

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: July 26, 2013

PROJECT ANALYST: Jane Rhoe-Jones  
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: M-10083-13 / Total Renal Care, Inc. d/b/a Sampson County Home Dialysis / Develop a new freestanding 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 freestanding home training program facility for peritoneal dialysis (PD) patients. Sampson County Home Dialysis will be located at 321 Northeast Boulevard, Clinton, NC 28328 (primary site). TRC does not propose to include any certified in-center or home hemodialysis stations in the new facility.

Neither the 2013 State Medical Facilities Plan (SMFP) nor the January 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- (2) Repealed effective July 1, 1987.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 proposes to construct a freestanding facility for a PD home training program, to be located in leased space in Clinton. TRC does not propose to include any certified in-center or home hemodialysis stations in the new facility.

Population to be Served

In Section III.7, page 30, the applicant identifies the projected home PD patients to be served by Sampson County Home Dialysis during each of the first two years of operation following completion of the project, as illustrated below in the table:

Sampson County Home Dialysis Projected Utilization						
County	Operating Year 1 1/1/15-12/1/15		Operating Year 1 1/1/16-12/1/16		% of Total	
	In-center	Home PD	In-center	Home PD	Year 1	Year 2
Sampson	0	7	0	8	38.9%	40.0%
Duplin	0	11	0	12	61.1%	60.0%
Total	0	18	0	20	100.0%	100.0%

The applicant adequately identifies the population proposed to be served. However, see discussion below regarding the reasonableness of the Duplin County projections.

Projected Utilization

In Section III.7, page 30, 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 Stat 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.”*

The following tables are reproduced from page 31 of the application.

<b>Total ESRD Patient Population - Statewide</b>
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SDR Date	July08	July09	July10	July11	July12	Average % Change
Statewide Patient Population	12,947	13,319	13,751	14,232	14,619	
Raw Change		372	432	481	387	
Percentage Change		2.87%	3.24%	3.50%	2.72%	3.08%

Total ESRD Home Patient Population - Statewide						
SDR Date	July08	July09	July10	July11	July12	Average % Change
Statewide Home Patient Population	1,183	1,251	1,344	1,554	1,697	
Raw Change		68	93	210	143	
Percentage Change		5.75%	7.53%	15.63%	9.20%	9.50%

In Section III.7, page 31, the applicant states:

*“The information indicates that the North Carolina ESRD home dialysis patient population is growing at a rate much higher than the State ESRD population as a whole.”*

The applicant uses statewide home trained dialysis patient population data from the July 2008-2011 SDRs to project utilization at the proposed Sampson County Home Dialysis Center, not county-specific data. An analysis of the Sampson and Duplin County data from the July 2008-2011 SDRs shows that the compound annual growth rate (CAGR) for home trained dialysis patients was 30.4%, which is significantly higher than the statewide growth rate used by the applicant.

However, the SDR data combines home PD and home hemodialysis patients together and it is not possible to separate them. The applicant acknowledges this and uses other data to estimate the number of home PD patients.

In Section III.7, pages 31-37, the applicant provides the following assumptions and methodology used to project the number of home PD patients. On pages 31-33, the applicant states:

Assumptions:

- *“The project is scheduled for completion and certification on January 1, 2015. Operating year one will be January 1, 2015-December 31, 2015. Operating year two will be January 1, 2016-December 31, 2016.*
- *The overall North Carolina five-year average annual change rate for home-trained patients between January 2008 through January 2012 was 9.5%.*
- *The North Carolina facilities operated by DaVita Healthcare Partners, Inc. subsidiaries have experienced an overall annual change rate of 17.23% in the peritoneal dialysis population for the past four years.*

- *DaVita facilities operated by subsidiaries in North Carolina have experienced a peritoneal dialysis patient growth rate almost twice the five-year average annual growth rate in North Carolina for all home training growth.*
- *DaVita facilities operated by subsidiaries in North Carolina indicate that 11.1% 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 9.5% each year during the first two years of operation.*
- *That Sampson County has not had a home training program for peritoneal dialysis patients until the FMC Roseboro facility in Sampson County was developed through a Certificate of Need application that was submitted on November 17, 2008. The facility was certified in 2012.*
- *Sampson County has experienced a 3% five year average annual change rate as indicated in the January 2013 SDR.*
- *The January 2013 SDR indicates in Table B that Sampson County has projected 11% home patient population.*
- *The January 2013 SDR indicates in Table B that Sampson County had projected 18 home trained patients as of June 30, 2012.*
- *The report provided by the ESRD Network 6 to the Medical Facilities Planning Section indicated that there was one home-trained patient at the FMC Roseboro facility as of June 30, 2013 [sic]. See **Exhibit 13** [sic] for a copy of the document. [Emphasis in original.]*
- *Sampson County Home Dialysis is projected to serve the following counties: Sampson County and Duplin County. There is no home training program in Duplin County.*
- *The January 2013 SDR indicates in Table B that Duplin County has projected 10.4% home patient population.*
- *The January 2013 SDR indicates in Table B that Duplin County had projected 14 home trained patients as of June 30, 2012.*
- *Duplin County has experienced a 3.3% five year average annual change rate as indicated in the January 2013 SDR.”*

