

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: January 27, 2014

PROJECT ANALYST: Tanya S. Rupp  
INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: H-10198-13 / Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Montgomery County / Add one dialysis station for a total of 20 stations upon project completion / Montgomery County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Montgomery County is currently certified for 19 in-center dialysis stations. In this application, the applicant proposes to add one dialysis station for a total of 20 stations upon completion of this project.

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 July 2013 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional dialysis facility or for any additional dialysis stations in Montgomery County. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis facility, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. In this application, Dialysis Care of Montgomery County (DC Montgomery) is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate is 3.31 patients per station, or 82.9%. This utilization rate was calculated based on 63 in-center dialysis patients and 19 certified dialysis stations as of December 31, 2012 (63 patients / 19 stations = 3.31 patients per station). See the following table, from Section III.1, page 18 of the application:

**OCTOBER 1 REVIEW-JULY SDR**

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/12		82.9%
Certified Stations		19
Pending Stations		
<b>Total Existing and Pending Stations</b>		<b>19</b>
In-Center Patients as of 12/31/12 (SDR2)		63
In-Center Patients as of 6/30/12 (SDR1)		63
Step	Description	
(i)	Difference (SDR2 - SDR1)	0
	Multiply the difference by 2 for the projected net in-center change	0
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/12	0.0000
(ii)	Divide the result of Step (i) by 12	0.0000
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/11 until 12/31/12)	0.0000
(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	63.0000
(v)	Divide the result of Step (iv) by 3.2 patients per station	19.6875
	and subtract the number of certified and pending stations as recorded in SDR2 [19] to determine the number of stations needed	1

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.*” As shown in the table above, based on the facility need methodology for dialysis stations, DC Montgomery has a need for one additional station. The applicant proposes to add one new station and, therefore, the application is consistent with the facility need determination for dialysis stations. Thus, at the completion of this project, DC Montgomery will be certified for 19 in-center dialysis stations.

Policy GEN-3 in the 2013 SMFP is also applicable to this review. Policy GEN-3 states:

*“A CON 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 (SMFP) 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 CON 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 CON applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the SMFP as well as addressing the needs of all residents in the proposed service area.”*

### Promote Safety and Quality

In Section II.3, on pages 16 – 17, the applicant describes the efforts undertaken by DaVita HealthCare Partners, Inc., the ultimate parent company of DC Montgomery, to ensure the delivery of quality care and safety to its dialysis patients. 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.*

...

*Dialysis Care of Montgomery County is attended by Pinehurst Nephrology Associates, admitting Nephrologists who directly oversee the quality of care of the dialysis facility. In addition, Dr. Edward Hoehn-Saric 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 company’s 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. The Quality Assurance Program addresses the Dialysis Care of Montgomery County as a whole, then compares each sister unit to the whole and to industry standards. ...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 54-55. In Exhibit 4, the applicant provides a copy of DaVita’s Quality Incentive Program Results. In Exhibit 15, the applicant provides a copy of its isolation policies and procedures, in Exhibit 23, a copy of the safety training outline, and in Exhibit 24, a copy of its in-service training schedule. The applicant adequately demonstrates how its proposal will promote safety and quality in the provision of dialysis services in Montgomery County.

### Promote Equitable Access

In Section VI, page 30, the applicant discusses accessibility with regard to DC Montgomery County. On page 30, the applicant states,

*“Dialysis Care of Montgomery 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.*

*Dialysis Care of Montgomery 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. Dialysis Care of Montgomery County currently provides dialysis six days per week with two patient shifts each day.*

*Dialysis Care of Montgomery 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 underserved persons. Dialysis Care of Montgomery County works with patients who need transportation, when necessary.”*

The applicant adequately demonstrates how its proposal will promote access to dialysis services for medically underserved groups.

