

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: January 16, 2015  
PROJECT ANALYST: Bernetta Thorne-Williams  
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: P-10344-14 / DVA Healthcare Renal Care, Inc. d/b/a Goldsboro Dialysis Center / Add one station for a total of 27 stations upon project completion / Wayne County

### 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. d/b/a Goldsboro Dialysis Center, whose parent company is DaVita HealthCare Partners Inc. (DaVita) proposes to add one dialysis station to be used for home hemodialysis training to the existing facility for a total of 27 certified dialysis stations upon project completion.

### **Need Determination**

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 10 dialysis stations in Wayne County. However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for Goldsboro Dialysis in the July 2014 SDR is 3.5 patients per station. This utilization rate was calculated based on 91 in-center dialysis patients and 26 certified dialysis stations. (91 patients / 26 stations = 3.5 patients per station).

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

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/13		87.5%
Certified Stations		26
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>26</b>
In-Center Patients as of 12/31/13 (SDR2)		91
In-Center Patients as of 6/30/13 (SDR1)		93
Step	Description	
(i)	Difference (SDR2 - SDR1)	-2
	Multiply the difference by 2 for the projected net in-center change	-4
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/13	-0.0430
(ii)	Divide the result of Step (i) by 12	-0.0036
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/12 until 12/31/13)	-0.0430
(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	87.0860
(v)	Divide the result of Step (iv) by 3.2 patients per station	27.2144
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations 26] to determine the number of stations needed	1

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is one station. 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 one new station and, therefore, is consistent with the facility need determination for dialysis stations.

**Policies**

Policy GEN-3: Basic Principles, page 38 of the 2014 SMFP, 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 II.3, pages 22-23, Section V.7, page 36, Section XI (g), pages 65-66, 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 VI.1, pages 37-40 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 III.9, pages 29-30, Section V.7, page 36, and referenced exhibits. 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. Therefore, the application is consistent with Policy GEN-3.

### **Conclusion**

The application is consistent with the facility need determination in the July 2014 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, DVA Healthcare Renal Care, Inc. (DVA) d/b/a Goldsboro Dialysis Center proposes to add one dialysis station to be used for home hemodialysis training to its existing facility located at 2609 Hospital Road, in Goldsboro for a total of 27 certified dialysis stations, upon project completion.

### **Population to be Served**

In Section IV.1, page 31, the applicant identifies the population it served, as of December 31, 2013, as

illustrated in the table below.

County of Residence	# of Patients Dialyzing In-Center	# of Home Hemodialysis Patients
Wayne	87	22
Lenoir	3	5
Sampson	1	8
Duplin	0	7
Greene	0	1
Johnson		1
<b>Total</b>	<b>91</b>	<b>44</b>

In Section III.7, page 26, the applicant projects the number of in-center patients to be served in the first two years of operation following project completion, as illustrated in the following table:

<b>GOLDSBORO DIALYSIS CENTER</b>						
COUNTY	Operating Year 1 2016		Operating Year 2 2017		County In-Center Patients as % of Total	
	In-Center	Home Dialysis	In-Center	Home Dialysis	Year 1	Year 2
Wayne	88	29	89	31	95.7%	95.7%
Lenoir	3	6	3	6	3.2%	3.2%
Sampson	1	10	1	11	1.1%	1.1%
Duplin	0	9	0	10	0.0%	0.0%
Greene	0	1	0	1	0.0%	0.0%
Johnston	0	1	0	1	0.0%	0.0%
<b>Total</b>	<b>92</b>	<b>56</b>	<b>93</b>	<b>60</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.7, pages 26-29, the applicant provides the assumptions and methodology used to project the number of patients expected to utilize the Goldsboro Dialysis Center. The projections are based on the following assumptions:

The majority of patients projected to utilize Goldsboro Dialysis Center will be Wayne County residents. The projections are based on the following assumptions:

- The Goldsboro Dialysis Center had 91 in-center patients dialyzing on 26 certified stations as of December 31, 2013.
- The applicant proposes to utilize the proposed station for home hemodialysis training.
- It is assumed that the number of dialysis patients living in Wayne County is projected to grow at a rate of 1.1% based on the Wayne County Five Year Average Annual Change

Rate (AACR) as indicated in Table B of the July 2014 Semiannual Dialysis Report. In Section III.7, pages 26-27, the applicant states in-center utilization projections begin with 87 in-center patients living in Wayne County and are increased by the Wayne County five year AACR of 1.1%. No growth was added for the patients that reside within other counties, as shown below.

