

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 26, 2016

Findings Date: February 26, 2016

Project Analyst: Gloria C. Hale

Team Leader: Fatimah Wilson

Project ID #: F-11109-15

Facility: Brookshire Dialysis

FID #: 150477

County: Mecklenburg

Applicant: DVA Healthcare Renal Care, Inc.

Project: Develop a new dialysis facility by relocating 10 stations from Charlotte Dialysis

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. (DVA) d/b/a Brookshire Dialysis proposes to develop a new 10-station dialysis facility in northwestern Charlotte by relocating 10 dialysis stations from Charlotte Dialysis. Both facilities are located in Mecklenburg County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

Need Determination

The applicant is proposing to relocate dialysis stations within Mecklenburg County, therefore there are no need methodologies in the 2015 State Medical Facilities Plan (2015 SMFP) applicable to this review.

Policies

There are two policies in the 2015 SMFP that are applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, on page 39, and *Policy ESRD-2 Relocation of Dialysis Stations*, on page 32.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

In Section B.5, pages 12-13, and Section K.1, page 43, the applicant describes how it will assure improved energy efficiency and water conservation. Therefore, the application is conforming to this criterion.

Policy ESRD-2: Relocation of Dialysis Stations 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 develop a new 10-station dialysis facility, Brookshire Dialysis, in Charlotte, by relocating existing dialysis stations from Charlotte Dialysis. Both facilities are located in Mecklenburg County, therefore there is no change in dialysis station inventory in Mecklenburg County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with applicable policies in the 2015 SMFP.

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 establish a new 10-station dialysis facility, Brookshire Dialysis, in northwestern Charlotte, Mecklenburg County, by relocating 10 existing dialysis stations from Charlotte Dialysis. Upon completion of this project, Brookshire Dialysis will be certified for 10 dialysis stations and Charlotte Dialysis will be certified for 26 dialysis stations.

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

Brookshire Dialysis will be a new facility in Mecklenburg County and therefore has no existing patient origin.

In Section C.1, page 14, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, including in-center (IC) patients and home peritoneal dialysis (PD) patients, as illustrated in the following table:

Projected Patient Origin

County	Operating Year 1 CY 2018		Operating Year 2 CY 2019		County Patients as % of Total	
	IC	PD	IC	PD	OY 1	OY2
Mecklenburg	33	2	35	3	100%	100%
Total	33	2	35	3	100%	100%

The applicant states, in Section A.8, page 4, that Brookshire Dialysis will be located in Charlotte within zip code 28216. The applicant states, on page 14, that it has letters of support from 53 patients currently dialyzing at DVA facilities in Mecklenburg County who live within zip code 28216 indicating their willingness to consider transferring to Brookshire Dialysis. Exhibit C-1 contains copies of 61 letters of support from patients willing to transfer to Brookshire Dialysis. Fifty-three of the letters are from in-center patients currently receiving dialysis at DVA facilities located in Charlotte and who live within zip code 28216. Eight of the letters are from home peritoneal dialysis patients currently receiving home peritoneal dialysis training at a DVA facility in Charlotte. The applicant states, in Section C.1, page 16, that five of the eight home peritoneal dialysis patients reside in Mecklenburg County, two reside in Gaston County, and one resides in Lincoln County. The applicant further states, on page 14, that all of the patients' letters indicate that Brookshire Dialysis would be closer to where they live and more convenient.

The applicant states, in Section C.1, page 15, that it assumes that at least 32 of the 53 in-center patients who signed letters will transfer their care to Brookshire Dialysis. In Section C.1, page 16, the applicant states that it assumes that at least one of the eight home peritoneal dialysis patients will transfer their care to Brookshire Dialysis.

The applicant adequately identifies the population to be served.

Analysis of Need

The applicant proposes to establish a new 10-station dialysis facility, Brookshire Dialysis, in northwestern Charlotte, Mecklenburg County, by relocating 10 existing dialysis stations from Charlotte Dialysis.

In Section C.2, page 17, the applicant states that it determined a need for a new dialysis facility in the northwestern part of Charlotte based on the fact that many of its in-center dialysis patients and several of its home peritoneal dialysis patients live in zip codes in the northwestern part of Charlotte where there is no DVA dialysis facility. In Section C.5, page 18, the applicant states that there were no other areas within the county that had significant numbers of DVA dialysis patients other than where it already had a dialysis facility or where one has already been proposed. The applicant states, in Section C.2, page 17, that 53 of its in-center patients dialyzing at four of DVA’s dialysis facilities in Charlotte live in zip code 28216, and eight home peritoneal dialysis (PD) patients live in either zip code 28216 or in four zip codes west or northwest of 28216. The applicant states, on page 17,

“In order to make the travel to dialysis – three times a week for in-patients and monthly for PD patients – more convenient, it was determined that DVA Healthcare Renal Care, Inc. needs to provide a dialysis center nearer to their homes for better access to their dialysis services and support.”