#### Maximize Healthcare Value

In Section III.9, pages 21 - 22, the applicant states,

*“Dialysis Care of Montgomery County promotes cost-effective approaches in the facility in the following ways:*

- *This application calls for the purchase of a dialysis machine, chair and TV (see section VIII of the application). The parent corporation, DaVita Healthcare Partners, Inc., operates over 1,900 dialysis facilities nationwide. 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.*
- *Dialysis Care of Montgomery County purchases all of the products utilized in the facility, from office supplies to drugs to clinical supplies, under a national contract in order to secure the best products at the best price.*
- *Dialysis Care of Montgomery County utilizes the reuse process that contains costs and the amount of dialyzer waste generated by the facility. The dialyzers are purchased under a national contract in order to get the best quality dialyzer for the best price.*
- *Dialysis Care of Montgomery 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.*
- *Dialysis Care of Montgomery County Bio-medical Technician assigned to the facility conducts preventive 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.*

- *Dialysis Care of Montgomery 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 its proposal will maximize healthcare value. Furthermore, the applicant demonstrates that projected volumes for the proposed services incorporate the basic principles in meeting the needs of dialysis patients to be served. Thus, the application is consistent with Policy GEN-3.

In summary, the application is consistent with the facility need determination in the 2013 SMFP and is consistent with Policy GEN-3. Therefore, 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

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Montgomery (DC Montgomery) currently operates a 19-station dialysis facility located in Biscoe, in Montgomery County. The applicant proposes to add one dialysis station to the existing facility for a total of 20 certified dialysis stations upon project completion. The applicant does not propose to provide home hemodialysis or peritoneal dialysis training and support at DC Montgomery. The July 2013 SDR reports DC Montgomery is currently certified for 19 in-center dialysis stations as of December 31, 2012, and was dialyzing 63 in-center patients from Montgomery, Moore, and Richmond Counties.

Population to be Served

In Section IV.1, page 23, the applicant identifies the population of in-center patients it currently serves, as illustrated in the table below.

COUNTY OF RESIDENCE	NO. IN-CENTER PATIENTS
Montgomery	54
Moore	6
Richmond	3
Total	63

In Section III.7, page 20, the applicant projects patient origin for DC Montgomery for the first two project years following the addition of the dialysis station. See the following table:

COUNTY OF RESIDENCE	OPERATING YEAR ONE	OPERATING YEAR TWO	COUNTY PATIENTS AS A % OF TOTAL	
	IN-CTR. PTS.	IN-CTR. PTS.	YEAR 1	YEAR 2
Montgomery	65	70	87.8%	88.6%
Moore	6	6	8.1%	7.6%
Richmond	3	3	4.1%	3.8%
Total	74	79	100.0%	100.0%

The applicant adequately identifies the population to be served.

Demonstration of Need

In Section III.7, pages 20-21, the applicant states its application is filed pursuant to the facility need methodology utilizing data from the July 2013 SDR. The applicant proposes to add one dialysis station to the existing facility for a total of 20 dialysis stations upon project completion.

In Section II.1, pages 13 – 14, the applicant provides the following assumptions for the proposed project:

- *“The facility had 63 in-center patients as of December 31, 2012[.]”*
- *The table in Section III.2 indicates that the facility is eligible for a one-station expansion, based facility need methodology[.]*
- *Dialysis Care of Montgomery County is located in Biscoe in Montgomery County, which has had an average annual change rate of 8% over the past five years.*
- *Utilizing the five-year average annual change rate for Montgomery County, the facility is projected to have 74 in-center patients at the end of operating year one for a utilization rate of 92% or 3.7 patients per station and 79 in-center patients at the end of operating year two for a utilization rate of 99% or 3.9 patients per station.*

In Section II.1, page 14, and Section III.7, page 20, the applicant states

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

*Operating Year Two is projected to begin January 1, 2016 and end on December 31, 2016”*

Thus, the applicant states the first two operating years will be the same as calendar years 2015 and 2016. However, in Sections II and III, all of the applicant’s calculations are based

on a fiscal year which runs from July 1 to June 30. Additionally, in Section XII, page 58, the applicant submitted a proposed timetable, including the projected completion date, which is July 1, 2014. Therefore, the analyst concludes that the statements on pages 14 and 20 are in error; the first two operating years for this project are Fiscal Years 2015 and 2016, not calendar years 2015 and 2016.

