

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: July 24, 2013

PROJECT ANALYST: Bernetta Thorne-Williams
CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: O-10125-13 / Total Renal Care of North Carolina, LLC d/b/a Hampstead Dialysis / Develop Hampstead Dialysis, a new dialysis facility, by relocating ten dialysis stations from Southeastern Dialysis Center – Burgaw, with a total of ten certified dialysis stations upon project completion / Pender 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 (TRC) d/b/a Hampstead Dialysis, whose parent company is DaVita Inc, proposes to relocate ten existing certified dialysis stations from Southeastern Dialysis Center – Burgaw (SEDC – Burgaw) in Burgaw to Hampstead Dialysis in Hampstead for a total of ten dialysis certified stations at Hampstead Dialysis upon completion of the project. The applicant does not propose to add new dialysis stations. Therefore, neither the county or facility need methodologies in the 2013 State Medical Facilities Plan (SMFP) are applicable to this review. Additionally, Policy GEN-3 is not applicable because the applicant is not proposing to develop a facility pursuant to a need determination in the 2013 SMFP. However, Policy ESRD-2: Relocation of Dialysis Stations, on page 36, 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:

- (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 ten existing dialysis stations within Pender County. Consequently, there is no change in the dialysis station inventory in Pender County, therefore, the application is consistent with Policy ESRD-2 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

Total Renal Care of North Carolina, LLC (TRC) d/b/a Hampstead Dialysis, proposes to relocate ten existing dialysis stations from Southeastern Dialysis Center – Burgaw (SEDC – Burgaw) to Hampstead Dialysis for a total of ten certified dialysis stations at Hampstead Dialysis upon completion of the project. The applicant does not propose to add new dialysis stations to an existing facility or to establish new dialysis stations. In Section II.7, page 13, the applicant states, “*The development of a second facility in Eastern Pender County would provide patients ... living in eastern Pender County, southern Onslow County and northeastern New Hanover County easier access to dialysis services.*”

Population to be Served

In Section III.7, page 23, the applicant projects the number of in-center patients to be served in the first two years of operation following project completion, as illustrated in the following table:

Hampstead Dialysis				
COUNTY	Operating Year 1 2015	Operating Year 2 2016	County Patients as % of Total	
	In-Center	In-Center	Year 1	Year 2
Pender	27	30	81.8%	83.3%
Onslow	2	2	6.1%	5.6%
New Hanover	4	4	12.1%	11.1%
Total	33	36	100.0%	100.0%

In Section III.7, pages 23-24, the applicant provides the assumptions and methodology used to project the number of patients expected to utilize the Hampstead Dialysis facility, as follows:

“Thirty-one patients who currently get dialysis at SEDC – Burgaw have signed letters of support for the proposed Hampstead Dialysis facility. All of the patients have indicated in their letters that they live closer to the proposed Hampstead facility and that the facility will be more convenient for them.

Based on these letters, Hampstead Dialysis will have at least 31 in-center ESRD patients dialyzing in the facility January 1, 2015, which we are projecting to be the beginning of the first year of operation. Those 31 patients are projected to transfer from SEDC – Burgaw. The facility is projected to have 34 in-center patients by the end of operating year one based on the current Average Annual Change Rate for the Past Five Years that is cited in the January 2013 Semiannual Dialysis Report ...

The January 3013 [sic] Semiannual Dialysis Report indicates that the five-year average change rate in Pender County is 8%. Listed below are the calculations that were performed to determine the utilization rates for the proposed Hampstead Dialysis facility at the end of the first and second operating years:

In-Center Utilization Projections using the average annual change rate for the past five years of 8.0% and starting out with 31 in-center patients dialyzing at SEDC-Burgaw who will transfer their treatment to Hampstead Dialysis as of January 1, 2015:

January 1, 2015-December 31, 2015 – 31 in-center patients X 1.08 = 33.48

January 1, 2016-December 31, 2016 – 33.48 in-center patients X 1.08 = 36.1584

January 1, 2015-December 31, 2015 is the first operating year.

January 1, 2016-December 31, 2016 is the second operating year.

Thus, we anticipate that there will be 33 in-center patients dialyzing at the facility at the end of operating year one and 36 in-center patients dialyzing at the facility at the end of

operating year two.

