

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 18, 2014  
PROJECT ANALYST: Bernetta Thorne-Williams  
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: B-10274-14/ Total Renal Care of North Carolina, LLC  
d/b/a Hendersonville Dialysis Center/ Relocate the  
existing facility and add five dialysis stations for a total of  
24 certified dialysis stations upon project completion of  
the proposed / Henderson County

### 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 d/b/a Hendersonville Dialysis Center proposes to add five dialysis stations for a total of 24 certified dialysis stations, and to relocate the existing facility within Henderson County, upon completion of the proposed project. The applicant proposes to relocate the existing facility to 146 Sugarloaf Road in Hendersonville, which the applicant reports is 3.7 miles from its current location at 500 Beverly Hanks Center, in Hendersonville.

According to the January 2014 Semiannual Dialysis Report (SDR), the county need methodology shows a surplus of one dialysis station in Henderson County. However, the applicant is not applying for the additional stations based on the county need methodology. The applicant is eligible to apply for additional stations in its existing facility based on the application of the facility need methodology because the utilization rate reported for Hendersonville Dialysis

Center in the January 2014 SDR is 4.0 patients per station. This utilization rate was calculated based on 80 in-center dialysis patients and 20 certified dialysis stations (80 patients / 20 stations = 4.0 patients per station).

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/13		100.0%
Certified Stations		20
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>20</b>
In-Center Patients as of 6/30/13 (SDR2)		80
In-Center Patients as of 12/31/12 (SDR1)		79
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	1
	Multiply the difference by 2 for the projected net in-center change	2
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/12	0.0243
(ii)	Divide the result of step (i) by 12	0.0021
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/13 until 12/31/13)	0.0127
(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	81.0127
(v)	Divide the result of step (iv) by 3.2 patients per station	24.3165
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations] to determine the number of stations needed	<b>5</b>

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

There are three policies in the 2014 State Medical Facilities Plan (SMFP) that are applicable to this review; Policy ESRD-2: Relocation of Dialysis Stations, Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities:

Policy ESRD-2: Relocation of Dialysis Stations 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 to contiguous counties shall:*

- (A) 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*
- (B) 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 19 stations dialysis facility within Henderson County. The applicant reports in supplemental information that the proposed relocation of the entire facility is based on the age of the existing facility and the lack of ability to expand the existing facility to meet the growing needs of dialysis patients within Henderson County. Therefore, the application is consistent with Policy ESRD-2.

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 II.3, pages 14-15, the applicant discusses the quality of services provided at DaVita HealthCare Partners, Inc. owned and operated ESRD facilities. The applicant states that its success in providing quality services stems from a comprehensive Quality Management Program that includes the following components:

- *“Quality Improvement Methodology – utilizing outcome-driven, patient centered management programs to measure, monitor and manage outcomes.*
- *Computerized Information System – integrating clinical and laboratory information for comprehensive outcomes tracking and reporting.*
- *Staff and Patient Education Program – ensuring continuous updates and training to ensure high quality patient care.*
- *Quality Assessment Audit Program – systematically utilizing a comprehensive detailed assessment tool to assure the highest quality standards in every facility.*
- *Quality Management Team – experienced clinical facilitators to implement and maintain ongoing quality improvement programs.*
- *Quality Biomedical Team – experienced specialists in all aspects of Biomedical requirements (i.e., water treatment, reuse, disinfection and machine maintenance).”*

The applicant further states on page 15, that the company’s goal is to have each facility serve as a quality improvement laboratory where successful outcomes can be disseminated throughout DaVita. Exhibit 22 contains DaVita’s Health and Safety Policy & Procedure Manual which includes a section on General Health and Safety Policies. The Health and Safety Policies state, in part:

*“The Health and Safety Policy & Procedure Manual is designed to ensure compliance and provide policy and procedure for teammate health and safety issues. Using this manual, each DaVita facility will meet Federal regulations as they relate to Risk and Occupational Safety Health and Administration (OSHA), support the corporate philosophy of consistent practice and operations of facilities within the company ...”*

The applicant adequately demonstrates that the proposal will promote safety and quality care at Hendersonville Dialysis Center.

### **Promote Equitable Access**

In Section VI.1, pages 27-28, the applicant states that Hendersonville Dialysis Center has and will continue to provide services to all residents of the service area without regard to race, sex, age, handicap, ethnic or socioeconomic groups in need of dialysis service regardless of their ability to pay. The applicant further states on page 27 that 85% of its patients had some or all of their services paid for by Medicare or Medicaid.

The applicant adequately demonstrates that the proposal will promote equitable access.

### **Maximize Healthcare Value**

In Section III.9, pages 19-20, the applicant states that Hendersonville Dialysis Center will maximize healthcare value in several ways which include utilization of a centralized purchasing department to negotiate national contracts with numerous vendors in order to secure the best product available at the best price; utilization of the reuse process that contains costs and the amount of dialyzer waste generated by the facility; the use of an electronic patient charting system that reduces the need for paper in the facility; preventative maintenance on the dialysis machines on a monthly, quarterly and semi-annual schedule to reduce the need for repairs of the dialysis equipment; and inventory control plan that ensures enough supplies are available without having an inordinate amount of supplies on hand.

