

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: May 16, 2013

PROJECT ANALYST: Jane Rhoe-Jones  
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: Q-10103-13 / Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Martin County / Add two stations to establish a home hemodialysis program for a total of 25 dialysis stations upon completion of this project. Two of the 25 stations will be dedicated to home hemodialysis training and support /Martin 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 (TRC) of North Carolina, LLC d/b/a Dialysis Care of Martin County (DC of Martin County), operates a 23-station dialysis facility at 100 Medical Drive, Williamston, North Carolina. The applicant proposes to add two dialysis stations at Dialysis Care of Martin County for a total of 25 stations upon completion of this project. Two of the 25 dialysis stations will be dedicated to home hemodialysis training and support.

The 2013 State Medical Facilities Plan (2013 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2013 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility in Martin County. However, the applicant is eligible to apply for additional stations in the existing facility based on the facility need methodology because the utilization rate reported for Dialysis Care of Martin County is 3.26 patients per station. This utilization rate was calculated based on 75 in-center

dialysis patients and 23 certified dialysis stations. (75 patients / 23 stations = 3.26 patients per station).

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

<b>APRIL 1 REVIEW --- DIALYSIS CARE OF MARTIN COUNTY Q-10103-13</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/12		81.5%
Certified Stations		23
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>23</b>
In-Center Patients as of 6/30/12(SDR2)		75
In-Center Patients as of 12/31/11 (SDR1)		71
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	4
	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/11	0.1127
(ii)	Divide the result of step (i) by 12	0.0094
(iii)	Multiply the result of step (ii) by the number of months from the most recent month reported in the January 2013 SDR (6/30/12) until the end of calendar year 2012 (6 months)	0.0563
(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	79.2254
(v)	Divide the result of step (iv) by 3.2 patients per station	24.7579
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations] to determine the number of stations needed	<b>2</b>

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

Policy GEN-3: Basic Principles, pages 42-43 of the 2013 SMFP is applicable to this review.

Policy GEN-3 states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

### **Promote Safety and Quality**

The applicant discusses DaVita’s quality index in Section I, pages 7-8. Also, in Section II.3, pages 18-19, the applicant states,

*“DaVita Healthcare Partners Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita’s Quality Management Program is facilitated by a dedicated clinical team of RN and Biomedical Quality Management Coordinators working under the direction of our Director of Quality Management and Director of Integrated Quality Development. ... The program exemplifies DaVita’s total commitment to enhancing the quality of patient care through its willingness to devote the necessary resources to achieve our clinical goals. ...*

*DC of Martin County is attended by Nephrologists associated with Eastern Nephrology Associates, admitting Nephrologists who admit and round ESRD patients. In addition, Dr. Richard Merrill serves as Medical Director and provides the overall medical supervision of the dialysis unit. The facility unit administrator is the day to day manager of the facility and maintains the DaVita Quality Management Program that monitors the overall care of the patients. The Quality Management Program is reviewed by the Quality Assurance Committee consisting of the Nephrologists, Unit Administrator, clinical teammates, social worker and the dietitian. ... Continuous Quality Improvement teams address facility issues with the goal of improving patient care patient outcomes.”*

The applicant also discusses its safety measures in Section XI.6.(g), pages 56-57. In Exhibit 4 the applicant provides a copy of the 2011 End Stage Renal Disease (ESRD) Quality Incentive Program (QIP) results from the Centers for Medicare and Medicaid Services (CMS). In Exhibit 23, the applicant provides a copy of the index of the DaVita Injury Prevention and Safety Training Program. In Exhibit 15 are the isolation policies and procedures. Exhibit 24 has a copy of the in-service calendar which documents clinical classes designed to improve the clinical skills of the clinical staff.

The applicant adequately demonstrates how this proposal will promote safety and quality in the provision of dialysis services at Dialysis Care of Martin County.

