

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 13, 2016

Findings Date: December 13, 2016

Project Analyst: Celia C. Inman

Team Leader: Fatimah Wilson

Project ID #: C-11255-16

Facility: McDowell Dialysis Center

FID #: 040266

County: McDowell

Applicant(s): Total Renal Care of North Carolina, LLC d/b/a McDowell Dialysis Center

Project: Add one dialysis station for a total of 15 dialysis stations upon project completion

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NC

Total Renal Care of North Carolina, LLC d/b/a McDowell Dialysis Center (MDC) proposes to add one dialysis station for a total of 15 dialysis stations upon completion of this project and Project ID #C-10108-13.

#### **Need Determination**

The 2016 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2016 Semiannual Dialysis Report (SDR), the county need

methodology indicates there will be a projected station deficit of one station in McDowell County, as of December 31, 2016 and thus, there will be no need determination for an additional facility in McDowell County, based on the county need methodology (1)(E), which states:

*“ ... If a county’s December 31, 2016 projected station deficit is less than 10 ..., the county’s December 31, 2016 station need determination is zero. ”*

Based on the July 2016 SDR, 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 MDC in the July 2016 SDR is 3.38 patients per station per week. This utilization rate was calculated based on 44 in-center dialysis patients and 13 certified dialysis stations as of December 31, 2015 (44 patients / 13 stations = 3.38 patients per station per week).

Application of the facility need methodology with the 13 certified stations, as listed in the July 2016 SDR, indicates that this facility could apply for one additional dialysis station, as illustrated in the following table:

| <b>October 1 REVIEW-July 2016 SDR</b>                   |   |               |
|---|---|---------------|
| Required SDR Utilization                                |   | 80%           |
| Center Utilization Rate as of 12/31/15                  |   | 84.62%        |
| Certified Stations                                      |   | 13            |
| Pending Stations  |   | 1             |
| <b>Total Existing and Pending Stations</b>              |   | <b>14</b>     |
| In-Center Patients as of 12/31/15- July 2016 SDR (SDR2) |   | 44            |
| In-Center Patients as of 6/30/15 – Jan 2016 SDR (SDR1)  |   | 42            |
| Step  | Description   | Result        |
| (i)   | Difference (SDR2 - SDR1)  | 2             |
|   | Multiply the difference by 2 for the projected net in-center change   | 4             |
|   | Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/15 (SDR1)   | 0.0952        |
| (ii)  | Divide the result of Step (i) by 12   | 0.0079        |
| (iii)   | Multiply the result of Step (ii) by 12  | 0.0952        |
| (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 | 48.1905       |
| (v)   | Divide the result of Step (iv) by 3.2 patients per station  | 15.0595       |
|   | and subtract the number of certified and pending stations to determine the number of stations needed  | <b>1.0595</b> |

As shown in the table above, based on the facility need methodology for dialysis stations, which allows for rounding to the nearest whole number only in Step (v), the potential number of stations needed at MDC is one. 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 one new station and, therefore, would be consistent with the facility need determination for dialysis stations, according to the utilization and number of certified stations listed in the July 2016 SDR.

However, the applicant received approval for Project ID #C-10108-13 (add one dialysis station for a total of 14 stations) and was awarded the certificate of need to develop the station effective June 4, 2013. The approved project stated that the station would be operational and receive certification by January 1, 2014. In progress reports submitted by the applicant, there is conflicting information as to whether or not the additional in-center dialysis station was needed at the facility. On January 16, 2015, the applicant submitted a material compliance request to utilize the station as a home hemodialysis training and support station, instead of an in-center dialysis station. The request was found to be in compliance on February 13, 2015. However, that station has yet to be developed and certified. In fact, none of the milestones authorized in the certificate of need or the material compliance request have been met, to date.

In response to an August 25, 2016 Notice of Intent to Consider Withdrawal of a Certificate of Need/Request for Comprehensive Progress Report, the applicant stated that MDC no longer needed to utilize the station for home hemodialysis training and intended to make renovations to the facility to accommodate two additional stations for in-center patients, based on the expected approval of a certificate of need application submitted on September 15, 2016 to add one in-center dialysis station for a total of 15 (Project ID #C-11255-16, the project under review).