The applicant projects in-center utilization by growing only the Montgomery County patient population according to the Five Year Average Annual Change Rate (AACR) of 8% as reported in Table B in the July, 2013 SDR. As of December 31, 2012, DC Montgomery was serving 54 Montgomery County in-center patients. On pages 14 and 20, the applicant states:

*“January 1, 2013 - June 30, 2013 - 54 patients X 1.04 = 56.16.*

*July 1, 2013 - June 30, 2014 - 56.16 patients X 1.08 = 60.6528.*

*July 1, 2014 - June 30, 2015 - 60.6528 patients X 1.08 = 65.505024.*

*July 1, 2015 - June 30, 2016 - 65.505024 patients X 1.08 = 70.74542592.*

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

*Operating Year Two is projected to begin January 1, 2016 and end on December 31, 2016.*

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

*Dialysis Care of Montgomery County is projected to have 74 in-center patients at the end of operating year one and 79 in-center patients at the end of operating year two.”*

After the applicant projects growth in the Montgomery County dialysis patient population, it adds the six Moore County patients and the three Richmond County patients. The applicant does not grow the Moore or Richmond County patient populations. Thus, by the end of Operating Year One the applicant projects to serve a total of 74 in-center dialysis patients [65 + 6 + 3 = 74]. By the end of Operating Year Two, the applicant projects to serve 79 in-center dialysis patients [70 + 6 + 3 = 79]. Thus, the utilization rate projected for DC Montgomery County is 92% in Operating Year One [74 patients / 20 stations = 3.7; 3.7 / 4 = 0.925] and 98% in Operating Year Two [79 / 20 = 3.95; 3.95 / 4 = 0.987]. The applicant's projected in-center patient utilization at the end of Operating Year One exceeds the 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and supported assumptions regarding continued growth of Montgomery County patients at DC Montgomery. The applicant adequately demonstrates the need to add one dialysis station.

### Access to Services

In Section VI.1, page 30, the applicant states:

*“Dialysis Care of Montgomery 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.”*

The applicant projects 89.7 percent of its patients will be covered by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the service area, including the medically underserved, will have access to the proposed services.

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need for one additional dialysis station at DC Montgomery, and adequately demonstrates the extent to which all residents in the service area, in particular underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

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

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 21, the applicant discusses two alternatives considered prior to the submission of this application, which include the following:

- 1) Maintain the status quo. The applicant states this alternative is not effective because the dialysis patient population in Montgomery County is growing at a rate of 8% per year. Furthermore, the patient population of DC Montgomery grew by 31% over the past four years [63 in-center patients as of December 31, 2012 and 48 in-center patients as of December 31, 2009:  $(63 / 48) - 1 = 0.3125$ ].
- 2) Add one dialysis station. The applicant states that adding one additional station to the existing treatment space at DC Montgomery is the most effective alternative to meet the increasing demand for dialysis services at the facility and in the county.

The applicant adequately demonstrates the need for one additional station based on the continued growth of the ESRD patient population of Montgomery County and the facility's projected utilization. See Criterion (3) for further discussion on need, which is incorporated hereby as if set forth fully herein.

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

In summary, the applicant adequately demonstrates that the 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 Dialysis Care of Montgomery County shall materially comply with all representations made in the certificate of need application.**
  - 2. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Montgomery County shall develop no more than one additional dialysis station at Dialysis Care of Montgomery County for a facility total of no more than 20 in-center dialysis stations upon completion of this project.**
  - 3. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Montgomery County shall install plumbing and electrical wiring through the walls for no more than one additional dialysis station, for a facility total of no more than 20 in-center dialysis stations, which shall include any isolation or home hemodialysis stations.**
  - 4. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Montgomery 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.1, pages 38 - 39, the applicant projects a capital cost of \$21,009 for the proposed project, which will cover the cost of the dialysis chair, RO water treatment, television, and computer terminal. In Section VIII.3, page 40, the applicant states it will fund the capital needs of the proposed project from the cash reserves of DaVita Healthcare Partners Inc., the

ultimate parent company of Total Renal Care of North Carolina, LLC. In Section IX.3, page 43, the applicant states there will be no start-up or initial operating expenses associated with the proposed project, since it is an operational facility.

