

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 7, 2017

Findings Date: April 7, 2017

Project Analyst: Julie Halatek

Team Leader: Lisa Pittman

Project ID #: J-11273-16

Facility: Downtown Durham Dialysis

FID #: 160556

County: Durham

Applicant(s): DVA Renal Healthcare, Inc.

Project: Develop a new 10-station dialysis facility by relocating eight stations from Durham Dialysis and two stations from Durham West Dialysis

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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

DVA Renal Healthcare, Inc. (DVA) proposes to develop a new 10-station dialysis facility, Downtown Durham Dialysis (DDD) by relocating eight existing certified dialysis stations from Durham Dialysis and two existing certified dialysis stations from Durham West Dialysis (DWD). All three facilities are located in Durham County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of the project and projects related to the other referenced facilities, DDD will be certified for 10 dialysis stations, Durham Dialysis will be certified for 17 stations [29 – 8 – 7 (J-10319-14) – 3 (J-11216-16) + 3 (J-11084-15) + 3 (J-11256-16)], and DWD will be certified for 21 stations [29 – 2 – 3 (J-10319-14) – 7 (J-11216-16) + 4 (J-10350-15)].

Need Determination

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

Policies

The following two policies are applicable to this review:

- Policy ESRD-2: Relocation of Dialysis Stations (page 33 of the 2016 SMFP)
- Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities (page 39 of the 2016 SMFP)

Policy ESRD-2: Relocation of Dialysis Stations states:

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

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous [sic] county is currently serving residents of that contiguous [sic] 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, DDD, in Durham County, by relocating 10 existing Durham County dialysis stations: eight from Durham Dialysis and two from DWD. Because all three facilities are located in Durham County, there is no change in the total dialysis station inventory in Durham County. Therefore, the application is consistent with Policy ESRD-2.

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, 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 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, the applicant provides a statement describing the strategies and features that the new facility will incorporate in order to comply with Policy GEN-4. The application is consistent with Policy GEN-4.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with both Policy ESRD-2 and Policy GEN-4 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.

C

The applicant, DVA, proposes to develop DDD, a new 10-station Durham County dialysis facility, by relocating eight existing certified dialysis stations from Durham Dialysis and two existing certified dialysis stations from DWD. All three facilities are located in Durham County.

Patient Origin

On page 369, the 2016 SMFP defines the service area for dialysis stations as *"the 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 is Durham County. Facilities may serve residents of counties not included in their service area.

DDD will be a new facility in Durham County; therefore, it has no existing patient origin.

In Section C.1, page 14, the applicant provides the projected patient origin for DDD for in-center patients for the first two operating years following completion of the project, Calendar Years (CY) 2019 and 2020, as follows:

DDD – Projected Patient Origin – CYs 2019 & 2020				
County	OY 1 – CY 2019	OY 2 – CY 2020	County Patients as % of Total	
	# Patients	# Patients	OY1	OY2
Durham	29	31	90.6%	91.2%
Orange	1	1	3.1%	2.9%
Granville	2	2	6.3%	5.9%
Total	32	34	100.0%	100.0%

In Section C.1, pages 14-16, the applicant provides the assumptions and data utilized to project patient origin. Exhibit C-1 contains 32 letters of support from existing patients utilizing a DVA facility in Durham County.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section C.2, page 16, the applicant states the need for the proposed project is based on an analysis of patients served by DVA which showed that it was serving patients living in or near central Durham County. In Section C.1, page 14, the applicant states that 32 in-center patients have signed letters of support indicating they would consider transferring to the proposed facility (see Exhibit C-1).

