

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 28, 2015  
Findings Date: January 30, 2015

Project Analyst: Jane Rhoe-Jones  
Assistant Chief: Martha J. Frisone

Project ID #: M-10323-14  
Facility: Sampson County Home Dialysis  
FID #: 140334  
County: Sampson  
Applicant(s): Total Renal Care, Inc.  
Project: Develop a new freestanding home training program for peritoneal dialysis patients

### 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.

NA

Total Renal Care, Inc. (TRC) d/b/a Sampson County Home Dialysis proposes to develop a new kidney disease treatment center which will provide only home peritoneal dialysis (PD) training and support services. Sampson County Home Dialysis will be located at 313 Northeast Boulevard, Clinton, NC 28328 (primary site). TRC does not propose to develop any certified dialysis stations as part of this project.

Neither the 2014 State Medical Facilities Plan (SMFP) nor the July 2014 Semiannual Dialysis Report (SDR) provides a need methodology for determining the need for PD home training programs. There are no policies in the SMFP applicable to this proposal. Therefore, this criterion is not applicable to this application.

- (2) Repealed effective July 1, 1987.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, Inc. (TRC) d/b/a Sampson County Home Dialysis, whose parent company is DaVita Healthcare Partners, Inc., proposes to develop a new kidney disease treatment center which will provide only home PD training and support services in leased space in Clinton. In Section I, page 3, the applicant states:

*“PD patients do not utilize dialysis stations for training. Rather, PD patients are taught the concepts of peritoneal dialysis which utilizes the peritoneal lining of the abdomen as the ‘filtering’ device. Peritoneal dialysis involves the introduction of a dialysate fluid into the peritoneal cavity of the abdomen. The dialysate is drained and replaced at regular intervals as prescribed by the physician treating the patient.”*

**Population to be Served**

In Section III.7, page 27, the applicant identifies the projected home PD patients to be served by county of residence during each of the first two years of operation following completion of the project, as illustrated below in the table:

<b>SAMPSON COUNTY HOME DIALYSIS</b>						
<b>Projected Utilization</b>						
<b>County</b>	<b>Operating Year 1 CY 2016</b>		<b>Operating Year 1 CY 2017</b>		<b>% of Total</b>	
	<b>In-center</b>	<b>Home PD</b>	<b>In-center</b>	<b>Home PD</b>	<b>Year 1</b>	<b>Year 2</b>
Sampson	0	7	0	8	77.8%	80.0%
Duplin	0	2	0	2	22.2%	20.0%
<b>Total</b>	<b>0</b>	<b>9</b>	<b>0</b>	<b>10</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant adequately identifies the population proposed to be served.

**Need Analysis**

In Section III.7, page 27, the applicant states:

*“TRC is proposing to develop a free standing home peritoneal dialysis training facility to be located at 313 North Boulevard in Clinton. The facility will exclusively offer home dialysis training and support for patients choosing home peritoneal dialysis.”*

In Section III.7, page 28, the applicant states:

*“The home dialysis patient population in North Carolina is growing. The information in the chart below is extracted from the July Semiannual Dialysis report for the years indicated. The row labeled ‘State Wide’ reports the total ESRD patient population in North Carolina. The row labeled ‘Home’ reflects the total home patient population for each of the years cited. The last column in each row calculates the five year average annual change in the ESRD patient population. This is the same methodology used by the Medical Facilities Planning Section to develop the county five year average annual change rate.”*

*Projected Utilization*

The applicant uses statewide and Sampson County home trained dialysis patient population data from the July 2009-2013 SDRs to project utilization at the proposed Sampson County Home Dialysis Center. The following tables are reproduced from page 28 of the application.

<b>Total ESRD Patient Population - Statewide</b>						
<b>Data is as of...</b>	<b>July09</b>	<b>July10</b>	<b>July11</b>	<b>July12</b>	<b>July13</b>	<b>Average % Change</b>
Statewide Patient Population	13,751	14,232	14,619	15,032	15,574	
Raw Change		481	387	413	452	
Percentage Change		3.50%	2.72%	2.83%	3.61%	3.17%

<b>Total ESRD Home Patient Population - Statewide</b>						
<b>Data is as of...</b>	<b>July09</b>	<b>July10</b>	<b>July11</b>	<b>July12</b>	<b>July13</b>	<b>Average % Change</b>
Statewide Home Patient Population	1,344	1,554	1,697	1,840	1,955	
Raw Change		210	143	143	115	
Percentage Change		15.63%	9.20%	8.43%	6.25%	11.37%

The applicant also states,

*“Over the past five years the statewide home patient population has grown at a rate of over 3.5 times the growth rate of the overall patient population. Even though the annual growth has declined, the 2013 data indicates that the home program growth is almost two times that of the overall patient population growth in North Carolina.”*

The following tables are reproduced from page 28.

