

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 4, 2015

Findings Date: December 4, 2015

Project Analyst: Bernetta Thorne-Williams

Team Leader: Fatimah Wilson

Project ID #: J-11084-15

Facility: Durham Dialysis

FID #: 955621

County: Durham

Applicant(s): DVA Renal Healthcare, Inc.

Project: Add three dialysis stations for a total of 25 dialysis stations upon completion of this project and Project I.D. # J-10319-14 (develop a new facility by relocating seven stations from Durham Dialysis and three stations from Durham West Dialysis)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

DVA Renal Healthcare, Inc., (DVA) d/b/a Durham Dialysis (“the applicant”) proposes to add three dialysis stations for a total of 25 stations upon completion of Project I.D. # J-10319-14 (relocate seven stations from Durham Dialysis and three stations from Durham West Dialysis to develop East Durham Dialysis) and this project.

Need Determination

The 2015 State Medical Facilities Plan (2015 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 26 dialysis stations in Durham County, thus the applicant cannot apply to add

additional stations based on the county need methodology. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Durham Dialysis in the July 2015 SDR is 3.2069 patients per station, or 80.17% (3.2069 / 4 patients per station = 0.8017). This utilization rate was calculated based on 93 in-center dialysis patients and 29 certified dialysis stations (93 patients / 29 stations = 3.20689 patients per station).

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

Durham Dialysis Center – October 1 Review – July 2015 SDR

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/14		80.2%
Certified Stations		29
Pending Stations		
Total Existing and Pending Stations		29
In-Center Patients as of 12/31/14 (July 2015 SDR) (SDR2)		93
In-Center Patients as of 6/30/14 (Jan 2015 SDR) (SDR1)		89
Step	Description	
(i)	Difference (SDR2 - SDR1)	4
	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/14	0.0899
(ii)	Divide the result of Step (i) by 12	0.0075
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/13 until 12/31/14)	0.0899
(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	101.3596
(v)	Divide the result of Step (iv) by 3.2 patients per station	31.6749
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	2.6749

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

Policies

There is one policy in the 2015 SMFP which is applicable to this review. POLICY GEN-3: BASIC PRINCIPLES on page 38 of the 2015 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN -3 states:

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

Promote Safety and Quality

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

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B-4(b), page 10, Section C, page 15, Section L, pages 43-47 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B-4(c), page 11, Section N, page 49, 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.

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the July 2015 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add three new stations at Durham Dialysis, an existing facility located at 201 Hood Street in Durham. Upon completion of Project I.D. # J-10319-14 (relocate seven stations from Durham Dialysis and three stations from Durham West Dialysis to develop East Durham Dialysis) and the proposed project, Durham Dialysis will be certified for 25 dialysis stations.

Population to be Served

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Durham County. Facilities may also serve residents of counties not included in their service area.

In Section C-8, page 17, the applicant identifies the population served as of December 31, 2014, as illustrated below in the table:

DURHAM DIALYSIS Patient Origin December 31, 2014			
County	# of In-Center Patients	# of Home Dialysis Patients	# PD Patients
Durham	79	NA	NA
Granville	3	NA	NA
Orange	3	NA	NA
Wake	1	NA	NA
Franklin	1	NA	NA
Brunswick	1	NA	NA
Virginia	1	NA	NA
Other States	4	NA	NA
TOTAL	93	NA	NA

In Section C-1, page 13, the applicant identifies the patient population it proposes to serve during the first two years of operation following completion of this project and Project I.D. # J-10319-14, as illustrated below in the table:

County	OY 1 2017	OY 2 2018	County Patients as a Percent of Total	
	In- Center Patients	In Center Patients	Year 1	Year 2
Durham	66	68	83.0%	83.0%
Granville	3	3	4.0%	4.0%
Orange	3	3	4.0%	4.0%
Wake	1	1	1.0%	1.0%
Franklin	1	1	1.0%	1.0%
Brunswick	1	1	1.0%	1.0%
Virginia	1	1	1.0%	1.0%
Other States	4	4	5.0%	5.0%
TOTAL	80	82	100.0%	100.0%

The applicant does not project to serve any home hemodialysis or peritoneal dialysis patients. The applicant provides the assumptions and methodology for the projections above on pages 13-14.