Projected Utilization

In Section C.1, page 14, the applicant provides projected utilization during the first two years of operation following project completion, as illustrated in the table below:

DDD – Projected Patient Origin – CYs 2019 & 2020				
County	OY 1 – CY 2019	OY 2 – CY 2020	County Patients as % of Total	
	# Patients	# Patients	OY1	OY2
Durham	29	31	90.6%	91.2%
Orange	1	1	3.1%	2.9%
Granville	2	2	6.3%	5.9%
Total	32	34	100.0%	100.0%

In Section C.1, pages 14-16, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below:

- A number of dialysis patients reside in or near the central part of Durham County in the general area of the proposed facility. Thirty-two of those patients have signed letters of support indicating an interest in transferring to the proposed facility. Of those 32 patients, 24 of them are Durham County residents, two are Granville County residents, and one is an Orange County resident, all dialyzing at Durham Dialysis; and five of them are Durham County residents dialyzing at DWD.
- The applicant assumes that all 32 of the patients who signed letters indicating a willingness to consider transfer will actually transfer to the proposed facility.
- The project is scheduled for completion on January 1, 2019. OY1 is CY 2019. OY2 is CY 2020.
- The applicant assumes that Durham County patients transferring to the proposed facility will remain part of the Durham County ESRD patient population, and will increase at a rate of 3.4 percent, the Five Year Average Annual Change Rate (AACR) for Durham County as published in the July 2016 Semiannual Dialysis Report (SDR).
- No growth will be projected for patients living outside of Durham County, but they will be included in the facility census at appropriate times.

In Section C.1, page 16, the applicant provides the calculations used to arrive at the projected in-center patient census for OY1 and OY2 as summarized in the table below.

DDD	In-Center Dialysis
Begin with 29 in-center patients from Durham County who are projected to transfer to DDD upon facility certification (January 1, 2019).	29
Durham County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (3.4%).	$29 \times 1.034 = 29.986$
The two patients from Granville County and one patient from Orange County are added. This is the patient census for December 31, 2019.	$29.986 + 3 = 32.986$
Durham County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (3.4%).	$29.986 \times 1.034 = 31.006$
The two patients from Granville County and one patient from Orange County are added. This is the patient census for December 31, 2020.	$31.006 + 3 = 34.006$

The applicant projects to serve 32 in-center patients on 10 stations, which is 3.2 patients per station per week ($32 \text{ patients} / 10 \text{ stations} = 3.2$), by the end of OY1 and 34 in-center patients on 10 stations, which is 3.4 patients per station per week ($34 \text{ patients} / 10 \text{ stations} = 3.4$), by the end of OY2. This meets the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. Therefore, the applicant adequately demonstrates the need to develop a new 10-station dialysis facility.

Home Hemodialysis and Peritoneal Dialysis

The applicant does not include any data on home hemodialysis or home peritoneal dialysis patients and there is no information in the application which suggests that the applicant would pursue any home modalities at this time.

Access

In Section L.1(a), pages 51-52, the applicant states that DDD, by policy, will make services available to all residents of its service area without qualifications and will “...serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability.” On page 52, the applicant projects the payor mix for the second operating year of the project, and it projects that 88.6 percent of projected patients will have some or all of their services paid for by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the proposed 10-station facility, and demonstrates the extent to which all residents, 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, DDD, by relocating eight existing certified dialysis stations from Durham Dialysis and two existing certified dialysis stations from DWD. All three facilities are located in Durham 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, Durham Dialysis will be certified for 17 stations [29 – 8 – 7 (J-10319-14) – 3 (J-11216-16) + 3 (J-11084-15) + 3 (J-11256-16)], and DWD will be certified for 21 stations [29 – 2 – 3 (J-10319-14) – 7 (J-11216-16) + 4 (J-10350-15)]. In Section D.1, pages 25-29, the applicant discusses how the needs of dialysis patients at Durham Dialysis and DWD will continue to be met after the relocation of stations to the proposed DDD dialysis facility.

