

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: March 28, 2014

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

PROJECT I.D. NUMBER: F-10219-13 / DVA Healthcare Renal Care, Inc. d/b/a Huntersville Dialysis / Develop a new 10-station dialysis facility in Huntersville by relocating 10 certified dialysis stations from North Charlotte Dialysis Center / Mecklenburg County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

DVA Healthcare Renal Care, Inc. d/b/a Huntersville Dialysis proposes to relocate ten in-center dialysis stations from the North Charlotte Dialysis Center to establish a new 10-station dialysis facility in Huntersville. The applicant does not propose to add new dialysis stations to an existing facility or to establish any new dialysis stations. Therefore, neither of the two need methodologies in the 2013 State Medical Facilities Plan (SMFP) is applicable to this review. Additionally, Policy GEN-3 is not applicable because the applicant is not proposing to develop a new institutional health service for which there is a need determination in the 2013 SMFP. Policy GEN-4 is not applicable because the proposed capital cost of this project is under \$2 million. However, Policy ESRD-2 is applicable to this review.

Policy ESRD-2: RELOCATION OF DIALYSIS STATIONS, on page 36 of the 2013 SMFP states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:

1. *Demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
2. *Demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate ten dialysis stations from North Charlotte Dialysis Center to establish Huntersville Dialysis. The two dialysis facilities are both in Mecklenburg County; therefore, the relocation of ten existing stations will be within the host county. Therefore, the application is consistent with Policy ESRD-2 and 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

DVA Healthcare Renal Care, Inc. d/b/a Huntersville Dialysis proposes to relocate ten in-center dialysis stations from North Charlotte Dialysis Center to establish a new 10-station dialysis facility in Huntersville in northern Mecklenburg County. Both facilities are located in Mecklenburg County.

Currently there are 16 dialysis facilities in Mecklenburg County, operated by four different dialysis providers. DaVita has a facility in the northern part of the county, North Charlotte Dialysis Center, and it is this 35-station facility from which the applicant proposes to relocate the 10 stations. In Section III.6, page 26, the applicant states:

“The facility utilization rate identified in the SDR was 106% since the facility was certified for 25 stations as of December 31, 2012. The stations pending certification identified in the July 2013 SDR were certified on September 23, 2013. If there were still 106 in-center patients, the utilization rate based on 35 stations would have been 75%.”

Population to be Served

In Section III.7, page 28, the applicant identifies the population it proposes to serve for the first two years of operation following project completion, as illustrated in the table below:

COUNTY	OPERATING YEAR 1 (2016)		OPERATING YEAR 2 (2017)		COUNTY PTS AS PERCENT OF TOTAL	
	IN-CTR. PTS	HOME PD PTS	IN-CTR. PTS	HOME PD PTS	YEAR 1	YEAR 2
Mecklenburg	32	4	33	5	97.3%	97.5%
Iredell	1	0	1	0	2.7%	2.5%
Total	33	4	34	5	100.0%	100.0%

On page 28, the applicant states:

“... the majority of the patients who are projected to utilize Huntersville Dialysis will be Mecklenburg County residents. Based on patient support letters and proximity, one resident of Iredell County is also projected to dialyze in this facility.”

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

The applicant proposes to relocate ten existing certified dialysis stations from North Charlotte Dialysis Center to a proposed new facility that will be located in Huntersville, in the northern section of Mecklenburg County. In Section III.3, page 19, the applicant states:

“DaVita’s North Charlotte facility, from which these stations will be transferred, opened in 2008 with ten stations and has grown rapidly since that time. As of December 31, 2012, it had 25 certified stations for 106 in-center patients. In January 2013, it was approved for an additional ten stations, which were certified on September 23, 2013, bringing the certified station count to 35. The physical footprint of this facility will not allow for expansion beyond the existing 35 stations. By transferring ten of these stations to Huntersville, there will be room for additional expansion at the North Charlotte facility to continue to accept patients who would prefer to receive dialysis there in the future, while establishing the proposed Huntersville Dialysis, which will increase access for patients who reside in northern Mecklenburg County.

... DaVita has 29 patients who have submitted letters of support for a facility in the Huntersville area. Nineteen of these patients report that they live in the Huntersville zip codes, 28078 or 28070; one lives in the Cornelius zip code, 28031; the others live in zip codes that are contiguous to the Huntersville zip code, 28078. These other zip codes are two Charlotte zip codes, 28216 and 28269, and the Mooresville zip code in Iredell County, 28115.”

In Section III.3(b), pages 20 – 21, the applicant states:

“Sixteen in-center patients who currently receive their dialysis treatments at the North Charlotte Dialysis Center have signed letters of support (see Exhibit 14) for the proposed Huntersville Dialysis. These patients live in the two Huntersville zip codes [28078, 28070]. All of the patients have indicated in their letters that the facility will be more convenient for them.

...

Six letters of support have come from patients receiving in-center dialysis at the South Charlotte Dialysis Center (see Exhibit 15). Two of these patients live in Huntersville, and four of the patients live in Charlotte. Three of the four Charlotte patients live in zip code 28216 and one patient lives in zip code 28269.

Four letters of support have come from patients receiving in-center dialysis at the Charlotte Dialysis Center (see Exhibit 16). All of the patients live in Charlotte - three in zip code 28216 and one patient lives in zip code 28269.

One letter of support has come from a patient receiving in-center dialysis at the Copperfield Dialysis Center in Cabarrus County (see Exhibit 17). This patient lives in the Mooresville zip code, 28115.

One in-center patient who currently receives their [sic] dialysis treatments at Dialysis Care of Kannapolis has signed a letter of support (see Exhibit 18) for the proposed Huntersville Dialysis. This patient lives in the Cornelius zip code, 28031.

