ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: June 20, 2018
Findings Date: June 20, 2018

Project Analyst: Julie M. Faenza
Team Leader: Fatimah Wilson

Project ID #: B-11488-18
Facility: Brevard Dialysis Center
FID #: 080169
County: Transylvania
Applicant: Total Renal Care of North Carolina, LLC
Project: Add two dialysis stations for a total of 11 dialysis stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC (TRC) d/b/a Brevard Dialysis Center (BDC) proposes to add two dialysis stations to the existing facility for a total of 11 dialysis stations upon project completion.

Need Determination

The 2018 State Medical Facilities Plan (2018 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is neither a surplus nor a deficit of dialysis stations in Transylvania County. Therefore, the January 2018 SDR does not indicate a need for additional stations in Transylvania County based on the county need methodology, which states that the county deficit must be 10 or greater to establish a need for additional stations. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the

dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80 percent. The utilization rate reported for BDC in the January 2018 SDR is 3.44 patients per station per week, or 86.11 percent, based on 31 in-center dialysis patients and nine certified dialysis stations [31 / 9 = 3.44; 3.44 / 4 = 0.8611 or 86.11%].

Below is a table that illustrates the facility need for additional dialysis stations at BDC:

JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/17		86.11%
Certified Stations		9
Pending Stations		0
Total Existing and Pending Stations		**9**
In-Center Patients as of 6/30/17 (January 2018 SDR) (SDR2)		31
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR1)		28
Step	**Description**	**Result**
(i)	Difference (SDR2 - SDR1)	3
	Multiply the difference by 2 for the projected net in-center change	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/16	0.2143
(ii)	Divide the result of Step (i) by 12	0.0179
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/17 until 12/31/17)	0.1071
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	34.3214
(v)	Divide the result of Step (iv) by 3.2 patients per station	10.7254
	and subtract the number of certified and pending stations to determine the number of stations needed	**2**

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is two stations. Step (C) of the facility need methodology states, *"The facility may apply to expand to meet the need established …, up to a maximum of ten stations."* The applicant proposes to add two new stations; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2018 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on page 33 of the 2018 SMFP, is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

> *"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing*

healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B.4(a), pages 9-10; Section K.1(g), page 40; Section N.1, page 50; Section O, page 51; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B.4(b), page 10; Section C.3, page 15; Section L, pages 44-48; Section N.1, page 50; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B.4(c), page 11; Section C, pages 13-15; Section F, pages 24-28; Section K, pages 39-40; Section N.1, page 50; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

The applicant adequately demonstrates how its proposal incorporates the concepts of quality, equitable access, and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

Conclusion

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.

(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

TRC proposes to add two dialysis stations to the existing BDC facility for a total of 11 dialysis stations upon project completion. BDC serves home peritoneal dialysis (PD) patients, and plans to continue to do so, but does not serve home hemodialysis patients and has no plans to add home hemodialysis services.

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 Transylvania County. Facilities may serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin as provided in Section C, pages 13 and 19.

BDC Patients by County						
	Historical (6/30/2017)			Projected (Operating Year 2)		
County	# of IC Patients	# of PD Patients	% of Total	# of IC Patients	# of PD Patients	% of Total
Transylvania	25	4	69.0%	35	4	75.0%
Haywood	0	1	2.4%	0	1	1.9%
Henderson	3	5	19.0%	3	5	15.4%
Jackson	0	1	2.4%	0	1	1.9%
Polk	1	0	2.4%	1	0	1.9%
Other States	2	0	4.7%	2	0	3.8%
Total	**31**	**11**	**100.0%**	**41**	**11**	**100.0%**

Table may not foot due to rounding.

In Section C, pages 13-15, the applicant provides the assumptions and methodology it used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.2, page 15, the applicant states that the facility need methodology shows that the facility needs two additional stations based on the population growth at BDC. Additionally, the applicant projects the 11-station facility to have a utilization rate 3.45 patients per station per week, or 86.25 percent, by the end of the first operating year. The projected utilization

exceeds the minimum operating standard of 3.2 patients per station per week as promulgated in 10A NCAC 14C. 2203(b).

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

- BDC is currently operating at a rate of 3.44 patients per station per day, or 86.11 percent of capacity.

- The applicant demonstrates eligibility to add dialysis stations to its facility via the facility need methodology. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.

Projected Utilization

In Section C, pages 13 and 19, the applicant provides historical and projected utilization as illustrated in the following table.

