

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: April 29, 2014

FINDINGS DATE: April 30, 2014

PROJECT ANALYST: Jane Rhoe-Jones

INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: M-10234-13 / Total Renal Care, Inc. dba Sampson County Home Dialysis / Develop a free standing home training program for peritoneal dialysis patients. / Sampson 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.

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 321 Northeast Boulevard, Clinton, NC 28328 (primary site). TRC does not propose to develop any certified dialysis stations as part of this project.

Neither the 2013 State Medical Facilities Plan (SMFP) nor the July 2013 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- (2) Repealed effective July 1, 1987.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.

NC

Total Renal Care, Inc. (TRC) d/b/a Sampson County Home Dialysis, whose parent company is DaVita Healthcare Partners, Inc, proposes to construct a freestanding facility for a PD home training program, to be located 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 25, the applicant identifies the projected home PD patients to be served by county of residence during each of the first two operating years following project completion, as illustrated in the following table:

Sampson County Home Dialysis Projected Utilization						
County	Operating Year 1 1/1/15-12/31/15		Operating Year 2 1/1/16-12/31/16		% of Total	
	In-center	Home PD	In-center	Home PD	Year 1	Year 2
Sampson	0	9	0	10	100.0%	100.0%
<b>Total</b>	<b>0</b>	<b>9</b>	<b>0</b>	<b>10</b>	<b>100.0%</b>	<b>100.0%</b>

As shown in the table above, the applicant projects that 100% of the patients to be served at the proposed facility will be residents of Sampson County.

The applicant adequately identifies the population it proposes to serve.

### **Need Analysis**

In Section II.1, page 13, the applicant states:

*“TRC is proposing to develop a freestanding home peritoneal dialysis training facility to be located at 321 Northeast Boulevard, Clinton, NC 28328. The facility will exclusively offer home dialysis training and support for patients choosing home peritoneal dialysis. TRC projects that the patients who will receive training and follow up at Sampson County Home Dialysis will be residents of Sampson County [sic] However, patients living in contiguous counties will also be accepted if they are referred to the facility by a Nephrologist with admitting privileges at the facility. This projection is based upon several factors:*

- 1 – *The support of two physician groups which are based in Goldsboro, each of which already has an office in Clinton, as indicated on their letterhead. TRC has chosen Clinton as the site of the facility because the physicians already have an established practice site there and have privileges at Sampson Memorial Hospital.*
- 2 – *Exhibit 18 contains six letters of support from Sampson County home patients who all state that they would consider transferring to Sampson County Home Dialysis.*

*Based upon these factors, TRC projects that it will provide home training services to a significant portion of Sampson County patients, with no substantial negative impact on Fresenius facilities in the area.”*

The line drawing provided in Exhibit 29 labels three rooms in the facility as “PD-HHD Exam” rooms, which could be interpreted to imply the offering of home hemodialysis (HHD) training and support services. However, the line drawing was prepared by an architectural firm, not the applicant and the statement quoted above regarding offering only home PD services at the proposed facility is also made on page 16. More importantly, the applicant projects only home PD patients during the first two operating years following completion of this project. TRC adequately demonstrates that it does not propose to offer home hemodialysis training and support services, which would require certified stations, as part of this project.

#### *Access*

In Section VI, pages 39-43, the applicant describes how residents of the proposed service area, in particular medically underserved groups, will have access to the proposed services. On page 39, the applicant states:

*“Sampson County Home Dialysis, by policy, will make peritoneal dialysis services available to all residents in the service area without qualifications. We will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.”*

On page 40, the applicant projects that 72.9% of the patients will be either Medicare or Medicaid recipients.

The applicant adequately demonstrates that all residents of the area and in particular, medically underserved groups, are likely to have access to the proposed services.