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section C-2, page 15, the applicant refers the reader to Section B-2, page 7, where the facility need methodology is provided, which supports a need for three additional dialysis stations. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference.

Projected Utilization

In Section C-1, pages 13-14, the applicant provides the assumptions and methodology it uses to demonstrate the need that this population has for the services proposed at Durham Dialysis.

- Based on information in the July 2015 SDR, Durham Dialysis had 93 in-center patients with a station utilization rate of 80.17%. This utilization was based on 93 in-center patients dialyzing on 29 stations. Seventy-nine of the 93 patients were residents of Durham County.
- The applicant proposed in Project I.D. # J-10319-14 to relocate seven stations from Durham Dialysis and three stations from Durham West Dialysis to develop East Durham Dialysis. The applicant stated in the application that 17 in-center patients dialyzing at Durham Dialysis would transfer their care to East Durham Dialysis. Durham Dialysis will have 64 Durham County in-center patients when East Durham Dialysis is certified.
- The applicant used the Five Year Average Annual Change Rate (AACR) for Durham County, 2.9%, as reported in the July 2015 SDR, to project future growth at Durham Dialysis from January 1, 2015 – December 31, 2018.

- The applicant projects to serve 14 patients who reside outside of Durham County. The applicant did not project growth for those 14 patients.
- The applicant projects to have 80 in-center patients by the end of operating year 1 (OY1) with a utilization rate of 80% or 3.2 patients per station and 82 in-center patients by the end of OY2, for a projected utilization rate of 82% or 3.28 patients per station.
- OY1 is January 1, 2017 – December 31, 2017
- OY2 is January 1, 2018 – December 31, 2018

The applicant’s assumptions and methodology are summarized below:

DURHAM DIALYSIS	CALCULATIONS
January 1, 2015 - December 31, 2015	$79 \text{ patients} \times 1.029 = 81.291$
January 1, 2016 - December 31, 2016*	$64 \times 1.029 = 65.856$
January 1, 2017 - December 31, 2017 (OY1)	$65.856 \times 1.029 = 66.885$
January 1, 2018 - December 31, 2018 (OY2)	$66.885 \times 1.029 = 68.824$
*17 in-center patients projected to transfer to East Durham Dialysis Durham County patients only. Number of patients rounded down to nearest whole number.	

As shown in the table above, the applicant is projecting to serve 66 Durham County in-center patients in OY1 2017 and 68 Durham County in-center patients in OY2 2018. The following table includes the total in-center patient projections, including the 14 in-center patients from other counties and states.

DURHAM DIALYSIS	CALCULATIONS
January 1, 2015 - December 31, 2015	$79 \text{ patients} \times 1.029 = 81.291 + 14 = 95$
January 1, 2016 - December 31, 2016*	$64 \times 1.029 = 65.856 + 14 = 79$
January 1, 2017 - December 31, 2017	$65.856 \times 1.029 = 66.885 + 14 = 80$
January 1, 2018 - December 31, 2018	$66.885 \times 1.029 = 68.824 + 14 = 82$
*17 in-center patients projected to transfer to East Durham Dialysis All in-center patients, Durham County and the 14 patients from other counties and states. Number of patients rounded down to nearest whole number.	

As shown in the previous table, at the end of OY1 2017, the applicant is projecting an in-center patient census of 80 patients, for a utilization rate of 80% or 3.2 patients per station ($80 \text{ patients} / 25 \text{ stations} = 3.2$; $3.2 / 4 = .80$ or 80%). At the end of OY2 2018, the applicant is projecting an in-center patient census of 82 patients for a utilization rate of 82% or 3.28 patients per station. The projected utilization of 3.2 patients per station per week for OY1 satisfies the 3.2 in-center patients per station, per week as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth in the dialysis patient population in Durham County.

