

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 21, 2016

Findings Date: December 21, 2016

Project Analyst: Bernetta Thorne-Williams

Assistant Chief: Martha J. Frisone

Project ID #: J-11256-16

Facility: Durham Dialysis

FID #: 955621

County: Durham

Applicant: DVA Renal Healthcare, Inc.

Project: Add three dialysis stations for a total of 25 dialysis stations upon completion of this project, Project I.D. # J-10319-14 (relocate seven stations to East Durham Dialysis), Project I.D. # J-11216-16 (relocate three stations to Durham Regional Dialysis) and Project I.D. # J-11084-15 (add 3 stations)

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 Durham Dialysis proposes to add three stations for a total of 25 stations upon completion of this project, Project I.D. # J-10319-14 (relocate seven stations to East Durham Dialysis), Project I.D. # J-11216-16 (relocate three stations to Durham Regional Dialysis) and Project I.D. # J-11084-15 (add 3 stations).

Need Determination

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 22 dialysis stations in Durham 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 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 2016 SDR is 3.5517 patients per station per week, or 88.79% (3.5517/ 4 patients per station = 0.8879.2). This utilization rate was calculated based on 103 in-center dialysis patients and 29 certified dialysis stations (103 patients / 29 stations = 3.5517 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:

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		88.8%
Certified Stations		29
Pending Stations		3
Total Existing and Pending Stations		32
In-Center Patients as of 12/31/15 (July 2016 SDR) (SDR2)		103
In-Center Patients as of 6/30/15 (Jan 2016 SDR) (SDR1)		98
Step	Description	Result
	Difference (SDR2 - SDR1)	5
(i)	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/15	0.1020
(ii)	Divide the result of Step (i) by 12	0.0085
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	0.1020
(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	113.5102
(v)	Divide the result of Step (iv) by 3.2 patients per station	35.4719
	and subtract the number of certified and pending stations to determine the number of stations needed	3.4719

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 2016 SMFP which is applicable to this review. *POLICY GEN-3: BASIC PRINCIPLES* on page 39 of the 2016 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4, page 9, and Section O, page 49. 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, page 10, Section C, page 15, Section L, pages 42-46, 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, page 11, Section C, pages 13-18, Section N, page 48, 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

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

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

C

The applicant proposes to add three stations for a total of 25 stations upon completion of this project, Project I.D. # J-10319-14 (relocate seven stations to East Durham Dialysis), Project I.D. # J-11216-16 (relocate three stations to Durham Regional Dialysis) and Project I.D. # J-11084-15 (add 3 stations).

Patient Origin

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining 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 provides a table showing the historical patient origin for in-center (IC) patients served by Durham Dialysis Center, as shown below:

Dialysis Patients as of 12/31/2015

COUNTY	IC PATIENTS
Durham	93
Granville	3
Orange	2
Beaufort	1
Franklin	1
Wake	1
Other States	1
Virginia	1
Total	103

In Section C.1, page 13, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table. The applicant does not propose to serve home hemodialysis or peritoneal dialysis patients.

Projected Patient Origin

County	Operating Year 1 CY 2018	Operating Year 2 CY 2019	County Patients as a % of Total	
	IC	IC	OY1	OY2
Durham	84	87	89.4%	89.7%
Granville	3	3	3.2%	3.1%
Orange	2	2	2.1%	2.1%
Beaufort	1	1	1.1%	1.0%
Franklin	1	1	1.1%	1.0%
Other States	1	1	1.1%	1.0%
Virginia	1	1	1.1%	1.0%
Wake	1	1	1.1%	1.0%
Total	94	97	100.0%	100.0%

The applicant provides the assumptions and methodology for the projections above on pages 13-15.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section B.2, page 7, the applicant states the application is filed pursuant to the facility need methodology in the 2016 SMFP utilizing data from the July 2016 SDR. In Section C.1, pages 13-15, the applicant provides the assumptions used to project utilization. The applicant used the Five-Year Average Annual Change Rate for Durham County, which is 3.4%, to project the number of Durham County in-center patients. The applicant does not project growth of any patients residing outside of Durham County; those existing patients

were added to the projected Durham County patients at appropriate points in the methodology.

Operating Year 1 (OY) = Calendar Year (CY) 2018
 OY 2 = CY 2019

Projected Utilization

In-Center Dialysis

The following table illustrates application of the applicant’s assumptions and methodology used to project utilization.