*“January 1, 2014-December 31, 2014 – 87 in-center patients X 1.011 = 87.957*

*January 1, 2015-December 31, 2015 – 87.957 in-center patients X 1.011 = 88.924527”*

The applicant then adds in the three patients who reside in Lenoir County and the one patient that resides in Sampson County for a beginning census of 92 in-center patients [88 + 3 + 1 = 92] on December 31, 2015. The applicant states that the period of growth begins on January 1, 2016 forward to December 31, 2017, as shown below:

*“January 1, 2016-December 31, 2016 – 88 in-center-patients X 1.011 = 88.968*

[Add in the three patients from Lenoir County and the one patient from Sampson County]

*January 1, 2017-December 31, 2017 – 88.968 in-center patients X 1.011 = 89.946618*

[Add in the three patients from Lenoir County and the one patient from Sampson County]

***Operating Year One is projected to begin January 1, 2016 and end December 31, 2016***

***Operating Year Two is projected to begin January 1, 2017 and end December 31, 2017”***

Based on the information above, Goldsboro Dialysis Center is projected to have 92 in-center patients at the end of operating year one for a utilization rate of 85.2% or 3.4 patients per station ( $92/27=3.41/4=85.2$ ). This meets the requirement that at the end of the first operating year the facility shall have at least 32 patients or 3.2 patients per station. Goldsboro Dialysis Center is projected to have 93 in-center patients at the end of operating year two for utilization rate of 86.1% or 3.4 patients per station.

### **Home-Training**

In Section III.7, pages 27-28, the applicant states that Goldsboro Dialysis Center had 44 home trained patients as of December 31, 2013. The applicant reports that 20 of those patients are home hemodialysis patients. The applicant states that the program has grown from nine patients in 2009 to its current 20 patients. The home hemodialysis program as a whole has experienced a 27.1% 5-year average annual growth rate.

Based on the average annual growth rate over the past five years, the applicant assumes that it is reasonable to project a 15% annual growth rate moving forward in its home hemodialysis program.

The applicant states that the period of growth begins on January 1, 2014 forward to December 31, 2017, as shown below:

*“January 1, 2014-December 31, 2014 – 20-patients X 1.15 = 23*

*January 1, 2015-December 31, 2015 – 23 patients X 1.15 = 26.45*

*January 1, 2016-December 31, 2016 – 26.45 patients X 1.15 = 30.4175*

*January 1, 2017-December 31, 2017 – 30.4175 patients X 1.15 = 34.980125*

*Operating Year One is projected to begin January 1, 2016 and end on December 31, 2016*

*Operating Year Two is projected to begin January 1, 2017 and end on December 31, 2017”*

The applicant adequately demonstrates the projected growth of home hemodialysis patients from 20 patients (December 31, 2013) to 30 patients as of December 31, 2016.

### **Peritoneal Dialysis**

In Section III.7, pages 28-29, the applicant provides its methodology and assumptions for its peritoneal dialysis patient population. The applicant reports that the peritoneal patient population has experienced an average annual growth rate of 2.8% over the past five years.

The applicant states that the period of growth begins on January 1, 2014 forward to December 31, 2017, as shown below:

*“January 1, 2014-December 31, 2014 – 24-patients X 1.028 = 26.672 [24.672]*

*January 1, 2015-December 31, 2015 – 24.672 patients X 1.028 = 25.36816*

*January 1, 2016-December 31, 2016 – 25.36816 patients X 1.028 = 26.07297484*

*January 1, 2017-December 31, 2017 – 26.07297484 patients X 1.028 = 26.80301813*

*Operating Year One is projected to begin January 1, 2016 and end on December 31, 2016*

*Operating Year Two is projected to begin January 1, 2017 and end on December 31, 2017”*

The applicant adequately demonstrates the projected growth of its peritoneal dialysis patient population from 24 patients (December 31, 2013) to 26 patients as of December 31, 2016.