One in-center patient who currently receives dialysis at Harrisburg Dialysis Center in Cabarrus County has signed a letter of support (see Exhibit 19) for the proposed Huntersville Dialysis. The patient lives in Huntersville in zip code 28078.”

Thus, the applicant proposes to relocate ten certified stations to develop a new 10-station dialysis facility to more effectively serve existing patients who live in the northern section of Mecklenburg County and who currently dialyze at North Charlotte Dialysis Center, South Charlotte Dialysis Center, Charlotte Dialysis Center, Copperfield Dialysis Center, Dialysis Care of Kannapolis or Harrisburg Dialysis Center. Each of the 29 patients states that the proposed facility would be a more convenient location for his or her dialysis treatments.

On page 22, the applicant states:

“Since the first four zip codes are closest to the site of the proposed facility, we believe that they will represent the area where the facility can reasonably expect future growth, but since we have received eight letters from patients in the two Charlotte zip codes and one letter from a Mooresville patient, all of whom indicate that they would consider transferring their dialysis to Huntersville Dialysis Center which would be more convenient for them, we are including all 29 in-center patients in the starting population of Huntersville Dialysis.”

The first four ZIP codes referenced by the applicant are 28216, 28269, 28115, 28031. The analyst analyzed these ZIP codes and their relation to the ZIP code of the proposed Huntersville facility, which is 28078, as shown in the following table:

PATIENT ZIP CODES	TOWN	DISTANCE FROM 28078
28216	Charlotte (north)	7.12 miles
28269	Charlotte (north)	5.80 miles
28031	Cornelius	5.01 miles
28115	Mooresville*	14.28 miles
28036	Davidson	6.92 miles
28070	Huntersville	1.49 miles
28078	Huntersville	0 miles

*This is an Iredell County ZIP code, which the applicant states represents the residence of one Mooresville patient.
 ZIP code information obtained from <http://www.zip-codes.com/zip-code-radius-finder.asp>

North Charlotte Dialysis Center is located in the northern area of Charlotte, in ZIP code 28269. In Section III.3, page 21, the applicant identifies the residence ZIP code of each patient who signed a letter. The applicant states that two patients who dialyze at North Charlotte Dialysis Center and reside in ZIP code 28269 signed letters stating that a facility in Huntersville would be closer to his or her residence and a more convenient location in which to receive dialysis treatments. ZIP code 28269 actually crosses county lines, so that part of it is located in northeastern Mecklenburg County and part is located in southwestern Cabarrus County. In addition, a small part of ZIP code 28269 is located in Iredell County, to the north of Mecklenburg County. It is not possible to tell from the letters exactly where the patients live. However, the patient would be in the best position to know if the proposed facility is more convenient for him or her, and indeed, the letters state as much. A patient who lives in ZIP code 28269 could live closer to a facility in Huntersville in ZIP code 28078 than to a facility in ZIP code 28269. The applicant adequately documents that a patient residing in ZIP code 28269 may choose to dialyze at a facility located in ZIP code 28078 because it is more convenient and/or closer to that patient’s residence.

In addition, in Section III.3, on page 22, the applicant states:

“Based on these letters, it is very reasonable to project that Huntersville Dialysis will have 29 in-center patients ready to transfer into the facility on its opening date on January 1, 2016.

...

To project the impact of additional patients who will start dialysis between the date of application, through the end of the first operating year, we will focus on the Huntersville, Cornelius, and Davidson zip codes in northern Mecklenburg County, which are closest to the proposed location of Huntersville Dialysis, and particularly on the Huntersville and Cornelius zip codes, because DaVita facilities provide in-

center dialysis treatments to patients living in each of those zip codes who have signed letters of support.

As indicated in the chart above, DVA has letters from 20 patients receiving dialysis at the following facilities who live in the Huntersville and Cornelius zip codes: 16 at North Charlotte, 2 at South Charlotte Dialysis, 1 at Kannapolis, and 1 at Harrisburg Dialysis. This represents a group of 20 patients who have been referred by their physicians to DaVita for dialysis, who live in the zip codes close to the proposed site, and for whom a Huntersville facility will be more convenient.”

The applicant states on page 22 that it projects growth of these 20 dialysis patients based on the Five Year Average Annual Change Rate (AACR) for Mecklenburg County published by the Agency in the July 2013 SDR, which is 6.6%.

On page 23, the applicant provides the following assumptions used to project utilization at the proposed Huntersville facility:

- *“The letters from in-center dialysis patients residing in zip codes 28078 and 28036 establish that DaVita facilities have been serving a portion of the patients who live in that area of Mecklenburg County and whose kidney disease has progressed to the point where they have ESRD and need in-center dialysis.*
- *Other patients who live in these zip codes and who will develop ESRD in the future will be referred by their physicians for dialysis to Huntersville Dialysis since it will be close to where they live.*
- *The number of patients needing in-center dialysis who live in zip codes 28078, 28070, 28036 and 28031 will grow from 1/1/2014 at the Mecklenburg County growth rate of 6.6% as shown in the July 2013 SDR.*
- *The dialysis patients in the two Charlotte zip codes (28216 and 28269) and in the Mooresville zip code (28115) who signed letters of support will be included in the total patient census for the end of Operating Years 1 and 2 at the Huntersville Dialysis Center, but based on the conservative assumption that new patients in those zip codes may choose other facilities, we will not project any growth in the patient population based on these other zip codes.”*

On page 23, the applicant projects utilization for the first two operating years, as follows:

