

## ATTACHMENT – REQUIRED STATE AGENCY FINDINGS

### FINDINGS

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

Decision Date: August 28, 2015  
Findings Date: August 28, 2015

Project Analyst: Tanya S. Rupp  
Assistant Chief: Martha Frisone

Project ID #: B-11037-15  
Facility: South Buncombe County Dialysis  
FID #: 150248  
County: Buncombe  
Applicant: Total Renal Care of North Carolina, LLC  
Project: Relocate the 10-station Swannanoa Dialysis Center to Arden and change the name to South Buncombe County Dialysis

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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 proposes to relocate the existing 10-station Swannanoa Dialysis Center to Arden and change the name to South Buncombe County Dialysis. Mapquest<sup>®</sup> indicates the distance between the two sites is approximately 16.4 miles, or 20 minutes driving time.

#### **Need Determination**

According to the January 2015 Semiannual Dialysis Report (SDR), Table A, Swannanoa Dialysis Center had zero patients and ten stations as of June 30, 2014. The applicant does not propose to add dialysis stations to an existing facility or to establish a new dialysis

facility. Neither the county or facility need methodologies in the 2015 State Medical Facilities Plan (SMFP) are applicable to this review.

### **Policies**

Policy ESRD-2: Relocation of Dialysis Stations, on page 32 of the 2015 SMFP, is applicable to this review. The policy states:

*“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of Need applicants proposing to relocate dialysis stations shall:*

- 1. Demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 2. Demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate the existing 10-station facility within Buncombe County.

### **Conclusion**

The application is consistent with Policy ESRD-2 in the 2015 SMFP and is 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.

C

TRC proposes to relocate the existing 10-station Swannanoa Dialysis Center (SDC) to Arden and change the name to South Buncombe County Dialysis (SBCD). The new site is approximately 16 miles south west of Swannanoa. SDC is currently certified for ten dialysis stations; however, the last four Semi-Annual Dialysis Reports (SDRs) report a station

utilization of zero, with no patients dialyzing at the facility. The proposal does not result in an increase in the number of dialysis stations or facilities in Buncombe County.

**Population to be Served**

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county in which they are located, with the exception of 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, in this application, the service area is Buncombe County. Dialysis facilities may serve residents of counties not included in their service area.

In Section III.7, pages 21 – 23, the applicant projects patient origin during the first two operating years following project completion.

| COUNTY    | OPERATING YEAR 1 | % OF TOTAL PATIENTS | OPERATING YEAR 2 | % OF TOTAL PATIENTS |
|-----------|------------------|---------------------|------------------|---------------------|
| Buncombe  | 31               | 32                  | 93.9%            | 94.1%               |
| Henderson | 2                | 2                   | 6.1%             | 5.9%                |
| Total     | 33               | 34                  | 100.0%           | 100.0%              |

The applicant states the patients who will be served at SBCD will be residents of either Buncombe or Henderson County who currently dialyze at either Asheville Kidney Center or Hendersonville Dialysis Center. Henderson County borders the southern edge of Buncombe County. On pages 21 – 22, the applicant provides the assumptions used to project patient origin. Exhibit 24 contains 32 letters from patients. These letters identify each patient’s residence zip code and where he or she currently receives dialysis. The following table is a summary:

**Number of Patients and Residence ZIP Codes**

| DIALYSIS CENTER                | BUNCOMBE COUNTY ZIP CODES |           |          |          | HENDERSON COUNTY ZIP CODES |          | TOTAL     |
|--------------------------------|---------------------------|-----------|----------|----------|----------------------------|----------|-----------|
|                                | 28704                     | 28803     | 28806    | 28730    | 28732                      | 28759    |           |
| Asheville Kidney Center        | 15                        | 11        | 1        | 0        | 0                          | 0        | 27        |
| Hendersonville Dialysis Center | 1                         | 0         | 0        | 2        | 1                          | 1        | 5         |
| <b>Total</b>                   | <b>16</b>                 | <b>11</b> | <b>1</b> | <b>2</b> | <b>1</b>                   | <b>1</b> | <b>32</b> |

The letters provided in Exhibit 24 support the projected patient origin. Each of the letters states:

*“I am a dialysis patient. I live in zip code ..., which is located in .... I understand that Total Renal Care of North Carolina, LLC, which is the same company that operates [the dialysis facility] where I receive my treatment now, is proposing to start a new dialysis facility in Arden to be known as Total Renal Care of North Carolina, LLC d/b/a South Buncombe County Dialysis.*

*... Having my dialysis treatments at South Buncombe County Dialysis may be closer to my home and more convenient for me. So I would consider transferring to South Buncombe County Dialysis for my dialysis treatments. ... I definitely would consider transferring because it would mean a shorter trip to dialysis that would make getting my treatments easier.”*

The applicant adequately identifies the population it proposes to serve.