The following table, based on patients’ letters of support in Exhibit C-1, illustrates where the patients who are willing to transfer currently receive dialysis services and where they live by zip code:

DVA Patients Willing to Transfer by Zip Code of Residence

Current Dialysis Facility	28216	28208	28012	28037	28052	Total
Charlotte Dialysis	18					18
Charlotte East Dialysis Center*	4	2	1	1	1	9
North Charlotte Dialysis Center	32					32
South Charlotte Dialysis Center	2					2
Total	56	2	1	1	1	61

*Three of the four patients at Charlotte East Dialysis Center who live in zip code 28216 and all of the patients listed in zip codes 28208, 28012, 28037, and 28052 are PD patients.

Projected Utilization

In Section C.1, pages 14-16, the applicant provides its assumptions and methodology to determine the need for an additional dialysis facility in Mecklenburg County and to project its utilization. The assumptions and methodology are summarized as follows:

- 53 in-center patients from DVA dialysis facilities in Mecklenburg County provided letters of support indicating their willingness to consider transferring their care to the proposed facility, Brookshire Dialysis.

- In Project ID #F-10219-13, a conditionally-approved application to develop Huntersville Dialysis, a new, 10-station dialysis facility, DVA stated that patients would be willing to consider transferring there from DVA facilities in Mecklenburg, Cabarrus and Rowan counties. The applicant states, on page 14, that these patients are distinct from those who provided letters indicating their willingness to transfer to Brookshire Dialysis and that further, *“These patient populations represent two distinctly different geographic areas of Mecklenburg County.”*
- 32 of the 53 in-center patients who provided letters of support are projected to transfer their care to Brookshire Dialysis upon certification of the facility.
- The applicant assumes that the in-center patient population at Brookshire Dialysis will increase at a rate commensurate with Mecklenburg County’s Five Year Average Annual Change Rate (AACR) of 5.8%, as indicated in Table B of the July 2015 Semi-Annual Dialysis Report (SDR), for both Operating Years 1 and 2, CY2018 and CY2019, respectively.

In Section C.1, page 15, the applicant provides the calculations used to arrive at the projected in-center patient census for Operating Years 1 and 2, as follows:

Brookshire Dialysis	In-Center Patients
January 1, 2018, the beginning of Operating Year 1, will begin with 32 in-center patients who have transferred their care from other DVA dialysis facilities in Mecklenburg County and who are residents of Mecklenburg County	32
Growth is projected during OY1 by multiplying the beginning census by the Mecklenburg County Five Year AACR of 5.8% to arrive at the end of year census for December 31, 2018	$(32 \times .058) + 32 = 33.86$
Growth is projected again for OY2 by multiplying the beginning census for January 1, 2019 by the Mecklenburg County Five Year AACR of 5.8% to arrive at the end of year census for December 31, 2019	$(33.86 \times .058) + 33.86 = 35.82$

The applicant states, on page 15, that the number of projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, OY1 is projected to have 33 in-center patients and OY2 is projected to have 35 in-center patients. The projected utilization rate for Brookshire Dialysis is 3.3 patients per station per week, or 82.5% ($3.3 \text{ patients} / 10 \text{ stations} = 0.33 / 4 = .825$). For OY2, projected utilization is 3.5 patients per station per week, or 87.5% ($35 \text{ patients} / 10 \text{ stations} = 3.5 / 4 = .875$). The projected utilization of 3.3 patients per station per week for OY1 exceeds the minimum standard of 3.2 in-center patients per station per week as required by 10A NCAC 14C .2203(b).

The applicant provides its assumptions and methodology for projecting the number of home peritoneal dialysis (PD) patients Brookshire Dialysis will have, as follows:

Exhibit C-1 contains copies of letters of support from eight PD patients indicating their willingness to transfer to Brookshire Dialysis because the proposed facility would be closer to their homes and more convenient.

In Section C.1, page 16, the applicant states:

- Five PD patients receiving support at Charlotte East Dialysis who live in Mecklenburg County are willing to consider transferring their care to Brookshire Dialysis.
- Two PD patients receiving support at Charlotte East Dialysis who live in Gaston County are willing to consider transferring their care to Brookshire Dialysis.
- One PD patient receiving support at Charlotte East Dialysis who lives in Lincoln County is willing to consider transferring his or her care to Brookshire Dialysis.
- Of the eight PD patients from Charlotte East Dialysis, at least one is projected to transfer his or her care to Brookshire Dialysis upon certification of the facility.
- The rate of growth of PD patients at Brookshire Dialysis will be one PD patient per year.

In Section C.1, page 17, the applicant provides the calculations used to arrive at the projected PD patient census for Operating Years 1 and 2, as follows:

Brookshire Dialysis	PD Patients
January 1, 2018, the beginning of Operating Year 1, will begin with 1 PD patient who has transferred his or her care from East Charlotte Dialysis	1
The facility census is projected to grow by 1 PD patient per year to arrive at the end of year census for December 31, 2018	$1 + 1 = 2$
Growth is projected again for OY2 by increasing the PD census by one patient to arrive at the end of year census for December 31, 2019	$2 + 1 = 3$

Therefore, the applicant projects there will be two PD patients receiving support at Brookshire Dialysis at the end of OY1 and that there will be three PD patients at the end of OY2. The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions.

Access to Services

In Section C.3, page 17, the applicant states,

“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.”