If Project ID #C-10108-13 had been implemented, as approved, with the addition of the 14<sup>th</sup> station, the applicant would no longer have been eligible to apply for additional stations pursuant to the facility need methodology because it would no longer meet the required utilization rate of 3.2 patients per station or 80%. With the development of the approved 14<sup>th</sup> station, the December 31, 2015 utilization rate would have been only 3.14 patients per station or 78.57% ( $44 / 14 = 3.14 / 4 = 0.7857$ ). Under these circumstances, the applicant would not meet the required 80% utilization and could not be approved to add stations pursuant to the facility need methodology.

### **Policies**

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

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to*

*provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

### Promote Safety and Quality

In Section A.11, page 5, the applicant states that it is a subsidiary of DaVita Inc., which currently operates over 70 dialysis facilities in North Carolina. The applicant describes how its proposal will promote safety and quality in Section B.4(a) and (d), pages 9-11, and Section N.1, page 48. In Section B.4(a), page 9, the applicant states:

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

The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

### Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B.4(b) and (d), pages 10-11; Section C.3, page 15; Section L, pages 43-46; and Section N.1, page 48. The applicant states in Section B.4(b), page 10,

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

In Section L.1(b), page 43, the applicant provides the projected payor mix, which shows that the majority of its dialysis patients are covered by Medicare and/or Medicaid and projects that greater than 84% of its total dialysis treatments will be reimbursed by some form of Medicare and/or Medicaid. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will promote equitable access.

### Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize health care value for resources expended in Section B.4, page 11, and Section N.1, page 48. In Section B.4(c), the applicant states that it will maximize healthcare value through centralized purchasing, electronic patient charting, preventative maintenance, and inventory control. However, the information provided by the applicant is not reasonable and does not adequately support the determination that the applicant’s proposal will maximize healthcare value, because:

- the applicant has not developed a dialysis station which was approved in Project ID #C-10108-13 and effective over three years ago; and
- the applicant does not adequately demonstrate that the proposed project was the most effective alternative. The discussion regarding alternatives found in Criterion (4) is incorporated herein by reference.

The applicant does not adequately demonstrate how its projected volumes incorporate the concepts of quality, equitable access, and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is not consistent with Policy GEN-3.

### **Conclusion**

In summary, the applicant does not adequately demonstrate that the proposal is consistent with *Policy GEN-3: Basic Principles*; nor does the applicant adequately demonstrate that the application is consistent with the facility need determination in the July 2016 SDR. Therefore, the application is not conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

NC

The applicant proposes to add one dialysis station to its existing facility for a total of 15 certified dialysis stations upon completion of the proposed project and Project ID #C-10108-13.

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

| <b>Stations</b> | <b>Description</b>  | <b>Project ID #</b> |
|-----------------|---|---------------------|
| 13              | Total existing certified stations as of the July 2016 SDR       |                     |
| +1              | Stations to be added as part of this project                    | C-11255-16          |
| +1              | Stations previously approved to be added, but not yet certified | C-10108-13          |
| 0               | Stations previously approved to be relocated from MDC           |                     |
| 15              | Total stations upon completion of above projects                |                     |

**Patient Origin**

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. MDC is located in McDowell County; thus, the service area for this facility consists of McDowell County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 17, the applicant provides a table showing the historical patient origin for MDC in-center, home hemodialysis (HH), and peritoneal dialysis (PD) patients, as shown below.

**MDC  
As of 12/31/2015**

| <b>Patient's County of Residence</b> | <b>In-Center Patients</b> | <b>HH Patients</b> | <b>PD Patients</b> |
|--------------------------------------|---------------------------|--------------------|--------------------|
| McDowell                             | 42                        | 0                  | 0                  |
| Burke                                | 1                         | 0                  | 0                  |
| Rutherford                           | 1                         | 0                  | 0                  |
| <b>Total</b>                         | <b>44</b>                 | <b>0</b>           | <b>0</b>           |

On page 14 of the application, the applicant states, *“This application does not call for any changes to home hemo or PD services at McDowell County Dialysis.”* However, as shown in the table on page 17 and above, the applicant does not indicate that MDC provides any home training and support services. In fact, in Section I.1, page 33, and Exhibit I-1, the applicant states that home training will be provided by Asheville Kidney Center.