- Begin with the 20 in-center patients who have signed letters and reside in ZIP codes 28078 and 28036
- Project growth of these patients using the Mecklenburg County AACR of 6.6% per year
- $20 \times 1.066 = 21.32$ (as of December 31, 2014)
- $21.32 \times 1.066 = 22.72$ (as of December 31, 2015)
- $22.72 \times 1.066 = 24.22$ (as of December 31, 2016 – Operating Year 1)

- $24022 \times 1.066 = 25.82$ (as of December 31, 2017 – Operating year 2)

In addition, the applicant states:

“Based on this computation, we can reasonably project that by the end of the first operating year, the population of 20 patients now receiving dialysis at a DaVita facility who signed support letters and live in the Huntersville and Davidson zip codes close to the proposed site will grow by 4 patients; and these 4 patients would receive in-center dialysis at the Huntersville facility along with all 29 of the patients who have signed letters indicating a willingness to transfer, so the facility would be providing in-center dialysis to 33 patients at the end of the first operating year. By the end of the second operating year, there would be additional growth of at least one full patient, resulting in a total in center census of 34 patients.”

Thus, the applicant projects that, by Operating Year One, the number of dialysis patients who would transfer to the Huntersville facility will grow by 4 patients at the end of Operating Year One, and by 5 patients at the end of Operating Year Two. Therefore, the applicant projects that the 29 patients who signed letters of support will grow to 33 patients, as follows:

- 29 initial patients who signed letters.
- 9 of those 29 patients live in Charlotte ZIP codes.
- 20 of those patients live in Huntersville ZIP codes.
- The applicant projects growth only of the 20 patients residing in the Huntersville ZIP codes.
- Therefore, 20 patients grows to 24 patients by the end of Operating Year One using the Mecklenburg County AACR.
- Add 24 to the 9 patients residing in the Charlotte ZIP codes = 33 patients at the end of Operating Year One.
- 24 Huntersville patients grows to 25 patients by the end of Operating Year Two using the Mecklenburg County AACR.
- Add 25 to the 9 patients residing in Charlotte ZIP codes = 34 patients at the end of Operating Year 2.

Thus, in Operating Year One, the applicant projects to serve 33 patients on ten certified stations, which is 3.3 patients per station per week, or 82.5% of capacity [$33 \text{ patients} / 10 \text{ stations} = 3.3 \text{ patients per station}$; $3.3 / 4 = 0.825$]. Likewise, in Operating Year Two, the applicant projects to serve 34 patients on ten certified stations, which is 3.4 patients per station, or 85.0% of capacity [$34 / 10 = 3.4$; $3.4 / 4 = 0.850$].

Projected utilization is based on reasonable, credible and supported assumptions. Specifically, assumptions regarding future growth are reasonable, based on the AACR for Mecklenburg County published by the Agency in the July 2013 SDR. Furthermore, the applicant assumes growth of only a portion of the patients expected to transfer to the proposed Huntersville Dialysis facility.

The applicant adequately demonstrates that a portion of the dialysis patient population currently utilizing other DaVita facilities will be better served by a facility located in Huntersville, which will be more convenient and/or closer to the patient's residence.

The applicant is not proposing to develop new stations, but rather to create a new facility through the in-county relocation of existing stations from an existing facility in order to more effectively serve its existing patient population as well as to effectively accommodate future patient growth in an established facility.

The applicant adequately demonstrates the need the population proposed to be served has for the relocation of the ten dialysis stations from North Charlotte Dialysis Center to the proposed Huntersville Dialysis facility.

With regard to peritoneal dialysis training (PD), the applicant states in Section III.7, page 29:

“Huntersville Dialysis will also be certified for peritoneal dialysis training and support, a home dialysis modality. It is anticipated that three peritoneal dialysis patients will transfer their care to Huntersville Dialysis upon certification of the facility. ... We project that the number of home trained patients will grow to 4 by the end of Operating Year One and 5 by the end of Operating Year Two.”

In Section III.6, page 28, the applicant provides a table to illustrate the projected number of home PD patients.

The analyst reviewed data obtained from the Southeastern Kidney Council, Network 6 (SEKC), which provides resources and information about dialysis facilities and care in North Carolina, South Carolina, and Georgia. SEKC publishes statistical data which reports the prevalence of End Stage Renal Disease (ESRD) by patient residence ZIP code in each state in the region.¹ According to the most recent report, dated January 22, 2014, Mecklenburg County had a total of 100 PD patients, and 27 of those patients were reportedly residents of the same ZIP codes projected to be served by the proposed Huntersville Dialysis.

The applicant's projections of the number of PD patients it proposes to serve in Operating Years One and Two (4 and 5 patients, respectively) are based on reasonable, credible and supported assumptions. Specifically, the applicant expects PD patients currently using a DaVita facility will transfer to the proposed facility.

Access to Services

In Section VI.1(a), on page 40, the applicant states,

“Huntersville Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. We will serve patients without regard to race,

¹ See <http://www.esrdnetwork6.org/publications/reports.html>

sex, age, or handicap. We will serve patients regardless of ethnic and socioeconomic situation.

...

Huntersville Dialysis will not require payment upon admission to its services; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

The applicant projects that 61.3% of its patients will be covered by Medicare, Medicaid or VA and another 27.0% will be covered by Medicare/Commercial. The applicant adequately demonstrates 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.

In addition, in Section V.7, page 39, the applicant states:

“...Huntersville Dialysis 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 member and other involved in the dialysis process to receive services.”

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

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

C

The applicant, DVA Healthcare Renal Care, Inc. d/b/a Huntersville Dialysis, proposes to relocate 10 certified dialysis stations from North Charlotte Dialysis Center to establish a new 10-station facility in Huntersville in Mecklenburg County. After the relocation of stations, North Charlotte Dialysis Center will have 25 certified dialysis stations ($35 - 10 = 25$).

