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:	Celia C. Inman
Team Leader:	Fatimah Wilson
Project ID #:	F-11245-16
Facility:	Dialysis Care of Kannapolis
FID #:	980409
County:	Rowan
Applicant(s):	Central Carolina Dialysis Centers, LLC
Project:	Add 5 dialysis stations for a total of 30 dialysis stations upon project completion

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

Central Carolina Dialysis Centers, LLC d/b/a Dialysis Care of Kannapolis (DC Kannapolis) proposes to add five dialysis stations for a total of 30 dialysis stations upon project completion.

Need Determination

The 2016 State Medical Facilities Plan (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 December 31, 2016 projected station deficit of five stations

in Rowan County and thus, no need for an additional facility in Rowan County, based on the county need methodology (1)(E), which states:

> *"... If a county's December 31, 2016 projected station deficit is less than 10 ..., the county's December31, 2016 station need determination is zero."*

However, 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 DC Kannapolis in the July 2016 SDR is 3.44 patients per station per week. This utilization rate was calculated based on 86 in-center dialysis patients and 25 certified dialysis stations as of December 31, 2015 (86 patients / 25 stations = 3.44 patients per station).

Application of the facility need methodology indicates that this facility could apply for up to nine additional dialysis stations, as illustrated in the following table:

October 1 REVIEW-July SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		86%
Certified Stations		25
Pending Stations		0
Total Existing and Pending Stations		**25**
In-Center Patients as of 12/31/15- July 2016 SDR (SDR2)		86
In-Center Patients as of 6/30/15 – Jan 2016 SDR (SDR1)		76
Step	**Description**	**Result**
(i)	Difference (SDR2 - SDR1)	10
	Multiply the difference by 2 for the projected net in-center change	20
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/15	0.2632
(ii)	Divide the result of Step (i) by 12	0.0219
(iii)	Multiply the result of Step (ii) by 12	0.2632
(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	108.6316
(v)	Divide the result of Step (iv) by 3.2 patients per station	33.9474
	and subtract the number of certified and pending stations to determine the number of stations needed	**8.9474**

As shown in the table above, based on the facility need methodology for dialysis stations, which allows for rounding to the nearest whole number only in Step (v), the potential number of stations needed at DC Kannapolis is nine. 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 five new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

Policy GEN-3: Basic Principles, page 39, of the 2016 SMFP is applicable to this review. *Policy GEN-3* states:

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

Promote Safety and Quality

In Section A.11, page 5, the applicant states that DaVita Inc., parent company to Central Carolina Dialysis Centers, LLC, currently operates over 70 dialysis facilities in North Carolina. The applicant describes how its proposal will promote safety and quality in Section B.4(a) and (d), pages 9-11, and Section N.1, page 51. In Section B.4(a), page 9, the applicant states:

> *"DaVita is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program."*

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 will promote equitable access in Section B.4(b) and (d), pages 10-11; Section C.3, page 16; Section L, pages 45-48; and Section N.1, page 51. The applicant states in Section B.4(b), page 10,

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

In Section L.1(b), page 46, the applicant provides the projected payor mix, which shows that the majority of its dialysis patients are covered by Medicare and/or Medicaid and

projects that greater than 82% of its total dialysis treatments will be reimbursed by some form of Medicare and/or Medicaid. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize health care value for resources expended in Section B.4, page 11, and Section N.1, page 51. In Section B.4(c), the applicant states that it will maximize healthcare value through centralized purchasing, electronic patient charting, preventative maintenance, and inventory control. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will 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 *Policy GEN-3: Basic Principles* and adequately demonstrates that the application is consistent with the facility need determination in the July 2016 SDR. 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 five dialysis stations to its existing facility for a total of 30 certified dialysis stations upon completion of the proposed project.

The following table, summarized from page 4 of the application, shows that there are no current projects under development which impact the number of dialysis stations at DC Kannapolis.