Durham Dialysis

In Section D.1, pages 25-26, the applicant provides the assumptions used to project utilization for Durham Dialysis through December 31, 2020, the end of the second operating year following completion of this project. The assumptions are summarized as follows:

- Durham Dialysis is certified for 29 dialysis stations as reported in the July 2016 SDR. Eight dialysis stations will be relocated to DDD.
- As of December 31, 2015 there were 103 patients dialyzing at Durham Dialysis; 93 from Durham County and 10 from other counties.
- Project I.D. #J-10319-14 approved DVA to develop RTP Dialysis (referred to in the application as East Durham Dialysis), which will include the transfer of seven stations from Durham Dialysis. DVA projected with that application that 17 in-center patients would transfer from Durham Dialysis to RTP Dialysis upon facility certification.
- Project I.D. # J-11084-15 approved DVA to add three stations to Durham Dialysis.
- In Project I.D. #J-11216-16, DVA proposed to develop Durham Regional Dialysis, which would include the transfer of three stations from Durham Dialysis. DVA projected with that application that 29 in-center patients would transfer care to the new Durham Regional Dialysis upon facility certification (which is proposed to be January 1, 2018). That application was under review at the time the current application was submitted. A certificate of need was issued for the new facility on December 17, 2016.
- In Project I.D. #J-11256-16, DVA proposed to add three stations to Durham Dialysis. That application was under review at the time the current application was submitted. A certificate of need was issued for the three additional stations on January 23, 2017.
- The applicant projects that 27 patients from Durham Dialysis (24 Durham County residents, two Granville County residents, and one Orange County resident) will transfer their care to DDD. These transfers are expected to take place January 1, 2019, when DDD becomes operational.
- As of January 1, 2019, the projected certification date for DDD, Durham Dialysis will have 17 stations following the addition of new stations and relocation of other stations.
- DVA projects the Durham County population will grow at an annual rate of 3.4 percent, which is the Five Year AACR published in the July 2016 SDR. No growth will be projected for patients living outside Durham County.
- The seven remaining patients from other counties are not projected to transfer to different facilities. They are added at the end of the calculations for each year.

Based on the above assumptions, the applicant projects utilization at Durham Dialysis from January 1, 2016 through December 31, 2020 as follows:

Durham Dialysis	
DVA begins with the Durham County ESRD patient population of Durham Dialysis as of January 1, 2016.	93
DVA projects this population forward 12 months to December 31, 2016, applying the Durham County Five Year AACR of 3.4%.	$93 \times 1.034 = 96.162$
DVA subtracts 17 Durham County patients projected to transfer to RTP Dialysis on January 1, 2017.	$96 - 17 = 79$
DVA projects this population forward 12 months to December 31, 2017, applying the Durham County Five Year AACR of 3.4%.	$79 \times 1.034 = 81.686$
DVA subtracts 29 Durham County patients projected to transfer to Durham Regional Dialysis on January 1, 2018.	$81 - 29 = 52$
DVA projects this population forward 12 months to December 31, 2018, applying the Durham County Five Year AACR of 3.4%.	$52 \times 1.034 = 53.768$
DVA adds the 10 patients from other counties to obtain the starting census for January 1, 2019, the date DDD is projected to be certified.	$53.768 + 10 = 63.768$
DVA subtracts 29 Durham County patients projected to transfer to Durham Regional Dialysis on January 1, 2019.	$63 - 29 = 34$
DVA projects this population forward 12 months to December 31, 2019, applying the Durham County Five Year AACR of 3.4%.	$34 \times 1.034 = 35.156$
DVA adds the seven patients from other counties (assuming that the three patients projected to transfer to DDD have done so) to obtain the ending census for December 31, 2019 (end of OY 1).	$35.156 + 7 = 42.156$
DVA projects the Durham County population forward 12 months to December 31, 2020, applying the Durham County Five Year AACR of 3.4%.	$42.156 \times 1.034 = 43.599$
DVA adds the seven patients from other counties to obtain the ending census for December 31, 2020 (end of OY 2).	$43.599 + 7 = 50.599$

The applicant projects that as of December 31, 2019, Durham Dialysis will have 36 in-center dialysis patients dialyzing on 17 stations for a utilization rate of 2.12 patients per station per week, or 53 percent of capacity ($36 / 17 = 2.12$; $2.12 / 4 = 0.53$ or 53%).