Projected utilization of in-center, home hemodialysis, and peritoneal dialysis is based on reasonable and adequately supported assumptions regarding continued growth.

The applicant adequately proposes to utilize the additional station for home hemodialysis training based on the growth rate of the home hemodialysis population.

### Access

In Section VI.1, pages 37-40, the applicant describes how underserved persons will have access to services provided by Goldsboro Dialysis Center. On page 37, the applicant states:

*“Goldsboro Dialysis Center, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve patients without regard to race, sex, age, handicap or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.”*

### **Conclusion**

In summary, the applicant adequately identified the population to be served, demonstrated the need the population has for the project and the demonstrated extent to which all residents of the area, in particular underserved groups are likely to have access to the services provided. 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.

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In Section III.9, pages 29-30, the applicant discusses the two alternatives considered, as follows:

- Maintain the Status Quo – The applicant concluded that this was not the best option due to the significant growth in Goldsboro Dialysis’s home hemodialysis modality.
- Develop the Facility as Proposed – The applicant concluded that the development of one additional dialysis station would allow Goldsboro Dialysis Center to address the growing need for home hemodialysis services.

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 Goldsboro Dialysis Center proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. DVA Healthcare Renal Care, Inc. d/b/a Goldsboro Dialysis Center shall materially comply with all representations made in the certificate of need application.**
  - 2. DVA Healthcare Renal Care, Inc. d/b/a Goldsboro Dialysis Center shall develop and operate no more than one additional dialysis station for a total of no more than 27 dialysis stations at Goldsboro Dialysis Center which shall include any home hemodialysis or isolation stations.**
  - 3. DVA Healthcare Renal Care, Inc. d/b/a Goldsboro Dialysis Center shall install plumbing and electrical wiring through the walls for no more than one additional dialysis station which shall include any home hemodialysis or isolation stations.**
  - 4. DVA Healthcare Renal Care, Inc. d/b/a Goldsboro Dialysis Center 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.

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In Section VIII.1, page 48, the applicant states that there will be no capital cost associated with the proposed project. In Section IX.2 page 52, the applicant states there will be no initial operating expenses or start-up expenses associated with the proposed project.

Exhibit 19 of the application 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 \$5,302,841,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project should any arise.

In Section X.1, page 53, the applicant provides the allowable charges, per treatment, for each payment source for Goldsboro Dialysis Center, as illustrated in the table below:

Payor Source	Charge per Treatment
Medicare	\$239.02
Medicaid	\$143.00
Medicare/Medicaid	\$239.02
Commercial Insurance	\$1,275.00
VA	\$193.00
Medicare/Commercial	\$239.02



On page 53, the applicant states that Medicare patient's reimbursement rate is at 80% of the \$239.02 for a payout of \$191.21.

In Section X.2-X.4, pages 54-59, the applicant reports projected revenues and expenses for Goldsboro Dialysis Center, as illustrated in the table below:

<b>Goldsboro Dialysis Center</b>		
	<b>Operating Year 1</b>	<b>Operating Year 2</b>
Total Net Revenue	\$7,405,922	\$7,716,806
Total Operating Costs	\$5,511,700	\$5,714,176
<b>Net Profit</b>	<b>\$1,894,223</b>	<b>\$2,002,630</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 pro formas, including the number of projected treatments, are reasonable, credible and supported. See Section X of the application for the applicant's assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**Conclusion**

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of this project, should a need arise. 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.