Stations	Description	Project ID #
25	Total existing certified stations as of the July 2016 SDR	
+5	Stations to be added as part of this project	F-11245-16
0	Stations previously approved to be added, but not yet certified	
0	Stations previously approved to be relocated from DC Kannapolis	
30	Total stations upon completion of above projects	

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. DC Kannapolis is located in Rowan County; thus, the service area for this facility consists of Rowan County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 20, the applicant provides a table showing the historical patient origin for DC Kannapolis in-center, home hemodialysis (HH), and peritoneal dialysis (PD) patients, as follows:

DC Kannapolis
As of 12/31/2015

Patient's County of Residence	In-Center Patients	HH Patients	PD Patients
Rowan	51	4	6
Cabarrus	34	6	15
Mecklenburg	1	1	3
Stanly	0	1	2
Anson	0	0	1
Union	0	0	1
Total	**86**	**12**	**28**

In Section C.1, page 13, the applicant provides the projected patient origin of dialysis patients to be served at DC Kannapolis for the first two years of operation following completion of the project, as summarized below:

County	Operating Year (OY) 1 1/1/18-12/31/18			Operating Year (OY) 2 1/1/19-12/31/19			Percent of Total	
	IC	HH	PD	IC	HH	PD	OY1	OY2
Rowan	73	7	9	83	8	10	57.8%	60.8%
Cabarrus	34	6	15	34	6	15	35.7%	33.1%
Mecklenburg	1	1	3	1	1	3	3.2%	3.0%
Stanly	0	1	2	0	1	2	1.9%	1.8%
Anson	0	0	1	0	0	1	0.6%	0.6%
Union	0	0	1	0	0	1	0.6%	0.6%
Total	**108**	**15**	**31**	**118**	**16**	**32**	**100.0%**	**100.0%**

In Section C.1, pages 13-14, the applicant provides the assumptions and methodology used to project patient origin. The projected patient origin is consistent with the historical patient origin. The applicant states on page 18 that it rounds down to the whole patient for projected utilization.

The applicant adequately identifies the population to be served.

Analysis of Need

The applicant proposes to add five dialysis stations to the existing DC Kannapolis for a total of 30 dialysis stations upon project completion.

Projected Utilization

In Section C.7, page 17, the applicant provides its methodology for projecting utilization for in-center patients at DC Kannapolis, as summarized below.

Dialysis Care of Kannapolis	In-Center Patients
Beginning census of Rowan County in-center patients only, January 1, 2016	51
The census of Rowan County in-center patients is projected forward to December 31, 2016, using the AACR for Rowan County (0.131).	51 x 1.131 = 57.681
The 35 patients outside Rowan County are added to reach the total census, as of December 31, 2016	57.681 + 35 = 92.681
The census of Rowan County in-center patients is projected forward one year to December 31, 2017, using the AACR for Rowan County.	57.681 x 1.131 = 65.2372
The 35 patients outside Rowan County are added to reach the total census, as of December 31, 2017.	65.2372 + 35 = 100.2372
The census of Rowan County in-center patients is projected forward one year to December 31, 2018, using the AACR for Rowan County.	65.2372 x 1.131 = 73.7832
The 35 patients outside Rowan County are added to reach the total census, as of December 31, 2018. This is the projected ending census for Operating Year 1.	73.7832 + 35 = 108.7833
The census of Rowan County in-center patients is projected forward one year to December 31, 2019, using the AACR for Rowan County.	73.7832 x 1.131 = 83.4489
The 35 patients outside Rowan County are added to reach the total census, as of December 31, 2019. This is the projected ending census for Operating Year 2.	83.4489 + 35 = 118.4489

The applicant provides its assumptions for projecting in-center patient utilization for DC Kannapolis on pages 17-18, as follows:

- Per Table A of the July 2016 SDR, as of December 31, 2015, DC Kannapolis had 86 in-center patients dialyzing on 25 stations for a station utilization rate of 86.00%.