#### *Projected Utilization*

In Section II.1, pages 16-19, and Section III.7, pages 26-29, the applicant provides projected utilization for the proposed facility and the assumptions and methodology used to make those projections. 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 [sic] reports the total ESRD patient population in*

*North Carolina. The row labeled Home reflects the total home 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 uses by the Medical Facilities Planning Section to develop the county five year average annual change rate.”*

The following table illustrates the information provided in the table which appears on both pages 16 and 26 of the application.

SDR Date	July 2008	July 2009	July 2010	July 2011	July 2012	Average % Change
Total NC Dialysis Patients	12,947	13,319	13,751	14,232	14,619	
Raw Change		372	432	481	387	
% Change		2.87%	3.24%	3.50%	2.72%	3.08%
SDR Date	July 2008	July 2009	July 2010	July 2011	July 2012	Average % Change
Total NC Home Dialysis Patients	1,183	1,251	1,344	1,554	1,697	
Raw Change		68	93	210	143	
% Change		5.75%	7.43%	15.63%	9.20%	9.50%

Following the table on pages 16 and 26 of the application, the applicant states “*The above data is significant. The information indicates that the North Carolina ESRD home dialysis patient population is growing a rate much higher than the State ESRD population as a whole.*” However, the data in the table above shows all home dialysis patients, not just home PD patients. Thus, based on the applicant’s data, it is not possible to determine if the growth rate for just home PD patients is higher or lower than the growth rate for all home dialysis patients combined.

Moreover, the applicant did not use the most recent data which was available to the applicant before the application was submitted. The table below was prepared by the Project Analyst using more current data from the July 2013 SDR and the June 2013 Division of Health Service Regulation SMFP ESRD Data Collection Forms (June 2013 ESRD Data Collection Forms).

SDR Date	July 2008	July 2009	July 2010	July 2011	July 2012	Average% Change	July 2013	CAGR
Total NC Dialysis Patients	12,947	13,319	13,751	14,232	14,619		15,032	
Raw Change		372	432	481	387		413	
% Change		2.87%	3.24%	3.50%	2.72%	3.08%	2.83%	3.03%
SDR Date	July 2008	July 2009	July 2010	July 2011	July 2012	Average% Change	July 2013	CAGR
Total NC Home Dialysis Patients	1,183	1,251	1,344	1,554	1,697		1,840	
Raw Change		68	93	210	143		143	
% Change		5.75%	7.43%	15.63%	9.20%	9.50%	8.43%	9.24%

As shown in the table above, the compound annual growth rate (CAGR) between July 2008 and July 2013 is 9.24% as compared to the CAGR between July 2008 and July 2012 which is 9.5%. This is a decrease of 0.26 percentage points [9.5% - 9.24% = 0.26%]. Although the total number of all home dialysis patients is still increasing, that growth could be slowing.

In Section III.7, pages 28-29, the applicant states:

*“Utilization Projection: TRC is using an annual change rate of 9.5% 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 TRC growth rate of peritoneal dialysis in North Carolina over the past four years has been over 17% and that 11.1% of the patient population served are patients on peritoneal dialysis.*

*Total Renal Care, Inc. projects that when the facility opens on January 1, 2015, there will be 8 peritoneal dialysis patients on the waiting list for admission. TRC projects that one additional peritoneal dialysis patient will be admitted during operating year one for a total of 9 peritoneal dialysis patients at the end of operating year one. TRC projects that one additional peritoneal dialysis patients [sic] will be admitted during operating year two for a total of 10 peritoneal dialysis patients.*

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

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

***The following is the Methodology for the development for Sampson County Home Dialysis:***

*The chart below demonstrates the growth projections for the home-trained patients living in Sampson County:*