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DVA Healthcare Renal Care, Inc. d/b/a Goldsboro Dialysis Center proposes to add one dialysis station to be used for home hemodialysis training to the existing facility for a total of 27 certified dialysis stations upon project completion. The July 2014 SDR reports that the following four ESRD facilities are currently located in Wayne County:

<b>Name of Facility</b>	<b># of Certified Stations</b>	<b>Number of In-center Patients</b>	<b>% of Utilization</b>	<b>Address</b>
Goldsboro Dialysis	26	91	87.50%	2609 Hospital Road - Goldsboro
Goldsboro South Dialysis	22	73	82.95%	1704 Wayne Memorial Drive - Goldsboro
Mt. Olive Dialysis	15	40	66.67%	105 Michael Martin Road - Mt. Olive
RAI Care Centers - Goldsboro	16	24	37.50%	2403 Wayne Memorial Drive - Goldsboro

Source: July 2014 SDR

Of those facilities listed above, DaVita owns and operates three of the facilities, with Fresenius Medical Care, Inc. owning/operating one. As reported in the July 2014 SDR, two of those facilities operated with a utilization of above 80%, as of December 31, 2013. The proposed addition of one ESRD station at Goldsboro Dialysis Center to be used for home hemodialysis training would increase the inventory of certified ESRD stations within Wayne County from 79 certified stations to 80. The July 2014 SDR reports a surplus of 10 ESRD stations in Wayne County. However, the applicant demonstrated a need, based on the facility need methodology to add one additional ESRD station to Goldsboro Dialysis Center. See Criterion (3) incorporated herein by reference.

Consequently, the applicant adequately demonstrates the proposal would not result in the unnecessary duplication of existing health service capabilities or facilities. 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.

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In Section VII.1, page 43, the applicant provides a table which demonstrates that Goldsboro Dialysis Center currently employs 23.50 Full Time Equivalent Staff (FTEs). The applicant states that no new staff will be hired as a result of the proposed addition of one ESRD station.

On page 44, the applicant discusses DaVita HealthCare Partners' recruitment policy and states that they do not anticipate difficulty in recruiting and retaining qualified staff because of their aggressive recruiting practice and their competitive salary structure. In Section V.4, page 35, the applicant identifies the Medical Director for Goldsboro Dialysis Center as Dr. David Dunmire. In Exhibit 13 the applicant provides a letter of support from Dr. Dunmire for the proposed project. Additionally, in Section VII.10,

page 45, the applicant states Goldsboro Dialysis Center 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.

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In Section V.1, page 33, the applicant lists the providers of the necessary ancillary and support services. The applicant adequately demonstrates that necessary ancillary and support services are 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.

NA

(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;

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In Section VI.1(b), page 37, the applicant reports that 90.9% of the patients who received treatments at Goldsboro Dialysis Center had some or all of their in-center patient services paid for by Medicare or Medicaid in the past year. The tables below illustrate the historical payment source for in-center patients and home trained patients, as reported on pages 37-38 of the application.

<b>GOLDSBORO DIALYSIS CENTER IN-CENTER PAYOR MIX</b>	
<b>SOURCE OF PAYMENT</b>	<b>PERCENTAGE</b>
Medicare	29.6%
Medicaid	7.1%
Medicare/Medicaid	13.3%
Commercial Insurance	7.1%
VA	1.0%
Medicare/Commercial	40.9%
<b>Total</b>	<b>100.0%</b>

<b>GOLDSBORO DIALYSIS CENTER HOME TRAINED PAYOR MIX</b>	
<b>SOURCE OF PAYMENT</b>	<b>PERCENTAGE</b>
Private Pay	7.7%
Medicare/Medicaid	15.4%
Commercial Insurance	19.2%
Medicare/Commercial	57.7%
<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 County and statewide.

	<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 County	20%	8.3%	20.3%
Statewide	17%	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 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.218). 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. 223). 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:

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

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

<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:

<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>

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

In Section VI.1(f), page 40, the applicant states,

*“Goldsboro Dialysis Center 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.”*

In Section VI.6(a), page 41, 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.

- (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

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In Section VI.1(c), page 38, the applicant provides the projected payor mix for in-center patients for the proposed Goldsboro Dialysis Center, as shown in the table below.