BDC Patients by County						
	Historical (6/30/2017)			Projected (Operating Year 2)		
County	# of IC Patients	# of PD Patients	% of Total	# of IC Patients	# of PD Patients	% of Total
Transylvania	25	4	69.0%	35	4	75.0%
Haywood	0	1	2.4%	0	1	1.9%
Henderson	3	5	19.0%	3	5	15.4%
Jackson	0	1	2.4%	0	1	1.9%
Polk	1	0	2.4%	1	0	1.9%
Other States	2	0	4.7%	2	0	3.8%
Total	**31**	**11**	**100.0%**	**41**	**11[15]***	**100.0%**

Table may not foot due to rounding.
*The applicant projects to serve 15 PD patients at the end of OY2. See page 15 of the application for utilization projections.

In Section C.1, pages 13-15, the applicant provides the assumptions and methodology it used to project in-center and PD patient utilization, which are summarized below.

In-Center

- The applicant begins its utilization projections by using its facility census as of June 30, 2017.

- The applicant assumes that the patient population currently receiving treatment at BDC and who currently reside in Transylvania County will increase annually at a rate of 7.8 percent, which is the Five Year Average Annual Change Rate (AACR) for Transylvania County published in the January 2018 SDR.

- The applicant assumes no population growth for the patients who utilize the facility and live in other counties, but assumes that the patients will continue to dialyze at BDC and adds them to the calculations when appropriate.

- The project is scheduled for completion on January 1, 2020. OY1 is CY 2020. OY2 is CY 2021.

In Section C.1, page 14, the applicant provides the calculations it used to arrive at the projected patient census for OY1 and OY2, as summarized in the table below.

BDC In-Center Patients*	
Starting point of calculations is Transylvania County patients dialyzing at BDC on June 30, 2017.	25
Transylvania County patient population is projected forward by six months to December 31, 2017, using the Five Year AACR (7.8%).	25 X 1.039 = 25.975
Transylvania County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (7.8%).	25.975 X 1.078 = 28.0011
Transylvania County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (7.8%).	28.0011 X 1.078 = 30.1851
The patients from other counties are added. This is the projected census on December 31, 2019 and the starting census for this project.	30.1851 + 6 = 36.1851
Transylvania County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (7.8%).	30.1851 X 1.078 = 32.5396
The patients from other counties are added. This is the projected census on December 31, 2020 (end of OY1).	32.5396 + 6 = 38.5396
Transylvania County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (7.8%).	32.5396 X 1.078 = 35.0777
The patients from other counties are added. This is the projected census on December 31, 2021 (end of OY2).	35.0777 + 6 = 41.0777

*On page 14, the applicant projects each year of growth starting on January 1. Doing so in this table would make it difficult to understand what the projections are for the end of OYs 1 and 2, which is important in determining whether the applicant meets the relevant performance standard. To avoid confusion, this table uses December 31 each year to explain the applicant's projections.

The applicant rounds down and projects to serve 38 in-center patients on 11 stations, which is 3.45 patients per station per week (38 patients / 11 stations = 3.45), by the end of OY1 and 41 in-center patients on 11 stations, which is 3.73 patients per station per week (41 patients / 11 stations = 3.73), by the end of OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Home Peritoneal Dialysis Patients

- The applicant begins its utilization projections by using its PD patient census as of July 1, 2017.

- The applicant assumes no growth through the end of 2017; after that, the applicant assumes that the PD program will grow at a rate of one patient per year.

- The project is scheduled for completion on December 31, 2019. OY1 is CY 2020. OY2 is CY 2021.

In Section C.1, page 15, the applicant provides the calculations it used to arrive at the projected HH patient census for OY1 and OY2, as summarized in the table below.

BDC PD Patients*	
Starting point of calculations is BDC PD patients on June 30, 2017.	11
The number of PD patients is held constant through the end of 2017.	11
The number of PD patients is projected forward by one year to December 31, 2018.	11 + 1 = 12
The number of PD patients is projected forward by one year to December 31, 2019.	12 + 1 = 13
The number of PD patients is projected forward by one year to December 31, 2020 (end of OY1).	13 + 1 = 14
The number of PD patients is projected forward by one year to December 31, 2021 (end of OY2).	14 + 1 = 15

*As discussed on page 6 of these findings, the applicant projects each year of growth starting on January 1. It was necessary to use December 31 instead of January 1 for the table on page 6 to avoid confusion. This table also uses December 31 to maintain consistency.

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

- The January 2018 SDR states that BDC's utilization was 3.44 patients per station per week (a utilization rate of 86.11 percent) as of June 30, 2017.

- The applicant projects future utilization based on historical utilization.

- The applicant uses the Five Year AACR for Transylvania County as published in the January 2018 SDR to project growth of Transylvania County residents.

- The applicant does not project growth for its patients who do not reside in Transylvania County.

