

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 20, 2015

Findings Date: November 20, 2015

Project Analyst: Jane Rhoe-Jones

Team Leader: Fatimah Wilson

Project ID #: F-11088-15

Facility: Harrisburg Dialysis Center

FID #: 070392

County: Cabarrus

Applicant(s): Total Renal Care of North Carolina, LLC

Project: Add six stations for a total of 25 stations upon project completion

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency 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.

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Total Renal Care of North Carolina, LLC (TRC) d/b/a Harrisburg Dialysis Center (“the applicant”) proposes to add six dialysis stations for a total of 25 stations upon completion of this project.

#### **Need Determination**

The 2015 State Medical Facilities Plan (2015 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 27 dialysis station in Cabarrus County, thus the applicant cannot apply to add additional stations based on the county need methodology. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate

for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Harrisburg Dialysis Center in the July 2015 SDR is 3.3684 patients per station, or 84.2% ( $3.3684 / 4$  patients per station = 0.8421). This utilization rate was calculated based on 64 in-center dialysis patients and 19 certified dialysis stations ( $64$  patients /  $19$  stations = 3.3684 patients per station).

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

<b>HARRISBURG DIALYSIS CENTER - OCTOBER 1 REVIEW-JULY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/14		84.0%
Certified Stations		19
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>19</b>
In-Center Patients as of 12/31/14 (July 2015 SDR) (SDR2)		64
In-Center Patients as of 6/30/14 (Jan 2015 SDR) (SDR1)		57
Step	Description	
	Difference (SDR2 - SDR1)	7
(i)	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/14	0.2456
(ii)	Divide the result of Step (i) by 12	0.0205
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/13 until 12/31/14)	0.2456
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	79.7193
(v)	Divide the result of Step (iv) by 3.2 patients per station	24.9123
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	5.9123

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

**Policies**

There is one policy in the 2015 SMFP which is applicable to this review. *POLICY GEN-3: BASIC PRINCIPLES* on page 38 of the 2015 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

### Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 9-10 and Section O, page 52. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

### Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B, page 11, Section C, page 16, Section I, pages 35-38, Section L, pages 45-49 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

### Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B, page 11, Section N, page 51, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

### Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the July 2015 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which

all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add six dialysis stations for a total of 25 dialysis stations at the existing Harrisburg Dialysis Center facility upon completion of the project.

**Population to be Served**

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Cabarrus County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 18, the applicant provides a table showing the historical patient origin for in-center (IC) and peritoneal dialysis (PD) patients served by Harrisburg Dialysis Center. The applicant does not currently serve home hemodialysis (HH) patients at this facility.

<b>HARRISBURG DIALYSIS CENTER Patient Origin December 31, 2014</b>			
<b>County</b>	<b>IC</b>	<b>HH</b>	<b>PD</b>
Cabarrus	55	NA	10
Mecklenburg	7	NA	6
Stanly	0	NA	1
Other States	2	NA	0
<b>TOTAL</b>	<b>64</b>	<b>NA</b>	<b>17</b>

In Section C, page 13, the applicant identifies the patient population it proposes to serve during the first two years of operation following project completion, as illustrated in the table below.

<b>HARRISBURG DIALYSIS CENTER Projected Patient Origin</b>						
<b>County</b>	<b>Operating Year 1 2017</b>		<b>Operating Year 2 2018</b>		<b>County Patients as Percent of Total</b>	
	<b>IC</b>	<b>PD</b>	<b>IC</b>	<b>PD</b>	<b>Year 1</b>	<b>Year 2</b>
Cabarrus	73	13	80	14	84.3%	85.5%
Mecklenburg	7	6	7	6	12.7%	11.8%
Stanly	0	1	0	1	1.0%	0.9%
Other States	2	0	2	0	2.0%	1.8%
<b>TOTAL</b>	<b>82</b>	<b>20</b>	<b>89</b>	<b>21</b>	<b>100.0%</b>	<b>100.0%</b>

Note: Harrisburg Dialysis Center does not provide home hemodialysis.