In Section III.5, pages 24 – 25, the applicant describes the impact of the relocation of stations and transfer of patients from North Charlotte Dialysis Center. According to the July 2013 SDR, the utilization rate at North Charlotte Dialysis Center was 106% with 25 certified stations and 106 in-center patients [$106 / 25 = 4.24$; $4.24 / 4 = 1.06$]. The facility was

certified for ten additional stations after the publication of the July 2013 SDR, bringing the total number of in-center stations to 35. However, in this application, the applicant proposes to relocate ten stations to develop the Huntersville facility. Once the relocation of stations and transfer of patients takes place, the applicant projects that the North Charlotte Dialysis Center utilization rate will be 112% of capacity. (128 total patients – 16 transferred to Huntersville Dialysis = 112 patients / 25 stations = 4.48 / 4 = 1.12). On page 27, the applicant states:

“However, to project the impact of the opening of Huntersville Dialysis Center in early 2016 on the North Charlotte facility, we can project the growth that the population of North Charlotte Dialysis Center will experience through the point when the station transfer will occur and Huntersville Dialysis opens. We have projected the growth of the entire current patient population at North Charlotte Dialysis Center by projecting the growth from the date of the most recent Semiannual Dialysis Report data, which is December 31, 2012. At that time, North Charlotte Dialysis Center had 106 in-center patients and Mecklenburg County had an Average Annual Change Rate for the Past Five Years of 6.6%. Using this basis, we have projected the growth in the patient population from January 1, 2013 to the date Huntersville Dialysis is projected to be certified.

1/1/13 to 12/31/13: 106 in-center patients x 1.066 = 112.996

1/1/14 to 12/31/14: 112.996 in-center patients x 1.066 = 120.453

1/1/15 to 12/31/15: 120.453 in-center patients x 1.066 = 128.403.

Using the projections above, North Charlotte Dialysis Center would have 128 in-center patients when Huntersville Dialysis is projected to be certified on January 1, 2016. With 16 in-center patients and 10 dialysis stations transferring from North Charlotte Dialysis Center to Huntersville Dialysis, this will leave 112 in-center patients....”

In Section III.6, on pages 26 - 28, the applicant describes its plans to increase the number of stations at North Charlotte Dialysis Center as the utilization increases. The applicant states North Charlotte Dialysis Center is not suited to any additional physical expansion, so the relocation of ten stations and transfer of 16 patients to establish a facility in Huntersville will leave open the possibility of adding back ten stations once the facility need becomes apparent.

The applicant demonstrates that the needs of the population presently served at North Charlotte Dialysis Center will continue to be adequately met following the proposed relocation of 10 dialysis stations to Huntersville Dialysis. See discussion in Criterion (13) with regard to access by medically underserved groups which is incorporated hereby as if set forth fully herein. Therefore, the application is conforming to this criterion.

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

CA

In Section III.9, pages 30 - 32, the applicant discusses the alternatives considered prior to the submission of its application, which include:

1. Relocate more than ten dialysis stations to develop Huntersville Dialysis – the applicant states there is insufficient need for more than ten stations in the Huntersville area of Mecklenburg County.
2. Add additional stations to the existing North Charlotte Dialysis Center – the applicant states that the existing North Charlotte Dialysis Center, with 35 stations, has reached the maximum limit on the number of stations that can be added without increasing the actual size of the building. Furthermore, the applicant states that to increase the size of the North Charlotte Dialysis Center would “*delay the creation*” of a dialysis facility that is more accessible to residents in and around Huntersville.
3. Maintain the Status Quo – the applicant concludes that continuing to serve the patients expected to utilize the Huntersville facility at North Charlotte Dialysis Center and other area DaVita facilities will not provide adequate access to the dialysis patients who reside in the Huntersville area as they would have to drive 30 minutes or more to receive thrice weekly dialysis treatments. On page 31 the applicant states:

“... I-77 is a major north-south travel artery, as well as the main local commuter route for persons living in Iredell and northern Mecklenburg communities and working in Charlotte. According to NCDOT, current traffic counts in the Cornelius and Davidson area average 7,800 to 26,000 cars a day.”

4. Chosen alternative – Develop a new dialysis facility in Huntersville by relocating existing stations from North Charlotte Dialysis Center. On page 31, the applicant states,

“This is a conservative proposal that will bring a facility closer to the patients in northern Mecklenburg County but will not change the number of dialysis stations in the county, even though the total dialysis patient population in Mecklenburg County is growing steadily.”

The applicant adequately demonstrates that the proposed alternative is its most effective or least costly alternative to meet the identified need based on the following:

- A sufficient number of DaVita’s existing dialysis patients live closer to the proposed Huntersville Dialysis location, as demonstrated by the letters of support provided in Exhibits 14, 15, 16, 17, 18, and 19. This number is reasonably projected to increase.

- Patients will not have to travel as far on congested roads to dialyze three times per week.
- Minimal capital will be required to upfit a shell building built by the developer. A centralized purchasing department within DaVita will secure the dialysis chairs and TVs, negotiating the best product available at the best price.
- The applicant states in Section III.3, page 19, that North Charlotte Dialysis Center cannot accommodate future growth in patients because the physical footprint of the existing building does not allow expansion beyond 35 stations.