**Analysis of Need**

Total Renal Care of North Carolina, LLC, the only provider of dialysis services in Buncombe County, owns Asheville Kidney Center, Swannanoa Dialysis Center, and Weaverville Dialysis. The last four SDRs reported the following utilization for the Buncombe County dialysis facilities:

| NAME OF FACILITY | JULY 2015 SDR* |            |         | JANUARY 2015 SDR |            |         | JULY 2014 SDR |            |         | JANUARY 2014 SDR |            |         |
|------------------|----------------|------------|---------|------------------|------------|---------|---------------|------------|---------|------------------|------------|---------|
|                  | # PTS.         | # STATIONS | % UTIL. | # PTS.           | # STATIONS | % UTIL. | # PTS.        | # STATIONS | % UTIL. | # PTS.           | # STATIONS | % UTIL. |
| Asheville KC     | 181            | 50         | 90.5%   | 188              | 50         | 94.0%   | 177           | 50         | 88.5%   | 176              | 50         | 88.0%   |
| Swannanoa        | 0              | 10         | 0.0%    | 0                | 10         | 0.0%    | 0             | 10         | 0.0%    | 0                | 10         | 0.0%    |
| Weaverville      | 44             | 20         | 55.0%   | 41               | 20         | 51.25%  | 44            | 20         | 55.0%   | 43               | 20         | 53.75%  |

\*The July 2015 was not yet published at the time this application was submitted.

As shown in the table above, utilization at the Asheville Kidney Center and Weaverville Dialysis Center has increased, while utilization at Swannanoa Dialysis Center has remained at zero percent.

In Section III.3, pages 18 – 19, the applicant states the need to relocate the facility to Arden is based on the following:

- To address the fact that SDC has not been utilized in a couple of years; and
- To provide geographic accessibility to in-center dialysis patients living in the southern part of Buncombe County.

In Section III.4, page 20, the applicant states:

*“The Swannanoa Dialysis Center was developed several years ago when the Asheville Kidney Center was located on the west side of Asheville and there was no dialysis facility in McDowell County. At the time the Swannanoa Dialysis Center was developed, the patients living on the east side of Buncombe County and in McDowell County were traveling long distances three times a week for their dialysis treatments. A certificate of need application was submitted to develop a facility in Swannanoa. This facility served a significant purpose until the Asheville Kidney Center was relocated to the east side of Buncombe County and the McDowell Dialysis Center was developed. The Swannanoa Dialysis*

*Center experienced a significant decrease in the patient population as the result of the development of these facilities. The stations are now needed to serve a different patient population in Buncombe County.*

*The facility is being relocated since there are no patients being served at the Swannanoa Dialysis Center and there is a need for the ten stations in South Buncombe County near the Arden and Fletcher communities. A total of 32 in-center patients have signed letters of support for the relocation of the facility....”*

On page 18, the applicant states:

*“This Certificate of Need application is submitted to provide geographic accessibility of in-center hemodialysis to a patient population located in the southern part of Buncombe County. Total Renal Care of North Carolina operates two ESRD facilities in Buncombe County and one in Henderson County. Weaverville Dialysis is located on the north side of Buncombe County, Asheville Kidney Center is located in the central part of Buncombe County, and Hendersonville Dialysis is located in the central part of Henderson County. In doing an analysis of the patients that are served by these three facilities, it was determined that the existing facilities are serving a total of at least thirty-two patients who live in six (6) zip codes in or near Arden, NC which is in the southern part of Buncombe County.*

Buncombe County is mountainous and thus potentially difficult to navigate in inclement weather or in winter. Likewise, Henderson County is mountainous and presents the same travel issues. Dialysis patients must travel to and from the dialysis center three times every week.

The applicant adequately demonstrates the need to relocate the facility to Arden.

#### Projected Utilization

In Section III.7, pages 21 – 23, the applicant provides the following assumptions used to project utilization of the relocated facility, as follows:

- *“It is assumed that sixteen (16) in-center patients dialyzing at Total Renal Care of North Carolina, LLC operated facilities in Buncombe County (15) and Henderson County (1) who live in the 28704 zip code, which is located in Buncombe County, have signed letters indicating they would consider transfer to South Buncombe County Dialysis.*
- *It is assumed that eleven [sic] (11) in-center patients dialyzing at Total Renal Care of North Carolina, LLC operated facilities in Buncombe County who live in the 28803 zip code, which is located in Buncombe County, have signed letters indicating they would consider transfer to South Buncombe County Dialysis.*

