

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 23, 2018

Findings Date: October 23, 2018

Project Analyst: Mike McKillip

Team Leader: Fatimah Wilson

Project ID #: J-11544-18

Facility: Hope Valley Dialysis

FID #: 180368

County: Durham

Applicant: Renal Treatment Centers - Mid-Atlantic, Inc.

Project: Develop a new 10-station dialysis facility by relocating six existing dialysis stations from Southpoint Dialysis and four existing dialysis stations from Durham West Dialysis

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Renal Treatment Centers - Mid-Atlantic, Inc. d/b/a Hope Valley Dialysis [**Hope Valley Dialysis**] proposes to develop a new 10-station dialysis facility in Durham County by relocating six existing dialysis stations from Southpoint Dialysis and four existing dialysis stations from Durham West Dialysis. Upon completion of the proposed project, Southpoint Dialysis will be certified for ten dialysis stations and Durham West Dialysis will be certified for 21 dialysis stations.

Need Determination

The county and facility need methodologies in the July 2018 SDR and the 2018 SMFP are not applicable to this review.

Policies

There are two policies in the 2018 SMFP applicable to this review: Policy ESRD-2: Relocation of Dialysis Stations, on page 27, and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 33.

Policy ESRD-2

Policy ESRD-2 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.”*

Hope Valley Dialysis proposes to develop a new 10-station dialysis facility in Durham County by relocating six existing dialysis stations from Southpoint Dialysis and four existing dialysis stations from Durham West Dialysis. Both Southpoint Dialysis and Durham West Dialysis, as well as the proposed site for Hope Valley Dialysis, are located in Durham County. Therefore there is no change in the dialysis station inventory in Durham County associated with the proposed relocation of dialysis stations. 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.

Policy GEN-4

Policy GEN-4 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, Certificate of Need 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 is required to submit a plan of 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."

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B.5, pages 11-12, the applicant describes the project's plan to improve energy efficiency and conserve water, including energy efficient lighting, water optimization protocols, sustainable design and building materials, high-performance HVAC systems, and high-efficiency equipment and appliances. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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.

Hope Valley Dialysis proposes to develop a new 10-station dialysis facility in Durham County by relocating six existing dialysis stations from Southpoint Dialysis and four existing dialysis stations from Durham West Dialysis. In Section A.4, page 2, the applicant states Hope Valley Dialysis is a subsidiary of DaVita, Inc.

The following tables, summarized from Section A.9, pages 4-5 of the application, show the proposed Hope Valley Dialysis facility, and the existing Southpoint Dialysis and Durham West Dialysis facilities from which the applicant plans to relocate 10 stations to develop the proposed new facility.

Hope Valley Dialysis		
Stations	Description	Project ID #
0	Total existing certified stations as of the July 2018 SDR	
+10	Stations to be added as part of this project	J-11544-18
10	Total stations upon completion of above project	
Southpoint Dialysis		
Stations	Description	Project ID #
16	Total existing certified stations as of the July 2018 SDR	
-6	Stations to be deleted as part of this project	J-11544-18
10	Total stations upon completion of above project	
Durham West Dialysis		
Stations	Description	Project ID #
30	Total existing certified stations as of the July 2018 SDR	
+4	Stations to be added but not yet certified	J-11413-17
-7	Stations to be deleted but not yet certified	J-11216-16
-2	Stations to be deleted but not yet certified	J-11273-16
-4	Stations to be deleted as part of this project	J-11544-18
21	Total stations upon completion of above project	

As shown in the table above, upon project completion, Hope Valley Dialysis will be certified for 10 dialysis stations, Southpoint Dialysis will be certified for 10 dialysis stations, and Durham West Dialysis will be certified for 21 dialysis stations.

Patient Origin

On page 365, the 2018 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 Durham County. Facilities may also serve residents of counties not included in their service area.