The applicant provides the assumptions and methodology for the projections above on pages 13-15.

The applicant adequately identifies the population it proposes to serve.

### **Analysis of Need**

The applicant proposes to add six dialysis stations to the existing Harrisburg Dialysis Center facility for a total of 25 certified dialysis stations upon project completion. In Section C, page 15, the applicant refers the reader to Section B, page 7, where the applicant states the need for the proposed project is based on the facility need methodology. The discussion regarding the need determination found in Criteria (1) is incorporated herein.

### **Projected Utilization**

The applicant projects to serve 82 in-center dialysis patients at the end of the first operating year. This is 3.28 patients per station or an 82% utilization rate.

In Section C, pages 13-15, the applicant provides the assumptions and methodology it uses to demonstrate the need that this population has for the services proposed at Harrisburg Dialysis Center. The applicant's assumptions and methodology are summarized below:

- Based on the July 2015 SDR, Harrisburg Dialysis Center had 64 in-center patients dialyzing on 19 certified stations yielding a station utilization rate of 84% ( $64 / 19 = 3.3684$ ;  $3.3684 / 4 = 0.8421$  or 84%) as of December 31, 2014.
- Fifty-five of the 64 in-center patients were residents of Cabarrus County and the other nine patients were residents of other counties and states.
- The applicant has chosen to project in-center patient utilization based on historical utilization growth at the facility as opposed to using the five year average annual change rate (AACR) for the county.
- The facility experienced a 12.3% in-center patient increase (7 patients) during the six month period from July 1, 2014 through December 31, 2014. Review of the most recent SDR, January and July 2015, confirms that the facility served seven additional patients during this time period. The applicant states that the 12.3% growth in patients during that six month period is 24.5% annualized for the facility, which exceeds the five year average annual change rate (AACR) of 0.9% as reported in the July 2015 SDR.
- The applicant assumes that the facility will continue to grow at a rate higher than the five year AACR (0.9%) but lower than the 24.5% annualized growth rate described above. The applicant uses a growth rate of 10% to project patient utilization for residents of Cabarrus County. No growth is being assumed for patients from other counties or states.

- Furthermore, the June 2015 ESRD data collection form for Harrisburg Dialysis Center showed that the facility experienced another increase in in-center patients (6 patients) during the six month period from January 1, 2015 – June 30, 2015. This is a 9.4% in-center patient increase for that six month period, 18.8% annualized.
- Using a 10% growth rate, the applicant projects that the facility will have 82 in-center patients by the end of operating year one (OY1) for a utilization rate or 82%, or 3.28 patients per station, and 89 in-center patients by the end of operating year two (OY2), for a utilization rate or 89%, or 3.568 patients per station.
- OY1 is January 2017 – December 2017
- OY2 is January 2018 – December 2018

In Section C, page 14, the applicant provides the calculations used to arrive at the projected in-center patient census for OY1, ending December 31, 2017 and OY 2, ending December 31, 2018, as shown below.

HARRISBURG DIALYSIS CENTER	CALCULATIONS
January 1, 2015 - December 31, 2015	55 patients x 1.1 = 60.5
January 1, 2016 - December 31, 2016	60.5 x 1.1 = 66.55
January 1, 2017 - December 31, 2017	66.55 x 1.1 = 73.205
January 1, 2018 - December 31, 2018	73.205 x 1.1 = 80.5255
Cabarrus County patients only. Number of patients rounded down to nearest whole number.	

As shown in the table above, the applicant is projecting to serve 73 Cabarrus County in-center patients (rounded down from 73.20) in OY1 2017 and 80 Cabarrus County in-center patients (rounded from 80.52) in OY2 2018. The following table includes the total in-center patient projections, including the nine in-center patients from Mecklenburg and Stanly counties and other states.

