

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 5, 2018

Findings Date: October 5, 2018

Project Analyst: Ena Lightbourne

Team Leader: Gloria C. Hale

Project ID #: H-11545-18

Facility: Dialysis Care of Anson County

FID #: 955840

County: Anson

Applicant: Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Anson County

Project: Relocate an existing dialysis facility, Dialysis Care of Anson County, to a new location in Wadesboro

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

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Anson County proposes to relocate an existing dialysis facility from 923 East Caswell Street, Wadesboro, to a leased space in an existing building located at 2004 US 74 West, Wadesboro in Anson County.

Need Determination

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The applicant is proposing to relocate existing dialysis stations within Anson County. Neither the county nor the facility need methodologies in the 2018 State Medical Facilities Plan (2018 SMFP) are applicable to this review. Additionally, Policy GEN-3: Basic Principles is not applicable because neither need methodology is applicable to the review.

Policies

There is one policy in the 2018 SMFP that is applicable to this review: *Policy ESRD-2 Relocation of Dialysis Stations*, on page 27.

Policy ESRD-2: Relocation of Dialysis Stations

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate an existing dialysis station within Anson County, thus there will be no change to the dialysis station inventory of Anson County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

The Agency reviewed the:

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

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

- (2) Repealed effective July 1, 1987.

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- (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

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Anson County proposes to relocate an existing dialysis facility from 923 East Caswell Street, Wadesboro to a leased space in an existing building located at 2004 US 74 West, Wadesboro in Anson County.

Patient Origin

On page 365, the 2018 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.*” Thus, the service area is Anson County. Facilities may serve residents of counties not included in their service area.

In Section C.1, page 13, the applicant provides the projected patient origin for Dialysis Care of Anson County (DC Anson County) for in-center patients for the first two years of operation following completion of the project as follows:

Total Projected In-Center Patients by County of Residence

County	OY1	OY2	County Patients as a Percent of Total	
	In-Center Patients	In-Center Patients	OY1	OY2
Anson	34	37	89.5%	90.2%
Montgomery	1	1	2.6%	2.4%
Union	1	1	2.6%	2.4%
Georgia	1	1	2.6%	2.4%
South Carolina	1	1	2.6%	2.4%
Total	38	41	100.0%	100.0%

The DC Anson County facility does not currently provide home hemodialysis (HHD) or peritoneal dialysis (PD) training or support, and the applicant is not proposing to add those services as part of the project. In Section C, pages 13-15, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 13-15, and Section C.13, page 21, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services.

On page 21, the applicant’s states the purposes of the proposed services is to address the inadequacies at the current DC Anson County location. The current location requires significant upgrades to the infrastructure of the facility’s physical plant that would be cost-prohibitive as opposed to relocating the entire facility and providing these upgrades to the current and projected patients.

On pages 13-14, the applicant describes the assumptions as follows:

- The applicant begins the projections for the future patient population of DC Anson County by using the ending in-center patient census of Anson County patients of 27 as of December 31, 2017.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Anson County which is 7.0% to project the Anson County patient population forward.
- The applicant projects a growth rate of 10.0% for the Anson County population during the first and second years of operation. The applicant assumes that more patients will choose a new, updated facility for their dialysis service and support.

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- The applicant assumes no growth for patients living outside of Anson County.
- Operating Year 1 (OY1) = January 1, 2020 – December 31, 2020 (CY2020)
Operating Year 2 (OY2) = January 1, 2021 – December 31, 2021 (CY2021)

Projected Utilization

In Section C.1, page 14, the applicant provides the methodology used to project in-center patient utilization, as shown in the following table.

Projected In-Center Utilization

Beginning service area census	Start date	# of service area patients	x	Growth Rate	=	Service Area year end census	+	# out of service area patients	=	Total Year-end census	Year-end date
Current Year	1/1/18	27	x	1.07	=	28.89	+	4	=	32.89	12/31/18
Interim Period	1/1/19	28.89	x	1.07	=	30.9123	+	4	=	34.9123	12/31/19
Census OY 1	1/1/20	30.9123	x	1.10	=	34.00353	+	4	=	38.00353	12/31/20
Census OY2	1/1/21	34.00353	x	1.10	=	37.40388	+	4	=	41.40388	12/31/21

Thus, the applicant projects that Dialysis Care will serve a total of 38 in-center patients at the end of OY1 for a utilization rate of 63.3% or 2.53 patients per station per week (38 patients / 15 stations = 2.53 / 4 = 0.6325 or 63.3%). The performance standard required by 10A NCAC 14C .2203(b) is not applicable to this review because the applicant is not proposing to establish a new facility or increase the number of dialysis stations in an existing facility.

