

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 25, 2019

Findings Date: January 25, 2019

Project Analyst: Tanya M. Saporito

Team Leader: Fatimah Wilson

Project ID #: H-11643-18

Facility: Pinehurst Home Training

FID #: 180570

County: Moore

Applicant(s): Total Renal Care of North Carolina, LLC

Project: Develop a new kidney disease treatment center to provide home peritoneal dialysis training and support services by relocating the existing PD program from Dialysis Care of Moore County

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.

NA

The applicant, Total Renal Care of North Carolina, LLC, (TRC) proposes to develop a new kidney disease treatment center, Pinehurst Home Training (PHT) in Pinehurst, dedicated to providing home training and support services for peritoneal dialysis (PD) patients by relocating the existing PD program currently located at Dialysis Care of Moore County (DC Moore County) in Pinehurst. The applicant does not propose to include any certified in-center stations or home hemodialysis stations as a part of the proposed project.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in 2018 State Medical Facilities Plan (SMFP) – neither the 2018 SMFP nor the July 2018 Semiannual Dialysis Report (SDR) provides a need methodology for determining the need for kidney disease treatment centers dedicated to providing home PD services.
- acquire any medical equipment for which there is a need determination in the 2018 SMFP.
- offer a new institutional health service for which there are any policies in the 2018 SMFP - Policy GEN-3 is not applicable to this review because the applicant does not propose to develop or offer a new institutional health service for which there is a need determination in the 2018 SMFP. Additionally, Policy GEN-4 is not applicable to this review because the proposed capital cost for the project is \$1,043,263, which is less than the \$2 million dollars required for this policy to be applicable.

Therefore, Criterion (1) is not applicable to this review.

- (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 develop a new kidney disease treatment center dedicated to providing home training and support services for PD patients by relocating the existing PD program currently located at DC Moore County in Pinehurst. The applicant does not propose to include any certified in-center stations or home hemodialysis stations as a part of the proposed project.

There are three existing dialysis facilities in Moore County, all of which are owned or operated by TRC or its parent company, DaVita, Inc.: Carthage Dialysis located in Carthage, Dialysis Care of Moore County located in Pinehurst and Southern Pines Dialysis Center located in Southern Pines. The applicant and/or its parent is the only provider of dialysis services in Moore County. Home PD services are currently available only at the DC Moore County facility.

Patient Origin

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

The following table illustrates current and projected patient origin, from Section C.1 pages 13 - 14:

COUNTY	CURRENT (AS OF 12/31/17)		OPERATING YEAR 2 (1/1/2022 – 12/31/2022)	
	# PATIENTS	% OF TOTAL	# PATIENTS	% OF TOTAL
Moore	16	42.1%	18	41.9%
Anson	1	2.6%	1	2.3%
Cumberland	2	5.3%	2	4.7%
Hoke	7	18.4%	8	18.6%
Lee	1	2.6%	1	2.3%
Montgomery	3	7.9%	4	9.3%
Richmond	4	10.5%	5	11.6%
Robeson	2	5.3%	2	4.7%
Scotland	2	5.3%	2	4.7%
Total	38	100.0%	43	100.0%

In Section C, pages 13 - 14, 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, page 15, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“The proposed project is to relocate the PD program at DC Moore County to a new location. ... the PD patient population at DC Moore County is projected to experience significant growth. While there are no deficiencies in facility-related quality of care metrics at DC Moore County, the condition and footprint of the facility’s physical plant limit the applicant’s ability to renovate and expand the PD training and support areas.

Dialysis patients spend a significant amount of time in their facilities preparing for and receiving treatment – at least once a month for home dialysis patients. It was determined that Total Renal Care of North Carolina, LLC needs to relocate DC Moore

County’s PD program so as to update, enhance and expand the environment in which current and projected PD patients receive their dialysis services and support.”

The information is reasonable and adequately supported for the following reasons:

- The applicant provides historical utilization data which support the need the patient population has for the proposed services.
- The applicant adequately explains why PD patients currently served at DC Moore County would be better accommodated at a standalone facility.