Using the projections above, SEDC – Burgaw would have 82 in-center patients at the point when Hampstead Dialysis is projected to be certified on January 2, 2015. With 31 patients and 10 dialysis stations transferring from the SEDC – Burgaw to Hampstead Dialysis, this will leave 51 patients ($82 - 31 = 51$) and 12 dialysis stations at SEDC – Burgaw. Once the transfer takes place, using the numbers above, The SEDC – Burgaw utilization rate would be 106%” [Emphasis in origin]

The applicant adequately identifies the population to be served.

Need Analysis

In Section III.3, page 19, the applicant states that improved accessibility of services is a key factor for the proposed project. The applicant discusses the number of end stage renal disease patients residing in the eastern portion of Pender County, southern Onslow County and northeastern New Hanover County. The applicant provides 31 letters of support from patients currently dialyzing at SEDC – Burgaw who have expressed a desire to transfer their care to the proposed Hampstead Dialysis facility because the facility would be more convenient for their use. Additionally, the applicant states that staff from the SEDC – Burgaw facility, which includes a nurse, patient care technicians, dietician and a social worker will continue to be involved with those patients at the Hampstead Dialysis facility, allowing for consistency in care and services. Further, in Section III.3(c), page 21, the applicant discusses the other ESRD facilities in surrounding areas. The applicant states after analyzing other areas of Pender County, the applicant determined that eastern Pender County had the greatest need for more accessible ESRD services. The applicant states that the SEDC – Burgaw facility is located in the center of Pender County with the TRC Wallace facility to the north, over the Duplin County line. The applicant also states that the TRC Cape Fear facility is to the south in New Hanover County. The applicant states that some ESRD patients residing in Pender County utilize those facilities because they are closer to their homes. Additionally, there are a significant number of patients traveling from eastern Pender County to the SEDC – Burgaw facility. The proposed project would allow 31 of those patients traveling to the SEDC – Burgaw facility to receive ESRD services closer to their homes.

Exhibit 15 of the application contains 31 letters of support from patients stating that the Hampstead facility would be closer to their residence and indicating a willing to consider transferring to the Hampstead facility. The letters of support state in part:

“Having my dialysis treatments in that part of the county would be much more convenient for me. I could travel between my home and that location more easily and quickly, which would save me time and money.”

In Section III.7, page 23, the applicant states:

“The January 3013 [sic] Semiannual Dialysis Report indicates that the five-year average

change rate in Pender County is 8%”

The following table summarizes the applicant’s assumptions and methodology used to project the utilization at Hampstead Dialysis for in-center dialysis patients, as reported in Section III, pages 23-24.

Hampstead In-Center Dialysis	
TRC begins with the patients projected to transfer to the new facility as of January 1, 2015 from the SEDC – Burgaw facility.	31
TRC projects this population forward to December 31, 2015 by using the five year average change rate of 8.0% for Pender County as reported in the 2013 SDR. This is the end of Operating Year 1.	$31 \times 1.08 = 33.48$
TRC projects Operating Year 2, from January 1, 2016 – December 31, 2016 by multiplying the county growth rate by the projected number of patients at the end of Operating year 1.	$33.48 \times 1.08 = 36.1584$

The applicant projects to serve 33 in-center patients by the end of Year One or 3.3 patients per station [$33/10 = 3.3$]; and 36 in-center patients by the end of Year Two or 3.6 patients per station [$36/10 = 3.6$]. The projected utilization rate is 82.5% at the end of Year One [$33/(4 \times 10) = 82.5$] and 90% in Year Two [$36/(4 \times 10) = 90$]. Projected in-center utilization at Hampstead Dialysis is based on reasonable, credible and supported assumptions.

Access

In Section VI.1, pages 33-35, the applicant describes how underserved persons will continue to have access to services provided by TRC and specifically those services provided at Hampstead Dialysis, stating, *“Hampstead Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, sex, age or handicap. We will serve patients regardless of ethnic or socioeconomic situation.”* The majority of patients have some portion of their care reimbursed by Medicare or Medicaid. See Criterion (13a and 13c) for additional discussion relating to promoting equitable access which is hereby incorporated by reference as if fully set forth herein.

In summary, the applicant adequately identified the population to be served, demonstrated the need the population has for the project and the extent to which all residents of the area, in particular underserved groups are likely to access the services provided. 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 ten existing dialysis stations from SEDC – Burgaw to establish the Hampstead Dialysis. In Section III.3(b), pages 20-21, the applicant discusses how the needs of dialysis patients at SEDC – Burgaw will continue to be met after the transfer of 10 stations to the proposed Hampstead Dialysis facility. SEDC – Burgaw is currently certified for 22 dialysis stations and will have 12 stations at the conclusion of this project.