The applicant demonstrates that the needs of the population presently served at Durham Dialysis will continue to be adequately met following the proposed relocation of eight dialysis stations from Durham Dialysis to DDD.

DWD

In Section D.1, pages 27-28, the applicant provides the assumptions used to project utilization for DWD through December 31, 2020, the end of the second operating year following completion of this project. The assumptions are summarized as follows:

- DWD is certified for 29 dialysis stations as reported in the July 2016 SDR. Two dialysis stations will be relocated to DDD.
- As of December 31, 2015 there were 90 patients dialyzing at DWD; 68 from Durham County and 22 from other counties.
- Project I.D. #J-10319-14 approved DVA to develop RTP Dialysis, which will include the transfer of three stations from DWD. DVA projected with that application that seven in-center patients would transfer from DWD to RTP Dialysis upon facility certification (which is proposed to be January 1, 2017).
- Project I.D. # J-10350-15 approved DVA to add four stations to DWD.
- In Project I.D. #J-11216-16, DVA proposed to develop Durham Regional Dialysis, which would include the transfer of seven stations from DWD. DVA projected with that application that nine in-center patients would transfer care to the new Durham Regional Dialysis upon facility certification (which is proposed to be January 1, 2018). That application was under review at the time the current application was submitted. A certificate of need was issued for the new facility on December 17, 2016.
- The applicant projects that five patients from DWD will transfer their care to DDD. These transfers are expected to take place January 1, 2019, when DDD becomes operational.
- As of January 1, 2019, the projected certification date for DDD, DWD will have 21 stations following the addition of new stations and relocation of other stations.
- DVA projects the Durham County population will grow at an annual rate of 3.4 percent, which is the Five Year AACR published in the July 2016 SDR. No growth will be projected for patients living outside Durham County.
- The 22 remaining patients from other counties are not projected to transfer to different facilities. They are added at the end of the calculations for each year.

Based on the above assumptions, the applicant calculates the in-center patient census for DWD from January 1, 2016 through December 31, 2020, illustrated as follows:

DWD	
DVA begins with the Durham County ESRD patient population of DWD as of January 1, 2016.	68
DVA projects this population forward 12 months to December 31, 2016, applying the Durham County Five Year AACR of 3.4%.	$68 \times 1.034 = 70.312$
DVA subtracts seven Durham County patients projected to transfer to RTP Dialysis on January 1, 2017.	$70 - 7 = 63$
DVA projects this population forward 12 months to December 31, 2017, applying the Durham County Five Year AACR of 3.4%.	$63 \times 1.034 = 65.142$
DVA subtracts nine Durham County patients projected to transfer to Durham Regional Dialysis on January 1, 2018.	$65 - 9 = 56$
DVA projects this population forward 12 months to December 31, 2018, applying the Durham County Five Year AACR of 3.4%.	$56 \times 1.034 = 57.904$
DVA adds the 22 patients from other counties to obtain the starting census for January 1, 2019, the date DDD is projected to be certified.	$57.904 + 22 = 79.904$
DVA subtracts five Durham County patients projected to transfer to Durham Regional Dialysis on January 1, 2019.	$79 - 5 = 74$
DVA projects this population forward 12 months to December 31, 2019, applying the Durham County Five Year AACR of 3.4%.	$74 \times 1.034 = 76.508$
DVA adds the 22 patients from other counties to obtain the ending census for December 31, 2019 (end of OY 1).	$76.508 + 22 = 98.508$
DVA projects the Durham County population forward 12 months to December 31, 2020, applying the Durham County Five Year AACR of 3.4%.	$98.508 \times 1.034 = 101.863$
DVA adds the 22 patients from other counties to obtain the ending census for December 31, 2020 (end of OY 2).	$101.863 + 22 = 123.863$

The applicant projects that as of December 31, 2019, DWD will have 75 in-center dialysis patients dialyzing on 21 stations for a utilization rate of 3.57 patients per station per week, or 89.25 percent of capacity ($75 / 21 = 3.57$; $3.57 / 4 = 0.8925$ or 89.25%).

