

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 12, 2016

Findings Date: May 12, 2016

Project Analyst: Gregory F. Yakaboski

Assistant Chief: Martha J. Frisone

Project ID #: L-11132-16

Facility: Sharpsburg Dialysis

FID #: 160066

County: Wilson

Applicant: DVA Renal Healthcare, Inc.

Project: Develop a new 10-station dialysis facility in Wilson County by relocating 5 stations from Forest Hills Dialysis and 5 stations from Wilson 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.

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DVA Renal Healthcare, Inc. (DVA) d/b/a Sharpsburg Dialysis proposes to develop a new 10-station dialysis facility in Sharpsburg by relocating 5 dialysis stations from Forest Hills Dialysis and 5 dialysis stations from Wilson Dialysis. The two existing facilities and the proposed facility are located in Wilson 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, Sharpsburg Dialysis will be certified for 10 dialysis stations, Forest Hills Dialysis will be certified for 26 dialysis stations (31-5 = 26) and Wilson Dialysis will be certified for 35 dialysis stations (40-5 = 35).

Need Determination

The applicant is proposing to relocate existing dialysis stations within Wilson County, therefore there are no need methodologies in the 2016 State Medical Facilities Plan (2016 SMFP) applicable to this review.

Policies

There are two policies in the 2016 SMFP that are applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, on pages 39-40, and *Policy ESRD-2 Relocation of Dialysis Stations*, on page 33.

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 11-13, and Section K.1, page 45, and Exhibit K-1 (d) the applicant describes how it will assure improved energy efficiency and water conservation. Therefore, the application is conforming to Policy GEN-4.

Policy ESRD-2: Relocation of Dialysis Stations

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, Sharpsburg Dialysis, in Wilson, by relocating existing dialysis stations from both Forest Hills Dialysis and Wilson Dialysis. The two existing facilities and the proposed facility are located in Wilson County, therefore there is no change in the dialysis station inventory in Wilson County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with all applicable policies in the 2016 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.

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The applicant proposes to develop a new 10-station dialysis facility in Sharpsburg by relocating 5 dialysis stations from Forest Hills Dialysis and 5 dialysis stations from Wilson Dialysis. The two existing facilities and the proposed facility are located in Wilson 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, Sharpsburg

Dialysis will be certified for 10 dialysis stations, Forest Hills Dialysis will be certified for 26 dialysis stations (31-5=26) and Wilson Dialysis will be certified for 35 dialysis stations (40-5=35).

Population to be Served

On page 369, the 2016 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 Wilson County. Facilities may also serve residents of counties not included in their service area.

Sharpsburg Dialysis will be a new facility in Wilson 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
Wilson	20	2	21	3	56.4%	58.5%
Nash	10	0	10	0	25.6%	25.6%
Edgecombe	5	0	5	0	12.8%	12.8%
Halifax	2	0	2	0	5.1%	5.1%
Total	37	2	38	3	100.0%	100.0%

See pages 14-15 for the assumptions and data utilized to project patient origin including a summary of the patient support letters found in Exhibit C-1.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section C.2, page 17, the applicant states that it determined a need for a new dialysis facility in Sharpsburg based on the fact that many of its in-center dialysis patients and several of its home peritoneal dialysis patients live in or near the northern part of Wilson County. In Section C.5, page 18, the applicant states that the patient census at both Forest Hills Dialysis and Wilson Dialysis continues to grow with no room for building expansion and that the proposed new facility is located closer to where a number of its patients reside. In Section C.2, page 17, the applicant states that

“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 Renal Healthcare, Inc. needs to provide a dialysis center nearer to their homes for better access to their dialysis services and support.”

On page 15, the applicant states, *“it is assumed that the thirty-six (36) in-center patients who signed letters of support for Sharpsburg Dialysis will transfer their care upon certification of the new facility.”* Exhibit C-1 contains only 34 patient letters of support.

The applicant adequately identifies the population to be served.