<b>Total ESRD Patient Population – Sampson County</b>
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Data is as of...	July09	July10	July11	July12	July13	Average % Change
Sampson County Patient Population	142	161	164	160	162	
Raw Change		19	3	-4	2	
Percentage Change		13.38%	1.86%	-2.44%	1.25%	3.51%
<b>Total ESRD Home Patient Population - Sampson County</b>						
Data is as of...	July09	July10	July11	July12	July13	Average % Change
Sampson County Home Patient Population	7	13	14	13	17	
Raw Change		6	1	-1	4	
Percentage Change		85.71%	7.69%	7.14%	30.77%	29.26%

The applicant further states,

*“Sampson County has experienced a 3.51% five year average change rate for the overall patient growth. The five year average annual change rate for the home training patient population in Sampson County has been 29.26%, which is over eight times the overall Sampson County patient population.”*

In Section III.7, pages 29-31, the applicant provides the following assumptions and methodology used to project the number of home PD patients. On pages 29-30, the applicant states:

[Assumptions:]

- *“The project is scheduled to be certified on January 1, 2016. Operating year one will be January 1, 2016-December 31, 2016. Operating year two will be January 1, 2017-December 31, 2017.*
- *The five-year average annual change rate for home-trained patients living in North Carolina between January 2009 through January 2013 was 11.37%*
- *The five-year average annual change rate for home-trained patients living in Sampson County between January 2009 through January 2013 was 29.26%*
- *The North Carolina facilities operated by DaVita Healthcare Partners, Inc. subsidiaries have experienced an overall annual change rate of 15.45% in the growth of peritoneal dialysis population between January 2009 and January 2013.*
- *DaVita facilities operated by subsidiaries in North Carolina indicate that 11.8% of the overall patient population they serve are peritoneal dialysis patients.*
- *TRC assumes that the Sampson County Home Dialysis program will grow at a rate of at least 11.3% each year during the first two years of operation which mirrors the five-year average annual change rate for home training growth in North Carolina, but is significantly lower than the five year average annual change rate experienced in Sampson County.*
- *Sampson County has experienced a 3.5% five year average annual change rate as indicated in the January 2014 SDR.*

- *The July 2014 SDR indicates in Table B that Sampson County has projected 10.5% home patient population.*
- *The July 2014 SDR indicates in Table B that Sampson County had projected 17.6 home trained patients as of December 31, 2014 using the five-year average annual change rate of 3.5%*
- *The July 2014 SDR indicates in Table B that Sampson County had 17 home trained patients as of December 31, 2013.*
- *The Patient Origin Report that was published by the Medical Facilities Planning Section indicates that DaVita facilities were serving 10 of the 17 home trained patients who live in Sampson County or 58.8% of the home trained patients. See **Exhibit 13** for copy of the Patient Origin Report. [Emphasis in original.]*
- *The ESRD Data Reports submitted by DaVita indicate that six of the ten home-trained patients living in Sampson County were peritoneal dialysis patients or 60%*
- *The two Fresenius facilities located in Sampson County were serving one home trained patient who lives in Sampson County or 5.9% of the home trained patient population living in Sampson County.”*

[Methodology:]

- *“TRC begins with the home trained projected patient population in Sampson County as of December 31, 2013 as stated in the July 2014 SDR: **17 home trained patients**. [Emphasis in original.]*
- *TRC projects this population forward to December 31, 2014 using the home-training five year average annual change rate of 11.3% **17 X 1.113 = 18.921**. [Emphasis in Original.]*
- *TRC projects this population forward for one year to December 31, 2015 using the five-year average annual change rate of 11.3% - **14.235** [sic] X **1.113 = 21.059073**” [Emphasis in Original. The applicant made a typographical error in the above formula. The formula should read **18.921 X 1.113 = 21.059073**.]*
- *“The above calculations indicate the number of projected home trained patients in Sampson County as of December 31, 2013 based on the information contained in Table B of the July 2014 SDR. The projected home trained patient population was grown through December 31, 2015 using an average annual growth rate of 11.3%*
- *Based on the above calculations, it is projected that there would be 21 home trained patients residing in Sampson County as of December 31, 2015, the day before the projected certification of Sampson County Home Dialysis.*
- *Given that 58.8% of the home-trained patient population residing in Sampson County receive services at DaVita owned facilities, then 12 of the home-trained patients would be receiving services at DaVita owned facilities (21 X .588 = 12.348).*
- *Given that 60% of the home trained patients being served at DaVita owned facilities are peritoneal dialysis patients, then 7 peritoneal dialysis patients would be receiving services at DaVita owned facilities (12.348 X .6 = 7.4088).*