In Section II, pages 13-14 the applicant states:

- *“SEDC – Burgaw had 68 in-center patients as of 6/30/2012 for a utilization of 77% [85.21% as reported in the January 2013 SDR].*
- *SEDC – Burgaw does not have the capacity to add additional dialysis stations to the facility and cannot [sic] does not have the property to expand the building.*
- *Many of the patients dialyzing at the SEDC – Burgaw facility live in Hampstead, Holly Ridge or Rocky Point.”*

In Section III.3, pages 20-21, the applicant states:

“...With 31 patients and ten dialysis stations transferring from the SEDC – Burgaw to Hampstead Dialysis, this will leave 46 in-center patients and 12 dialysis stations at SEDC – Burgaw ...

...We have projected the growth for the entire current patient population at SEDC – Burgaw by projecting the growth from the date of the most recent Southeastern Kidney Council date, which is June 30, 2012. ... SEDC – Burgaw had 68 in-center patients as of June 30, 2012 and that Pender County had an Average Annual Change Rate for the Past Five Years of 8%, we have projected the growth in the patient population from July 1, 2012 to the date Hampstead Dialysis is projected to be certified.

July 1, 2012-December 31, 2012 – 68 in center patients X 1.04 = 70.72

January 1, 2013-December 31, 2013 – 70.72 in-center patients X 1.08 = 76.3776

January 1, 2014-July 1, 2014 [December 31, 2014] – 76.3776 X 1.08 = 82.487808.

Using the projections above, SEDC – Burgaw would have 82 in-center patients at the point when Hampstead Dialysis is projected to be certified on January 1, 2015. With 31 patients and ten dialysis stations transferring from SEDC – Burgaw to Hampstead Dialysis, this will leave 51 patients (82 – 31 = 51) and 12 dialysis stations at SEDC – Burgaw. ...”

Thus, the applicant projects to serve 51 in-center patients by January 1, 2015 at SEDC –

Burgaw. This is a utilization rate of 4.2 patients per station [51/12 = 4.25]. Should this growth projection be realized, SEDC – Burgaw would be eligible to apply to add stations. The proposed project does not reduce the total number of stations in Pender County; it merely splits them into two separate facilities owned and operated by the same provider.

The applicant states the medically underserved population will continue to have access to services provided by TRC, as stated in Section VI.1, pages 33-35. Therefore, the applicant demonstrates that the needs of the population presently served at SEDC – Burgaw will be adequately met following relocation of ten stations to Hampstead Dialysis. See Criterion (13) for additional discussion relating to promoting equitable access which is hereby incorporated by reference as if fully set forth herein.

- (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.

C

In Section III.9, pages 24-25, the applicant discusses the analysis that TRC engaged in to determine the need for the proposed ESRD facility. The applicant states on page 25, “*Total Renal Care of North Carolina, LLC studied appropriate alternatives to this application and concluded that developing a new facility in the eastern area of Pender County is the best option.*” The applicant does not however discuss other alternatives considered other than the development of the proposed Hampstead Dialysis facility. Thus, it is assumed that the applicant concluded the following:

- Maintaining the Status Quo was not considered because of the number of patients that reside closer to the Hampstead area which includes those patients traveling from eastern Pender County, southern Onslow County (Holly Ridge area), and northeastern New Hanover County (Highway 17) to receive dialysis service at the SEDC – Burgaw facility.

The applicant concluded that the development of the project, as proposed, would provide a more convenient option for the 31 patients currently dialyzing at the SEDC – Burgaw facility who submitted letters of support for the Hampstead Dialysis facility expressing their willingness to transfer to the proposed facility. Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the Hampstead Dialysis proposal is the least costly or most effective alternative to meet the need. Therefore, 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 Hampstead 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 Hampstead Dialysis shall develop and operate no more than ten dialysis stations at Hampstead Dialysis which shall include any isolation stations.**
 - 3. Total Renal Care of North Carolina, LLC d/b/a Hampstead Dialysis shall install plumbing and electrical wiring through the walls for no more than ten dialysis stations which shall include any isolation stations.**
 - 4. Total Renal Care of North Carolina, LLC d/b/a Hampstead Dialysis shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**
 - 5. Total Renal Care of North Carolina, LLC d/b/a Hampstead Dialysis shall take the necessary steps to decertify ten stations at Southeastern Dialysis Center – Burgaw for a total of no more than twelve certified dialysis stations at Southeastern Dialysis Center – Burgaw upon project completion.**
 - 6. Prior to the issuance of the certificate of need, Total Renal Care of North Carolina, LLC d/b/a Hampstead Dialysis shall provide the Certificate of Need Section documentation of an agreement with a transplantation center to provide transplantation services.**
 - 7. Total Renal Care of North Carolina, LLC d/b/a Hampstead Dialysis 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.1, pages 42-43, the applicant states that the total capital cost of the project will be \$1,500,811 which includes \$924,000 in construction contract cost, \$131,700 for dialysis machine cost, \$90,000 for water treatment equipment cost, \$221,181 in equipment/furniture cost, \$70,000 in architect/engineering cost, \$9,700 for dialysis chairs cost, \$4,475 for scale cost, \$28,500 for television system cost, and \$21,255 for patient computer system.