Exhibit 18 includes a letter dated September 6, 2013 from the Chief Accounting Officer of DaVita Healthcare Partners Inc., which states

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

*We are submitting a Certificate of Need application to expand our Dialysis Care of Montgomery County ESRD facility by one ESRD dialysis station. The project calls for a capital expenditure of \$21,009. This letter will confirm that DaVita Healthcare Partners Inc. has committed cash reserves in the total sum of \$21,009, for the project capital expenditure. DaVita Healthcare Partners Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to Total Renal Care of North Carolina, LLC.”*

In Exhibit 19, the applicant provides the audited financial statements for DaVita Healthcare Partners Inc. for the years ending December 31, 2012, 2011, and 2010. That report shows that, as of December 31, 2012, DaVita Health Care 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 needs of the project.

In Section X.1, page 45, the applicant projects the following charges per treatment for each payment source as shown below.

PAYMENT SOURCE	IN-CENTER CHARGE
Medicare	\$202.84
Medicaid	\$143.00
Medicare/Medicaid	\$253.55
Commercial Insurance	\$1,442.00
VA	\$193.00
Medicare/Commercial	\$253.55

The applicant projects net revenue in Section X.2, page 45, and operating expenses in Section X.4, page 48, of the application. The applicant projects revenues will exceed expenses in each of the first two operating years following completion of the project, as illustrated in the table below.

	OY 1 (CY 2015)	OY2 (CY 2015)
Total Projected Net Revenue	\$2,879,768	\$3,080,933
Total Projected Operating	\$2,531,713	\$2,675,269

Costs		
Projected Net Profit	\$348,055	\$405,664

In Section X.3, page 47, the applicant provides the following assumptions to project revenue for OY1 and OY2:

Assumptions

1. With regard to the first operating year, the number of in-center patients is based on 69 patients treated at the beginning of the year with growth during the year to 74 in-center patients;
2. The total number of treatments includes the in-center patients at an average of three treatments per week, per patient, for 52 weeks;
3. The total number of treatments is reduced by five percent to allow for missed treatments; and
4. Average reimbursement per treatment is based on the applicant’s historical experience and expected future reimbursement.
5. With regard to the second operating year, the number of in-center patients is based on 74 in-center patients treated at the beginning of the year with growth during the year to 79 in-center patients.
6. The total number of treatments is reduced by five percent to allow for missed treatments; and
7. Average reimbursement per treatment is based on the applicant’s historical experience and expected future reimbursement.

In Section X, pages 48-49, the applicant provides projected staffing and salaries. In Section VII, page 34, the applicant states the facility is in compliance with the requirements of 42 C.F.R. Section 494 (formerly 405.2100). Staffing by shift is provided on page 36. The applicant projects adequate staffing to provide dialysis treatments for the number of patients projected.

The applicant 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.

Total Renal Care of North Carolina, LLC, d/b/a Dialysis Care of Montgomery County proposes to add one dialysis station to the existing facility for a total of 20 certified dialysis stations upon project completion.

The applicant adequately demonstrates the need for one additional station based on the number of in-center patients it proposes to serve. According to the July 2013 SDR, as of December 31, 2012, DC Montgomery was operating at 83 percent of capacity, with 63 in-center patients on 19 stations ( $63 / 19 = 3.3$ ;  $3.3 / 4 = 0.829$ ). The target utilization rate is 80 percent or 3.2 patients per station, per week, at the end of the first operating year. Therefore, the applicant is eligible to expand its facility and may apply for additional stations, consistent with the facility need methodology in the 2013 SMFP. In Section III.7, page 20, the applicant states that at the end of Operating Year One, the facility will have 20 stations serving 74 patients, which is a utilization rate of 92 percent ( $72 / 20 = 3.7$ ;  $3.7 / 4 = 0.925$ ). The application is conforming to the performance standard promulgated in 10A NCAC 14C .2203. In addition, DC Montgomery County is the only dialysis facility in Montgomery County.

In Section V.7, on page 29, the applicant states:

*“The proposed expansion of the facility is an effort to provide dialysis services to this community and is not intended to be a competitive venture. Dialysis Care of Montgomery County is the only dialysis facility in Montgomery County. There are six counties contiguous to Montgomery County. Moore County has three dialysis facilities. All are operated by Total Renal Care of North Carolina, LLC and all are served by Pinehurst Nephrology Associates. Richmond County has two dialysis facilities. Both are operated by Total Renal Care of North Carolina, LLC and are served by Pinehurst Nephrology Associates....*

*... 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. Dialysis Care of Montgomery County provides access to all qualified Nephrologists to admit his or her patients.”*

The applicant adequately demonstrates a need for one additional station at DC Montgomery according to the facility need methodology, based on the number of in-center patients currently utilizing the facility.