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

| County       | Operating Year (OY) 1<br>1/1/18-12/31/18 |          |          | Operating Year (OY) 2<br>1/1/19-12/31/19 |          |          | Percent of Total |               |
|--------------|--|----------|----------|--|----------|----------|------------------|---------------|
|              | IC                                       | HH       | PD       | IC                                       | HH       | PD       | OY1              | OY2           |
| McDowell     | 49                                       | 0        | 0        | 52                                       | 0        | 0        | 96.08%           | 96.30%        |
| Burke        | 1  | 0        | 0        | 1  | 0        | 0        | 1.96%            | 1.85%         |
| Rutherford   | 1  | 0        | 0        | 1  | 0        | 0        | 1.96%            | 1.85%         |
| <b>Total</b> | <b>51</b>                                | <b>0</b> | <b>0</b> | <b>54</b>                                | <b>0</b> | <b>0</b> | <b>100.0%</b>    | <b>100.0%</b> |

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

The applicant adequately identifies the population to be served.

**Analysis of Need**

The applicant proposes to add one dialysis station to the existing MDC for a total of 15 dialysis stations upon completion of this project and Project ID #C-10108-13, pursuant to the facility need methodology.

*Projected Utilization*

In Section C.7, pages 16-17, the applicant provides its methodology for projecting utilization for in-center patients at MDC, as summarized below.

| <b>McDowell Dialysis Center</b>  | <b>In-Center Patients</b>        |
|--|----------------------------------|
| Beginning census of McDowell County in-center patients only, January 1, 2016   | 42                               |
| The census of McDowell County in-center patients is projected forward to December 31, 2016, using the July 2016 SDR five-year Average Annual Change Rate (AACR) for McDowell County (0.056). | $42 \times 1.056 = 44.352$       |
| The 2 patients outside McDowell County are added to reach the total census, as of December 31, 2016  | $44.352 + 2 = 46.352$            |
| The census of McDowell County in-center patients is projected forward one year to December 31, 2017, using the AACR for McDowell County.   | $44.352 \times 1.056 = 46.8357$  |
| The 2 patients outside McDowell County are added to reach the total census, as of December 31, 2017.   | $46.8357 + 2 = 48.8357$          |
| The census of McDowell County in-center patients is projected forward one year to December 31, 2018, using the AACR for McDowell County.   | $46.8357 \times 1.056 = 49.4585$ |
| The 2 patients outside McDowell County are added to reach the total census, as of December 31, 2018. This is the projected ending census for Operating Year 1.                               | $49.4585 + 2 = 51.4585$          |
| The census of McDowell County in-center patients is projected forward one year to December 31, 2019, using the AACR for McDowell County.   | $49.4585 \times 1.056 = 52.2281$ |
| The 2 patients outside McDowell County are added to reach the total census, as of December 31, 2019. This is the projected ending census for Operating Year 2.                               | $52.2281 + 2 = 54.2281$          |

The applicant provides its assumptions for projecting in-center patient utilization for MDC on pages 16-17, as follows:

- Per Table A of the July 2016 SDR, as of December 31, 2015, MDC had 44 in-center patients dialyzing on 13 stations for a station utilization rate of 84.62%. However, if the undeveloped station approved in Project ID #C-10108-13 were added to the inventory at MDC, as proposed and authorized, the utilization rate would be only 78.57% ( $44 / 14 = 3.14 / 4 = .7857$ )
- Of the 44 patients, the applicant states that 42 were from McDowell County and 2 lived outside McDowell County, one in Burke County and one in Rutherford County.
- Operating Year 1 = January 1, 2018 through December 31, 2018.
- Operating Year 2 = January 1, 2019 through December 31, 2019.
- Per Table B of the July 2016 SDR, the McDowell County five-year AACR is 5.6%.



- No growth is projected for the two patients living outside of McDowell County.

On page 17, the applicant states that it averages the beginning and end of year census for each year in the period of growth and rounds down to the nearest whole number to arrive at average number of patients per year.

