

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 15, 2019

Findings Date: February 15, 2019

Project Analyst: Bernetta Thorne-Williams

Assistant Chief: Lisa Pittman

Project ID #: P-11596-18

Facility: Goldsboro Dialysis Center

FID #: 944654

County: Wayne

Applicant: DVA Renal Healthcare, Inc.

Project: Add no more than 6 stations for a total of no more than 23 stations upon completion of this project and Project I.D. # P-11451-18 (relocate 7 stations to Rosewood Dialysis)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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 Renal Healthcare, Inc., (DVA), d/b/a Goldsboro Dialysis proposes to add 6 stations for a total of 23 stations upon completion of this project and Project I.D. # P-11451-18 (relocate 7 stations to Rosewood Dialysis).

Need Determination

The 2018 State Medical Facilities Plan (2018 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of two dialysis stations in Wayne County. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the July 2018 SDR, is at

least 3.2 patients per station per week, or 80%. The applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Goldsboro Dialysis in the July 2018 SDR is 3.5926 patients per station per week, or 89.81% ($3.5926 / 4 \text{ patients per station} = 0.8981$). This utilization rate was calculated based on 97 in-center dialysis patients and 27 certified dialysis stations ($97 \text{ patients} / 27 \text{ stations} = 3.5926 \text{ patients per station per week}$). Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table:

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

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/17		89.8%
Certified Stations		24
Pending Stations		0
Total Existing and Pending Stations		24
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2)		97
In-Center Patients as of 6/30/17 (Jan 2018 SDR) (SDR1)		98
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	-1
	Multiply the difference by 2 for the projected net in-center change	-2
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/17	-0.0204
(ii)	Divide the result of Step (i) by 12	-0.0017
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/16 until 12/31/17)	-0.0204
(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	95.0204
(v)	Divide the result of Step (iv) by 3.2 patients per station	29.6939
	and subtract the number of certified and pending stations to determine the number of stations needed	5.6939

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

Policies

There is one policy in the 2018 SMFP which is applicable to this review. *POLICY GEN-3: BASIC PRINCIPLES* on page 33 of the 2018 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 9-10, Section N.1, page 51, Section O, page 52 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 10, Section L, pages 45-49, Section C.3, page 16, Section N.1, page 51 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Sections B.4(c) and B.4(d), page 11, Section C.3, page 16, Section K.1, page 40 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 as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

Conclusion

The Agency reviewed the:

- Application

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

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

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

C

The applicant proposes to add 6 stations for a total of 23 stations upon completion of this project and Project I.D. # P-11451-18 (relocate 7 stations to Rosewood Dialysis).

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Wayne County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 20 and C.1, page 13, the applicant provides the historical and the projected patient origin for in-center (IC), home hemodialysis (HHD), and peritoneal dialysis (PD) patients, as illustrated in the tables below.

County	DIALYSIS PATIENTS AS OF DECEMBER 31, 2017		
	IC	HHD	PD
Wayne	92.0	6.0	21.0
Johnston	1.0	1.0	2.0
Lenoir	4.0	1.0	3.0
Sampson	0.0	2.0	2.0
Total	97.0	10.0	28.0

County	Operating Year 1 CY2020			Operating Year 2 CY2021			Percent of Total	
	IC	HHD	PD	IC	HHD	PD	OY1	OY2
Wayne	74.0	14.0	25.0	78.0	17.0	27.0	87.6%	88.4%
Johnston	1.0	1.0	2.0	1.0	1.0	2.0	3.1%	2.9%
Lenoir	4.0	1.0	3.0	4.0	1.0	3.0	6.2%	5.8%
Sampson	0.0	2.0	2.0	0.0	2.0	2.0	3.1%	2.9%
Total	79.0	18.0	32.0	83.0	21.0	34.0	100.0%	100.0%

The applicant provides the assumptions and methodology for its patient origin projections on pages 13-15. The applicant’s assumptions are reasonable and supported.

