

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 16, 2017

Findings Date: August 16, 2017

Project Analyst: Julie Halatek

Team Leader: Fatimah Wilson

Project ID #: Q-11351-17

Facility: Murfreesboro Dialysis Center

FID #: 170240

County: Hertford

Applicant(s): DVA Healthcare Renal Care, Inc.

Project: Develop a new 10-station dialysis facility by relocating 10 stations from Ahsokie Dialysis Center and offer home peritoneal dialysis training and support

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. § 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

The applicant, DVA Healthcare Renal Care, Inc. (DVA) d/b/a Murfreesboro Dialysis Center (Murfreesboro Dialysis), proposes to develop a new 10-station dialysis facility in Murfreesboro by relocating 10 stations from Ahsokie Dialysis Center (ADC). Both facility locations are in Hertford County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, Murfreesboro Dialysis will be certified for 10 dialysis stations and ADC will be certified for 16 dialysis stations. The applicant also proposes to offer home peritoneal dialysis (PD) training and support.

Need Determination

The applicant is proposing to relocate existing dialysis stations within Hertford County; therefore, there are no need determinations in the 2017 State Medical Facilities Plan (SMFP) applicable to this review.

Policies

There is one policy in the 2017 SMFP that is applicable to this review: **Policy ESRD-2: Relocation of Dialysis Stations.**

On page 27, **Policy ESRD-2: Relocation of Dialysis Stations** states:

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

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing 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*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing 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 in Murfreesboro by relocating 10 stations from ADC. Both facility locations are in Hertford County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the applicable policy in the 2017 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 develop a new 10-station dialysis facility in Murfreesboro by relocating 10 stations from ADC. Both facility locations are in Hertford County. Upon completion of this project, Murfreesboro Dialysis will be certified for 10 dialysis stations and ADC will be certified for 16 dialysis stations. The applicant also proposes to offer home PD training and support.

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis stations 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 Hertford County. Facilities may also serve residents of counties not included in their service area.

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

In Section C.1, page 13, and in clarifying information received August 10, 2017, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table:

Murfreesboro Dialysis – Projected Patient Origin – OYs 1 & 2						
County	OY 1 CY 2019		OY 2 CY 2020		County Patients as % of Total	
	In-Center	PD	In-Center	PD	OY1	OY2
Hertford	32	3	33	4	92.2%	92.5%
Bertie	1	0	1	0	2.6%	2.5%
Gates	1	0	1	0	2.6%	2.5%
Halifax	0	1	0	1	2.6%	2.5%
Total	34	4	35	5	100.0%	100.0%

The applicant does not propose to serve home hemodialysis patients.

In Section C.1, pages 13-16, the applicant provides the assumptions and methodology used to project patient origin. The applicant states that projected patient origin is based on the existing 34 Hertford County patients, one Bertie County patient, one Gates County patient, and one Halifax County patient who signed letters stating their willingness to transfer their care to the proposed facility. Exhibit C-1 contains copies of the 37 signed letters.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section C.2, page 16, the applicant states that the need for the new facility is based on an analysis done by the applicant which determined it is serving a total of 34 in-center patients who live in or near northern Hertford County and three PD patients who live in or near northern Hertford County. The applicant states that it wants to provide a dialysis center closer to the homes of these patients. Exhibit C-1 contains 37 letters of support from in-center and PD patients, indicating they would consider transferring to the proposed dialysis facility.

Projected Utilization – In-Center Patients

In Section C.1, page 13, and in clarifying information received August 10, 2017, the applicant provides the projected patient origin for Murfreesboro Dialysis for in-center and PD patients for the first two operating years following completion of the project, Calendar Years (CY) 2019 and 2020, as follows:

Murfreesboro Dialysis – Projected Patient Origin – OYs 1 & 2						
County	OY 1 CY 2019		OY 2 CY 2020		County Patients as % of Total	
	In-Center	PD	In-Center	PD	OY1	OY2
Hertford	32	3	33	4	92.2%	92.5%
Bertie	1	0	1	0	2.6%	2.5%
Gates	1	0	1	0	2.6%	2.5%
Halifax	0	1	0	1	2.6%	2.5%
Total	34	4	35	5	100.0%	100.0%

In Section C.1, pages 13-14, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below:

- The Hertford County patient population will grow at a rate of 3.0 percent (the Five Year Average Annual Change Rate [AACR] for Hertford County, as published in the January 2017 Semiannual Dialysis Report [SDR]), through the end of the second year of operation.
- The applicant assumes that the patients who signed letters indicating they would consider transferring to the facility and who live outside of Hertford County will actually transfer to the facility. The applicant projects no increase in that patient population but adds them to the calculations when appropriate.
- The project is scheduled for completion on January 1, 2019. OY1 is CY 2019. OY2 is CY 2020.