The applicant adequately demonstrates that the proposal will maximize healthcare value.

The applicant adequately demonstrates the proposal will incorporate the basic principles of Policy GEN-3.

Policy GEN-4 states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”*

The applicant projects that the total capital cost for the proposed project will be \$2,120,257 which includes a construction cost of \$1,213,000 for the upfit of the new building. In Section IX.6(d), page 50, the applicant states that the facility will be constructed with energy-efficient glass, cooling and heating system and mechanically operated patient access doors. On page 51, the applicant states how the proposed facility will conserve water and comply with 42 C.F.R. Section 405 .2100.

The applicant adequately demonstrates that the proposed relocated facility will be designed and operated to assure improved energy efficiency and water conservation.

In summary, the applicant is consistent with Policy ESRD-2, Policy GEN-3, Policy GEN-4 and with the facility need determination in the 2014 SMFP and is therefore 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

The applicant, Total Renal Care of North Carolina, LLC d/b/a Hendersonville Dialysis Center proposes to add five dialysis stations for a total of 24 certified dialysis stations and to relocate the existing facility, upon project completion.

Population to be Served

In Section IV.1, page 21, the applicant identifies the population it served, as of June 30, 2013, as illustrated in the table below.

<b>Hendersonville Dialysis Center Current Patient Origin</b>	
<b>County</b>	<b>In-Center Patients</b>
Henderson	59
Transylvania	19
Polk	2
<b>TOTAL</b>	<b>80</b>

In Section III.7, page 18, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the table below:

**Projected Dialysis Patient Origin**

COUNTY	Operating Year 1 2016	Operating Year 2 2017	County Patients as a Percent of Total	
	In-Center Patients	In Center Patients	Year 1	Year 2
Henderson	59	59	73.8%	73.8%
Transylvania	19	19	23.8%	23.8%
Nash	2	2	2.4%	2.4%
TOTAL	80	80	100.0%	100.0%

As illustrated in the table above, the applicant does not project a change in its patient population for OY 1 or OY 2. In Section III, pages 18-19, the applicant provides the following data to support the above projected patient origin:

- Hendersonville Dialysis Center had 80 in-center patients as of 6/30/2013.
- The facility is eligible for a five-station expansion based on the facility need methodology.
- Henderson County, the location of the facility, had an average annual change rate of -0.11% over the past five years.
- No projected increase in the number of patients being served by Hendersonville Dialysis.
- 59 of the 80 patients being served by the Hendersonville Dialysis Center lived in Henderson County.
- 21 of those patients receiving in-center services at Hendersonville Dialysis Center lived in two other counties.

The applicant adequately identified the population it proposes to serve.

**Need Analysis**

In Section III, page 18, the applicant indicates the application for a five-station expansion of the existing ESRD is being filed pursuant to the Facility Need Methodology. The applicant utilizes data from the January 2014 SDR and proposes to add five dialysis stations to Hendersonville Dialysis Center for a total of 24 stations upon completion of this project.

According to the January SDR, the county need methodology shows a surplus of one dialysis station in Henderson County. However, the applicant is not applying for the additional stations based on the county need methodology. The applicant is eligible to apply for additional stations in its existing facility based

on the application of the facility need methodology because the utilization rate reported for Hendersonville Dialysis Center in the January 2014 SDR is 4.0 patients per station. This utilization rate was calculated based on 80 in-center dialysis patients and 20 certified dialysis stations (80 patients / 20 stations = 4.0 patients per station).

In Section III.7, page 18, the applicant provides the following assumptions regarding in-center patient utilization for the proposed project:

*“The Hendersonville Dialysis Center had 80 in-center patients as of June 30 2013 based on information included on Page [sic] 4 of Table A of the January 2014 Semiannual Dialysis Report (SDR). This is a station utilization rate of 100% based on the 20 certified stations in the facility. Of the 80 in-center patients cited in the SDR, 59 of those patients lived in Henderson County, 19 patients lived in Transylvania County and two patients lived in Polk County. ...*

*The January 2014 SDR indicates on page 2 of Table B that Henderson County has experienced an average annual change rate of -.011% for the past five years.*

*Since the five year annual change rate is a negative percentage, the projections for operating years one and two are based on 80 in-center patients with no growth indicated. We have taken the 80 in-center patients and divided by 3.2 patients per station which equals a need for 25 stations (80 / 3.2 = 25). We are projecting that the facility will serve 80 in-center patients at the end of operating years one and two.”*

The applicant reports in supplemental information to making an egregious mistake in stating in its methodology and assumptions that Hendersonville Dialysis Center currently had 20 certified dialysis stations and with the addition of the five proposed dialysis stations, the facility would operate with a total of 25 stations upon project completion. Per Project I.D. # B-10036-12, Total Renal Care of North Carolina, LLC d/b/a Brevard Dialysis Center, one station was relocated from Hendersonville Dialysis Center to Brevard Dialysis Center. The relocation of the one station from Hendersonville Dialysis Center left the facility with 19 certified dialysis stations. Therefore, the applicant should have projected to serve 80 in-center patients dialyzing on 24 stations by the end of operating years 1 and 2 for a utilization rate of 83% or 3.3 patients per station [ $80 / 24 = 3.33 / 4.0 = 0.83$  or 83%]. In Section VII.10, page 33, the applicant indicates that two shifts will operate, a total of 10 hours a day, with 5 FTEs per shift, six days per week. This meets the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and supported assumptions regarding continued growth in the proposed service area.