- *TRC begins with the home trained projected patient population in Sampson County as of December 31, 2012 as stated in the July 2013 SDR: **13 home trained patients.***
- *TRC projects this population forward for one year to December 31, 2013 using the five-year average annual change rate of 9.5%  **$13 \times 1.095 = 14.235$***
- *TRC projects this population forward for one year to December 31, 2014 using the five-year average annual change rate of 9.5% -  **$14.235 \times 1.095 = 15.587325$***
- *TRC projects this population forward for one year to December 31, 2015 using the five-year average annual change rate of 9.5% -  **$15.587325 \times 1.095 = 17.06812087$** .*
- *TRC projects this population forward for one year to December 31, 2016 using the five-year average annual change rate of 9.5% -  **$17.06812087 \times 1.095 = 18.68959235$** .*
- *The above calculations indicate the number of projected home trained patients in Sampson County as of December 21, 2012 based on the information contained in Table B of the July 2013 SDR. The projected home trained patient population was grown through December 31, 2016 using an average annual growth rate of 9.5%.*

- *Based on the above calculations, it is projected that there would be 15 home trained patients residing in Sampson County as of December 31, 2014, the day before the projected certification of Sampson County Home Dialysis. Taking into consideration that some of the home trained patients are trained in home hemodialysis and not all of the peritoneal dialysis patients living in Sampson County will not [sic] transfer their care to Sampson County Home Dialysis, TRC conservatively projects that 8 peritoneal dialysis patients will be on the waiting list when the facility opens on January 1, 2015.” [Emphasis in original.]*

The applicant’s projected growth rate is overstated by 026 percentage points if more current data, available to the applicant before it submitted its application, is taken into account. Moreover, the applicant states that there is only one PD patient utilizing the FMC Roseboro facility. However, according to the June 2013 ESRD Data Collection Forms, there are three patients utilizing the FMC Roseboro facility. Using the more current data which was available to the applicant before submitting its application would have improved the credibility of its utilization projections.

However, the applicant does not adequately demonstrate that projected utilization is based on reasonable, credible and supported assumptions for all of the following reasons:

- The applicant states that FMC Roseboro offers PD training and support and the facility in Clinton has been approved to offer PD training and support. However, the applicant does not adequately explain why the proposed facility is needed in addition to those two PD training and support sites.
- The applicant provides letters from six Sampson County patients expressing an interest in utilizing the proposed facility in Clinton. However, those letters are dated January 2013 and are the exact same letters included in an application submitted in February 2013 (Project ID #M-10083-13), seven months before this application was submitted. The applicant did not adequately document that those six patients are still interested in utilizing the proposed facility for PD training and support. While letters are not expressly required by the statutory or regulatory review criteria, they would support the applicant’s projections if they were credible.
- The applicant does not adequately document that home PD patients residing in Sampson County would prefer to utilize the proposed facility but would not be willing to utilize the existing and approved home PD training and support sites.

Although the applicant adequately identifies the population to be served, the applicant does not adequately demonstrate the need that population has for the proposed PD home training facility. Therefore, the application is nonconforming 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.

NC

Section III.9 of the application form requests that the applicant answer the following question: “Where alternative methods of meeting the needs for the proposed project exist, explain that the least costly or most effective alternative has been proposed.” On page 29 of the application, the applicant states:

*“TRC reviewed the home-trained patient data for Sampson County since historically there has not been a peritoneal dialysis program available in either [sic] county for patients desiring to dialyze with this modality. The FMC Roseboro facility was recently certified and has a peritoneal dialysis training program. However, there is only one PD patient at the FMC Roseboro facility as of June 30, 2012 as indicated in the document provided to the Medical Facilities Planning Section from the Southeastern Kidney Council. The BMA Clinton facility has recently received a certificate of need to add home training services to be open in mid 2014. However, the two Nephrology groups that have offices in Clinton plan to admit their home-trained patients to the TRC facility when it is certified.*

*The majority of home-trained patients in North Carolina are patients trained for peritoneal dialysis. The Southeastern Kidney Council zip code report dated March 31, 2012 indicates that there were a total of 1,697 home-trained patients living in North Carolina. Of those patients, 277 were home hemodialysis patients and 1,420 were peritoneal dialysis patients or 86.7% of the home-trained patient population. The DaVita affiliated facilities in North Carolina are growing at a rate of over 17%.*

*Based on this information and the information outlined in Section III.7, there is a substantial need for a peritoneal dialysis facility in Sampson County.”*

However, the applicant does not state that no alternatives exist to meet the stated need for home PD services in Sampson County. Indeed, the applicant does not state whether it even considered any alternatives. The applicant does not provide data or documentation to show that the proposal is the least costly or most effective alternative; particularly since FMC Roseboro is offering home PD services and BMA of Clinton, Inc. was issued a certificate of need effective September 25, 2013 to offer home training services. However, the applicant does not adequately explain why the proposed facility is needed in addition to those two PD training and support sites.