In Section C.1, page 14, the applicant provides the calculations used to arrive at the projected in-center patient census for OY1 and OY2 as summarized in the table below.

Murfreesboro Dialysis	
Begin with 32 in-center patients from Hertford County, who are projected to transfer to Murfreesboro Dialysis upon facility certification (January 1, 2019), but who are currently dialyzing at ADC.	32
The two patients from other counties are added. This is the beginning patient census for January 1, 2019.	$32 + 2 = 34$
Hertford County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR for Hertford County (3.0%).	$32 \times 1.03 = 32.96$
The two patients from other counties are added. This is the patient census for the end of OY 1 (December 31, 2019).	$32.96 + 2 = 34.96$ (34)
Hertford County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR for Hertford County (3.0%).	$32.96 \times 1.03 = 33.95$
The two patients from other counties are added. This is the patient census for the end of OY 2 (December 31, 2020).	$33.95 + 2 = 35.95$ (35)

The applicant projects to serve 34 in-center patients on 10 stations, which is 3.4 patients per station per week ($34 \text{ patients} / 10 \text{ stations} = 3.4$), by the end of OY 1 and 35 in-center patients on 10 stations, which is 3.5 patients per station per week ($35 \text{ patients} / 10 \text{ stations} = 3.5$), by the end of OY 2. This meets the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Projected Utilization – Home PD Patients

The applicant provides projected utilization for its PD patients in Section C.1, pages 15-16, as follows:

Murfreesboro Dialysis PD Patient Projected Utilization – OY1 & OY2		
Operating Year	Beginning Census of PD Patients	Ending Census of PD Patients
CY 2019 (OY1)	3	4
CY 2020 (OY2)	4	5

On page 15, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- In Exhibit C-1, the applicant provides three letters of support signed by patients currently receiving PD support at ADC which indicated they would consider transferring their care to Murfreesboro Dialysis upon certification.
- The applicant assumes all of the patients who signed letters of support for the proposed facility will transfer their care to Murfreesboro Dialysis upon certification.
- The applicant assumes that the PD patient population will increase by one patient per year.

Projected PD utilization is based on reasonable and adequately supported assumptions regarding continued growth at Murfreesboro Dialysis.

Home Hemodialysis

In Section I.1, page 38, the applicant indicates that home hemodialysis training will be provided through ADC. The applicant does not indicate anywhere else in the application that it plans to offer home hemodialysis training and support at Murfreesboro Dialysis.

Access

In Section L.1, page 48, the applicant states:

“Murfreesboro Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability.

Murfreesboro Dialysis will make every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work.”

In Section L.1, page 49, the applicant projects that 90.5 percent of its patients will have some or all of their services paid for by Medicare and/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; demonstrates the need the population projected to be served has for the proposed services based on reasonable and supported utilization projections and assumptions; and demonstrates 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

The applicant proposes to develop a new 10-station dialysis facility in Murfreesboro by relocating 10 stations from ADC. Both facility locations are in Hertford County. Upon completion of this project, Murfreesboro Dialysis will be certified for 10 dialysis stations and ADC will be certified for 16 dialysis stations. The applicant also proposes to offer home PD training and support.

Upon completion of this project, ADC will be certified for 16 stations (26 - 10). In Section D.1, pages 23-24, the applicant discusses how the needs of dialysis patients at ADC will continue to be met after the relocation of stations to the proposed Murfreesboro Dialysis facility:

- The January 2017 SDR indicates there were 80 in-center dialysis patients receiving care at ADC as of June 30, 2016. 61 in-center patients lived in Hertford County and 19 in-center patients lived outside of Hertford County.
- The 32 in-center Hertford County patients who signed letters of support indicating they would consider transferring to the new Murfreesboro Dialysis facility will be subtracted from the patient population projections at the time in the projections where the new facility is certified.
- The in-center Hertford County patient population at ADC is projected to grow at a rate of 3.0 percent, the Five Year AACR for Hertford County published in the January 2017 SDR. No growth is projected for the 19 in-center patients who reside outside of Hertford County, but those patients will be included in the projections when appropriate.