**Access to Services**

In Section VI.1(a), page 27, the applicant states:

*“Hendersonville Dialysis Center, 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 patients without regard to race, sex, age, handicap, or other ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.*

...

*Hendersonville Dialysis Center does 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 persons. Hendersonville Dialysis Center works with patients who need transportation, when necessary.”*

The applicant projects that 85% of its patients will have all or part of their services covered by Medicare and or Medicaid, and 4.1% will be covered by VA. The applicant adequately demonstrates 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.

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the proposed project and the extent to which all residents of the area are likely to have access to the services proposed. 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

The applicant proposes to relocate the existing facility from its current location at 500 Beverly Hanks Center in Hendersonville to 146 Sugarloaf Road in

Hendersonville. The applicant reports that the proposed new site is approximately 3.7 miles from the current facility. The applicant further states in supplemental information that the need to relocate the existing facility stems from the facility being operated at its current location since the 1990s. The applicant reports that the parking lot floods during heavy rain and that the facility lacks the space to continue to expand to meet the consistent need of the ESRD population in Henderson County.

The applicant states the following in supplemental information:

*“The primary site ... is located 3.7 miles from the current location of the Hendersonville Center. The current location is in a congested area of downtown Hendersonville. The proposed location is near I-26, which will offer better access to the facility by the patients. Most of the patients will not be affected by the relocation of the facility since they are transported to and from their treatment by the county transportation agency.”*

The applicant adequately demonstrates that the needs of the population currently served will be met by the proposed relocation of Hendersonville Dialysis Center, including those patients that are low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups.

- (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.

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In Section III.9, pages 19-20, the applicant discusses the two alternatives considered by Hendersonville Dialysis Center, which include:

- 1) Maintain the Status Quo – the applicant concluded that, to do nothing would not be in the best interest of the patients opting to have their dialysis care at Hendersonville Dialysis Center since the facility is currently operating at 100% utilization since the relocation of one state to Brevard Dialysis Center.
- 2) Adding five stations – the applicant concluded that the proposal of five additional dialysis stations and the relocation of the facility, as proposed in the application, was its best alternative. Thus, the applicant concluded that the project, as proposed, was its least costly and most effective alternative

The applicant adequately demonstrates the need for five additional stations based on the stability of the ESRD patient population in Henderson County and the

facility's projected utilization. The applicant also adequately demonstrates the need to relocate the existing ESRD facility based on the age of the facility and the lack of space to further expand the facility. See Criterion (3) for discussion on need which is incorporated hereby as if fully set forth herein. The application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable.

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

1. **Total Renal Care of North Carolina, LLC d/b/a Hendersonville Dialysis Center shall materially comply with all representations made in the certificate of need application.**
  2. **Total Renal Care of North Carolina, LLC d/b/a Hendersonville Dialysis Center shall be certified for no more than five additional stations for a total of 24 certified stations, which shall include any home hemodialysis training or isolation stations, upon project completion.**
  3. **Total Renal Care of North Carolina, LLC d/b/a Hendersonville Dialysis shall install plumbing and electrical wiring through the walls to accommodate the relocation of 19 existing dialysis stations and the addition of five stations for a total of no more than 24 dialysis stations, which shall include any home hemodialysis training or isolation stations.**
  4. **Total Renal Care of North Carolina, LLC d/b/a Hendersonville Dialysis Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the 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, page 35 and supplemental information, the applicant projects the total capital cost for the proposed project is estimated to be \$2,120,257. The estimated capital cost includes the following:

Construction Contract	\$1,213,000
Dialysis Machines	\$ 316,080
Water Treatment Equip.	\$ 95,000

Equipment/Furniture	\$ 307,042
Architect/Engineering	\$ 100,000
Dialysis Chairs	\$ 27,810
Televisions	\$ 43,500
Chair side Computer Terminals	<u>\$ 17,824</u>
Total	\$ 2,120,257

On page 40, the applicant projects no initial start-up costs or initial operating expenses. The applicant states on page 37, that the capital costs for the proposed project will be funded by cash reserves from DaVita Inc., the parent company to DVA Healthcare Renal Care, Inc.