Access

In Section C-3, page 15, the applicant states:

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

In Section L, page 47, the applicant provides its historical payor mix which indicates that Medicare and Medicaid represented 49% of in-center dialysis treatments in calendar year 2014. The applicant confirms that low income and medically underinsured persons will continue to have access to all services provided by DVA and that the facility will conform to all federal, state and local codes and standards for handicapped access.

The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

Conclusion

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

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

NA

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

CA

In Section E-1, page 21, the applicant discusses the two alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo - the applicant states that this option would not support the growth rate at the facility.
2. Apply to add three stations – the applicant states the three-station expansion would help to meet the growing demand for dialysis services at Durham Dialysis.

The applicant also considered a third shift but determined that a third shift would be inconvenient for patients; and a facility at maximum capacity eliminates patient choice. After considering the alternatives above, the applicant believes the most effective alternative is to add three stations to the existing facility to ensure adequate access for the dialysis patients of Durham County.

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

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

- 1. DVA Renal Healthcare, Inc. d/b/a Durham Dialysis shall materially comply with all representations made in the certificate of need application.**
 - 2. DVA Renal Healthcare, Inc. d/b/a Durham Dialysis shall add no more than three dialysis stations at Durham Dialysis for a total of no more than 25 certified dialysis stations upon completion of Project I.D. # J-10319-14 (relocate seven stations from Durham Dialysis and three station from Durham West Dialysis to develop East Durham Dialysis) and this project, which shall include any home hemodialysis training or isolation stations.**
 - 3. DVA Renal Healthcare, Inc. d/b/a Durham Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add three dialysis stations to Durham Dialysis, for a total of 25 dialysis stations at Durham Dialysis upon completion of this project and Project I.D. # J-10319-14.

Capital and Working Capital Costs

In the table in Section F-1, page 22, the applicant states there are no capital costs associated with the proposed project. Additionally, in Section F-10, page 24, the applicant states that there are no working capital needs as Durham Dialysis is an existing facility.

Financial Feasibility

The applicant projects revenues and expenses and provides assumptions in Section R, Form B, pages 1-2, as summarized below in the table:

DURHAM DIALYSIS		
Revenue and Expenses - Total Facility		
	OPERATING YEAR 1 CY 2017	OPERATING YEAR 2 CY 2018
Gross Patient Revenue	\$ 4,163,627	\$ 4,242,766
Deductions from Gross Patient Revenue	(\$153,331)	(\$156,252)
Net Patient Revenue	\$ 4,010,296	\$ 4,086,514
Operating Expenses	\$ 3,165,100	\$ 3,238,747
Net Profit	\$ 845,196	\$ 847,767

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The applicant’s projections of treatments and revenues are reasonable based on the number of in-center patients projected for the first two operating years. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In Section H, page 29, the applicant provides projected staffing and salaries. Form A in Section R, page 1, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates the financial feasibility of the project is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add three stations to Durham Dialysis for a total of 25 certified dialysis station at Durham Dialysis upon completion of Project I.D. # J-10319-14 and this project.

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Durham County. Facilities may also serve residents of counties not included in their service area.

Table A in the July 2015 SDR indicates there are eight existing dialysis facilities in Durham County and one facility pending certification, as illustrated in the table below:

DIALYSIS FACILITY	CERTIFIED STATIONS	# PATIENTS	PATIENTS PER STATION	% UTILIZATION
Duke Hospital Dialysis	16	50	3.12	78.13%
DVA Facilities				
Durham Dialysis	29	93	3.20	80.17%
Durham West Dialysis	29	101	3.48	87.07%
East Durham Dialysis*	10	0	0	0%
Southpoint Dialysis	16	53	3.31	82.81%
FMC Facilities				
FMC Dialysis Briggs Ave	29	80	2.73	68.97%
FMC Dialysis West Pettigrew	20	61	3.05	79.25%
FMC South Durham	14	45	3.21	80.36%
Freedom Lake Dialysis	26	83	3.19	79.81%
Data reported in the July 2015 SDR, as of 12/31/14.				
*Certification Pending				

The applicant owns four of the nine Durham County dialysis facilities listed above. Fresenius Medical Care operates four and Duke Hospital operates one of the facilities listed above. Of the four facilities owned by the applicant, three operated above 80% utilization. East Durham Dialysis is pending certification of its stations.