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

- The applicant begins its utilization projections with the existing in-patient census for Anson County for DC Anson County.
- The applicant’s growth projections are based on an assumption that the dialysis patient census of Anson County patients will increase annually by 7.0%, which is consistent with the Five Year AACR for Anson County, reported in the July 2018, SDR, Table D.
- The applicant does not project an increase in the facility’s patient population not residing in Anson County.
- The facility proposes to serve the same population as historically served by DC Anson County.

Access

In Section C.3, page 15, the applicant states the facility will serve patients without regard to race, sex, age or handicap, ethnic or socioeconomic situation. In Section L.7, page 49, the applicant provides the historical (CY2017) payor mix for DC Anson County, as shown below.

Payment Source	Percent of Total Patients
Medicare	34.5%
Medicaid	3.4%
Commercial Insurance	6.9%
Medicare / Commercial	31.0%
Medicare / Medicaid	20.7%
VA	3.4%
Total	100.0%

As shown in the table above, DC Anson County reports that 89.6% of its patients were Medicare or Medicaid recipients in CY2017. In Section L.1, page 46, the applicant projects 88.5% of Medicare and Medicaid recipients for DC Anson County in the second operating year of the project. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

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

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be

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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.

C

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Anson County proposes to relocate an existing dialysis facility from 923 East Caswell Street, Wadesboro to a leased space in an existing building located at 2004 US 74 West, Wadesboro in Anson County.

In Section C.12, page 21, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 21, the applicant states:

“Total Care of North Carolina, LLC searched within a five mile radius of its current site for a new location. The sites proposed for the new facility were selected because they will allow us to provide comparable geographic access to the patient population presently served by DC Anson County, make significant updates and upgrades to the facility’s physical plant, as well as accommodate the projected growth.”

DC Anson County proposes to relocate an existing dialysis facility from 923 East Caswell Street in Anson to leased space in an existing building located at 2004 US 74 West in Anson, which is 3 miles and 6 minutes driving time from the current site. Thus the facility will still be accessible to the same population presently served, including underserved.

Projected utilization is reasonably and adequately supported based on the fact that the facility proposes to serve the same population as historically served by DC Anson County at the existing facility.

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. We will serve patients regardless of ethnic or socioeconomic situation.”

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be relocated will be adequately met following project completion.
 - The project will not adversely impact the ability of underserved groups to access these services following project completion.
- (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

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Anson County proposes to relocate an existing dialysis facility from 923 East Caswell Street, Wadesboro, to a leased space in an existing building located at 2004 US 74 West, Wadesboro in Anson County.

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

- Maintain the Status Quo. The applicant states doing nothing would only prolong the need for upgrades to the facility.
- Renovate the Current Facility. The applicant states that renovating the current facility was not an option because it would be cost prohibitive due to the age of the facility.

In Section E.2, page 24, the applicant states that its proposal is the most effective alternative because of the facility's age and condition. The applicant states that providing current and projected patients the updates and upgrades that have been made in other DaVita facilities requires that the applicant move this facility to a new location.

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

- The applicant states there are limits to the extent to which it can develop the proposed updates to the existing facility because of the age of the facility.
- The applicant states there is a significantly higher cost to renovate the current location as opposed to relocating the facility.

Conclusion

The Agency reviewed the:

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

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

- 1. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Anson County shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Anson County shall materially comply with the last made representation.**
 - 2. Pursuant to Policy ESRD-2, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Anson County shall relocate 15 stations from existing location of Dialysis Care of Anson County to the proposed new site for a total of no more than 15 stations at Dialysis Care of Anson County upon project completion.**
 - 3. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Anson County shall install plumbing and electrical wiring through the walls for no more than 15 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 - 4. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Anson County 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

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Anson County proposes to relocate an existing dialysis facility from 923 East Caswell Street, Wadesboro, to a leased space in an existing building located at 2004 US 74 West, Wadesboro in Anson County.

Capital and Working Capital Costs

In Section F.1, page 25, the applicant projects \$1,926,198 [\$1,926,197] in capital costs to develop the proposed project as summarized below:

Projected Capital Costs

Site Costs	\$ 40,596
Construction Costs	\$1,124,018
Miscellaneous Costs	\$ 761,583
Total	\$1,926,198 [\$1,926,197]

In Section F.1, page 25, the applicant provides the assumptions used to project the capital cost.