In Exhibit 17, the applicant provides a letter dated March 3, 2014 from the Chief Accounting Officer of DaVita Healthcare Partners Inc. which states, in part:

*“I am the Chief Accounting Officer of DaVita Healthcare Partners Inc., the parent and 100% owner of Total Renal Care, Inc. I also serve as the Chief Accounting Officer of Total Renal Care, Inc., which owns 85% of the ownership interests in Total Renal Care of North Carolina, LLC.*

*We are submitting a Certificate of Need application to relocate and expand our Hendersonville Dialysis Center by five ESRD dialysis stations. The project calls for a capital expenditure of \$2,120,257. This letter will confirm that DaVita HealthCare Partners Inc. has committed case reserves in the total sum of \$2,120,257, for the project [sic] capital expenditure. DaVita HealthCare Partners Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to Total Renal Care of North Carolina.*

*...”*

In Exhibit 18 the applicant provides the audited financial statements for DaVita Healthcare Partners Inc. for the fiscal years ended December 31, 2013 and 2012. As of December 31, 2013, DaVita had \$946,249,000 in cash and cash equivalents, \$17,098,877,000 in total assets and \$5,302,841,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the project.

In Section X.1, page 41, the applicant provides the allowable charges per treatment for each payment source for Hendersonville Dialysis Center, as illustrated in the table below:

Payor	Allowable Charge Per In-center Treatment
Medicare	\$240.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,175.00
VA	\$193.00
Medicare/Commercial	\$240.00

In Sections X.2-X.4, pages 42-45, the applicant projects revenues and operating expenses for Hendersonville Dialysis Center, as illustrated in the table below:

	Operating Year 1	Operating Year 2
Total Net Revenue	\$3,701,036	\$3,701,036
Total Operating Costs	\$3,057,333	\$3,075,465
<b>Net Profit</b>	<b>\$643,703</b>	<b>\$624,571</b>

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, credible and supported. See Section X, pages 41-46, for the applicant's assumptions.

The applicant proposes to relocate the existing ESRD facility to one of two proposed sites. The site will be owned by Hill/Gray Seven, LLC and leased for no less than 10 years to Total Renal Care of North Carolina, LLC d/b/a Hendersonville Dialysis Center. The primary site under consideration is projected to cost \$750,000 and is located on 2.3 acres at 146 Sugarloaf Road in Hendersonville (PIN: 9579567956). This site is not currently zoned for dialysis facility use and would require a special permit. See Exhibit 24 for documentation on the availability of the land and a letter dated February 27, 2014 from the Planning Director of the City of Hendersonville concerning the request for a special use permit for the property located at 146 Sugarloaf Road. Exhibit 24 also contains a letter dated February 24, 2014 from the Utilities Director for the City of Hendersonville concerning water and sewer service and a letter dated February 24, 2014 from Duke Energy concerning electric availability. The secondary site under considered is located on 2.5 acres with a cost of \$1,124,000 and is located at 6034 Asheville Highway in Fletcher (PIN: 9652401419, 9652403528, 9652402383, 9652404478, and 9652406558). This property is currently zoned for medical offices and dialysis center use. See Exhibit 26 for documentation on the availability of the land and a letter dated February 24 from the Director of Henderson County Code Enforcement Services stating the land is zoned for commercial use. See Exhibit 26 also contains a letter dated February 24, 2014 from the Utilities Director for the City of Hendersonville concerning water and sewer service and a letter dated February 24, 2014 from Duke Energy concerning electric availability.

In Section VIII, page 36 and supplemental information, the applicant states that the total construction cost for the proposed project is \$1,213,000. Throughout the application, the applicant was inconsistent with whether the facility would have 24 certified dialysis stations (including one isolation station) or 25 certified stations (including one isolation station). The applicant clarified this information in supplemental information by stating the applicant made a mistake in stating the Hendersonville Dialysis Center currently had 20 certified dialysis stations and with the addition of the five proposed dialysis stations, the facility would operate with a total of 25 stations upon project completion. Per Project I.D. # B-10036-12, Total Renal Care of North Carolina, LLC d/b/a Brevard Dialysis Center, one station was relocated from Hendersonville Dialysis Center to Brevard Dialysis Center. The relocation of the one station from Hendersonville Dialysis Center left the facility with 19 certified dialysis stations. Therefore, the applicant proposes to operate 24 stations by the end of operating years 1 and 2.

The applicant references Exhibit 1, of the application for a copy of its Medicare Certification letter, however, Exhibit 1 is empty. The applicant provides a floor plan in Exhibit 20, which depicts 19 existing stations (one of which is an isolation station), with space for five additional certified ESRD stations, as proposed in this application, for a total of 24 certified stations, upon project completion.

The applicant adequately demonstrated that the financial feasibility of the proposal is based on reasonable and supported projections regarding revenues and operating expenses. 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

Total Renal Care of North Carolina, LLC d/b/a Hendersonville Dialysis Center proposes to add five dialysis stations for a total of 24 certified dialysis stations and to relocate the existing facility upon project completion. Hendersonville Dialysis Center served 80 patients weekly at 4.0 patients per station, which is 100.0% of its capacity ( $80 / (4/20) = 100$ ) as of June 30, 2013. Hendersonville Dialysis Center is the only end-stage renal disease facility operating in Henderson County.