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 its proposal is the least costly or most effective alternative to meet the identified need for a 10-station dialysis facility in Huntersville. 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 Huntersville Dialysis shall materially comply with all representations made in the certificate of need application.**
 - 2. Total Renal Care of North Carolina, LLC d/b/a Huntersville Dialysis shall relocate and operate no more than a total of ten (10) certified dialysis stations which shall include any home hemodialysis training stations or isolation stations.**
 - 3. After the certification of the ten (10) relocated dialysis stations at Huntersville Dialysis, Total Renal Care of North Carolina, LLC d/b/a North Charlotte Dialysis Center shall take steps to decertify ten (10) dialysis stations for a total of no more than twenty-five (25) certified stations at North Charlotte Dialysis Center upon completion of this project.**
 - 4. Total Renal Care of North Carolina, LLC d/b/a Huntersville Dialysis shall install plumbing and electrical wiring through the walls for no more than ten (10) dialysis stations which shall include any home training or isolation stations.**
 - 5. Total Renal Care of North Carolina, LLC d/b/a Huntersville Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial

feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII, page 50, the applicant projects that the capital cost will be \$1,983,114, which includes \$1,315,724 in construction and site costs, \$90,000 in RO water treatment equipment, \$222,187 in other equipment, \$134,100 in architect and engineering fees; and \$221,103 in miscellaneous costs, including dialysis chairs, patient TVs, and computer systems.

In Sections IX.2 and IX.3, page 53, the applicant projects that there will be start-up expenses in the amount of \$145,610 and initial operating expenses in the amount of \$874,210 for a total working capital of \$1,019,820.

In Exhibit 31, the applicant provides a letter dated October 14, 2013 from the Vice President of Tax of DaVita Healthcare Partners Inc. (DaVita), which is the parent company of Total Renal Care, Inc., confirming DaVita's commitment of cash reserves in the sum of \$3,002,934 for the capital and working capital needs of the project [project cost of \$1,983,114 plus working capital of \$1,019,820]. DaVita's Form 10-K provided in Exhibit 32 confirms the availability of cash reserves in the amount of \$3,002,934 on the consolidated balance sheet, page F-6.

In Section X.1, page 55, the applicant provides the projected allowable charges per treatment for each payment source, as follows:

SOURCE OF PAYMENT	ALLOWABLE CHARGE PER TREATMENT
Medicare	\$240.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,442.00
VA	\$193.00
Medicare/Commercial	\$240.00

In Section X.3, page 58, the applicant provides the projected reimbursement rates per treatment for each payment source, as follows:

SOURCE OF PAYMENT	REIMBURSEMENT PER TREATMENT
Medicare	\$192.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,442.00
VA	\$193.00
Medicare/Commercial	\$240.00

In Sections X.2 - X.4, pages 56 - 61, the applicant reported projected revenues and expenses as follows:

	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$1,965,500	\$2,117,483
Total Operating Costs	\$1,748,420	\$1,843,762
Net Profit	\$217,080	\$273,721

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Section X of the application for the applicant's assumptions on number of treatments (3 days/week, 52 weeks/year with 5% missed treatments). In Section III.7, page 29, the applicant states,

“NOTE: The patient numbers for operating year 1 and 2 will be used to determine the number of treatments, operating revenue and operating expenses in Section X of this application. This includes the patients who are home-trained in peritoneal dialysis.” [Emphasis in original]

Projected treatments and revenues are reasonable based on the number of in-center and home patients projected for the first two operating years. In Section VII.1, page 46 and Section X.5, page 62, the applicant provides projected staffing and staff salaries. The applicant states the facility will be in compliance with all staffing requirements in 42 C.F.R. Section 494 (formerly 405.2100). Staffing by shift is provided on page 48. The applicant provides adequate staffing to provide dialysis treatments for the number of patients projected.

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

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

The applicant proposes to develop a new 10-station dialysis facility in Huntersville, in northern Mecklenburg County by relocating 10 existing dialysis stations from North Charlotte Dialysis Center to Huntersville Dialysis. There are currently 16 dialysis facilities in Mecklenburg County. Of those 16 facilities, four are operated by DaVita. One of those four facilities is located in north Charlotte. The majority of the patients who indicated they would consider transferring their care to Huntersville Dialysis currently utilize the north Charlotte facility. There is no dialysis facility in the Huntersville area of Mecklenburg County.

The applicant adequately demonstrates the need to relocate 10 existing dialysis stations to create Huntersville Dialysis based on the inability to physically expand the existing North Charlotte Dialysis Center to meet the growing need for dialysis services and the desire of existing DaVita patients to dialyze at a facility in a more convenient location. The total number of dialysis stations in Mecklenburg County will not change as a result of this project. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Mecklenburg County. Consequently, the application is conforming to this criterion.

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

C

In Section VII.1, page 46, the applicant provides a table, reproduced below, to illustrate projected staffing for the Huntersville Dialysis facility.

POSITION	TOTAL FTE* POSITION
Registered Nurse	1.5
HTPDRN	0.5
Patient Care Technician	4.5
Bio-Medical Technician	0.3
Administrative	1.0
Dietician	0.25
Social Worker	0.25
Unit Secretary	1.0
Total	9.3

As shown in the above table, the applicant proposes to employ a total of 9.3 full-time equivalent (FTE) positions to staff the Huntersville Dialysis facility upon completion of the proposed project.

In addition, the following table from Section VII.10, page 48 of the application shows the projected number of direct care staff for each shift offered in the Huntersville Dialysis facility following completion of the project.

	SHIFT TIMES	SUN	MON	TUE	WED	THURS	FRI	SAT
Morning	6am to 11am	0	3	3	3	3	3	3
Afternoon	11am to 4pm	0	3	3	3	3	3	3
Evening	N/A	0	0	0	0	0	0	0

In Section V.4(c), page 37, the applicant states that Dr. James Wood, who is board certified in internal medicine and nephrology, will serve as Medical Director of the proposed facility. Exhibit 23 contains a letter dated September 9, 2013 signed by Dr. Wood which expresses his support for the proposed project, and confirms his willingness to be the medical director for the new facility.