In Section C, page 13, the applicant provides the total projected patients by county of residence for the proposed project, as shown in the following table:

County	OY 1 2017	OY 2 2018	County Patients as a Percent of Total	
	In-Center Patients	In-Center Patients	Year 1	Year 2
Durham	66	68	83.0%	83.0%
Granville	3	3	4.0%	4.0%
Orange	3	3	4.0%	4.0%
Wake	1	1	1.0%	1.0%
Franklin	1	1	1.0%	1.0%
Brunswick	1	1	1.0%	1.0%
Virginia	1	1	1.0%	1.0%
Other States	4	4	5.0%	5.0%
TOTAL	80	82	100.0%	100.0%

As shown in the previous table, at the end of OY1 2017, the applicant is projecting an in-center patient census of 80 patients, for a utilization rate of 80% or 3.2 patients per station (80 patients / 25 stations = 3.2; 3.2 / 4 = .80 or 80%). At the end of OY2 2018, the applicant is projecting an in-center patient census of 82 patients for a utilization rate of 82% or 3.28 patients per station. The projected utilization of 3.2 patients per station per week for OY1 satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

The applicant states that projected utilization is based on growth of in-center patients at the facility.

The applicant adequately demonstrates the need to add three stations to Durham Dialysis Center based on the number of in-center patients it proposes to serve. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on competition found in Criterion (18a) is incorporated herein by reference.

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

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

C

In Section H, page 29, the applicant provides the following table to illustrate current and projected staffing in full time equivalents (FTEs) for Durham Dialysis Center. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart.

POSITION	CURRENT # FTEs	# FTEs TO BE ADDED	PROJECTED # FTEs
Registered Nurse	3.0	1.0	4.0
Technician (Patient Care)	9.0	1.0	10.0
Administrator	1.0	-	1.0
Dietician	1.0	-	1.0
Social Worker	1.0	-	1.0
Bio-med Technician	1.0	-	1.0
Administrative Assistant	1.0	-	1.0
Total	17.0	2.0	19.0

In Section H-7, page 32, the applicant provides the projected direct care staff for Durham Dialysis in Operating Year 2, as shown below in the table:

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

In Section I-3(a), page 35, the applicant identifies Dr. David W. Butterly as the Medical Director of the facility. In Exhibit I-3, the applicant provides a copy of an August 2015 letter signed by

Dr. Butterly of Duke University Medical Center, supporting the project and confirming his commitment to serve as Medical Director. In Section H-3, pages 30-31, the applicant states that staff positions are filled by one or more of the following: the DaVita Teammate Recruiter, Teammate Referral Program and/or Student Internship Program.

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

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

C

In Section I-1, page 34, the applicant lists the providers of the necessary ancillary and support services to be provided at the existing facility. The applicant discusses coordination with the existing health care system on pages 35-36. Exhibits I-1, and I-3 contain documents from Durham West Dialysis, Dr. Butterly (Medical Director), respectively, documenting availability of the necessary ancillary and support services. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information in Section I and corresponding exhibits is reasonable and supports a finding of conformity to this criterion.