- Of the 86 patients, the applicant states that 51 were from Rowan County and 35 lived outside Rowan County, in Cabarrus, Mecklenburg, Stanly, Anson and Union counties.

- Operating Year 1 = January 1, 2018 through December 31, 2018.

- Operating Year 2 = January 1, 2019 through December 31, 2019.

- Per Table B of the July 2016 SDR, the Rowan County five-year AACR is 13.1%.

- The 35 patients living outside of Rowan County will remain constant.

On page 18, the applicant states that it averages the beginning and end of year census for each year in the period of growth and rounds down to the nearest whole number.

Based on the methodology and assumptions above, the applicant projects DC Kannapolis will serve 108 in-center patients by the end of Operating Year 1 for a utilization rate of 90.0%, or 3.6 patients per station per week (108 / 30 = 3.6 / 4.0 = 0.90). This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C.2203(b). Projected utilization is based on reasonable and adequately supported assumptions. Therefore, the applicant demonstrates that the proposed addition of dialysis stations to DC Kannapolis would meet the minimum performance standard requirements in the Rule.

The applicant also provides the methodology and assumptions for projecting DC Kannapolis home hemodialysis and peritoneal dialysis utilization on pages 18-19, resulting in 15 home hemodialysis patients and 31 peritoneal dialysis patients (rounded up) by the end of the first operating year.

Access

In Section L.1(a), pages 45-46, the applicant states,

> *"DC Kannapolis, by policy, makes dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability.*
>
> *…*
>
> *DC Kannapolis 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."*

The applicant projects, in Section L.1(b), page 46, that 82.6% of its patients will be Medicare or Medicaid recipients. This is consistent with the facility's existing payor mix. The applicant adequately demonstrates the extent to which all residents of the service 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 the population projected to be served has for the proposed services based on reasonable and supported utilization projections and assumptions; and demonstrates 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 24, the applicant discusses the alternatives considered prior to the submission of this application, summarized as follows:

1) Maintaining the status quo - the applicant states that it dismissed this alternative given the growth rate at the facility.

2) The proposed alternative, add five dialysis stations to DC Kannapolis - the applicant states that this alternative would *"help meet the growing demand for dialysis services at the DC Kannapolis, as documented in Section B-2 and Section C."*

Section B-2, page 7 of the application, provides the October 1 Review Table based on the July 2016 SDR, which shows that Dialysis Care of Kannapolis' current utilization could support nine additional dialysis stations, based on the facility need methodology. Section C, page 14, includes the applicant's projected utilization, which shows an in-center patient census that supports five additional stations at a utilization rate of 90.0% by the end of the first operating year (108 / 30 = 3.6 / 4 = 0.90).

After considering the above alternatives, the applicant states that the second alternative, to add five dialysis stations is the more effective alternative as it ensures that the facility will proactively address the issues of growth and access at the facility.

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 need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **Central Carolina Dialysis Centers, LLC d/b/a Dialysis Care of Kannapolis shall materially comply with all representations made in the certificate of need application.**

2. **Central Carolina Dialysis Centers, LLC d/b/a Dialysis Care of Kannapolis develop no more than five additional stations for a total of no more than 30 certified stations upon project completion, which shall include any home hemodialysis or isolation stations.**

3. **Central Carolina Dialysis Centers, LLC d/b/a Dialysis Care of Kannapolis shall install plumbing and electrical wiring through the walls for five additional dialysis stations for a total of 30 dialysis stations which shall include any home hemodialysis training or isolation stations.**

4. **Central Carolina Dialysis Centers, LLC d/b/a Dialysis Care of Kannapolis 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 five dialysis stations to its existing DC Kannapolis facility for a total of 30 certified dialysis stations upon completion of the proposed project.

Capital and Working Capital Costs

In Section F.1, page 25, the applicant states that the capital costs for the project will total $24,031, consisting of dialysis machines, and other equipment and furniture.