- *Since two peritoneal dialysis patients who live in Duplin County live closer to the primary site for the Sampson County Home Dialysis than to either the Goldsboro Dialysis Center or the Wallace Dialysis Center, TRC projects that these two patients will transfer their care to Sampson County Home Dialysis. These two patients have signed letters indicating they will consider transferring to Sampson County Home Dialysis.”*

On pages 30-31, the applicant states,

*“TRC is using an annual change rate of 11.3% which is the experience the dialysis home training and support program has averaged over the past five years in North Carolina. TRC sees this as a conservative number since the Sampson County five-year average change rate for home training is 29.26%”*

*Total Renal Care, Inc. projects that when the facility opens on January 1, 2016, there will be nine (9) peritoneal dialysis patients on the waiting list for admission (7 Sampson County patients and 2 Duplin County patients = 9 patients). TRC projects that no additional peritoneal dialysis patients will be admitted during operating year one. TRC projects that one additional peritoneal dialysis patient will be admitted during operating year two for a total of ten (10) peritoneal dialysis patients (8 Sampson County patients and 2 Duplin County patients = 10 patients). The calculations below indicate the growth of the Sampson County Home Dialysis patient population from the proposed certification date through operating year two based on the seven Sampson County Peritoneal Dialysis patients. The two Duplin County patients were then added.*

*January 1, 2016-December 31, 2016 -  $7 \times 1.113 = 7.791$  + 2 Duplin County PD patients = 9.791*

*January 1, 2017-December 31, 2017 -  $7.791 \times 1.113 = 8.671383$  + 2 Duplin County PD patients = 10.67138.3*

*The patient numbers were rounded down to the nearest whole number.*

*Operating Year 1 is projected to begin January 1, 2016 and end December 31, 2016  
Operating Year 2 is projected to begin January 1, 2017 and end December 31, 2017*

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth of the home trained population.

### **Access**

In Section VI, page 41, the applicant states that DaVita has “a long history of providing dialysis services to the underserved populations in North Carolina.” On page 42, the applicant projects that 72.9% of its patients will be covered by Medicare (70.7%) or Medicaid

(2.2%). The applicant adequately demonstrates the extent to which all residents of the area, including medically underserved groups, are likely to have access to the proposed services.

### **Conclusion**

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the proposed project based on reasonable and adequately supported utilization projections and demonstrates the extent to which all residents of the area, including medically underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

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

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, pages 31-32, the applicant describes having considered four alternatives which include the following:

1. Do nothing – the applicant concludes that ten home PD patients would have to continue to travel outside of Sampson County for services at DaVita facilities. Any future patients would have to travel outside the county as well.
2. Develop the facility in other counties – the majority of the patients to be served live in Sampson County and the treating nephrologists have satellite offices in Clinton. Therefore, the applicant concludes the most effective location is in Sampson County.
3. Develop the facility in a location other than Clinton – Clinton is near the center of Sampson County and provides the most effective location within Sampson County.
4. Develop the facility in Clinton - The applicant concluded that this option is the most effective and least costly alternative to meet the need. The applicant states, “*Clinton is located just east of the center of Sampson County. DaVita affiliates are serving six peritoneal dialysis patients in three facilities that are contiguous to Sampson*

*County. The town of Faison with two peritoneal dialysis patients is much closer to Clinton than to Goldsboro or Wallace, the two closest DaVita affiliates that offer peritoneal dialysis training and support.”*