Methodology:

- *“TRC begins with the home trained projected patient population in Sampson County as of June 30, 2012 as stated in the January 2013 SDR: **18 home trained patients.** [Emphasis in original.]*
- *TRC begins with the home trained projected patient population in Duplin County as of June 30, 2012 as stated in the January 2013 SDR: **14 home trained patients.** [Emphasis in original.]*
- ***18 + 14 = 32 home-trained patients.** [Emphasis in Original.]*
- *TRC projects this population forward for six months to December 31, 2012 using the five year average annual change rate of 9.5% divided by 2 ( $.095/2 = .0475$ ). **32 X .0475 + 1.52 + 32 = 33.52.** [Emphasis in Original.]*
- *TRC projects this population forward for one year to December 31, 2013 using the five-year average annual change rate of 9.5% - **33.52 X .095 = 3.1844 + 33.52 = 36.7044.** [Emphasis in Original.]*

- *TRC projects this population forward for one year to December 31, 2014 using the five-year average annual change rate of 9.5% -  $36.7044 \times .095 = 3.486918 + 36.7044 = 40.191318$ . [Emphasis in Original.]*
- *TRC projects this population forward for one year to December 31, 2015 using the five-year average annual change rate of 9.5% -  $40.191318 \times .095 = 3.81817521 + 40.191318 = 44.00949321$ . [Emphasis in Original.]*
- *TRC projects this population forward for one year to December 31, 2016 using the five-year average annual change rate of 9.5% -  $44.00949321 \times .095 = 4.180901854 + 44.00949321 = 48.19039506$ . [Emphasis in Original.]*
- *The above calculations indicate the number of projected home trained patients in Sampson and Duplin Counties as of June 30, 2012 based on the information contained in Table B of the January 2013 SDR. The projected home trained patient population was grown through December 31, 2015 [sic] using an average annual growth rate of 9.5%.*
- *Based on the above calculations, it is projected that there would be 40 home trained patients residing in Sampson and Duplin Counties 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 [sic] Duplin Counties will not transfer their care to Sampson County Home Dialysis, TRC conservatively projects that 17 peritoneal dialysis patients will be on the waiting list when the facility opens on January 1, 2015.”*

On pages 33-34, the applicant states,

*“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% of the patient population served are patients on peritoneal dialysis.*

*Total Renal Care, Inc. projects that when the facility opens on January 2015, there will be 17 peritoneal dialysis patients on the waiting list for admission. TRC projects that one additional peritoneal patient will be admitted during operating year one for a total of 18 peritoneal dialysis patients at the end of operating year one. TRC projects that two additional peritoneal dialysis patients will be admitted during operating year two for a total of 20 peritoneal dialysis patients.*

*January 1, 2015-December 31, 2015- 17 PD patients  $\times 1.095 = 18.615$*

*January 1, 2016-December 31, 2016- 18.615 PD patients  $\times 1.095 = 20/383425$  [sic]*

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

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

*TRC projects that 7 of the 18 peritoneal dialysis patients served by the end of operating year one at Sampson County Home dialysis will reside in Sampson County.*

*TRC projects that 11 of the 18 peritoneal dialysis patients served by the end of operating year one at Sampson County Home Dialysis will reside in Duplin County.*

*TRC projects that 8 of the 20 peritoneal dialysis patients served by the end of operating year one at 12 of the 20 peritoneal dialysis patients served by the end of operating year one at Sampson County Home Dialysis will reside in Duplin County.”*

In Section III.7, page 30, the applicant identifies the projected home PD patients to be served by Sampson County Home Dialysis 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 Projected Utilization</b>						
<b>County</b>	<b>Operating Year 1 1/1/15-12/1/15</b>		<b>Operating Year 1 1/1/16-12/1/16</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	38.9%	40.0%
Duplin	0	11	0	12	61.1%	60.0%
<b>Total</b>	0	18	0	20	100.0%	100.0%

Analysis of Need

The applicant proposes to develop a new home PD training facility in Clinton in Sampson County. In Section II.1, pages 13-14, the applicant states:

*“TRC projects that the patients who will receive training and follow up at Sampson County Home Dialysis will be residents of Sampson and Duplin counties. 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 .... TRC has chosen Clinton as the site of the facility because the physicians already have an established practice site there ....*
- 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.*
- 3-There is no facility offering home training in Duplin County, so patients must travel out of the county to receive this service. Currently, Duplin County patients are traveling down I-40 into Wilmington for home training and follow up services. If you take Town Hall in Wallace as a departure point, which would be among the closest in Duplin County to Wilmington, the distance to Southeastern Dialysis Center at 2215 Yaupon Drive in Wilmington is about 49 miles. From the same point, which would be among the farthest away from Clinton, the distance is only about 31 miles.”*

Moreover, in Section II.1, page 18, the applicant states “*There is no home training program in Duplin County.*” In Section II.1, page 22, the applicant states “*Because there is no other home training program at any of the facilities in Duplin County, the home dialysis patients in that county are currently traveling to a DaVita facility in Wilmington, New Hanover County, to receive their training and follow up for home dialysis ....*” Finally, in Section V.7, page 46, the applicant states “*There are three dialysis facilities in Duplin County – two are owned by DaVita and one is owned by Fresenius. None of these facilities have a home training program.*”

Clinton is located approximately in the center of Sampson County. Sixty percent of the patients expected to utilize the proposed home PD facility are projected to be residents of Duplin County while only 40% are projected to be residents of Sampson County. Duplin County shares a common border with Sampson County and is located on the eastern side of Sampson County.