Based on the methodology and assumptions above, the applicant projects MDC will serve 51 in-center patients by the end of Operating Year 1 for a utilization rate of 85.0%, or 3.4 patients per station ( $51 / 15 = 3.4 / 4.0 = 0.85$ ). 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). The applicant's methodology demonstrates that the proposed addition of dialysis stations to MDC would meet the minimum performance standard requirements in the Rule. However, the applicant does not provide reasonable documentation of the development of both the 14<sup>th</sup> and the 15<sup>th</sup> dialysis stations and the costs associated with that development. The floor plan and financial letter document only 14 total stations, at completion project completion. The discussions regarding development costs found in Criteria (5) and (12) are incorporated herein by reference. Therefore, the projected utilization is not based on reasonable and adequately supported assumptions.

### **Access**

In Section L.1(a), pages 42-43, the applicant states,

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

...

*McDowell County Dialysis helps uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”*

The applicant projects, in Section L.1(b), page 43, that 84.1% of its patients will be Medicare or Medicaid recipients. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

### **Conclusion**

In summary, the applicant adequately identifies the population to be served; adequately demonstrates the need the population projected to be served has for the proposed services based on reasonable and supported utilization projections and assumptions; and

demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. However, the applicant does not demonstrate that the proposed project is the most effective alternative. The discussion regarding alternatives found in Criterion (4) and the discussions regarding costs found in Criteria (5) and (12) are incorporated herein by reference. Therefore, the application is not conforming to this criterion.

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

NA

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

NC

In Section E.1, page 21, the applicant discusses the alternatives considered prior to the submission of this application, summarized as follows:

- 1) Maintain the status quo - the applicant states that this alternative was dismissed given the growth rate at the facility.
- 2) The proposed alternative, add one dialysis station to MDC - the applicant states that this alternative would *"help meet the growing demand for dialysis services at McDowell County Dialysis, as documented in Section B-2 and Section C."*

Section B-2, page 7 of the application, provides the October 1 Review Table based on the July 2016 SDR, which shows that MDC's current utilization could support one additional dialysis stations, based on the facility need methodology. However, this does not take into consideration the one additional station from Project ID #C-10108-13, approved for development in 2013, which has yet to be developed. Section C, pages 16-17, includes the applicant's projected utilization, which shows an in-center patient census that supports one additional station at a utilization rate of 85.0% by the end of the first operating year.

After considering the above alternatives, the applicant states that the second alternative, to add one dialysis station is the more effective alternative as it ensures that the facility will proactively address the issues of growth and access at the facility. However, the applicant does not provide reasonable documentation on the projected development of both the 14<sup>th</sup> and 15<sup>th</sup> dialysis stations and the costs associated with that development. The floor plan

provided by the applicant in support of the proposed renovations in Exhibit K-1(a) shows only 14 total dialysis stations, not 15. This calls into question the proposed construction/renovation costs, the availability of funds and the financial feasibility of the project. Therefore, this project, as proposed, cannot be the most effective alternative. The discussions regarding capital cost, availability of funds and financial feasibility found in Criterion (5) and the discussion regarding construction/renovation costs found in Criterion (12) are incorporated herein by reference.

Furthermore, the application is not conforming to all other statutory and regulatory review criteria, and thus, is not approvable. A project that cannot be approved cannot be an effective alternative. See Criteria (1), (3), (5), (6), (12), (18a) and Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C.2203(b).

In summary, the applicant does not adequately demonstrate that this proposal is the least costly or most effective alternative to meet the need. Therefore, the application is not conforming to this criterion and cannot be approved.

- (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.

NC

The applicant proposes to add one dialysis station to its existing MDC facility for a total of 15 certified dialysis stations upon completion of the proposed project and Project ID #C-10108-13.

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

In Section F.1, page 22, the applicant states that the capital costs for the project will total \$238,998, as summarized below:

|                           |            |
|---------------------------|------------|
| Construction              | \$ 200,000 |
| Machines                  | \$29,700   |
| Other Equipment/Furniture | \$9,298    |
| Total Capital Costs       | \$238,998  |

However, the floor plan supplied by the applicant in Exhibit K-1(a) shows only 14 stations, not the proposed 15 stations. The applicant does not provide a cost estimate by an architect, developer, or other authority for the proposed construction/renovation to document that the cost is for 15 stations, as opposed to 14 stations. Therefore, the applicant does not adequately demonstrate that the floor plan and cost estimate are reasonable.

In Sections F.10 and F.11, pages 24-25, the applicant states that there will be no initial start-up expenses or initial operating expenses because the existing facility is already operational.