In Section C.1, page 13, the applicant provides the projected patient origin for Hope Valley Dialysis for in-center (IC), home hemodialysis (HHD) and peritoneal dialysis (PD) patients for the first two years of operation following completion of the project as follows:

County	Operating Year 1 CY2020			Operating Year 2 CY2021			Percent of Total	
	IC	HHD	PD	IC	HHD	PD	OY1	OY2
Durham	32	0	0	33	0	0	100.0%	100.0%
Total	32	0	0	33	0	0	100.0%	100.0%

In Section C, pages 16-18, the applicant provides the assumptions and methodology used to project its patient origin. As shown in the table above, the applicant does not propose to provide home dialysis therapies. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.2, page 15, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section C.1, pages 13-15, the applicant describes its need methodology assumptions for projecting utilization of the proposed facility as follows:

1. The applicant projects the first two full operating years of the project will be January 1, 2020 – December 31, 2020 (CY2020) and January 1, 2021 – December 31, 2021 (CY2021).
2. The applicant states that 39 in-center dialysis patients who are currently being treated at DaVita dialysis facilities in Durham County have signed letters indicating they would consider transferring to Hope Valley Dialysis. Exhibit C-1 contains copies of the letters.
3. The applicant assumes that 32 of the 39 patients identified above will transfer their care to the proposed Hope Valley Dialysis facility. The applicant assumes that the Durham County patient population will increase by 3.0 percent per year through the first two operating years of the project. On page 13, the applicant states,

“All thirty-nine (39) patients who signed letters have indicated in their letters that they live closer to the proposed facility and that the new facility will be more convenient for them. ... It is assumed that at least 32 of the 39 in-center patients who signed letters of support for Hope Valley Dialysis will transfer their care upon certification of the new facility.”

Projected Utilization

The applicant’s methodology for in-center patients is shown in the following table.

	In-Center
The applicant begins with the 32 Durham County residents currently dialyzing at Southpoint Dialysis and Durham West Dialysis who expressed their intention to transfer to Hope Valley Dialysis upon certification of the new facility on December 31, 2019.	32
The census of Durham County in-center patients is increased by 3.0% to project the census forward one year to December 31, 2020. This is the projected ending census for Operating Year 1.	$[32 \times 0.03] + 32 = 32.96$
The census of Durham County in-center patients is increased by 3.0% to project the census forward one year to December 31, 2021. This is the projected ending census for Operating Year 2.	$[32.96 \times 0.03] + 32.96 = 33.9488$

The applicant projects to serve 32 in-center patients or 3.2 patients per station per week ($32/10 = 3.2$) by the end of Operating Year 1 and 33 in-center patients or 3.3 patients per station per week ($33/10 = 3.3$) by the end of Operating Year 2 for the proposed 10-station facility. This exceeds 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). In this application, the applicant assumes a projected annual rate of growth of 3.0 percent for the in-center patient census at Hope Valley Dialysis, which is equal to the Durham County Five Year Average Annual Change Rate as published in the July 2018 SDR. Projected in-center utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Projected utilization for the in-center patients at Hope Valley Dialysis is reasonable and adequately supported for the following reasons:

- The applicant projects the starting patient census for the proposed facility based on existing Southpoint Dialysis and Durham West Dialysis patients who have signed letters expressing their intention to transfer their care to the proposed Hope Valley Dialysis facility.
- The applicant’s growth projections are based on an assumption that patient census will increase at an annual rate of 3.0 percent, which is consistent with the Five Year Average Annual Change Rate (AACR) for Durham County, as reported in Table D of the July 2018 SDR.

Access

In Section C.3, page 15, the applicant states that DaVita facilities serve all patients without regard to income, race, ethnicity, gender, age, or handicap. In Section L.1, page 48, the applicant projects the following payor mix during the second full fiscal year of operation (CY2021) following completion of the project, as illustrated in the following table.

Payment Source	Total Patients by Percent of Total
Medicare	23.9%
Medicaid	4.8%
Commercial Insurance	19.1%
Medicare/Commercial Insurance	38.8%
Medicare/Medicaid	13.3%
Total	100.00%

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (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

Hope Valley Dialysis proposes to develop a new 10-station dialysis facility in Durham County by relocating six existing dialysis stations from Southpoint Dialysis and four existing

dialysis stations from Durham West Dialysis. Upon completion of the proposed relocation, Southpoint Dialysis will be certified for ten dialysis stations and Durham West Dialysis will be certified for 21 dialysis stations.