There are two existing dialysis facilities located in Sampson County, which are:

- 1) BMA of Clinton (Fresenius)
- 2) FMC of Roseboro (Fresenius)

There are three existing dialysis facilities located in Duplin County, which are:

- 1) Wallace Dialysis Center (DaVita)
- 2) Southeastern Dialysis Center – Kenansville (DaVita)
- 3) Warsaw Dialysis Center (Fresenius)

The applicant or a related entity owns and operates the facilities located in Wallace and Kenansville while the facility located in Warsaw is owned and operated by the same company that owns and operates both Sampson County facilities.

According to Google:

- 1) Wallace Dialysis Center is located 33.8 miles or 36 minutes from the proposed home PD facility in Clinton.
- 2) Southeastern Dialysis Center – Kenansville is located 22.8 miles or 34 minutes from the proposed home PD facility in Clinton.
- 3) Warsaw Dialysis Center is located 13.4 miles or 21 minutes from the proposed home PD facility in Clinton.

Southeastern Dialysis Center – Kenansville does not offer home PD or hemodialysis services.

Effective July 2, 2012, a certificate of need was issued to Wallace Dialysis Center authorizing that facility to begin offering home PD and home hemodialysis services. (See Section II.2, page 16, of Project I.D. #P-8803-12, where the applicant stated “*The facility will also offer home training in peritoneal dialysis and home hemodialysis training.*”) In that application, Wallace Dialysis Center was projected to provide home training services to

five Duplin County residents in each of the first two operating years following completion of that project. However, the applicant failed to mention that fact in the Sampson County Home Dialysis application which was submitted on February 15, 2013, seven months after the certificate of need was issued authorizing the addition of home PD and home hemodialysis services at Wallace Dialysis Center.

Moreover, nowhere in the Sampson County Home Dialysis application does the applicant state that home training will not be offered by Wallace Dialysis Center after all. Furthermore, an examination of the records in the CON Section did not reveal any correspondence in which it was represented that Wallace Dialysis Center would not offer home training services after all.

Therefore, the applicant's mileage analysis on pages 13-14 of the Sampson County Home Dialysis application is not persuasive since the Town Hall in Wallace is only 1.3 miles from Wallace Dialysis Center which is considerably less than the 31 miles to Clinton. Clearly, Duplin county residents now traveling to Wilmington will not have to travel as far to Wallace Dialysis Center as they would to the proposed facility in Clinton.

The following table illustrates July 2011 population estimates for municipalities located in Duplin County and the total population of Duplin County. The data was obtained from the Office of State Budget and Management website.

MUNICIPALITY	JULY 2011 POPULATION
Beulaville	1,307
Calypso	544
Faison(Part)	979
Greenevers	639
Harrells (Part)	23
Kenansville	854
Magnolia	949
Mount Olive (Part)	52
Rose Hill	1,645
Teachey	381
Wallace (Part)	3,922
Warsaw	3,071
Total for all Municipalities	14,366
Total Duplin County Population	59,476

As shown in the table above, the largest municipality in Duplin County as of July 2011 was Wallace with 3,922 residents. Some Wallace residents live in Pender County as Wallace is located close to the border between Duplin and Pender counties. The next largest municipality is Warsaw with 3,071 residents. Of the 59,476 residents of Duplin County in July 2011, only 14,366 or 24% lived in a municipality [ $14,366 / 59,476 = 0.24$ ]. What this data tends to show in conjunction with a Department of Transportation map of North Carolina, which shows the locations of the municipalities listed in the table above, is that there does not appear to be any concentration of residents in any particular location or



locations within Duplin County. The applicant does not state where in Duplin County the projected patients live. In other words, the applicant does not state that they live in or nearby Warsaw as opposed to in or near Wallace, Kenansville, Beulaville or Rose Hill.

The following summarizes why the applicant did not adequately demonstrate the need the population projected to be served has for the proposed home PD training facility in Clinton in Sampson County:

- The majority of the patients projected to be served at the proposed facility in Sampson County are Duplin County patients (60% of the total).
- The applicant states in several places in the application that no home training services are available anywhere in Duplin County. However, nowhere in the application does the applicant acknowledge that Wallace Dialysis Center was approved in Project I.D. #P-8803-12 to offer home PD and home hemodialysis services. The certificate of need for Project I.D. #P-8803-12 was issued on July 2, 2012, seven months before the application identified as Project I.D. #M-10083-13 was submitted to the Certificate of Need Section.
- The applicant uses Wallace to illustrate that the Duplin County patients projected to utilize the proposed Sampson County Home Dialysis would not have to travel as far to the proposed facility in Clinton as they do to the existing facility in Wilmington. However, the Wallace facility, which is approved to offer home PD services, will be significantly closer for residents of the Wallace area than the proposed facility in Clinton.
- The applicant does not state that home training will not be offered at Wallace Dialysis Center after all.
- The applicant does not say where in Duplin County the home PD patients that are projected to utilize the proposed Sampson County Home Dialysis live. Therefore, the applicant did not adequately demonstrate that the Duplin County patients projected to be served at the proposed facility in Clinton live closer to that facility than they do to the facilities in Wallace or Wilmington.
- The applicant did not provide any letters from any Duplin County patients expressing an interest in utilizing the proposed facility in Clinton. In contrast, the applicant did provide six letters from Sampson County patients expressing an interest in utilizing the proposed facility. Indeed, the applicant assumes that six Sampson County patients will utilize the proposed facility when it opens. The Sampson County patient letters document and support the applicant's assumptions regarding the number of Sampson County patients expected to utilize the proposed facility. Similar documentation was not provided in the application to support the applicant's assumptions regarding the number of Duplin County patients projected to utilize the proposed facility. While letters are not expressly required by the statutory or regulatory review criteria, they would have tended to show that there are Duplin County patients interested in utilizing the proposed facility in Clinton. The applicant recognized this when it included letters of support from Sampson County patients.
- The applicant does not provide any information in the application to show that the Duplin County home PD patients projected to utilize the proposed Clinton

facility would be unwilling to utilize the facility in Wallace, which has been authorized to add home PD services.

- The applicant does not provide sufficient information in the Sampson County Home Dialysis application to show that the Duplin County home PD patients proposed to be served in Clinton are not the same Duplin County home PD patients proposed to be served in Wallace.

In summary, although the applicant adequately identifies the population to be served, the applicant does not adequately demonstrate the need to develop a PD home training facility in Clinton in Sampson County to serve primarily Duplin County patients. Consequently, 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 requests that the applicant respond to the following: “*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 38 of the application, the applicant states:

*“TRC reviewed the home-trained patient data for Sampson and Duplin Counties since historically there has not been a peritoneal dialysis program available in either 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.*

*Utilizing a five year average annual change rate of 9.5% statewide for the growth of the home training modalities in North Carolina, the total number of home-trained patients projected to live in Sampson and Duplin Counties by December 31, 2016 is 48 patients. 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 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. The residents of Duplin County who choose the peritoneal dialysis modality will also benefit from this facility. These patients currently travel to the Southeastern Dialysis Center - Wilmington for their training and follow-up.”*

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 Wallace Dialysis Center is already approved to offer home PD services and the majority of the patients projected to utilize the proposed facility in Sampson County are Duplin County patients (60% of the total). Without data provided by the applicant in the application to refute this, it appears that it would be less costly and more effective to proceed with the approved development of home PD services at the existing Wallace Dialysis Center rather than develop a new facility in Sampson County to serve primarily Duplin County patients.

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), (18a) and 10A NCAC 14C .2203(b)(8). 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 more 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 56, the applicant states that the proposed capital cost of the project is \$644,281, including \$490,400 for construction contract costs, \$80,531 for equipment and furniture costs, \$45,000 for architect/engineering fees, and \$28,350 for other costs (computer server and terminal, television system, dialysis chairs). In Section IX.1, page 61, the applicant states there will be start-up expenses of \$88,801 associated with the proposed project (consumable supplies - \$25,000 and staff training - \$63,801). Also on page 61, the applicant projects an initial operating expense of \$395,449. The initial operating expenses are projected to cover the first six months of operation of Sampson County Home Dialysis.

In Section VIII.2, page 58 and Section IX, page 62, the applicant states that the project will be funded by the cash reserves of DaVita Healthcare Partners, Inc, the parent company of Total Renal Care, Inc. Exhibit 24 of the application contains the audited financial statements for DaVita Healthcare Partners, Inc. for the years ending December 31, 2011 and December 31, 2010. As of December 31, 2011, DaVita had \$393,752,000 in cash and cash equivalents. Exhibit 23 contains a letter dated February 12, 2013 from the Chief Accounting Officer of DaVita Healthcare Partners, Inc. The letter states in part:

*“I am the Chief Accounting Officer of DaVita Healthcare Partners, Inc.,(‘DaVita’) the parent company and 100% owner of Total Renal Care, Inc. (‘TRC’). ...*

*I am writing this letter as Chief Accounting Officer of DaVita, to confirm DaVita’s commitment of \$644,281 for the capital expenditures associated with this project; a commitment of \$88,801 for its start up expenses; and a further commitment of \$395,449 in working capital to cover the expenses for the six months of operations of Sampson County Home Dialysis.*

*DaVita has committed cash reserves in the total sum of \$1,128,531 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 65, 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 treatments. ...”*

In Section X.3, page 65, the applicant provides the projected rates and payor mix for the proposed facility, as shown below in the two tables:

<b>Sampson County Home Dialysis</b>			
<b>PD Home Training</b>			
<b>Revenue Source Year 1</b>	<b>Patient Payment % by Revenue Source</b>	<b># Treatments</b>	<b>Reimbursement per Treatment</b>
Medicare	81.1%	2,148	\$192
Medicaid	7.5%	199	\$143
Commercial	6.6%	175	\$1,442
VA	4.8%	126	\$193
<b>Revenue Source Year 2</b>	<b>Patient Payment % by Revenue Source</b>	<b># Treatments</b>	<b>Reimbursement per Treatment</b>
Medicare	81.1%	2,331	\$192

Medicaid	7.5%	216	\$143
Commercial	6.6%	190	\$1,442
VA	4.8%	138	\$193

This information is consistent with the payor mix reported by the applicant in Section VI.1(c), page 48 of the application: Additionally, the rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.