A project that cannot be approved cannot be an effective alternative. The application is conforming to all other applicable statutory and regulatory review criteria, and thus, is approvable. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **Total Renal Care, Inc. d/b/a Sampson County Home Dialysis shall materially comply with all representations made in the certificate of need application.**
  2. **Total Renal Care, Inc. d/b/a Sampson County Home Dialysis shall establish a kidney disease treatment center to provide only home peritoneal dialysis (PD) training and support services.**
  3. **Prior to the insurance of the certificate of need, Total Renal Care, Inc. d/b/a Sampson County Home Dialysis shall provide to the Agency copies of letters sent to the President of Sampson Community College and to the Sampson County Schools offering Sampson County Home Dialysis as a clinical training site.**
  4. **Total Renal Care, Inc. d/b/a Sampson County Home Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to the issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, page 50, the applicant states that the proposed capital cost of the project is \$644,281 including \$353,500 for construction contract costs, \$217,981 for equipment and furniture costs, \$45,000 for architect/engineering costs, \$23,300 for other costs (dialysis chairs and computer terminal), and \$4,500 for televisions. In Section IX.1, page 54, the applicant projects start-up expenses associated with the proposed project will be \$73,125, including \$25,000 for consumable supplies and \$48,125 for staff training. Also on page 54, the applicant projects initial operating expenses of \$277,009. The initial operating expenses are projected to cover the first six months of operation of Sampson County Home Dialysis including the “*up-fit of the facility*”. Therefore, the applicant projects total working capital at \$350,134. In Section VIII.2, page 51 and Section IX, page 55, the applicant states that these costs will be funded by cash reserves provided by DaVita HealthCare Partners Inc., the parent company of Total Renal Care, Inc. Exhibit 25 of the application contains the audited financial statements for DaVita HealthCare Partners Inc. for the years ending December 31, 2013 and December 31, 2012. As of December 31, 2013, DaVita had \$946,249,000 in cash and cash equivalents, \$17,098,877,000 in total assets and \$5,302,841,000 in net assets [total assets (\$17,098,877,000) less total liabilities (\$11,796,036,000)].



Exhibit 24 contains a letter dated August 13, 2014 from the Chief Accounting Officer of DaVita, Inc. The letter states in part:

*“I am the Chief Accounting Officer for DaVita HealthCare Partners, Inc., (‘DaVita’) the parent company and 100% owner of Total Renal Care, Inc. (‘TRC’). TRC is submitting a Certificate of Need application to develop a stand-alone peritoneal dialysis outpatient training and follow-up facility, at a site in Clinton, in Sampson County.*

...

*I am writing this letter ... to confirm DaVita’s commitment of \$644,281 for the capital expenditures associated with this project; a commitment of \$73,125 for its start-up expenses; and a further commitment of \$277,009 in working capital to cover expenses ...*

*DaVita has committed cash reserves in the total sum of \$994.415. for the capital costs, start-up costs and working capital for this project. ...”*

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

In Section X.3, page 58, the applicant states:

*“For each source of revenue the assumption used was ... total # of treatments times 3% for missed treatments times payor percentage times payor reimbursement rate for the projected in-center [sic] treatments. The total reimbursement each week is based on three treatments [sic] billed and reimbursed.”*

In Section X.3, page 58, the applicant provides the projected rates by payor for the proposed facility, as shown below in the table.

<b>SAMPSON COUNTY HOME DIALYSIS</b>			
<b>PD Home Training</b>	<b>% of Total</b>	<b># Treatments</b>	<b>Reimbursement per Treatment</b>
<b>Operating Year 1</b>			
Medicare	70.7%	963	\$239.02
Commercial	24.9%	339	\$1,275.00
Medicaid	2.2%	30	\$143.00
VA	2.2%	30	\$193.00
<b>Operating Year 2</b>			
Medicare	70.7%	1,016	\$239.02
Commercial	24.9%	358	\$1,275.00
Medicaid	2.2%	32	\$143.00
VA	2.2%	32	\$193.00

This information is consistent with the payor mix reported by the applicant in Section VI.1(c), pages 41-42 of the application.

In Section X.4, page 60, the applicant reports projected revenues and expenses, as illustrated below in the table:

<b>SAMPSON COUNTY HOME DIALYSIS</b>		
	<b>OPERATING YEAR 1</b>	<b>OPERATING YEAR 2</b>
Total Net Revenue	\$626,446	\$661,477
Total Operating Costs	\$554,017	\$577,291
<b>Net Profit</b>	<b>\$72,429</b>	<b>\$84,186</b>

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. 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

According to the January 2014 SDR, there are two Kidney Disease Treatment Centers (dialysis facilities) located in Sampson County – BMA of Clinton and FMC of Roseboro. Fresenius, though a subsidiary, is the owner of both facilities. TRC proposes to develop a third facility which will provide only home PD training and support services in Clinton. TRC does not propose to develop any hemodialysis stations as a part of this project. In the second operating year, the facility is projected to serve ten home PD patients living in Sampson (80%) and Duplin (20%) counties. The discussion regarding projected utilization found in Criterion (3) is incorporated herein.