The following table shows the projected relocation of stations from Southpoint Dialysis and Durham West Dialysis to the proposed Hope Valley Dialysis facility and identifies the number of patients who signed letters expressing an interest in transferring from the existing facility to the proposed new facility.

Proposed Hope Valley Dialysis Project		
Facility	Number of Stations to be Relocated	Number of Patients Transferring
Southpoint Dialysis	6	28
Durham West Dialysis	4	11
Total Relocated and Transferred	10	39

In Section D.1, pages 22-24, the applicant explains why it believes the needs of the population presently utilizing the dialysis services to be relocated will be adequately met following completion of the project.

Southpoint Dialysis

According to the July 2018 Semiannual Dialysis Report (SDR), there were 76 patients dialyzing at Southpoint Dialysis and 16 certified dialysis stations for a utilization rate of 118.75%, or 4.75 patients per station per week ($76/16 = 4.75$) as of December 31, 2017. In Section D.1, page 22, the applicant states that 59 of the 76 in-center patients reside in Durham County, and the 17 remaining patients originate from outside Durham County.

The applicant assumes that the number of in-center patients at Southpoint Dialysis who reside in Durham County will increase at a rate of 3.0 percent per year through the first two operating years of the project based on the Five Year Average Annual Change Rate (AACR) for Durham County, as reported in Table D of the July 2018 SDR. The applicant assumes that there will be no increase in the number of patients from the other counties. The applicant projects that 28 Southpoint Dialysis patients, all of whom will reside in Durham County, will transfer their care to Hope Valley Dialysis upon certification of that facility on December 31, 2019.

In Section D.1, page 29, the applicant calculates the in-center patient census for Southpoint Dialysis starting December 31, 2017 through the first two operating years (CY2020 and CY2021), summarized as follows:

Southpoint Dialysis	In-Center Patients
Begin with the ESRD patient population of Durham County, as of December 31, 2017.	59
Project the Durham County population forward one year to December 31, 2018, using the Five Year AACR for Durham County.	$59 \times 1.03 = 60.77$
Add 17 out-of-county patients for total year-end census at December 31, 2018.	$60.77 + 17 = 77.77$
Project the Durham County population forward one year to December 31, 2019, using the Five Year AACR for Durham County.	$60.77 \times 1.03 = 62.5931$
Add 17 out-of-county patients for total year-end census at December 31, 2019.	$62.5931 + 17 = 79.5931$
Subtract 28 Durham County patients from the Southpoint Dialysis census who are projected to transfer to Hope Valley Dialysis	$62 - 28 = 34$
Project the remaining Durham County population forward one year to December 31, 2020, using the Five Year AACR for Durham County.	$34 \times 1.03 = 35.02$
Add 17 out-of-county patients for total year-end census at December 31, 2020.	$35.02 + 17 = 52.02$
Project the Durham County population forward one year to December 31, 2021, using the Five Year AACR for Durham County.	$35.02 \times 1.03 = 36.0706$
Add the 17 out-of-county patients expected to remain at Southpoint Dialysis for total year-end census at December 31, 2021.	$36.0706 + 17 = 53.0706$

Thus, on December 31, 2020, Southpoint Dialysis is projected to have 10 certified dialysis stations with an in-center patient population of 52, which is equivalent to a utilization rate of 5.2 patients per station per week ($52 / 10 = 5.2$) or 130.0% ($5.2 / 4 = 1.30$). In Section D.1, page 23, the applicant states, *“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.”*

Projected utilization for Southpoint Dialysis is reasonable and adequately supported for the following reasons:

- The applicant projects the patient census for Southpoint Dialysis based on existing Southpoint Dialysis patients, and those patients who have signed letters expressing their intention to transfer their care to the proposed Hope Valley Dialysis facility.
- The applicant’s growth projections are based on an assumption that the Durham County patient census will increase at an annual rate of 3.0 percent, which is consistent with the Five Year Average Annual Change Rate (AACR) for Durham County, as reported in Table D of the July 2018 SDR.

Durham West Dialysis

According to the July 2018 Semiannual Dialysis Report (SDR), there were 95 patients dialyzing at Durham West Dialysis and 30 certified dialysis stations for a utilization rate of 79.17%, or 3.2 patients per station per week ($95/30 = 3.2$) as of December 31, 2017. In Section D.1, page 23, the applicant states that 70 of the 95 in-center patients reside in Durham County, and the 25 remaining patients originate from outside Durham County.