### **Promote Equitable Access**

In Section VI, pages 31-34, Dialysis Care of Martin County provides information about accessibility to services. On page 31, the applicant states,

*“DC of Martin County, 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, or handicap or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.*

*DC of Martin County makes every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. DC of Martin County provides dialysis six days per week with two patient shifts per day.*

*DC of Martin County 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. DC of Martin County works with patients who need transportation, when necessary.”*

The applicant adequately demonstrates how this proposal will promote access to medically underserved groups.

### **Maximize Healthcare Value**

In Section III.9, page 24, the applicant states,

*“DC of Martin County promotes cost-effective approaches in the facility in the following ways:*

- *... The corporation has a centralized purchasing department that negotiates national contracts with numerous vendors in order to secure the best product available at the best price.*
- *DC of Martin County utilizes the reuse process that contains costs and the amount of dialyzer waste generated by the facility.*
- *DC of Martin County has installed an electronic patient charting system that reduces the need for paper in the facility. Much of the other documentation in the facility is also done on computer which reduces the need for paper.*
- *DC of Martin County Bio-Medical Technician assigned to the facility conducts preventative maintenance on the dialysis machines on a monthly, quarterly, and*

*semi-annual schedule that reduces the need for repair maintenance and parts. This extends the life of the dialysis machines.*

- *DC of Martin County also has an inventory control plan that ensures enough supplies are available without having an inordinate amount of supplies on hand. Supply orders are done in a timely manner to ensure that the facility does not run out of supplies, thus avoiding emergency ordering, which is costly.”*

The applicant adequately demonstrates how this proposal will maximize healthcare value. Additionally, the applicant demonstrates projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. The application is consistent with Policy GEN-3.

The application 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

The applicant, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Martin County, proposes to add two dialysis stations to its existing facility for a total of 25 certified stations upon completion of the project. Two of the 25 stations will be dedicated to home hemodialysis training and support.

Population to be Served

The January 31, 2013 SDR indicates a total of 23 certified stations and 75 in-center patients at the Dialysis Care of Martin County facility, as of December 31, 2012. In Section IV.1, page 25, the applicant identifies in-center the population, as illustrated below in the table.

Dialysis Care of Martin County December 31, 2012	
Patient Origin	In-center Patients
Martin County	73
Bertie County	1
Pitt County	1
Total	75

In Section IV.2, page 25, the applicant provides the following chart which depicts the in-center and home hemodialysis patients for the past three years. As of December 31, 2012, the applicant had eight home-trained patients.

Dialysis Care of Martin County		
Year	Beginning In-Center & Home Patients	Ending In-Center & Home Patients
2012	81	83
2011	77	81
2010	74	77

Based on patient origin information provided in the table in Section III.7, page 22 of the application, the applicant proposes dialysis units dedicated to home hemodialysis training and support. The projections for in-center and home hemodialysis for the first two years of operation following project completion are illustrated in the following table.

Dialysis Care of Martin County Projected Utilization						
County	Operating Year 1 1/1/14-12/1/14		Operating Year 1 1/1/15-12/1/15		% of Total	
	In-center	Home	In-center	Home	Year 1	Year 2
Martin	84	9	91	10	97.0%	98.0%
Bertie	1	0	1	0	1.1%	1.0%
Pitt	1	0	1	0	1.1%	1.0%
Total	86	9	93	10	100.0%	100.0%

The applicant adequately identifies the population to be served.

**Demonstration of Need/Need Analysis**

See Section II, pages 14-15, and Section III.7, pages 22-23. The applicant utilizes data from the January 2013 SDR and proposes to add two dialysis stations to Dialysis Care of Martin County, for a total of 25 stations; including two dedicated home hemodialysis training stations to serve the facility. The applicant provides the assumptions and methodology used to project utilization at Dialysis Care of Martin County.

