

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 21, 2019

Findings Date: May 21, 2019

Project Analyst: Mike McKillip

Assistant Chief: Lisa Pittman

Project ID #: B-11688-19

Facility: Brevard Dialysis

FID #: 080169

County: Transylvania

Applicant: Total Renal Care of North Carolina, LLC.

Project: Add no more than two stations for a total of no more than 13 stations upon completion of the project

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC (TRC) proposes to add two stations for a total of 13 stations at Brevard Dialysis upon completion of the project.

#### **Need Determination**

The 2019 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D in the January 2019 Semiannual Dialysis Report (SDR), there is a surplus of two dialysis stations in Transylvania County. Therefore, there is no county need determination for new dialysis stations in Transylvania County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Brevard Dialysis in the January 2019 SDR is 3.8889 patients per station per week. This utilization rate was calculated based on 35 in-center dialysis patients

and nine certified dialysis stations as of June 30, 2018 (35 patients / 9 stations = 3.8889 patients per station per week). [Note: Brevard Dialysis was approved to add two dialysis stations for a total of 11 stations (Project I.D. # B-11488-18) and the two stations were certified on October 14, 2018.] The facility need methodology requires a facility’s utilization rate in the latest SDR to be at least 3.2 patients per station per week to be eligible to apply for additional stations based on facility need.

Application of the facility need methodology indicates that up to a potential maximum of three additional stations are needed for this facility, as illustrated in the following table.

| <b>APRIL 1 REVIEW-JANUARY SDR</b>                        |   |               |
|--|---|---------------|
| Required SDR Utilization                                 |   | 80%           |
| Center Utilization Rate as of 6/30/18                    |   | 79.55%        |
| Certified Stations                                       |   | 11            |
| Pending Stations   |   | 0             |
| <b>Total Existing and Pending Stations</b>               |   | <b>11</b>     |
| In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR2)   |   | 35            |
| In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR1) |   | 27            |
| <b>Step</b>  | <b>Description</b>  | <b>Result</b> |
| (i)  | Difference (SDR2 - SDR1)  | 8             |
|  | Multiply the difference by 2 for the projected net in-center change   | 16            |
|  | Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/17   | 0.5926        |
| (ii)   | Divide the result of step (i) by 12   | 0.0494        |
| (iii)  | Multiply the result of step (ii) by 6 (the number of months from 6/30/18 until 12/31/18)  | 0.2963        |
| (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 | 45.3704       |
| (v)  | Divide the result of step (iv) by 3.2 patients per station  | 14.1782       |
|  | and subtract the number of certified and pending stations to determine the number of stations needed  | <b>3</b>      |

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

**Policies**

There is one policy in the 2019 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles* on page 31 of the 2019 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.”*

The applicant addresses *Policy GEN-3* as follows:

#### Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4, pages 9-10, Section K.1(g), page 39, Section N.1, page 49, Section O, page 50 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

#### Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4, page 10, Section C.3, page 15, Section L, pages 43-47, Section N.1, page 49 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

#### Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Sections B.4, page 11, Section K.1, pages 38-39 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. 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

The applicant proposes to add two stations for a total of 13 stations at Brevard Dialysis upon completion of the project.

**Patient Origin**

On page 369, the 2019 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 for this facility consists of Transylvania County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 18, the applicant provides the historical patient origin for Brevard Dialysis for in-center (IC), home hemodialysis (HHD) and peritoneal dialysis (PD) patients as of June 30, 2018 as follows:

| <b>County</b> | <b>IC Patients</b> | <b>HHD Patients</b> | <b>PD Patients</b> |
|---------------|--------------------|---------------------|--------------------|
| Transylvania  | 28                 | 0                   | 4                  |
| Henderson     | 6                  | 0                   | 3                  |
| Buncombe      | 1                  | 0                   | 0                  |
| <b>Totals</b> | <b>35</b>          | <b>0</b>            | <b>7</b>           |

Source: Section C.8, page 18.