In addition, the applicant projects, in Section L.1, page 50, that 86.1% of its in-center patients at Brookshire Dialysis will be covered by either Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, 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 proposed project 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.

C

DVA proposes to establish a new 10-station dialysis facility, Brookshire Dialysis, in northwestern Charlotte, Mecklenburg County, by relocating 10 existing dialysis stations from Charlotte Dialysis. Upon completion of this project, Brookshire Dialysis will be certified for 10 dialysis stations and Charlotte Dialysis will be certified for 26 dialysis stations.

In Section D.1, pages 24-25, the applicant states that as of December 31, 2014, as reported in the July 2015 SDR, there were 113 in-center dialysis patients at Charlotte Dialysis dialyzing on 36 dialysis stations, for a utilization rate of 78.47%. In addition, the applicant states that 105 of the 113 in-center patients lived in Mecklenburg County and that eight lived outside Mecklenburg County.

The applicant assumes that the number of in-center patients at Charlotte Dialysis who live in Mecklenburg County will increase at 5.8% per year based on the Five Year AACR for Mecklenburg County, as reported in Table B of the July 2015 SDR. The applicant

assumes that no growth will occur for the in-center patients living outside of Mecklenburg County. In Section D.1, page 24, the applicant calculates the in-center patient census for Charlotte Dialysis for CY2015 through OY1 (CY2018) and OY2 (CY2019), however there is an error in the number used for the beginning census of in-center patients who live in Mecklenburg County. The applicant uses the total number of in-center patients at Charlotte Dialysis, 113, instead of 105, the number of in-center patients who live in Mecklenburg County. The Project Analyst provides the calculations using the beginning census of 105 in-center patients, as follows:

Charlotte Dialysis	In-Center Patients
Beginning census for January 1, 2015 for Mecklenburg County patients only, increased by 5.8% Five Year AACR for Mecklenburg County. Add 8 patients from outside Mecklenburg County to arrive at ending census for December 31, 2015.	$(105 \times 0.058) + 105 =$ $111.09 + 8 = 119.09$
Mecklenburg County patient census for CY2016 increased by 5.8% Five Year AACR for Mecklenburg County. Add 8 patients from outside Mecklenburg County to arrive at ending census for December 31, 2016.	$(111.09 \times 0.058) + 111.09 =$ $117.53 + 8 = 125.53$
Mecklenburg County patient census for CY2017 increased by 5.8% Five Year AACR for Mecklenburg County. Add 8 patients from outside Mecklenburg County to arrive at ending census for December 31, 2017.	$(117.53 \times 0.058) + 117.53 =$ $124.35 + 8 = 132.35$
Mecklenburg County patient census for OY1 (CY2018) increased by 5.8% Five Year AACR for Mecklenburg County. Add 8 patients from outside Mecklenburg County to arrive at ending census for December 31, 2018.	$(124.35 \times 0.058) + 124.35 =$ $131.56 + 8 = 139.56$
Mecklenburg County patient Census for OY2 (CY2019) increased by 5.8% Five Year AACR for Mecklenburg County. Add 8 patients from outside Mecklenburg County to arrive at ending census for December 31, 2019.	$(131.56 \times 0.058) + 131.56 =$ $139.19 + 8 = 147.19$

The applicant rounds down the ending census numbers for OY1 and OY2, on page 25, therefore the Project Analyst rounds down the corrected ending census numbers calculated above. Charlotte Dialysis is projected to have 139 in-center patients at the end of OY1 for a utilization rate of 134%, or 5.35 patients per station ($139 \text{ patients} / 26 \text{ stations} = 5.35/4 = 1.34$). At the end of OY2 Charlotte Dialysis is projected to have 147 in-center patients for a utilization rate of 141%, or 5.65 patients per station ($147 \text{ patients} / 26 \text{ stations} = 5.65/4 = 1.41$). The applicant states, on page 25,

“Given this projected growth of the in-center patient population, additional Certificate of Need application(s) will be submitted based on facility need as the facility approaches full capacity of stations to ensure that the needs of the facility’s patients will continue to be met.”

The Project Analyst concludes that the above statement is reasonable, despite the errors made by the applicant in calculating the facility’s projected census for OY1 and OY2, based on Mecklenburg County’s Five Year AACR of 5.8% and the fact that the projected

utilization of the facility at the end of CY2017, the year prior to OY1, would be 91.9%, or 3.68 patients per station (132.35 patients/ 36 stations = 3.68/4 = 0.919).

The applicant demonstrates that the needs of the population presently served at Charlotte Dialysis will continue to be adequately met following the proposed relocation of ten dialysis stations from Charlotte Dialysis to Brookshire Dialysis and that access for medically underserved groups will not be negatively impacted.

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 E.1, pages 26-27, the applicant discusses the alternatives considered prior to submitting this application, which include:

- 1) Maintain the Status Quo - the applicant states that this option does not address the growth in the dialysis population at DVA's dialysis facilities in Mecklenburg County, with the exception of Mint Hill Dialysis. The applicant states that all but one of its facilities is at "*station capacity*" and therefore, cannot be expanded. The applicant further states that patients would either have no option to use DVA facilities or a third shift would need to be added which would be inconvenient for patients.