Analysis of Need

In Section C, pages 13-15, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section B.2, page 7, the applicant states the application is filed pursuant to the facility need methodology in the 2018 SMFP utilizing data from the July 2018 SDR.

On pages 14-17, the applicant states:

- The applicant begins the projections for the future patient population of Goldsboro Dialysis by using the ending in-center patient census of 97 patients, as of December 31, 2017.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Wayne County which is 5.9%, as published in the July 2018 SDR, to project the Wayne County patient population forward.
- The applicant does not project an increase in the patient population for Johnson County nor Lenoir County.
- The applicant subtracts the seven dialysis stations to be relocated to Rosewood Dialysis per Project I. D # P-11451-18.
- The applicant subtracts the 33 patients projected to transfer their care to Rosewood Dialysis.
- Operating Year 1 (OY1) = Calendar Year (CY) 2020
 Operating Year 2 (OY2) = Calendar Year (CY) 2021

Projected Utilization

The applicant’s methodology, which begins with the Wayne County in-center patient census as of December 31, 2017 and applies the Wayne County AACR of 5.9%, as illustrated in the following table, from application page 14:

Date	# Patients	Growth Rate	End Patients	+ Out of SA Patients	Total Year End Census
01/01/18	92	1.059	97.428	5	102.428
01/01/19	97	1.059	103.1763	5	108.1763
01/01/20 OY1	103 - 33 = 70	1.059	74.13	5	79.13
01/01/21 OY2	74.13	1.059	78.503	5	83.503

The applicant projects to serve 79 in-center patients at the end of CY1 and 83 in-center patients at the end of CY2. Thus, the applicant projects that Goldsboro Dialysis will have a utilization rate of 85.86% or 3.43 patients per station per week (79 patients / 23 stations = 3.4347 / 4 = 0.8586 or 85.86%) at the end of CY1. The projected utilization of 3.436 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- the applicant begins with the existing in-center patients,
- the applicant grows the Wayne County in-center patients using the Wayne County 5-year AACR (5.9%) and holds the patient population from other counties constant, and
- the utilization rate by the end of OY1 exceeds the minimum standard of 3.2 patients per station per week.

Home Hemodialysis and Peritoneal Dialysis

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

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

- the applicant begins with the existing HHD and PD patients, all of whom are from Wayne County, and
- the applicant grows the HHD and PD patients by one patient per year for each service component.

Access

In Section C.3, page 16, the applicant states that, by policy, the proposed services will be available to all patients in need of dialysis, without regard to race, sex, age, handicap,

socioeconomic status or the ability to pay. In Section L.1, page 46, the applicant provides the projected payor mix during OY2, as illustrated below.

Projected Payor Mix OY2

Payment Source	Percent of Total Revenue	Percent of In-Center Revenue	Percent of HHD Revenue	Percent of PD Revenue
Private Pay	0.0%	0.0%	0.0%	0.00%
Medicare	19.10%	20.80%	20.00%	12.00%
Medicaid	11.80%	12.90%	0.00%	12.00%
Commercial Insurance	8.80%	5.90%	0.00%	24.00%
Medicare / Commercial	35.30%	34.70%	60.00%	28.00%
Medicare / Medicaid	18.40%	20.80%	10.00%	12.00%
VA	6.60%	5.00%	10.00%	12.00%
Total	100.00%	100.00%	0.0%	100.00%

As shown in the table above, OY2, the applicant projects 72.80% of total services will be provided to Medicare (includes Medicare, Medicare/Commercial and Medicare/Medicaid) and 30.2% to Medicaid patients.

On page 46, the applicant provides the assumptions and methodology used to project payor mix during OY2. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization at Goldsboro Dialysis.

Conclusion

The Agency reviewed the:

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

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

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

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons,

racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce, eliminate or relocate a facility or a service. The applicant proposes to add six dialysis stations to an existing facility pursuant to the facility need determination. Therefore, Criterion (3a) is not applicable to this review.