<b>Source of Payment In-Center Patients</b>	<b>As a % of Total</b>
Medicare	29.6%
Medicaid	7.1%
Medicare/Medicaid	13.3%
Commercial Insurance	7.1%
VA	1.0%
Medicare/Commercial	40.9%
<b>Total</b>	<b>100.0%</b>

As shown in the table above, the applicant projects 90.9% of all patients will have their care paid for by Medicare or Medicaid, which represents no change from its historical in-center payor source.

Additionally, on page 38, the applicant also provides the projected payor source for its home trained patients, as illustrated in the table below.

<b>GOLDSBORO DIALYSIS CENTER HOME TRAINED PAYOR MIX</b>	
<b>SOURCE OF PAYMENT</b>	<b>PERCENTAGE</b>
Private Pay	7.7%
Medicare/Medicaid	15.4%
Commercial Insurance	19.2%
Medicare/Commercial	57.7%
<b>Total</b>	<b>100.0%</b>

The applicant does not project a change in its payor source for those patients that receive home hemodialysis training.

The applicant demonstrates that medically underserved populations would have adequate access to the proposed services at Goldsboro Dialysis Center. 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(a), pages 40-41, the applicant states:

*“Patients with End Stage Renal Disease will have access to dialysis services upon referral by a Nephrologist with privileges at Goldsboro Dialysis Center. Goldsboro Dialysis Center will grant privileges to all qualified nephrologists. These referrals most commonly come from primary care physicians or specialty physicians in Wayne County or transfer referrals from other Nephrologists outside of the immediate area. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. ... Patients from outside the Goldsboro Dialysis Center catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies which comprise **Exhibit 14.**”* [Emphasis in original]

The applicant adequately demonstrates that Goldsboro Dialysis Center will offer a range of means by which a person can access its 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 35, the applicant states that Goldsboro Dialysis Center is utilized as a clinical training site by Miller-Motte College and James Sprunt Community College.

Supplemental information provided by the applicant includes training agreements with Miller-Motte College and James Sprunt Community College.

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

The applicant proposes to add one dialysis station to be used for home hemodialysis training to the existing facility for a total of 27 certified dialysis stations upon project completion. According to the July 2014 SDR there are currently four ESRD facilities and a surplus of 10 dialysis stations located in Wayne County.

<b>Name of Facility</b>	<b># of Certified Stations</b>	<b>Number of In-center Patients</b>	<b>% of Utilization</b>	<b>Address</b>
Goldsboro Dialysis	26	91	87.50%	2609 Hospital Road - Goldsboro
Goldsboro South Dialysis	22	73	82.95%	1704 Wayne Memorial Drive - Goldsboro
Mt. Olive Dialysis	15	40	66.67%	105 Michael Martin Road - Mt. Olive
RAI Care Centers - Goldsboro	16	24	37.50%	2403 Wayne Memorial Drive - Goldsboro

Of those facilities listed above, DaVita owns and operates three of the facilities, with Fresenius Medical Care, Inc. owning/operating one. As reported in the July 2014 SDR, two of those facilities operated with a utilization of above 80%, as of December 31, 2013. The applicant projects that 90.9% of all patients who receive services at Goldsboro Dialysis Center will have their care paid for by Medicare or Medicaid.

In Section V.7, page 36, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost effectiveness, quality and access. The applicant states in part:

*“The proposed expansion of the facility by adding one home hemodialysis station is not intended to be a competitive venture.*

...

*The effect upon competition is unknown. ...”*

See also Sections II, III, V, VI and VII 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 area would have a positive impact on quality and access to the proposed services. This determination is based on the following analysis:

- The applicant adequately demonstrates the need to add one dialysis station to provide home hemodialysis training and that it is a cost-effective alternative. The discussion regarding analysis of need and alternatives found in Criteria (3) and (4), respectively are incorporated herein by reference.
- The applicant will continue to provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is 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

According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, Goldsboro Dialysis Center operated in compliance with the Medicare Conditions of Participation within the 18 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 application is conforming to all applicable criteria which are discussed below.

