dialysis Center (Wayne County) to develop a new 12-station dialysis facility in Wayne County.

Furthermore, the proposed project includes relocating the home training program (home hemodialysis and peritoneal dialysis and support) from Goldsboro Dialysis Center to Coastal Carolina Dialysis. There are currently four existing EDRD treatment facilities in Wayne County – three in Goldsboro where the applicant proposes to develop the new facility.

The applicant adequately demonstrates the need for the new dialysis facility and that it would not result in an unnecessary duplication. The discussions regarding need found in Criteria (3) and (6), respectively, are incorporated herein by reference.

In Section V.7, page 59, the applicant discusses how any enhanced competition in the service area will promote the cost effectiveness, quality and access to the proposed services. The applicant states:

*“The proposed ... facility is an effort to provide dialysis services to this community and is not intended to be a competitive venture. ...*

*The effect upon competition is unknown. However, patient selection is the determining factor ...*

*We view this project as having no impact, positive or negative, on the cost effectiveness or quality of our services. ... However, we do feel that accessibility to our services by the patients living in the service area identified will be enhanced. ”*

See also Sections II (pages 30-32), III (pages 34, 41-43, and 50-52), V (pages 56-59), VI (pages 60-65), VII (pages 66-68) and referenced exhibits, where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-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 it will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

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

The applicant currently provides dialysis services at Goldsboro Dialysis Center and Goldsboro South Dialysis Center and is proposing to relocate dialysis stations from each center to develop Coastal Carolina Dialysis. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, Goldsboro Dialysis Center and Goldsboro South Dialysis Center operated in compliance with the Medicare Conditions of Participation during the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

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

C

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

## **SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES**

### **.2202 INFORMATION REQUIRED OF APPLICANT**

(a) *An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:*

(1) *Utilization rates;*

-C- In Section III.6, pages 42-43, the applicant states the utilization rates at Goldsboro Dialysis Center and Goldsboro South Dialysis Center are reported in the July 2014 SDR provided in Exhibit 7. For Goldsboro Dialysis Center, the July 2014 SDR utilization rate was 87.5% as of December 31, 2013. For Goldsboro South Dialysis Center, the July 2014 SDR utilization rate was 82.9% as of December 31, 2013.

(2) *Mortality rates;*

-C- In Section IV.2, page 53, the applicant reports the following:

- Goldsboro Dialysis Center
  - 2011 12.3%
  - 2012 14.1%
  - 2013 17.3%
- Goldsboro South Dialysis Center
  - 2011 29.3%
  - 2012 35.9%
  - 2013 23.9%

(3) *The number of patients that are home trained and the number of patients on home dialysis;*

-C- In Section IV.3, page 54, the applicant states, “Goldsboro [sic] had 20 home hemodialysis and 24 peritoneal dialysis patients as of December 31, 2013. Goldsboro South has an agreement with Goldsboro Dialysis to provide home training services.”

(4) *The number of transplants performed or referred;*

-C- In Section IV.4, page 54, the applicant states, “Goldsboro [sic] had six patients receive a transplant in 2013. Seventeen patients were referred for transplant evaluation in 2013. Goldsboro South Dialysis Center had one patient receive a transplant in 2013. Seventeen patients were referred for transplant evaluation in 2013.”

(5) *The number of patients currently on the transplant waiting list;*

- C- In Section IV.5, page 54, the applicant states, “*Goldsboro [sic] has 18 patients on the transplant waiting list. Goldsboro South Dialysis Center has five patients on the transplant waiting list.*”
- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- In Section IV.6, page 55, the applicant states that for Goldsboro Dialysis Center there were 258 hospital admissions in 2013, 47 (18.2%) of which were dialysis related and 211 (81.8%) non-dialysis related. For Goldsboro South Dialysis Center, there were 152 hospital admissions in 2013, 63 (41.4%) of which were dialysis related and 89 (58.6%) non-dialysis related.
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
- C- In Section IV.7, page 32, the applicant states that there were 14 patients dialyzing at Goldsboro Dialysis Center with Hepatitis B, and no patients with AIDS as of June 30, 2014. Also, there were no patients treated who have converted to infectious status within the last year. The applicant further states as of June 30, 2014, at Goldsboro South Dialysis Center there were four patients dialyzing with Hepatitis B, and no patients with AIDS. And there were no patients who have converted to infectious status within the last year.
- (b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*
- (1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*
- C- Exhibit 8 contains a signed letter of intent from Wayne Memorial Hospital agreeing to enter into a Patient Transfer Agreement with Coastal Carolina Dialysis and to provide the following services to patients receiving their dialysis treatments at Coastal Carolina Dialysis:
- Acute Dialysis
  - Emergency Room Care
  - Diagnostic Evaluation Services
  - X-ray Services

- Special, Immunological and Routine Laboratory Services
- Blood Banking Services
- Surgical Services including Vascular Surgery

(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) *composition of the assessment/evaluation team at the transplant center,*
- (C) *method for periodic re-evaluation,*
- (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
- (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-C- Exhibit 9 contains a letter from Duke University Medical Center agreeing to enter into a Transplant Agreement with Coastal Carolina Dialysis including the above identified components.

(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-C- Exhibits 12 and 13 contain letters from the Utility Division of the City of Goldsboro attesting that water and sewer lines extend along the proposed primary and secondary property sites for Coastal Carolina Dialysis.