- *It is assumed that one (1) in-center patient dialyzing at Total Renal Care of North Carolina, LLC operated facilities in Buncombe County who lives in the 28806 zip code, which is located in Buncombe County, has signed a letter indicating they [sic] would consider transfer to South Buncombe County Dialysis.*
- *It is assumed that two (2) in-center patients dialyzing at a Total Renal Care of North Carolina, LLC operated facility in Henderson County who live in the 28730 zip code, which is located in Buncombe County, have signed a letter indicating that they would consider transfer to South Buncombe County Dialysis.*
- *It is assumed that one (1) in-center patient dialyzing at a Total Renal Care of North Carolina, LLC operated facility in Henderson County who lives in the 28732 zip code, which is located in Henderson County, has signed a letter indicating they [sic] would consider transfer to South Buncombe County Dialysis.*
- *It is assumed that one (1) in-center patient dialyzing at a Total Renal Care of North Carolina, LLC operated facility in Henderson County who lives in the 28759 zip code, which is located in Henderson County, has signed letter indicating they [sic] would consider transfer to South Buncombe County Dialysis.*
- *It is assumed that at least thirty-two (32) in-center patients living in Buncombe County and the northern part of Henderson County will transfer their care from Asheville Kidney Center (27) and Hendersonville Dialysis (5) based on the patients' letters.*
- *It is assumed that the number of patients living in Buncombe County is projected to grow at a rate of 3.9% based on the Buncombe County growth experience over the past five years as indicated in Table B of the January 2015 SDR.”*

Exhibit 24, includes the letters referenced by the applicant.

On page 22, the applicant states:

*“Based on the number of patients who signed letters, it is reasonable to assume that thirty-two (32) of these patients will transfer their care to South Buncombe County Dialysis upon certification of the facility.*

*Based on this assumption, South Buncombe County Dialysis will have at least 32 in-center ESRD patients dialyzing in the facility January 1, 2018, which is*

*projected to be the beginning of the first year of operation. Those 32 patients are projected to transfer from the Asheville Kidney Center and Hendersonville Dialysis. The facility is projected to have 33 in-center patients by the end of operating year one based on the current Average Annual Change Rate for the Past Five Years which is cited in the January 2015 Semiannual Dialysis Report in Table B: ESRD Dialysis Station Need Determination by Planning Area.”*

The applicant also states that it does not project growth for the two patients who are residents of Henderson County who signed letters indicating a willingness to transfer their care to SBCD.

The January 2015 SDR, in Table B: ESRD Dialysis Station Need Determination by Planning Area indicates the Five Year Average Annual Change Rate (AACR) for Buncombe County is 3.9%.

At the end of Operating Year One, the applicant projects that 33 in-center patients will be using the replacement facility, which is a utilization rate of 82.5% [33 patients / 10 stations = 3.3 patients per station;  $3.3 / 4 = 0.825$ ]. At the end of Operating Year 2, the applicant projects that 34 in-center patients will be utilizing the replacement facility [34 / 10 = 3.4;  $3.4 / 4 = 0.85$ ].

In addition, in Exhibit 24, the applicant provides letters of support signed by ten physicians who practice with Mountain Kidney & Hypertension Associates, P.A. and two letters from physicians at Carolina Vascular. These letters state the physicians would refer patients to the facility, and that a dialysis facility located in southern Buncombe County would benefit their patients. Projected utilization is based on reasonable and adequately supported assumptions regarding patient and physician interest in the new location.

### **Access**

In Section IV, pages 33 – 37, the applicant describes how residents of the area, including medically underserved groups, would have access to the proposed dialysis services. On page 33, the applicant states:

*“South Buncombe County Dialysis, by policy, will always make dialysis services available to all residents in its service area without qualifications. We will 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.”*

On page 34, the applicant projects that 85.7% of the patients at the relocated facility will be either Medicaid or Medicare recipients.

The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

### **Conclusion**

The applicant adequately identifies the population it proposes to serve, adequately demonstrates the need the population to be served has for the proposal, and adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is 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.

### C

In Section III.4, page 20, the applicant states utilization at SDC has “*decreased significantly*” since the development of McDowell Dialysis and the relocation of Asheville Kidney Center to the eastern side of Asheville. SDC was developed before Asheville Kidney Center was relocated and before McDowell Dialysis Center was developed. Thereafter, the utilization at SDC decreased, because the patients using SDC stations transferred their care to either Asheville Kidney Center or McDowell Dialysis.

In Section III.6, page 20, the applicant states:

*“The population presently served at Swannanoa Dialysis is zero in-center patients as of June 30, 2014 based on information included in Table A of the January 2015 Semiannual Dialysis Report .... This is a station utilization rate of 0.0%. The transfer of stations from Swannanoa Dialysis will have no effect on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other under-served group and the elderly to obtain needed health care.”*

The applicant demonstrates that the needs of the population presently served (0) will continue to be adequately met following the proposed relocation of the facility to Arden. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

The application is conforming to this criterion.

- (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

In Section III.9, pages 23 – 24, the applicant states maintaining the status quo was the only alternative considered. The applicant states this is not an effective alternative because SDC is not utilized and the patient letters indicate a facility is needed in the southern part of Buncombe County.