The Project Analyst notes that according to the July 2015 SDR, DVA's Huntersville Dialysis facility would also be an exception since it has received Agency approval but is not yet operational.

- 2) Development of the new facility in another area of Charlotte or Mecklenburg County – the applicant states in Section C.5, page 18, that it reviewed other areas within the county to determine whether there were significant patient populations, but determined that other areas were already being served by its existing facilities or would be by those under development. In Section E.1, pages 26-27, the applicant states that the site proposed would provide better geographic access for patients it identified, as evidenced by patient letters in Exhibit C-1.

After considering the above alternatives, the applicant states that development of the new Brookshire Dialysis facility would address the capacity limitations at four of its five operational dialysis facilities in Mecklenburg County and avoid having to create third shifts that are inconvenient for patients. Therefore, DVA believes that developing the new

Brookshire Dialysis facility will address the growing dialysis population at its facilities in Mecklenburg County and is, therefore, the most effective alternative.

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. **DVA Healthcare Renal Care, Inc. (DVA) d/b/a Brookshire Dialysis shall materially comply with all representations made in the certificate of need application.**
 2. **DVA Healthcare Renal Care, Inc. (DVA) d/b/a Brookshire Dialysis shall relocate no more than 10 dialysis stations from Charlotte Dialysis.**
 3. **DVA Healthcare Renal Care, Inc. (DVA) d/b/a Brookshire Dialysis shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 4. **DVA Healthcare Renal Care, Inc. (DVA) d/b/a Brookshire Dialysis shall take the necessary steps to decertify 10 dialysis stations at Charlotte Dialysis for a total of no more than 26 dialysis stations at Charlotte Dialysis upon project completion.**
 5. **DVA Healthcare Renal Care, Inc. (DVA) d/b/a Brookshire Dialysis 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.

C

Capital Costs

In Section F.1, page 28, the applicant provides the capital cost of the project as summarized in the following table:

**Brookshire Dialysis
Project Capital Costs**

Site Costs	\$13,000
Construction Contract	\$2,400,000
Dialysis Machines	\$144,870
Water Treatment Equipment	\$283,358
Equipment/Furniture	\$500,548
Architect & Engineering Fees	\$150,000
Total Capital Cost	\$3,491,776

In Section F.10, pages 30-31, and Section F.11, page 31, the applicant estimates start-up expenses of \$195,033 and initial operating expenses of \$569,691, respectively. Total working capital needed will equal \$764,724.

Availability of Funds

In Section F.2, page 29, the applicant states that accumulated reserves/owner's equity will be used to finance the project's capital costs. In Section F.13, page 32, the applicant states that the working capital costs will be financed with cash reserves. Exhibit F-5 contains a letter from DVA's Chief Accounting Officer, dated October 15, 2015, confirming DVA's commitment to funding the project's capital costs and working capital costs with cash reserves.

In Exhibit F-7, the applicant provides a copy of DaVita HealthCare Partners, Inc. (DaVita) United States Securities and Exchange Commission Form 10-K for the fiscal year ended December 31, 2014. DaVita is DVA's parent company. DaVita had cash and cash equivalents of \$965,241,000, total assets of \$17,942,715,000, and \$6,190,276,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.

Financial Feasibility

In Section R, Form C of the pro formas, page 69, the applicant provides its allowable charge per treatment for each payment source and provides its operating expense and revenue assumptions in Forms A-C, pages 66-72.

The applicant projects revenues in Section R, Form B, pages 67, and operating expenses in Section R, Form A, pages 64-65, summarized in the table below:

Brookshire Dialysis	Operating Year 1 CY2018	Operating Year 2 CY2019
Total Net Revenue	\$1,605,226	\$1,745,728
Total Operating Expenses	\$1,280,719	\$1,326,787
Net Profit	\$324,507	\$418,942

Note: Totals may not foot due to rounding.

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. However, the applicant does not include the contractual cost of the Medical Director in the operating expenses in Form A of the pro formas. In Section H, page 35, the applicant lists this expense as \$65,000. Nevertheless, the addition of this expense would decrease the applicant's net profit in both operating years, but would still result in a net profit. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable and adequately supported. See Section R, pages 66-72, of the pro formas for the applicant's assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In Section H.1, page 35, and in supplemental information, the applicant provides projected staffing and salaries. Form A in Section R, page 64, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

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 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

DVA proposes to establish a new 10-station dialysis facility, Brookshire Dialysis, in northwestern Charlotte, Mecklenburg County, by relocating 10 existing dialysis stations from Charlotte Dialysis.