Based on the above assumptions, the applicant projects utilization at ADC from June 30, 2016 through December 31, 2020 as follows:

ADC	
Begin with the Hertford County ESRD patient population at ADC as of June 30, 2016.	61
Project this population forward six months to December 31, 2016, applying one half of the Hertford County Five Year AACR of 3.0% (1.5%).	$61 \times 1.015 = 61.915$
Add the 19 patients residing outside of Hertford County to obtain the facility census for December 31, 2016.	$61.915 + 19 = 80.915$
Project the Hertford County population forward 12 months to December 31, 2017, applying the Hertford County Five Year AACR of 3.0%.	$61.915 \times 1.03 = 63.773$
Add the 19 patients residing outside of Hertford County to obtain the facility census for December 31, 2017.	$63.773 + 19 = 82.773$
Project the Hertford County population forward 12 months to December 31, 2018, applying the Hertford County Five Year AACR of 3.0%.	$63.773 \times 1.03 = 65.686$
Add the 19 patients residing outside of Hertford County to obtain the facility census for December 31, 2018.	$65.686 + 19 = 84.686$
Subtract 32 Hertford County patients projected to transfer to Murfreesboro Dialysis.	$65 - 32 = 33$
Project the remaining Hertford County population at ADC forward 12 months to December 31, 2019, applying the Hertford County Five Year AACR of 3.0%.	$33 \times 1.03 = 33.99$
Subtract two patients residing outside of Hertford County projected to transfer to Murfreesboro Dialysis and adds the remaining 17 patients to obtain the facility census for December 31, 2019.	$33.99 + (19-2) = 50.99$
Project the Hertford County population forward 12 months to December 31, 2020, applying the Hertford County Five Year AACR of 3.0%.	$33.99 \times 1.03 = 35.01$
Add the 17 patients residing outside of Hertford County to obtain the facility census for December 31, 2020.	$35.01 + 17 = 52.01$

The applicant projects that as of December 31, 2020, ADC will have 52 in-center dialysis patients dialyzing on 16 stations for a utilization rate of 3.25 patients per station per week, or 81.3 percent of capacity ($52 / 16 = 3.25$; $3.25 / 4 = 0.813$ or 81.3%). The applicant states that as the facility population grows, it will submit additional applications for stations based on facility need.

Thus, the applicant demonstrates that the needs of the population presently served at ADC will continue to be adequately met following the proposed relocation of dialysis stations and transfer of patients to Murfreesboro 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 25-26, the applicant discusses the alternatives considered prior to the submission of this application, summarized as follows:

1. Maintain the Status Quo – the applicant states that it dismissed this alternative because it does not meet the needs of a population that resides in a specific region of the service area. Therefore, the applicant determined the status quo would not be the most effective alternative.
2. Develop Facility in Another Area in Hertford County – the applicant states that a facility located in a different area of Hertford County would not address the needs of the identified patients because the patients live in a specific region of Hertford County. Therefore, the applicant determined any other location would be less effective.

Thus, after considering the above alternatives, the applicant concludes that its proposal to develop a new 10-station dialysis center in Murfreesboro by relocating stations from ADC is the most cost effective alternative.

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

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

- 1. DVA Healthcare Renal Care, Inc. d/b/a Murfreesboro Dialysis Center shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, DVA Healthcare Renal Care, Inc. d/b/a Murfreesboro Dialysis Center shall develop a new kidney disease treatment center to be known as Murfreesboro Dialysis Center by relocating 10 dialysis stations from Ahoskie Dialysis Center, which shall include any home hemodialysis training or isolation stations.**
- 3. DVA Healthcare Renal Care, Inc. d/b/a Murfreesboro Dialysis Center shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations which shall include any isolation stations.**
- 4. Upon completion of this project, DVA Healthcare Renal Care, Inc. shall take the necessary steps to decertify 10 dialysis stations at Ahoskie Dialysis Center for a total of no more than 16 dialysis stations at Ahoskie Dialysis Center.**

5. DVA Healthcare Renal Care, Inc. d/b/a Murfreesboro Dialysis Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new 10-station dialysis facility in Murfreesboro by relocating 10 stations from ADC. The applicant also proposes to offer home PD training and support.