In Sections X.2-X.4, pages 64-67, 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	\$717,541	\$779,054
Total Operating Costs	\$704,179	\$748,986
Net Profit	\$13,362	\$30,068

As shown in the above table, the applicant projects that revenues will exceed operating expenses in each of the first two operating years. However, the applicant’s utilization projections are unsupported and unreliable. Consequently, costs and revenues that are based on the applicant’s projected utilization are also not reliable. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. Therefore, the applicant did 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 January 2013 SDR, there are two Kidney Disease Treatment Centers in Sampson County – BMA of Clinton and FMC of Roseboro. Fresenius, though a subsidiary, is the owner of both facilities. Also, as reported in the January 2013 SDR, there are three Kidney Disease Treatment Centers in Duplin County: Southeastern Dialysis Center-Kenansville in Kenansville, Wallace Dialysis Center in Wallace and Warsaw Dialysis Center in Warsaw. Total Renal Care of North Carolina, LLC (a subsidiary of DaVita) is the owner of Wallace Dialysis Center and Southeastern Dialysis Center-Kenansville; while Fresenius is the owner of Warsaw Dialysis Center.

In this application, Total Renal Care, Inc. (TRC) d/b/a Sampson County Home Dialysis proposes to develop a new freestanding home training program facility for peritoneal dialysis (PD) patients. TRC does not propose to include any hemodialysis stations in the new Sampson County Home Dialysis facility. Sampson County Home Dialysis will be located in

Clinton; however, Sampson Home Dialysis will serve PD patients from both Sampson (40% of the total) and Duplin (60% of the total) counties.

There are no home training services currently provided in Duplin County. However, Wallace Dialysis Center is approved to offer home PD services. See Project I.D.# P-8803-12 and discussion in Criterion (3) which is incorporated hereby as if set forth fully herein. Moreover, Warsaw Dialysis Center was authorized in March 2013 to offer home PD services. Also, one of the two existing facilities in Sampson County – FMC Roseboro provides home PD training and support.

The applicant does not adequately demonstrate the need to develop the proposed home PD facility in Clinton in addition to the existing facility in Roseboro, which offers home PD services and the facilities in Duplin County that are approved to offer home PD services.

- The majority of the patients projected to be served at the proposed facility in Sampson County are Duplin County patients (60% of the total).
- The applicant states in several places in the application that no home training services are available anywhere in Duplin County. However, nowhere in the application does the applicant acknowledge that Wallace Dialysis Center was approved in Project I.D. #P-8803-12 to offer home PD and home hemodialysis services. The certificate of need for Project I.D. #P-8803-12 was issued on July 2, 2012, seven months before the application identified as Project I.D. #M-10083-13 was submitted to the Certificate of Need Section.
- The applicant uses Wallace to illustrate that the Duplin County patients projected to utilize the proposed Sampson County Home Dialysis would not have to travel as far to the proposed facility in Clinton as they do to the existing facility in Wilmington. However, the Wallace facility, which is approved to offer home PD services, will be significantly closer for residents of the Wallace area than the proposed facility in Clinton.
- The applicant does not state that home training will not be offered at Wallace Dialysis Center after all.
- The applicant does not say where in Duplin County the home PD patients that are projected to utilize the proposed Sampson County Home Dialysis live. Therefore, the applicant did not adequately demonstrate that the Duplin County patients projected to be served at the proposed facility in Clinton live closer to that facility than they do to the facilities in Wallace or Wilmington.
- The applicant did not provide any letters from any Duplin County patients expressing an interest in utilizing the proposed facility in Clinton. In contrast, the applicant did provide six letters from Sampson County patients expressing an interest in utilizing the proposed facility. Indeed, the applicant assumes that six Sampson County patients will utilize the proposed facility when it opens. The Sampson County patient letters document and support the applicant's assumptions regarding the number of Sampson County patients expected to utilize the proposed facility. Similar documentation was not provided in the application to support the applicant's assumptions regarding the number of Duplin County patients projected to utilize the proposed facility. While letters are not expressly required by the statutory or regulatory review criteria, they would have tended to show that there are Duplin County patients interested in utilizing the proposed facility

in Clinton. The applicant recognized this when it included letters from Sampson County patients.

- The applicant does not provide any information in the application to show that the Duplin County home PD patients projected to utilize the proposed Clinton facility would be unwilling to utilize the facility in Wallace, which has been authorized to add home PD services.
- The applicant does not provide sufficient information in the Sampson County Home Dialysis application to show that the Duplin County home PD patients proposed to be served in Clinton are not the same Duplin County home PD patients proposed to be served in Wallace.

Thus, the applicant does not adequately demonstrate that development of Sampson County Home Dialysis in Clinton will not result in the unnecessary duplication of existing and approved home PD services in Sampson or Duplin counties. 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.1, pages 53-54, the applicant provides the proposed staffing during the first two operating years following completion of the project, as illustrated below in the table.