The applicant demonstrates that the needs of the population presently served at DWD will continue to be adequately met following the proposed relocation of two dialysis stations from DWD to DDD.

Conclusion

The applicant demonstrates that the needs of the population presently served at both Durham Dialysis and DWD will continue to be adequately met following the proposed relocation of eight dialysis stations from Durham Dialysis and two dialysis stations from DWD to DDD 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.

C

In Section E, page 30, the applicant describes the alternatives it considered prior to submitting this application for the proposed project, which include:

- Maintaining the Status Quo – the applicant states that all three of DVA’s dialysis facilities in Durham County are at capacity and, therefore, cannot be further expanded to meet the need. Additionally, maintaining the status quo does not address the needs of the patients identified as living in that area. Therefore, this is not an effective alternative.
- Develop a Facility in Another Area of Durham County - the applicant states that it will not be able to provide better geographic access to the patients who submitted letters found in Exhibit C-1 with a different site location. Therefore, this is not an effective alternative.

After considering the above alternatives, the applicant states that given the residence location of the existing patients projected to be served at DDD and the constraints of existing DVA facilities in the county, the proposed project is 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 the 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 Downtown Durham Dialysis shall materially comply with all representations made in the certificate of need application.**
- 2. DVA Renal Healthcare, Inc. d/b/a Downtown Durham Dialysis shall relocate no more than eight dialysis stations from Durham Dialysis and no more than two dialysis stations from Durham West Dialysis.**
- 3. DVA Renal Healthcare, Inc. d/b/a Downtown Durham 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 eight dialysis stations at Durham Dialysis for a total of no more than 17 dialysis stations at Durham Dialysis upon completion of this project and all of the following projects: Project I.D. #J-10319-14, Project I.D. #J-11084-15, Project I.D. #J-11216-15, and Project I.D. #J-11256-16.**

5. **DVA Renal Healthcare, Inc. shall take the necessary steps to decertify two dialysis stations at Durham West Dialysis for a total of no more than 21 dialysis stations at Durham West Dialysis upon completion of this project and all of the following projects: Project I.D. #J-10319-14, Project I.D. #J-10350-15, and Project I.D. #J-11216-15.**
 6. **DVA Renal Healthcare, Inc. d/b/a Downtown Durham 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

The applicant proposes to develop a new 10-station dialysis facility in Durham County, DDD, by relocating eight stations from Durham Dialysis and two stations from DWD.

Capital and Working Capital Costs

In Section F.1, page 31, the applicant projects \$3,025,525 in capital costs to develop the proposed project, summarized as follows:

DDD

Site Costs	\$70,400
Construction Contract	\$2,100,000
Dialysis Machines	\$165,360
Water Treatment Equipment	\$190,425
Other Equipment/Furniture	\$379,340
<u>Architect/Engineering Fees</u>	<u>\$120,000</u>
Total	\$3,025,525

In Section F.10, pages 33-34, the applicant states that it will have \$191,530 in start-up expenses and in Section F.11, page 34, the applicant states it will have six months of initial operating expenses of \$734,864. The total estimated working capital for the project is \$926,394.

Availability of Funds

In Section F.2, page 32, and Section F.13, pages 34-35, the applicant states it will finance the capital costs and working capital costs with accumulated reserves of FMC. Exhibit F-5 contains a letter dated November 11, 2016, from the Chief Accounting Officer of DaVita, Inc., the parent company of DVA, authorizing and committing \$4,143,449 in capital and working costs for the project.