### **Availability of Funds**

In Section F.5, page 23, the applicant refers to Exhibit F-5 for the response as to how the project will be financed. In Exhibit F-5, the applicant provides a letter dated September 12, 2016 from the Chief Accounting Officer of the parent company, DaVita Inc., authorizing the project and committing DaVita cash reserves for the development of the project. The letter in Exhibit F-5 gives authorization “*to expand the existing facility by one ESRD dialysis station*”, which does not help to clarify whether the total number of dialysis stations is 14 or 15.

In Section F.7, page 24, in reference to providing the most recent financial report, the applicant states:

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

Exhibit F-7 contains DaVita’s Form 10-K for the fiscal year ended December 31, 2014, not 2015, as stated by the applicant. The 2014 financials were more than 20 months old on the application submission date. However, the Agency has DaVita’s Form 10-K for the year ended December 31, 2015 on file from Project ID #F-11154-16, which indicates that as of December 31, 2015, it had \$1,499,116,000 in cash and cash equivalents, \$18,514,875,000 in total assets and \$5,084,172,000 in net assets (total assets less total liabilities).

Moreover, the applicant does not provide a floor plan or cost estimate that clearly supports the addition of the 15<sup>th</sup> station at MDC.

Therefore, the applicant does not adequately demonstrate the availability of funds for the capital needs of the project; thus, the application is not conforming with this criterion.

### **Financial Feasibility**

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

**Allowable Charges**

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

In Section R, in the Revenue Assumptions, the applicant states that the missed treatment rate is 5% and an average patient number per year is used to calculate its revenues for the first and second operating years of the project. Therefore, the number of in-center patients used in operating year one was 49.5 and the number of in-center patients used in operating year two was 52.5.

- The applicant’s methodology for calculating projected utilization for the beginning of operating year one, January 1, 2018, is 48 in-center patients, as stated in Section C.1, page 14. The applicant projects 51 in-center patients at the end of operating year one. Therefore, the average number of in-center patients for operating year one, rounded down to the nearest whole number, is 49  $(48 + 51) / 2 = 49.5$ ).
- Likewise, the applicant begins operating year two with 51 in-center patients and ends with 54 in-center patients. The average number of in-center patients for operating year two is 52 (rounded down to the nearest whole number).

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

| <b>MDC</b>  | <b>Operating Year 1<br/>CY 2018</b> | <b>Operating Year 2<br/>CY 2019</b> |
|---|-------------------------------------|-------------------------------------|
| Average # of In-Center Patients                                       | 49.5                                | 52.5                                |
| Projected Treatments ((156/Pt) -5%)                                   | 7,336                               | 7,781                               |
| Projected Avg Charge (Gross Patient Revenue / Projected # Treatments) | \$282                               | \$282                               |
| Gross Patient Revenue   | \$2,070,363                         | \$2,197,119                         |
| Deductions from Gross Patient Revenue                                 | \$76,766                            | \$81,420                            |
| Net Patient Revenue   | \$1,993,597                         | \$2,115,699                         |
| Total Expenses  | \$1,931,723                         | \$2,030,855                         |
| <b>Net Income</b>   | <b>\$61,874</b>                     | <b>\$84,844</b>                     |

The applicant projects that revenues will exceed operating expenses in each of the first two operating years of the project. However, the applicant does not adequately demonstrate that the assumptions used in preparation of the pro forma financial statements are reasonable, including projected utilization, cost and charges. The

discussions regarding construction/renovation and number of dialysis stations found in Criterion (12) are incorporated herein by reference.

### **Conclusion**

In summary, the applicant does not adequately demonstrate that sufficient funds will be available for the capital and operating needs of the project. Furthermore, the applicant does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. The discussion regarding construction/renovation found in Criterion (12) is incorporated herein by reference. Therefore, the application is not conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

NC

On page 369, the 2016 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” MDC is located in McDowell County; thus, the service area for this project is McDowell County. Facilities may serve residents of counties not included in their service area.

The applicant proposes to add one dialysis station to its existing MDC facility for a total of 15 certified dialysis stations upon completion of this project and Project ID #C-10108-13.