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

The July 2015 SDR indicates there are 18 dialysis facilities in Mecklenburg County, as follows:

**Mecklenburg County Dialysis Facilities
 December 31, 2014**

Dialysis Facilities	Owner	# of Patients	# of Certified Stations	Percent Utilization
BMA Beatties Ford	FMC	113	32	88.28%
BMA Nations Ford	FMC	110	24	114.58%
BMA of East Charlotte	FMC	84	25	84.00%
BMA of North Charlotte	FMC	117	28	104.46%
BMA West Charlotte	FMC	91	29	78.45%
Carolinas Medical Center	CMHA	0	9	0.00%
Charlotte Dialysis	DVA	113	36	78.47%
Charlotte East Dialysis	DVA	96	26	92.31%
DSI Charlotte Latrobe Dialysis	DSI	64	24	66.67%
DSI Glenwater Dialysis	DSI	130	42	77.38%
FMC Charlotte	FMC	132	40	82.50%
FMC Matthews	FMC	96	21	114.29%
FMC of Southwest Charlotte	FMC	0	0	0.00%
FMC Regal Oaks	FMC	0	0	0.00%
Huntersville Dialysis	DVA	0	0	0.00%
Mint Hill Dialysis	DVA	40	10	100.00%
North Charlotte Dialysis Center	DVA	139	35	99.29%
South Charlotte Dialysis	DVA	66	20	82.50%

As illustrated above, DVA owns six of the 18 dialysis facilities in Mecklenburg County. Two FMC dialysis facilities and one DVA dialysis facility show zero patients and zero certified dialysis stations because they have received Agency approval but have not been certified yet. Carolinas Medical Center also shows zero patients although it does have certified stations. Notwithstanding the facilities with zero patients, only four have utilization rates less than 80% and three of those have utilization rates above 75%. Therefore, all of the operational dialysis facilities in the county are reasonably well utilized.

The applicant states, on page 34, that it is not increasing the number of dialysis stations in Mecklenburg County, rather it is relocating 10 of them to develop a new facility that is closer to patients living in the area where the new facility will be located. Therefore, it is not duplicating services, rather it is proposing to create a new facility to better serve patients.

In Section C.1, page 14, the applicant demonstrates that Brookshire Dialysis will serve a total of 33 in-center patients on 10 stations at the end of the first operating year, which is 3.3 patients per station per week, or a utilization rate of 82.5% ($33/10 = 3.3$; $3.3/4 = 0.825$). The applicant provides documentation in Exhibit C-1 from 53 in-center patients at its Mecklenburg County facilities indicating their willingness to consider transferring to Brookshire Dialysis upon completion because its location would be more convenient.

The applicant adequately demonstrates the need to relocate BMA stations to develop a new dialysis facility in Mecklenburg County. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on the needs of the population presently served at Charlotte Dialysis, found in Criterion (3a), 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 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

The applicant provides the projected staffing for Brookshire Dialysis in Section H.1, page 35, and in supplemental information, illustrated as follows:

Position	Projected Number of FTEs
Medical Director*	
Registered Nurse	2.0
Patient Care Technician	4.0
Administrator	1.0
Dietitian	0.5
Social Worker	0.5
Home Training Nurse	0.5
Administrative Assistant	1.0
Biomedical Technician	0.3
Total	9.8

*The Medical Director is a contract position, not an employee of the facility.

In Section H.3, pages 36-37, the applicant states that it will fill positions by using a DVA Teammate Recruiter, the Teammate Referral Program, and its Student Internship Program. In addition, the applicant states that it provides a wide range of benefits and competitive salaries to attract candidates for positions.

In Section H.7, page 38, the applicant provides the projected Direct Care Staff Hours for OY2, as follows:

Projected Direct Care Staff Hours – OY2

Direct Care Positions	# FTEs [a]	Hours / Year / FTE [b]	Total Annual FTE Hours [c] = [a] x [b]	Total Annual Hours of Operation [d]	FTE Hours / Hours of Operation [e] = [c] ÷ [d]
RN	2	2,080	4,160	3,120	1.3
Patient Care Technician	4	2,080	8,320	3,120	2.7
Total	6	2,080	12,480	3,120	4.0

In Section H.2, page 36, the applicant states that the Medical Director for Brookshire Dialysis will be Dr. James Wood. In Exhibit I-3, the applicant provides a letter signed by Dr. Wood, dated October 1, 2015, confirming his commitment to serve as Medical Director. In Exhibit I-3, the applicant provides an additional letter signed by Dr. Wood, dated October 1, 2015, stating that his Nephrology practice, Wood Medical Consulting, PA, will “*secure admission privileges and make referrals to the facility.*” The applicant does not list any other Nephrologists in the practice who will make referrals to the facility, nor provide documentation from other Nephrologists who will have admitting privileges. However, given the fact that there are 14 operational dialysis facilities and 26 licensed and active Nephrologists in Mecklenburg County¹, it is reasonable to assume that there would be other Nephrologists in the area who would seek admitting privileges and be willing to refer patients to the proposed facility.

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.

C

In Section I, pages 39-41, the applicant discusses the provision of necessary ancillary and support services to be provided for the proposed facility and provides a list of service providers on page 39. The applicant provides documentation regarding coordination with the existing health care system in Exhibits I-1, I-2 and I-3 from several providers, including DaVita Laboratory Services, Inc., the NC Division of Vocational Rehabilitation Services, transportation services, Carolinas Medical Center, and Wood Medical Consulting, PA. The information in Section I and Exhibits I-1, I-2 and I-3 is reasonable and supports a finding of conformity with this criterion.