Begin with the Durham County patients dialyzing at Durham Dialysis Center as of January 1, 2016.	93
Project the Durham County patient population forward one year using the Five-Year Average Annual Change Rate for Durham County of 3.4%.	$93 \times 1.034 = 96.162$
Subtract the 17 patients projected to transfer their care to East Durham Dialysis (See Project I.D. # J-10319-14)	$96 - 17 = 79$
Project this patient population forward one year to December 31, 2017.	$79 \times 1.034 = 81.686$
Project this patient population forward one year to December 31, 2018.	$81.686 \times 1.034 = 84.463326$
OY1: Add ten patients from outside the county. This is the projected ending census for OY 1 (CY2018).	$84.46332 + 10 = 94.46332$
Project the Durham County patient population forward one year to December 31, 2019.	$84.46332 \times 1.034 = 87.33508$
OY2: Add 10 patients from outside the county. This is the projected ending census for OY 2.	$87.33508 + 10 = 97.35508$

The applicant projects that Durham Dialysis Center will serve a total of 94 in-center patients at the end of OY 1 for a utilization rate of 94.0% or 3.76 patients per station per week (94 patients / 25 stations = 3.76 / 4 = 0.94 or 94.0%). The projected utilization of 3.76 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).

Home Hemodialysis and Peritoneal Dialysis

The applicant does not currently nor does the applicant propose to provide home hemodialysis or peritoneal dialysis training. Those services are provided through a service agreement with Durham West Dialysis Center. See the discussion concerning hemodialysis or peritoneal dialysis training in Section C, pages 13 and 15.

Access

In Section L, page 42, the applicant states that Durham Dialysis Center makes services available to all patients in the service area without qualifications which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other traditionally underserved persons. The applicant provides its historical payor mix for CY2015 on page 46, as illustrated below.

Payment Source	Percent of Total Patients
Medicare	40.5%
Medicaid	17.0%
Commercial Insurance	8.2%
Medicare/Commercial	15.1%
Medicare/Medicaid	19.2%
Total	100.0%

On page 43, the applicant projects that 91.8% of its patients will be Medicare or Medicaid recipients. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the services proposed 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 alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo - the applicant states that this option would result in higher utilization rates given the historical growth rate at the facility (10.2% over the last six months as reflected in the July and January 2016 SDRs).
2. Apply for the Three-Station Expansion - Application of the facility need methodology indicated a need for an additional three stations based on the continued growing need for dialysis services at Durham Dialysis Center.

The applicant states on page 21 that development of the project as proposed in the application would ensure that the facility proactively addresses the issues of growth and access to dialysis services by its patients and eliminate the need to consider a third shift. Therefore, DVA believes that adding three dialysis stations at Durham Dialysis Center is the most effective alternative to meet the identified need.

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 develop and operate no more than three additional dialysis stations at Durham Dialysis for a total of no more than 25 certified dialysis stations upon completion of this project, Project I.D. # J-10319-14, Project I.D. # J-11084-15 and Project I.D. # J-11216-16, which shall include any isolation or home hemodialysis training 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 stations for a total of 25 stations upon completion of this project, Project I.D. # J-10319-14 (relocate seven stations to East Durham Dialysis), Project I.D. # J-11216-16 (relocate three stations to Durham Regional Dialysis) and Project I.D. # J-11084-15 (add 3 stations).

Capital and Working Capital Costs

In Section F.1, page 22 and Section F.10, page 24, the applicant states there will be no capital cost or start-up and initial operating expenses associated with the proposed project.

Availability of Funds

In Exhibit F-7, the applicant provides a copy of DaVita HealthCare Partners, Inc. (DaVita) United States Securities and Exchange Commission Form 10-K for the fiscal year ended December 31, 2014. DaVita is DVA's parent company. DaVita had \$965,241,000 in cash and cash equivalents, \$17,942,715,000 in total assets, and \$6,190,276,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds, should the need arise, for the capital and working capital needs of the 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, as shown in the table below.