In Sections F.10 and F.11, page 28, the applicant states that there will be no initial start-up expenses or initial operating expenses because the existing facility is already operational.

Availability of Funds

In Section F.5, page 26, the applicant refers to Exhibit F-5 for the response as to how the project will be financed. In Exhibit F-5, the applicant provides a letter dated September 12, 2016 from the Chief Accounting Officer of the parent company, DaVita Inc.,

authorizing the project and committing DaVita cash reserves for the development of the project.

In Section F.7, page 27, in reference to providing the most recent financial report, the applicant states:

> *"Corporate financial statements serve as Exhibit F-7. These statements include a copy of the United States Securities and Exchange Commission Form 10-K for the fiscal year ended December 31, 2015.*

However, Exhibit F-7 contains DaVita's Securities and Exchange Commission (SEC) Form 10-K for the fiscal year ended December 31, 2014, not 2015, as stated by the applicant. However, the Agency has DaVita's Form 10-K for the year ended December 31, 2015 on file from Project ID #F-11154-16, which documents that as of December 31, 2015, DaVita had $1,499,116,000 in cash and cash equivalents, $18,514,875,000 in total assets and $5,084,172,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital and operating needs of the project.

Financial Feasibility

In Section R, Form C, the applicant provides the allowable charges per treatment for each payment source, as illustrated in the table below:

Allowable Charges

Payor	In-Center Charge
Self Pay/Indigent/ Charity	-
Medicare	$230.39
Medicaid	$143.00
Commercial Insurance	$1,275.00
Medicare/Commercial	$230.39
Medicare/Medicaid	$230.39
VA	$193.00

In Section R, in the Revenue Assumptions, the applicant states that the missed treatment rate is 5% and an average patient number per year is used to calculate its revenues for the first and second operating years of the project. Therefore, the number of in-center patients used in operating year one was 104 and the number of in-center patients used in operating year two was 113.

- The applicant's methodology for calculating projected utilization for the beginning of operating year one, January 1, 2018, is 100 in-center patients, as stated in Section C.1, page 14. The applicant projects 108 in-center patients at the end of operating year one. Therefore, the average number of in-center patients for

operating year one, rounded down to the nearest whole number, is 104 (100+108 / 2 = 104).

- Likewise, the applicant begins operating year two with 108 in-center patients and ends with 118 in-center patients. The average number of in-center patients for operating year two is 113.

In Section R, Form B, the applicant projects operating expenses and revenues, respectively, summarized as follows:

DC Kannapolis	Operating Year 1 CY 2018	Operating Year 2 CY 2019
Average # of In-Center Patients	104	113
Projected Treatments ((156/Pt) -5%)	7,336	7,781
Projected Avg Charge (Gross Patient Revenue / Projected # In-Center Patient Treatments)	$1,026	$1,032
Gross Patient Revenue	$7,523,599	$8,029,342
Deductions from Gross Patient Revenue	$288,725	$310,935
Net Patient Revenue	$7,234,874	$7,718,407
Total Expenses	$5,218,881	$5,550,395
Net Income	**$2,015,993**	**$2,168,012**

Form B in the application includes data for In-center, HHD and PD patients; therefore revenues and operating costs are not limited to In-Center patients. The average charge, as shown above, includes charges for HHD and PD patients, but are calculated per In-Center patient.

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 the availability of sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges 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

On page 369, the 2016 SMFP defines the service area for dialysis stations as *"the 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."* DC Kannapolis is located in Rowan County; thus, the service area for this project is Rowan County. Facilities may serve residents of counties not included in their service area.

The applicant proposes to add five dialysis stations to its existing DC Kannapolis facility for a total of 30 certified dialysis stations upon project completion.