¹North Carolina Medical Board.
<http://wwwapps.ncmedboard.org/Clients/NCBOM/Public/LicenseeInformationResults.aspx>

- (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.2, page 44, the applicant states there will be 8,337 square feet of treatment area, which will include home training and isolation room space. The applicant provides the proposed facility's line drawings in Exhibit K-1(a). The drawing depicts a 12,690 square foot facility, including office space, nine dialysis stations located in open space and one isolation dialysis station in an enclosed room, for a total of 10 stations. In Section F.1, page 28, the applicant lists its project costs, including \$2,400,000 for construction, \$1,078,776 in miscellaneous costs including dialysis machines, water treatment equipment, furniture, and architect/engineering fees for a total project cost of \$3,491,776. In Section B.5, pages 12-13, the applicant describes its plans to assure improved energy-efficiency and water conservation, including the following:

- The use of full LED lighting packages with occupancy and vacancy sensors, dimmers, and a full lighting control system that will provide 28% energy reduction.
- Interior finishes and materials will be used based on sustainable design and *“Indoor Environmental Quality criteria...defined in the US Green Building Council’s LEED Rating system.”*
- The HVAC system will be selected for its high performance and energy efficiency.
- All appliances, when possible, and most information technology equipment will be Energy Star rated.
- Water optimization protocols will be utilized to reduce the volume of water required to provide patient care, including adjusting the recovery rate for reverse osmosis devices and utilizing water-conserving plumbing fixtures.

Costs and charges are described by the applicant in Section F, pages 28-33, and in Section R pro forma financial statements. 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 have been incorporated into the construction plans 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.7, page 53, the applicant provides the payor mix for Charlotte Dialysis for CY2014, the facility that will be relocating 10 dialysis stations to develop the proposed facility, Brookshire Dialysis, and from which at least some patients will transfer (See Exhibit C-1 for patients’ letters of support), illustrated as follows:

**Charlotte Dialysis
 Payor Mix CY2014**

Payor Type	Percent of Total Patients
Medicare	31.2%
Medicaid	5.5%
Commercial Insurance	4.7%
Medicare/Commercial	30.5%
Medicare/Medicaid	25.8%
Other	2.3%
Total	100.0%

As the table above indicates, 93% of Charlotte Dialysis' patients are covered by Medicare or Medicaid. The applicant provides a copy of DVA's policy on acceptance of patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability in Exhibit L-3.

The *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*² provides prevalence data on North Carolina dialysis patients by age, race and gender on page 59, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
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%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

²<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).

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 applicants;

C

In Section L.3(e) page 52, the applicant states,

“Brookshire Dialysis 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.6, page 53, the applicant states, in reference to any facilities owned by DVA in the state, that there have been no civil rights equal 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 L.1, page 50, and in supplemental information, the applicant states that the projected payor mix for Brookshire Dialysis is based on sources of payment of its DVA facilities in Mecklenburg County for CY2014 and is illustrated as follows:

**Brookshire Dialysis
Projected Payor Mix OY2**

Payor Source	Percent of Total Patients	Percent In-Center Patients	Percent Home PD Patients
Medicare	27.9%	28.1%	17.5%
Medicaid	6.7%	6.8%	0.0%
Commercial Insurance	9.3%	9.0%	25.0%
Medicare/Commercial	29.3%	29.0%	45.0%
Medicare/Medicaid	21.9%	22.2%	5.0%
VA	4.9%	4.9%	7.5%
Total	100.0%	100.0%	100.0%

The applicant projects that 86.1% of Brookshire Dialysis' in-center patients and 67.5% of its home PD patients will be covered by Medicare or Medicaid. For the facility as a whole, 85.8% of the patients will be covered by Medicare or Medicaid.

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.4, page 52, the applicant states that patients will have access to the facility for dialysis services upon referral from a Nephrologist with admitting privileges at the facility. Patients, family, and friends who contact the facility seeking access to services will be referred to *“a qualified nephrologist for evaluation and subsequent admission...”*

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.1, page 54, the applicant states that it has offered Brookshire Dialysis as a clinical training site for nursing students from Central Piedmont Community College. A

copy of a letter sent by the applicant to the college, dated October 1, 2015, is included in Exhibit M-2.

The information provided in Section M.1 and Exhibit M-2 is reasonable 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

DVA proposes to establish a new 10-station dialysis facility, Brookshire Dialysis, in northwestern Charlotte, Mecklenburg County, by relocating 10 existing dialysis stations from Charlotte Dialysis.

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

The July 2015 SDR indicates there are 18 dialysis facilities in Mecklenburg County, as follows:

**Mecklenburg County Dialysis Facilities
 December 31, 2014**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	Percent Utilization
BMA Beatties Ford	FMC	113	Charlotte	32	88.28%
BMA Nations Ford	FMC	110	Charlotte	24	114.58%
BMA of East Charlotte	FMC	84	Charlotte	25	84.00%
BMA of North Charlotte	FMC	117	Charlotte	28	104.46%
BMA West Charlotte	FMC	91	Charlotte	29	78.45%
Carolinas Medical Center	CMHA	0	Charlotte	9	0.00%
Charlotte Dialysis	DVA	113	Charlotte	36	78.47%
Charlotte East Dialysis	DVA	96	Charlotte	26	92.31%
DSI Charlotte Latrobe Dialysis	DSI	64	Charlotte	24	66.67%
DSI Glenwater Dialysis	DSI	130	Charlotte	42	77.38%
FMC Charlotte	FMC	132	Charlotte	40	82.50%
FMC Matthews	FMC	96	Matthews	21	114.29%
FMC of Southwest Charlotte	FMC	0	Charlotte	0	0.00%
FMC Regal Oaks	FMC	0	Charlotte	0	0.00%
Huntersville Dialysis	DVA	0	Huntersville	0	0.00%
Mint Hill Dialysis	DVA	40	Mint Hill	10	100.00%
North Charlotte Dialysis Center	DVA	139	Charlotte	35	99.29%
South Charlotte Dialysis	DVA	66	Charlotte	20	82.50%