FMC Roseboro is currently the only existing provider of home PD training and support services in Sampson County. BMA of Clinton was issued a certificate of need effective September 25, 2013 authorizing BMA of Clinton to offer home PD training and support services. According to Google Maps, the proposed facility would be located approximately 2.0 miles or three minutes from BMA of Clinton and it would be located 12.7 miles (via NC-24) or 13.7 miles) via NC-411, or 18-19 minutes from Roseboro.

According to the June 2014 ESRD Data Collection Form (Time Period: January 1, 2014 – June 30, 2014), FMC Roseboro reported serving one home PD patient. In the June 2013 ESRD Data Collection Form, FMC Roseboro reported serving three home PD patients. FMC Roseboro reported serving no home PD patients in the December 2012 ESRD Data Collection Form.

The applicant adequately demonstrates that the proposed facility will not result in the unnecessary duplication of existing or approved home PD training and support services located in Sampson County. Consequently, the application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.10, page 48, the applicant states that the Sampson County Home Dialysis will operate Monday-Friday, from 7 a.m. to 5 p.m. with a qualified home training registered nurse on call 24 hours a day / 7 days a week. In Section VII.1, page 46, the applicant provides the proposed staffing during the first two operating years following completion of the project, as illustrated below in the table.

<b>SAMPSON COUNTY HOME DIALYSIS</b>	
<b>POSITION</b>	<b>PROJECTED FULL TIME EQUIVALENT POSITIONS (FTES) YEARS 1 AND 2</b>
PD HTRN	1.0
Admin.	0.3
Dietitian	0.3
Social Worker	0.3
Unit Secretary	0.5
<b>Total</b>	<b>2.4</b>

As shown in the above table, the applicant proposes to employ a total of 2.4 FTE positions to staff the PD home training facility during the first two operating years following completion of the project. In Section V.4(c), page 38, the applicant states that Dr. Ajay Shreenath has agreed to serve as the Medical Director for Sampson County Home Dialysis. See Exhibit 17 for a letter dated June 25, 2014, from Dr. Shreenath expressing his willingness to serve as the Medical Director for Sampson County Home Dialysis.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel, including a medical director, for the provision of PD home training and support services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section V.1, pages 35-36, the applicant provides a list of proposed providers of ancillary and support services. Exhibit 7 contains a copy of a letter of intent to enter a transplantation

agreement with Vidant Medical Center-Greenville. Exhibit 6 contains letters of intent to execute Patient Transfer Agreements from Wayne Memorial Hospital and Sampson Regional Medical Center. Each letter identifies the services to be provided by the hospital. Exhibit 15 contains a copy of a laboratory services agreement between DaVita Laboratory Services, Inc. and DVA Laboratory Services, Inc. and DaVita, Inc. to provide special, immunological and routine laboratory services to DaVita, Inc.

The following table from Section V.1, pages 35-36, illustrates proposed ancillary and support services and the proposed providers.

<b>SAMPSON COUNTY HOME DIALYSIS</b>	
<b>Service</b>	<b>Proposed Facility(ies)</b>
Acute dialysis in acute care setting	Wayne Memorial Hospital
Emergency care	Wayne Memorial Hospital & Sampson Regional Medical Center
Diagnostic evaluation services	Wayne Memorial Hospital & Sampson Regional Medical Center
X-Ray services	Wayne Memorial Hospital & Sampson Regional Medical Center
Blood bank	Wayne Memorial Hospital & Sampson Regional Medical Center
Pediatric nephrology	Vidant Medical Center-Greenville
Vascular surgery	Wayne Memorial Hospital

In Section II.2, page 23 and Section V.1, pages 35-36, the applicant states that Sampson County Home Dialysis will provide the following services: (1) CAPD, (2) CCPD, (3) psychological counseling, (4) nutritional counseling, (5) patient education, (6) emergency care, (7) diagnostic services, (8) social work services, (9) pharmaceutical support, (10) home training assessment, (11) transplant evaluation, and (12) intermittent peritoneal dialysis. Goldsboro Dialysis (a TRC or DaVita facility) will provide maintenance dialysis and hemodialysis. The NC Department of Vocational Rehabilitation will provide vocational rehabilitation counseling and services and Sampson Area Transportation will provide transportation services.