Durham Dialysis	Operating Year 1 CY2018	Operating Year 2 CY2019
Total Treatments	13,709	14,153
Total Gross Revenues (Charges)	\$4,130,357	\$4,264,076
Total Net Revenue	\$3,874,532	\$3,999,911
Total Operating Expenses (Costs)	\$3,573,802	\$3,684,649
Net Profit	\$300,730	\$315,262

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based on reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates the availability of sufficient funds for the operating needs of the proposal and that the financial feasibility of the project is based on reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add three stations for a total of 25 stations upon completion of this project, Project I.D. # J-10319-14 (relocate seven stations to East Durham Dialysis), Project I.D. # J-11216-16 (relocate three stations to Durham Regional Dialysis) and Project I.D. # J-11084-15 (add 3 stations).

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining 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.

The July 2016 SDR indicates there are nine dialysis facilities in Durham County, as shown in the table below:

**Durham County Dialysis Facilities
as of December 31, 2015**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Duke Hospital Dialysis	Duke	52	Durham	16	0	81.25%
Durham Dialysis	DVA	103	Durham	29	-4	88.79%
Durham West Dialysis	DVA	90	Durham	29	1	77.59%
East Durham Dialysis	DVA	Under development – New 10-station facility created by relocating existing stations				
FMC Briggs Avenue	Fresenius	82	Durham	29	0	70.69%
FMC West Pettigrew	Fresenius	63	Durham	24	0	65.63%
FMC South Durham	Fresenius	49	Durham	18	0	68.06%
Freedom Lake Dialysis	Fresenius	84	Durham	26	0	80.77%
Southpoint Dialysis	Fresenius	65	Durham	16	0	101.56%

As illustrated above, there are eight existing dialysis facilities located in Durham and one facility under development. Of those nine facilities, three facilities are operated by DVA,

one by Duke University Hospital and the remaining five facilities are operated by Fresenius. Three of the facilities operated with a utilization rate over 80.0%, two with a utilization rate over 70.0%, two with a utilization rate over 65.0% and one of the Fresenius facilities operated with a utilization rate over 100.0%. Thus, all of the operational dialysis facilities in the county are reasonably well utilized.

In Section C, pages 13-15, the applicant projects that Durham Dialysis Center will serve a total of 94 in-center patients on 25 stations at the end of the OY 1 for a utilization rate of 94.0% or 3.76 patients per station (94 patients / 25 stations = 3.76 / 4 = 0.94 or 94%). The projected utilization of 3.76 patients per station per week for OY 1 exceeds the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates the need to add three additional stations at Durham Dialysis Center based on the number of in-center patients it proposes to serve. Therefore, the applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or dialysis stations 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	4.00		4.00
Technician (PCT))	11.00		11.00
Administrator	1.00	1.00	2.00
Dietician	1.00		1.00
Social Worker	1.00		1.00
Admin. Assistant	1.00		1.00
Biomed Tech	1.00		1.00
Total	20.0	1.00	21.0

In Section I, page 34, the applicant identifies Dr. David Butterly as the Medical Director of the facility. In Exhibit I-6, the applicant provides a copy of a letter signed by Dr. Butterly of Duke University Medical Center supporting the project and confirming his commitment to continue to serve as Medical Director. In Section H.3, pages 30-31, the applicant states that it will fill positions by using a DVA Teammate Recruiter, the

Teammate Referral Program, and its Student Internship Program. In addition, the applicant states that it provides a wide range of benefits and competitive salaries to attract candidates for positions.

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, page 33, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I-3 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system on pages 33-35. Exhibits I-1 through I-5, respectively, contain copies of agreements with Duke University Hospital (acute dialysis care), Durham West Dialysis (home hemodialysis and peritoneal dialysis training), DaVita Laboratory Services, Inc., and Duke University Hospital (transplant services). The information in Section I and Exhibits I-1 and I-3 is reasonable and adequately supports a finding of conformity with 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, page 46, the applicant reports that 91.8% of the patients who received treatments at Durham Dialysis Center had some or all of their services paid for by Medicare or Medicaid in CY 2015, as illustrated in the table below.