In Section IX.3, page 46, the applicant projects that the total working capital (start-up and initial operating expenses) associated with the proposed project will be \$813,796, as illustrated below.

- Start-up Expenses \$152,484
- Initial Operating Expenses \$661,312

Total Working Capital **\$813,796**

In Section VIII.2, page 43, the applicant states that the project will be funded by means of DaVita Healthcare Partners Inc., the parent company of Total Renal Care of North Carolina, LLC cash reserves

Exhibit 20 contains a letter dated April 12, 2013 from the Chief Accounting Officer of DaVita Healthcare Partners, 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 Operating Officer of Total Renal Care, Inc. which owns 85% of the ownership interest in Total Renal Care of North Carolina, LLC ("TRC").

... I am writing this letter as Chief Accounting Officer of DaVita, to confirm DaVita's commitment of \$1,500,811, for the capital expenditures associated with this project; a commitment of \$152,484, for its start up expenses; and a further \$66,312 in working capital.

DaVita has committed cash reserves in the total sum of \$2,314,607, for the capital costs, start-ups and working capital for this project. ... "

Exhibit 21 of the application contains the audited financial statements for DaVita Healthcare Partners Inc for the fiscal year ended December 31, 2012. As of December 31, 2012, DaVita Healthcare Partners Inc had \$533,748,000 in cash and cash equivalents, \$16,018,596,000 in total assets and \$4,508,740,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.

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

SEDC - Burgaw	
Payor	Charge Per treatment
Medicare	\$240.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,442.00
VA	\$193.00
Medicare/Commercial	\$240.00

The applicant projects revenues in Section X.2, page 48 and operating expenses in Section X.4, page 50, of the application. In Section X.2-X.4, pages 48-50, the applicant reports projected revenues and expenses for Hampstead Dialysis, as illustrated in the table below:

Hampstead Dialysis		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$1,357,635	\$1,461,117
Total Operating Costs	\$1,322,624	\$1,386,977
Net Profit	\$35,011	\$74,140

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 of the application for the applicant's assumptions.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and charges. 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 (TRC) d/b/a Hampstead Dialysis proposes to relocate ten existing certified dialysis stations from Southeastern Dialysis Center – Burgaw (SEDC – Burgaw) in Burgaw to Hampstead Dialysis in Hampstead for a total of ten dialysis certified stations at Hampstead Dialysis upon completion of the project. SEDC – Burgaw is the only provider of ESRD services in Pender County. This proposal would split the existing stations into two facilities, with Hampstead Dialysis operating 10 certified stations and SEDC – Burgaw operating 12 certified stations. The proposal will not result in an increase in the number of certified dialysis stations located in Pender County.

The applicant adequately demonstrates the need to relocate ten dialysis stations from SEDC – Burgaw to develop a new ten station facility based continued population growth and the

number of patients currently traveling from the eastern portion of Pender County, southern Onslow County and northeastern New Hanover County to receive dialysis services at SEDC – Burgaw. Thirty-one of those patients' currently receiving services at SEDC – Burgaw have expressed a willingness to transfer their care to the proposed Hampstead Dialysis facility. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved certified dialysis stations in Pender 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 provides projected staffing for Hampstead Dialysis upon project completion, as illustrated in the following table:

Hampstead Dialysis Full-Time Equivalent (FTE) Positions	
RN	1.5
PCT	4.5
Bio-Med Tech	.30
Admin.	1.00
Dietician	.30
Social Worker	.30
Unit Secretary	1.00
Reuse Tech	.50
Total FTEs	9.40

The applicant projects a total of 9.40 FTE positions upon project completion and states on page 39 that some teammates will transfer from the SEDC – Burgaw facility to the Hampstead Dialysis facility and states there is no difficulty expected in recruiting staff for the remaining positions. In Section V.4, page 30, the applicant identifies the Medical Director for Hampstead Dialysis as Dr. Eric Pierson. In Exhibit 14 the applicant provides a letter from Dr. Pierson indicating his willingness to serve as Medical Director of the facility. Additionally, in Section VII.10, page 41, the applicant states Hampstead Dialysis will operate two shifts, six days a week from 6:00 a.m. to 4:00 p.m.