HARRISBURG DIALYSIS CENTER	CALCULATIONS
January 1, 2015 - December 31, 2015	55 patients x 1.1 = 60.5 + 9 = 69.9
January 1, 2016 - December 31, 2016	60.5 x 1.1 = 66.55 + 9 = 75.55
January 1, 2017 - December 31, 2017	66.55 x 1.1 = 73.205 + 9 = 82.205
January 1, 2018 - December 31, 2018	73.205 x 1.1 = 80.5255 + 9 = 89.5255
All in-center patients for Cabarrus County, Mecklenburg and Stanly counties and other states. Number of patients rounded down to nearest whole number.	

As shown in the previous table, at the end of OY1 2017, the applicant is projecting an in-center patient census of 82 patients, for a utilization rate of 84% or 3.28 patients per station (82 patients / 25 stations = 3.28; 3.28 / 4 = .82 or 82%). At the end of OY2 2018, the applicant is projecting an in-center patient census of 89 patients for a utilization rate of 89% or 3.56 patients per station. The projected utilization of 3.28 patients per station per week for OY1 satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth in the dialysis patient population in Cabarrus County.

### Peritoneal Dialysis

The applicant currently provides peritoneal dialysis (PD). See Section C, page 15 for the applicant's discussion of its PD services.

### Access

In Section C, page 16, the applicant states:

*“By policy, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly, and other underserved persons.”*

In Section L, page 49, the applicant provides its historical payor mix which indicates that Medicare and Medicaid represented 56.2% of in-center dialysis treatments in calendar year 2014. The applicant confirms that low income and medically underinsured persons will continue to have access to all services provided by TRC and that the facility will conform to all federal, state and local codes and standards for handicapped access.

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

### Conclusion

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

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

NA

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

CA

In Section E, page 22, the applicant discusses the two alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo - the applicant states that this option would not support the growth rate at the facility.
2. Apply to add six stations – the applicant states the six-station expansion would help to meet the growing demand for dialysis services at Harrisburg Dialysis Center.

The applicant also considered a third shift but determined that a third shift would be inconvenient for patients; and a facility at maximum capacity eliminates patient choice. After considering the alternatives above, the applicant believes the most effective alternative is to add six stations to the existing facility to ensure adequate access for the dialysis patients of Cabarrus County.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center shall materially comply with all representations made in the certificate of need application.**
  - 2. Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center shall add no more than six dialysis stations at Harrisburg Dialysis Center for a total of no more than 25 certified dialysis stations which shall include any home hemodialysis training or isolation stations.**
  - 3. Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center shall install plumbing and electrical wiring through the walls for no more than six additional dialysis stations, which shall include any home hemodialysis training or isolation stations.**
  - 4. Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.



TRC proposes to add six dialysis stations to Harrisburg Dialysis Center, for a total of 25 dialysis stations at Harrisburg Dialysis Center upon completion of this project.

**Capital and Working Capital Costs**

In Section F, page 24, the applicant provides the capital cost of the proposed project as summarized in the table below:

<b>Harrisburg Dialysis Center Proposed Project Capital Costs</b>	
Construction Contract	\$ 122,250
Dialysis Machines	\$ 92,190
Water Treatment Equipment	\$ 95,000
Equipment/Furniture	\$ 59,478
Architect & Engineering Fees	\$ 28,000
<b>Total Capital Cost</b>	<b>\$ 396,918</b>

In Section F, pages 26 - 27, the applicant states that there are no working capital needs for the proposed project as Harrisburg Dialysis Center is an existing facility.

**Availability of Funds**

In Section F, page 25, the applicant states that cash reserves/owner’s equity is being used to finance the proposed project. Exhibit F-5 contains a September 10, 2015 letter from the Vice President of Tax of DaVita HealthCare Partners, parent company of the applicant, which states,

*“We are submitting a Certificate of Need Application to expand our Harrisburg Dialysis Center by six ESRD dialysis stations. The project calls for a capital expenditure of \$396,918. This letter will confirm that DaVita HealthCare Partners, Inc. has committed cash reserves in the total sum of \$398,918. for the project capital expenditure [sic]. DaVita HealthCare Partners, Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to Total Renal Care of North Carolina.”*

In Section F, page 26, the applicant states:

*“The financial strength of the company precludes any financial impact upon the operation and performance of the expansion that this application proposes. Therefore, there is no appreciable impact on either this application or from any that has been approved previously or is currently under review.”*

In Section F, page 26, the applicant refers to Exhibit F-7 [sic] for a copy of the most recent audited financial statements for DaVita HealthCare Partners, Inc. (years ended December 31, 2014 and 2013). As of December 31, 2014, DaVita HealthCare Partners, Inc. had \$965,241,000 in cash and cash equivalents with \$17,942,715,000 in total assets and \$5,360,311,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

**Financial Feasibility**

In Section R, Form B, page one, the applicant projects revenues and expenses for the first two full operating years of the project (2017-2018) and provides the assumptions used to project revenues and expenses in Section R, Form B, page two, as summarized in the table below.

<b>HARRISBURG DIALYSIS CENTER</b>		
<b>Revenue and Expenses - Total Facility</b>		
	<b>OPERATING YEAR 1</b>	<b>OPERATING YEAR 2</b>
	<b>CY 2017</b>	<b>CY 2018</b>
Gross Patient Revenue	\$ 6,355,148	\$ 6,677,873
Deductions from Gross Patient Revenue	\$ 232,582	\$ 244,210
Net Patient Revenue	\$ 6,122,566	\$ 6,433,663
Operating Expenses	\$ 4,289,088	\$ 4,476,751
<b>Net Profit</b>	<b>\$ 1,833,478</b>	<b>\$ 1,956,912</b>

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The applicant’s projections of treatments and revenues are reasonable based on the number of in-center and home patients projected for the first two operating years. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

In Section H, page 31, the applicant provides projected staffing and salaries. Form A in Section R, page one, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

**Conclusion**

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project. The applicant also adequately demonstrates that the financial feasibility of the project is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

**C**

TRC proposes to add six dialysis stations to Harrisburg Dialysis Center, for a total of 25 dialysis stations at Harrisburg Dialysis Center upon completion of this project.

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Cabarrus County. Facilities may also serve residents of counties not included in their service area.

Table A in the July 2015 SDR indicates there are two existing dialysis facilities in Cabarrus County, as follows:

DIALYSIS FACILITY	CERTIFIED STATIONS	# PATIENTS	PATIENTS PER STATION	% UTILIZATION
Harrisburg Dialysis Center	19	64	3.36	84.21%
Copperfield Dialysis	21	73	3.47	86.90%
Data reported in the July 2015 SDR, as of 12/31/14.				

The applicant operates both of the Cabarrus County dialysis facilities listed above. Both of the dialysis facilities are operating above 80% utilization.

In Section C, page 13, the applicant provides the total projected patients by county of residence for the proposed project, as shown in the following table:

HARRISBURG DIALYSIS CENTER: Projected Patient Origin						
County	OY 1 2017		OY 2 2018		County Patients as a Percent of Total	
	IC	PD	IC	PD	Year 1	Year 2
Cabarrus	73	13	80	14	84.3%	85.5%
Mecklenburg	7	6	7	6	12.7%	11.8%
Stanly	0	1	0	1	1.0%	0.9%
Other States	2	0	2	0	2.0%	1.8%
<b>TOTAL</b>	<b>82</b>	<b>20</b>	<b>89</b>	<b>21</b>	<b>100.0%</b>	<b>100.0%</b>
Note: Harrisburg Dialysis Center does not provide Home Dialysis.						

As shown in the table above, at the end of OY1 2017, the applicant is projecting an in-center patient census of 82 patients, for a utilization rate of 84% or 3.28 patients per station (82 patients / 25 stations = 3.28; 3.28 / 4 = .82 or 82%). At the end of OY2 2018, the applicant is projecting an in-center patient census of 89 patients for a utilization rate of 89% or 3.56 patients per station. The projected utilization of 3.28 patients per station per week in OY1 2017 satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

The applicant states that projected utilization is based on growth of in-center patients at the facility.

The applicant adequately demonstrates the need to add six stations to Harrisburg Dialysis Center based on the number of in-center patients it proposes to serve. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on competition found in Criterion (18a) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Cabarrus County. Consequently, the application is conforming to this criterion.