In Exhibit 18, the applicant provides letters of support to include: five Sampson County patients and two Duplin County patients, area physicians, Sampson County, the City of Clinton, other local government and community agencies, and the North Carolina Division of Vocational Rehabilitation Services.

The applicant adequately demonstrates that the proposal will be coordinated with the existing health care system and that necessary ancillary and support services will be available. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

- (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;

NA

Sampson County Home Dialysis is not an existing facility.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by

minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.1(f), page 43, the applicant states:

*“Sampson County Home Dialysis will have no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993.”*

In Section VI.6(a), page 45, the applicant states there have been no patient civil rights access complaints filed within the last five years against any TRC or DaVita facility in North Carolina. 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), pages 41-42, the applicant provides the projected payor mix for the proposed services at Sampson County Home Dialysis, as illustrated below in the table.

SAMPSON COUNTY HOME DIALYSIS	
PAYOR	%
Medicare	70.7%
Commercial Insurance	24.9%
Medicaid	2.2%
VA	2.2%
<b>Total</b>	<b>100.0%</b>

As shown in the table above, the applicant projects that 72.9% of all patients will have their care paid for by Medicare (70.7%) or Medicaid (2.2%).

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(a), page 44, the applicant states:

*“Patients with End Stage Renal Disease will have access to peritoneal dialysis services upon referral to a Nephrologist with privileges at Sampson County Home Dialysis. These referrals will come from primary care physicians or specialty physicians in Sampson County, Duplin County, Wayne County or counties in the area or transfer referrals from other Nephrologists outside of the immediate area. Patients, families and friends may obtain access by contacting a Nephrologist with privileges at Sampson County Home Dialysis. Should a patient contact Sampson County Home Dialysis either directly or indirectly, the patient will be referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. Patients from outside Sampson County Home Dialysis service area requesting transfer to this facility will be processed in accordance with the facility transient policies that comprise **Exhibit 19** [Emphasis in original.] ...”*

The applicant adequately demonstrates Sampson County Home Dialysis will offer a range of means by which patients will have access to the proposed 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.

CA

In Section V.3, page 37, the applicant states:

*“Sampson County Home Dialysis will employ registered nurses, a social worker and dietician. ... Sampson County Home Dialysis has offered to extend our services as a clinical training site for nursing students of the community college once the facility is operational and certified. Sampson County Home Dialysis has offered to extend our services as a clinical training/observation site to students in the Health Occupations Program at Sampson County Schools.”*

The applicant refers the reader to Exhibit 16 for letters it sent to the President of Sampson Community College and to the Sampson County Schools offering Sampson County Home Dialysis as a clinical training site. However, the applicant did not provide these letters in Exhibit 16 or elsewhere in the application.

The information provided in Section V.3, page 37 is reasonable and credible and supports a finding of conformity to this criterion as conditioned in Criterion (4), Condition #3.

- (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

According to the July 2014 SDR, there are two Kidney Disease Treatment Centers (dialysis facilities) located in Sampson County – BMA of Clinton and FMC of Roseboro. Fresenius, though a subsidiary, is the owner of both facilities. TRC proposes to develop a third facility which will provide only home PD training and support services in Clinton. TRC does not propose to develop any hemodialysis stations as a part of this project. In the second operating year, the facility is projected to serve ten DaVita home PD patients living in Sampson (80%) and Duplin (20%) counties. The discussion regarding projected utilization found in Criterion (3) is incorporated herein.

FMC Roseboro is currently the only existing provider of home PD training and support services in Sampson County. BMA of Clinton was issued a certificate of need effective September 25, 2013 authorizing BMA of Clinton to offer home PD training and support services. According to Google Maps, the proposed facility would be located approximately 2.0 miles or three minutes from BMA of Clinton and it would be located 12.7 miles (via NC-24) or 13.7 miles) via NC-411, or 18-19 minutes from Roseboro.

According to the June 2014 ESRD Data Collection Form (Time Period: January 1, 2014 – June 30, 2014), FMC Roseboro reported serving one home PD patient. In the June 2013 ESRD Data Collection Form, FMC Roseboro reported serving three home PD patients. FMC Roseboro reported serving no home PD patients in the December 2012 ESRD Data Collection Form.