The applicant adequately documents the availability of resources, including health manpower and management personnel, for provision of the proposed 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 lists the providers of the necessary ancillary and support services. Exhibits 8-12 contain documentation on service agreements. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will 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 (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, pages 52-54, the applicant discusses the primary and secondary sites being considered for the proposed Hampstead Dialysis facility. The applicant states that TRC

plans to lease space for the proposed new facility. The applicant states the primary site sits on 1.013 acres and is located at 17160 US Highway 17 North Hampstead and is currently zoned for dialysis facility use. The secondary site sits on 5 acres and is located at Highway 210, in Surf City and is currently zoned for dialysis facility use. See Exhibit 24 for maps of the proposed site areas. The applicant further states on pages 53-54, that both sites are located on major highways that are easily accessible by patients and transportation agencies.

In Exhibit 25, the applicant states the facility will be 7,025 square. In Section XI.6, page 55, the applicant states that each dialysis station will be 213 square feet with energy saving features as described on page 56. The applicant projects the construction upfit cost will be \$924,000 and architect and engineering fees will be \$70,000, which is a total of \$994,000. Thus, the per square foot cost is projected to be \$141.49 ($\$994,000/7,025 = \141.49). See Section VIII.1, pages 42-43 and Section XI.6(h), page 58. The following table illustrates the square footage breakdown as provided by the applicant in Section XI.6(h), page 58:

Hampstead Dialysis	
Facility Area	Estimated Total Sq. Ft.
Ancillary Areas:	
Administration/Offices/Receptions/Elevator & Lobby	521
Public Lobby	383
Mechanical Equipment	50
Biomedical	100
General Storage/Medical Records	487
Exam/Treatment & Medical Offices	264
Staff Lounge & Lockers	360
RO	512
Other: Handicap baths, dock and walkways	283
Sub-Total Support	2,960
Treatment Areas:	
Nurses Station	280
Dialysis Stations	2,138
Isolation Room(s)	116
Other: Walkways, Lab, Storage	95
Sub-Total Treatment	2,629
Miscellaneous	1,436
Total Square Feet	7,025

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative and that the construction project would not unduly increase the costs of or charges for providing the proposed dialysis services if the project were approved. 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, page 5 the applicant states:

“...[I]t has been DaVita’s practice in North Carolina to acceptations in of dialysis treatment first Our goal is to serve the needs of our patient population ...”

In Section VI.1(c), page 34, the applicant states that the projected payor mix at Hampstead Dialysis is the same as the current payor mix for SEDC – Burgaw. Furthermore, in Section, VI.1(b)., page 33, the applicant provides the current payor mix as of January 1, 2013 for SEDC – Burgaw, as illustrated in the table below.

Source of Payment	As a % of Total
Medicare	18.2%
Medicaid	1.5%
Medicare/Medicaid	28.8%
Commercial Insurance	4.5%
VA	4.5%
Medicare/Commercial	42.5%
Total	100.0%

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 Pender County and statewide.

	CY 2009 Total # of Medicaid Eligibles as % of Total Population *	CY 2009 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	CY 2009 % Uninsured (Estimate by Cecil G. Sheps Center)*
Pender County	17%	7.4%	21.0%
Statewide	17%	6.7%	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 services offered by the Hampstead Dialysis facility. In fact, only 5.8% of all newly diagnosed ESRD patients (incident ESRD patients) in North Carolina’s Network 6 were under the age of 35.

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

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. About 25% of the Medicare-covered patients had employer group plans as primary insurance, with Medicare as the secondary payer. Also, the CMS website states,

“Although the ESRD population is less than 1% of the entire U.S. population it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings. ...

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9) populations.”

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report (page 225) provides these national statistics for FY 2010: *“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy.”* Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”

The report provides 2010 ESRD spending, by payor as follows:

ESRD Spending by Payor		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 340.