**In-Center Assumptions and Methodology:**

- *“Dialysis Care of Martin County had 75 in-center patients as of June 30, 2012 based on information included on Page 6 of Table A of the January 2013 Semiannual Dialysis Report. This is station utilization rate of 81% based on the 23 certified stations in the facility. Of the 75 in-center patients cited in the SDR, 73 of the patients live in Martin County.*
- *We are applying for a two station expansion of the Martin County facility. These stations will be used for the development of a home hemodialysis training and support modality. The facility is currently certified for peritoneal dialysis and support. Even though the station [sic] will be utilized for home hemodialysis training and support, the additional stations will be added to the current twenty-three stations in order to justify need, that the facility will have at least 3.2 in-center patients per station, based on twenty-five stations, at the end of the proposed operating year one, which is December 31, 2014.*

- *Based on the patients and stations above, Dialysis Care of Martin County is projected to have at least 86 in-center patients by the end of operating year 1 for a utilization of 86% or 3.4 patients per station and at least 93 in-center patients by the end of operating year 2 for a utilization rate of 93% or 3.7 patients per station. This information is based on the calculations below. We have used a growth rate of 7.7% for the 73 in-center patients who live in Martin County.*
- *The period of growth begins with January 1, 2013 forward to December 31, 2015. The following are the in-center patient projections using the 7.7% Average Annual Change Rate for the Past Five Years as indicated on page 2 of Table B of the January 2013 Semiannual Dialysis Report for the 73 in-center patients residing in Martin County.*

*January 1, 2013-December 30, 2013 --- 73 patients X 1.077 = 78.621*

*January 1, 2014-December 30, 2014 --- 78.621 patients X 1.077 = 84.674817*

*January 1, 2014-December 30, 2014 --- 84.674817 patients X 1.077 = 91.1947779*

*Operating Year One is projected to begin January 1, 2014 and end on December 31, 2014*

*Operating Year Two is projected to begin January 1, 2015 and end on December 31, 2015*

*The number of patients stated in the chart above was rounded down to the nearest whole number.”*

- *“We did not provide a growth rate for the one patient living in Bertie County and the one patient living in Pitt County. Therefore, Dialysis Care of Martin County is projected to have 86 in-center patients at the end of operating year one (84 Martin County patients, one Bertie County patient and one Pitt County patient = 86 patients). The facility is projected to have 93 in-center at the end of operating year two (91 Martin County patients, one Bertie County patient and one Pitt County patient = 93 patients).*

Projected utilization at the end of Year One is greater than 3.2 in-center patients per station per week as required by 10A NCAC 14C .2203(b). Further, the number of in-center patients projected to be served is based on reasonable and supported assumptions regarding future growth.

#### Home Hemodialysis Assumptions and Methodology:

- *We are applying for a two station expansion of the Martin County facility. These stations will be used for the development of a home hemodialysis training and support modality. The facility is currently certified for peritoneal dialysis and support. Even though the station [sic] will be utilized for home hemodialysis training*

*and support, the additional stations will be added to the current twenty-three stations in order to justify need, that the facility will have at least 3.2 in-center patients per station, based on twenty-five stations, at the end of the proposed operating year one, which is December 31, 2014.*

- *The facility is projecting a total home-trained patient population of 9 patients at the end of operating year one and 10 patients at the end of operation year two. These projections are based on the projected number of home-trained patients living in Martin County on June 30, 2012 as indicated in the January 2013 SDR on page 2 of Table B. The home-trained patient population was projected to increase at 7.7%, which is the five-year average annual change rate for Martin County. See the calculations below:*

*January 1, 2013-December 30, 2013 --- 8 patients X 1.077 = 8.616*

*January 1, 2014-December 30, 2014 --- 8.616 patients X 1.077 = 9.279432*

*January 1, 2014-December 30, 2014 --- 9.279432 patients X 1.077 = 9.993948264*

*Operating Year One is projected to begin January 1, 2014 and end on December 31, 2014*

*Operating Year Two is projected to begin January 1, 2015 and end on December 31, 2015*

*The operating year two patient number was rounded up to ten since it was only a small fraction of a patient below ten patients.*

*The number of patients stated in the chart above was rounded down to the nearest whole number (except for the home-trained operating [sic] two number of patients.*

***NOTE: The patient numbers for operating year 1 and 2 will be used to determine the number of treatments, operating revenue and operating expenses in Section X of this application. This includes the home-trained patients.”*** [Emphasis in original.]