Projected Utilization

On pages 14-15, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant begins with the number of PD patients served at DC Moore County as of December 31, 2017 based on Table C in the July 2018 Semiannual Dialysis Report (SDR).
- The applicant shows the growth in the PD patient population in North Carolina, as recorded in the July 2017 and July 2018 SDRs. The applicant calculates a 3.28% growth in PD patients in the state during that time, based on 1,738 PD patients reported in the July 2017 SDR and 1,795 PD patients reported in the July 2018 SDR $[(1,795 / 1,738) - 1 = 0.032796]$.
- The applicant shows the historical growth in the PD patient population at DC Moore County using data reported in the facility’s data collection forms published in each July SDR from 2014 to 2018. The results are shown in the following table, from page 14:

	JULY 2014 SDR	JULY 2015 SDR	JULY 2016 SDR	JULY 2017 SDR	JULY 2018 SDR	AVERAGE % CHANGE
DC Moore County PD Patient Population	34	29	26	30	38	
Raw Change	--	-5	-3	4	8	
Percent Change	--	-14.71%	-10.34%	15.38%	26.67%	4.25%

- The applicant anticipates that additional PD patients who reside in the service area may also choose to receive their treatments at PHT.
- Operating Year (OY) one is projected to be calendar year (CY) 2021, from January 1, 2021 to December 31, 2021.
- OY two is projected to be CY 2022, from January 1, 2022 to December 31, 2022.

- The applicant assumes that the 38 PD patients currently being treated at DC Moore County will transfer their care to PHT when the facility is operational.
- The applicant projects growth in the PD patient population at PHT using a 7.0% growth rate, which is between the 4.25% growth rate experienced by the DC Moore County PD patient population from 2014 to 2018 and the 26.67% growth rate experienced by DC Moore County PD patient population within the last year (July 2017 SDR to July 2018 SDR).

The applicant’s methodology is illustrated in the following table:

Begin with 38 PD patients receiving treatment at DC Moore County as of 12/31/2017.	38
The applicant assumes that at least 38 PD patients will transfer their care to PHT when that facility is operational, 1/1/2021.	38
Project that PD patient population forward one year to 12/31/2021. This is the ending census for OY 1.	$38 \times 1.07 = 40.66$
Project that PD patient population forward one year to 12/31/2022. This is the ending census for OY 2.	$40.66 \times 1.07 = 43.51$

*Source: application page 15.

The applicant projects to serve 40 PD patients at the end of OY 1 and 43 PD patients at the end of OY 2. The minimum utilization standard of 3.2 in-center patients per station per week as required by 10A NCAC 14C .2203(b) does not apply to PD patients. On October 10, 2018, in response to a declaratory ruling request, the Agency issued a declaratory ruling to another dialysis provider, noting that when 10A NCAC 14C .2203 is re-promulgated, the Rule could be changed to make it clear that the minimum utilization standard of 3.2 patients per station per week applies only to in-center dialysis stations. Thus, there is no utilization standard which applies to PD treatments. Additionally, the analyst notes that the applicant begins its utilization projections with the number of PD patients receiving treatment *as of December 31, 2017*, rather than choosing to grow that patient population for four years until the beginning of OY 1 (January 1, 2021) of the proposed project, thus resulting in a conservative initial patient census. Furthermore, the most recent ESRD data collection form dated June 18, 2018 (six months after the information was submitted to the Healthcare Planning and Certificate of Need Section for the July 2018 SDR) showed that DC Moore County was serving 40 PD patients, which is equivalent to the applicant’s projection of PD patients in the first operating year.

Publicly available data in the 2018 United States Renal Data System (USRDS) Annual Data Report¹ indicates that since 2007, a nadir point for home dialysis utilization, the number of ESRD patients utilizing all home treatment modalities, including PD, continues to increase.

¹ https://www.usrds.org/2018/view/v2_01.aspx (last accessed January 15, 2019)

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

- The applicant begins with the existing PD patients receiving treatments at DC Moore County as reported in the July 2018 SDR,
- The applicant adequately explains the need the PD patients have for a standalone facility in Moore County,
- The applicant provides historical utilization data that are unique to the DC Moore County facility and the PD patients it serves,
- The applicant chooses to begin its patient census for PHT in OY 1 (CY 2021) with the *current* (as of 12/31/2017) PD patient census, despite potential growth of that population for four years,
- The applicant’s historical utilization data are consistent with available national data regarding the increase in home dialysis training modalities by dialysis patients, and
- In Exhibit I-3, the applicant provides a letter from a nephrology group in Pinehurst that indicates support for the standalone PD facility, and expresses their intent to refer and treat PD patients at the new facility.