<b>POSITION</b>	<b>PROJECTED FULL TIME EQUIVALENT POSITIONS (FTES) YEARS 1 AND 2</b>
PD HTRN	1.5
Admin.	0.3
Dietitian	0.3
Social Worker	0.3
Unit Secretary	0.3
Total	2.7

As shown in the above table, the applicant proposes to employ a total of 2.7 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 44, 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 January 21, 2013, from Dr. Shreenath expressing his willingness to serve as the Medical Director for Sampson County Home Dialysis. In Section VII.10, page 55, the applicant states that the 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.

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 41-42, the applicant provides a list of proposed providers of ancillary and support services. Exhibit 7 contains copies of letters of intent to enter transplantation agreements with Carolinas Medical Center-Charlotte and Vidant Medical Center-Greenville. Exhibit 6 contains a letter of intent from Sampson Regional Medical Center which states the hospital will provide the following services: emergency room care, diagnostic evaluation services, X-Ray services, and special, immunological and routine laboratory services. 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 41-42, illustrates additional 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 & Cape Fear Valley Medical Center
Emergency care	Wayne Memorial Hospital, Cape Fear Valley Medical Center & Sampson Regional Medical Center
Diagnostic evaluation services	Wayne Memorial Hospital, Cape Fear Valley Medical Center & Sampson Regional Medical Center
X-Ray services	Wayne Memorial Hospital, Cape Fear Valley Medical Center & Sampson Regional Medical Center
Blood bank	Wayne Memorial Hospital, Cape Fear Valley Medical Center & Sampson Regional Medical Center
Pediatric nephrology	Vidant Medical Center-Greenville
Vascular surgery	Wayne Memorial Hospital & Cape Fear Valley Medical Center

In Section II.2, pages 41-42, the applicant states that Sampson County Home Dialysis will provide the following services: (1) intermittent peritoneal dialysis, (2) CAPD, (3) CCPD, (4) psychological counseling, (5) nutritional counseling, and (6) social work services. 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 from area physicians, a vascular surgeon in Wake County, the City of Clinton, the Sampson County Department of Social Services and the Sampson County Economic Development Commission.

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.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
  - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - (iii) would cost no more than if the services were provided by the HMO; and
  - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs

identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

NA

- (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 49, 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 51, the applicant states there have been no 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), page 48, 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	
SOURCE OF PAYMENT	PERCENT OF TOTAL
Medicare	81.1%
Medicare/Medicaid	7.5%
Commercial Insurance	6.6%
VA	4.8%
Total	100.0%

As shown in the table above, the applicant projects that 88.6% of all patients will have their care paid for by Medicare (81%) or Medicare/Medicaid (7.5%).

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 50, 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 or 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.

C

In Section V.3, page 43, 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.”*

See Exhibit 16 for letters dated January 21, 2013 to the President of Sampson Community College and to the Health Occupations Career and Technical Education Program of the Sampson County Schools offering Sampson County Home Dialysis as a clinical training site.

The information provided in Sections V.3, page 31 and Exhibit 16 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

The applicant proposes to develop a new Kidney Disease Treatment Center to provide home PD training and support in Clinton in Sampson County. Clinton is located approximately in the center of Sampson County. Only 40% of the patients expected to utilize the proposed

home PD facility are projected to be residents of Sampson County. The majority of the patients (60%) are projected to be residents of Duplin County. Duplin County shares a common border with Sampson County and is located on the eastern side of Sampson County.

There are two existing dialysis facilities located in Sampson County, which are:

- 1) BMA of Clinton (owned by Fresenius)
- 2) FMC of Roseboro (owned by Fresenius)

FMC of Roseboro offers home PD services.

There are three existing dialysis facilities located in Duplin County, which are:

- 1) Wallace Dialysis Center (owned by DaVita)
- 2) Southeastern Dialysis Center – Kenansville (owned by DaVita)
- 3) Warsaw Dialysis Center (owned by Fresenius)

Southeastern Dialysis Center – Kenansville does not offer home PD or hemodialysis services.

However, effective July 2, 2012, a certificate of need was issued to Wallace Dialysis Center authorizing that facility to begin offering home PD and home hemodialysis services. (See Section II.2, page 16, of Project I.D. #P-8803-12, where the applicant stated “*The facility will also offer home training in peritoneal dialysis and home hemodialysis training.*”) In that application, Wallace Dialysis Center was projected to provide home training services to five Duplin County residents in each of the first two operating years following completion of that project. However, the applicant failed to mention that fact in the Sampson County Home Dialysis application which was submitted on February 15, 2013, seven months after the certificate of need was issued authorizing the addition of home PD and home hemodialysis services at Wallace Dialysis Center.

Moreover, nowhere in the Sampson County Home Dialysis application does the applicant state that home training will not be offered by Wallace Dialysis Center after all. Furthermore, an examination of the records in the CON Section did not reveal any correspondence in which it was represented that Wallace Dialysis Center would not offer home training services after all.