After considering that alternative, the applicant states the proposal represented in the application was the most effective alternative.

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria, and thus, the application is approvable. An application that cannot be approved is not an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and is approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC d/b/a South Buncombe County Dialysis shall materially comply with all representations made in the certificate of need application.**
  - 2. Total Renal Care of North Carolina, LLC d/b/a South Buncombe County Dialysis shall relocate the 10-station Swannanoa Dialysis Center to Arden and change the name of the facility.**
  - 3. Total Renal Care of North Carolina, LLC d/b/a South Buncombe County Dialysis shall install plumbing and electrical wiring through the walls for no more than ten dialysis stations which shall include any home hemodialysis training or isolation stations.**
  - 4. Total Renal Care of North Carolina, LLC d/b/a South Buncombe County Dialysis 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 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

In Section VIII.1, page 42, the applicant states the proposed capital cost of the project is \$1,272,525, which includes \$781,000 in construction costs; \$111,380 for RO water treatment equipment, \$158,040 for dialysis machines, \$50,358 for dialysis chairs, TVs, scales, and patient computer systems; and \$171,747 for equipment, furniture, and consultant fees. In Section IX, page 46, the applicant projects that there will be \$154,431 in start-up expenses and \$746,002 in initial operating expenses, for a total working capital of \$900,433. In Section VIII.2, page 43, and Section IX.4, page 47, the applicant states the entire capital and working capital costs of the project will be funded with cash reserves of DaVita Healthcare Partners, Inc., (DaVita) the parent company of Total Renal Care of North Carolina, Inc.

Exhibit 30 contains audited financial statements for DaVita for the years ending December 31, 2014 and December 31, 2013. As of December 31, 2014, DaVita had \$965,241,000 in cash and cash equivalents. Exhibit 29 contains a May 5, 2015 letter from the Vice President of Tax for DaVita which states:

*“I am the Vice President of Tax for DaVita HealthCare Partners, Inc., the parent and 100% owner of Total Renal Care, Inc. I also serve as the Vice President of Tax for Total Renal Care, Inc., which owns 85% of the ownership interests in Total Renal Care of North Carolina, LLC.*

*... I am writing this letter as the Vice President of Tax for DaVita HealthCare Partners to confirm DaVita’s commitment of \$1,272,525, for the capital expenditures associated with this project; a commitment of \$151,431 for its start-up expenses; and a further commitment of \$746,002 in working capital. Note that this working capital commitment is sufficient to cover all of the projected operating expenses for a period of six months of operation of this new facility.*

*DaVita HealthCare Partners has committed cash reserves in the total sum of \$2,172,958 for the capital costs, start-up costs and working capital for this project. As the Vice President of Tax for DaVita HealthCare Partners and Total Renal Care, Inc., I can also confirm that Total Renal Care of North Carolina, LLC will ensure that these funds are made available for the development and operation of this project.”*

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the proposed project.

In Section X.1, page 48, the applicant provides the allowable charges per treatment for each payment source, as illustrated in the table below:

| PAYOR                | CHARGE/TREATMENT |
|----------------------|------------------|
| Medicare             | \$239.43         |
| Medicaid             | \$143.00         |
| Medicare/Medicaid    | \$239.43         |
| Commercial Insurance | \$1,275.00       |
| VA                   | \$193.00         |
| Medicare Commercial  | \$239.43         |

In the *Notes* on page 48, the applicant states that the reimbursement for Medicare patients is 80% of the allowable charge of \$239.02 or \$191.54. Furthermore, the applicant states the Medicare rate is the 2015 bundle reimbursement rate as documented in the Federal Register dated November 6, 2014. The applicant includes additional details about other charges and reimbursement rates on page 48.

In Sections X.2 - X.4, pages 49 - 53, the applicant projects revenues and operating expenses for Southern Buncombe County Dialysis, as illustrated in the table below:

|                      | OPERATING YEAR 1 | OPERATING YEAR 2 |
|----------------------|------------------|------------------|
| Total Net Revenue    | \$1,497,102      | \$1,542,774      |
| Total Operating Cost | \$1,438,690      | \$1,478,267      |
| Net Revenue          | \$58,412         | \$64,507         |

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable and adequately supported. See Section X, pages 50 - 53, for the applicant’s assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates the financial feasibility of the proposal is based upon reasonable projections of the costs of and charges for providing the proposed dialysis services. Therefore, the application is 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.

C

TRC proposes to relocate the existing 10-station SDC to Arden and change the name. The new site is approximately 16 miles south west of Swannanoa. SDC is currently certified for ten dialysis stations; however, the last four SDRs report a station utilization of zero, with no patients dialyzing at the facility. The proposal does not result in an increase in the number of dialysis stations or facilities in Buncombe County.