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

C

In Section H, page 31, the applicant provides the following table to illustrate current and projected staffing in full time equivalents (FTEs) for Harrisburg Dialysis Center. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart.

POSITION	CURRENT # FTEs	# FTEs TO BE ADDED	PROJECTED # FTEs
Registered Nurse	3.0	1.0	4.0
Technician (Patient Care)	8.0	2.0	10.0
Administrator	1.0	-	1.0
Dietician	1.0	-	1.00
Social Worker	1.0	-	1.00
Home Training RN	1.0	-	1.00
Bio-med Technician	.5	-	.5
Administrative Assistant	1.0	-	1.00
<b>Total</b>	<b>16.5</b>	<b>3.0</b>	<b>19.5</b>

In Section H, page 34, the applicant provides the projected direct care staff for Harrisburg Dialysis Center in Operating Year 2, as shown below in the table:

DIRECT CARE POSITIONS	# FTEs	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	4.0	2,080	8,320	3,120	2.67
Patient Care Tech	10.0	2,080	20,800	3,120	6.67
<b>Total</b>	<b>14.0</b>	<b>2,080</b>	<b>29,120</b>	<b>3,120</b>	<b>9.34</b>

In Section I, page 37, the applicant identifies Dr. Charles Stoddard as the Medical Director of the facility. In Exhibit I-3, the applicant provides a copy of an August 2015 letter signed by Dr. Stoddard of Metrolina Nephrology Associates, supporting the project and confirming his commitment to serve as Medical Director. In Section H, pages 32 -33, the applicant states that staff positions are filled by one or more of the following: the DaVita Teammate Recruiter, Teammate Referral Program and/or Student Internship Program.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

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

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In Section I, page 36, the applicant lists the providers of the necessary ancillary and support services to be provided at the existing facility. The applicant discusses coordination with the existing health care system on pages 37 - 38. On page 38, the applicant states that over the years, they have established relationships with other healthcare providers and social service agencies in the county and that these agencies are aware of the proposed project. Exhibits I-1, and I-3 contain documents from Spectra Labs, and Dr. Stoddard (Medical Director), respectively. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information in Section I and corresponding exhibits is reasonable and supports a finding of conformity to this criterion.

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

NA

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

NA

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

C

In Section K, page 41, the applicant provides a table to illustrate the additional square feet proposed at the facility. The project calls for 815 total square feet in the treatment area for dialysis

stations. The applicant provides the proposed line drawing for the facility in Exhibit K-1. The line drawing shows what the applicant states will be a 4,258 square foot facility with 24 main floor dialysis stations, one isolation dialysis station, and one room for home peritoneal dialysis training, for a total of 25 in-center stations.

In Section F, page 24, the applicant states that the costs associated with this project are for construction, dialysis machines, water treatment equipment, furnishings and architect/engineering fees. In Section K, page 40, the applicant states that the facility was previously constructed with energy saving features such as energy efficient glass, mechanically operated doors and an energy efficient heating and cooling system.

Costs and charges are described by the applicant in Section F, pages 23 - 29, and in the proforma financial statements in Section R. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features are already in use at this existing facility, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, pages 45-56, the applicant states, "*Harrisburg Dialysis Center, by policy, makes dialysis services available to all residents in its service area. ... Harrisburg Dialysis Center helps uninsured, underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.*"

In addition, on pages 46 - 48, the applicant discusses its financial policies to help the underserved population. In Section L, page 49, the applicant states that Medicare/Medicaid represented 50.7% of dialysis treatments at Harrisburg Dialysis Center in calendar year 2014. The following table illustrates the historical payor sources for Harrisburg Dialysis Center, as follows:

PAYOR TYPE	PERCENT PATIENTS
Private Pay	0.0%
Commercial Insurance	20.9%
Medicare	33.4%
Medicaid	2.5%
Medicare/ Medicaid	14.8%
VA	8.6%
Other	19.8%
<b>Total</b>	<b>100.0%</b>

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Cabarrus, Mecklenburg and Stanly counties and statewide.