Furthermore, the application is not conforming to all other applicable statutory and regulatory review criteria, and thus, is not approvable. See Criteria (3), (5), (6) and (18a). A project that cannot be approved cannot be an effective alternative.

In summary, the applicant does not adequately demonstrate that this proposal is the least costly or most effective alternative to meet the stated need. Therefore, the application is nonconforming to this criterion and cannot be approved.

- (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.

NC

In Section VIII.1, page 47, the applicant states that the proposed capital cost of the project is \$644,281, including \$490,400 for construction, \$80,531 for equipment and furniture, \$6,000 for dialysis chairs, \$4,500 for televisions, \$17,850 for a computer system and \$45,000 for architect/engineering fees. In Section IX.1, page 52, the applicant projects the start-up expenses will be \$88,801 and the initial operating expenses will be \$270,656. The total working capital required is projected to be \$359,457. In Section VIII.2, page 49, and Section IX, page 53, the applicant states that cash reserves of DaVita Healthcare Partners, Inc., the parent company of Total Renal Care, Inc., will be used to finance the capital and working capital costs.

Exhibit 22 contains the audited financial statements for DaVita Healthcare Partners, Inc. for the years ending December 31, 2012, December 31, 2011 and December 31, 2010. As of December 31, 2012, DaVita had \$533,748,000 in cash and cash equivalents. Exhibit 21 contains a letter dated November 15, 2013 from the Vice President of Tax for DaVita Healthcare Partners, Inc., which states in part:

*“I am the Vice President of Tax 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.*

...

*DaVita has committed cash reserves in the total sum of \$1,003,738 for the capital costs, start-up costs and working capital for this project. ... I can also confirm that TRC will ensure that these funds and any additional funds that may be needed are made available for the development and operation of 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.2, page 55, and Section X.4, page 58, the applicant provides projected revenues and operating costs (expenses), as illustrated in the following table:

<b>SAMPSON COUNTY HOME DIALYSIS</b>		
	<b>OPERATING YEAR 1</b>	<b>OPERATING YEAR 2</b>
Total Net Revenue	\$645,568	\$722,252
Total Operating Costs	\$541,311	\$585,023
<b>Net Profit</b>	<b>\$104,257</b>	<b>\$137,229</b>

In Section X.4, page 58, the applicant fails to include the salary for the 0.5 of a full-time equivalent (FTE) unit secretary position. Moreover, the applicant only includes salary for 1.0 FTE home training registered nurse (HTRN) position. In Section VII, the applicant projects 1.5 FTE HTRN positions. However, assuming that the applicant employs 0.5 of a FTE unit secretary position and 1.5 FTE HTRN positions, net revenues would still exceed total operating costs. See Criterion (7) for additional discussion regarding staffing which is incorporated hereby as if set forth fully herein and see the working papers for the Project Analyst's calculations.

Although the net revenues are projected to exceed total operating costs in each of the first two operating years, net revenues are not based on reasonable assumptions regarding projected utilization. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. Therefore, the applicant does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Consequently, the application is nonconforming 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.

NC

According to the July 2013 SDR, there are two Kidney Disease Treatment Centers located in Sampson County – BMA of Clinton and FMC Roseboro. Fresenius, through a subsidiary, is the owner of both facilities. TRC proposes to develop a third facility in Clinton which will provide only home PD training and support services. Clinton is located approximately in the center of Sampson County. The applicant projects that 100% of the patients expected to utilize the proposed facility will be residents of Sampson County. TRC does not propose to develop any hemodialysis stations as part of this project.