According to the July 2016 SDR, MDC is the only dialysis facility in McDowell County, with the following utilization:

**McDowell Dialysis Center Facility Data  
December 31, 2015**

| <b>Facility</b>          | <b>Owner</b>                        | <b># of Stations</b> | <b>Utilization</b> |
|--------------------------|-------------------------------------|----------------------|--------------------|
| McDowell Dialysis Center | TRC of North Carolina, LLC (DaVita) | 13                   | 84.62%             |

According to Table B in the July 2016 SDR, there is a deficit of one dialysis stations in McDowell County; therefore, stations cannot be added pursuant to the county need methodology, which requires a minimum deficit of ten stations. However, the applicant states that it is eligible to apply for additional stations based on facility need methodology and the information in the July 2016 SDR. In Section C.1, page 14, the applicant demonstrates that MDC will serve a total of 51 in-center patients on 15 dialysis stations at the end of the first operating year, which is 3.4 patients per station per week ( $51/15 = 3.4$ ). Therefore, based on this information, the facility is expected to serve more than 3.2

patients per station per week at the end of the first operating year as required by 10A NCAC 14C.2203(b).

However, the SDR and the applicant’s methodology does not take into consideration the undeveloped 14<sup>th</sup> station approved in Project ID #C-10108-13 for development and certification by January 1, 2014, which would have lowered the utilization to below 80% ( $44 / 14 = 3.14 / 4 = .7857$ ) if it had been developed, as approved and prior to the submission of this application. In this circumstance, the applicant would not have been eligible to apply for additional stations under the facility need methodology, which requires the facility to have a minimum utilization of 3.2 patients per station or 80%.

The applicant does not adequately demonstrate that the proposed project will not result in the unnecessary duplication of existing or approved dialysis services or facilities in McDowell County. Consequently, the application is not conforming to this criterion.

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

C

In Section H.1, page 29, the applicant projects the number of FTE positions at MDC following completion of the proposed project, as illustrated in the table below.

| <b>MDC</b>                       |                |                   |              |
|----------------------------------|----------------|-------------------|--------------|
| <b>Current and Proposed FTEs</b> |                |                   |              |
| <b>Position</b>                  | <b>Current</b> | <b>Additional</b> | <b>Total</b> |
| RN                               | 2.00           | 0.00              | 2.00         |
| Patient Care Tech                | 5.00           | 1.00              | 6.00         |
| Administrator                    | 1.00           | 1.00              | 2.00         |
| Dietitian                        | 0.50           | 0.00              | 0.50         |
| Social Worker                    | 0.50           | 0.00              | 0.50         |
| Admin Asst                       | 0.50           | 0.00              | 0.50         |
| Bio-Medical Technician           | 0.50           | 0.00              | 0.50         |
| <b>Total FTEs</b>                | <b>10.00</b>   | <b>2.00</b>       | <b>12.00</b> |

Note: The Medical Director is not an employee of the facility and the facility does not provide home training.

In Section I.3, pages 34-35, the applicant states that the Medical Director for MDC, Dr. Blake Pruitt, has indicated his willingness to continue to serve in that capacity. In Exhibit I-3, the applicant provides a letter from Dr. Pruitt, dated August 15, 2016, confirming his support for the additional dialysis station proposed for MDC and his role as Medical Director of the facility. In Section H.3, pages 30-31, the applicant describes its methods for recruiting and hiring staff, including a recruiting partner, a teammate referral program, a competitive salary structure and range of benefits to attract qualified employees. The

applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section I.1, page 33, the applicant lists the providers of the necessary ancillary and support services to be provided at MDC. The applicant discusses coordination with the existing health care system on pages 34-35, stating that over the years it has established relationships with other healthcare providers and social service agencies in McDowell County. In addition, Exhibit I-1 contains a copy of a letter from the Facility Administrator which states that the facility has established relationships with various healthcare providers and that it will continue to provide necessary services through existing agreements with them. A copy of the facility's agreement with Asheville Kidney Center for home training services and a copy of the existing laboratory services agreement is also included in Exhibit I-1. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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



NA

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

NC

Upon completion of this project (add one dialysis station) and Project ID #C-10108-13 (add one dialysis station), MDC will be operating 15 in-center dialysis stations. The floor plan, as provided by the applicant in Exhibit K-1(a), documents only 14 dialysis stations in the facility, not 15. In Section F.1, page 45, the applicant lists the project costs, including \$200,000 for construction/renovations and \$38,998 in miscellaneous costs including dialysis machines and other equipment for a total project cost of \$238,998. Furthermore, the letter documenting funding in Exhibit F-5 documents that the facility will expand by only one station. Operating costs and charges are described by the applicant in Section R of the application. In Section K.1, pages 44-45, the applicant describes its plans for energy-efficiency and water conservation.