According to the July 2016 SDR, there are two dialysis facilities in Rowan County, as follows:

Rowan County Dialysis Facility Data
December 31, 2015

Facility	Owner	# of Stations	Utilization
Dialysis Care of Kannapolis	Central Carolina Dialysis Centers, LLC (DaVita)	25	86.00%
Dialysis Care of Rowan County	Total Renal Care of North Carolina, LLC (DaVita)	29	90.52%

As illustrated above, both facilities are DaVita-owned/operated facilities, and are operating above 80% utilization and are therefore, reasonably well utilized.

According to Table B in the July 2016 SDR, there is a deficit of five dialysis stations in Rowan County; therefore, stations cannot be applied for pursuant to the county need methodology, which requires a deficit of 10 stations to establish a county need determination. However, the applicant is eligible to apply for additional stations based on the facility need methodology. In Section C.1, page 13, the applicant demonstrates that DC Kannapolis will serve a total of 108 in-center patients on 30 dialysis stations at the end of the first operating year, which is 3.6 patients per station per week (108/30 = 3.6). Therefore, the facility is expected to serve more than 3.2 patients per station per week at the end of the first operating year as required by 10A NCAC 14C.2203(b).

The applicant adequately demonstrates the proposed project will not result in the unnecessary duplication of existing or approved dialysis services or facilities in Rowan 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.1, page 32, the applicant projects the number of FTE positions following completion of the proposed project, as illustrated in the table below.

DC Kannapolis Current and Proposed FTE Positions			
Position	Current	Additional	Total
RN	4.00	0.00	4.00
Patient Care Tech	10.00	2.00	12.00
Administrator	1.00	1.00	2.00
Dietitian	1.00	0.00	1.00
Social Worker	1.00	0.00	1.00
Home Training RN	1.00	0.00	1.00
Admin Asst	1.00	0.00	1.00
Bio-Medical Technician	1.00	0.00	1.00
Total FTEs	**20.00**	**3.00**	**23.00**

Note: The Medical Director is not an employee of the facility.

In Section I.3, page 37, the applicant states that the Medical Director for DC Kannapolis, Dr. John Gerig, has indicated his willingness to continue to serve in that capacity. In Exhibit I-3, the applicant provides a letter from Dr. John Gerig, dated August 15, 2016, confirming his support for the additional dialysis stations proposed for DC Kannapolis and his role as Medical Director of the facility. In Section H.3, pages 33-34, the applicant describes its methods for recruiting and hiring staff, including a competitive salary structure and range of benefits to attract qualified employees. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed 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 36, the applicant lists the providers of the necessary ancillary and support services to be provided for the proposed facility. The applicant discusses coordination with the existing health care system on page 38, stating that over the years it has established relationships with other healthcare providers and social service agencies in the area. In addition, Exhibit I-1 contains a copy of a letter from the Facility Administrator which states that the facility has established relationships with various healthcare providers and that it will continue to provide necessary services through existing agreements with them. A copy of the facility's existing laboratory services agreement is also included in Exhibit I-1. 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. Therefore, the application is conforming to this criterion.

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

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

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

NA

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of

determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.1, page 45, the applicant states,

> *"DC Kannapolis, by policy, makes dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion or disability."*

In Section L.7, page 49, the applicant states that 82.6% of the patients who received dialysis services at DC Kannapolis, had some or all of their services paid for by Medicare and/or Medicaid in the past year. The table below illustrates the historical payment sources for the existing facility during CY2015:

Payor Type	Percent of Total Patients
Medicare	27.3%
Medicaid	9.1%
Commercial Insurance	12.4%
Medicare/Commercial	19.8%
Medicare/Medicaid	26.4%
VA	5.0%
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 and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Rowan	16%	51%	27%	18%	12%	19%
Statewide	15%	51%	36%	17%	10%	15%

http://www.census.gov/quickfacts/table Latest Data as of 12/22/15
*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."*

However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*[1] 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, inc. not specified	365	2.3%

[1] http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf

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;

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In Section L.3(d), page 48, the applicant states,

> *"DC Kannapolis has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993."*

In Section L.6, page 48, the applicant states, *"There have been no civil rights equal access complaints 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