As illustrated above, all but three facilities are located in Charlotte. DVA operates six of the 18 dialysis facilities in Mecklenburg County and four of those are located in Charlotte. The proposed site for Brookshire Dialysis is approximately three to four miles from Charlotte Dialysis, nine miles from Charlotte East Dialysis, seven miles from North Charlotte Dialysis, and 17-18 miles from South Charlotte Dialysis. Notwithstanding the facilities with zero patients, only four have utilization rates less than 80% and three of those have utilization rates above 75%. Therefore, all of the operational dialysis facilities in the county are reasonably well utilized.

In Section N.1, page 55, 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 development of Brookshire Dialysis will have no effect on any dialysis facilities located in Mecklenburg County or in counties contiguous to Mecklenburg County. Metrolina Nephrology Associates serves as the referral source for all of the facilities in Mecklenburg County and the counties contiguous to Mecklenburg County, except Iredell County. The patients being

treated by Metrolina Nephrology Associates Nephrologists have a choice of dialysis facility. It has been our experience that patients generally choose a dialysis facility because it is closest to their home and most convenient.

DVA Healthcare Renal Care has made the case for a dialysis facility on the northwest side of Charlotte by identifying the need for a dialysis facility and identifying a population to be served, which is already being served by DaVita facilities.

...Brookshire 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 members and other [sic] involved in the dialysis process to receive services.”

See also Sections B, C, D, F, G, 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 referred to 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 a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that DVA will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that DVA will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3), (3a) and (6) 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.

In Section B, pages 8-9, the applicant discusses the methods it uses to insure and maintain quality. In Exhibit O-3, the applicant provides a listing of three dialysis facilities that were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application. One facility had three citations and the other two facilities had two each. There is no pattern of citations and each facility is back in compliance.

Based on a review of this certificate of need application and publicly available data, 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 G, page 34, and Table A of the July 2015 SDR, the applicant provides the utilization rates for Charlotte Dialysis. The December 31, 2014 utilization is 78.47% with 113 patients dialyzing on 36 stations.

.2202(a)(2) Mortality rates;

- C- In supplemental information, the applicant states that the mortality rates for Charlotte Dialysis were 8.51%, 4.39%, and 9.13% for CY2013, CY2014, and CY2015,

respectively.

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

-NA- There are no home-trained patients or patients on home dialysis at Charlotte Dialysis as reported by the applicant in supplemental information and as reported in the facility's June 2015 ESRD Data Collection Form submitted to the Agency.

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

-C- The applicant states, in supplemental information, that the number of transplants performed or referred from Charlotte Dialysis during 2015 was three.

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

-C- The applicant states, in supplemental information, that the number of patients currently on the transplant waiting list from Charlotte Dialysis is nine.

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

-C- The applicant states, in supplemental information, that there were 40 dialysis related hospital admissions for Charlotte Dialysis in CY2015, or 16% of its total hospital admissions. The number of hospital admissions for non-dialysis related reasons in CY2015 was 218, or 84% of its total hospital admissions.

.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- The applicant states, in supplemental information, that there was one patient with infectious disease and none who converted to infectious status during CY2015 for Charlotte Dialysis.

(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).

-C- Exhibit I-2 contains a copy of a letter, dated October 1, 2015, and signed by the

Assistant Vice President of Carolinas HealthCare System, which states the hospital's intention to enter into a patient transfer agreement with DVA to provide a range of services to patients receiving dialysis care at Brookshire Dialysis. A listing of services to be provided by Carolinas HealthCare System is included in the letter.

- .2202(b)(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) timeframe for initial assessment and evaluation of patients for transplantation,*
 - (B) composition of the assessment/evaluation team at the transplant center,*
 - (C) method for periodic re-evaluation,*
 - (D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*
 - (E) Signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- C- In supplemental information, the applicant provides a copy of a letter of intent from Carolinas HealthCare System, dated October 1, 2015, and signed by the Assistant Vice President, to enter into a Transplant Agreement with DVA Healthcare Renal Care, Inc. upon issuance of a Certificate of Need for the proposed project.
- .2202(b)(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- Exhibits K-4(h)) and K-5(h) contain documentation that power and water will be available at the primary and secondary site, respectively.
- .2202(b)(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- Exhibit K-1(f) contains a written policy for back up electrical service in the event of a power outage.
- .2202(b)(5) For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- C- In Section K.4(c), page 45, the applicant states that its primary site is located at 3401 Brookshire Blvd., Charlotte. The applicant states, in Section K.4, page 46, that it is willing to pursue acquisition of the site if approval is granted for the certificate of

need. In Section K.5, page 46, the applicant states that the secondary site is located at 2901 Freedom Drive, Charlotte. Exhibits K-4(h) and K-5(h) contain documentation on the availability of each site, respectively.