The applicant assumes that the number of in-center patients at Durham West Dialysis who reside in Durham County will increase at a rate of 3.0 percent per year through the first two operating years of the project based on the Five Year Average Annual Change Rate (AACR) for Durham County, as reported in Table D of the July 2018 SDR. The applicant assumes that there will be no increase in the number of patients from the other counties. The applicant projects that eleven Durham West Dialysis patients, all of whom will reside in Durham County, will transfer their care to Hope Valley Dialysis upon certification of that facility on December 31, 2019.

In Section D.1, page 29, the applicant calculates the in-center patient census for Durham West Dialysis starting December 31, 2017 through the first two operating years (CY2020 and CY2021), summarized as follows:

Durham West Dialysis	In-Center Patients
Begin with the ESRD patient population of Durham County, as of December 31, 2017.	72.1
Project the Durham County population forward one year to December 31, 2018, using the Five Year AACR for Durham County.	$72.1 \times 1.03 = 74.263$
Add 25 out-of-county patients for total year-end census at December 31, 2018.	$74.263 + 25 = 99.263$
Project the Durham County population forward one year to December 31, 2019, using the Five Year AACR for Durham County.	$74.263 \times 1.03 = 76.49089$
Add 25 out-of-county patients for total year-end census at December 31, 2019.	$76.49089 + 25 = 101.4909$
Subtract eleven Durham County patients from the Durham West census who are projected to transfer to Hope Valley Dialysis	$76 - 11 = 65$
Project the remaining Durham County population forward one year to December 31, 2020, using the Five Year AACR for Durham County.	$65 \times 1.03 = 66.95$
Add 25 out-of-county patients for total year-end census at December 31, 2020.	$66.95 + 25 = 91.95$
Project the Durham County population forward one year to December 31, 2021, using the Five Year AACR for Durham County.	$66.95 \times 1.03 = 68.9585$
Add the 25 out-of-county patients expected to remain at Durham West Dialysis for total year-end census at December 31, 2021.	$68.9585 + 25 = 93.9585$

Thus, on December 31, 2020, Durham West Dialysis is projected to have 21 certified dialysis stations with an in-center patient population of 91, which is equivalent to a utilization rate of 4.33 patients per station per week ($91 / 21 = 4.33$) or 108.3% ($4.3 / 4 = 1.083$). In Section D.1, page 24, the applicant states, *“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.”*

Projected utilization for Durham West Dialysis is reasonable and adequately supported for the following reasons:

- The applicant projects the patient census for Durham West Dialysis based on existing Durham West Dialysis patients, and those patients who have signed letters expressing their intention to transfer their care to the proposed Hope Valley Dialysis facility.
- The applicant’s growth projections are based on an assumption that the Durham County patient census will increase at an annual rate of 3.0 percent, which is consistent with the Five Year Average Annual Change Rate (AACR) for Durham County, as reported in Table D of the July 2018 SDR.

In Section D.2, page 25, the applicant states that the proposed relocation of stations will not will not adversely affect 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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, pages 32-33, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo –The applicant states that maintaining the status quo is not an effective alternative due to the fact that it would not address the need for dialysis services in the proposed area of Durham County.
- Develop the facility in another part of Durham County – The applicant states that it considered developing the facility elsewhere but rejected that alternative because of the geographic proximity of the proposed site to the locations of the patients who signed letters of support for the proposed facility.