County	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Cabarrus	14.3%	4.9%	18.5%
Mecklenburg	14.7%	5.1%	20.1%
Stanly	17.4%	7.6%	18.3%
Statewide	16.5%	6.7%	19.7%
*More current data, particularly with regard to the estimated uninsured percentages, was not available.			

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those persons who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).<sup>1</sup>

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. But it does not include information on the number of elderly, handicapped, minorities or women utilizing health services.

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*, provides prevalence data on North Carolina dialysis patients by age, race and gender, and is summarized as follows, on page 59:

<sup>1</sup><http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2014</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
<b>Gender</b>		
Female	7,064	44.2%
Male	8,934	55.8%
<b>Race</b>		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%
Source: Southeastern Kidney Council Network6 Inc. 2014 Annual Report. <sup>2</sup>		

The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

In Section L, page 48, the applicant states:

*“Harrisburg Dialysis Center has 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. The facility has no obligation under the Hill Burton Act.”*

In Section L, page 49, the applicant states, *“There have been no civil rights equal access filed within the last five years.”*

The application is conforming to this criterion.



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

C

In Section C, page 16, the applicant states, *“By policy, the proposed services will be made available to all residents in its service area without qualifications. ...*

*Payment will not be required upon admission. Therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”*

In Section L, page 48, the applicant states:

*“Harrisburg Dialysis Center makes no effort to categorize patients into groups according to their financial ability to obtain medical care. Physicians identify the patients in need of dialysis services and only then will a financial counselor and/or social worker evaluate their medical insurance and financial status.”*

In Section L, page 46, the applicant projects that 50.7% of patients who will receive dialysis treatment at Harrisburg Dialysis Center will have all or part of their services paid for by Medicare and or Medicaid, as indicated in the table below.

PAYOR TYPE	PERCENT PATIENTS
Private Pay	0.0%
Commercial Insurance	20.9%
Medicare	33.4%
Medicaid	2.5%
Medicare/ Medicaid	14.8%
VA	8.6%
Other	19.8%
<b>Total</b>	<b>100.0%</b>

On page 46, the applicant also states that the payor mix for Harrisburg Dialysis Center will remain the same as it currently is.

The applicant demonstrates that medically underserved populations will 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 L, page 48, the applicant states:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral by a nephrologist with privileges [sic] Harrisburg Dialysis Center. ... Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies, found at Exhibit L-3. ...”*

The applicant adequately demonstrates that 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 M, page 50, the applicant states that Harrisburg Dialysis Center has been offered as a clinical training site for student nurses attending Rowan-Cabarrus Community College.

Exhibit M-2 contains a copy of the applicant’s letter to Rowan-Cabarrus Community College for student nurse clinical rotations at Harrisburg Dialysis Center. The information provided in Section M and referenced exhibits is reasonable and supports a finding of conformity to this criterion.

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

C

The applicant proposes to add six stations to Harrisburg Dialysis Center based on the facility need methodology. There will be 25 certified dialysis station at Harrisburg Dialysis Center upon project completion.

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of

the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Cabarrus County. Facilities may also serve residents of counties not included in their service area.

Table A in the July 2015 SDR indicates there are two existing dialysis facilities in Cabarrus County, as follows:

DIALYSIS FACILITY	CERTIFIED STATIONS	# PATIENTS	PATIENTS PER STATION	% UTILIZATION
Harrisburg Dialysis Center	19	64	3.36	84.21%
Copperfield Dialysis	21	73	3.47	86.90%

Data reported in the July 2015 SDR, as of 12/31/14.

The applicant operates both of the dialysis facilities listed above in the table. Both of the dialysis facilities are operating above 80% utilization.