FMC Roseboro is currently the only provider of PD home dialysis 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 2.4 miles or two minutes from BMA of Clinton and it would be located 13 miles (via NC-24) or 19.5 miles (via NC-411) or 21 – 27 minutes from FMC Roseboro.

According to the December 2012 ESRD Data Collection Forms, FMC Roseboro did not report serving any PD patients as of December 31, 2012. In the June 2013 ESRD Data Collection Forms, FMC Roseboro reported serving three home PD patients as of June 30, 2013.

However, the applicant did not adequately demonstrate that the patients proposed to be served need another facility to provide home PD training and support services. See the Need Analysis discussion in Criterion (3) which is incorporated hereby as if set forth fully herein. Therefore, the applicant did not adequately demonstrate that the proposal would not result in the unnecessary duplication of existing and approved home PD training and support services in Sampson County. Consequently, the application is nonconforming 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 46, the applicant states that Sampson County Home Dialysis will operate Monday-Friday, from 7 am to 5 pm with a qualified home training registered nurse on call 24 hours a day / 7 days a week. In Section VII.1, pages 44, the applicant provides the proposed staffing during the first two operating years following completion of the project, as illustrated below in the table.

SAMPSON COUNTY HOME DIALYSIS	
POSITION	PROJECTED FULL TIME EQUIVALENT POSITIONS (FTES) YEARS 1 AND 2
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 table above, 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 project completion. Furthermore, the applicant proposes 1.0 FTE PD HTRN position. However, on page 45, the applicant states:

*“Nurse Responsible for Nursing Service: The facility will hire a full-time registered nurse and a half-time registered nurse to train and follow-up the peritoneal dialysis patients.”*

Thus, on page 45, the applicant appears to propose 1.5 FTE PD HTRN positions, which is not consistent with the representation on page 44. In other parts of the application, such as Section X, pages 58-59, the applicant proposes only 1 FTE PD HTRN position, which is consistent with the representation on page 44. Thus, the Project Analyst concludes that the statement on page 45 is an unintentional error on the applicant’s part.

In Section V.4(c), page 36, the applicant states that Dr. Ajay Shreenath has agreed to serve as the Medical Director for the proposed facility. See Exhibit 15 for a letter dated January 21, 2013 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 home PD 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 33-34, the applicant provides a list of providers of the necessary ancillary and support services. See also Section II, pages 19-20. Exhibit 7 contains copies of letters of intent to execute transplant agreements with Carolinas Medical Center (Charlotte, Mecklenburg County) and Vidant Medical Center (Greenville, Pitt County). Exhibit 6 contains a letter of intent to execute an agreement with Sampson Regional Medical Center (Clinton, Sampson County). The letter states that the following services will be provided by the hospital:

- Emergency Room Care
- Diagnostic Evaluation
- X-ray Services, and
- Special Immunological and Routine Laboratory Services

On page 33, the applicant states that acute dialysis and vascular surgery services will be available at Wayne Memorial Hospital (Goldsboro, Wayne County) and Cape Fear Valley Medical Center (Fayetteville, Cumberland County). On page 34, the applicant states that patient transfer agreements will be executed before certification of the facility with Sampson Regional Medical Center, Cape Fear Valley Medical Center and Wayne Memorial Hospital.

In Section II.2, page 21, the applicant states that Sampson County Home Dialysis will provide the following services: social work services, nutritional counseling, patient education, emergency care, diagnostic services, pharmaceutical support, home training assessment and transplant evaluation.

The information regarding coordination of services in Section V, pages 33-36, and referenced exhibits is reasonable and credible and supports a finding of conformity with this criterion. The applicant adequately demonstrates that the necessary ancillary and support services will be provided and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

- (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 41, 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 43, the applicant states that there have been no patient civil rights access complaints filed within the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section VI.1(c), page 39, the applicant provides the projected payor mix for the proposed facility.