**Durham Dialysis
Payor Mix CY2015**

Payor Type	Percent of Total Patients
Medicare	40.5%
Medicaid	17.0%
Commercial Insurance	8.2%
Medicare/Commercial	15.1%
Medicare/Medicaid	19.2%
Total	100.0%

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

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Durham	11%	52%	58%	17%	7%	18%
Granville	15%	49%	42%	16%	15%	17%
Orange	11%	52%	30%	14%	6%	15%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

*Excludes "White alone" who are "not Hispanic or Latino"

***This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable... The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

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

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

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

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

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

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

C

In Section L.3(d) page 45, 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 45, the applicant states that there have been no civil rights equal access complaints filed against any DVA facilities in the state 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 L.1, page 43, the applicant states that the projected payor mix for Durham Dialysis is based on its historical payor mix for the last full operating year and that no adjustments have been made, as illustrated below:

**Durham Dialysis
Projected Payor Mix OY2**

Payor Source	Percent of Total Patients
Medicare	40.5%
Medicaid	17.0%
Commercial Insurance	8.2%
Medicare/Commercial	15.1%
Medicare/Medicaid	19.2%
Total	100.0%

As illustrated above, the applicant projects that 91.8% of Durham Dialysis' patients will be covered by Medicare or Medicaid. 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 45, the applicant states that patients will have access to the facility for dialysis services upon referral from a Nephrologist with admitting privileges at the facility. Patients, family, and friends who contact the facility seeking access to services will be referred to *“a qualified nephrologist for evaluation and subsequent admission if it were found to be medically necessary.”* 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 47, the applicant states that Durham Dialysis Center has an agreement with Durham Technical Community College to serve as a facility for clinical rotations for nursing students. See Exhibit M-2 for a copy of the agreement between Durham Dialysis Center and Durham Technical Community College. The information provided in Section M.1 and Exhibit M-2 is reasonable and credible 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 for a total of 25 stations upon completion of this project, Project I.D. # J-10319-14 (relocate seven stations to East Durham Dialysis), Project I.D. # J-11216-16 (relocate three stations to Durham Regional Dialysis) and Project I.D. # J-11084-15 (add 3 stations).

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining 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.

The July 2016 SDR indicates there are nine dialysis facilities in Durham County, as shown in the table below:

**Durham County Dialysis Facilities
as of December 31, 2015**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Duke Hospital Dialysis	Duke	52	Durham	16	0	81.25%
Durham Dialysis	DVA	103	Durham	29	-4	88.79%
Durham West Dialysis	DVA	90	Durham	29	1	77.59%
East Durham Dialysis	DVA	Under development – New 10-station facility created by relocating existing stations				
FMC Briggs Avenue	Fresenius	82	Durham	29	0	70.69%
FMC West Pettigrew	Fresenius	63	Durham	24	0	65.63%
FMC South Durham	Fresenius	49	Durham	18	0	68.06%
Freedom Lake Dialysis	Fresenius	84	Durham	26	0	80.77%
Southpoint Dialysis	Fresenius	65	Durham	16	0	101.56%

As illustrated above, there are eight existing dialysis facilities located in Durham and one facility under development. Of those nine facilities, three facilities are operated by DVA, one by Duke University Hospital and the remaining five facilities are operated by Fresenius. Three of the facilities operated with a utilization rate over 80.0%, two with a utilization rate over 70.0%, two with a utilization rate over 65.0% and one of the Fresenius facilities operated with a utilization rate over 100.0%. Thus, all of the operational dialysis facilities in the county are reasonably well utilized.

In Section N.1, page 48, 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. 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...) by DVA Renal Healthcare, Inc.

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 other [sic] 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 referred to 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 a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that Durham Dialysis Center will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that Durham Dialysis Center will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

In Section B, pages 9-10 and Section O, page 49, the applicant discusses the methods it uses to insure and maintain quality. In Exhibit O-3, the applicant provides a listing of four dialysis facilities that were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application, as shown below.

DVA QUALITY CARE			
FACILITY	SURVEY DATE	BACK IN COMPLIANCE	
Southeastern Dialysis Kenansville	3/22/2016	Yes	6/10/2016
Durham Dialysis	3/22/2016	Yes	5/31/2016
Marshville Dialysis	2/29/2016	Yes	4/15/16
Durham West Dialysis	10/7/2015	Yes	9/30/2015

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

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- Durham 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 13-17, the applicant projects that Durham Dialysis Center will serve a total of 94 in-center patients at the end of OY 1 for a utilization rate of 94.0% or 3.76 patients per station per week ($94 \text{ patients} / 25 \text{ stations} = 3.76 / 4 = 0.94$ or 94.0%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 13-17, 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.