On page 26, the applicant states that its proposal is the most effective alternative because the proposed facility is convenient to the patients currently served.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Renal Treatment Centers - Mid-Atlantic, Inc. d/b/a Hope Valley Dialysis shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Policy ESRD-2, Renal Treatment Centers - Mid-Atlantic, Inc. d/b/a Hope Valley Dialysis shall develop a new kidney disease treatment center to be known as Hope Valley Dialysis by relocating six dialysis stations from Southpoint Dialysis and four dialysis stations from Durham West Dialysis.**
 - 3. Upon completion of this project, Renal Treatment Centers - Mid-Atlantic, Inc. d/b/a Hope Valley Dialysis shall take the necessary steps to decertify six dialysis stations at Southpoint Dialysis for a total of no more than ten dialysis stations at Southpoint Dialysis.**
 - 4. Upon completion of this project, Renal Treatment Centers - Mid-Atlantic, Inc. d/b/a Hope Valley Dialysis shall take the necessary steps to decertify four dialysis stations at Durham West Dialysis for a total of no more than 21 dialysis stations at Durham West Dialysis.**
 - 5. Renal Treatment Centers - Mid-Atlantic, Inc. d/b/a Hope Valley Dialysis shall install plumbing and electrical wiring through the walls for no more than ten dialysis stations which shall include any isolation stations.**
 - 6. Renal Treatment Centers - Mid-Atlantic, Inc. d/b/a Hope Valley 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

Hope Valley Dialysis proposes to develop a new 10-station dialysis facility in Durham County by relocating six existing dialysis stations from Southpoint Dialysis and four existing dialysis stations from Durham West Dialysis.

Capital and Working Capital Costs

In Section F.1, page 27, the applicant projects the total capital cost of the project as shown in the table below.

Site Costs	\$57,150
Construction Costs	\$1,486,403
Miscellaneous Costs	\$731,504
Total	\$2,275,057

In Section F.1, page 27, the applicant provides the assumptions used to project the capital cost.

In Sections F.10 and F.11, pages 29-30, the applicant projects that start-up costs will be \$194,574 and initial operating expenses will be \$841,120 for a total working capital of \$1,035,694. On pages 29-30, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F.2, page 28, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing		
Type	DaVita, Inc.	Total
Loans	\$	\$
Accumulated reserves or OE *	\$2,275,057	\$2,275,057
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$2,275,057	\$2,275,057

* OE = Owner's Equity

In Section F.13, page 31, the applicant states that the working capital needs of the project will be funded as shown in the table below.

Sources of Financing for Working Capital		Amount
(a)	Loans	\$
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$1,035,694
(c)	Lines of credit	\$
(d)	Bonds	\$
(e)	Total	\$1,035,694

Exhibit F-1 contains a letter dated July 16, 2018 from the Chief Accounting Officer for DaVita, Inc. authorizing and committing accumulated reserves of DaVita, Inc. for the capital and working capital costs of the project. Exhibit F-2 contains a copy of the Form 10K for DaVita, Inc. for the year ending December 31, 2017. The report indicates that as of December 31, 2017, DaVita, Inc. had \$508 million in cash and cash equivalents, \$18.9 billion in total assets and \$4.9 billion in net assets (total assets less total liabilities).

Financial Feasibility

The applicant provided pro forma financial statements in Section R for the first two full fiscal years of operation following completion of the project. In 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.

	1st Full Fiscal Year CY2020	2nd Full Fiscal Year CY2021
Total Treatments	4,742	4,817
Total Gross Revenues (Charges)	\$1,921,173	\$1,951,452
Total Net Revenue	\$1,865,557	\$1,894,961
Average Net Revenue per Treatment	\$393.41	\$393.39
Total Operating Expenses (Costs)	\$1,682,240	\$1,713,664
Average Operating Expense per Treatment	\$354.75	\$355.75
Net Income	\$183,317	\$181,296

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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- 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.

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

Hope Valley Dialysis proposes to develop a new 10-station dialysis facility in Durham County by relocating six existing dialysis stations from Southpoint Dialysis and four existing dialysis stations from Durham West Dialysis. Upon completion of the proposed relocation, Southpoint Dialysis will be certified for ten dialysis stations and Durham West Dialysis will be certified for 21 dialysis stations.

On page 365 the 2018 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 Durham County. Facilities may also serve residents of counties not included in their service area.

According to the July 2018 SDR, there are currently nine operational dialysis facilities and three facilities under development in Durham County, as illustrated below.