In Section F.10, page 28, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since this is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 26, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	DaVita, Inc.	Total
Loans	\$	\$
Accumulated reserves or OE *	\$1,926,198 [\$1,926,197]	\$1,926,198 [\$1,926,197]
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$1,926,198 [\$1,926,197]	\$1,926,198 [\$1,926,197]

* OE = Owner's Equity

Exhibit F-6 contains a letter dated July 16, 2018 from the Chief Accounting Officer, authorizing and committing accumulated reserves of DaVita Inc., the parent and 100% owner of Total Renal Care, Inc., for the capital costs of the project. Exhibit F-7 contains a copy of the Consolidated Financial Statements for DaVita, Inc., for the year ending December 31, 2017. For year ending December 31, 2017, DaVita, Inc., had \$508,234,000 in cash and cash equivalents, \$18,948,193,000 in total assets and \$5,897,426,000 in net assets (total assets less total liabilities).

Financial Feasibility

The applicant provided pro forma financial statements in Section R for the first two full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	1st Full Fiscal Year CY2020	2nd Full Fiscal Year CY2021
Total Treatments	5,335	5,854
Total Gross Revenues (Charges)	\$1,652,680	\$1,814,341
Total Net Revenue	\$1,570,569	\$1,724,213
Average Net Revenue per Treatment	\$ 294.39	\$ 294.54
Total Operating Expenses (Costs)	\$1,558,328	\$1,674,748
Average Operating Expense per Treatment	\$ 292.10	\$ 286.09
Net Income	\$ 12,241	\$ 49,465

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

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicant adequately demonstrates 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.

- (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

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Anson County proposes to relocate an existing dialysis facility from 923 East Caswell Street, Wadesboro, to a leased space in an existing building located at 2004 US 74 West, Wadesboro in Anson County.

On page 365, the 2018 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.*” Thus, the service area is Anson County. Facilities may serve residents of counties not included in their service area.

The applicant operates one facility in Anson County. Fresenius Medical Care (FMC) Anson is the only other provider of dialysis services in Anson County, and currently operates one dialysis center. The existing and approved Anson County dialysis facilities are shown below:

Facility Name	Provider	Location	# of Stations	Utilization
Dialysis Care of Anson County	DaVita	Wadesboro	15	51.67%
Fresenius Medical Care Anson	FMC	Wadesboro	16	85.94%

Source: July 2018 SDR, Table B.

In Section G.2, page 31 of the application, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis facilities in Anson County. The applicant states:

“As of December 31, 2017, there were two dialysis facilities in Anson County with a total of 31 certified stations. This certificate of need application does not propose to increase the number of stations in Anson County. Relocating the existing stations from DC Anson County to a facility at a different location will allow DaVita to better serve its current and projected patients, but it will not result in the duplication of existing services.”

The applicant adequately demonstrates its proposal would not result in an unnecessary duplication of existing or approved dialysis services in the service area for the following reasons:

- The proposal would not result in an increase in the number of dialysis stations in Anson County.
- The applicant adequately demonstrates that the proposed relocation of existing dialysis stations is needed in addition to the existing or approved dialysis stations in Anson County.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section H.1, page 32, the applicant provides current and projected staffing in full time equivalents (FTEs) for DC Anson County. The applicant does not project any changes in its FTE staff for DC Anson County associated with the proposed location. The assumptions and methodology used to project staffing are provided in Section R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, Section R. In Section H.2, page 33, the applicant identifies the current medical director for the facility. Exhibit I-3 of the application contains a letter from the medical director expressing his intention to continue serving in that capacity for DC Anson County. In Exhibit H-3, the applicant provides supporting documentation.

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

Conclusion

The Agency reviewed the:

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

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

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

C

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

Dialysis Care of Anson County Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	Dialysis Care of Anson County
Self-care training (in-center)	Dialysis Care of Anson County
Home training: Home hemodialysis Peritoneal dialysis Accessible follow-up program	Carolinas Healthcare System
Psychological counseling	Dialysis Care of Anson County
Isolation – hepatitis	Dialysis Care of Anson County
Nutritional counseling	Dialysis Care of Anson County
Social Work services	Dialysis Care of Anson County
Acute dialysis in an acute care setting	Carolinas Healthcare System
Emergency care	Carolinas Healthcare System
Blood bank services	Carolinas Healthcare System
Diagnostic and evaluation services	Carolinas Healthcare System
X-ray services	Carolinas Healthcare System
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	Carolinas Healthcare System
Vascular surgery	Carolinas Healthcare System
Transplantation services	Carolinas Medical Center
Vocational rehabilitation & counseling	NC Division of Vocational Rehabilitation Services
Transportation	Anson County Transportation Services (ACTS)