Projected Utilization

In Section C.1, pages 14-17, the applicant provides the assumptions and methodology used to determine the need for the proposed dialysis facility in Wilson County and to project utilization. The assumptions and methodology are summarized as follows:

- The applicant states that it received 36 letters of support from in-center patients utilizing DVA dialysis facilities indicating their willingness to consider transferring their care to the proposed facility. However, only 34 letters are included in Exhibit C-1.
- The applicant assumes that the in-center patients who are residents of Wilson County will increase at a rate commensurate with Wilson County’s Five Year Average Annual Change Rate (AACR) of 5.4%, as published in Table B of the January 2016 Semi-Annual Dialysis Report (SDR), through the second operating year.
- The applicant states that there are 17 in-center patients who are residents of Wilson County.
- The applicant assumes no growth in the 19 in-center patients who are not residents of Wilson County.

In Section C.1, page 16, the applicant provides the calculations used to arrive at the projected in-center patient census for Operating Years 1 and 2, as follows:

Sharpsburg Dialysis	In-Center Patients
January 1, 2018, the beginning of Operating Year 1, will begin with 36 in-center patients who have transferred their care from other DVA dialysis facilities.	36
Growth is projected during OY1 by multiplying the beginning census by the Wilson County Five Year AACR of 5.4% to arrive at the end of year census for December 31, 2018 and then adding in the 19 in-center patients living outside Wilson County.*	$17 \times 1.054 = 17.918 + 19$ $= 36.918$
Growth is projected again for OY2 by multiplying the beginning census for January 1, 2019 by the Wilson County Five Year AACR of 5.4% to arrive at the end of year census for December 31, 2019 and then adding in the 19 in-center patients living outside Wilson County.	$17.918 \times 1.054 = 18.885 + 19 = 37.88$

*Note- On page 16, as part of the calculation, the applicant assumed 19 patients in the column labeled “# of SA Patients”. The SA (service area) is Wilson County. However, elsewhere the applicant stated that there were 17 patients from Wilson and 19 patients from outside the service area. In the table above, the project analyst assumed 17 patients from Wilson, not 19.

The applicant states, on page 16 that the number of projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2018) the facility is projected to serve 36 in-center patients and at the end of OY2 (CY2019) the facility is projected to serve 37 in-center patients.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.6 patients per station per week, or 90.0% (36 patients/ 10 stations = 3.6/4 = .9 or 90.0%).
- OY2: 3.7 patients per station per week, or 92.5% (37 patients/ 10 stations = 3.7/4 = .925 or 92.5%).

The projected utilization of 3.6 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

However, the application only contained 34 patient letters, 15 of which were from patients who are residents of Wilson County. See patient letters of support in Exhibit C-1. In the table below the project analyst recalculated projected utilization based on 15 patients who are residents of Wilson County and 19 patients who are not residents of Wilson County.

Sharpsburg Dialysis	In-Center Patients
January 1, 2018, the beginning of Operating Year 1, will begin with 36 in-center patients who have transferred their care from other DVA dialysis facilities.	36
OY1: Growth is projected during OY1 by multiplying the beginning census by the Wilson County Five Year AACR of 5.4% to arrive at the end of year census for December 31, 2018 and then adding in the 19 in-center patients living outside Wilson County. *	$15 \times 1.054 = 15.81 + 19 = 34.81$
OY2: Growth is projected again for OY2 by multiplying the beginning census for January 1, 2019 by the Wilson County Five Year AACR of 5.4% to arrive at the end of year census for December 31, 2019 and then adding in the 19 in-center patients living outside Wilson County.	$15.81 \times 1.054 = 16.6637 + 19 = 35.66$

The corrected projected utilization rates for the first two operating years are as follows:

- OY1: 3.4 patients per station per week, or 90.0% (34 patients/ 10 stations = 3.4/4 = .85 or 85.0%).
- OY2: 3.5 patients per station per week, or 92.5% (35 patients/ 10 stations = 3.5/4 = .875 or 87.5%).

Even based on 15 patients who are residents of Wilson County, the projected utilization is 3.4 patients per station per week at the end of OY1, which exceeds the minimum standard of 3.2 in-center patients per station per week as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates that projected utilization is likely to equal or exceed the 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

Access to Services

In Section C.3, pages 17-18, 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 52, that 90.2% of its in-center patients at Sharpsburg 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 develop a new 10-station dialysis facility in Sharpsburg by relocating 5 dialysis stations from Forest Hills Dialysis and 5 dialysis stations from Wilson Dialysis. The two existing facilities and the proposed facility are located in Wilson County. Upon completion of this project, Sharpsburg Dialysis will be certified for 10 dialysis stations, Forest Hills Dialysis will be certified for 26 dialysis stations ($31-5=26$) and Wilson Dialysis will be certified for 35 dialysis stations ($40-5=35$).