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

CA

The applicant proposes to add 6 stations for a total of 23 stations upon completion of this project and Project I.D. # P-11451-18 (relocate 7 stations to Rosewood Dialysis).

In Section E.1, page 24, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo - The applicant states that based on the growth rate at Goldsboro Dialysis this alternative was dismissed.
- Relocate existing stations from another DaVita facility in Wayne County - The applicant states that all the facilities operated in Wayne County for more than one year have operated with a utilization above 80%. Therefore, this alternative was rejected.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- the facility is operating above 80% capacity,
- the applicant's need methodology indicates a need for six additional stations, and
- maintaining the status quo does not address the high utilization and need for additional stations at the facility.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

1. **Goldsboro Dialysis shall materially comply with all representations made in the certificate of need application.**
 2. **Pursuant to the facility need determination in the July 2018 SDR, applicant shall develop no more than six additional dialysis stations for a total of no more than 23 certified stations at Goldsboro Dialysis upon project completion, which shall include any home hemodialysis training or isolation stations.**
 3. **Goldsboro Dialysis shall install plumbing and electrical wiring through the walls for no more than six additional dialysis stations which shall include any isolation stations**
 4. **DVA Renal Healthcare, Inc., shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to the issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add 6 stations for a total of 23 stations upon completion of this project and Project I.D. # P-11451-18 (relocate 7 stations to Rosewood Dialysis).

Capital and Working Capital Costs

In Section F.1, pages 25, the applicant states there will be no capital or working capital cost associated with the proposed project.

Financial Feasibility

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	Operating Year 1 CY2020	Operating Year 2 CY2021
Total Treatments	11,411	12,004
Total Gross Revenues (Charges)	\$5,714,547	\$5,983,652
Total Net Revenue	\$5,563,043	\$5,824,268
Average Net Revenue per Treatment	\$487.52	\$485.19
Total Operating Expenses (Costs)	\$4,087,368	\$4,266,206
Average Operating Expense per Treatment	\$358.20	\$355.40
Net Income	\$1,475,675	\$1,558,062

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add 6 stations for a total of 23 stations upon completion of this project and Project I.D. # P-11451-18 (relocate 7 stations to Rosewood Dialysis).

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Wayne County. Facilities may serve residents of counties not included in their service area.

According to the July 2018 SDR, there are currently four operational dialysis facilities in Wayne County, including three operated by DaVita, Inc., and one operated by RAI Care Centers of North Carolina. Also, DaVita has been approved to develop a new dialysis facility, Coastal Plains Dialysis, but that facility was not operational as of December 31,

2017. Rosewood Dialysis, Project I.D. # Project I.D. # P-11451-18, was issued a certificate of need effective date of June 30, 2018. The existing and approved dialysis facilities in Wayne County are listed in the table below.

WAYNE COUNTY DIALYSIS FACILITIES				
Dialysis Facility (Owner)	Certified Stations 12/31/2017	# In-center Patients 12/31/2017	Percent Utilization 12/31/2017	Patients per Station 12/31/2017
Coastal Plains Dialysis (DaVita)*	0	0	NA	NA
Goldsboro Dialysis (DaVita)	27	97	89.81%	3.5926
Goldsboro South Dialysis (DaVita)	22	71	80.68%	3.2273
Mt. Olive Dialysis (DaVita)	15	50	83.33%	3.3333
RAI Care Centers - Goldsboro	16	65	101.56%	4.0625
Total / Average	80	283	88.43%	3.5375

Source: July 2018 SDR, Table B.

*According to the data collection form 12 stations were certified effective 1/1/2018

As illustrated in the table above, the existing facilities in Wayne County are well utilized with an average utilization of 3.5 patients per station per week $[283/80=3.5375]$ or 88.43% $[3.5375/4=0.8843]$.