Capital and Working Capital Costs

In Section F.1, page 27, the applicant projects \$1,990,634 in capital costs to develop the proposed project, summarized as follows:

Murfreesboro Dialysis

Site Costs	\$78,280
Construction Contract	\$1,167,066
Dialysis Machines	\$151,580
Water Treatment Equipment	\$141,860
Other Equipment/Furniture	\$365,148
<u>Architect/Engineering Fees/Expenses</u>	<u>\$86,700</u>
Total	\$1,990,634

In Section F.10, pages 29-30, the applicant states that it will have \$191,283 in start-up expenses and in Section F.11, page 30, the applicant states it will have six months of initial operating expenses totaling \$758,378. The total estimated working capital for the project is \$949,661.

Availability of Funds

In Exhibit F-5, the applicant provides a letter dated May 15, 2017 from the Chief Accounting Officer of the parent company, DaVita, Inc. (DaVita), authorizing the project and committing cash reserves for the capital expenditure in the amount of \$2,940,295. Exhibit F-7 contains the DaVita Consolidated Financial Statements, as of December 31, 2016, which shows cash and cash equivalents of \$913,187,000, total assets of \$18,741,257,000, and net assets (total assets less total liabilities) of \$5,822,999,000. The applicant adequately demonstrates the availability of funds for the capital, working capital, and operating needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

Murfreesboro Dialysis Revenues and Expenses – Operating Years 1 & 2		
	Operating Year 1	Operating Year 2
Total Treatments	5,557	5,779
Total Gross Revenues (Charges)	\$1,608,733	\$1,693,137
Total Net Revenue	\$1,561,964	\$1,644,848
Total Operating Expenses (Costs)	\$1,516,475	\$1,570,057
Net Income	\$45,489	\$74,790

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates the financial feasibility of the project is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges), 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

The applicant proposes to develop a new 10-station dialysis facility in Murfreesboro by relocating 10 stations from ADC. Both facility locations are in Hertford County. Upon completion of this project, Murfreesboro Dialysis will be certified for 10 dialysis stations and ADC will be certified for 16 dialysis stations. The applicant also proposes to offer home PD training and support.

On page 373, the 2017 SMFP defines the service area for dialysis stations 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 Hertford County. Facilities may also serve residents of counties not included in their service area.

Currently, the applicant is the only provider of dialysis services in Hertford County. According to the January 2017 SDR, ADC was serving 80 patients on 26 stations as of June 30, 2016, for

a utilization rate of 76.92 percent or 3.0769 patients per station per week (80 patients / 26 stations = 3.0769; $3.0769 / 4 = 0.7692$ or 76.92%).

According to Table B in the January 2017 SDR, there is a surplus of two dialysis stations in Hertford County. However, the applicant is not increasing the number of dialysis stations in Hertford County. It is relocating 10 existing Hertford County stations to develop a new facility that the applicant states is closer to patients living in the area where the new facility will be located. Therefore, it is not duplicating services, but rather proposing to create a new facility to better serve existing patients using existing stations.

In Section C.1, page 14, the applicant demonstrates that Murfreesboro Dialysis will serve a total of 34 in-center patients on 10 stations at the end of the first operating year, which is 3.4 patients per station per week, or a utilization rate of 85 percent ($34 / 10 = 3.4$; $3.4 / 4 = 0.85$ or 85%). The applicant provides documentation in Exhibit C-1 from 32 Hertford County in-center patients, two in-center patients residing outside Hertford County, two Hertford County PD patients, and one PD patient residing outside Hertford County stating their willingness to consider transferring to Murfreesboro Dialysis because its location would be more convenient. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates the need to relocate existing Hertford County dialysis stations to develop a new dialysis facility in Hertford County. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference. The discussion regarding the need of the population presently served at ADC, 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 Hertford County. Consequently, the application is conforming to this criterion.