Exhibit F-7 contains the Consolidated Financial Statements for DaVita Healthcare Partners, Inc. for the years ending December 31, 2015 and December 31, 2014. These statements indicate that as of December 31, 2015, it had \$1,499,116,000 in cash and cash equivalents, \$18,514,875,000 in total assets and \$5,084,172,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

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

Projected Revenues and Operating Expenses		
DDD	Operating Year 1 CY 2019	Operating Year 2 CY 2020
Total Treatments	4,742	4,891
Total Gross Revenues (Charges)	\$1,562,013	\$1,611,389
Total Net Revenue	\$1,488,012	\$1,535,084
Total Operating Expenses (Costs)	\$1,469,728	\$1,511,678
Net Income	\$18,284	\$23,406

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

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

The applicant, DVA, proposes to develop a new 10-station dialysis facility in Durham County, DDD, by relocating eight stations from Durham Dialysis and two stations from DWD.

On page 369, the 2016 SMFP defines the service area for dialysis stations as *“the 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 is Durham County. Facilities may also serve residents of counties not included in their service area.

The applicant operates three dialysis centers in Durham County. Also, DVA has been approved to develop two additional facilities in Durham County – Durham Regional Dialysis and RTP Dialysis – but the facilities were not yet operational on June 30, 2016. Fresenius Medical Care operates four dialysis centers in Durham County and Duke University Hospital operates one dialysis center in Durham County. The existing and approved Durham County dialysis facilities are shown below:

Durham County Dialysis Facilities as of December 31, 2015				
Dialysis Facility	Certified Stations	CON Issued Not Certified	% Utilization	Patients Per Station
Duke Hospital Dialysis	16	0	81.25%	3.25
Durham Dialysis (DVA)	29	-4	88.79%	3.55
Durham West Dialysis (DVA)	29	1	77.59%	3.10
Durham Regional Dialysis (DVA)	0	10	NA	NA
RTP Dialysis (DVA)	0	10	NA	NA
FMC Dialysis Services of Briggs Avenue	29	0	70.69%	2.83
FMC Dialysis Services West Pettigrew	24	0	65.63%	2.63
FMC South Durham Dialysis	18	0	68.06%	2.72
Freedom Lake Dialysis Unit (BMA)	26	0	80.77%	3.23
Southpoint Dialysis (DVA)	16	0	101.56%	4.06

Source: July 2016 SDR, Table A.

As shown in the table above, four of the eight operational Durham County dialysis facilities were operating above 80 percent utilization (3.2 patients per station), and five of the eight operational facilities were operating at or above 75 percent utilization (3.0 patients per station) as of December 31, 2015. All three operational DVA facilities were operating above 75 percent utilization as of December 31, 2015.

The applicant is not increasing the number of dialysis stations in Durham County; rather, it is relocating 10 of them to develop a new facility that is closer to patients living in or near the area where the new facility will be located. Therefore, it is not duplicating services; rather, it is relocating existing services by proposing to create a new facility to better serve existing patients using existing stations.

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

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

C

In Section H.1, page 38, the applicant provides the proposed staffing for the new facility, which includes 9.3 full-time equivalent (FTE) employee positions, summarized as follows:

DDD Proposed Staffing	
Position	Projected # of FTE Positions
Medical Director*	
RN	2.0
Patient Care Technician	4.0
Administrator	1.0
Dietitian	0.5
Social Worker	0.5
Admin. Assistant	1.0
Biomed Technician	0.3
Total FTE Positions	9.3

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

In Section H.3, pages 39-40, the applicant describes its experience and process for recruiting and retaining staff.

Exhibit I-3 contains a copy of a letter dated October 15, 2016 from Dr. Stephen R. Smith, stating that he has agreed to serve as Medical Director of DDD.