(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- Exhibit 10 contains copies of written policies and procedures for back-up for dialysis services in the event of a power outage.

(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-C- The applicant provides written documentation of availability and commitment to pursue acquiring the proposed primary and/or secondary site in Exhibits 12 and 13.

(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- See Section XI.6(g), page 89. See also Exhibit 14 for excerpts from the applicant’s Health and Safety Policy and Procedure Manual, Exhibit 15 regarding water quality, and Exhibit 34 for the In-Service Calendar with mandatory training classes.

(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- The applicant provides projected patient origin in Section III.7, page 44, which is reproduced in the following table:

COASTAL CAROLINA DIALYSIS Projected Dialysis Patient Origin						
COUNTY	OPERATING YEAR 1 2016		OPERATING YEAR 2 2017		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Wayne	40	28	40	30	75.6%	76.1%
Duplin	0	7	0	7	7.8%	7.6%
Greene	0	1	0	1	1.1%	1.1%
Johnston	0	1	0	1	1.1%	1.1%
Lenoir	0	5	0	5	5.6%	5.4%
Sampson	0	8	0	8	8.8%	8.7%
<b>TOTAL</b>	40	50	40	52	<b>100.0%</b>	<b>100.0%</b>

See Section III.7, pages 44-50 of the application for the applicant’s methodology and assumptions used to project patient origin. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-C- In Section III.8, page 50, the applicant states, “100% of the patients will travel less than 30 miles one way for dialysis treatments This is documented by the zip codes where the patients live and the zip code map ....” See Exhibit 21 for the 30-mile radius zip code map.

(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom*

*payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*

- C- In Section II.1(8), page 19, the applicant states, “*DVA Healthcare Renal Care, Inc. d/b/a Coastal Carolina Dialysis will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*”

**.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.*

- C- The applicant proposes to establish Coastal Carolina Dialysis, a new ESRD facility, by relocating 12 stations from other dialysis facilities in the host county. In Section II, page 20, the applicant states that it anticipates 40 in-center patients and 3.3 patients per station per week at the end of operating year one, based on the methodology and assumptions found on pages 15-19 and 19-29 of the application. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

- (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.*

- NA- Coastal Carolina Dialysis is not an existing facility.

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

The applicant provides all assumptions, including the methodology by which patient utilization is projected in Sections II and III. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

**.2204 SCOPE OF SERVICES**

*To be approved, the applicant must demonstrate that the following services will be available:*

(1) *diagnostic and evaluation services;*

- C- The table in Section V.1, page 56, states patients will be referred to Wayne Memorial Hospital for diagnostic and evaluation services.

(2) *maintenance dialysis;*

- C- The table in Section V.1, page 56, states the applicant will provide in-center maintenance dialysis.

(3) *accessible self-care training;*

- C- The table in Section V.1, page 56, states the applicant will provide in-center hemodialysis self-care training, intermittent peritoneal dialysis, CAPD and CCPD.

(4) *accessible follow-up program for support of patients dialyzing at home;*

- C- The applicant addresses the accessible follow-up program for support of patients dialyzing at home in Section V, Question 2(d), page 57.

(5) *x-ray services;*

- C- The table in Section V.1, page 56, states patients will be referred to Wayne Memorial Hospital for x-ray services.

(6) *laboratory services;*

- C- The table in Section V.1, page 56, states patients will be referred to Dialysis Laboratories for routine and special laboratory services.

(7) *blood bank services;*

- C- The table in Section V.1, page 56, states patients will be referred to Wayne Memorial Hospital for blood bank services.

(8) *emergency care;*

- C- The table in Section V.1, page 56, states patients will be referred to Wayne Memorial Hospital for emergency care.

(9) *acute dialysis in an acute care setting;*

- C- The table in Section V.1, page 56, states patients will be referred to Wayne Memorial Hospital for acute dialysis in an acute care setting. See Exhibit 8 for

a copy of the hospital's letter of intent to enter into a patient transfer agreement with Coastal Carolina Dialysis.

(10) *vascular surgery for dialysis treatment patients;*

-C- The table in Section V.1, page 56, states dialysis patients will be referred to Wayne Memorial Hospital for vascular surgery.

(11) *transplantation services;*

-C- The table in Section V.1, page 56, states patients will be referred to Duke University Medical Center and Vidant Medical Center-Greenville. See Exhibit 9 for documentation from Duke University Medical Center and Vidant Medical Center-Greenville.

(12) *vocational rehabilitation counseling and services; and*

-C- The table in Section V.1, page 56, states patients will be referred to the North Carolina Division of Vocational Rehabilitation Services for vocational rehabilitation counseling and services.

(13) *transportation.*

-C- The table in Section V.1, page 56, states patients will be referred to DSS and various transportation providers.

## **.2205 STAFFING AND STAFF TRAINING**

(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100 [sic].*

-C- In Section VII.1, page 66, the applicant provides the proposed staffing for Coastal Carolina Dialysis. The applicant states, "*The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100 [sic] ...*" The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*

-C- In Section VII.5, page 68, the applicant refers to Exhibit 20 for a copy of the training program description/outline which is DaVita's "*Training Programs for New Patient Care Provider Teammates.*" Exhibit 34 contains the proposed Annual In-Service Calendar for Coastal Carolina Dialysis.