In Section N, page 51, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states:

*“The expansion of Harrisburg Dialysis will have no effect on competition in Cabarrus County. The addition of six stations at this facility serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by Total Renal Care of North Carolina, LLC and not any other providers in the service area.*

*The expansion of Harrisburg Dialysis Center will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services.”*

See also Sections C, F, G, H, L and P where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicant adequately demonstrates that Harrisburg Dialysis Center will continue to provide quality dialysis services. The discussions regarding quality found in Criterion (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that Harrisburg Dialysis Center will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

In Section O, page 52, the applicant refers the reader to Section B-4(a), for its discussion regarding the methods it uses to ensure and maintain quality. The discussion is found on pages 9 - 10. In Section O, page 52, the applicant states:

*“Exhibit O-3 lists facilities located in NC owned by the parent company DaVita HealthCare Partners Inc. that did not operate in compliance with the Medicare conditions of participation during the 18 month look back period. Each facility is currently in compliance.”*

In Exhibit O-3, the applicant lists three facilities that were cited for deficiencies that resulted in Immediate Jeopardy during the 18-month look back period: Burlington Dialysis, Dialysis Care of Edgecombe County and Dialysis Care of Rowan County. See the table below which shows the survey dates and the dates the facilities were found to be back in compliance with CMS.

TRC Quality Care			
Facility	Survey Date	Back in Compliance	
Burlington Dialysis	6/16/2014	Yes	7/29/2014
Dialysis Care of Edgecombe County	7/1/2014	Yes	7/30/2014
Dialysis Care of Rowan County	9/17/2014	Yes	10/22/2014

Based on a review of this certificate of need application and publicly available information, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming or conditionally conforming to all applicable criteria, as discussed below.

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

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

*.2202(a)(1) Utilization rates;*

- C- In Section P, page 54, the applicant refers the reader to Section G, page 30 where the applicant provides the historical utilization rates for Harrisburg Dialysis Center. The December 31, 2014 utilization rate was reported as 84.21% with 64 in-center patients dialyzing on 19 stations.

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

- C- In Section P, page 54, the applicant refers the reader to Section C-9 where it provides the Harrisburg Dialysis Center mortality rates, as follows:

<b>Harrisburg Dialysis Center</b>	<b>Beginning In-center Patients</b>	<b>Ending In-center Patients</b>	<b>Average</b>	<b>Deaths</b>	<b>% Gross Mortality</b>
2014	75	81	78	18	23.1%
2013	63	75	69	11	15.9%
2012	60	63	61.5	14	22.8%

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

- C- In Section P, page 54, the applicant refers the reader to Section C-8, page 18 and provides the following home training and home dialysis data for the Harrisburg Dialysis Center facility.

<b>Residence</b>	<b># PD Patients</b>
Cabarrus	10
Mecklenburg	6
Stanly	1
Other States	0
<b>Total</b>	<b>17</b>

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

- C- In Section P, page 54, the applicant refers the reader to Section C-10, page 19, and states that Harrisburg Dialysis Center referred two patients for transplants in 2014.

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

- C- In Section P, page 54, the applicant refers the reader to Section C-10, page 19, and states that Harrisburg Dialysis Center had six patients on the transplant waiting list.

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

- C- In Section P, page 54, the applicant refers the reader to Section C-10, page 19 and states hospital admission rates as follows: Dialysis related 10 or 5.9%; Non-dialysis related 160 or 94.1%.

.2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*

- C- In Section P, page 55, the applicant refers the reader to Section C-10, page 19 and states that at Harrisburg Dialysis Center, there were seven persons with infectious disease and no patients converted to an infectious status during the last calendar year.

*(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 (Replaced with 42 CFR Part 494).*

-NA- This application is to add stations and does not propose a new facility.

- .2202(b)(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) timeframe for initial assessment and evaluation of patients for transplantation,*
  - (B) composition of the assessment/evaluation team at the transplant center,*
  - (C) method for periodic re-evaluation,*
  - (D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*
  - (E) Signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- This application is to add stations and does not propose a new facility.

- .2202(b)(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- This application is to add stations and does not propose a new facility.

- .2202(b)(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- In Section P, page 55, the applicant refers the reader to Section K-1(f), page 40, and there refers the reader to Exhibit K-1(f) where the copies of written policies and procedures for back up electrical service in the event of a power outage are provided.