The applicant documents the availability of adequate health manpower and management personnel, including a Medical Director, to provide 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.1, page 42, the applicant includes a list of providers of the necessary ancillary and support services that will be provided to patients receiving dialysis services at DDD. Exhibits I-1 and I-2 contain documentation regarding the availability of laboratory, vascular surgery services, Division of Vocational Rehabilitation, transit, and kidney transplant services. Exhibit I-3 contains a letter from Dr. Stephen R. Smith agreeing to serve as the Medical Director for the facility. The applicant discusses coordination with the existing health care system in Sections I.3 and I.4, pages 43-44. The applicant adequately demonstrates that the necessary ancillary and

support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicant proposes to construct a 5,402 square foot building to house the proposed services which will be located in the city of Durham in Durham County. In Section F.1, page 31, the applicant lists the project costs, including \$2,170,400 for site and construction costs and \$855,125 in miscellaneous costs including dialysis machines, water treatment equipment, furniture, and architect/engineering fees for a total project cost of \$3,025,525. In Section B.5, pages 11-13, the applicant describes its plans for energy-efficiency and water conservation. Costs and charges are described by the applicant in Section R at the end of the application. 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.1, pages 52-53, the applicant lists the ways DVA helps provide access to dialysis services for the underserved populations of North Carolina and states its policy to provide services to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and any other underserved group. In addition, the applicant describes its admission and financial policies in Section L.3, pages 52-54, and provides a copy of its admission policy in Exhibit L-3.

In Section L.7, page 55, the applicant provides the historical payor mix for Durham Dialysis. Eight dialysis stations will be relocated from Durham Dialysis to the proposed facility and some patients will transfer to DDD (See Exhibit C-1 for patients' letters of support.) The historical payor mix is as follows:

Durham Dialysis Historical Payor Mix – CY 2015	
Payor Type	% of In-Center Patients
Medicare	41.0%
Medicaid	15.2%
Commercial Insurance	6.7%
Medicare/Commercial	16.1%
Medicare/Medicaid	21.0%
Total	100.0%

In Section L.7, page 55, the applicant provides the historical payor mix for DWD. Two dialysis stations will be relocated from DWD to the proposed facility and some patients will transfer to DDD (See Exhibit C-1 for patients' letters of support.) The historical payor mix is as follows:

DWD Historical Payor Mix – CY 2015	
Payor Type	% of Total Patients
Medicare	22.8%
Medicaid	4.1%
Commercial Insurance	23.6%
Medicare/Commercial	39.8%
Medicare/Medicaid	8.1%
VA	1.6%
Total	100.0%

As illustrated in the tables above, 93.3 percent of Durham Dialysis patients and 74.8 percent of DWD patients had some or all of their services paid for by Medicare and/or Medicaid.

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**
Durham	11%	52%	58%	17%	7%	18%
Statewide	15%	51%	36%	17%	10%	15%

Source: [http://www.census.gov/quickfacts/table_2014 Estimate as of December 22, 2015](http://www.census.gov/quickfacts/table_2014%20Estimate%20as%20of%20December%22,%202015).

*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%

<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.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 provide adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

In Section L.3, page 54, the applicant states that it has no obligations under any federal regulations to provide uncompensated care or community service except those federal requirements of the Rehabilitation Act of 1973 and subsequent amendments. The applicant states that the facility has no Hill-Burton obligations.

In Section L.6, page 54, the applicant states there have been no civil rights complaints filed against any DVA facilities in North Carolina within the past five years. Therefore, 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 provides the projected payor mix for the proposed project for the second operating year (CY 2020). The applicant states on page 52 that the projected payor mix for DDD is based on the sources of payment received by DVA facilities in Durham County during the last full operating year. The projected payor mix is illustrated as follows:

DDD Projected Payor Mix – CY 2020	
Payor Type	% of In-Center Patients
Medicare	33.9%
Medicaid	10.9%
Commercial Insurance	10.4%
Medicare/Commercial	27.1%
Medicare/Medicaid	16.7%
VA	1.0%
Total	100.0%