SAMPSON COUNTY HOME DIALYSIS PROJECTED PAYOR MIX	
SOURCE OF PAYMENT	AS A PERCENT OF TOTAL
Medicare	70.7%
Medicaid	2.2%
Commercial Insurance	24.9%
VA	2.2%
<b>Total</b>	<b>100.0%</b>

As shown in the above table, the applicant projects that 72.9% of all patients will have their care paid for by Medicare (70.7%) and 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 42, 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 other 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 16**. ...”* [Emphasis in original]

The applicant adequately demonstrates it 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.

C

In Section V.3, page 35, the applicant states:

*“The local community colleges are engaged in the training of nursing students. Sampson County Home Dialysis will be offered as a clinical learning site for nursing at area community colleges. ... 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 ...”*

Exhibit 14 includes copies of the letters sent to the President of Sampson Community College and the health occupations program in the Sampson County schools. The information provided in Section V.3, page 35, and Exhibit 14 is reasonable and credible and supports a finding of conformity to this criterion.

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

demonstrate that its application is for a service on which competition will not have a favorable impact.

NC

According to the July 2013 SDR, there are two Kidney Disease Treatment Centers located in Sampson County – BMA of Clinton and FMC Roseboro. Fresenius, through a subsidiary, is the owner of both facilities. TRC proposes to develop a third facility in Clinton which will provide only home PD training and support services. Clinton is located approximately in the center of Sampson County. The applicant projects that 100% of the patients expected to utilize the proposed facility will be residents of Sampson County. TRC does not propose to develop any hemodialysis stations as part of this project.

FMC Roseboro is currently the only provider of PD home dialysis 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 2.4 miles or two minutes from BMA of Clinton and it would be located 13 miles (via NC-24) or 19.5 miles (via NC-411) or 21 – 27 minutes from FMC Roseboro.

According to the December 2012 ESRD Data Collection Forms, FMC Roseboro did not report serving any PD patients as of December 31, 2012. In the June 2013 ESRD Data Collection Forms, FMC Roseboro reported serving three home PD patients as of June 30, 2013.

In Section V.3, pages 37-38, the applicant discusses how any enhanced competition will have a positive impact on the cost effectiveness, quality and access to the proposed home PD training and support services. See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access. The information in the application regarding quality and access is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates that it will continue to provide quality services; and
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations.

However, the applicant did not adequately demonstrate that any enhanced competition includes a positive impact on the cost effectiveness of the proposed services based on the following analysis:

- The applicant did not adequately demonstrate that projected utilization is based on reasonable, credible and supported assumptions. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein.
- The applicant did not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of revenues and costs because projected revenues

and costs are based, in part, on projected utilization. See Criterion (5) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein.

- Development of a facility that is not needed is not cost effective.

Therefore, the application is nonconforming 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

The applicant does not currently provide dialysis services in Sampson County.

- (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 APPLICANTS**

*(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- The applicant does not propose to increase stations in an existing facility or to 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 letter of intent to execute a written agreement with Sampson Regional Medical Center that specifies the relationship with the hospital and describes the services to be provided. The applicant adequately documents that the written agreement will comply with the federal rules.

.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 letter of intent dated January 21, 2013 from Vidant Medical Center and a letter of intent dated February 13, 2013 from Carolinas Medical Center. The letters adequately document that the proposed transplant agreements will include the elements listed in this Rule.

.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 power and water will be available at the proposed primary and secondary sites.