In Section C.1, page 13, the applicant provides the projected patient origin for Brevard Dialysis for in-center (IC), home hemodialysis (HHD) and peritoneal dialysis (PD) patients for the first two years of operation following completion of the project as follows:

| County       | End of Operating Year 1<br>CY2021 |          |           | End of Operating Year 2<br>CY2022 |          |           | Percent of Total |               |
|--------------|-----------------------------------|----------|-----------|-----------------------------------|----------|-----------|------------------|---------------|
|              | IC                                | HHD      | PD        | IC                                | HHD      | PD        | OY1              | OY2           |
| Transylvania | 35                                | 0        | 7         | 38                                | 0        | 8         | 79.2%            | 80.7%         |
| Henderson    | 6                                 | 0        | 4         | 6                                 | 0        | 4         | 18.9%            | 17.5%         |
| Buncombe     | 1                                 | 0        | 0         | 1                                 | 0        | 0         | 1.9%             | 1.8%          |
| <b>Total</b> | <b>42</b>                         | <b>0</b> | <b>11</b> | <b>45</b>                         | <b>0</b> | <b>12</b> | <b>100.0%</b>    | <b>100.0%</b> |

Source: Section C.1, page 13.

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 B.2, page 7, the applicant states the application is filed pursuant to the facility need methodology in the 2019 SMFP utilizing data from the July 2018 SDR and the January 2019 SDR. The facility need methodology shows a need for three dialysis stations and the proposed project is for two dialysis stations.

In Section C.1 pages 13-14, the applicant states:

- The applicant begins the projections for the future patient population of Brevard Dialysis by using the ending in-center patient census of 28 patients, as of June 30, 2018.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Transylvania County which is 7.3%, as published in the January 2019 SDR, to project the Transylvania County patient population forward.
- The applicant does not project an increase in the patient population for patients residing outside of Transylvania County.
- Operating Year 1 (OY1) = Calendar Year (CY) 2021  
 Operating Year 2 (OY2) = Calendar Year (CY) 2022

The information is reasonable and adequately supported.

**Projected Utilization**

The applicant's methodology begins with the Transylvania County in-center patient census as of June 30, 2018 and applies the Transylvania County AACR of 7.3%, as illustrated in the following table, from page 17 of the application:

| Date                     | # Patients | Growth Rate | End Patients | + Out of SA Patients | Total Year End Census | Year End Date |
|--------------------------|------------|-------------|--------------|----------------------|-----------------------|---------------|
| 7/1/2018                 | 28         | 1.0365      | 29.002       | 7                    | 36.022                | 12/31/18      |
| 1/1/2019                 | 29         | 1.073       | 31.117       | 7                    | 38.117                | 12/31/19      |
| 1/1/2020                 | 31.117     | 1.073       | 33.38854     | 7                    | 40.38854              | 12/31/20      |
| 01/01/2021<br><b>OY1</b> | 33.38854   | 1.073       | 35.82590     | 7                    | 42.82590              | 12/31/21      |
| 01/01/2022<br><b>OY2</b> | 35.82590   | 1.073       | 38.44119     | 7                    | 45.44119              | 12/31/22      |

The applicant rounded down to the nearest whole number for OY1 and OY2. The applicant projects to serve 42 in-center patients at the end of OY1 and 45 in-center patients at the end of OY2. Thus, the applicant projects that Brevard Dialysis will have a utilization rate of 80.8% or 3.23 patients per station per week (42 patients / 13 stations = 3.23 / 4 = 0.808 or 80.8%) at the end of OY1. The projected utilization of 3.23 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant begins with the existing in-center patient census at Brevard Dialysis.
- The applicant grows the Transylvania County in-center patients using the Transylvania County 5-year AACR (7.3%) and holds the patient population from other counties constant.
- The projected utilization rate by the end of OY1 exceeds the minimum standard of 3.2 patients per station per week.