- The applicant's projected utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Access

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

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

We will make every reasonable effort to accommodate all patients, especially those with special needs such as the handicapped, patients attending school or patients who work. …

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

In Section L, page 45, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

BDC Projected Payor Mix CY 2021			
Payment Source	**% Total Patients**	**% In-Center Patients**	**% PD Patients**
Private Pay	0.0%	0.0%	0.0%
Medicare	28.5%	25.9%	37.5%
Medicaid	2.9%	0.0%	12.5%
Commercial Insurance	5.7%	7.5%	0.0%
Medicare/Commercial	31.4%	33.3%	25.0%
Medicare/Medicaid	28.6%	29.6%	25.0%
Misc. (including VA)	2.9%	3.7%	0.0%
Total	**100.00%**	**100.00%**	**100.00%**

The applicant states on page 45 that the future payor mix is based on BDC's historical experience during the last full operating year. 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 (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 met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

(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

TRC proposes to add two dialysis stations to the existing BDC facility for a total of 11 dialysis stations upon project completion.

In Section E, page 23, 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 applicant stated that the only other alternative to developing the two stations was to maintain the status quo. The applicant states that its proposal is the most effective alternative because maintaining the status quo does not proactively address growth and access.

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 utilizes the facility need methodology to show the need for additional stations.

- The applicant's projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- The applicant adequately demonstrates that maintaining the status quo is not the most effective alternative to meet the need for additional dialysis stations at BDC.

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 Brevard Dialysis Center shall materially comply with all representations made in the certificate of need application.**

2. **Pursuant to the facility need determination in the January 2018 SDR, Total Renal Care of North Carolina, LLC d/b/a Brevard Dialysis Center shall develop no more than two additional dialysis stations for a total of no more than 11 certified stations upon completion of this project, which shall include any home hemodialysis training or isolation stations.**

3. **Total Renal Care of North Carolina, LLC d/b/a Brevard Dialysis Center shall install plumbing and electrical wiring through the walls for no more than two dialysis stations, which shall include any isolation stations.**

4. **Total Renal Care of North Carolina, LLC d/b/a Brevard Dialysis Center 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

TRC proposes to add two dialysis stations to the existing BDC facility for a total of 11 dialysis stations upon project completion.

Capital and Working Capital Costs

In Section F.1, page 24, the applicant projects the total capital cost to be $34,033, with $27,560 to be used for dialysis machines and $6,473 for other equipment. In Sections F.10 and F.11, pages 26-27, the applicant states that there are no projected start-up expenses or initial operating expenses because it is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 25, the applicant states that it will fund the entire capital cost of the proposed project with accumulated reserves. Exhibit F-5 contains a letter from the applicant on behalf of the Chief Accounting Officer of DaVita, Inc. (DaVita), TRC's parent company, authorizing the use of accumulated reserves for the capital needs of the project. Exhibit F-7 contains a Form 10-K Consolidated Financial Statement from DaVita, which showed that as

of December 31, 2016, DaVita had adequate cash and assets to fund the capital cost of the proposed project.

Financial Feasibility

The applicant provides pro forma financial statements 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.

Projected Revenues and Operating Expenses		
BDC	**Operating Year 1 CY 2020**	**Operating Year 2 CY 2021**
Total Treatments	7,484	8,003
Total Gross Revenues (Charges)	$2,127,590	$2,274,122
Total Net Revenue	$2,027,462	$2,167,037
Average Net Revenue per Treatment	$271	$271
Total Operating Expenses (Costs)	$1,895,020	$1,999,607
Average Operating Expense per Treatment	$253	$250
Net Income/Profit	**$132,442**	**$167,429**

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 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 because 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

TRC proposes to add two dialysis stations to the existing BDC facility for a total of 11 dialysis stations upon project completion.

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 Transylvania County. Facilities may serve residents of counties not included in their service area.

According to Table B of the January 2018 SDR, BDC is the only existing or approved dialysis facility in Transylvania County. As of June 30, 2017, the facility's utilization rate was 3.44 patients per station per week, or 86.11 percent.

In Section G, page 30, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Transylvania County. The applicant states:

> *"In Section B-2 and Section C of this application, we demonstrate the need that Brevard Dialysis, the only provider in the county, has for adding stations. While adding stations at this facility does increase the number of stations in Transylvania County, it serves to meet the needs of the facility's growing population of patients referred by the facility's admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area."*

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

- There is a facility need determination, as calculated using the methodology in the January 2018 SDR, for the proposed dialysis stations.

- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

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.

(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 31, the applicant provides information about current and projected staffing for the proposed services. The applicant projects to increase its patient care technician staffing level from 4.0 full time equivalent staff (FTEs) to 5.0 FTEs. The applicant does not project to change any other staffing levels upon project completion.