The applicant adequately demonstrates the proposed project will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Therefore, 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.

In Section VII.1, page 34, the applicant provides the current and projected number of full-time equivalent (FTE) positions as shown in the table below.

POSITION	NUMBER OF CURRENT FTES	TOTAL FTES
Registered Nurse	3.0	3.0
Patient Care Technician	8.0	8.0
Bio-Medical Technician	0.5	0.5
Administrative	1.0	1.0
Dietician	0.5	0.5
Social Worker	0.5	0.5
Unit Secretary	1.0	1.0
Other (Reuse)	1.0	1.0
<b>Total</b>	<b>15.5</b>	<b>15.5</b>

The applicant does not propose to add any additional staff members following the addition of one in-center dialysis station to the existing facility. As shown in the table above, the applicant proposes to continue to employ a total of 15.5 FTE positions to staff DC Montgomery upon completion of the proposed project. In Section V.4, page 27, the applicant states that Dr. Edward Hoehn-Saric will continue to serve as medical director of the facility. Exhibit 13 contains a letter of support from Dr. Hoehn-Saric.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed in-center 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 Sections V.1 and V.2, on pages 25 - 26, the applicant lists the providers of the necessary ancillary and support services that will serve the patients dialyzing at DC Montgomery. Moore Regional Medical Center provides emergency services, acute hemodialysis services, diagnostic and evaluation services, X-ray services, blood bank services, and vascular surgery services. The other services are provided by the individual providers listed in the table provided on page 25. In addition, the applicant provides supporting documentation in Exhibits 9, 10, and 11. The applicant discusses coordination with the existing health care system in Sections V.2 – V.6, pages 26 - 28. The applicant provides supporting documentation of coordination with the existing health care system in Exhibits 12 and 13. The information provided in those sections and exhibits is reasonable and credible and supports a finding of conformity with 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;

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In Section VI.1, page 30, the applicant states

*“Dialysis Care of Montgomery 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.”*

The applicant’s dialysis policies, procedures, and guidelines with regard to accepting patients for dialysis care are located in Exhibit 14.

In Section VI.1, page 30, the applicant reports that 89.7% of the patients who received treatments at DC Montgomery had some or all of the services paid for by Medicare or Medicaid in the past year. The table below illustrates the current historical payor mix for the facility, as reported by the applicant.

<b>DC MONTGOMERY HISTORICAL PAYOR MIX</b>	
<b>PAYOR SOURCE</b>	<b>PERCENTAGE</b>
Medicare	24.1%
Medicaid	5.2%
Medicare/Medicaid	34.5%
Commercial Insurance	3.4%
VA	6.9%
Medicare/Commercial	25.9%
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 Montgomery County and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Montgomery County	23%	9.69%	23.6%
Statewide	17%	6.71%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the dialysis services offered by DC Montgomery. In fact, in

2011 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 or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

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 health 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 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 2011 Incident ESRD patient data by age, race and gender for Network 6, as shown below.

<b>NUMBER AND PERCENT OF DIALYSIS PATIENTS BY AGE, RACE, AND GENDER*</b>		
	<b># OF ESRD PATIENTS</b>	<b>% OF DIALYSIS POPULATION</b>
<b>Age</b>		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1529	16.4%
55-64	2370	25.4%
65-74	2258	24.2%
75+	1872	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	4,027	43.11%
Other	219	2.3%
Total	9,342	100.0%

\*Source: SKC Network 6, which includes North Carolina, South Carolina and Georgia.

The applicant demonstrates that medically underserved populations currently have adequate access to services available at DC Montgomery. Therefore, the application is conforming to this criterion.

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

**C**

In Section VI.1, page 31, the applicant states, “*Dialysis Care of Montgomery County has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons...*” In Section VI.6, page 33, the applicant states “*There have been no civil rights equal access complaints filed within the last five years.*” The application is conforming to this criterion.

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

C

In Section VI.1(c), page 31, the applicant provides the projected payor mix for the proposed dialysis services at the facility. The applicant projects no change from the current payor mix. The applicant projects 89.7% of all in-center patients will have some or all of the services paid for by Medicare and Medicaid, with VA covering another 6.9 percent.