The applicant projects to serve nine home hemodialysis patients by the end of Year 1 and ten hemodialysis patients by the end of Year 2. Projected utilization is based on reasonable and supported assumptions regarding continued growth.

### **Access**

In Section VI, page 32, the applicant projects that 89% of the patients at Dialysis Care of Martin County will be covered by Medicare and Medicaid based on the current payor mix which is shown below in the table.

<b>Dialysis Care of Martin County Projected Payor Source</b>	
Medicare/Medicaid	34.2%
Medicare	27.4%
Medicare Commercial	26.0%
Commercial Insurance	5.5%
VA	5.5%
Medicaid	1.4%

Total	100.0%
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In summary, the applicant identifies the population to be served, adequately demonstrates access for medically underserved populations, and adequately demonstrates the need for two additional dialysis stations at Dialysis Care of Martin County. Consequently, 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.

NA

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

CA

In Section III.9, page 24, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – The applicant states this is not an effective alternative because the volume at Dialysis Care of Martin County is growing rapidly.
- 2) Add two stations for the home hemodialysis training and support services. The applicant states this is the most effective alternative to meet the growing demand for dialysis services at Dialysis Care of Martin County. Table B in the January 2013 SDR indicates an average annual change rate of over 7% in Martin County. Dialysis Care of Martin County is the only dialysis facility in Martin County. The applicant projects an in-center utilization rate of 86% or 3.4 patients per station by the end of the first operating year and 93% or 3.7 patients per station by the end of the second operating year; and nine home hemodialysis training patients by the end of the first operating year and ten home hemodialysis training patients by the end of the second operating year.

The applicant adequately demonstrates the need for two additional stations based on the continued growth of the ESRD patient population of Martin County and the facility's projected utilization. See Criterion (3) for further discussion on need which is incorporated hereby as if fully set forth herein. Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. An application that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal to add two stations 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 (TRC) of North Carolina, LLC d/b/a Dialysis Care of Martin County (DC of Martin County) shall materially comply with all representations made in the Certificate of Need application.**
  2. **Total Renal Care (TRC) of North Carolina, LLC d/b/a Dialysis Care of Martin County (DC of Martin County) shall develop no more than two additional stations for a total of no more than 25 stations, which shall include any home hemodialysis training and isolation stations.**
  3. **Total Renal Care (TRC) of North Carolina, LLC d/b/a Dialysis Care of Martin County (DC of Martin County) 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 39, the applicant states that the capital cost is projected to be \$38,640; which is itemized in the following chart.

<b>Dialysis Care of Martin County Capital Costs</b>	
<b>Item</b>	<b>Cost</b>
2 Dialysis Machines (home training)	\$29,700
2 Dialysis Chairs	1,940
2 TVs	3,000
Furniture	4,000
Total	\$38,640

In Sections IX.3, page 44, the applicant projects that there will be no start-up or initial operating expenses associated with the proposed project.

In Exhibit 18, the applicant provides a letter dated March 15, 2013 from the Interim Chief Financial Officer of DaVita which states that DaVita has committed cash reserves in the amount of \$38,640 for this project to expand Dialysis Care of Martin County by two stations.

In Exhibit 19, the applicant provides the audited financial statements for DaVita Healthcare Partners, Inc. for years ending December 31, 2011 and 2012. As of December 31, 2012, DaVita Healthcare Partners, Inc. had cash and cash equivalents totaling \$533,748,000 and

\$16,018,596,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the proposed project.