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

NA

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

NA

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

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;

C

In Section L-1, pages 43-54, the applicant states, “*Durham Dialysis, by policy, makes dialysis services available to all residents in its service area. ... Durham Dialysis helps uninsured, underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.*”

In addition, on pages 44-46, the applicant discusses its financial policies to help the above named classification of persons. In Section L-7, page 47, the applicant states that Medicare/Medicaid represented 49% of the dialysis treatments provided at Durham Dialysis in calendar year 2014. The following table illustrates the historical payor sources for Durham Dialysis:

PAYOR TYPE	PERCENT PATIENTS
Private Pay	27.2%
Medicare	9.8%
Medicaid	12.0%
Commercial Insurance	23.9%
Medicare/ Commercial	26.1%
Medicare/Medicaid	1.1%
Total	100.0%

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 Durham County, Granville and Orange counties and statewide.

County	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Durham	16.0%	5.7%	20.1%
Granville	15.0%	6.3%	18.4%
Orange	9.0%	3.4%	18.9%
Statewide	17.0%	6.7%	19.7%

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

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those persons who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).¹

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. But it does not include information on the number of elderly, handicapped, minorities or women utilizing health services.

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*, provides prevalence data on North Carolina dialysis patients by age, race and gender, and is summarized as follows, on page 59:

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, not specified	365	2.3%
Source: Southeastern Kidney Council Network6 Inc. 2014 Annual Report. ²		

The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

In Section L-3(d), page 46, the applicant states:

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

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

The application is conforming to this criterion.

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

C

In Section C-3, page 15, the applicant states:

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

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

In Section L-3(c), page 46, the applicant states:

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

In Section L-1(b), page 44, the applicant reports that it expects 49% of the patients who receive treatments at Durham Dialysis to have all or part of their services paid for by Medicare and Medicaid, as indicated below in the table.

PAYOR TYPE	PERCENT PATIENTS
Private Pay	27.2%
Medicare	9.8%
Medicaid	12.0%
Commercial Insurance	23.9%
Medicare/ Commercial	26.1%
Medicare/Medicaid	1.1%
Total	100.0%

On page 44, the applicant states it assumes the payor mix for Durham Dialysis will remain the same as its historical payor mix.

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

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

C

In Section L-4, page 46, the applicant states:

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

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

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

C

In Section M-1, page 48, the applicant states that Durham Dialysis has been offered as a clinical training site for student nurses attending Durham Technical Community College.

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

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

C

The applicant proposes to add three stations to Durham Dialysis for a total of 25 certified dialysis stations at Durham Dialysis upon completion of Project I.D. # J-10319-14 (relocate seven stations from Durham Dialysis and three stations from Durham West Dialysis to develop East Durham Dialysis) and this project.

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the

service area for this facility consists of Durham County. Facilities may also serve residents of counties not included in their service area.

Table A in the July 2015 SDR indicates there are eight existing dialysis facilities in Durham County and one facility pending certification, as illustrated in the table below:

DIALYSIS FACILITY	CERTIFIED STATIONS	# PATIENTS	PATIENTS PER STATION	% UTILIZATION
Duke Hospital Dialysis	16	50	3.12	78.13%
DVA Facilities				
Durham Dialysis	29	93	3.20	80.17%
Durham West Dialysis	29	101	3.48	87.07%
East Durham Dialysis*	10	0	0	0%
Southpoint Dialysis	16	53	3.31	82.81%
FMC Facilities				
FMC Dialysis Briggs Ave	29	80	2.73	68.97%
FMC Dialysis West Pettigrew	20	61	3.05	79.25%
FMC South Durham	14	45	3.21	80.36%
Freedom Lake Dialysis	26	83	3.19	79.81%
Data reported in the July 2015 SDR, as of 12/31/14.				
*Certification pending				

The applicant owns four of the nine Durham County dialysis facilities listed above. Fresenius Medical Care operates four and Duke Hospital operates one of the facilities listed above. Of the four facilities owned by the applicant, three operated above 80% utilization. East Durham Dialysis is pending certification of its stations.

In Section N-1, page 49, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states:

“The expansion of Durham Dialysis will have no effect on competition in Durham County. The addition of three stations at this facility serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DVA Renal Healthcare, Inc. and not any other providers in the service area.