## **10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT**

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

*.2202(a)(1) Utilization rates;*

-C- See Section IV, page 31, and Exhibit 7 (copy of the July 2014 SDR, Tables A and B). As of December 31, 2013, the utilization rate for Goldsboro Dialysis Center was 87.50%.

*.2202(a)(2) Mortality rates;*

-C- In Section IV.2, page 31, the applicant states mortality rates for Goldsboro Dialysis Center were 12.5% in 2011, 14.1% in 2012, and 17.4% in 2013.

*.2202(a)(3) The number of patients that are home trained and the number of patients on home dialysis;*

-C- In Section IV.3, page 31, the applicant reports as of December 31, 2013, Goldsboro Dialysis Center had 24 peritoneal dialysis patients and 20 home hemodialysis patients.

*.2202(a)(4) The number of transplants performed or referred;*

-C- In Section IV.4, page 32, the applicant states Goldsboro Dialysis Center referred 17 patients for transplant evaluation and six transplants were performed in 2013.

*.2202(a)(5) The number of patients currently on the transplant waiting list;*

-C- In Section IV.5, page 32, the applicant states there are currently 18 patients on the transplant waiting list at Goldsboro Dialysis Center.

*.2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

-C- In Section IV.6, page 32, the applicant provides the hospital admissions rates, by admission diagnosis, as illustrated in the tables below.

*Goldsboro Dialysis Center  
 Patient Hospital Admissions*

<i>1/13-12/13 Hospital Admissions</i>	<i>Total</i>
<i>Number dialysis related</i>	<i>47</i>
<i>Percent Dialysis related</i>	<i>18.2%</i>
<i>Number non-dialysis related</i>	<i>211</i>
<i>Percent non-dialysis related</i>	<i>81.8%</i>
<b><i>Total number Admissions</i></b>	<b><i>258</i></b>

.2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*

-C- In Section IV.7, page 32, the applicant reported as of December 31, 2013 there were no patients dialyzing at Goldsboro Dialysis Center with an infectious disease (Hepatitis B or AIDS). Additionally, the applicant reports that none of the patients dialyzing at the facility converted to infectious disease status.

(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:*

.2202(b)(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.*

-NA- Goldsboro Dialysis is an existing facility.

.2202(b)(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.*

-NA- Goldsboro Dialysis Center is an existing facility.

.2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- Goldsboro Dialysis Center is an existing facility.

.2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- See Exhibit 8 for copies of the applicant's policies, procedures and guidelines; which includes a section on power failure.

.2202(b)(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.*

-NA- Goldsboro Dialysis Center is an existing facility.

.2202(b)(6) *Documentation that the services will be provided in conformity to applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- See Section VII.2, pages 43-44 and Section XI.6, pages 64-66. In Section XI.6(g), page 65, the applicant states, “*Goldsboro Dialysis Center has and will continue to operate within the applicable laws and regulations pertaining to staffing, and fire safety equipment, physical environment and other relevant health safety requirements.*”

.2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- See Section III.7, pages 26-29, for all assumptions, including the methodology by which patient origin is projected. The applicant provides projected patient origin which is based on the historical utilization of Goldsboro Dialysis Center facility, as shown in the below table.

<b>GOLDSBORO DIALYSIS CENTER</b>						
<b>COUNTY</b>	<b>Operating</b>		<b>Operating</b>		<b>County In-Center Patients as % of Total</b>	
	<b>Year 1 2016</b>		<b>Year 2 2017</b>		<b>Year 1</b>	<b>Year 2</b>
	<b>In-Center</b>	<b>Home Dialysis</b>	<b>In-Center</b>	<b>Home Dialysis</b>		
<b>Wayne</b>	<b>88</b>	<b>29</b>	<b>89</b>	<b>31</b>	<b>95.7%</b>	<b>95.7%</b>
<b>Lenoir</b>	<b>3</b>	<b>6</b>	<b>3</b>	<b>6</b>	<b>3.2%</b>	<b>3.2%</b>
<b>Sampson</b>	<b>1</b>	<b>10</b>	<b>1</b>	<b>11</b>	<b>1.1%</b>	<b>1.1%</b>
<b>Duplin</b>	<b>0</b>	<b>9</b>	<b>0</b>	<b>10</b>	<b>0.0%</b>	<b>0.0%</b>
<b>Greene</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0.0%</b>	<b>0.0%</b>
<b>Johnston</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0.0%</b>	<b>0.0%</b>
<b>Total</b>	<b>92</b>	<b>56</b>	<b>93</b>	<b>60</b>	<b>100.0%</b>	<b>100.0%</b>