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

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

C

In Section V.1, page 35, the applicant provides a table to illustrate the providers of the necessary ancillary and support services. Acute dialysis in an acute care setting, emergency care, diagnostic evaluation services, X-ray services, blood bank and vascular surgery will be provided by Carolinas Medical Center and Lake Norman Regional Medical Center. Exhibit 8 contains a letter dated September 12, 2013 from the CEO of Lake Norman Regional Medical Center agreeing to enter into a transfer agreement to provide Huntersville Dialysis patients with the above services. In Exhibit 9, the applicant provides a letter dated September 9, 2013 signed by the Assistant Vice President of Carolinas Medical Center which confirms the hospital's intent to enter into a transplant agreement with Huntersville Dialysis. Exhibit 24 contains letters of support from area health care providers and the local community. 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 system. Therefore, the application is conforming to this criterion.

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

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 XI.6(h), page 69, the applicant provides a table to illustrate the estimated square feet proposed for the Huntersville Dialysis facility. The applicant proposes to construct a 9,600 square foot dialysis facility, with 296 square feet per dialysis station. In Section XI.6 (d), page 66, the applicant states the facility will be constructed with energy-efficient glass, mechanically operated patient access doors and energy-efficient cooling and heating.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges which is incorporated hereby as if set forth fully herein. 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

Huntersville Dialysis is a new facility and thus has no current patients. However, In Section VI.1(a), page 40, the applicant states Huntersville Dialysis will utilize a policy of making dialysis services available to all residents in its service area without qualifications.

In Section VI.1(b), page 40, the applicant reports that 88.0% of the patients who received treatments at North Charlotte Dialysis Center had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payment source for the existing facility:

NORTH CHARLOTTE DIALYSIS CENTER PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	25.4%
Medicaid	1.5%
Medicare/Medicaid	31.2%
Commercial Insurance	9.0%
VA	3.0%
Medicare/Commercial	29.9%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Mecklenburg County and statewide.

	Total # of Medicaid Eligibles as % of Total Population * as of June 2010	Total # of Medicaid Eligibles Age 21 and older as % of Total Population * as of June 2010	% Uninsured (Estimate by Cecil G. Sheps Center) * CY 2008 - 2009
Mecklenburg County	15%	5.1%	20.1%
Statewide	17%	6.7%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2011 only 5.8% of all newly-diagnosed ESRD patients (incident ESRD patients) in North Carolina's Network 6 were under the age of 35.²

² Southeastern Kidney Council ESRD Network 6 2011 Annual Report; Table 3, page 16.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data are available by age, race or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender do not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. About 25% of the Medicare-covered patients had employer group health plans as primary insurance, with Medicare as the secondary payer. Also, the CMS website states:

“Although the ESRD population is less than 1% of the entire U.S. population, it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings. ...

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.”³

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report provides these national statistics for FY 2010: *“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy.”* Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”⁴

The report provides 2010 ESRD spending by payor, as follows:

³<http://www.cms.gov/Medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf>

⁴United States Renal Data System 2012 USRDS Report, Chapter 1, page 225:
http://www.usrds.org/2012/pdf/v2_ch1_12.pdf.

ESRD Spending by Payor⁵		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender, as shown below:

Number and Percent of Dialysis Patients by Age, Race, and Gender		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1529	16.4%
55-64	2370	25.4%
65-74	2258	24.2%
75+	1872	20.0%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African-American	5,096	54.55%
White	4,027	43.11%
Other	219	2.3%
Total	9,342	100.0%

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

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

⁵United States Renal Data System 2012 USRDS Report, Chapter 11, page 340: http://www.usrds.org/2012/pdf/v2_ch11_12.pdf

⁶Southeastern Kidney Council ESRD Network 6 2011 Annual Report; Table 3, page 16.

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

“Huntersville 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. Huntersville Dialysis will have no obligation under the Hill Burton Act.”

In Section VI.6 (a), page 44, the applicant states, *“There have been no civil rights access complaints filed within the last five years.”*

The application is conforming to this criterion.

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

C

In Section VI.1(c), page 41, the applicant provides the projected payor mix for the proposed in-center and peritoneal dialysis services at the proposed facility as follows:

Projected Payor Mix – In-Center Dialysis	
HUNTERSVILLE DIALYSIS PROJECTED PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	25.4%
Medicaid	5.5%
Medicare/Medicaid	26.7%
Commercial Insurance	11.7%
VA	3.7%
Medicare/Commercial	27.0%
Total	100.0%

Projected Payor Mix – Peritoneal Dialysis

HUNTERSVILLE DIALYSIS PROJECTED PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	18.1%
Medicaid	6.0%
Medicare/Medicaid	15.7%
Commercial Insurance	21.7%
VA	4.8%
Medicare/Commercial	33.7%
Total	100.0%

The applicant states the projected payor mix at Huntersville Dialysis for in-center and peritoneal dialysis services is based on current payor mix at other DaVita facilities in Mecklenburg County; in particular, Charlotte Dialysis Center.

In Section VI.1(a), page 40, the applicant states,

“Huntersville Dialysis will not require payment upon admission to its services; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

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 VI.5, page 43, the applicant states:

“Patients with End Stage Renal Disease have access to dialysis services upon referral by a Nephrologist with privileges at Huntersville Dialysis. Huntersville Dialysis will grant privileges to all qualified nephrologists. Referrals to nephrologists most commonly come from primary care physicians or specialty physicians in Mecklenburg and surrounding counties or transfer referrals from other Nephrologists outside of the immediate area. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact the facility directly or indirectly, the patient will be referred to a qualified Nephrologist for evaluation and subsequent admission if found to be medically necessary. Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies which comprise Exhibit 26. [Emphasis in original] The patient,

again, will be referred to a qualified Nephrologist for final evaluation and then admission based on a doctor's orders."