The applicant projects to serve 80 in-center dialysis patients in operating year 1 (2016) dialyzing on 24 stations for a utilization rate of 83% or 3.3 patients per station [ $80 / 24 = 3.3 / 4.0 = 0.833$  or 83%]. The applicant projects no change in the number of in-center patients in operating year 2 (2017). The projections use a zero growth rate because the applicant believes the number of patients

dialyzing at Hendersonville Dialysis Center is stable and because Henderson County’s projected five-year average annual growth rate in the number of dialysis patients is -0.11.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. 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.

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In Section VII.1, page 31, the applicant states that Hendersonville Dialysis Center currently employs 16.1 full time equivalent staff (FTEs). The applicant proposes to hire one additional Patient Care Technician (PCT) staff as a result of the proposed project. The applicant further states on page 31, “*The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405 .2100 ....*”

In Section VII.10, pages 33-34, the applicant provides the following tables that illustrate the current and projected number of direct care staff per shift offered:

Current Direct Care Staff per Shift

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6am to 11am	5	5	5	5	5	5
Afternoon	11am to 4pm	5	5	5	5	5	5
Evening	N/A	0	0	0	0	0	0

Projected Direct Care Staff per Shift

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6am to 11:00am	6	6	6	6	6	6
Afternoon	11am to 4pm	6	6	6	6	6	6
Evening	N/A	0	0	0	0	0	0

The applicant states on page 34, that the staff charts above indicate patient care technicians, who provide direct care to the patients. The facility is also staffed Monday through Saturday during its operational hours of 6:00 a.m to 4:00 p.m. with two registered nurses.

In Section V.4(c), page 24, the applicant states that Dr. Joseph Aiello currently serves as the Medical Director of Hendersonville Dialysis Center and has expressed his willingness to continue serving in that role. See Exhibit 12 for a letter dated March 13, 2014 from Dr. Aiello expressing his willingness to continue in his current role of Medical Director.

The applicant documents the availability of adequate health manpower and management personnel, including the medical director, 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.

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In Section V.1, pages 23-24, the applicant provides a list of providers of the necessary ancillary and support services. Acute dialysis in an acute care setting, emergency care, diagnostic evaluation services, X-ray services and blood bank will be provided by Memorial Mission Medical Center. See Exhibit 9 for a copy of the acute care agreement and Exhibit 10 for a copy of the Transplant Agreement with Carolinas Medical Center and Emory University School of Medicine. The applicant adequately demonstrates the necessary ancillary and support services are available and that the proposed services will continue to be coordinated with the existing healthcare 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

NA

- (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

The applicant proposes to relocate the existing facility from its current location at 500 Beverly Hanks Center. In Section XI, the applicant identifies two sites under consideration. The primary site is located at 146 Sugarloaf Road, in Hendersonville and consists of 2.3 acres of land with a purchase price of \$750,000. The secondary site under consideration is located at 6034 Asheville Highway, in Fletcher and consists of 2.5 acres of land with a purchase price of \$1,125,000. The site will be owned by Hill/Gray Seven, LLC, and Total Renal Care of North Carolina, LLC d/b/a Hendersonville Dialysis will enter into a leasehold interest agreement for not less than 10 years. See Exhibit 25 for a copy of a signed lease agreement. The applicant states on page 36 that they have allocated \$1,213,000 for the construction contract cost consisting of \$720,000 for material costs, \$480,000 for labor costs and \$13,000 for tap fees for the upfit of the building. The applicant states on page 53, that the proposed relocated ESRD will consist of 8,600 square feet. The applicant states that the ancillary areas will encompass 2,771 square feet and the treatment areas will encompass 5,829 square feet, as illustrated in the table below.

<b>Area</b>	<b>Estimated Square Feet</b>
<b>Ancillary Areas</b>	
Administration Offices, Reception Area, Elevator Lobby	305 sq. ft.
Public Lobby	489 sq. ft.
Mechanical Equipment, Machine Maintenance & Freight Elevator	64 sq. ft.
Biomedical	141 sq. ft.
General Storage/ Medical Records	49 sq. ft.
Exam/ Treatment & Medical Offices	605 sq. ft.
Staff Lounge and Lockers	355 sq. ft.
RO	485 sq. ft.
Handicap Bathrooms/ Dock and Walkways	278 sq. ft.
<b>Treatment Areas</b>	
Nurses Station	470 sq. ft.
Utility / Linen Equipment Storage	325 sq. ft.
Dialysis Stations	3,602 sq. ft.
Isolation Room	102 sq. ft.
Patient Bathroom / Corridor/ Walls	1,330 sq. ft.
<b>Total Square Footage</b>	<b>8,600</b>

See Exhibit 20 for a copy of the line drawing for the proposed facility.

The applicant adequately demonstrates that the cost, design, and means of construction represent the most reasonable alternative for the proposed relocated ESRD and the expansion of the facility by five ESRD stations. See Criterion (5) for discussion of costs and charges which is incorporated hereby by as if fully set forth herein. 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

In Section VI.1(a), page 27, the applicant states Hendersonville Dialysis Center, by policy, will make dialysis services available to all residents in its service area without qualifications.