Home Therapy Programs

The applicant does not currently provide home hemodialysis (HHD). On page 15, the applicant provides the following table showing its projections of peritoneal dialysis (PD) patients through the first two operating years of the project.

| PD Patient Projections | Start Date | # of Patients Start of Year | # of Patients End of Year | Average # of Patients in Year |
|------------------------|------------|-----------------------------|---------------------------|-------------------------------|
| Interim Period         | 1/1/2018   | 7                           | 8                         | 7.5                           |
| Current Year           | 1/1/2019   | 8                           | 9                         | 8.5                           |
| Interim Period         | 1/1/2020   | 9                           | 10                        | 9.5                           |
| Operating Year 1       | 1/1/2021   | 10                          | 11                        | 10.5                          |
| Operating Year 2       | 1/1/2022   | 11                          | 12                        | 11.5                          |

Source: Table on page 18 of the application.

On page 18, the applicant describes its assumptions as follows:

*“Brevard Dialysis had 7 PD patients as of June 30, 2018 based on information included in Table C of the January 2019 SDR. ... The period of growth begins July 1,*

*2018 and is calculated forward to December 31, 2022. It is reasonable to assume that the Brevard Dialysis home-training program will grow at a rate of at least one patient per year during the period of growth.”*

Projected utilization for PD training and support is based on reasonable and adequately supported assumptions regarding continued growth.

### **Access**

In Section C.3, page 15, 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 44, the applicant provides the projected payor mix during OY2, as illustrated below.

| <b>Brevard Dialysis<br/>Projected Payor Mix OY2</b> |                                  |
|---|----------------------------------|
| <b>Payment Category</b>                             | <b>Percent of Total Patients</b> |
| Medicare  | 31.6%                            |
| Medicaid  | 7.9%                             |
| Commercial Insurance                                | 5.3%                             |
| Medicare / Commercial                               | 34.2%                            |
| Medicare / Medicaid                                 | 21.1%                            |
| <b>Total</b>  | <b>100.0%</b>                    |

As shown in the table above, in the second operating year the applicant projects 86.9% of total services will be provided to Medicare patients (includes Medicare, Medicare/Commercial and Medicare/Medicaid) and 7.9% to Medicaid patients.

On page 44, the applicant provides the assumptions and methodology used to project payor mix during OY2. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization at Brevard Dialysis.

### **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, eliminate or relocate a facility or a service. The applicant proposes to add two dialysis stations to an existing facility pursuant to the facility need determination. 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

The applicant proposes to add two stations for a total of 13 stations at Brevard Dialysis upon completion of the project.

In Section E.1, page 22, 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 based on the growth rate at Brevard Dialysis, this alternative was dismissed.
- Relocate existing stations from another DaVita facility - The applicant states that it doesn't have any other facilities in Transylvania County so this is not an alternative.

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 Brevard Dialysis facility is operating above 80% of capacity.
- The applicant's application of the facility need methodology, as published in the January 2019 SDR, indicates a need for three additional stations.
- Maintaining the status quo does not address the high utilization and need for additional stations at the facility.

## **Conclusion**



The Agency reviewed the:

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

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

- 1. Total Renal Care of North Carolina, LLC shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to the facility need determination in the January 2019 SDR, the applicant shall develop no more than two additional dialysis stations for a total of no more than 13 certified stations at Brevard Dialysis, which shall include any home hemodialysis training or isolation stations.**
  - 3. Total Renal Care of North Carolina, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to the issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

### C

The applicant proposes to add two stations for a total of 13 stations at Brevard Dialysis upon completion of the project.

#### **Capital and Working Capital Costs**

In Section F.1, pages 23, the applicant projects the total capital cost of the project as shown in the table below.

|                     |                 |
|---------------------|-----------------|
| Dialysis Machines   | \$15,000        |
| Equipment/Furniture | \$7,758         |
| <b>Total</b>        | <b>\$22,758</b> |

In Section F, pages 25-26, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project because Brevard Dialysis is an existing facility.

In Section F.2, page 24, the applicant states that the capital cost will be funded as shown in the table below.