Forest Hills Dialysis

In Section D.1, pages 26-27, the applicant states that as of June 30, 2015, as reported in the January 2016 SDR, there were 111 in-center dialysis patients at Forest Hills Dialysis dialyzing on 31 dialysis stations, for a utilization rate of 89.52%. In addition, the applicant states that 94 of the 111 in-center patients lived in Wilson County and that 17 lived outside Wilson County.

The applicant assumes that the number of in-center patients at Forest Hills Dialysis who live in Wilson County will increase at 5.4% per year based on the Five Year AACR for Wilson County, as reported in Table B of the July 2016 SDR. The applicant assumes that no growth will occur for the in-center patients living outside of Wilson County. In Section D.1, page 27, the applicant calculates the in-center patient census for Forest Hills Dialysis starting June 30, 2015 through OY1 (CY2018) and OY2 (CY2019), illustrated follows:

Forest Hills Dialysis	In-Center Patients
Beginning census for July 1, 2015 for Wilson County patients only, increased by half the 5.4% Five Year AACR for Wilson County. Add 17 patients from outside Wilson County to arrive at ending census for December 31, 2015 (six months).	$94 \times 1.027 = 96.538 + 17 = 113.538$
Wilson County patient census for CY2016 increased by 5.4% Five Year AACR for Wilson County. Add 17 patients from outside Wilson County to arrive at ending census for December 31, 2016.	$96.538 \times 1.054 = 101.7511 + 17 = 118.7511$
Wilson County patient census for CY2017 increased by 5.4% Five Year AACR for Wilson County. Add 17 patients from outside Wilson County to arrive at ending census for December 31, 2017.	$101.751 \times 1.054 = 107.2456 + 17 = 124.2456$
OY1 (CY2018) Wilson County patient census for CY2018 increased by 5.4% Five Year AACR for Wilson County. (After subtracting out 4 Wilson County patients and 5 patients from outside Wilson County who are projected to transfer to the proposed Sharpsburg Dialysis facility). Add 12 patients from outside Wilson County to arrive at ending census for December 31, 2018.	$107 - 4 = 103 \times 1.054 = 108.562 + (17-5=12) = 120.562$
OY2 (CY2019) Wilson County patient census for CY2019 increased by 5.4% Five Year AACR for Wilson County. Add 12 patients from outside Wilson County to arrive at ending census for December 31, 2019.	$108.562 \times 1.054 = 114.4243 + 12 = 126.4243$

The applicant rounds down the ending census numbers for OY1 and OY2. (See page 27) Forest Hills Dialysis is projected to have 120 in-center patients at the end of OY1 for a utilization rate of 115%, or 4.62 patients per station (120 patients/ 26 stations = 4.62/4 = 1.155 or 115.0%). The applicant states, on page 27,

“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.”

Wilson Dialysis

In Section D.1, pages 27-28, the applicant states that as of June 30, 2015, as reported in the January 2016 SDR, there were 137 in-center dialysis patients at Wilson Dialysis dialyzing on 40 dialysis stations, for a utilization rate of 85.63%. In addition, the applicant states that 119 of the 137 in-center patients lived in Wilson County and that 18 lived outside Wilson County.

The applicant assumes that the number of in-center patients at Wilson Dialysis who live in Wilson County will increase at 5.4% per year based on the Five Year AACR for Wilson County, as reported in Table B of the July 2016 SDR. The applicant assumes that no growth will occur for the in-center patients living outside of Wilson County. In

Section D.1, page 28, the applicant calculates the in-center patient census for Wilson Dialysis starting June 30, 2015 through OY1 (CY2018) and OY2 (CY2019), illustrated follows:

Wilson Dialysis	In-Center Patients
Beginning census for July 1, 2015 for Wilson County patients only, increased by half the 5.4% Five Year AACR for Wilson County. Add 18 patients from outside Wilson County to arrive at ending census for December 31, 2015 (six months).	$119 \times 1.027 = 122.213 + 18 = 140.213$
Wilson County patient census for CY2016 increased by 5.4% Five Year AACR for Wilson County. Add 18 patients from outside Wilson County to arrive at ending census for December 31, 2016.	$122.213 \times 1.054 = 128.8125 + 18 = 146.8125$
Wilson County patient census for CY2017 increased by 5.4% Five Year AACR for Wilson County. Add 18 patients from outside Wilson County to arrive at ending census for December 31, 2017.	$128.813 \times 1.054 = 135.7684 + 18 = 153.7684$
OY1 (CY2018) Wilson County patient census for CY2018 increased by 5.4% Five Year AACR for Wilson County. (After subtracting out 11 Wilson County patients and 6 patients from outside Wilson County who are projected to transfer to the proposed Sharpsburg Dialysis facility). Add 12 patients from outside Wilson County to arrive at ending census for December 31, 2018.	$153 - 11 = 124 \times 1.054 = 130.696 + (18-6=12) = 142.696$
OY2 (CY2019) Wilson County patient census for CY2019 increased by 5.4% Five Year AACR for Wilson County. Add 12 patients from outside Wilson County to arrive at ending census for December 31, 2019.	$130.696 \times 1.054 = 137.7536 + 12 = 149.7546$

The applicant rounds down the ending census numbers for OY1 and OY2. (See page 28) Wilson Dialysis is projected to have 142 in-center patients at the end of OY1 for a utilization rate of 101.4%, or 4.06 patients per station (142 patients/ 35 stations = 4.06/4 = 1.015 or 101.4%). The applicant states, on page 28,

“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 applicant demonstrates that the needs of the populations presently served at Forest Hills Dialysis and Wilson Dialysis will continue to be adequately met following the proposed relocation of five dialysis stations from Forest Hills Dialysis and five dialysis stations from Wilson Dialysis to Sharpsburg 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, page 29, the applicant discusses the alternatives considered prior to submitting this application, which include maintaining the status quo or developing the new facility in another area of Wilson County. The applicant discusses the fact that dialysis can be a time consuming and physically demanding process and that the proposed location in northern Wilson County would place the facility in close proximity to existing dialysis patients who currently utilize other existing DVA owned facilities in Wilson County and the fact that these patients residing in northern Wilson County have signed letters of support for the proposed project.

After considering the above alternatives, the applicant states that development of the new Sharpsburg Dialysis facility would reduce the transportation demands faced by existing patients and increase the patients' quality of life and compliance with treatment schedules. Therefore, DVA believes that developing the new Sharpsburg Dialysis facility will address the growing dialysis population at its facilities in Wilson County and is, therefore, the most effective alternative to meet the identified need.

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 Renal Healthcare, Inc. d/b/a Sharpsburg Dialysis shall materially comply with all representations made in the certificate of need application.**
- 2. DVA Renal Healthcare, Inc. d/b/a Sharpsburg Dialysis shall relocate no more than 5 dialysis stations from Forest Hills Dialysis and no more than 5 dialysis stations from Wilson Dialysis.**
- 3. DVA Renal Healthcare, Inc. d/b/a Sharpsburg 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 Renal Healthcare, Inc. shall take the necessary steps to decertify 5 dialysis stations at Forest Hills Dialysis for a total of no more than 26 dialysis stations at Forest Hills Dialysis and to decertify 5 dialysis stations at Wilson**

Dialysis for a total of no more than 35 dialysis stations at Wilson Dialysis upon project completion.

- 5. DVA Renal Healthcare, Inc. d/b/a Sharpsburg 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 30, the applicant provides the capital cost of the project as summarized in the following table:

**Sharpsburg Dialysis
Project Capital Costs**

Site Costs	\$25,000
Construction Contract	\$1,500,000
Dialysis Machines	\$137,500
Water Treatment Equipment	\$118,075
Equipment/Furniture	\$273,464
Architect & Engineering Fees	\$75,000
Total Capital Cost	\$2,129,039

In Section F.10, pages 30-31, and Section F.11, page 31, the applicant estimates start-up expenses of \$191,283 and initial operating expenses of \$759,856, respectively. Total working capital needed equals \$951,138.