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 Section H, pages 32-33, the applicant describes the methods it uses to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 36, the applicant identifies the current medical director. In Exhibit I-3, the applicant provides a letter from the current medical director indicating his intent to continue serving as medical director for the facility.

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 35, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

BDC – Ancillary and Support Services	
Services	**Provider**
In-center dialysis/maintenance	On site
Self-care training (in-center)	On site
Home training HH PD Accessible follow-up program	 Asheville Kidney Center On site On site/Asheville Kidney Center
Psychological counseling	On site
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	Margaret R. Pardee Hospital, Mission Hospital
Emergency care	Margaret R. Pardee Hospital, Mission Hospital
Blood bank services	Margaret R. Pardee Hospital, Mission Hospital
Diagnostic and evaluation services	Margaret R. Pardee Hospital, Mission Hospital
X-ray services	Margaret R. Pardee Hospital, Mission Hospital
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	Margaret R. Pardee Hospital, Mission Hospital
Vascular surgery	Margaret R. Pardee Hospital, Mission Hospital
Transplantation services	UNC Healthcare
Vocational rehabilitation & counseling	NC DHHS Vocational Rehab Services
Transportation	Transylvania County DSS

The applicant provides supporting documentation in Exhibit I-1.

In Section I, pages 36-37, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-3.

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.

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

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

State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

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

C

In Section L, page 48, the applicant provides the historical payor mix during CY 2017 for its existing services, as shown in the table below.

BDC Historical Payor Mix CY 2017			
Payment Source	**% Total Patients**	**% In-Center Patients**	**% PD Patients**
Private Pay	0.0%	0.0%	0.0%
Medicare	28.5%	25.9%	37.5%
Medicaid	2.9%	0.0%	12.5%
Commercial Insurance	5.7%	7.5%	0.0%
Medicare/Commercial	31.4%	33.3%	25.0%
Medicare/Medicaid	28.6%	29.6%	25.0%
Misc. (including VA)	2.9%	3.7%	0.0%
Total	**100.00%**	**100.00%**	**100.00%**

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

Percent of Population						
County	**% 65+**	**% Female**	**% Racial & Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
Transylvania	29%	52%	10%	15%	9%	14%
Statewide	16%	51%	37%	16%	10%	13%

Source: http://www.census.gov/quickfacts/table; Latest Data 7/1/16 as of 8/22/17
*Excludes *"White alone"* who are *"not Hispanic or Latino"*
***"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable…The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."*

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina, and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*[1] percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

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

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28[2]. In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

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 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, the applicant states in Section L, page 47, that it has no obligation by any of its facilities to provide uncompensated care or community service under any federal regulations.

In Section L, page 47, 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.

Conclusion

The Agency reviewed the:

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

[2]http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

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, page 45, 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.

BDC Projected Payor Mix CY 2021			
Payment Source	**% Total Patients**	**% In-Center Patients**	**% PD Patients**
Private Pay	0.0%	0.0%	0.0%
Medicare	28.5%	25.9%	37.5%
Medicaid	2.9%	0.0%	12.5%
Commercial Insurance	5.7%	7.5%	0.0%
Medicare/Commercial	31.4%	33.3%	25.0%
Medicare/Medicaid	28.6%	29.6%	25.0%
Misc. (including VA)	2.9%	3.7%	0.0%
Total	**100.00%**	**100.00%**	**100.00%**

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 91.4 percent of all patients will have some or all of their services covered by Medicare and/or Medicaid.

On page 45, the applicant provides the assumptions and methodology it uses 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 projected payor mix is based on the historical payor mix.

- Projected utilization is reasonable and adequately supported. 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 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, page 47, the applicant adequately describes the range of means by which patients will have access to 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.

(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 49, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

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 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

TRC proposes to add two dialysis stations to the existing BDC facility for a total of 11 dialysis stations upon project completion.

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 Transylvania County. Facilities may serve residents of counties not included in their service area.

According to Table B of the January 2018 SDR, BDC is the only existing or approved dialysis facility in Transylvania County. As of June 30, 2017, the facility's utilization rate was 3.44 patients per station per week, or 86.11 percent.

In Section N, page 50, 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 50, the applicant states:

> *"The expansion of Brevard Dialysis will have no effect on competition in Transylvania 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 expansion of Brevard Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services."*

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 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.

(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 kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 79 of this type of facility located in North Carolina.

In Section O, page 51, 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. Supporting documentation is provided in Exhibit O-3. The applicant states that all of the problems have been corrected. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 79 facilities, the applicant provides 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.

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- BDC is an existing facility.

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

-C- In Section C, page 13, the applicant projects that BDC will serve 38 patients on 11 stations, or a rate of 3.45 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 13-15, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.