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

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

The information provided by the applicant in the sections referenced above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive

impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that Durham Dialysis will continue to provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that Durham Dialysis will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section O, page 50, the applicant refers the reader to Section B-4(a), for its discussion regarding the methods it uses to ensure and maintain quality. The discussion is found on pages 9-11. In Section O-3, page 50, the applicant states:

“Exhibit O-3 lists facilities located in NC owned by the parent company DaVita HealthCare Partners Inc. that did not operate in compliance with the Medicare conditions of participation during the 18 month look back period. Each facility is currently in compliance.”

In supplemental information, the applicant states that three facilities were cited for deficiencies that resulted in Immediate Jeopardy, during the 18 months immediately preceding submittal of the application, as shown in the table below:

DVA Quality Care			
Facility	Survey Date	Back in Compliance	
Burlington Dialysis	6/16/2014	Yes	7/29/2014
Dialysis Care of Edgecombe County	7/1/2014	Yes	7/30/2014
Dialysis Care of Rowan County	9/17/2014	Yes	10/22/2014

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

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

C

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

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- In Section P, page 52, the applicant refers the reader to Section G-1, page 28 where the applicant provides the utilization rates for Durham Dialysis. The December 31, 2014 utilization rate was reported as 80.17% with 93 in-center patients dialyzing on 29 stations.

.2202(a)(2) Mortality rates;

- C- In Section P, page 52, the applicant refers the reader to Section C-9, page 18 where it provides the Durham Dialysis mortality rates, as follows:

Durham Dialysis	Beginning In-center Patients	Ending In-center Patients	Average	Deaths	% Gross Mortality
2014	91	93	92	10	10.87%
2013	90	91	90.5	9	9.94%
2012	83	90	86.5	11	12.72%

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

- C- In Section P, page 52, the applicant refers the reader to Section C-8, page 17. Durham Dialysis reports having no home trained and home dialysis patients.

Patients in need of home dialysis training and support are referred to Durham West Dialysis.

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

- C- In Section P, page 52, the applicant refers the reader to Section C-10, page 18, and states the number of transplants performed or referred by Durham Dialysis in 2014 was 14.

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

- C- In Section P, page 52, the applicant refers the reader to Section C-10, page 18, and states that Durham Dialysis had five patients on the transplant waiting list.

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

- C- In Section P, page 52, the applicant refers the reader to Section C-11, page 18 and states hospital admission rates as: Dialysis related 18 or 9.6%; Non-dialysis related 170 or 90.4%.

.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 P, page 53, the applicant refers the reader to Section C-10, page 18 and states that at Durham Dialysis, there were 17 persons with infectious disease and one patients converted to an infectious status during the last calendar year.

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

.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 (Replaced with 42 CFR Part 494).

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

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

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

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

-C- In Section P, page 53, the applicant refers the reader to Section K-1(f), page 48, and there refers the reader to Exhibit K-1(f). In supplemental information, the applicant provides copies of written policies and procedures for back up electrical service in the event of a power outage.

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

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

-C- In Section P, page 54, the applicant refers the reader to Section K-1(g), page 39, where it states: “*Durham Dialysis will provide service in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply and other relevant health and safety requirements ...*.” See also Section H-2, page 30.

.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- In Section P, page 54, the applicant refers the reader to Section C-1, page 13, where the applicant provides projected patient origin by county for Durham Dialysis, based on the patients who currently dialyze there. The applicant’s assumptions and

methodology for its projections are provided on pages 13-14 of the application. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

.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- This application is to add stations and does not propose a new 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 P, page 54, the applicant refers the reader to Section L-3(c), page 46, where the applicant states, “*Durham Dialysis makes no effort to categorize patients into groups according to their financial ability to obtain medical care. Physicians identify the patients in need of dialysis services and only then will a financial counselor and/or social worker evaluate their medical insurance and financial status.*”

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

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

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

-C- In Section P, page 54, the applicant refers the reader to Section C-1, pages 13-14, where the applicant documents the need for the project and demonstrates that it will serve a total of 80 in-center patients on 25 stations at the end of the first operating year, which is 3.2 patients per station per week, or a utilization rate of 80%. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

- C- In Section P, page 55, the applicant refers the reader to Section C.1, pages 13-14, where the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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 P-1, page 55, the applicant refers the reader to Section I-1, page 34, where the applicant states that diagnostic and evaluation services will be referred to Duke University Hospital.