As illustrated in the table above, the applicant projects that 88.6 percent of all of the patients receiving dialysis services at DDD in the second year of operation will have some or all of their services paid for by Medicare or Medicaid. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at DDD. 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 describes the range of means by which a person will have access to the dialysis services at DDD. The applicant states that nephrologists with medical staff privileges will admit patients to the facility for dialysis. Referrals to these nephrologists may come from patients themselves, family, or friends. In Exhibit I-3, the applicant provides a letter signed by Dr. Stephen R. Smith of Duke University Medical Center, indicating his willingness to serve as Medical Director. Exhibit I-3 also contains letters of support from local nephrologists who state they plan to refer patients to DDD. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis 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 it has offered the facility as a clinical learning site to nursing students at Durham Technical Community College. Exhibit M-1 contains a letter from the applicant to Durham Technical Community College's Department of Nursing, inviting the school to do clinical rotations for nursing students at its proposed facility. The information provided is reasonable and adequately supports a determination that 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

The applicant, DVA, proposes to develop a new 10-station dialysis facility in Durham County, DDD, by relocating eight stations from Durham Dialysis and two stations from DWD.

On page 369, the 2016 SMFP defines the service area for dialysis stations as *“the 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 is Durham County. Facilities may also serve residents of counties not included in their service area.

The applicant operates three dialysis centers in Durham County. Also, DVA has been approved to develop two additional facilities in Durham County – Durham Regional Dialysis and RTP Dialysis – but the facilities were not yet operational on June 30, 2016. Fresenius Medical Care operates four dialysis centers in Durham County and Duke University Hospital operates one dialysis center in Durham County. The existing and approved Durham County dialysis facilities are shown below:

Durham County Dialysis Facilities as of December 31, 2015				
Dialysis Facility	Certified Stations	CON Issued Not Certified	% Utilization	Patients Per Station
Duke Hospital Dialysis	16	0	81.25%	3.25
Durham Dialysis (DVA)	29	-4	88.79%	3.55
Durham West Dialysis (DVA)	29	1	77.59%	3.10
Durham Regional Dialysis (DVA)	0	10	NA	NA
RTP Dialysis (DVA)	0	10	NA	NA
FMC Dialysis Services of Briggs Avenue	29	0	70.69%	2.83
FMC Dialysis Services West Pettigrew	24	0	65.63%	2.63
FMC South Durham Dialysis	18	0	68.06%	2.72
Freedom Lake Dialysis Unit (BMA)	26	0	80.77%	3.23
Southpoint Dialysis (DVA)	16	0	101.56%	4.06

Source: July 2016 SDR, Table A.

As shown in the table above, four of the eight operational Durham County dialysis facilities were operating above 80 percent utilization (3.2 patients per station), and five of the eight operational facilities were operating at or above 75 percent utilization (3.0 patients per station) as of December 31, 2015. All three operational DVA facilities were operating above 75 percent utilization as of December 31, 2015.

In Section N.1, page 57, the applicant discusses how any enhanced competition will have a positive impact on cost-effectiveness, quality and access to the proposed services. The applicant states:

“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. ...

The bottom line is Downtown Durham 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 involved in the dialysis process to receive services. Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs.”

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

The information in the application is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality, and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicant adequately demonstrates that it will continue to provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is 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 Exhibit O-3, the applicant identifies four of its 70+ North Carolina facilities (Southeastern Dialysis Center – Kenansville, Durham Dialysis, Marshville Dialysis, and Durham West Dialysis) as having been cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant states that all four facilities are back in full compliance with CMS Guidelines as of the date of submission of this application and provides copies of letters to each facility from the Agency’s Acute and Home Care Licensure and Certification Section that state each facility is back in compliance. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it 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

- (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 DDD will serve at least 32 in-center patients on 10 dialysis stations at the end of the first operating year, which is 3.2 patients per station per week, or a utilization rate of 80.0 percent ($32 / 10 = 3.2$; $3.2 / 4 = 0.80$ or 80.0%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.
- (b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- NA- The applicant is seeking to develop a new 10-station dialysis facility.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 14-16, 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.