Section V.7 requests that the applicant “*Explain the expected effects of the proposed project on competition in the proposed service area, including how any enhanced competition will have a positive impact on the cost effectiveness, quality and access to the proposed services.*” In Section V.7, pages 45-46, the applicant responded as follows:

*“This CON application is for the location of a standalone peritoneal dialysis training and follow-up facility to be located in Clinton in Sampson County. ... The addition of a standalone peritoneal dialysis and follow-up program in Sampson County will bring a new provider of home dialysis services to the county and will*

*provide patients ... a location in Sampson County where they can train and be followed without leaving the county.*

...

*At the present time Fresenius is the only provider of dialysis services in Sampson County. ... There are three dialysis facilities in Duplin County – two are owned by DaVita and one is owned by Fresenius. None of these facilities have a home training program.” (Emphasis added.)*

In the first paragraph above, the applicant states the patients will not have to leave the county. However, 60% of the patients expected to be served are projected to be residents of Duplin County, not Sampson County. Thus, they will have to leave their county to utilize the proposed facility in Sampson County. Moreover, in the second paragraph, the applicant states none of the facilities in Duplin County have a home training program. While none have one at present, Wallace Dialysis Center (owned by DaVita) was approved in July 2012 to develop a home PD and home hemodialysis program. See discussion above.

The applicant did not adequately demonstrate that the proposal is needed for the following reasons:

- The majority of the patients projected to be served at the proposed facility in Sampson County are Duplin County patients (60% of the total).
- The applicant states in several places in the application that no home training services are available anywhere in Duplin County. However, nowhere in the application does the applicant acknowledge that Wallace Dialysis Center was approved in Project I.D. #P-8803-12 to offer home PD and home hemodialysis services. The certificate of need for Project I.D. #P-8803-12 was issued on July 2, 2012, seven months before the application identified as Project I.D. #M-10083-13 was submitted to the Certificate of Need Section.
- The applicant uses Wallace to illustrate that the Duplin County patients projected to utilize the proposed Sampson County Home Dialysis would not have to travel as far to the proposed facility in Clinton as they do to the existing facility in Wilmington. However, the Wallace facility, which is approved to offer home PD services, will be significantly closer for residents of the Wallace area than the proposed facility in Clinton.
- The applicant does not state that home training will not be offered at Wallace Dialysis Center after all.
- The applicant does not say where in Duplin County the home PD patients that are projected to utilize the proposed Sampson County Home Dialysis live. Therefore, the applicant did not adequately demonstrate that the Duplin County patients projected to be served at the proposed facility in Clinton live closer to that facility than they do to the facilities in Wallace or Wilmington.
- The applicant did not provide any letters from any Duplin County patients expressing an interest in utilizing the proposed facility in Clinton. In contrast, the applicant did provide six letters from Sampson County patients expressing an interest in utilizing the proposed facility. Indeed, the applicant assumes that six Sampson County patients will

utilize the proposed facility when it opens. The Sampson County patient letters document and support the applicant's assumptions regarding the number of Sampson County patients expected to utilize the proposed facility. Similar documentation was not provided in the application to support the applicant's assumptions regarding the number of Duplin County patients projected to utilize the proposed facility. While letters are not expressly required by the statutory or regulatory review criteria, they would have tended to show that there are Duplin County patients interested in utilizing the proposed facility in Clinton. The applicant recognized this when it included letters from Sampson County patients.

- The applicant does not provide any information in the application to show that the Duplin County home PD patients projected to utilize the proposed Clinton facility would be unwilling to utilize the facility in Wallace, which has been authorized to add home PD services.
- The applicant does not provide sufficient information in the Sampson County Home Dialysis application to show that the Duplin County home PD patients proposed to be served in Clinton are not the same Duplin County home PD patients proposed to be served in Wallace.

Development of a facility that is not needed is not cost effective. Therefore, the applicant did not adequately demonstrate how this proposal would enhance competition, including a positive impact on cost-effectiveness. Consequently, 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

- (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.

NC

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 not 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;*

- Sampson County Home Dialysis proposes a peritoneal dialysis home training facility  
NA- and does not propose to develop a facility with hemodialysis stations.

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

- Sampson County Home Dialysis proposes a peritoneal dialysis home training facility  
NA- and does not propose to develop a facility with hemodialysis stations.

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

- Sampson County Home Dialysis proposes a peritoneal dialysis home training facility  
NA- and does not propose to develop a facility with hemodialysis stations.

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

- Sampson County Home Dialysis proposes a peritoneal dialysis home training facility  
NA- and does not propose to develop a facility with hemodialysis stations.

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

- Sampson County Home Dialysis proposes a peritoneal dialysis home training facility  
NA- and does not propose to develop a facility with hemodialysis stations.

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

- Sampson County Home Dialysis proposes a peritoneal dialysis home training facility  
NA- and does not propose to develop a facility with hemodialysis stations.

*.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.*

- Sampson County Home Dialysis proposes a peritoneal dialysis home training facility  
NA- and does not propose to develop a facility with hemodialysis 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 February 6, 2013 letter of intent to sign a written 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.

*.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 January 21, 2013 transplant agreement letter from the Director of Transplant Services of Vidant Medical Center-Greenville and a February 13, 2013 transplant agreement letter from the Director of Business Operations of Carolinas Medical Center-Charlotte.