In Section X.1, page 46, the applicant projects that the allowable charges per treatment for each payment source are as follows:

<b>Dialysis Care of Martin County</b>	
<b>Payment Source</b>	<b>Charge per Treatment</b>
Medicare	\$240.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Medicare/Commercial	\$240.00
VA	\$193.00
Commercial Insurance	\$1,442.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. In Section X.2-X.4, pages 46-50, the applicant reported projected revenues and expenses as follows:

<b>Dialysis Care of Martin County</b>		
	<b>Operating Year 1</b>	<b>Operating Year 2</b>
Total Net Revenue	\$3,919,280	\$4,100,520
Total Operating Costs	\$3,269,320	\$3,431,870
Net Profit	\$649,960	\$668,650

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 48-49 of the application for the applicant’s assumptions.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the 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 d/b/a Dialysis Care of Martin County proposes to add two hemodialysis home training stations to the existing facility for a total of 25 dialysis stations upon project completion. Dialysis Care of Martin County, the only dialysis facility in Martin County is currently serving 75 patients weekly at 3.26 patients per station, which is 81% of capacity. The target utilization rate is 80%. Dialysis facilities that operate four shifts per week (2 per day on alternate days/ 3days per week) have a capacity of four patients per station. The applicant does not propose to establish a new facility. The applicant therefore is eligible to expand its facility and may apply for additional stations under the facility need

methodology. The applicant is therefore conforming to the requirement in 10A NCAC 14C .2203.

The applicant discusses projections for the in-center and hemodialysis home training patient populations in Section II, pages 13-14 and Section III, pages 22-23 of the application.

- In-Center Dialysis

At the end of Operating Year Two, with 25 dialysis stations and 93 dialysis patients after the two-station addition, the applicant projects utilization will be 3.7 in-center patients per station (93 patients / 25 dialysis stations = 3.72).

- Home Hemodialysis Training

At the end of Operating Year Two, with two dialysis stations and ten dialysis patients after the two-station addition, the applicant projects utilization will be five home-trained patients per station (10 patients / 2 dialysis stations = 5).

The applicant states that the growth projections are based on Martin County projected Average Annual Growth Rate of 7.7%. Dialysis Care of Martin County is the only dialysis facility in Martin County.

The applicant adequately demonstrates the need to add two dialysis stations for home hemodialysis training to the existing facility based on the number of in-center patients and home hemodialysis patients proposed in this application. 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 applicant 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 35, the applicant provides current and projected staffing for Dialysis Care of Martin County, as illustrated in the following table:

<b>Dialysis Care of Martin County</b>			
POSITION	CURRENT FTES	PROJECTE D # OF NEW FTES	TOTAL # FTES
RN	3.0	0	3.0
Home Training RN	1.0	0	1.0
PCT	10.0	1.0	11.0
Bio-Med Tech	.8	0	.8
MD	Contract		
Admin	1.0	0	1.0
Dietician	.8	0	.8
Social Worker	.8	0	.8
Unit Secretary	1.0	0	1.0
Other-Reuse	1.5	0	1.5
<b>Total</b>	<b>19.9</b>	<b>1.0</b>	<b>20.9</b>

As shown in the above table, the applicant plans to employ a total of 20.9 full-time equivalent (FTE) positions to staff the Dialysis Center of Martin County upon completion of the proposed project.

In Section VII.10, page 37-38, the applicant provides the following information on the proposed number of direct care staff for each shift offered at Dialysis Care of Martin County. The applicant states that the information provided in the chart is for patient care technicians, who are the direct care staff. The facility is staffed with two registered nurses Monday through Saturday, 6 a.m. to 4 p.m.

<b>Dialysis Care of Martin County</b>							
<b>Proposed Direct Care Staffing</b>							
	Hours	M	T	W	TH	F	SA
Morning	6a-10:30a	7	7	7	7	7	7
Afternoon	11a-4 pm	7	7	7	7	7	7

In Section VII.2, page 36, the applicant states Dr. Richard Merrill, Board Certified in Nephrology is current medical director and will continue in that role in the facility. The applicant provides a support letter from Dr. Merrill in Exhibit 13.