.2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

- NA- Goldsboro Dialysis Center is an existing facility.
- .2202(b)(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 for such services.*
- C- In Section II, page 14, the applicant states, “*DVA Healthcare Renal Care, Inc. d/b/a Goldsboro Dialysis Center 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.*”

#### **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- Goldsboro Dialysis Center is an existing 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- See Section II, pages 14-15 and Section III.7, pages 26-27, for the assumptions used by the applicant in determining its utilization for Goldsboro Dialysis Center. The applicant states the facility would have 3.4 patients per station per week as of the end of the first operating year of the additional stations ( $92/27 = 3.40$ ).
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section II, pages 14-19 and Section III.7, pages 26-30, the applicant provides the assumptions and methodology used to project in-center, home hemodialysis and peritoneal dialysis’ utilization for the existing facility.

#### **10 NCAC 14C .2204 SCOPE OF SERVICES**

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

- .2204(1) *Diagnostic and evaluation services;*
- C- In Section V.1(e), page 33, the applicant states that diagnostic and evaluation services will be provided by Wayne Memorial Hospital.
- .2204(2) *Maintenance dialysis;*
- C- In Section V.1(c), page 33, the applicant states that maintenance dialysis will be provided at Goldsboro Dialysis Center.
- .2204(3) *Accessible self-care training;*
- C- In Section V.1(d), page 33, the applicant states that accessible self-care training will be provided by Goldsboro Dialysis Center.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
- C- In Section V.1, page 33, the applicant states that an accessible follow-up program for support of peritoneal patients dialyzing at home will be provided by Goldsboro Dialysis Center.
- .2204(5) *X-ray services;*
- C- In Section V.1(g), page 33, the applicant states that X-ray services will be provided by Wayne Memorial Hospital.
- .2204(6) *Laboratory services;*
- C- In Section V.1(h), page 33, the applicant states that routine, special and immunological laboratory services will be provided by Dialysis Laboratories.
- .2204(7) *Blood bank services;*
- C- In Section V.1(i), page 33, the applicant states that blood bank services will be provided by Wayne Memorial Hospital.
- .2204(8) *Emergency care;*
- C- In Section V.1(b), page 33, the applicant states emergency care will be provided by Wayne Memorial Hospital.
- .2204(9) *Acute dialysis in an acute care setting;*
- C- In Section V.1(a), page 33, the applicant states that acute dialysis in an acute care setting will be provided by Wayne Memorial Hospital.

- .2204(10) *Vascular surgery for dialysis treatment patients*
- C- See Section V.1(p), page 33, the applicant states vascular surgery for dialysis treatment patients will be provided by Wayne Memorial Hospital.
- .2204(11) *Transplantation services;*
- C- In Section V.1(F), page 33, the applicant indicates that transplantation services will be provided by Wayne Memorial Hospital.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
- C- In Section V.1(o), page 33, the applicant states that referrals will be made to NC Department of Vocational Rehabilitation for vocational rehabilitation counseling and services.
- .2204(13) *Transportation*
- C- In Section V.1(q), page 33, the applicant states that transportation will be provided by DSS and various providers.

**10 NCAC 14C .2205 STAFFING AND STAFF TRAINING**

- .2205(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.*
- C- In Section VII, page 43, the applicant provides the current staffing for Goldsboro Dialysis Center and states that the facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100. The applicant states no new full time equivalent staff (FTEs) will be hired for the proposed addition of one dialysis station to the facility. See discussion of staffing in Criterion (7) incorporated herein by reference.
- .2205(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- See Exhibit 17 for a copy of DVA's training program description/outline for patient care teammates.