The applicant adequately demonstrates that it provides a range of means by which a person can access 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(a), page 37, the applicant states,

"Huntersville Dialysis will be offered as a clinical learning site for nursing students at the local community colleges and nursing programs."

In Section V.3(b), the applicant states the facility will be open to developing relationships with *"any program that offers clinical training programs."*

In Exhibit 21, the applicant provides a letter signed by Doug Heaps, the Director of Education at Kaplan College of Charlotte, which states that the college will consider entering into a clinical training agreement with Huntersville Dialysis upon project completion. The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion

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

C

The applicant proposes to develop a new 10-station dialysis facility in Huntersville, Mecklenburg County by relocating 10 existing stations from North Charlotte Dialysis Center.

Although there are a total of 16 dialysis facilities in Mecklenburg County, there is no dialysis facility in the Huntersville area, which is the northwestern tip of the county. The nearest

dialysis facility is located in Charlotte and is operated by Independent Nephrology Services, Inc.

In Section III.9, pages 30 – 32, and Section V.7, page 39, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed dialysis services. On page 30, the applicant states: *“This is the best alternative of the dialysis patient population in northern Mecklenburg county which continues to grow, but lacks a dialysis facility in their area of the county.”* See also Sections II, III, V, VI and VII, where the applicant discusses the cost-effectiveness, quality and access to the proposed services.

The information in the application is reasonable and credible 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 a cost-effective alternative;
- The applicant adequately demonstrates that it will continue to provide quality services; and
- The applicant adequately demonstrates that it will continue to provide adequate access to medically underserved populations.

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

DVA Healthcare Renal Care Inc. currently provides dialysis services at North Charlotte Dialysis Center. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, North Charlotte Dialysis Center operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an

academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

.2202 INFORMATION REQUIRED OF APPLICANT

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

(1) *Utilization rates;*

-C- In Section II.1, page 10, the applicant states the utilization rate is reported in the July 2013 SDR provided in Exhibit 7. The July 2013 SDR utilization rate of 106% was calculated based on 106 in-center dialysis patients and 25 certified dialysis stations as of December 31, 2012 (106 patients / 25 stations = 4.24 patients per station; 4.24 patients per station / 4.00 patients per station = 1.060). In January 2013, North Charlotte Dialysis Center was approved to add ten additional stations to the facility. Those stations were certified on September 23, 2013, which brought the facility total to 35 certified stations. The applicant provides a copy of the certification letter in Exhibit 1.

(2) *Mortality rates;*

-C- In Section IV.2, page 33, the applicant reports the 2010, 2011 and 2012 facility mortality rates as 6.0%, 8.0% and 8.7%, respectively.

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

-C- In Section IV.3, page 33, the applicant states, “*North Charlotte Dialysis Center has an agreement with the Charlotte Dialysis Center for the provision of home dialysis training and support services.*”

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

-C- In Section IV.4, page 33, the applicant states, “*North Charlotte Dialysis Center had no patient receive a transplant in 2012. Thirty patients were referred for transplant evaluation in 2012.*”

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

- C- In Section IV.5, page 34, the applicant states, “*North Charlotte Dialysis Center has six patients on the transplant waiting list.*”
- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- In Section IV.6, page 34, the applicant states that there were 171 hospital admissions in CY 2012 for North Charlotte Dialysis Center, 14 (8.2%) of which were dialysis related and 157 (91.8%) were non-dialysis related.
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
- C- In Section IV.7, page 34, the applicant states that there was one patient dialyzing at North Charlotte Dialysis Center with Hepatitis B; and four patients with a diagnosis of AIDS as of December 31, 2012. The number of patients treated with infectious disease who have converted to infectious status within the last year is zero.
- (b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*
- (1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*
- C- In Exhibit 8 the applicant provides a signed letter of intent from Carolinas Medical Center and a signed letter of intent from Lake Norman Regional Medical Center. Each letter confirms that each facility will enter into a Patient Transfer Agreement with Huntersville Dialysis and to provide the following services to patients receiving their dialysis treatments at Huntersville Dialysis:
- Acute Dialysis
 - Emergency Room Care
 - Diagnostic Evaluation Services
 - X-ray Services
 - Special, Immunological and Routine Laboratory Services
 - Blood Banking Services
 - Surgical Services including Vascular Surgery
- (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 9 contains a letter from Carolinas Medical Center agreeing to enter into a Transplant Agreement with Huntersville Dialysis, including the components identified above.

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

-C- In Exhibit 10 and in Section XI.6(f), page 67, the applicant provides site specific documentation of the availability of power and water for Huntersville Dialysis.

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

-C- See Exhibit 10, in which the applicant provides copies of written policies and procedures for back up for electrical service in the event of a power outage.

- (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- The applicant provides written documentation of availability and commitment to pursue acquiring the proposed primary and/or secondary site in Exhibits 35 and 37.

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

-C- In Section XI.6(g), page 67, the applicant states, “*Huntersville Dialysis will operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment, and other relevant health safety requirements.*”

The applicant also states that Huntersville Dialysis will acquire and maintain Medicare Certification. See Exhibit 27 for excerpts from the DaVita Health and Safety Policy and Procedures Manual, and Exhibit 29 for excerpts from the DaVita Policy and Procedures Manual regarding patient care and safety.