In Section G, page 31, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wayne County. The applicant states:

“All of the DaVita facilities that have been open for more than a year in Wayne County were operating at 80% utilization as reported in the July 2018 SDR. Therefore, each facility has the potential for adding stations, given that they show a need. In Section B-2 and Section C of this application, we demonstrate the need that Goldsboro Dialysis has for adding stations. While adding stations at this facility does increase the number of stations in Wayne County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services because the applicant adequately demonstrates that the proposed addition of six dialysis stations at Goldsboro Dialysis is needed in addition to the existing or approved dialysis stations.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section H.1, page 32, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

POSITION	CURRENT FTE STAFF	PROJECTED FTE STAFF YEAR 2
Registered Nurse	3.00	3.00
Patient Care Technician	9.00	9.00
Administrator	1.00	1.00
Dietitian	1.00	1.00
Social Worker	1.00	1.00
Home Training RN	1.00	1.00
Administrative Assistant	1.00	1.00
Biomed Technician	1.00	1.00
Total	18.00	18.00

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H, page 33, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit I-3, the applicant provides a letter from the medical director indicating his interest in continuing to serve as the medical director of Goldsboro Dialysis. In Exhibit H, the applicant provides supporting documentation.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section I.1, page 36, the applicant provides a list of the necessary ancillary and support services, as illustrated below.

Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	Goldsboro Dialysis
Self-care training (in-center)	Goldsboro Dialysis
Home training: Home hemodialysis Peritoneal dialysis Accessible follow-up program	Goldsboro Dialysis
Psychological counseling	Goldsboro Dialysis
Isolation – hepatitis	Goldsboro Dialysis
Nutritional counseling	Goldsboro Dialysis
Social Work services	Goldsboro Dialysis
Acute dialysis in an acute care setting	Wayne Memorial Hospital
Emergency care	Wayne Memorial Hospital
Blood bank services	Wayne Memorial Hospital
Diagnostic and evaluation services	Wayne Memorial Hospital
X-ray services	Wayne Memorial Hospital
Laboratory services	DaVita Laboratories Services, Inc.
Pediatric nephrology	UNC Hospitals
Vascular surgery	Wayne Memorial Hospital
Transplantation services	Vidant Health
Vocational rehabilitation & counseling	NC Division of Vocational Rehab Services
Transportation	Wayne County DSS

In Section I.3, pages 37-38, and Section I.4, page 38, the applicant describes its existing and proposed relationships with other local health care and social services providers. The applicant provides supporting documentation in Exhibit I. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

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

NA

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

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

services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose any new construction or renovation of existing space as part of this project. Therefore, Criterion (12) is not applicable to this review.

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

C

In Section L.7, page 49, the applicant provides the historical payor mix during CY2017, as shown below.

Payment Source	Percent of Total Revenue	Percent of In-Center Revenue	Percent of HHD Revenue	Percent of PD Revenue
Private Pay	0.0%	0.0%	0.0%	0.00%
Medicare	19.10%	20.80%	20.00%	12.00%
Medicaid	11.80%	12.90%	0.00%	12.00%
Commercial Insurance	8.80%	5.90%	0.00%	24.00%
Medicare / Commercial	35.30%	34.70%	60.00%	28.00%
Medicare / Medicaid	18.40%	20.80%	10.00%	12.00%
VA	6.60%	5.00%	10.00%	12.00%
Total	100.00%	100.00%	0.0%	100.00%

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Wayne	16%	51%	47%	21%	13%	15%
Statewide	16%	51%	37%	15%	10%	12%

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

* Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

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

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

Conclusion

The Agency reviewed the:

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

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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3, page 48, the applicant states:

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

In Section L.6, page 48, the applicant states, *“There have been no civil rights equal access complaints filed within the last five years.”*

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.1, page 46, the applicant provides the projected payor mix during OY2, as illustrated below.