In Section V.7, pages 39-40, the applicant discusses how any enhanced competition in the service area will promote cost effectiveness, quality and access to the proposed services. The applicant states:



*“TRC does not expect this proposal to have any negative effect on the other provider in Sampson County because TRC is projecting its starting population solely based on the number of Sampson County peritoneal dialysis patients who signed letters and the two Duplin County patients who live in Faison. All of these patient are being served by a DaVita affiliate in Goldsboro.*

*Once developed, Sampson County Dialysis would offer a new alternative to peritoneal dialysis patients in Sampson County, enhancing competition and further encouraging the need for cost effective care to be provided.”*

See also Sections II (pages 14, 15, 21, and 23-25), III (pages 31-32), V (pages 39-40), VI (pages 41-45), VII (pages 46-47) and referenced exhibits, where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on information in the application and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

The application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

NA

- (21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed.

No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

.2202(a)(2) Mortality rates;

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

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

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

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

-NA- Sampson County Home Dialysis does not propose to increase stations or relocate stations.

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

.2202(b)(1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.

-C- Exhibit 6 contains a July 8, 2014 letter of intent to sign a written patient transfer

agreement from Sampson Regional Medical Center which states the hospital will provide emergency room care, diagnostic evaluation services, X-ray services and laboratory services, including special, immunological and routine. Exhibit 6 also contains an August 13, 2014 letter of intent to sign a written patient transfer agreement from Wayne Memorial Hospital which states the hospital will provide acute dialysis, emergency room care, diagnostic evaluation services, X-ray services, laboratory services, including special, immunological and routine, blood banking services, and surgical services including vascular surgery.

- .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.*
- C- Exhibit 7 contains a June 9, 2014 transplant agreement letter from the Professor and Chief of Surgical Immunology and Transplantation of Vidant Medical Center-Greenville, which includes the above listed items.
- .2202(b)(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- Exhibits 8 and 9 contain documentation that the primary and secondary sites have water and sewer service available.
- .2202(b)(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- Exhibit 10 contains a copy of written policies and procedures for back-up electrical service in the event of a power outage. Also, in Exhibit 10 is an August 8, 2014 letter from the DaVita Director of Healthcare Planning to the DaVita Regional Operations Director requesting that Sampson County Home Dialysis be added to the DaVita network of facilities that back each other up when circumstances affect the power in a facility. Goldsboro Dialysis Center is designated to backup Sampson County Home Dialysis. In Section II.(b)(4), page 13, the applicant states, “*All peritoneal dialysis patients are taught to perform manual exchange in the event of a power failure which interrupts the peritoneal cyclers.*”
- .2202(b)(5) For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- C- Exhibits 8 and 9 contain documentation which indicates that the applicant has identified

both a primary and a secondary site (in case the primary site is unavailable upon certificate of need approval) to lease for the Sampson County Home Dialysis 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- In Section II(b)(6), page 14, Sections VII.2, page 46 and Section XI.6(e-g), page 66, the applicant documents that Sampson County Home Dialysis will provide all services in conformance with all applicable laws and regulations for staffing and safety. Exhibit 11 contains a copy of the applicant’s health and safety policies and procedures. Exhibit 20 contains a copy of the applicant’s isolation policies and procedures. Exhibit 30 contains a copy of the applicant’s water culture policy.

.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- In Section II(b)(7), pages 14-15, 17-21, and Section III.7, pages 27-32, the applicant provides the assumptions and methodology by which patient origin is projected for Sampson County Home Dialysis. On page 27, the applicant provides the projected patient origin for Sampson County Home Dialysis, as shown in the following table:

<b>Sampson County Home Dialysis Projected Utilization</b>						
<b>County</b>	<b>Operating Year 1 2016</b>		<b>Operating Year 1 2017</b>		<b>% of Total</b>	
	<b>In-center</b>	<b>Home PD</b>	<b>In-center</b>	<b>Home PD</b>	<b>Year 1</b>	<b>Year 2</b>
Sampson	0	7	0	8	77.8%	80.0%
Duplin	0	2	0	2	22.2%	20.0%
<b>Total</b>	<b>0</b>	<b>9</b>	<b>0</b>	<b>10</b>	<b>100.0%</b>	<b>100.0%</b>

.2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-C- In Section II.(b)(8), page 15, the applicant states that it “*expects that 100% of the patient population being served by the facility will reside within 30 miles of the facility. Thirty miles from the primary location for Sampson County Home Dialysis covers the entirety of Sampson County. ...*” In Section III.7, page 27, the applicant projects that by the end of operating year two the proposed facility in Clinton will serve eight residents of Sampson County and two residents of Duplin County. The applicant states that the two Duplin County residents live in Faison. *Google Driving Directions* indicates two distances and travel time between Clinton and Faison - 15.1 miles and 19 minutes and/or 14.5 miles and 22 minutes. Exhibit 12 contains a copy of a map with zip codes showing Sampson County and adjacent counties on which has been drawn a circle with the center

of the circle located presumably at the primary site for the proposed facility. The zip codes for Clinton (28328) and Faison (28341) are within the 30-mile radius.