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

-C- The applicant provides the following projected patient origin in Section III, on page 28 of the application, as shown below.

COUNTY	OPERATING YEAR 1 (2016)		OPERATING YEAR 2 (2017)		COUNTY PATIENTS AS PERCENT OF TOTAL	
	IN-CTR.	HOME	IN-CTR.	HOME	YEAR 1	YEAR 2
Mecklenburg	32	4	33	5	97.3%	97.5%
Iredell	1	0	1	0	2.7%	2.5%
Total	33	4	34	5	100.0%	100.0%

See Section III.7, pages 28 – 29 of the application and the discussion in Criterion (3) with regard to the applicant’s methodology and assumptions used to project patient origin, which is incorporated hereby as if set forth fully herein.

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

-C- In Section III.8, page 230, the applicant states, “100% of the patients will travel less than 30 miles one way for dialysis treatments.”

Mapquest[®] confirms the applicant’s statement. The proposed facility will be located in zip code area 28078. According to the signed patient letters provided by the applicant in Exhibits 14, 15, 16, 17, 18 and 19, a large number of patients live in ZIP codes that are within ten miles or less to the proposed Huntersville Dialysis ZIP code.⁷

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

-C- In Section II.1, page 12, the applicant states,

“DVA Healthcare Renal Care, Inc. d/b/a Huntersville Dialysis will admit and provide dialysis services to patients who have no insurance or other

⁷ www.mapquest.com for directions from each ZIP code provided by patients, including Davidson and Cornelius, to the ZIP code of the proposed facility.

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.”

.2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- C- The applicant proposes to establish Huntersville Dialysis, a new 10-station ESRD facility, by relocating 10 existing stations. In Section II, page 13 and Section III.7, page 29, the applicant projects to serve 33 in-center patients and 3.3 patients per station per week at the end of operating year one, based on the methodology and assumptions found on pages 12-13 and 28 – 29 of the application.
- (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- Huntersville Dialysis is proposing to develop a new ESRD facility through the relocation of existing Mecklenburg County dialysis stations.

.2204 SCOPE OF SERVICES

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

- (1) *diagnostic and evaluation services;*
- C- The table provided in Section V.1, page 35, states patients will be referred to Carolinas Medical Center and Lake Norman Regional Medical Center for diagnostic and evaluation services.
- (2) *maintenance dialysis;*
- C- The table provided in Section V.1, page 35, states the applicant will provide in-center maintenance dialysis at Huntersville Dialysis.
- (3) *accessible self-care training;*

-C- The table provided in Section V.1, page 35, states the applicant will provide in-center hemodialysis self-care training and intermittent peritoneal dialysis at Huntersville Dialysis.

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

-C- In Section V.2(d), on pages 36 - 37, the applicant states:

“Huntersville Dialysis will provide protocols and routines for patient follow-up. The social workers and dieticians contact the home-trained patients monthly. The patients are supported by monthly visits to their Board Certified Nephrologist for examination. The Home Training nursing teammates 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 are sent to a Medicare certified laboratory where they are analyzed. The results are reviewed by the teammates for adequacy and then reviewed by the dietitian and Nephrologist. Home trained patients are monitored by our Quality Management team.”

In addition, in Section III.7, page 29, the applicant states it proposes to develop a home training program for peritoneal dialysis at Huntersville Dialysis, and projects three patients to transfer their care to the facility upon project completion.

(5) *x-ray services;*

-C- The table provided in Section V.1, page 35, states patients will be referred to Carolinas Medical Center and Lake Norman Regional Medical Center for x-ray services.

(6) *laboratory services;*

-C- The table provided in Section V.1, page 35, states patients will be referred to Dialysis Laboratories for routine and special laboratory services.

(7) *blood bank services;*

-C- The table provided in Section V.1, page 35, states patients will be referred to Carolinas Medical Center and Lake Norman Regional Medical Center for blood bank services.

(8) *emergency care;*

-C- The table provided in Section V.1, page 35, states patients will be referred to Carolinas Medical Center and Lake Norman Regional Medical Center for emergency care.

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

-C- The table provided in Section V.1, page 35, states patients will be referred to Carolinas Medical Center and Lake Norman Regional Medical Center for acute dialysis in an acute care setting. In Exhibit 8 the applicant provides a copy of each hospital's letter of intent to enter into a patient transfer agreement with Huntersville Dialysis.

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

-C- The table provided in Section V.1, page 36, states dialysis patients will be referred to Carolinas Medical Center and Lake Norman Regional Medical Center for vascular surgery.

(11) *transplantation services;*

-C- The table provided in Section V.1, page 35, states patients will be referred to Carolinas Medical Center for transplantation services. In Exhibit 9 the applicant provides signed documentation from Carolinas Medical Center.

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

-C- The table provided in Section V.1, page 35, states patients will be referred to the North Carolina Division of Vocational Rehabilitation Services for vocational rehabilitation counseling and services.

(13) *transportation.*

-C- The table provided in Section V.1, page 36, states patients will be referred to the Department of Social Services and "various providers" for transportation.

.2205 STAFFING AND STAFF TRAINING

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

-C- In Section VII.1, page 46, the applicant provides the proposed staffing for Huntersville Dialysis. The applicant states, "*The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100....*" According to a table provided by the applicant in Section VII.9, on page 48, Huntersville Dialysis plans for two dialysis shifts; direct care staffing of 3.0 FTEs per shift on Monday through Saturday.

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

-C- In Section VII.5, page 48, the applicant refers to Exhibit 29 for a copy of the training program description and outline. Exhibit 29 does contain a copy of DaVita's Training Programs for New Patient Care Provider.