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

C

In Section H.1, page 34, the applicant provides the projected staffing for Murfreesboro Dialysis in OY2 by full-time equivalent (FTE) positions, as shown in the table below:

Murfreesboro Dialysis Proposed FTE Positions OY2	
Position	Total
Registered Nurse	2.0
Patient Care Technician	4.0
Administrator	1.0
Dietitian	0.5
Social Worker	0.5
Home Training RN	0.5
Admin Assistant	1.0
Biomed Tech	0.3
Total FTEs	9.8

Note: The Medical Director is an independent contractor, not an employee.

In Section I.2, page 39, the applicant states that Dr. Greg Warren, a board certified nephrologist, will serve as medical director. In Exhibit I-3, the applicant provides a letter from Dr. Warren, dated April 28, 2016 (which appears to be a typo), indicating support for the project, and stating his willingness to serve as the medical director for the facility. In Section H.3, pages 35-36, the applicant provides a list of resources it will use to find qualified candidates and states it offers a competitive salary structure and benefits to attract qualified candidates. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed 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.1, page 38, the applicant lists the providers of the necessary ancillary and support services for the proposed project. The table states that acute dialysis in an acute care setting, emergency care, blood bank services, diagnostic/evaluation services, x-ray services, and pediatric nephrology services will be referred to Sentara Albemarle Medical Center. The table states transplantation services will be referred to Sentara Norfolk Medical Center. Exhibit I-2 includes letters from both Sentara hospitals affirming a willingness to provide those services to Murfreesboro Dialysis patients. Exhibit I-1 contains an agreement for lab services between DaVita Lab Services and Murfreesboro Dialysis. The applicant discusses coordination with the existing health care system in Sections I.3 and I.4, pages 39-40, stating that DVA has relationships with the medical community in the area, including healthcare providers and social service agencies. 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 healthcare 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 K.2, page 43, the applicant states that the proposed facility will have 3,321 square feet of treatment area, which includes isolation space. The applicant provides the proposed facility's line drawings in Exhibit K-1. The drawing depicts a 6,800 square foot facility, with nine main floor dialysis stations and one isolation dialysis station, for a total of 10 stations. In Section K.1, page 42, the applicant describes its plans for energy-efficiency, including water conservation. The applicant states its plans for implementing applicable energy saving features, including energy-efficient glass, mechanically operated patient access doors, and energy-efficient heating and cooling systems.

Costs and charges are described by the applicant in Section F, pages 27-31, 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

Murfreesboro Dialysis is not an existing facility; thus, it has no historical payor mix. In Section L.7, page 52, the applicant provides the payor mix for ADC for CY2016. The historical payor mix is illustrated as follows:

ADC – Historical Payor Mix – CY 2016			
Payor Type	% Total Patients	% IC Patients	% PD Patients
Medicare	17.9%	18.8%	13.3%
Medicaid	8.4%	7.4%	13.3%
Commercial Insurance	7.4%	5.0%	20.0%
Medicare/Commercial	27.4%	27.5%	26.7%
Medicare/Medicaid	36.8%	38.8%	26.7%
VA	2.1%	2.5%	0.0%
Totals	100.0%	100.0%	100.0%

Totals may not foot due to rounding.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Hertford	18%	51%	66%	26%	16%	17%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable... The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina, and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

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

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

C

In Section L.3, page 51, the applicant states that it has no obligations under any federal regulations to provide uncompensated care or community service except those federal requirements of the Rehabilitation Act of 1973 and subsequent amendments. The applicant states that the facility has no Hill-Burton obligations.

In Section L.6, page 51, the applicant states that no civil rights complaints have been lodged against any DaVita North Carolina facilities in the past 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(b), page 49, the applicant provides the projected payor mix for the proposed services at Murfreesboro Dialysis as shown in the table below:

¹<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

²http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

Murfreesboro Dialysis – Projected Payor Mix – Project Year 2			
Payor Type	% Total Patients	% IC Patients	% PD Patients
Medicare	17.9%	18.8%	13.3%
Medicaid	8.4%	7.4%	13.3%
Commercial Insurance	7.4%	5.0%	20.0%
Medicare/Commercial	27.4%	27.5%	26.7%
Medicare/Medicaid	36.8%	38.8%	26.7%
VA	2.1%	2.5%	0.0%
Totals	100.0%	100.0%	100.0%

Totals may not foot due to rounding.