The information regarding staffing that the applicant provides in Section VII is reasonable and credible. The applicant adequately demonstrates the availability of adequate health manpower and management personnel, including a 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.

In Section V.1, page 27, the applicant lists the providers of the necessary ancillary and support services in response to 10A NCAC 14C .2204. Acute hospital care, emergency care beyond facility capability, diagnostic evaluation, transplantation, X-ray, blood bank, pediatric nephrology and vascular surgery will be provided by Vidant Medical Center-Greenville. Vocational rehabilitation counseling will be provided by the state Division of Vocational Rehabilitation Services and transportation will be provided by the Martin County DSS/Transportation Agencies. Other services will be provided by the applicant on site. Exhibits 9-11 contain documentation on service agreements.

The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health system. The information regarding coordination of services in Section V.2, page 28, includes the acute hospital agreement, transplant agreement, and follow-up care. Section V.4, page 29 includes physician referral relationships and physician support information. Section V.5, pages 29-30 documents relationships with physicians, hospitals and other health professionals. Section VII, pages 35-38 has healthcare staffing information. The documentation referenced in Exhibits 9-11 is reasonable and credible and supports a finding of conformity 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.

NA

- (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(b), page 31, the applicant reports that 89% of the patients who received treatments at Dialysis Center of Martin County had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payor mix for the facility. The applicant expects no change in the payor mix after implementation of this project:

<b>Dialysis Center of Martin County</b>	
<b>Payment Source</b>	<b>Percentage</b>
Medicare/Medicaid	34.2%
Medicare	27.4%
Medicare/Commercial	26.0%
VA	5.5%
Commercial Insurance	5.5%
Medicaid	1.4%
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 Martin County and statewide.

	<b>CY 2009 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>CY 2009 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>CY 2009 % Uninsured (Estimate by Cecil G. Sheps Center)*</b>
Martin County	25.0%	12.2%	21.5%

Statewide	17.0%	6.7%	19.7%
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\*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 Dialysis Care of Martin County facility. In fact, only 5.8% of all 2011 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.

The Centers for Medicare & Medicaid Services (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.*<sup>[1]</sup>

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:

<b>ESRD Spending by Payor</b>		
<b>Payor</b>	<b>Spending in Billions</b>	<b>% of Total Spending</b>
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 demonstrating the following:

<b>Number and Percent of Dialysis Patients by Age, Race and Gender</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Ages</b>		
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%
<b>Gender</b>		
Female	4,237	45.35%
Male	5,105	54.65%
<b>Race</b>		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%
Other	219	2.3%

Source: Southeastern Kidney Council (SKC) Network 6. Includes NC, SC & GA ([www.cms.gov/medicare/end-stage-renal-disease/esrd-network-organizations/downloads/esrd-network-program-background-public.pdf](http://www.cms.gov/medicare/end-stage-renal-disease/esrd-network-organizations/downloads/esrd-network-program-background-public.pdf))

The applicant demonstrates that it 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;

In Section VI.6 (a), page 34, the applicant states there have been no civil rights access complaints filed within 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 31, the applicant provides the projected payor mix for the proposed services at Greene County Dialysis Center. The applicant projects no change from the current Medicare and Medicaid payor mix for dialysis visits which is 89% of all patients served. The current payor mix is described above in Criterion (13a). The applicant demonstrates that medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5, page 33, the applicant states,

*“Patients with End Stage Renal Disease have access to dialysis services upon referral to a Nephrologist with privileges at DC of Martin County. These referrals most commonly come from primary care physicians or specialty physicians in Martin County. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact DC of Martin County directly or indirectly, the patient is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. Patients from outside the DC of Martin County catchment area requesting transfer to this facility are processed in accordance with the DC of Martin County transfer and transient policies which comprise **Exhibit 15** [sic]. The patient, again, is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary.” [Emphasis in original.]*

The transfer and transient policies are in Exhibit 14. The applicant adequately demonstrates that Dialysis Care of Martin County will provide a range of means by which a person can access the 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 28, the applicant states that Dialysis Care of Martin County has a clinical training agreement with Martin Community College. The applicant provides the agreement is provided in Exhibit 12.