Access

In Section C.3, page 16, the applicant states that, by policy, the proposed services will be available to all patients in need of dialysis, without regard to race, sex, age, handicap, socioeconomic status or the ability to pay. In Section L.1, page 43, the applicant projects the following payor mix during the second full fiscal year of operation (CY 2022) following completion of the project, as illustrated in the following table.

PAYMENT SOURCE	% PD PATIENTS
Medicare	20.6%
Medicaid	2.9%
Commercial Insurance	20.6%
Medicare/Commercial	26.5%
Medicare/Medicaid	14.7%
VA	14.7%
Total	100.00%

*Source: Application page 43.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

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

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

C

The applicant proposes to develop a new kidney disease treatment center in Pinehurst, dedicated to providing home training and support services for PD patients by relocating the existing PD program currently located at DC Moore County.

In Section D, page 20, the applicant explains why it believes the needs of the PD population presently utilizing the services to be relocated will continue to be adequately met following project completion. The applicant states:

“In order to make it convenient for all of DC Moore County’s current PD patients, DaVita searched within a five mile radius of its current site for a new location. The proposed primary site is only 2.8 miles from the facility’s current location. The needs of the population presently served at DC Moore County will continue to be met because PD patients will have comparable geographic access to their dialysis services.”

In Exhibit K-4g, the applicant provides a map showing the relative distance between DC Moore County and the proposed site of PHT.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

The applicant proposes to develop a new kidney disease treatment center in Pinehurst, dedicated to providing home training and support services for PD patients by relocating the existing PD program currently located at DC Moore County.

In Section E.1, page 21, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo - The applicant states that maintaining the status quo is not an effective alternative because of the growth rate of the PD patient population at DC Moore County. Additionally, the applicant states that doing nothing prolongs the need to address updates and upgrades that DaVita would like to make to better service its patient population.
- Renovate the current facility - The applicant states that the existing footprint of the facility limit the ability to renovate and expand the PD training and support areas to meet the needs of the PD patient population.

- Relocate the PD program to another existing facility in the county - The applicant states it operates the other two dialysis facilities in Moore County, Carthage Dialysis and Southern Pines Dialysis, neither of which has the capacity to expand sufficiently to accommodate the needs of the PD patient population.

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 application is conforming to all statutory and regulatory review criteria, and
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information provided at the Agency's request

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 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 shall materially comply with the last made representation.**
 - 2. Total Renal Care of North Carolina, LLC shall establish a freestanding home dialysis training and support program to provide only peritoneal dialysis training and support services.**
 - 3. Total Renal Care of North Carolina, LLC d/b/a Pinehurst Home Training 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 develop a new kidney disease treatment center in Pinehurst, dedicated to providing home training and support services for PD patients by relocating the existing PD program currently located at DC Moore County.

Capital and Working Capital Costs

In Section F, page 22, the applicant projects the total capital cost of the project, as shown in the table below.

ITEM	COST
Site Inspection and Survey	\$62,690
Construction Costs	\$729,353
Equipment / Furniture	\$173,932
Architect / Engineering Fees	\$61,870
Miscellaneous Costs (interest)	\$15,418
Total	\$1,043,263

In Section F.10, page 24, the applicant projects \$143,773 in start-up costs. In Section F.11, page 25, the applicant projects \$710,471 in initial operating expenses, for a total working capital requirement of \$854,243. On page 25, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F.2 and F.13, pages 23 and 26, respectively, the applicant states that the capital cost will be funded with the cash reserves of DaVita, the parent company of TRC, as shown in the table below.

Sources of Capital Cost Financing	
Type	Total
Loans	\$0
Accumulated reserves or OE* – Capital Cost	\$1,043,263
Accumulated reserves or OE* – Working Capital	\$854,243
Other (Specify)	\$0
Total Financing	\$1,897,506

* OE = Owner's Equity

Exhibit F-5 contains a letter dated November 15, 2018 from the Chief Accounting Officer for DaVita, authorizing and committing cash reserves of DaVita, Inc. for the capital costs of the project. Exhibit F-7 contains a copy of the balance sheet for DaVita, Inc. for the year ending December 31, 2017. The report indicates that as of December 31, 2017, DaVita, Inc. had

\$508,234,000 in cash and cash equivalents, \$18 billion in total assets and \$5.8 billion 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.