In Section VI.2, pages 31-32, the applicant states the facility is designed and constructed to accommodate handicapped persons.

The applicant demonstrates that the elderly and medically underserved populations will continue to have adequate access to the proposed dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5, pages 32 - 33, the applicant describes the range of means by which patients will have access to the proposed dialysis services. The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity with this criterion.

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

C

In Section V.3, page 27, the applicant states DC Montgomery County has existing clinical training agreements with Montgomery Community College. Exhibit 12 contains a copy of the applicant's letter, addressed to the President of Montgomery Community College, offering DC Montgomery County as a clinical training site for nursing students. The applicant adequately demonstrates that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. The information provided is reasonable and credible and supports a finding of conformity with this criterion.

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

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

C

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Montgomery County proposes to add one dialysis station to its existing facility for a total of 20 in-center dialysis stations upon project completion.

The July 2013 SDR shows there is only one dialysis facility located in Montgomery County. The applicant is applying for one additional station based on the facility need methodology. The applicant adequately demonstrates the need for one additional station at DC Montgomery based on the number of in-center patients it proposes to serve. The July 2013 SDR reports that as of December 31, 2012, DC Montgomery was operating at 82.9% capacity, with 63 patients dialyzing on 19 stations [ $63 / 19 = 3.31$ ;  $3.31 / 4 = 0.8290$ ]. The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility, pursuant to 10A NCAC 14C .2203(b).

In Section V.7, pages 28 - 29, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services. DC Montgomery is the only dialysis facility in Montgomery County.

See also Sections II, III, V, VI and VII, in which the applicant discusses the cost-effectiveness, quality and access to the proposed services.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that adding one dialysis station to DC Montgomery will have a positive impact on cost-effectiveness, quality and access to the proposed service because:

- The applicant adequately demonstrates the need, based on the facility need methodology, to add one dialysis station for a total of 20 certified in-center dialysis stations upon completion of the proposed project. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to DC Montgomery dialysis patients;
- 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 (pages 25 - 28), and VII (pages 34 - 37), and referenced exhibits is reasonable and credible and demonstrates the provision of quality care.

- The applicant adequately demonstrates it will continue to provide adequate access to medically underserved populations. In Section VI.1, page 30, the applicant states:

*“Dialysis Care of Montgomery 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.”*

In Section VI, on pages 30 – 33, the applicant states that medically underserved populations will continue to have adequate access to DC Montgomery dialysis services.

The applicant states in Section VI.1(a), page 30, that DC Montgomery has a long history of providing dialysis services to all segments of the population, regardless of race, ethnicity, Medicaid and Medicare recipients, gender, or other considerations.

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

The applicant currently provides dialysis services at DC Montgomery. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen 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 Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

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

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

*(1) Utilization rates;*

-C- In Sections II and III, pages 12 and 20, the applicant states the utilization rate was 82.9% or 3.3 patients per station ( $63 / 19 = 3.31$ ).

*(2) Mortality rates;*

-C- In Section IV.2, page 23, the applicant states the mortality rates were 14.1%, 12.5% and 3.2% in 2010, 2011 and 2012, respectively.

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

-NA- In Section IV.3, page 23, the applicant states those patients who are candidates for home training are referred to Dialysis Care of Moore County. In Exhibit 11, the applicant provides a copy of the home training agreement currently in place.

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

-C- In Section IV.4, page 24, the applicant states DC Montgomery referred two patients for transplant evaluation in 2012. The applicant states four transplants were actually performed in 2012.

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

-C- In Section IV.5, page 24, the applicant states DC Montgomery has one patient currently on the transplant waiting list.

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

-C- In Section IV.6, page 24, the applicant states that there were 111 hospital admissions in 2012, 20 of which were dialysis related and 91 that were non-dialysis related.

- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*  
-C- In Section IV.7, page 24, the applicant states that there were no patients at the facility in 2011 or 2012 with an infectious disease.

*(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*

- (1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*  
-NA- DC Montgomery is an existing facility.