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county in which they are located, with the exception of 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, in this application, the service area is Buncombe County. Dialysis facilities may serve residents of counties not included in their service area.

Total Renal Care of North Carolina, LLC, the only provider of dialysis services in Buncombe County, owns Asheville Kidney Center, Swannanoa Dialysis Center, and Weaverville Dialysis. The last four SDRs reported the following utilization for the Buncombe County dialysis facilities:

| NAME OF FACILITY | JULY 2015 SDR* |            |         | JANUARY 2015 SDR |            |         | JULY 2014 SDR |            |         | JANUARY 2014 SDR |            |         |
|------------------|----------------|------------|---------|------------------|------------|---------|---------------|------------|---------|------------------|------------|---------|
|                  | # PTS.         | # STATIONS | % UTIL. | # PTS.           | # STATIONS | % UTIL. | # PTS.        | # STATIONS | % UTIL. | # PTS.           | # STATIONS | % UTIL. |
| Asheville KC     | 181            | 50         | 90.5%   | 188              | 50         | 94.0%   | 177           | 50         | 88.5%   | 176              | 50         | 88.0%   |
| Swannanoa        | 0              | 10         | 0.0%    | 0                | 10         | 0.0%    | 0             | 10         | 0.0%    | 0                | 10         | 0.0%    |
| Weaverville      | 44             | 20         | 55.0%   | 41               | 20         | 51.25%  | 44            | 20         | 55.0%   | 43               | 20         | 53.75%  |

\*The July 2015 was not yet published at the time this application was submitted.

As shown in the table above, utilization at the Asheville Kidney Center and Weaverville Dialysis Center has increased, while utilization at Swannanoa Dialysis Center has remained at zero percent.

In Section III.4, page 20, the applicant states:

*“The Swannanoa Dialysis Center was developed several years ago when the Asheville Kidney Center was located on the west side of Asheville and there was no dialysis facility in McDowell County. At the time the Swannanoa Dialysis Center was developed, the patients living on the east side of Buncombe County and in McDowell County were traveling long distances three times a week for their dialysis treatments. A certificate of need application was submitted to develop a facility in Swannanoa. This facility served a significant purpose until the Asheville Kidney Center was relocated to the east side of Buncombe County and the McDowell Dialysis Center was developed. The Swannanoa Dialysis Center experienced a significant decrease in the patient population as the result of the development of these facilities. The stations are now needed to serve a different patient population in Buncombe County.*

*The facility is being relocated since there are no patients being served at the Swannanoa Dialysis Center and there is a need for the ten stations in South Buncombe County near the Arden and Fletcher communities. A total of 32 in-center patients have signed letters of support for the relocation of the facility....”*

Buncombe County is mountainous and thus potentially difficult to navigate in inclement weather or in winter. Likewise, Henderson County is mountainous and presents the same travel issues. Dialysis patients must travel to and from the dialysis center three times every week.

The applicant adequately demonstrates the need to relocate the existing facility to Arden, where the stations would be utilized. Therefore, the applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved dialysis services in Buncombe County. Consequently, the application is 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 VII.1, page 38, the applicant proposes to hire 8.8 full-time equivalent (FTE) positions to staff SBDC during the first two years of operation following project completion. In Section VII.4, page 39, the applicant states it does not anticipate any difficulty in filling any teammate openings that may occur at the facility. The following table shows the projected number of direct care staff for each shift offered in the facility following project completion, as reported by the applicant in Section VII.10, page 40:

|           | Shift Time         | Sun. | Mon. | Tues. | Wed. | Thurs. | Fri. | Sat. |
|-----------|--------------------|------|------|-------|------|--------|------|------|
| Morning   | 6:00 am – 11:00 am | 0    | 3    | 3     | 3    | 3      | 3    | 3    |
| Afternoon | 11:00 am – 4:00 pm | 0    | 3    | 3     | 3    | 3      | 3    | 3    |
| Evening   | 4:00 pm – 9:00 pm  | 0    | 0    | 0     | 0    | 0      | 0    | 0    |

In Section VII, page 40, the applicant states there are several nephrologists in the area with privileges at Mission Hospital who will attend to the patients at the facility.

In Section V.4, page 30, the applicant states that Dr. Brian England will serve as Medical Director of the facility. In Exhibit 24, the applicant provides letters of support from area physicians, and in Exhibit 23, the applicant provides a letter signed by the proposed Medical Director. In Section VII.2, page 38, the applicant states: *“The facility will comply with all staffing requirements as stated in 42 C.F.R. Section 405 .2100.”* The applicant documents the availability of adequate health manpower and management personnel for the provision of dialysis 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 V.1, page 28, the applicant identifies the providers of the necessary ancillary and support services. See also Section V pages 28 - 33. Exhibits 8, 9 and 17 document that the proposed services will be coordinated with the existing health care system. 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 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.