	CY 2021 OPERATING YEAR 1	CY 2022 OPERATING YEAR 2
Total Treatments	6,084	6,474
Total Gross Revenues (Charges)	\$2,528,102	\$2,691,685
Total Net Revenue	\$2,473,269	\$2,633,305
Total Operating Expenses (Costs)	\$1,874,115	\$1,982,213
Net Income	\$ 599,195	\$ 651,092

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

The applicant proposes to develop a new kidney disease treatment center in Pinehurst, dedicated to providing home training and support services for PD patients by relocating the existing PD program currently located at DC Moore 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 for this facility is Moore County. Facilities may serve residents of counties not included in their service area.

There are three existing dialysis facilities in Moore County, all of which are owned or operated by TRC or its parent company, DaVita, Inc.: Carthage Dialysis located in Carthage, Dialysis Care of Moore County located in Pinehurst and Southern Pines Dialysis Center located in Southern Pines. The applicant and/or its parent is the only provider of dialysis services in Moore County. Home PD services are currently available only at the DC Moore County facility. The existing and approved Moore County dialysis facilities are shown below:

Facility	# Certified Stations	# Patients	# Patients per Station	% Utilization
Carthage Dialysis	12	29	2.42	60.4%
Dialysis Care of Moore County	23	68	2.95	73.9%
Southern Pines Dialysis	15	54	3.60	90.0%
Total	50	151		

Source: July 2018 SDR, Table B.

In Section G, page 28, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Moore County. The applicant states:

“As of December 31, 2017, there were three dialysis facilities in Moore County with a total of 50 certified stations. This certificate of need application does not propose to increase the number of certified stations in Moore County. Relocating the existing PD program from DC Moore County to a facility dedicated to home PD training and follow up services at a different location will allow DaVita to better serve its current and projected PD patients. It will not result in the duplication of existing services since only one facility in Moore County, DC Moore County, offers home training and follow up services to ESRD patients. Transferring the PD program form DC Moore County to

Pinehurst Home Training will create a new facility at a different location to better serve existing patients at updated an expanded facility [sic]....”

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

- The applicant adequately demonstrates that the PD patients need the standalone PD facility proposed in this application.
- There is no other provider of home dialysis services in Moore County.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section H.1, page 29, the applicant provides projected staffing for OY 2 (CY 2022) for the proposed PD program. See the following table, from page 29 of the application:

Pinehurst Home Training Projected Staffing

POSITION	TOTAL FTE POSITIONS
Medical Director	NA*
Registered Nurse	0.0
Patient Care Technician	0.0
Administrator	1.0
Dietician	0.5
Social Worker	0.5
Home Training RN	2.0
Administrative Assistant	0.5
Bio-Medical Technician	0.5
Total	5.0

*Medical Director is an independent contractor, not an employee

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, which is found in Section R. In Sections H.3 and H.4, pages 30 - 31, the applicant describes the methods used to recruit or fill new positions and describes its existing training and continuing education programs. In Section I.3, page 34, the applicant identifies the proposed medical director. In Exhibit I-5, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services.

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.

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

C

In Section I, page 33, the applicant provides a list of the necessary ancillary and support services that will be provided at PHT when the facility is operational, as illustrated below.

Pinehurst Home Training Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	DC Moore County
Self-care training (in-center)	DC Moore County
Home training HH PD Accessible follow-up program	DC Moore County Pinehurst Home Training Pinehurst Home Training
Psychological counseling	Pinehurst Home Training
Isolation – hepatitis	Pinehurst Home Training
Nutritional counseling	Pinehurst Home Training
Social Work services	Pinehurst Home Training
Acute dialysis in an acute care setting	FirstHealth Moore Regional Hospital
Emergency care	FirstHealth Moore Regional Hospital
Blood bank services	FirstHealth Moore Regional Hospital
Diagnostic and evaluation services	FirstHealth Moore Regional Hospital
X-ray services	FirstHealth Moore Regional Hospital
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	UNC Healthcare
Vascular surgery	UNC Hospital or Pinehurst Surgical
Transplantation services	UNC Hospitals
Vocational rehabilitation & counseling	NC DHHS Division of Vocational Rehab.
Transportation	Moore County Transportation

The applicant provides supporting documentation in Exhibit I.1-5. Exhibits I-1 through I-4, respectively, contain copies of agreements for home training services with CD - Carrboro, Spectra for laboratories services, UNC Hospitals for transfer agreement and transplant services.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health

service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

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

NA

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

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

C

In Section K, page 38, the applicant states that the project involves constructing 1,578 square feet of space to accommodate four home training rooms and support space. Line drawings are provided in Exhibit K.1a.