(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

- (A) timeframe for initial assessment and evaluation of patients for transplantation,  
(B) composition of the assessment/evaluation team at the transplant center,  
(C) method for periodic re-evaluation,  
(D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and  
(E) signatures of the duly authorized persons representing the facilities and the agency providing the services.  
-NA- DC Montgomery is an existing facility.

(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*  
-NA- DC Montgomery is an existing facility.

(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*  
-C- See Exhibit 8 for a copy of the policies and procedures for back-up electrical service in the event of a power outage for DC Montgomery.

(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- DC Montgomery is an existing facility.

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

-C- In Section XI.6(g), page 54, the applicant states, “*Dialysis Care of Montgomery County has and will continue to operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment and other relevant health safety requirements.*”

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

-C- In Section II.1, pages 13 - 14, and Section III.7, pages 20 - 21, the applicant provides the methodology and assumptions to project patient origin as presented in the following table:

COUNTY	OPERATING YEAR 1	OPERATING YEAR 2	COUNTY PATIENTS AS PERCENT OF TOTAL	
	IN-CTR.	IN-CTR.	YEAR 1	YEAR 2
Montgomery	65	70	87.8%	88.6%
Moore	6	6	8.1%	7.6%
Richmond	3	3	4.1%	3.8%
Total	74	79	100.0%	100.0%

Also see discussion in Criterion (3) which is incorporated hereby as if fully set forth herein.

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

-NA- DC Montgomery is an existing facility.

(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*

-C- In Section II.1, page 12, the applicant states, “*Total Renal Care of North Carolina d/b/a Dialysis Care of Montgomery 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.*”

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

(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the*

*performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- DC Montgomery does not propose to establish a new End Stage Renal Disease facility.

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

-C- DC Montgomery projects 3.7 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 12 - 13, and Section III.7, pages 20 - 21. See also Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 12 - 13, and Section III.7, pages 20 - 21. See also Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

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

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

*(1) diagnostic and evaluation services;*

-C- In Section V.1, page 25, the applicant states patients will receive diagnostic and evaluation services from Moore Regional Hospital.

*(2) maintenance dialysis;*

-C- In Section V.1, page 25, the applicant states patients will receive maintenance dialysis services at the facility.

*(3) accessible self-care training;*

-C- In Section II.1, page 15, the applicant refers to Section V.1, page 25 for the information which responds to this rule. However, the section of the table on page 25 that refers to self-care training is blank, but on page 23 the applicant states patients are referred to Dialysis Care of Montgomery County for home training.

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

-C- In Section II.1, page 15, the applicant refers to Section V.1, page 25. The table on page 25 provides no information with regard to an accessible follow-up program for patients dialyzing at home. However, in Section IV.4, on page 23, the applicant

states those patients desiring home dialysis training and support will be served at Dialysis Care of Moore County.

(5) *x-ray services;*

-C- In Section V.1, page 25, the applicant states x-ray services will be provided by Moore Regional Hospital.

(6) *laboratory services;*

-C- In Section V.1, page 25, the applicant states laboratory services will be provided by Dialysis Laboratories.

(7) *blood bank services;*

-C- In Section V.1, page 25, the applicant states blood bank services will be provided by Moore Regional Hospital.

(8) *emergency care;*

-C- In Section V.1, page 25, the applicant states emergency care services will be provided by Moore Regional Hospital.

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

-C- In Section V.1, page 25, the applicant states acute dialysis services will be provided by Moore Regional Hospital.

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

-C- In Section V.1, page 25, the applicant states vascular surgery services will be provided by Moore Regional Hospital.

(11) *transplantation services;*

-C- In Section V.1, page 25, the applicant states transplantation services will be provided by UNC and Duke UMC.

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

-C- In Section V.1, page 25, the applicant states vocational rehabilitation counseling and services will be provided by North Carolina Division of Vocational Rehabilitation Services.

(13) *transportation.*

-C- In Section V.1, page 25, the applicant states transportation services will be provided by the department of social services and “*other providers.*”.

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

(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.*

- C- In Section VII.1, on page 34, the applicant states that all staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). See Criterion (7) for further discussion on staffing which is incorporated hereby as if fully set forth herein.
  
- (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.5, on page 36, and in Exhibit 17 the applicant provides a copy of the applicant's policies with regard to training for nurses and technicians in dialysis techniques at the facility.