Because the applicant's floor plan includes only 14 dialysis stations and the funding letter states expansion of the facility by one station, the applicant does not adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative. The discussions regarding costs, charges and availability of funds found in Criterion (5) are incorporated herein by reference.

Thus, the applicant does not adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is not conforming to this criterion.

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

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

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

C

In Section L.1, page 42, the applicant states,

*“McDowell County Dialysis, by policy, makes dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion or disability.”*

In Section L.7, page 46, the applicant states that 84.1% of the patients who received dialysis services at MDC, had some or all of their services paid for by Medicare and/or Medicaid in the past year. The table below illustrates the historical payment sources for the existing facility during CY2015:

| <b>Payor Type</b>    | <b>Percent of Total Patients</b> |
|----------------------|----------------------------------|
| Medicare             | 22.7%                            |
| Medicaid             | 18.2%                            |
| Commercial Insurance | 6.8%                             |
| Medicare/Commercial  | 22.7%                            |
| Medicare/Medicaid    | 20.5%                            |
| VA                   | 9.1%                             |
| <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.

| Percent of Population |               |               |                               |                        |                              |                                       |
|-----------------------|---------------|---------------|-------------------------------|------------------------|------------------------------|---------------------------------------|
| County                | % 65+         | % Female      | % Racial and Ethnic Minority* | % Persons in Poverty** | % < Age 65 with a Disability | % < Age 65 without Health Insurance** |
| 2014 Estimate         | 2014 Estimate | 2014 Estimate | 2014 Estimate                 | 2010-2014              | 2010-2014                    | 2014 Estimate                         |
| McDowell              | 19%           | 50%           | 12%                           | 18%                    | 18%                          | 18%                                   |
| Statewide             | 15%           | 51%           | 36%                           | 17%                    | 10%                          | 15%                                   |

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

\*Excludes "White alone" who are "not Hispanic or Latino"

\*\*\*"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

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

The *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*<sup>1</sup> provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

| Number and Percent of Dialysis Patients by Age, Race, and Gender 2014 |                    |                          |
|---|--------------------|--------------------------|
|   | # of ESRD Patients | % of Dialysis Population |
| <b>Age</b>  |                    |                          |
| 0-19  | 52                 | 0.3%                     |
| 20-34   | 770                | 4.8%                     |
| 35-44   | 1,547              | 9.7%                     |
| 45-54   | 2,853              | 17.8%                    |
| 55-64   | 4,175              | 26.1%                    |
| 65+   | 6,601              | 41.3%                    |
| <b>Gender</b>   |                    |                          |
| Female  | 7,064              | 44.2%                    |
| Male  | 8,934              | 55.8%                    |
| <b>Race</b>   |                    |                          |
| African-American  | 9,855              | 61.6%                    |
| White   | 5,778              | 36.1%                    |
| Other, inc. not specified   | 365                | 2.3%                     |

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

The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

In Section L.3(d), page 45, the applicant states,

*“McDowell County 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 upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993.”*

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

The application is conforming to this criterion.

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

C

In Section L.1(b), page 43, the applicant provides the projected payor mix for MDC for in-center dialysis patients, as follows:

**MDC**  
**Projected Patient Payor Mix**

| <b>Payor Source</b>  | <b>% of Total Patients</b> | <b>% of In-Center Patients</b> | <b>% of HH Patients</b> | <b>% Of PD Patients</b> |
|----------------------|----------------------------|--------------------------------|-------------------------|-------------------------|
| Medicare             | 22.7%                      | 22.7%                          | 0.0%                    | 0.0%                    |
| Medicaid             | 18.2%                      | 18.2%                          | 0.0%                    | 0.0%                    |
| Commercial Insurance | 6.8%                       | 6.8%                           | 0.0%                    | 0.0%                    |
| Medicare/Commercial  | 22.7%                      | 22.7%                          | 0.0%                    | 0.0%                    |
| Medicare/Medicaid    | 20.5%                      | 20.5%                          | 0.0%                    | 0.0%                    |
| VA                   | 9.1%                       | 9.1%                           | 0.0%                    | 0.0%                    |
| <b>Total</b>         | <b>100.0%</b>              | <b>100.0%</b>                  | <b>0.0%</b>             | <b>0.0%</b>             |