- .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 letter to the DaVita Regional operations director requesting that Sampson County Home Dialysis be added to the network of facilities that provide back up in the event of a power failure. The primary facility providing back up for the proposed facility is Mt. Olive Dialysis Center in Wayne County. Exhibit 10 also contains documentation of the written policies and procedures for back up for electrical service in the event of a power outage.
- .2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- C- In Section XI, page 60, the applicant states that Sampson County Home Dialysis will be located in leased space in an existing building. Exhibit 26 contains a copy of a letter stating the intent to locate Sampson County Home Dialysis at the property located at 321 Northeast Boulevard, in Clinton. Exhibit 24 has a copy of a standard DaVita lease.
- .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, page 1,3 and Section XI, pages 64-65 the applicant states that services will be provided in conformity with applicable laws and regulations. Exhibit 11 contains a copy of DaVita's Health and Safety Policy & Procedure Manual.
- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- See Section II.1, pages 16-19, Section III.7, pages 26-29, and discussion in Criterion (3) which is incorporated hereby as if set forth fully herein.
- .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, page 14, the applicant states that at least 80 percent of the projected patient population resides within 30 miles of the proposed PD home training and support facility. One hundred percent of the patients are projected to be residents of Sampson County.

.2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*

-C- In Section II, page 14, the applicant states that Sampson County Home Dialysis will provide home PD training and support 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.

**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- The applicant does not propose to establish a new facility.

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

-NA- The applicant 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, pages 16-19, and Section III, pages 25-29, the applicant provides the assumptions and methodology used to project utilization of the proposed PD home training facility. See Criterion (3) for discussion regarding the reasonableness of the applicant's assumptions.

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

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

.2204(1) *Diagnostic and evaluation services;*

-C- In Section V, page 33, the applicant states that diagnostic and evaluation services will be provided by Sampson Regional Medical Center, Cape Fear Valley Medical Center and Wayne Memorial Hospital.

.2204(2) *Maintenance dialysis;*

-C- In Section V, page 33, the applicant states that dialysis maintenance will be provided by Goldsboro Dialysis Center.

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

-C- In Section V, pages 33 and 35, the applicant documents that accessible self-care training will be provided.

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

-C- See Section V, page 35. Accessible follow-up and support of patients dialyzing at home will be provided at Sampson County Home Dialysis.

- .2204(5) *X-ray services;*
  - C- In Section V, page 33, the applicant states that x-ray services will be provided at by Sampson Regional Medical Center, Cape Fear Valley Medical Center and Wayne Memorial Hospital.
- .2204(6) *Laboratory services;*
  - C- In Section V, page 33, the applicant states that laboratory services will be provided by Dialysis Laboratories. Exhibit 13 contains a copy of a laboratory services agreement with DaVita Laboratory Services, Inc.
- .2204(7) *Blood bank services;*
  - C- In Section V, page 33, the applicant states blood bank services will be provided by Sampson Regional Medical Center, Cape Fear Valley Medical Center and Wayne Memorial Hospital.
- .2204(8) *Emergency care;*
  - C- In Section V, page 33, the applicant states emergency care will be provided by Sampson Regional Medical Center, Cape Fear Valley Medical Center and Wayne Memorial Hospital.
- .2204(9) *Acute dialysis in an acute care setting;*
  - C- In Section V, page 33, the applicant states acute dialysis care will be provided at Cape Fear Valley Medical Center and Wayne Memorial Hospital.
- .2204(10) *Vascular surgery for dialysis treatment patients*
  - C- In Section V, page 34, the applicant states that vascular surgery will be provided at Cape Fear Valley Medical Center and Wayne Memorial Hospital.
- .2204(11) *Transplantation services;*
  - C- In Section V, page 33, the applicant states that transplantation services will be provided at Carolinas Medical Center and Vidant Medical Center. In Exhibit 7 the applicant provides letters from Carolinas Medical Center and Vidant Medical Center which state that the hospitals will enter into transplant agreements with the proposed facility.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
  - C- In Section V, page 34, the applicant states that vocational rehabilitation counseling and services will be provided by the N.C. Department of Vocational Rehabilitation.
- .2204(13) *Transportation*
  - C- In Section V, page 34, the applicant states that 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 Sections VII, pages 44-45, the applicant provides the proposed staffing. The applicant states on page 44 that the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 494 (formerly 405.2100). The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion which is incorporated hereby as if set forth fully herein.

.2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*

-C- See Section VII.5, page 45 and Exhibits 20 and 31.