In Section I, page 36, the applicant explains how each ancillary and support service will be made available and provides supporting documentation in Exhibit I-1. In Section I.4, page, 38, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-1. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

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

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

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

NA

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

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

- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

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

C

In Section K.2, page 41, the applicant states that the project involves upfitting 2,621 square feet of leased space. Line drawings are provided in supplemental information. On pages 40-41, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibits K-1 and K-4.

Conclusion

The Agency reviewed the:

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

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

- (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:

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- (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 the facility's services are available to all residents of the service area without regard to income, race, gender, handicap, age or ability to pay. In Section L.7, page 49, the applicant provides the historical (CY2017) payor mix for Dialysis Care of Anson County as shown below.

Payor Category	Percent of Total Patients
Medicare	34.5%
Medicaid	3.4%
Commercial Insurance	6.9%
Medicare / Commercial	31.0%
Medicare / Medicaid	20.7%
VA	3.4%
Total*	100.0%

*Total may not foot due to rounding.

As shown in the table above, 89.6% of Dialysis Care of Anson County's patients were Medicare or Medicaid recipients in CY2017.

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance **
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Anson	18%	48%	55%	25%	15%	13%
Statewide	16%	51%	37%	15%	10%	12%

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

*Excludes "White alone, not Hispanic or Latino"

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

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

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

The Agency reviewed the:

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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.1, page 46, the applicant states:

“DC Anson County 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.”

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

In Section L.6, page 48, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

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

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

- (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(b), page 46, the applicant provides the following table showing the projected payor mix during the second operating year of the project (CY2021).

Projected Payor Mix Project Year 2	
Payment Source	Percent of Total Patients
Medicare	33.4%
Medicaid	3.4%
Commercial Insurance	8.0%
Medicare / Commercial	31.0%
Medicare / Medicaid	20.7%
VA	3.4%
Total*	100.0%

*Total may not foot due to rounding.

As shown in the table above, during the second year of operation, the applicant projects that 64.4% of total services will be provided to Medicare patients (includes Medicare and Medicare/Commercial), 20.7% to Medicare/Medicaid patients and 3.4% to Medicaid patients.

On page 46, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for Dialysis Care of Anson County.

The Agency reviewed the:

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

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

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

C

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

The Agency reviewed the:

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

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

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

C

In Section M.1, page 50, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

The Agency reviewed the:

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

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

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

C

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Anson County proposes to relocate an existing dialysis facility from 923 East Caswell Street, Wadesboro, to a leased space in an existing building located at 2004 US 74 West, Wadesboro in Anson County.

On page 365, the 2018 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.*” Thus, the service area is Anson County. Facilities may serve residents of counties not included in their service area.

The applicant operates one facility in Anson County. FMC is the only other provider of dialysis services in Anson County, and currently operates one dialysis center. The existing and approved Anson County dialysis facilities are shown below:

Dialysis Care of Anson County
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Facility Name	Provider	Location	# of Stations	Utilization
Dialysis Care of Anson County	DaVita	Wadesboro	15	51.67%
Fresenius Medical Care Anson	FMC	Wadesboro	16	85.94%

Source: July 2018 SDR, Table B.

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

“The relocation of DC Anson County will have no effect on competition in Anson County. This project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by Total Renal Care of North Carolina, LLC. The relocation of DC Anson County will address the physical inadequacy of the existing facility.”

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

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

Conclusion

The Agency reviewed the:

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

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

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

C

In Exhibit A-11, the applicant identifies the dialysis facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies more than 100 of this type of facility located in North Carolina.

In Exhibit O-3, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two facilities, Southeastern Dialysis Center-Wilmington and Goldsboro South Dialysis. The applicant states in Section O.3, page 52, and in Exhibit O-3, that both facilities are currently back in full compliance with all CMS requirements. The applicant provides documentation regarding the deficiencies and subsequent compliance with CMS Conditions for Coverage for Southeastern Dialysis Center-Wilmington and Goldsboro South Dialysis in Exhibit O-3. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

NA

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are not applicable to this review because the applicant does not propose to establish a new end stage renal disease facility nor does that applicant propose to add stations to an existing facility.