The information provided in Section V.3 is reasonable and credible for an existing 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 add two dialysis stations (for home hemodialysis training) to its existing dialysis facility for a total of 25 certified stations upon completion of the proposed project. The January 2013 SDR shows that there is no deficit of dialysis stations in Martin County. However, the applicant proposes to add two stations based on the facility need methodology. DaVita is the only provider of dialysis services in Martin County. The utilization rate currently exceeds 82%.

In Section V.7, page 30, 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:

*“The proposed expansion of the facility is an effort to provide dialysis services to Martin and surrounding counties and is not intended to be a competitive venture. The effect of other facilities in surrounding counties would be difficult to determine since most patients from Martin County already receive treatment at the Dialysis Care of Martin County.*

*The effect upon competition 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 Dialysis Care of Martin County provides access to all qualified Nephrologists to admit his or her patients*

*There are six counties contiguous to Martin County: Washington, Bertie, Halifax, Edgecombe, Pitt and Beaufort Counties. Fresenius Medical care operates one facility in Washington, one facility in Bertie County, two facilities in Halifax County, one in county [sic] in Edgecombe County, three facilities in Pitt County and one facility in Beaufort County. TRCNC operates one facility in Edgecombe County. All of these facilities have their own sources of referrals.*

*The bottom line is that 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. DC of Martin County provides access to all qualified Nephrologists to admit his or her patients.”*

See also 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 two dialysis stations to the existing Dialysis Care of Martin County facility will have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- The applicant adequately demonstrates the need, based on ‘facility need,’ to add two dialysis stations (specifically for hemodialysis home training) for a total of 25 certified dialysis stations following project completion. The applicant also demonstrates that the proposed project will provide additional access to Martin County residents and is a cost-effective alternative.
- The applicant adequately demonstrates quality services will continue to be provided. 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 (Section V, pages 27-30) and staffing (Section VII, pages 35-38), as well as referenced exhibits is reasonable and credible and demonstrates the provision of quality services.
- The applicant adequately demonstrates it will continue to provide adequate access to medically underserved populations. In Section VI.1, page 31 the applicant states:

*“DC of Martin County, 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

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

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is conforming to all applicable regulatory review criteria. The specific criteria 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- The utilization rate shown in the July 2012 SDR is 81.5% as of June 30, 2012. See Section II, page 14, Section III.7, page 22, and Exhibit 7 (copy of the January 2013 SDR, Tables A and B).

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

- C- In Section IV.2, page 25, the applicant reports the 2010, 2011, and 2012 facility mortality rates, which were 7.9%, 8.9%, and 8.5%, respectively.

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

- C- In Section IV.3, page 25, the applicant states that Dialysis Care of Martin County has eight patients for whom home dialysis is provided.

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

- C- In Section IV.4, page 25, the applicant states that Dialysis Care of Martin County referred 14 patients for transplant evaluation in 2012. Dialysis Care of Martin County had one patient receive a transplant in 2012.

- .2202(a)(5) *The number of patients currently on the transplant waiting list;*  
-C- In Section IV.5, page 26, the applicant states that the Dialysis Care of Martin County has eight patients on the transplant waiting list.
- .2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*  
-C- In Section IV.6, page 26, the applicant reports a total of 78 hospital admissions in 2012; 87.2% were non-dialysis related and 12.8% were dialysis-related.
- .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- In Section IV.7, page 26, the applicant reports that in 2012 there was one patient with an infectious disease and that no patients converted to infectious status in 2012.