.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 15, the applicant states, “*Total Renal Care Inc. d/b/a Sampson County Dialysis will admit and provide dialysis services to patients who have no insurance or other source of payment if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*”

#### **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- Sampson County Home Dialysis proposes a home PD training facility and does not propose to develop a facility with hemodialysis stations. In Section II., page 15, the applicant states, “*There is not a prescribed utilization standard for home peritoneal dialysis training and support facilities. ...*”

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

-NA- Sampson County Home Dialysis does not propose to increase the number of stations in an existing facility.

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

-C- In Section II(b)(7), pages 14-15, 17-21, and Section III.7, pages 27-32, 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 35. The applicant states that diagnostic evaluation services will be provided by Sampson Regional Medical Center - Clinton and Wayne Memorial Hospital - Goldsboro.

.2204(2) *Maintenance dialysis;*

- C- See Section V.1, page 35. The applicant states that Goldsboro Dialysis Center will provide maintenance dialysis.

.2204(3) *Accessible self-care training;*

- C- See Section V.1, page 35. The applicant proposes to provide home peritoneal dialysis training and support services. The patients will be taught self-care.

.2204(4) *Accessible follow-up program for support of patients dialyzing at home;*

- C- See Section V.2(d), pages 37. The applicant states, “*Sampson County Home Dialysis will provide home training in peritoneal dialysis services and follow-up. The facility will provide protocols and routines for patient follow-up. The social worker and dietician will contact the home-trained patients monthly. The patients will be supported by monthly visits to their Board Certified Nephrologist for examination. The Home Training Nurse teammate will perform monthly medication reviews, nursing assessments and laboratory review of blood work in order to continuously monitor the well-being of home patients. Patient’s blood chemistries will be sent to a Medicare certified laboratory where they will be analyzed. The results will be reviewed by the teammate for adequacy and then reviewed by the dietician and Nephrologist. Home trained patients will be monitored by our Quality Management team.*”

.2204(5) *X-ray services;*

- C- See Section V.1, page 35. The applicant states that Sampson Regional Medical Center - Clinton and Wayne Memorial Hospital - Goldsboro will provide X-ray services.

.2204(6) *Laboratory services;*

- C- See Section V.1, page 35. Laboratory services will be provided by Dialysis Laboratories. See Exhibit 15 for the agreement with Dialysis Laboratories.

.2204(7) *Blood bank services;*

- C- See Section V.1, page 35. The applicant states that blood bank services will be provided

by Sampson Regional Medical Center - Clinton and Wayne Memorial Hospital - Goldsboro.

.2204(8) *Emergency care;*

- C- See Section V.1, page 35. The applicant states that Sampson Regional Medical Center-Clinton and Wayne Memorial Hospital-Goldsboro will provide emergency care.

.2204(9) *Acute dialysis in an acute care setting;*

- C- See Section V.1, page 35. The applicant states that Wayne Memorial Hospital-Goldsboro will provide acute dialysis in an acute care setting.

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

- C- See Section V.1, page 36. The applicant states that Wayne Memorial Hospital-Goldsboro will provide vascular surgery for dialysis treatment patients.

.2204(11) *Transplantation services;*

- C- Exhibit 7 contains the letter of intent from Vidant Medical Center to provide transplantation services.

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

- C- See Section V.1, page 36. Vocational rehabilitation counseling and services will be provided by the North Carolina Division of Vocational Rehabilitation Services.

.2204(13) *Transportation;*

- C- See Section V.1, page 36. Transportation will be provided by *Sampson Area Transportation*.

#### **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 pages 46-47, the applicant provides the proposed staffing. In Section VII.2, page 46, the applicant states the proposed facility will comply with all staffing requirements set forth in the C.F.R. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

.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 47, for the qualifications or certifications required for the staff of Sampson County Home Dialysis. Also see Exhibit 22 for DaVita's training outline, Exhibit 11 for DaVita's Health and Safety Policy and Procedure Manual, and Exhibit 31 for the proposed Sampson County Home Dialysis annual in-service calendar.