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender as shown below:

Number and Percent of Dialysis Patients by Age, Race and Gender		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%
Other	219	2.3%

Source: Southeastern Kidney Council (SKC) Network 6. Includes North Carolina, South Carolina and Georgia

The applicant demonstrates that medically underserved populations have adequate access to the services provided at SEDC - Burgaw. 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.6(a), page 37, the applicant states there have been no civil rights access complaints filed against SEDC – Burgaw or any facility owned by the parent company in North Carolina in the last five years. Therefore, 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 34, the applicant provides the projected payor mix for the proposed services at Hampstead Dialysis, as shown in the table below. The applicant projects no change from the current payor mix at SEDC – Burgaw.

Source of Payment	As a % of Total
Medicare	18.2%
Medicaid	1.5%
Medicare/Medicaid	28.8%
Commercial Insurance	4.5%
VA	4.5%
Medicare/Commercial	42.5%
Total	100.0%

The applicant demonstrates that medically underserved populations would have adequate access to the proposed services at Hampstead Dialysis. 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 36, the applicant states,

“Patients with End Stage Renal Disease will have access to dialysis services upon referral by a Nephrologists with privileges at Hampstead Dialysis. Hampstead Dialysis will grant privileges to all qualified nephrologists. Referrals to nephrologists most commonly come from primary care physicians or specialty physicians in Pender, Onslow and New Hanover Counties or transfer referral from other Nephrologists outside of the immediate area. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. ...”

The applicant adequately demonstrates that Hampstead Dialysis will offer a range of means by which a person can access its services. Therefore, the application is conforming to this criterion.

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

C

In Section V.3, page 30, the applicant states that Hampstead Dialysis will be offered as a training site for nursing students. Exhibit 13 includes a letter dated February 6, 2013 from the Department Chair of Health Science and Nursing, at Cape Fear Community College. The letter states, Cape Fear Community College would be interested in adding Hampstead Dialysis to its list of clinical training sites.

The information provided in Section V.3 is reasonable and credible for a new facility and supports a finding of conformity to this criterion.

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

C

The applicant proposes to transfer ten dialysis stations from SEDC – Burgaw (the existing 22 stations facility) to Hampstead Dialysis (the new 10-station facility), for a total of twelve certified stations at SEDC – Burgaw and ten stations at Hampstead Dialysis upon project completion. TRC is the sole provider of dialysis services in Pender County. The utilization rate at SEDC – Burgaw, as reported in the 2013 SDR exceeds 85%.

In Section V.7, page 32, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost effectiveness, quality and access. The applicant states in part:

“The development of this facility will have no impact on the other outpatient dialysis facility, SEDC – Burgaw. Total Renal Care of North Carolina, LLC operates SEDC – Burgaw.

There are seven counties contiguous to Pender County. In six of the counties, Total Renal Care of North Carolina, LLC operates facilities. ...

Fresenius Medical Care operates facilities in Sampson County (BMA Clinton and FMC Roseboro), Duplin County (Warsaw Dialysis Center) and Brunswick County (FMC Supply). None of these facilities are in close proximity of the proposed Hampstead Dialysis facility.

The development of Hampstead Dialysis is a proposal to relocate stations and a number of patients receiving their dialysis treatments at SEDC – Burgaw. ... Our goal is to locate an in-center ESRD facility closer to where many of our current patients live, and closer to an area of Pender County where there is a large concentration of patients.

For these reasons, we do not believe that this new facility will have an impact on any Fresenius facility located in contiguous counties. Hampstead Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and other involved in the dialysis process to receive services.”

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal in Pender County (where the applicant is the sole provider of dialysis services) include a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the following analysis:

- The applicant adequately demonstrates the need to relocate ten dialysis stations to the eastern portion of Pender to better serve those patients residing in eastern Pender County, southern Onslow County and northeastern New Hanover County. The applicant also adequately demonstrates that the proposed project is a cost-effective alternative to meet the need.
- The applicant adequately demonstrates it 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 and VII is reasonable and credible and demonstrates the provision of quality services.
- The applicant demonstrates it will continue to provide adequate access to medically underserved populations. In Section VI.1, page 33 the applicant states:

“Hampstead Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. We will serve patients without regard to

race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.”

In Section VI.1(c), page 34, the applicant provides the projected payor mix at Hampstead Dialysis, as illustrated in the table below.