In Section VI.1(b), page 27, the applicant reports that 85% of the patients who received treatments at Hendersonville Dialysis Center had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payment source for the existing facility:

<b>HENDERSONVILLE DIALYSIS CENTER PAYOR MIX</b>	
<b>SOURCE OF PAYMENT</b>	<b>PERCENTAGE</b>
Medicare	27.4%
Medicaid	15.1%
Medicare/Medicaid	17.8%
Commercial Insurance	10.9%
VA	4.1%
Medicare/Commercial	24.7%
<b>Total</b>	<b>100.0%</b>

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Henderson County and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Henderson County	14%	5.39%	19.7%
Statewide	17%	6.71%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the dialysis services offered by Hendersonville Dialysis Center. In fact, in 2012 only 6.5% of all newly-diagnosed ESRD patients in North Carolina's Network 6 were under the age of 35 (*ESRD Network 6 2012 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2012 – 12/21/2012*, page 74).

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicant's 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 or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides the following national statistics for FY 2011:

*"The December 31, 2011 prevalent population included 430,273 patients on dialysis ..."*<sup>1</sup> (p. 216)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were White, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p. 218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states:

*"In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant."*(p. 216)

The Southeastern Kidney Council (SKC) Network 6 2012 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 76, summarized as follows:

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<sup>1</sup> [www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

<b>Number and Percent of Dialysis Patients by Age, Race and Gender 2012</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Ages</b>		
0-19	73	0.5%
20-34	751	5.0%
35-44	1,442	9.7%
45-54	2,644	17.7%
55-64	4,013	26.9%
65+	5,995	40.2%
<b>Gender</b>		
Female	6,692	44.9%
Male	8,226	55.1%
<b>Race</b>		
African American	9,346	62.7%
White/Caucasian	5,191	34.8%
Other	380	2.6%

Source: Southeastern Kidney Council (SKC) Network 6.  
 Table includes North Carolina statistics only.<sup>2</sup>

The 2013 United States Renal Data System (USRDS) Annual Data Report provides 2011 ESRD spending by payor, as follows:

<b>ESRD SPENDING BY PAYOR*</b>		
<b>PAYOR</b>	<b>SPENDING IN BILLIONS</b>	<b>% OF TOTAL SPENDING</b>
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
<b>TOTAL</b>	<b>\$49.2</b>	<b>100.0%</b>

\*Source: 2013 United States Renal Data System (USRDS) Annual Data Report, page 332.

Hendersonville Dialysis Center 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 applicant;

<sup>2</sup> [www.esrdnetwork6.org/publications/reports.html](http://www.esrdnetwork6.org/publications/reports.html)

C

In Section VI.1(f), page 28, the applicant states,

*“Hendersonville Dialysis Center 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 VI.6 (a), page 30, 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(c), page 28, the applicant provides the projected payor mix for the proposed services at the existing facility, as follows:

<b>HENDERSONVILLE DIALYSIS CENTER PAYOR MIX</b>	
<b>SOURCE OF PAYMENT</b>	<b>PERCENTAGE</b>
Medicare	27.4%
Medicaid	15.1%
Medicare/Medicaid	17.8%
Commercial Insurance	10.9%
VA	4.1%
Medicare/Commercial	24.7%
<b>Total</b>	<b>100.0%</b>

As illustrated in the table above, the applicant does not project a change in its payor mix.

In Section VI.1(a), page 27, the applicant states,

*“Hendersonville Dialysis Center does 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 persons.”*

The applicant demonstrates that medically underserved populations will continue to 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(a), page 29, the applicant states that:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral to a Nephrologist with privileges at Hendersonville Dialysis Center. These referrals most commonly come from primary care physicians or specialty physicians in Henderson County and Buncombe County or transfer referrals from other Nephrologists outside of the immediate area. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact the Hendersonville Dialysis Center directly or indirectly, the patient is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. Patients from outside the Hendersonville Dialysis Center catchment area requesting transfer to this facility are processed in accordance with the Hendersonville Dialysis Center transfer and transient policies which comprise **Exhibit 13**. The patient, again, is referred to a qualified Nephrologist for evaluation and subsequent admission, if medically necessary.”* [Emphasis in original]

The applicant adequately demonstrates that it provides a range of means by which a person can access services at Hendersonville Dialysis Center. 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 V.3(a), page 24, the applicant discusses how the proposed project will relate to the clinical needs of the health professional training program in the service area. The applicant states:

*“Hendersonville Dialysis Center has an agreement with Western Carolina University.”*

Exhibit 11 includes a copy of an agreement between Hendersonville Dialysis Center and Western Carolina University to be included in its clinical rotation schedule for student nurses. The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion.