Availability of Funds

In Section F.2, page 31, the applicant states that accumulated reserves/owner's equity will be used to finance the project's capital costs. In Section F.13, page 34, 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 February 15, 2016, 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 \$965,241,000 in cash and cash equivalents, \$17,942,715,000 in total assets, and \$6,190,276,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

Financial Feasibility

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

The applicant projects revenues in Section R, Form B, and operating expenses in Section R, Form A, summarized in the table below:

Sharpsburg Dialysis	Operating Year 1 CY2018	Operating Year 2 CY2019
Total Net Revenue	\$1,701,098	\$1,814,211
Total Operating Expenses	\$1,519,711	\$1,563,779
Net Profit	\$181,387	\$250,432

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable and adequately supported. See Section R, pro formas, for the applicant's assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The Project Analyst notes that while using corrected patient numbers in the projected utilization calculations found in Criterion (3) results in two less projected in-center patients per operating year the applicant projected sufficient net profit in operating year 1 and operating year 2 that

two less projected in-center patients per year would not result in a net loss for either of the first two operating years.

In Section H.1, page 37, the applicant provides projected staffing and salaries. Form A in Section R, 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 develop a new 10-station dialysis facility in Sharpsburg by relocating 5 dialysis stations from Forest Hills Dialysis and 5 dialysis stations from Wilson Dialysis. The two existing facilities and the proposed facility are located in Wilson 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, Sharpsburg Dialysis will be certified for 10 dialysis stations, Forest Hills Dialysis will be certified for 26 dialysis stations (31-5=26) and Wilson Dialysis will be certified for 35 dialysis stations (40-5=35).

On page 369, the 2016 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 Wilson County. Facilities may also serve residents of counties not included in their service area.

The January 2016 SDR indicates there are 2 dialysis facilities in Wilson County, as follows:

**Wilson County Dialysis Facilities
 June 30, 2015**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Forest Hills Dialysis	DVA	111	Wilson	31	0	89.52%
Wilson Dialysis	DVA	137	Wilson	40	0	85.63%

As illustrated above, the two existing facilities are located in Wilson. The proposed site for Sharpsburg Dialysis is in Sharpsburg. Both of the existing facilities have a utilization rate over 85.0%. Therefore, all of the operational dialysis facilities in the county are reasonably well utilized.

The applicant is not increasing the number of dialysis stations in Wilson 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 existing patients using existing stations.

In Section C.1, page 14, the applicant demonstrates that Sharpsburg 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 85.0% ($34/10 = 3.4$; $3.4/4 = 0.85$ or 85.0%). The applicant provides documentation in Exhibit C-1 from 34 in-center patients at its Wilson County facilities indicating their willingness to consider transferring to Sharpsburg Dialysis upon completion 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 stations to develop a new dialysis facility in Wilson 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 both Forest Hills Dialysis and Wilson 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 Wilson 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 Sharpsburg Dialysis in Section H.1, page 37, 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 an independent contractor, not an employee of the facility.

In Section H.3, pages 38-39, 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 40, 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 38, the applicant states that the Medical Director for Sharpsburg Dialysis will be Dr. Nirav Jasani. In Exhibit I-3, the applicant provides a letter signed by Dr. Jasani, dated January 4, 2016, confirming his commitment to serve as Medical Director. In Exhibit I-3, the applicant provides an additional letter signed by Dr. Jasani, dated January 7, 2016, stating that his Nephrology practice, will “*secure admission privileges and make referrals to the facility.*” In a letter dated January 4, 2016 Dr. Al-Haidary states that his nephrology practice, Wilson Nephrology-Internal Medicine, P.A. will also “*secure admission privileges and make referrals to the 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 41-42, 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 41. The applicant provides documentation regarding coordination with the existing health care system in Exhibits I-1, I-2 and I-3 including letters from several providers such as DaVita Laboratory Services, Inc., the NC Division of Vocational Rehabilitation Services, transportation services, Carolinas Medical Center, and Wilson Medical Center. The information in Section I and Exhibits I-1, I-2 and I-3 is reasonable and adequately supports a finding of conformity with 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 46, the applicant states there will be 3,956 square feet of treatment area, which will include home training and isolation room space. The applicant provides line drawings of the proposed facility in Exhibit K-1(a). The drawing depicts a 7,969 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 \$1,525,000 for site work and construction and \$604,039 for miscellaneous costs including dialysis machines, water treatment equipment, furniture, and architect/engineering fees for a total project cost of \$2,129,039. 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 30-33, 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 55, the applicant provides the payor mix for both Forest Hills Dialysis and Wilson Dialysis for CY2015. These are the facilities that will be contributing 5 dialysis stations each to develop the proposed facility and from which at least some patients will transfer (See Exhibit C-1 for patients' letters of support). The historical payer mix is illustrated as follows:

**Forest Hills Dialysis
 Payor Mix CY2015**

Payor Type	Percent of Total Patients
Medicare	31.5%
Medicaid	5.5%
Commercial Insurance	9.9%
Medicare/Commercial	21.6%
Medicare/Medicaid	28.8%
Other	2.7%
Total	100.0%

**Wilson Dialysis
 Payor Mix CY2015**

Payor Type	Percent of Total Patients
Medicare	23.8%
Medicaid	4.9%
Commercial Insurance	9.1%
Medicare/Commercial	30.6%
Medicare/Medicaid	30.1%
Other	1.5%
Total	100.0%

As the tables above indicate, 87.4% of Forest Hills’ patients and 89.4% of Wilson 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 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**
Wilson	16%	53%	52%	24%	11%	20%
Nash	16%	52%	48%	18%	11%	18%
Edgecombe	17%	54%	63%	26%	13%	17%
Halifax	18%	52%	61%	24%	17%	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 *Southeastern Kidney Council Network 6 Inc. Annual Report* 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%

Source:<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 54, the applicant states,

“Sharpsburg 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 54, 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 52, the applicant states that the projected payor mix for Sharpsburg Dialysis is based on sources of payment for its DVA facilities in Wilson County for the last full operating year, illustrated as follows:

**Sharpsburg Dialysis
Projected Payor Mix OY2**

Payor Source	Percent of Total Patients	Percent In-Center Patients	Percent Home PD Patients
Medicare	27.4%	28.3%	20.0%
Medicaid	5.8%	6.6%	0.0%
Commercial Insurance	9.1%	7.4%	23.3%
Medicare/Commercial	26.3%	25.0%	36.7%
Medicare/Medicaid	29.2%	30.3%	20.0%
VA	2.2%	2.4%	0.0%
Total	100.0%	100.0%	100.0%

The applicant projects that 90.2% of Sharpsburg Dialysis' in-center patients and 76.7% of its home PD patients will be covered by Medicare or Medicaid. For the facility as a whole, 88.7% 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 54, 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 56, the applicant states that it has offered Sharpsburg Dialysis as a clinical training site for nursing students from Wilson Community College. A copy of a letter sent by the applicant to the college, dated January 15, 2016, is included in Exhibit M-2.

The information provided in Section M.1 and Exhibit M-2 is reasonable and adequately 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 develop a new 10-station dialysis facility in Sharpsburg by relocating 5 dialysis stations from Forest Hills Dialysis and 5 dialysis stations from Wilson Dialysis. The two existing facilities and the proposed facility are located in Wilson 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, Sharpsburg Dialysis will be certified for 10 dialysis stations, Forest Hills Dialysis will be certified for 26 dialysis stations (31-5=26) and Wilson Dialysis will be certified for 35 dialysis stations (40-5=35).

On page 369, the 2016 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 Wilson County. Facilities may also serve residents of counties not included in their service area.

The January 2016 SDR indicates there are 2 dialysis facilities in Wilson County, as follows:

**Wilson County Dialysis Facilities
June 30, 2015**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Forest Hills Dialysis	DVA	111	Wilson	31	0	89.52%
Wilson Dialysis	DVA	137	Wilson	40	0	85.63%

As illustrated above, the two existing facilities are located in Wilson. The proposed site for Sharpsburg Dialysis is in Sharpsburg. Both of the existing facilities have a utilization rate over 85.0%. Therefore, all of the operational dialysis facilities in the county are reasonably well utilized.

In Section N.1, page 57, 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 Sharpsburg Dialysis will have no effect on any dialysis facilities located in Wilson County or in counties contiguous to it. DaVita operates the other facilities 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.

... Sharpsburg 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 (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

In Section 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 two 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 two citations and the other facility had one citation. Each facility is back in compliance as of the date of this decision.

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. 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 to all applicable criteria, as discussed below.

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 adequately demonstrates that Sharpsburg Dialysis will serve at least 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 85.0% ($34/10 = 3.4$; $3.4/4 = 0.85$). 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.