Source of Payment	As a % of Total
Medicare	18.2%
Medicaid	1.5%
Medicare/Medicaid	28.8%
Commercial Insurance	4.5%
VA	4.5%
Medicare/Commercial	42.5%
Total	100.0%

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

According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, SEDC – Burgaw 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.
- (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 .2200, are applicable to this review. The application is conforming to all applicable criteria which are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

(a) *An applicant that proposes to increase stations in an existing certified facility or relocate stations must provide the following information:*

.2202(a)(1) *Utilization rates;*

-C- See Section II.1, pages 10-13, and Section IV, pages 26-27, and Exhibit 7 (copy of the January 2013 SDR, Tables A and B). As of June 30, 2012, the utilization rate was 85.2% at SEDC – Burgaw.

.2202(a)(2) *Mortality rates;*

-C- See Section II.1, page 10, and Section IV, page 26. The mortality rates for SEDC – Burgaw were 50.5% in 2010, 4.4% in 2011, and 8.8% in 2012.

.2202(a)(3) *The number of patients that are home trained and the number of patients on home dialysis;*

-C- See Section II, page 10, and Section IV, page 26. SEDC – Burgaw does not offer home training. Patients desiring home training are referred to Southeastern Dialysis Center – Wilmington.

.2202(a)(4) *The number of transplants performed or referred;*

-C- See Section II, page 10, and Section IV, page 26. In 2012 there were seven transplant referrals and one transplant performed.

.2202(a)(5) *The number of patients currently on the transplant waiting list;*

-C- See Section II, page 10, and Section IV, page 26. SEDC – Burgaw has five patients on the transplant waiting list.

.2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

-C- See Section II, page 12 and Section IV, page 27, for hospital admissions rates, by admission diagnosis, as illustrated in the table below.

SEDC – Burgaw Hospital Admissions

<i>01/12-12/12 Hospital Admissions</i>	<i>Total</i>
<i>Number dialysis related</i>	<i>31</i>
<i>Percent Dialysis related</i>	<i>30.4%</i>
<i>Number non-dialysis related</i>	<i>71</i>

<i>Percent non-dialysis related</i>	<i>69.6%</i>
<i>Total number Admissions</i>	<i>102</i>

.2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*

-C- See Section II, page 10 and Section IV, page 27. The applicant reported there was one patient dialyzing at SEDC – Burgaw with an infectious disease (Hepatitis B).

(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:*

.2202(b)(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 8 for a letter of intent to sign a written agreement between Hampstead Dialysis and New Hanover Regional Medical Center to provide acute care hospital services, in Wilmington.

.2202(b)(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.*

-CA- In Section V.1, page 28, the applicant indicates that transplantation services will be provided by Carolinas Medical Center. The applicant references Exhibit 9 as containing a transplantation agreement. However, the applicant failed to provide a copy of a transplantation agreement with Carolinas Medical Center or any center. Therefore, the application is approved subject to the following condition.

Prior to the issuance of the certificate of need, Total Renal Care of North Carolina, LLC d/b/a Hampstead Dialysis shall provide the Certificate of Need Section documentation of an agreement with a transplantation center to provide transplantation services.

.2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-C- In Section XI.6(e), page 56, the applicant states that the facility will be located in an area that will be supplied by portable city water and in Section XI.6(f), the applicant further states that the facility will be served by standing power service. See Exhibit 10 for copies of the applicant's policies, procedures and guidelines which include policies on, *Termination of Dialysis in an Emergency, Using Hand Crank During Power Failure and Back Up Generator Operational Checks*. See also Exhibit 11 for copies of the applicant's policies, procedures and guidelines which include policies on, *Water Culture Policy and General Water Quality Policy*.

.2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- See Exhibit 10 for copies of the applicant's policies, procedures and guidelines; which includes a section on power failure.

.2202(b)(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 Sections XI.2(j), page 53 and XI.3(j), page 51, the applicant states, Mr. Hill, manager of Hill/Gray Seven, LLC, has diligently pursued the purchase of the primary and the secondary sites. See Exhibit 23 for documentation that the primary site located at 17160 Highway 17 North, Hampstead and Highway 210, Surf City, both of which are located in Pender County, are available for a build to suit lease to TRC.

.2202(b)(6) *Documentation that the services will be provided in conformity to applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- See Section VII.2, pages 38-39, Section XI.6, pages 56-57, and Exhibits 10 and 11. In Section X1.6(g), page 56, the applicant states, “*Hampstead Dialysis will operate within the applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment and other relevant health safety requirements.*”

.2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- Section III.7, page 23, Hampstead Dialysis provides projected patient origin which is based on the historical experience of SEDC – Burgaw, as shown in the below table:

Hampstead Dialysis				
COUNTY	Operating	Operating	County Patients as	
	Year 1 2015	Year 2 2016	% of Total	
	In-Center	In-Center	Year 1	Year 2
Pender	27	30	81.8%	83.3%
Onslow	2	2	6.1%	5.6%
New Hanover	4	4	12.1%	11.1%
Total	33	36	100.0%	100.0%

.2202(b)(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 24, the applicant states that 100% of its patients will reside within 30 miles of the proposed Hampstead Dialysis facility. See Exhibit 24 for Google Maps of the proposed location of the facility.