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

C

The applicant proposes to add five dialysis stations and to relocate the facility within Henderson County, for a total of 24 dialysis stations upon project completion. The January 2014 SDR reported the utilization rate for Hendersonville Dialysis Center was 4.0 patients per stations. This utilization rate was calculated based on 80 in-center dialysis patients and 20 certified dialysis stations (80 patients / 20 stations = 4 patients per station).

In Section V.7, page 26, the applicant discusses the impact of the proposed project on competition as it relates to promoting cost-effectiveness, quality and access, the applicant states:

*“Henderson County is an urban county. The proposed expansion of the facility is not intended to be a competitive venture. There are no other dialysis facilities in Henderson County. The effect of other facilities in surrounding counties would be difficult to determine.”*

*The effect upon completion is unknown. However, patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs. The Hendersonville Dialysis Center provides access to all qualified Nephrologist to admit his or her patients.”*

According to the January 2014 SDR, the only provider of ESRD services in Henderson County, is Hendersonville Dialysis Center with a utilization of 100.0%. Thereby making it evident that there is a continued need for cost-effective, quality ESRD services in Henderson County.

The applicant proposes to relocate the existing facility from 500 Beverly Hanks Center, Highway 24 N. Hendersonville to 146 Sugarloaf Road (primary site), in Hendersonville. According to Google Maps<sup>3</sup> the proposed new location on Sugarloaf Road is 2.8 miles from the existing facility, thus, this relocation would not negatively impact the patients currently seeking services at Hendersonville Dialysis Center.

See Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that adding five dialysis stations and relocating the existing Hendersonville Dialysis Center will have a positive impact on cost-effectiveness, quality and access to the proposed service based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to add five additional stations to the existing facility based on facility need methodology. The applicant also adequately demonstrates the need to relocate the existing facility due to the inability to expand the existing facility at its current location, as well as the age of the facility and the issues with the parking lot flooding during heavy rain. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to Hendersonville Dialysis Center patients.
- The applicant has and will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 (pages 23-26), and VII (pages 31-34), and referenced exhibits is reasonable and credible and demonstrates the provision of quality care.

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<sup>3</sup> <https://maps.google.com/maps>

- The applicant has and will continue to provide adequate access to medically underserved populations. In Section VI.1, page 27, the applicant states:

*“Hendersonville Dialysis Center, 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.”*

Therefore, 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

DVA Healthcare Renal Care, Inc. currently provides dialysis services at Hendersonville Dialysis Center. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the Hendersonville Dialysis Center operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183(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, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C Section .2200. The specific findings are discussed below.

**SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE  
RENAL DISEASE SERVICES**

**.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 9, the applicant states the utilization rate is reported in the January 2014 SDR provided in Exhibit 7. The January 2014 SDR reports a utilization rate of 100.0% which was calculated based on 80 in-center dialysis patients and 20 certified dialysis stations as of June 30, 2013.

(2) *Mortality rates;*

-C- In Section IV.2, page 21, the applicant reports the 2011<sup>4</sup>, 2012 and 2013 facility mortality rates as 18.5%, 26.5% and 10.7%, respectively.

(3) *The number of patients that are home trained and the number of patients on home dialysis;*

-C- In Section IV.3, page 21, the applicant states, “*The Asheville Kidney Center provides home training for patients living in [sic] under an agreement with Hendersonville Dialysis Center.*”

(4) *The number of transplants performed or referred;*

-C- In Section IV.4, page 21, the applicant states, “*Hendersonville Dialysis Center referred 29 patients for transplant evaluation in 2013. The Hendersonville Dialysis Center had no patients who received transplants in 2013.*”

(5) *The number of patients currently on the transplant waiting list;*

-C- In Section IV.5, page 22, the applicant states, “*The Hendersonville Dialysis Center has 10 patients on the transplant waiting list.*”

(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

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<sup>4</sup> On page 21, the applicant states that in Year 2001, the mortality rate was 18.5%. The project analyst assumed this was a typographical error and the applicant was referring to Year 2011 mortality rate.

- C- In Section IV.6, page 22, the applicant states that Hendersonville Dialysis Center had 99 hospital admissions in 2013; five or (5.1%) of those admitted were due to dialysis related reasons. An additional 94 patients or (94.9%) of those patients were admitted for non-dialysis related reasons.
  - (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
  
- C- In Section IV.7, page 22, the applicant states that there were no in-center patients dialyzing at Hendersonville Dialysis Center with AIDS or Hepatitis B as of December 31, 2013. The applicant also states that the number of patients treated with infectious disease who have converted to infectious status within the last year is zero.
  