.2204(2) Maintenance dialysis;

- C- In Section P-1, page 55, the applicant refers the reader to Section I-1, page 34, where the applicant states that in-center maintenance dialysis is provided at Durham Dialysis.

.2204(3) Accessible self-care training;

- C- In Section P-1, page 55, the applicant refers the reader to Section I-1, page 34, where the applicant states that self-care training is provided at Durham Dialysis.

.2204(4) Accessible follow-up program for support of patients dialyzing at home;

- C- In Section P-1, page 55, the applicant refers the reader to Section I-1, page 34, where the applicant states that an accessible follow-up program for support of patients dialyzing at home is provided at Durham West Dialysis. See Exhibit I for a copy of a service agreement with Durham West Dialysis.

.2204(5) X-ray services;

- C- In Section P-1, page 55, the applicant refers the reader to Section I-1, page 34, where the applicant states that patients in need of x-ray services will be referred to Duke University Hospital

.2204(6) Laboratory services;

- C- In Section P-1, page 55, the applicant refers the reader to Section I-1, page 34, where the applicant states that laboratory services will be provided by DaVita Laboratory Services, Inc.

.2204(7) Blood bank services;

- C- In Section P-1, page 55, the applicant refers the reader to Section I-1, page 34, where the applicant states that patients in need of blood bank services will be referred to Duke University Hospital.

.2204(8) Emergency care;

- C- In Section P-1, page 55, the applicant refers the reader to Section I-1, page 34, where the applicant states that patients in need of emergency care will be referred to Duke University Hospital.

.2204(9) Acute dialysis in an acute care setting;

- C- In Section P-1, page 55, the applicant refers the reader to Section I-1, page 34, where the applicant states that patients in need of acute dialysis services will be referred to Duke University Hospital.

.2204(10) Vascular surgery for dialysis treatment patients;

- C- In Section P-1, page 55, the applicant refers the reader to Section I-1, page 34, where the applicant states that patients in need of vascular surgery services will be referred to Carolina Vascular.

.2204(11) Transplantation services;

- C- In Section P-1, page 55, the applicant refers the reader to Section I-1, page 34, where the applicant states that patients in need of transplantation services will be referred to Duke University Medical Center. Exhibit I-3 contains a copy of the August 2015 letter from Dr. Butterly, the medical director at Durham Dialysis which documents the provision of transplantation services to the proposed facility.

.2204(12) Vocational rehabilitation counseling and services; and

- C- In Section P-1, page 55, the applicant refers the reader to Section I-1, page 34, where the applicant states that vocational rehabilitation counseling services are provided by the North Carolina Division of Vocational Rehabilitation Services.

.2204(13) Transportation

- C- In Section P-1, page 55, the applicant refers the reader to Section I-1, page 34, where the applicant states that transportation services will be provided by the Durham County Department of Social Services (DSS).

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 (Replaced with 42 CFR Part 494).*
- C- In Section P-1, page 55, the applicant refers the reader to Section H-2, page 30, where the applicant states that it will comply with *42 C.F.R. Section 405.2100* (Replaced with 42 CFR Part 494). In Section H-1, page 29, the applicant provides a staffing chart. The discussion regarding proposed staffing found in Criterion (7) is 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- In Section P-1, page 55, the applicant refers the reader to Section H-4, page 31, where the applicant discusses its training at DVA facilities.