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In Section L.1, page 46, the applicant provides the projected payor mix for DC Kannapolis for both in-center and home-trained dialysis patients, as follows:

DC Kannapolis
Projected Patient Payor Mix

Payor Source	% of Total Patients	% of In-Center Patients	% of HH Patients	% Of PD Patients
Medicare	27.3%	28.0%	55.6%	16.7%
Medicaid	9.1%	12.2%	0.0%	3.3%
Commercial Insurance	12.4%	6.1%	11.1%	30.1%
Medicare/Commercial	19.8%	18.3%	22.2%	23.3%
Medicare/Medicaid	26.4%	30.5%	0.0%	23.3%
VA	5.0%	4.9%	11.1%	3.3%
Total	**100.0%**	**100.0%**	**100.0%**	**100.0%**

As shown in the table above, the applicant projects that 82.6% of its total dialysis patients will have some or all of their services paid for by Medicare or Medicaid, which is consistent with the facility's existing 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.

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In Section L.4, page 48, the applicant describes the range of means by which a person will have access to the dialysis services at DC Kannapolis, including referrals from nephrologists with privileges at the facility. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis 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.

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In Section M.1, page 50, the applicant states that it has offered the facility as a clinical learning site for medical assisting students from Kings College. Exhibit M-2 includes a student training agreement between Kings College and DaVita, which includes the Kannapolis facility as one of the training sites. The information provided in Section M.1 and Exhibit M-1 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.

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On page 369, the 2016 SMFP defines the service area for dialysis stations as *"the 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."* DC Kannapolis is located in Rowan County; thus, the service area for this facility is Rowan County. Facilities may serve residents of counties not included in their service area.

The applicant proposes to add five dialysis stations to its existing DC Kannapolis facility for a total of 30 certified dialysis stations upon project completion.

According to the July 2016 SDR, there are two dialysis facilities in Rowan County, as follows:

Rowan County Dialysis Facility Data
December 31, 2015

Facility	Owner	# of Stations	Utilization
Dialysis Care of Kannapolis	Central Carolina Dialysis Centers, LLC (DaVita)	25	86.00%
Dialysis Care of Rowan County	Total Renal Care of North Carolina, LLC (DaVita)	29	90.52%

As illustrated above, both facilities are DaVita-owned/operated facilities, and are operating above 80% utilization and are therefore, reasonably well utilized.

In Section N.1, page 51, the applicant discusses the expected effects of the proposed project on competition, including cost-effectiveness, quality and access, stating,

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

The expansion of DC Kannapolis 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 involved in the dialysis process to receive services."

See also Sections B, C, E, F, H, L, N and O where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application 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 it 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 it 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.

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.

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In Section O.3, page 52, the applicant states that Exhibit O-3 contains a list the DaVita-owned/operated facilities located in North Carolina that did not operate in compliance with the Medicare Conditions of Participation during the 18 months prior to the submission of this application (March 1, 2015 through September 15, 2016). Exhibit O-3 lists only four facilities of the over 70 DaVita dialysis facilities in North Carolina that did not operate in compliance. Included in the Exhibit are the facilities' summaries of deficiencies, the follow-up survey letters, and the dates upon which the facilities were found to be back in compliance. One of the facilities had an immediate jeopardy citation; the others were standard level deficiencies of the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities, 42 CFR Part 494. In Section O.3, page 52, the applicant states that each facility is currently in compliance with CMS

Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, 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.

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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, which are 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- The applicant is not proposing to establish a new facility. DC Kannapolis 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.1, pages 13-14, and Section C.7, page 17, the applicant demonstrates the need for five additional dialysis stations for a total of 30 stations, projecting 108 in-center patients at the end of the first operating year for a utilization rate of 3.6 patients per station per week (108 / 30 = 3.6).

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

-C- In Section C.1, pages 17-19, the applicant provides the assumptions and methodology used to project utilization of the facility.