**Sources of Capital Cost Financing**

| Type                         | DaVita, Inc.    | Total           |
|------------------------------|-----------------|-----------------|
| Loans                        | \$0             | \$0             |
| Accumulated reserves or OE * | \$22,758        | \$22,758        |
| Bonds                        | \$0             | \$0             |
| Other (Specify)              | \$0             | \$0             |
| <b>Total Financing</b>       | <b>\$22,758</b> | <b>\$22,758</b> |

\* OE = Owner's Equity

Exhibit F.1 contains a letter dated March 13, 2019 from the Chief Accounting Officer of DaVita, Inc stating their intention to fund the capital costs of the proposed project with accumulated reserves. Exhibit F.7 contains a copy of Form 10-K Consolidated Financial Statement from DaVita, Inc., which showed that as of December 31, 2018, DaVita had adequate cash and assets to fund the capital costs of the proposed project.

**Financial Feasibility**

The applicant provided pro forma financial statements for the first two operating years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

|   | Operating Year 1<br>CY2021 | Operating Year 2<br>CY2022 |
|---|----------------------------|----------------------------|
| Total Treatments                        | 7,632                      | 8,151                      |
| Total Gross Revenues (Charges)          | \$2,129,157                | \$2,270,764                |
| Total Net Revenue                       | \$2,001,217                | \$2,133,036                |
| Average Net Revenue per Treatment       | \$262                      | \$262                      |
| Total Operating Expenses (Costs)        | \$1,860,161                | \$1,959,923                |
| Average Operating Expense per Treatment | \$244                      | \$240                      |
| Net Income                              | \$141,056                  | \$173,113                  |

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 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 add two stations for a total of 13 stations at Brevard Dialysis upon completion of the project.

On page 369, the 2019 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 for this facility consists of Transylvania County. Facilities may also serve residents of counties not included in their service area.

According to the January 2019 SDR, Brevard Dialysis is the only existing dialysis facility in Transylvania County.

In Section G, page 29, 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:

*“The lone operational DaVita facility in Transylvania County operated at 80% or greater utilization as reported in the January 2019 SDR. Therefore, Brevard Dialysis has the potential for adding stations, given that they can show a need. ... The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services.”*

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 demonstrates the need for the additional two stations based on the facility need methodology, as shown in Section C.1, pages 13-15.
- The applicant demonstrates that the proposed stations are needed in addition to the existing or approved stations in Transylvania County.

### **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 30, the applicant provides current full-time equivalent (FTE) staffing for the proposed services, and states that no additional staffing will be required as part of the proposed project. The applicant provides projected direct care staff in OY2 in Section H.7, page 33. 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 used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit I.3, the applicant provides a letter from the medical director indicating his interest in continuing to serve as the medical director of Brevard Dialysis. In Exhibit H, the applicant provides supporting documentation.

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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.1, page 34, the applicant provides a list of the necessary ancillary and support services, as illustrated below.

| <b>Brevard Dialysis<br/>Ancillary and Support Services</b> |  |
|--|--|
| <b>Services</b>  | <b>Provider</b>                          |
| In-center dialysis/maintenance                             | Brevard Dialysis                         |
| Self-care training (in-center)                             | Brevard Dialysis                         |
| Home training:   | Asheville Kidney Center                  |
| Home hemodialysis  | Asheville Kidney Center                  |
| Peritoneal dialysis  | Brevard Dialysis                         |
| Accessible follow-up program                               | Brevard Dialysis                         |
| Psychological counseling                                   | Brevard Dialysis                         |
| Isolation – hepatitis                                      | Brevard Dialysis                         |
| Nutritional counseling                                     | Brevard Dialysis                         |
| Social Work services                                       | Brevard Dialysis                         |
| Acute dialysis in an acute care setting                    | Pardee Hospital                          |
| Emergency care   | Pardee Hospital                          |
| Blood bank services  | Pardee Hospital                          |
| Diagnostic and evaluation services                         | Pardee Hospital                          |
| X-ray services   | Pardee Hospital                          |
| Laboratory services  | DaVita Laboratories Services, Inc.       |
| Pediatric nephrology                                       | Pardee Hospital                          |
| Vascular surgery   | Pardee Hospital                          |
| Transplantation services                                   | UNC Health Care System                   |
| Vocational rehabilitation & counseling                     | NC Division of Vocational Rehab Services |
| Transportation   | Transylvania County DSS                  |

In Section I.3, pages 35-36, and Section I.4, page 36, the applicant describes its existing and proposed relationships with other local health care and social services providers. The applicant provides supporting documentation in Exhibit I. 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.