- (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- See Exhibit 9 for a letter dated September 1, 1993 from the President of Memorial Mission Medical Center agreeing to provide acute care hospital services which includes inpatient services, back-up hemodialysis, laboratory and x-ray services, as required.
  - (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a 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.*

- NA- Hendersonville Dialysis Center is an existing facility.
- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- See Exhibit 25 for letters from Duke Energy and Hendersonville Water and Sewer documenting that power and water will be available at the proposed sites.
- (4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- See Exhibit 8, in which the applicant provides copies of written policies and procedures for back up electrical service in the event of a power outage.
- (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- See Exhibit 25 for a letter dated March 3, 2014 from Jon Blatt, with Southern Commercial Corporation which states that the property on Sugarloaf Road is available for sale and zoned for C-3 highway commercial. Exhibit 25 also contains a letter dated February 24, 2014 from a Broker Associate with Beverly Hanks, which states the property at 6034 Asheville Highway is available for sale and zoned for C-4.
- (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 51, the applicant states, “*Hendersonville Dialysis Center has and will continue to operate within the applicable laws and regulations pertaining to staffing and fire*

*safety equipment, physical environment, and other relevant health safety requirements.”*

- (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 18-19, the applicant provides the projected patient origin, including all assumptions, the methodology by which the patient origin is projected, as illustrated in the table below.

**Projected Dialysis Patient Origin**

COUNTY	Operating Year 1 2016	Operating Year 2 2017	County Patients as a Percent of Total	
	In-Center Patients	In Center Patients	Year 1	Year 2
Henderson	59	59	73.8%	73.8%
Transylvania	19	19	23.8%	23.8%
Nash	2	2	2.4%	2.4%
<b>TOTAL</b>	<b>80</b>	<b>80</b>	<b>100.0%</b>	<b>100.0%</b>

See Criterion (3) for discussion with regard to the methodology and assumptions the applicant uses to project patient origin which is incorporated hereby as if set forth fully herein.

- (8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- Hendersonville Dialysis Center is an existing facility.

- (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 11, the applicant states, “*Total Renal Care of North Carolina, LLC d/b/a Hendersonville Dialysis Center 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.*”

**.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- Hendersonville Dialysis Center is an existing facility.

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

-C- In Section II, pages 11-12, the applicant states that there were 80 in-center patients dialyzing on 20 stations as of December 31, 2013 which resulted in a utilization rate of 100%. The applicant projects to have 80 in-center patients by the end of year one for a utilization rate of 83% or 3.3 patients per station per week [ $80 / 24 = 3.33 / 4.0 = 0.83$  or 83%].

**.2204 SCOPE OF SERVICES**

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

(1) *diagnostic and evaluation services;*

-C- The table in Section V.1(e), page 23, states patients will be referred to Memorial Mission Medical Center for diagnostic and evaluation services.

(2) *maintenance dialysis;*

-C- The table in Section V.1(c), page 23, states the applicant will provide in-center maintenance dialysis.

(3) *accessible self-care training;*

-C- The table in Section V.1(d), page 23, the applicant states that self-care training for hemodialysis, intermittent peritoneal dialysis, CAPD and CCPD will be provided by Asheville Kidney Center.

(4) *accessible follow-up program for support of patients dialyzing at home;*

-C- In Section V.1(d), page 23, the applicant states follow-up support for patients dialyzing at home will be provided by Asheville Kidney Center.

(5) *x-ray services;*

-C- The table in Section V.1(g), page 23, states patients will be referred to Memorial Mission Medical Center for x-ray services.

(6) *laboratory services;*

-C- The table in Section V.1(h), page 23, states patients will be referred to Dialysis Laboratories for routine and special laboratory services.

(7) *blood bank services;*

-C- The table in Section V.1(i), page 23, states patients will be referred to Memorial Mission Medical Center for blood bank services.

(8) *emergency care;*

-C- The table in Section V.1(b), page 23, states patients will be referred to Memorial Mission Medical Center for emergency care.

(9) *acute dialysis in an acute care setting;*

-C- The table in Section V.1(a), page 23, states patients will be referred to Memorial Mission Medical Center for acute dialysis in an acute care setting.

(10) *vascular surgery for dialysis treatment patients;*

-C- The table in Section V.1(p), page 23, states dialysis patients will be referred to Asheville Cardiovascular & Thoracic Surgeons for vascular surgery.

(11) *transplantation services;*

-C- The table in Section V.1(f), page 23, states patients will be referred to Carolinas Medical Center and Emory University

School of Medicine for transplantation services. See Exhibit 10 for documentation of transplantation agreements.

(12) *vocational rehabilitation counseling and services; and*

-C- The table in Section V.1(o), page 23, states patients will be referred to the NC Department of Vocational Rehabilitation for vocational rehabilitation counseling and services.

(13) *transportation.*

-C- The table in Section V.1(q), page 24, states patients will be referred to Arc Angel Transportation Support Services.

**.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 31 the applicant provides the current staffing for Hendersonville Dialysis Center. The applicant states, “*The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100 as evidenced below.*” Hendersonville Dialysis Center currently has 16.1 FTEs and proposes to add one additional staff as a result of the proposed project for a total of 17.1 FTEs upon completion of the project. The applicant currently operates with 5.0 FTEs per shift on Monday through Saturday as noted in response to VII.10, page 33 of the application.

(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- Exhibit 16 contains a copy of DaVita’s Training Programs for New Patient Care Provider Teammates. Exhibit 23 contains the Hendersonville Dialysis Center Annual In-Service Calendar.