.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- The applicant states, in Section K.1(g), page 44, Section H.2, Exhibit H-2, and Exhibit K-1(d) that Brookshire Dialysis will provide services in conformity with all applicable laws and regulations, including all those described above.

.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 C.1, page 14, the applicant provides the projected patient origin by county for Brookshire Dialysis, based on the patients that are expected to transfer from DVA-operated facilities in Mecklenburg County. The applicant's assumptions and methodology for its projections are provided on pages 14-17 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.*

-C- In Section C.4, page 18, the applicant indicates that 100% of the anticipated patient population resides within 30 miles or less from the proposed 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 60, the applicant states, "Brookshire Dialysis will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services."

10 NCAC 14C .2203 PERFORMANCE STANDARDS

.2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

- C- In Section C.1, page 16, the applicant provides its projected in-center utilization for the end of the first operating year for the proposed facility. The applicant states it will have 33 patients for a utilization rate of 3.30 patients per station per week or 82.5%. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.
- .2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- NA- The applicant is seeking to develop a new 10-station dialysis facility.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 14-17, 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 I.1, page 39, the applicant states that Carolinas Medical Center will provide diagnostic and evaluation services. Exhibit I-2 contains a letter from Carolinas HealthCare System stating that its hospital will provide these services to patients at Brookshire Dialysis.

.2204(2) Maintenance dialysis;

- C- In Section I.1, page 39, the applicant states that maintenance dialysis will be provided by the proposed facility.

.2204(3) Accessible self-care training;

- C- In Section I.1, page 39, the applicant states that accessible self-care training will be provided by the proposed facility.

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

- C- In Section I.2, page 40, the applicant states that Brookshire Dialysis “...will provide

protocols and routines for PD patient follow-up.” In addition, as stated in Section I.2, page 40, the proposed facility has an agreement with Charlotte East Dialysis to provide support and follow-up services for home-trained patients. A copy of an agreement between Charlotte East Dialysis and Brookshire Dialysis to provide home training is included in Exhibit I-1.

.2204(5) X-ray services;

- C- In Section I.1, page 39, the applicant states that Carolinas Medical Center will provide x-ray services. Exhibit I-2 contains a letter from Carolinas HealthCare System stating that its hospital will provide these services to patients at Brookshire Dialysis.

.2204(6) Laboratory services;

- C- In Section I.1, page 39, the applicant states that laboratory services will be provided by DaVita Laboratory Services, Inc. In Exhibit I-1, the applicant provides a copy of an agreement between DaVita Laboratory Services, Inc. and Total Renal Care of North Carolina, LLC, a subsidiary of DVA, to provide laboratory services.

.2204(7) Blood bank services;

- C- In Section I.1, page 39, the applicant states that Carolinas Medical Center will provide blood bank services. Exhibit I-2 contains a letter from Carolinas HealthCare System stating that its hospital will provide these services to patients at Brookshire Dialysis.

.2204(8) Emergency care;

- C- In Section I.1, page 39, the applicant states that Carolinas Medical Center will provide emergency care services. Exhibit I-2 contains a letter from Carolinas HealthCare System stating that its hospital will provide these services to patients at Brookshire Dialysis.

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

- C- In Section I.1, page 39, the applicant states that Carolinas Medical Center will provide acute dialysis services. Exhibit I-2 contains a letter from Carolinas HealthCare System stating that its hospital will provide these services to patients at Brookshire Dialysis.

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

- C- In Section I.1, page 39, the applicant states that Carolinas Medical Center will provide vascular surgery services. Exhibit I-2 contains a letter from Carolinas

HealthCare System stating that its hospital will provide these services to patients at Brookshire Dialysis.

.2204(11) Transplantation services;

- C- In Section I.1, page 39, the applicant states that Carolinas Medical Center will provide transplantation services. In supplemental information, the applicant provides a letter from Carolinas HealthCare System stating that these services will be provided to patients at the proposed facility.

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

- C- In Section I.1, page 39, the applicant states that vocational rehabilitation counseling and services will be provided by the North Carolina Division of Vocational Rehabilitation Services. Exhibit I-1 contains a letter from the North Carolina Division of Vocational Rehabilitation Services stating that they will provide these services to patients at the proposed facility upon referral.

.2204(13) Transportation

- C- In Section I.1, page 39, the applicant states that Mecklenburg County DSS and other providers will provide transportation. Exhibit I-1 contains copies of letters from A-1 Patient Transport, Inc. and Royal Cab and Transportation Company stating that they support the proposed facility and that *“This will save our transportation agency time and financial resources.”*

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 H.1, page 35, the applicant provides a proposed staffing chart. In Section H.2, page 36, the applicant states the proposed facility will comply with all staffing requirements set forth in the Federal code. 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 H.4, page 37, the applicant discusses the required training for staff, including continuing education. Exhibit H-4 contains an outline of DaVita’s annual in-service training and a listing of continuing education opportunities for employees.