Projected Payor Mix OY2

Payment Source	Percent of Total Revenue	Percent of In-Center Revenue	Percent of HHD Revenue	Percent of PD Revenue
Private Pay	0.0%	0.0%	0.0%	0.00%
Medicare	19.10%	20.80%	20.00%	12.00%
Medicaid	11.80%	12.90%	0.00%	12.00%
Commercial Insurance	8.80%	5.90%	0.00%	24.00%
Medicare / Commercial	35.30%	34.70%	60.00%	28.00%
Medicare / Medicaid	18.40%	20.80%	10.00%	12.00%
VA	6.60%	5.00%	10.00%	12.00%
Total	100.00%	100.00%	0.0%	100.00%

As shown in the table above, OY2, the applicant projects 72.80% of total services will be provided to Medicare (includes Medicare, Medicare/Commercial and Medicare/Medicaid) and 30.2% to Medicaid patients.

On page 46, the applicant provides the assumptions and methodology used to project payor mix during OY2. The applicant states that no adjustments have been applied to the projected payor mix, therefore the projected payor mix is the same as the historical payor mix. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization at Goldsboro Dialysis.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.4, page 48, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M.1, page 50, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

The applicant proposes to add 6 stations for a total of 23 stations upon completion of this project and Project I.D. # P-11451-18 (relocate 7 stations to Rosewood Dialysis).

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Wayne County. Facilities may serve residents of counties not included in their service area.

According to the July 2018 SDR, there are currently four operational dialysis facilities in Wayne County, including three operated by DaVita, Inc., and one operated by RAI Care Centers of North Carolina. Also, DaVita has been approved to develop a new dialysis facility, Coastal Plains Dialysis, but that facility was not operational as of December 31, 2017. Rosewood Dialysis, Project I.D. # Project I.D. # P-11451-18, was issued a certificate of need effective date of June 30, 2018. The existing and approved dialysis facilities in Wayne County are listed in the table below.

WAYNE COUNTY DIALYSIS FACILITIES				
Dialysis Facility (Owner)	Certified Stations 12/31/2017	# In-center Patients 12/31/2017	Percent Utilization 12/31/2017	Patients per Station 12/31/2017
Coastal Plains Dialysis (DaVita)*	0	0	NA	NA
Goldsboro Dialysis (DaVita)	27	97	89.81%	3.5926
Goldsboro South Dialysis (DaVita)	22	71	80.68%	3.2273
Mt. Olive Dialysis (DaVita)	15	50	83.33%	3.3333
RAI Care Centers - Goldsboro	16	65	101.56%	4.0625
Total / Average	80	283	88.43%	3.5375

Source: July 2018 SDR, Table B.

*According to the data collection form 12 stations were certified effective 1/1/2018

As illustrated in the table above, the existing facilities in Wayne County are well utilized with an average utilization of 3.5 patients per station per week $[283/80=3.5375]$ or 88.43% $[3.5375/4=0.8843]$.

In Section N.1, page 51, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states:

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

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

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

Conclusion

The Agency reviewed the:

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

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

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

C

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

In Section O.3, page 52, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two of these facilities, Southeastern Dialysis Center-Wilmington and Goldsboro South Dialysis. The applicant provides documentation regarding the deficiencies and subsequent measures taken by those facilities to ensure compliance with CMS Conditions for Coverage in Exhibit O-3. The applicant states that all of the problems have been corrected and that Southeastern Dialysis Center-Wilmington was back in compliance as of March 21, 2018 and that Goldsboro South Dialysis was back in compliance as of November 20, 2017. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception

that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- Goldsboro Dialysis 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- In Section C, pages 13 - 15, the applicant demonstrates that Goldsboro Dialysis will serve a total of 79 in-center patients at the end of OY 1 (CY 2020) for a utilization rate of 85.86 or 3.43 patients per station per week ($79 \text{ patients} / 23 \text{ stations} = 3.4347 / 4 = 0.8586$ or 85.86%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 13 - 15, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.