C

In Section XI.2, page 55, the applicant states the proposed site is 360 Airport Road, Arden. The applicant states it will lease the space and upfit 5,600 square feet. Upfit costs are \$139.46 per sq.ft. (\$781,000 / 5,600). In Section XI.6(d), page 58, the applicant states that applicable energy saving features will be incorporated into the construction plans, including “...energy-efficient glass, mechanically operated patient access doors and energy-efficient cooling and heating.” The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will

not unduly increase costs and charges for health services. The discussion of costs and charges found in Criterion (5) is incorporated herein by reference. Therefore, the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

SDC has not served any patients for some time. However, the applicant provides the payor mix for Asheville Kidney Center because the majority of the patients who will use the relocated facility reside in the Asheville area and dialyze at Asheville Kidney Center. In Section VI.1(b), page 34, the applicant reports that 82.18% of its in-center patients had some or all of their services paid for by Medicare or Medicaid, as illustrated in the following table.

**Asheville Kidney Center  
 In-Center Patients Utilization by Payor Source**

| PAYOR                | % UTILIZATION |
|----------------------|---------------|
| Medicare             | 13.79%        |
| Medicaid             | 7.47%         |
| Medicare/Medicaid    | 28.74%        |
| Commercial Insurance | 11.49%        |
| VA                   | 6.32%         |
| Other                | 9.52%         |
| Medicare/Commercial  | 33.33%        |
| TOTAL                | 100.00%       |

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Buncombe and Henderson counties and statewide.

|                  | <b>2010<br/>Total # of Medicaid<br/>Eligibles as % of Total<br/>Population *</b> | <b>2010<br/>Total # of Medicaid<br/>Eligibles Age 21 and older<br/>as % of Total Population *</b> | <b>2008-2009<br/>% Uninsured<br/>(Estimate by Cecil G.<br/>Sheps Center) *</b> |
|------------------|--|---|--|
| Buncombe County  | 36%  | 16.1%   | 18.3%  |
| Henderson County | 14%  | 5.4%  | 19.7%  |
| Statewide        | 16.5%  | 6.7%  | 19.7%  |

\*More current data, particularly with regard to the estimated uninsured percentages, was not available.

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).<sup>1</sup>

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. But it does not include information on the number of elderly, handicapped, minorities or women utilizing health services.

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report* provides prevalence data on North Carolina dialysis patients by age, race and gender on page 59, summarized as follows:

---

<sup>1</sup> <http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>



| <b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2014</b> |                           |                                 |
|--|---------------------------|---------------------------------|
|  | <b># of ESRD Patients</b> | <b>% of Dialysis Population</b> |
| <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%                            |

Source: Southeastern Kidney Council Network 6 Inc. 2014 Annual Report.<sup>2</sup>

The applicant demonstrates that the elderly and medically underserved have adequate access to the existing services at Asheville Kidney Center. 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

In Section VI.1(f), page 36, the applicant states:

*“South Buncombe 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.”*

<sup>2</sup><http://www.esrdnetwork6.org/utis/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

In Section VI.6(a), page 37, 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 VI.1(a), page 33, the applicant states:

*“South Buncombe County Dialysis, by policy, will always make dialysis services available to all residents in its service area without qualifications. We will 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.*

...

*South Buncombe County Dialysis will not require payment upon admission to its services; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served [sic] persons. South Buncombe County Dialysis will work with patients who need transportation, when necessary.”*

In Section VI.1(c), page 34, the applicant projects that 85.7% of its in-center patients will have some or all of their services paid for by Medicare or Medicaid, as illustrated in the following table.

**South Buncombe County Dialysis  
 In-Center Patients Utilization by Payor Source**

| PAYOR SOURCE         | PERCENT UTILIZATION<br>BY PAYOR SOURCE |
|----------------------|--|
| Medicare             | 9.52%                                  |
| Medicaid             | 33.33%                                 |
| Medicare/Medicaid    | 9.52%                                  |
| Commercial Insurance | 4.76%                                  |
| Other                | 9.52%                                  |
| Medicare/Commercial  | 33.33%                                 |
| <b>TOTAL</b>         | <b>100.00%</b>                         |

The applicant demonstrates that medically underserved populations would 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 VI.5, pages 36, the applicant describes the range of means by which patients will have access to the proposed dialysis services. The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity with 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 V.3(c), page 30, the applicant states “*Local nursing schools and community colleges will be contacted during the construction phase of the facility to explore possible clinical training rotations at South Buncombe County Dialysis.*” Exhibit 22 contains a copy of a letter addressed to Asheville-Buncombe Community College offering the proposed facility as a clinical rotation site for nursing students when the facility is operational. The application is conforming to this criterion.