*(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*  
-NA- Dialysis Care of Martin County is an existing facility.
- .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.*  
-NA- Dialysis Care of Martin County is an existing facility.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*  
-NA- Dialysis Care of Martin County is an existing facility.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*  
-C- Exhibit 8 contains a copy of written policies and procedures for back up for electrical service in the event of a power outage.
- .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.*

- NA- Dialysis Care of Martin County is an existing facility.
- .2202(b)(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- See Sections VII.2, page 35 and XI.6(e-g), pages 56-57.
- .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- See Section III.7, page 22. Dialysis Care of Martin County provides projected patient origin based on historical experience using Martin County’s growth rate. The first two years of operation following completion of the project are as follows:

Dialysis Care of Martin County Projected Utilization						
County	Operating Year 1 1/1/14-12/1/14		Operating Year 1 1/1/15-12/1/15		% of Total	
	In-center	Home	In-center	Home	Year 1	Year 2
Martin	84	9	91	10	97.0%	98.0%
Bertie	1	0	1	0	1.1%	1.0%
Pitt	1	0	1	0	1.1%	1.0%

- .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.*
- NA- Dialysis Care of Martin County is an existing 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.1.(9), page 12, the applicant states, “*Total Renal Care of North Carolina, d/b/a Dialysis Care of Martin County 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.*
- NA- Dialysis Care of Martin County is an existing facility.
- .2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section II, pages 13-15 and Section III.7, page 21-23, the applicant projects to serve

86 in-center patients by the end of Year 1, which is 3.4 patients per station (86 / 25 = 3.4) or 86%.

- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section II, pages 12-14 and Section III.7, pages 22-23, 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- See Section V.1, page 27. Diagnostic evaluation services are provided by Vidant Medical Center-Greenville.
- .2204(2) *Maintenance dialysis;*
- C- See Section V.1, page 27. Dialysis Care of Martin County provides maintenance dialysis.
- .2204(3) *Accessible self-care training;*
- C- See Section V.1, page 27. The applicant proposes to add home hemodialysis services.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
- C- See Section V.2(d), page 28. Dialysis Care of Martin County provides an accessible follow-up program for support of patients dialyzing at home.
- .2204(5) *X-ray services;*
- C- See Section V.1, page 27. Vidant Medical Center-Greenville provides X-ray services for Dialysis Center of Martin County.
- .2204(6) *Laboratory services;*
- C- See Section V.1, page 27. Laboratory services are provided by Dialysis Laboratories.
- .2204(7) *Blood bank services;*
- C- See Section V.1, page 27. Blood bank services are provided by Vidant Medical Center-Greenville.
- .2204(8) *Emergency care;*
- C- See Section V.1, page 27. Emergency care is provided Vidant Medical Center-Greenville.
- .2204(9) *Acute dialysis in an acute care setting;*
- C- See Section V.1, page 27. Acute dialysis in an acute care setting is provided by Vidant Medical Center-Greenville.
- .2204(10) *Vascular surgery for dialysis treatment patients*
- C- See Section V.1, page 27. Vascular surgery for dialysis treatment patients is provided by Vidant Medical Center-Greenville.
- .2204(11) *Transplantation services;*
- C- See Section V.1, page 27. Transplantation services are provided by Vidant Medical Center- Greenville.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
- C- See Section V.1, page 27. Vocational rehabilitation counseling and services are provided by the North Carolina Division of Vocational Rehabilitation Services.
- .2204(13) *Transportation*
- C- See Section V.1, page 27. Transportation is provided by the Martin County Department of Social Services and various other providers.

**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.1-2 page 35-36, the applicant provides the proposed staffing. In Section VII.2, page 35, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. 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- See Section VII.3 and 5, page 35 for the qualifications or certifications held or required for the staff of Dialysis Care of Martin County. Also see Exhibit 17 for DaVita's training outline, Exhibit 23 for DaVita's Health and Safety Policy and Procedure Manual, and Exhibit 24 for the Dialysis Care of Martin County Annual In-Service Calendar.