- .2202(b)(5) For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-NA- This application is to add stations and does not propose a new 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 P, page 56, the applicant refers the reader to Section K-1(g), page 41, where it states: “Durham Dialysis [sic] will provide service in conformity with

*applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply and other relevant health and safety requirements ....” See also Sections H-2 and K-1(d) and Exhibit K-1(g).*

*.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 P, page 56, the applicant refers the reader to Section C-1, page 13, where the applicant provides projected patient origin by county for Harrisburg Dialysis Center, based on the patients who currently dialyze there. The applicant’s assumptions and methodology used to project patient origin are provided on pages 13 - 15 of the application. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

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

-NA- This application is to add stations and does not propose a new facility.

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

-C- In Section P, page 56, the applicant refers the reader to Section L-3(c), page 48, where the applicant states, “*Harrisburg Dialysis Center makes no effort to categorize patients into groups according to their financial ability to obtain medical care. Physicians identify the patients in need of dialysis services and only then will a financial counselor and/or social worker evaluate their medical insurance and financial status.*”

## **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- This application is to add stations and does not propose 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.*



-C- In Section P, page 57, the applicant refers the reader to Section C-1, pages 13 - 16, where the applicant documents the need for the project and demonstrates that it will serve a total of 82 in-center patients on 25 stations at the end of the first operating year, which is 3.28 patients per station per week, or a utilization rate of 82%. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-C- In Section P, page 57, the applicant refers the reader to Section C.1, pages 13 - 16, where the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

## **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- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 36, where the applicant states that diagnostic and evaluation services will be referred to Carolinas Medical Center (CMC) Northeast.

*.2204(2) Maintenance dialysis;*

-C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 36, where the applicant states that in-center maintenance dialysis is provided at Harrisburg Dialysis Center.

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

-C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 36, where the applicant states that self-care training is provided Harrisburg Dialysis Center.

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

-C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 36, where the applicant states that an accessible follow-up program for support of patients dialyzing at home is provided at the Harrisburg Dialysis Center.

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

-C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 36, where the applicant states that patients in need of x-ray services will be referred to CMC Northeast.

*.2204(6) Laboratory services;*

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 36, where the applicant states that laboratory services will be provided by DaVita Laboratory Services, Inc. Exhibit I-1 contains a copy of the laboratory agreement.

*.2204(7) Blood bank services;*

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 36, where the applicant states that patients in need of blood bank services will be referred to CMC Northeast.

*.2204(8) Emergency care;*

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 36, where the applicant states that patients in need of emergency care will be referred to CMC Northeast.

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

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 36, where the applicant states that patients in need of acute dialysis services will be referred to CMC Northeast.

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

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 36, where the applicant states that patients in need of vascular surgery services will be referred to Piedmont Surgical.

*.2204(11) Transplantation services;*

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 36, where the applicant states that patients in need of transplantation services will be referred to Carolinas Medical Center. Exhibit I-3 contains a copy of the August 2015 letter from Dr. Stoddard, the medical director at Harrisburg Dialysis Facility which documents the provision of transplantation services.

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

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 36, where the applicant states that vocational rehabilitation counseling services are provided by the North Carolina Division of Vocational Rehabilitation Services.

*.2204(13) Transportation*

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 36, where the applicant states that transportation services will be provided by the Cabarrus County Department of Human Services (HS).

**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 (Replaced with 42 CFR Part 494).*

- C- In Section P-1, page 57, the applicant refers the reader to Section H-2, page 32, where the applicant states that it will comply with *42 C.F.R. Section 405.2100* (Replaced with 42 CFR Part 494). In Section H-1, page 31, the applicant provides a staffing chart. The discussion regarding proposed staffing found in Criterion (7) is incorporated herein by reference.

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

- C- In Section P-1, page 57, the applicant refers the reader to Section H-4, page 33, where the applicant discusses its training at TRC facilities. In Section H-4, page 42, the applicant further discusses its ongoing training program. See also Exhibit H-4, which contains the FMC Training Program Outline and an outline of FMC's continuing education program courses.