As shown in the table above, the applicant projects that 84.1% of its total dialysis patients will have some or all of their services paid for by Medicare or Medicaid. The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, page 45, the applicant describes the range of means by which a person will have access to the dialysis services at MDC, including referrals from nephrologists with privileges at the facility. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section M.1, page 50, the applicant states that it has offered the facility as a clinical learning site for patient care technicians from McDowell Technical Community College. Exhibit M-2 includes a 2008 student training agreement between McDowell Technical Community College and MDC. The information provided in Section M.1 and Exhibit M-1 is reasonable and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

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

NC

On page 369, the 2016 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” MDC is located in McDowell County; thus, the service area for this facility is McDowell County. Facilities may serve residents of counties not included in their service area.

The applicant proposes to add one dialysis station to its existing MDC facility for a total of 15 certified dialysis stations upon completion of this project and Project ID #C-10108-13.

According to the July 2016 SDR, MDC is the only dialysis facility in McDowell County, with the following utilization:

**McDowell Dialysis Center Facility Data  
December 31, 2015**

| <b>Facility</b>          | <b>Owner</b>                        | <b># of Stations</b> | <b>Utilization</b> |
|--------------------------|-------------------------------------|----------------------|--------------------|
| McDowell Dialysis Center | TRC of North Carolina, LLC (DaVita) | 13                   | 84.62%             |

According to Table B in the July 2016 SDR, there is a deficit of one dialysis stations in McDowell County.

In Section N.1, page 48, the applicant discusses the expected effects of the proposed project on competition, including cost-effectiveness, quality and access, stating,

*“The expansion of McDowell County Dialysis will have no effect on the competition in McDowell 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 expansion of McDowell County 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 other involved in the dialysis process to receive services.”*

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

However, the information provided by the applicant is not reasonable and does not adequately demonstrate that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant does not adequately demonstrate the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant does not adequately demonstrate the availability of funds or the financial feasibility of the project, as proposed. The discussions regarding cost, availability of funds and financial feasibility found in Criteria (5) and (12) are incorporated herein by reference.

The application is not conforming to this criterion.

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

## C

In Section O.3, page 49, the applicant states that Exhibit O-3 contains a list the DaVita-owned/operated facilities located in North Carolina that did not operate in compliance with the Medicare Conditions of Participation during the 18 months prior to the submission of this application (March 1, 2015 through September 15, 2016). Exhibit O-3 lists only four facilities (of the over 70 DaVita dialysis facilities in North Carolina) that were found to be not operating in compliance. Included in the Exhibit are the facilities' summaries of deficiencies, the follow-up survey letters, and the dates on which the facilities were found to be back in compliance. One of the facilities had an immediate jeopardy citation; the others were standard level deficiencies of the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities, 42 CFR Part 494. In Section O.3, page 49, the applicant states that each facility is currently in compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicant adequately

demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NC

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

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

*.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- The applicant is not proposing to establish a new facility. MDC 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.*

-NC- In Section C.1, pages 13-14, and Section C.7, page 16, the applicant demonstrates the need for one additional dialysis stations for a total of 15 stations, projecting 51 in-center patients at the end of the first operating year for a utilization rate of 3.4 patients per station. However, the applicant does not demonstrate that the proposed project is the most effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, and the discussions regarding costs found in Criteria (5) and (12) are incorporated herein by reference.



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

-NC- In Section C.7, pages 16-17, the applicant provides the assumptions and methodology used to project utilization of the facility. However, the applicant does not provide evidence of renovating the facility to support the proposed 15 dialysis stations. Therefore, the assumptions regarding capital costs, funding and financial feasibility are not adequately supported. The discussions regarding costs and financial feasibility found in Criteria (5) and (12), respectively, are incorporated herein by reference.