On page 37, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit K.

On pages 37 - 38, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.

On page 39, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 supplemental information provided to the Agency on January 22, 2019, the applicant provides the historical payor mix during FY 2018 for the proposed services at DC Moore County, as shown in the table below.

PAYOR CATEGORY	PD SERVICES AS PERCENT OF TOTAL
Medicare	20.6%
Medicaid	2.9%
Commercial Insurance	20.6%
Medicare Commercial	26.5%
Medicare / Medicaid	14.7%
VA	14.7%
Total	100.0%

Numbers may not sum due to rounding

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
Moore	24%	52%	23%	11%	10%	12%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217>

Latest Data 7/1/17 as of 7/17/18

* Excludes "White alone, not Hispanic or Latino"

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

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

The IPRO SA Network 6 2016 Annual Report (pages 25-26²) 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
- Supplemental information provided to the Agency on January 22, 2019

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.3, page 45, the applicant states:

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

In Section L.6, page 45, the applicant states, *“There have been no civil rights equal access complaints filed within the last five years.”*

² <https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.1(b), page 43, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

**Pinehurst Home Training Projected Payor Mix
OY 2 (CY 2022)**

PAYMENT SOURCE	% PD PATIENTS
Medicare	20.6%
Medicaid	2.9%
Commercial Insurance	20.6%
Medicare/Commercial	26.5%
Medicare/Medicaid	14.7%
VA	14.7%
Total	100.00%

Note numbers may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 64.7% of total services will be provided to Medicare and Medicaid patients.

On page 43, 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 for the following reasons:

- The applicant projects future payor mix for the PD Program at the Pinehurst Home Training facility based on the historical sources of payment for PD patients at the existing DC Moore County facility,

- The applicant projects no change in its payor mix following the development of a standalone PD training facility as proposed in this application.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.4, pages 44 - 45, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 47, the applicant states that Pinehurst Home Training will be offered to nursing students from Sandhills Community College for training purposes and provides supporting documentation in Exhibit M-2.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop a new kidney disease treatment center in Pinehurst, dedicated to providing home training and support services for PD patients by relocating the existing PD program currently located at DC Moore 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 for this facility is Moore County. Facilities may serve residents of counties not included in their service area.

There are three existing dialysis facilities in Moore County, all of which are owned or operated by TRC or its parent company, DaVita, Inc.: Carthage Dialysis located in Carthage, Dialysis Care of Moore County located in Pinehurst and Southern Pines Dialysis Center located in Southern Pines. The applicant and/or its parent is the only provider of dialysis services in Moore County. Home PD services are currently available only at the DC Moore County facility. The existing and approved Moore County dialysis facilities are shown below:

Facility	# Certified Stations	# Patients	# Patients per Station	% Utilization
Carthage Dialysis	12	29	2.42	60.4%
Dialysis Care of Moore County	23	68	2.95	73.9%
Southern Pines Dialysis	15	54	3.60	90.0%
Total	50	151		

Source: July 2018 SDR, Table B.

In Section N.1, page 48, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states:

“The relocation of the PD program at DC Moore County to a new standalone PD training and follow-up facility will have no effect on competition in Moore 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 applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

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

Conclusion

The Agency reviewed the:

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

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

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

C

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

In Section O.3, page 49, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two of these facilities, Southeastern Dialysis Center-Wilmington and Goldsboro South Dialysis. The applicant provides documentation regarding the deficiencies and subsequent measures taken by those facilities to ensure compliance with CMS Conditions for Coverage in Exhibit O-3. 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 applicant proposes to develop a new kidney disease treatment center dedicated to providing home training and support services for PD patients by relocating the existing PD program currently located at DC Moore County in Pinehurst. The applicant does not propose to include any certified in-center stations or home hemodialysis stations as a part of the proposed project. The Criteria and Standards for End Stage Renal Disease Services, promulgated in 10A NCAC 14C .2200, are not applicable to this review due to a declaratory ruling issued to another provider by the Agency on October 10, 2018, which exempts the Criteria and Standards from applying to proposals to develop or expand facilities exclusively serving HH and PD patients.