As shown in the table above, the applicant projects that 90.5 percent of all patients will have some or all of their services paid for by Medicare or Medicaid. In Section L.1(b), page 49, the applicant states that the projected payor mix is calculated based upon the payor mix of Hertford County patients during the last full operating year. The applicant demonstrates that medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L.4, page 51, the applicant states that patients will have access to dialysis services at Murfreesboro Dialysis through a nephrologist with privileges at Murfreesboro Dialysis. The applicant states that patients who contact the facility in any way will be referred to a qualified nephrologist.

The applicant adequately demonstrates that Murfreesboro Dialysis will provide a range of means by which a person can access its 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 53, the applicant states that it has offered Murfreesboro Dialysis as a clinical site for health professional training programs at Chowan University. Exhibit M-2 contains a letter from the applicant to the nursing program at Chowan University, dated May 1, 2017, inviting the school to include Murfreesboro Dialysis in its clinical rotations for its nursing students. The information provided in Section M.1 and Exhibit M-2 is reasonable and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.

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

C

The applicant proposes to develop a new 10-station dialysis facility in Murfreesboro by relocating 10 stations from ADC. Both facility locations are in Hertford County. Upon completion of this project, Murfreesboro Dialysis will be certified for 10 dialysis stations and ADC will be certified for 16 dialysis stations. The applicant also proposes to offer home PD training and support.

On page 373, the 2017 SMFP defines the service area for dialysis stations 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 Hertford County. Facilities may also serve residents of counties not included in their service area.

Currently, the applicant is the only provider of dialysis services in Hertford County. According to the January 2017 SDR, ADC was serving 80 patients on 26 stations as of June 30, 2016, for a utilization rate of 76.92 percent or 3.0769 patients per station per week (80 patients / 26 stations = 3.0769; 3.0769 / 4 = 0.7692 or 76.92%).

According to Table B in the January 2017 SDR, there is a surplus of two dialysis stations in Hertford County. However, the applicant is not increasing the number of dialysis stations in Hertford County. It is relocating 10 existing Hertford County stations to develop a new facility that the applicant states is closer to patients living in the area where the new facility will be located. Therefore, it is not duplicating services, but rather proposing to create a new facility to better serve existing patients using existing stations.

In Section N.1, page 54, the applicant discusses the expected effects of the proposed project on competition, including cost-effectiveness, quality, and access, stating:

“The development of Murfreesboro Dialysis will have no effect on any dialysis facilities located in Hertford County or in counties contiguous to it. DaVita operates the other facility in the county.

The proposed facility will not have an adverse effect on competition since the patients already being served by DaVita will be transferring their care from one DaVita facility to

another DaVita facility, which will be more convenient for the patients who have indicated this in the letters they signed. There are no other dialysis facilities in the proposed service area; therefore, there can be no effect on the competition.”

See also Sections B, C, E, F, H, L, N, and O where the applicant discusses the impact of the project on cost-effectiveness, quality, and access.

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 discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

The application is conforming to this criterion.

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

C

In Section A.11, page 5, the applicant states that DVA is a subsidiary of DaVita, which owns and operates over 70 existing kidney disease treatment centers in North Carolina. In Exhibit O-3, the applicant provides information on three DaVita facilities that were out of compliance with Conditions of Coverage for Medicare during the 18 months prior to the submission of this application. Three facilities – Southeastern Dialysis Center-Kenansville, Durham Dialysis, and Marshville Dialysis – had condition-level deficiencies. The applicant includes in Exhibit O-3 the letters from the Acute and Home Care Licensure and Certification Section, DHSR, documenting that the facilities had returned to compliance. The applicant states in Section O.3, page 55, that all facilities are currently in compliance. Based on a review of the 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. 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

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

10A NCAC 14C .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- In Section C.1, pages 13-15, the applicant documents the need for the project and demonstrates that it will serve a total of 34 in-center patients on 10 stations at the end of the first operating year, which is 3.4 patients per station per week, or a utilization rate of 85 percent (34 patients / 10 stations = 3.4; 3.4 / 4 = 0.85 or 85%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.
- (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.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section C.1, pages 13-15. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.