DURHAM COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of DECEMBER 31, 2017				
Dialysis Facility/Owner	Certified Stations 12/31/17	# In-center Patients 12/31/2017	Percent Utilization 12/31/2017	Patients per Station
Bull City Dialysis*(DaVita)	0	0	NA	NA
Downtown Durham Dialysis* (DaVita)	0	0	NA	NA
Duke Hospital Dialysis (DaVita)	16	40	62.50%	2.5000
Durham Dialysis (DaVita)	28	96	85.71%	3.4286
Durham Regional Dialysis* (DaVita)	0	0	NA	NA
Durham West Dialysis (DaVita)	30	95	79.17%	3.1667
FMC Dialysis Services of Briggs Ave. (BMA)	29	97	83.62%	3.3448
FMC Dialysis Ser. W. Pettigrew (BMA)	24	69	71.88%	2.8750
Freedom Lake Dialysis Unit (BMA)	26	90	86.54%	3.4615
FMC South Durham (BMA)	18	63	87.50%	3.5000
FKC Eno River* (BMA)	0	0	NA	NA
Research Triangle Dialysis (DaVita)	10	11	27.50%	1.1000
Southpoint Dialysis (DaVita)	16	76	118.75%	4.7500

Source: Table B, July 2018 SDR

*New Facility

As shown in the table above, four facilities are under development, three of which will be operated by DaVita and one of which will be operated by BMA.

In Section G.2, page 33, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Durham County. The applicant states:

“This certificate of need application does not propose to increase the number of stations in Durham County. Transferring stations from Southpoint Dialysis and Durham West Dialysis will create a new facility at a different location to better serve patients living in the area of the new facility, but will not result in the duplication of existing services.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The proposal will not result in an increase in the number of dialysis stations in Durham County.
- The applicant adequately demonstrates that the proposed facility is needed in addition to the existing or approved facilities in Durham County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 projected staffing for the proposed facility in the second year of operation (CY2021) as shown in the following table.

Hope Valley Dialysis Projected Staffing CY2021	
Position	Total FTE Positions
Medical Director	NA*
Registered Nurse	2.0
Technician (PCT)	4.0
Administrator	1.0
Dietitian	0.5
Social Worker	0.5
Administrative Assistant	1.0
Biomedical Technician	0.5
Total FTEs	9.5

*Medical Director is an independent contractor, not an employee.

The assumptions and methodology used to project staffing are provided in Section H.1, page 34, and Sections H.6 and H.7, page 37. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Sections H.3 and H.4, pages 35-36, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H.2, page 35, the applicant identifies the proposed medical director. In Exhibit I-3 the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 provides a table showing the ancillary and support services necessary for the proposed services, as shown below.

Hope Valley Dialysis Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	Hope Valley Dialysis
Self-care training (in-center)	Hope Valley Dialysis
Home training Home Hemodialysis Peritoneal Dialysis Accessible follow-up program	Durham West Dialysis
Psychological counseling	Hope Valley Dialysis
Isolation – hepatitis	Hope Valley Dialysis
Nutritional counseling	Hope Valley Dialysis
Social Work services	Hope Valley Dialysis
Acute dialysis in an acute care setting	Duke University Hospital
Emergency care	Duke University Hospital
Blood bank services	Duke University Hospital
Diagnostic and evaluation services	Duke University Hospital
X-ray services	Duke University Hospital
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	Duke University Hospital
Vascular surgery	Duke University Hospital
Transplantation services	Duke University Hospital
Vocational rehabilitation & counseling	NC DHHS Division of Vocational Rehab
Transportation	First Transit

On page 38, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.

In Section I, pages 39-40, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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 55, the applicant states that the project involves construction and up-fitting of 2,971 square feet in leased space in a building to be constructed by a developer near Fayetteville Road in Durham. A line drawing of the proposed facility is provided in Exhibit K-1.

On page 42, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On page 42, and Exhibit K-4, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 51, the applicant reports that 88 percent of the patients who received treatments at Southpoint Dialysis had some or all of their services paid for by Medicare or Medicaid, and that 78 percent of the patients who received treatments at Durham West Dialysis had some or all of their services paid for by Medicare or Medicaid, in CY2017. The table below shows the historical (CY2017) payment source for Southpoint Dialysis and Durham West Dialysis:

Payment Sources CY2017	Southpoint Dialysis Patients as Percent of Total	Durham West Dialysis Patients as Percent of Total
Medicare	25.0%	22.0%
Medicaid	5.3%	3.5%
Commercial Insurance	11.8%	22.0%
Medicare/Commercial Insurance	43.4%	39.7%
Medicare/Medicaid	14.5%	12.8%
Total	100.0%	100.00%