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

C

TRC proposes to relocate the existing 10-station SDC to Arden and change the name. The new site is approximately 16 miles south west of Swannanoa. SDC is currently certified for ten dialysis stations; however, the last four SDRs report a station utilization of zero, with no patients dialyzing at the facility. The proposal does not result in an increase in the number of dialysis stations or facilities in Buncombe County.

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county in which they are located, with the exception of 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, in this application, the service area is Buncombe County. Dialysis facilities may serve residents of counties not included in their service area.

Total Renal Care of North Carolina, LLC, the only provider of dialysis services in Buncombe County, owns Asheville Kidney Center, Swannanoa Dialysis Center, and Weaverville Dialysis. The last four SDRs reported the following utilization for the Buncombe County dialysis facilities:

| NAME OF FACILITY | JULY 2015 SDR* |            |         | JANUARY 2015 SDR |            |         | JULY 2014 SDR |            |         | JANUARY 2014 SDR |            |         |
|------------------|----------------|------------|---------|------------------|------------|---------|---------------|------------|---------|------------------|------------|---------|
|                  | # PTS.         | # STATIONS | % UTIL. | # PTS.           | # STATIONS | % UTIL. | # PTS.        | # STATIONS | % UTIL. | # PTS.           | # STATIONS | % UTIL. |
| Asheville KC     | 181            | 50         | 90.5%   | 188              | 50         | 94.0%   | 177           | 50         | 88.5%   | 176              | 50         | 88.0%   |
| Swannanoa        | 0              | 10         | 0.0%    | 0                | 10         | 0.0%    | 0             | 10         | 0.0%    | 0                | 10         | 0.0%    |
| Weaverville      | 44             | 20         | 55.0%   | 41               | 20         | 51.25%  | 44            | 20         | 55.0%   | 43               | 20         | 53.75%  |

\*The July 2015 was not yet published at the time this application was submitted.

As shown in the table above, utilization at the Asheville Kidney Center and Weaverville Dialysis Center has increased, while utilization at Swannanoa Dialysis Center has remained at zero percent.

In Section III.4, page 20, the applicant states:

*“The Swannanoa Dialysis Center was developed several years ago when the Asheville Kidney Center was located on the west side of Asheville and there was no dialysis facility in McDowell County. At the time the Swannanoa Dialysis Center was developed, the patients living on the east side of Buncombe County and in McDowell County were traveling long distances three times a week for their dialysis treatments. A certificate of need application was submitted to develop a facility in Swannanoa. This facility served a significant purpose until the Asheville Kidney Center was relocated to the east side of Buncombe County and the McDowell Dialysis Center was developed. The Swannanoa Dialysis Center experienced a significant decrease in the patient population as the result of the development of these facilities. The stations are now needed to serve a different patient population in Buncombe County.*

*The facility is being relocated since there are no patients being served at the Swannanoa Dialysis Center and there is a need for the ten stations in South Buncombe County near the Arden and Fletcher communities. A total of 32 in-center patients have signed letters of support for the relocation of the facility....”*

In Section V.7, page 31, the applicant 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 proposed South Buncombe County Dialysis will not have an adverse effect on competition since the patients already being served by Total Renal Care of North Carolina will be transferring their care from one TRC facility to another TRC facility, which will be more convenient for the patients who have indicated this in the letters they signed. There are no other dialysis facilities in the proposed service area; therefore, there can be no effect on the competition.”*

The information in the application is reasonable and credible and adequately demonstrates that any enhanced competition would have 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 adequately demonstrates 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 adequately demonstrates that it will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- ◆ The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

The application is 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 I.13 and referenced exhibits, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. 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.

C

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

**10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT**

- (a) *An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:*
- (1) *Utilization rates;*  
-C- In Section II.1, page 11, Section III.6, page 20, and Exhibit 7, the applicant states the utilization rate at SDC was zero as of June 30, 2014. However, the utilization rate at Asheville Kidney Center was 94% as of June 30, 2014.
- (2) *Mortality rates;*  
-C- In Section IV.2, pages 25 - 26, the applicant states the mortality rates were zero for SDC. However, the mortality rates were 16.34%, 15.11% and 13.41% in 2012, 2013 and 2014, respectively, for Asheville Kidney Center.
- (3) *The number of patients that are home trained and the number of patients on home dialysis;*  
-C- Since SDC is not operational, there are no home trained patients.
- (4) *The number of transplants performed or referred;*  
-C- SDC had no patients and therefore no referrals. However, in Section IV.4, page 26, the applicant states Asheville Kidney Center referred 37 patients for transplant evaluation in 2014. The applicant states two transplants were actually performed in 2014.
- (5) *The number of patients currently on the transplant waiting list;*  
-C- SDC had no patients and therefore no wait list. However, in Section IV.5, page 26, the applicant states Asheville Kidney Center has 9 patients currently on the transplant waiting list.

- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- SDC had no patients and therefore no hospital admissions. However, in Section IV.6, page 27, the applicant states that Asheville Dialysis Center had 314 total hospital admissions in CY 2014, 59 of which were dialysis related (18.8%) and 255 of which were non-dialysis related (81.2%).
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
- C- SDC had no patients and therefore no patients with infectious diseases in 2014. However, in Section IV.7, page 27, the applicant states that, as of December 31, 2014, Asheville Kidney Center reported four patients with AIDS and seven patients with Hepatitis.
- (b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*
- (1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*
- C- In Exhibit 8, the applicant provides a May 6, 2015 letter from Mission Hospital that specifies the relationship with SBCD and describes the services that the hospital will provide to patients of the dialysis facility.
- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) *composition of the assessment/evaluation team at the transplant center,*
- (C) *method for periodic re-evaluation,*
- (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
- (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- C- In Exhibit 9, the applicant provides a May 5, 2015 letter from Carolinas Healthcare System that indicates the hospital is willing to sign an agreement with SBCD, including the items (A) through (E) listed above.

- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*  
-C- In Section XI.6(e), and Exhibit 12, the applicant provides documentation that power and water will be available at the proposed site for SBCD.
- (4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*  
-C- In Exhibit 10, the applicant provides a copy of the policies and procedures for back-up electrical service in the event of a power outage for SBCD.
- (5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*  
-C- In Section XI, and in Exhibits 11, 12, and 13, the applicant documents that the primary site is available for the applicant to lease to provide dialysis services.
- (6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*  
-C- In Section XI.6(g), page 59, the applicant states, “*The proposed facility will operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment and other relevant health safety requirements.*” Additional detail is provided on pages 59 – 60.
- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*  
-C- In Section III.7, pages 21 - 23, the applicant provides the methodology and assumptions used to project patient origin for the proposed facility. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.
- (8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*  
-C- In Section III.8, page 23, and Exhibit 21, the applicant documents that 100% of the anticipated patient population resides within 30 miles of SBCD.
- (9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*



- C- In Section II.1, page 13, the applicant states, “*Total Renal Care of North Carolina d/b/a South Buncombe County Dialysis will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*”

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

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

-NA- The applicant proposes to relocate an existing facility.

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

-NA- The applicant does not propose to increase the number of stations.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section III, pages 18 - 23. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

#### **10A NCAC 14C .2204 SCOPE OF SERVICES**

*To be approved, the applicant must demonstrate that the following services will be available:*

- (1) *diagnostic and evaluation services;*

-C- In Section V.1, page 28, the applicant states Mission Hospital will provide diagnostic and evaluation services.

- (2) *maintenance dialysis;*

-C- In Section V.1, page 28, the applicant states patients will receive maintenance dialysis services at the facility.

- (3) *accessible self-care training;*

- C- In Section III, pages 26, the applicant states Asheville Kidney Center will train those patients who are candidates for home training.
  
- (4) *accessible follow-up program for support of patients dialyzing at home;*
- C- In Section III, page 26, and Section V.2, page 29, the applicant states Asheville Kidney Center provides services for those patients who are home trained.
  
- (5) *x-ray services;*
- C- In Section V.1, page 28, the applicant states x-ray services will be provided by Mission Hospital.
  
- (6) *laboratory services;*
- C- In Section V.1, pages 28 - 29, the applicant states laboratory services will be provided by Mission Hospital.
  
- (7) *blood bank services;*
- C- In Section V.1, page 28, the applicant states blood bank services will be provided by Mission Hospital.
  
- (8) *emergency care;*
- C- In Section V.1, page 28, the applicant states emergency care services will be provided by Mission Hospital.
  
- (9) *acute dialysis in an acute care setting;*
- C- In Section V.1, page 28, the applicant states acute dialysis services will be provided by Mission Hospital.
  
- (10) *vascular surgery for dialysis treatment patients;*
- C- In Section V.1, page 28, the applicant states vascular surgery services will be provided by Mission Hospital.
  
- (11) *transplantation services;*
- C- In Section V.1, page 28, the applicant states transplantation services will be provided by Carolinas Medical Center. See Exhibit 9 for copies of the agreement.
  
- (12) *vocational rehabilitation counseling and services; and*
- C- In Section V.1, page 28, the applicant states vocational rehabilitation counseling and services will be provided by “*Vocational Rehabilitation.*”
  
- (13) *transportation.*
- C- In Section V.1, page 28, the applicant states transportation services will be provided by Mountain Mobility Administration.

**10A NCAC 14C .2205 STAFFING AND STAFF TRAINING**

- (a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.*
- C- In Section VII.1, page 38, the applicant states the facility will comply with all staffing requirements as stated in 42 C.F.R. Section 494 (formerly 405.2100). The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.
  
- (b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
- C- In Exhibit 20 the applicant provides a copy of the applicant's training program outline for dialysis nurses and technicians.