.2202(b)(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 for such services.*

-C- In Section II, page 12, the applicant states, “*Total Renal Care of North Carolina, LLC d/b/a Hampstead 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.”

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-C- In Section II, page 12, the applicant states, “*The facility is projected to have 34 in-center patients by the end of operating year one*” Therefore, the applicant is projected to have patients 3.4 [34/10 = 3.4] per station per week as of the end of the first operating year of Hampstead Dialysis. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein.

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

-NA- Hampstead Dialysis is a new ESRD facility.

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

-C- In Section II, pages 13-14 and Section III.7, pages 23-24, the applicant provides the assumptions and methodology used to project utilization of the proposed facility.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

.2204(1) Diagnostic and evaluation services;

-C- In Section V, page 28, the applicant states that diagnostic and evaluation services will be provided by New Hanover Regional Medical Center.

- .2204(2) *Maintenance dialysis;*
- C- In Section V, page 28, the applicant states that maintenance dialysis will be provided at Hampstead Dialysis.
- .2204(3) *Accessible self-care training;*
- C- In Section V, page 28, the applicant states that accessible self-care training will be provided by Southeastern Dialysis Center – Wilmington. See Exhibit 12 for a copy of a service agreement between SEDC – Wilmington and Hampstead Dialysis facility for SEDC – Wilmington to provide home training in home hemodialysis and peritoneal dialysis training.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
- C- In Section V, page 28, the applicant states that an accessible follow-up program for support of patients dialyzing at home will be provided by Southeastern Dialysis Center – Wilmington. See Exhibit 12 for a copy of a service agreement between SEDC – Wilmington and Hampstead Dialysis facility for SEDC – Wilmington to provide home training in home hemodialysis and peritoneal dialysis training.
- .2204(5) *X-ray services;*
- C- In Section V, page 28, the applicant states that X-ray services will be provided by New Hanover Regional Medical Center.
- .2204(6) *Laboratory services;*
- C- In Section V, page 28, the applicant states that laboratory services will be provided by Dialysis Laboratories.
- .2204(7) *Blood bank services;*
- C- In Section V, page 28, the applicant states that blood bank services will be provided by New Hanover Regional Medical Center.
- .2204(8) *Emergency care;*
- C- In Section V, page 28, the applicant states emergency care will be provided by New Hanover Regional Medical Center.
- .2204(9) *Acute dialysis in an acute care setting;*

-C- In Section V, page 28, the applicant states that acute dialysis in an acute care setting will be provided by New Hanover Regional Medical Center.

.2204(10) *Vascular surgery for dialysis treatment patients*

-C- See Section V, page 28, the applicant states vascular surgery for dialysis treatment patients will be provided by New Hanover Regional Medical Center and Wilmington Health.

.2204(11) *Transplantation services;*

-CA- In Section V.1, page 28, the applicant indicates that transplantation services will be provided by Carolinas Medical Center. However, the applicant failed to provide a copy of a transplantation agreement with Carolinas Medical Center or any center. Therefore, the application is approved subject to the following condition.

Prior to the issuance of the certificate of need, Total Renal Care of North Carolina, LLC d/b/a Hampstead Dialysis shall provide the Certificate of Need Section documentation of an agreement with a transplantation center to provide transplantation services.

.2204(12) *Vocational rehabilitation counseling and services; and,*

-C- In Section V, page 28, the applicant states that referrals will be made to NC Department of Vocational Rehabilitation for vocational rehabilitation counseling and services.

.2204(13) *Transportation*

-C- In Section V, page 28, the applicant states that transportation will be provided by MV Transportation, Inc.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

.2205(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, page 38, the applicant provides the proposed staffing for Hampstead Dialysis. The applicant states on page 38 that the facility will comply with all staffing requirements set forth in the Code of Federal Regulations. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be

provided. See Criterion (7) for discussion which is incorporated hereby as if set forth fully herein.

.2205(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 Section VII, pages 39-40 the applicant describes the training for new employees, ongoing in-service training and continuing education programs. Exhibit 19 contains the training outline.