*.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 from the Clinton Director of Public Works that the primary and secondary sites each 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 a 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. Mt. Olive Dialysis Center is designated to backup Sampson County Home Dialysis. Further, in Section II, page 12, 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 11 and 12 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, page 13, Sections VII.2, page 53 and Section XI.6(e-g), pages 73-74, 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 13 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, pages 13-14, the applicant provides the assumptions regarding patient origin for Sampson County Home Dialysis. In Section III.7, page 30, the applicant provides the projected patient origin for Sampson County Home Dialysis, as shown in the following table:

Sampson County Home Dialysis Projected Utilization						
County	Operating Year 1 1/1/15-12/1/15		Operating Year 1 1/1/16-12/1/16		% of Total	
	In-center	Home PD	In-center	Home PD	Year 1	Year 2
Sampson	0	7	0	8	38.9%	40.0%
Duplin	0	11	0	12	61.1%	60.0%

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

-NC- In Section II, page 14, the applicant states that it “*expects that greater than 80 percent of the patient population being served by the facility will reside within 30 miles of the facility.*” Indeed, the applicant states “*All of the projected patients will live within the 30-mile radius of the primary site in Clinton.*” (Emphasis added.) In Section III.7, page

30, the applicant projects that the proposed facility in Clinton will serve 8 residents of Sampson County and 12 residents of Duplin County in Year 2. However, the applicant does not say where in Duplin County the home PD patients that are projected to utilize the proposed Sampson County Home Dialysis live. Exhibit 14 contains a copy of a map 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. Thus, it appears that the circle shows what is included within a 30-mile radius of the proposed facility in Clinton. The 30-mile circle does not include all of Duplin County but only about two thirds of Duplin County, though it does include the label on the map for the City of Wallace. The applicant also included a map obtained from Google showing the distance from the Town Hall in Wallace to the primary site in Clinton, which is 31.4 miles. The difference is due to the fact that the 30-mile circle shows distances in a straight line (ignoring roads) but the Google Map shows the distance between the Town Hall in Wallace and the proposed site in Clinton based on the roads that must be taken to get between the two locations. Given that 60% of the patients are expected to be residents of Duplin County but the applicant does not state where in Duplin County the patients are expected to live and a 30-mile circle with the proposed facility at the center does not include all of Duplin County, the applicant did not adequately demonstrate that 80% of the patients would reside within 30 miles of the proposed facility in Clinton in 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.1(9), page 14, the applicant states, “*Total Renal Care Inc. d/b/a Sampson County Dialysis Center [sic] 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 peritoneal dialysis home training facility and does not propose to develop a facility with hemodialysis stations. 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 proposes a new peritoneal dialysis home training facility and does not propose to develop a facility with hemodialysis stations.

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

-C- In Section II, pages 16-23 and Section III.7, pages 30-37, 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 41. The applicant states that diagnostic evaluation services will be provided by Cape Fear Valley Medical Center - Fayetteville, Sampson Regional Medical Center - Clinton, and Wayne Memorial Hospital - Goldsboro.

.2204(2) *Maintenance dialysis;*

-C- See Section V.1, page 41. The applicant states that Goldsboro Dialysis Center will provide maintenance dialysis.

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

-C- See Section V.1, page 41. 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 42-43. The applicant states, “*Sampson County Home Dialysis will provide home training in peritoneal dialysis services and 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 41. The applicant states that Cape Fear Valley Medical Center-Fayetteville, 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 41. 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 41. The applicant states that blood bank services will be provided by Cape Fear Valley Medical Center-Fayetteville,

*.2204(8) Emergency care;*

- C- See Section V.1, page 41. The applicant states that emergency care will be provided TRC teammates until first responders arrived. Patients will be transferred to Cape Fear Valley Medical Center-Fayetteville, Sampson Regional Medical Center-Clinton, or Wayne Memorial Hospital-Goldsboro.

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

- C- See Section V.1, page 41. The applicant states that acute dialysis in an acute care setting will be provided by Cape Fear Valley Medical Center-Fayetteville and Wayne Memorial Hospital-Goldsboro.

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

- C- See Section V.1, page 42. The applicant states that vascular surgery for dialysis treatment patients will be provided by Cape Fear Valley Medical Center-Fayetteville and Wayne Memorial Hospital-Goldsboro.

*.2204(11) Transplantation services;*

- C- See Section V.1, page 41. Transplantation services will be provided by Carolinas Medical Center-Charlotte and Vidant Medical Center-Greenville. Exhibit 7 contains the respective letters of intent.

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

- C- See Section V.1, page 42. 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 42. Transportation will 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 page 53-55, the applicant provides the proposed staffing. In Section VII.2, page 53, 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. See Criterion (7) for additional discussion which is incorporated hereby as if set forth fully herein.

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

- C- See Section VII.3 and 5, page 54, for the qualifications or certifications required for the staff of Sampson County Home Dialysis. Also see Exhibit 22 for DaVita's training outline, Exhibit 13 for DaVita's Health and Safety Policy and Procedure Manual, and Exhibit 31 for the proposed Sampson County Home Dialysis Annual In-Service Calendar.