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 and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Durham	12%	52%	58%	17%	7%	14%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217> Latest Data 7/1/17 as of 7/17/18

* Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. 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., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina’s based on the Network’s recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

¹ <https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

- (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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3, page 50, the applicant states

“Hope Valley 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 50, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 48, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payment Source	Patients as Percent of Total
Medicare	23.9%
Medicaid	4.8%
Commercial Insurance	19.1%
Medicare/Commercial Insurance	38.8%
Medicare/Medicaid	13.3%
Total	100.0%

Source: Table on page 48 of the application.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 76 percent of total services will be provided to Medicare patients (includes Medicare, Medicare/Commercial and Medicare/Medicaid) and 4.8 percent to Medicaid patients.

On page 48, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for DaVita's existing Durham County dialysis facilities.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 50, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 52, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming 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

Hope Valley Dialysis proposes to develop a new 10-station dialysis facility in Durham County by relocating six existing dialysis stations from Southpoint Dialysis and four existing dialysis stations from Durham West Dialysis. Upon completion of the proposed relocation, Southpoint Dialysis will be certified for ten dialysis stations and Durham West Dialysis will be certified for 21 dialysis stations.

On page 365 the 2018 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 Durham County. Facilities may also serve residents of counties not included in their service area.

According to the July 2018 SDR, there are currently nine operational dialysis facilities and three facilities under development in Durham County, as illustrated below.

DURHAM COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of DECEMBER 31, 2017				
Dialysis Facility/Owner	Certified Stations 12/31/17	# In-center Patients 12/31/2017	Percent Utilization 12/31/2017	Patients per Station
Bull City Dialysis*(DaVita)	0	0	NA	NA
Downtown Durham Dialysis* (DaVita)	0	0	NA	NA
Duke Hospital Dialysis (DaVita)	16	40	62.50%	2.5000
Durham Dialysis (DaVita)	28	96	85.71%	3.4286
Durham Regional Dialysis* (DaVita)	0	0	NA	NA
Durham West Dialysis (DaVita)	30	95	79.17%	3.1667
FMC Dialysis Services of Briggs Ave. (BMA)	29	97	83.62%	3.3448
FMC Dialysis Ser. W. Pettigrew (BMA)	24	69	71.88%	2.8750
Freedom Lake Dialysis Unit (BMA)	26	90	86.54%	3.4615
FMC South Durham (BMA)	18	63	87.50%	3.5000
FKC Eno River* (BMA)	0	0	NA	NA
Research Triangle Dialysis (DaVita)	10	11	27.50%	1.1000
Southpoint Dialysis (DaVita)	16	76	118.75%	4.7500

Source: Table B, July 2018 SDR

*New Facility

As shown in the table above, four facilities are under development, three of which will be operated by DaVita and one of which will be operated by BMA.

In Section N.1, page 53, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 53, the applicant states:

“The development of Hope Valley Dialysis will have no effect on any dialysis facilities located in Durham County or in counties contiguous to it. DaVita operates five facilities in the county. ... The proposed facility will not have 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 patients who have indicated this in the letters they signed.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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, page 5, the applicant states DaVita operates more than 85 dialysis facilities in North Carolina. Exhibit A-11 contains a list of the DaVita dialysis facilities located in North Carolina.

In Section O, page 56, and Exhibit O-3 the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two of these facilities, Southeastern Dialysis Center-Wilmington and Goldsboro South Dialysis. The applicant states that all of the problems have been corrected and that Southeastern Dialysis Center-Wilmington was back in compliance as of March 21, 2018 and that Goldsboro South Dialysis was back in compliance as of November 20, 2017. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided sufficient evidence that quality care has been provided in the past. 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 application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are 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 13, the applicant projects to serve 32 in-center patients by the end of Operating Year 1, which is 3.2 patients per station per week ($32 / 10 = 3.2$). The discussion regarding projected utilization 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 not proposing to increase the number of dialysis stations in an existing facility or one that was not operational prior to the beginning of the review period.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 13-15, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.