NA

The applicant does not propose any new construction or renovation of existing space as part of this project. 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.7, page 47, the applicant provides the historical payor mix during CY2018, as shown below.

| <b>Brevard Dialysis<br/>Current Payor Mix CY2018</b> |                                  |
|--|----------------------------------|
| <b>Payment Category</b>                              | <b>Percent of Total Patients</b> |
| Medicare   | 31.6%                            |
| Medicaid   | 7.9%                             |
| Commercial Insurance                                 | 5.3%                             |
| Medicare / Commercial                                | 34.2%                            |
| Medicare / Medicaid                                  | 21.1%                            |
| <b>Total</b>   | <b>100.0%</b>                    |

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.

| <b>Percent of Population</b> |                      |                      |                                      |                               |  |   |
|------------------------------|----------------------|----------------------|--------------------------------------|-------------------------------|--|---|
| <b>County</b>                | <b>% 65+</b>         | <b>% Female</b>      | <b>% Racial and Ethnic Minority*</b> | <b>% Persons in Poverty**</b> | <b>% &lt; Age 65 with a Disability</b> | <b>% &lt; Age 65 without Health Insurance**</b> |
| <b>2017 Estimate</b>         | <b>2017 Estimate</b> | <b>2017 Estimate</b> | <b>2017 Estimate</b>                 | <b>2017 Estimate</b>          | <b>2017 Estimate</b>                   | <b>2017 Estimate</b>                            |
| Transylvania                 | 29%                  | 52%                  | 10%                                  | 15%                           | 9%                                     | 14%   |
| 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 25-26<sup>1</sup>) 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.

### **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, in Section L.3, page 46, the applicant states:

*“Brevard Dialysis has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed 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 46, the applicant states, *“There have been no civil rights equal access complaints filed within the last five years.”*

### **Conclusion**

---

<sup>1</sup> <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, page 44, the applicant provides the projected payor mix during OY2, as illustrated below.

| <b>Brevard Dialysis<br/>Projected Payor Mix OY2</b> |                                  |
|---|----------------------------------|
| <b>Payment Category</b>                             | <b>Percent of Total Patients</b> |
| Medicare  | 31.6%                            |
| Medicaid  | 7.9%                             |
| Commercial Insurance                                | 5.3%                             |
| Medicare / Commercial                               | 34.2%                            |
| Medicare / Medicaid                                 | 21.1%                            |
| <b>Total</b>  | <b>100.0%</b>                    |

As shown in the table above, in the second operating year, the applicant projects 86.9% of total services will be provided to Medicare patients (includes Medicare, Medicare/Commercial and Medicare/Medicaid) and 7.9% to Medicaid patients.

On page 44, the applicant provides the assumptions and methodology used to project payor mix during OY2. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization at Brevard Dialysis.

### **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.

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

C

In Section L.4, page 46, 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.1, page 48, 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

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 add two stations for a total of 13 stations at Brevard Dialysis upon completion of the project.

On page 369, the 2019 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 for this facility consists of Transylvania County. Facilities may also serve residents of counties not included in their service area.

According to the January 2019 SDR, Brevard Dialysis is the only existing dialysis facility in Transylvania County.

In Section N.1, page 49, 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 expansion of Brevard Dialysis will have no effect on competition in Transylvania County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by 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 Exhibit O.3, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two 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. The applicant states that all of the problems have been corrected and that Southeastern Dialysis Center-Wilmington was back in compliance as of March 21, 2018 and that Goldsboro South Dialysis was back in compliance as of November 21, 2017. 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.

C

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

**10 NCAC 14C .2203 PERFORMANCE STANDARDS**

*.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per*

*station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- Brevard Dialysis is an existing facility.

*.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section C, pages 13 - 17, the applicant demonstrates that Brevard Dialysis will serve a total of 42 in-center patients at the end of OY 1 (CY2021) for a utilization rate of 80.8 or 3.23 patients per station per week ( $42 \text{ patients} / 13 \text{ stations} = 3.23 / 4 = 0.808$  or 80.8%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 13 - 17, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.