

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 16, 2016

Findings Date: November 16, 2016

Project Analyst: Bernetta Thorne-Williams

Team Leader: Fatimah Wilson

Project ID #: J-11216-16

Facility: Durham Regional Dialysis

FID #: 160396

County: Durham

Applicant: DVA Renal Healthcare, Inc.

Project: Develop a new 10-station dialysis facility in Durham County by relocating three stations from Durham Dialysis and seven stations from Durham West Dialysis

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

DVA Renal Healthcare, Inc. (DVA) d/b/a Durham Regional Dialysis proposes to develop a new 10-station dialysis facility in Durham by relocating three dialysis stations from Durham Dialysis and seven dialysis stations from Durham West Dialysis. The two existing facilities and the proposed facility 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 Regional Dialysis will be certified for 10 dialysis stations, Durham Dialysis will be certified for 22 dialysis stations following completion of Project I.D. # J-11084-15 (add three stations) and Project I.D. # J-10319 (relocate seven stations) ( $29-3+3-7=22$ ) and Durham West Dialysis will be certified for

23 dialysis stations following completion of Project I.D. # J-10350-14 (add four stations) and Project I.D. # J-10319-14 (relocate three stations) (29 -7+4-3 = 23).

### **Need Determination**

The applicant is proposing 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**

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

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

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

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

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

The proposed capital expenditure is greater than \$2 million, but less than \$5 million. In Section B.5, pages 11-13, Section K.1, page 45, and Exhibit K-1 (d) the applicant describes how it will assure improved energy efficiency and water conservation. Therefore, the application is conforming to Policy GEN-4.

*Policy ESRD-2: Relocation of Dialysis Stations*

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

*1. Demonstrate that the facility losing dialysis stations or moving to a contiguous [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, Durham Regional Dialysis, in Durham, by relocating existing dialysis stations from both Durham Dialysis and Durham West Dialysis. The two existing facilities and the proposed facility are located in Durham County, therefore there is no change in the dialysis station inventory in Durham County. Therefore, the application is consistent with Policy ESRD-2.

### **Conclusion**

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

Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

### C

The applicant proposes to develop a new 10-station dialysis facility in Durham by relocating three dialysis stations from Durham Dialysis and seven dialysis stations from Durham West Dialysis. The two existing facilities and the proposed facility 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 Regional Dialysis will be certified for 10 dialysis stations, Durham Dialysis will be

certified for 22 dialysis stations following completion of Project I.D. # J-11084-15 (add three stations) and Project I.D. # J-10319) (relocate seven stations) (29-3+3-7= 22) and Durham West Dialysis will be certified for 23 dialysis stations following completion of Project I.D. # J-10350-14 (add four stations) and Project I.D. # J-10319-14 (relocate three stations) (29-7+ 4-3= 23).

**Patient Origin**

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Durham County. Facilities may also serve residents of counties not included in their service area.

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

In Section C.1, page 14, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion for in-center (IC) patients. The applicant does not propose to serve home hemodialysis or peritoneal dialysis patients, as illustrated in the following table:

**Projected Patient Origin**

County	Operating Year 1 CY 2018	Operating Year 2 CY 2019	County Patients as a % of Total	
	IC	IC	OY1	OY2
Durham	35	36	100.0%	100.0%
<b>Total</b>	<b>35</b>	<b>36</b>	<b>100.0%</b>	<b>100.0%</b>

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

The applicant adequately identifies the population to be served.

**Analysis of Need**

In Section C.2, page 16, the applicant states that it determined a need for a new dialysis facility in Durham County based on the fact that many of its in-center dialysis patients live in or near the northern part of the county in the 27704 ZIP Code Area. In Section C.5, pages 16-17, the applicant states after an analysis of patient data it determined that at least 38 in-center patients who currently received dialysis treatment at DaVita operated facilities lived in the 27704 ZIP Code Area of northern Durham. The applicant compared this analysis to other areas in Durham County with a significant population of end stage

renal patients (ESRD) and concluded that those areas were currently being served or had facilities currently under development. The applicant further concluded that the proposed new facility is located closer to where a significant number of its patients reside. In Section C.2, page 16, the applicant states:

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

On page 14, the applicant states, *“It is assumed that the thirty-four (34) of the thirty-eight (38) in-center patients living in Durham County who signed letters of support for Durham Regional Dialysis will transfer their care upon certification of the new facility.”*

See Exhibit C-1 which contains 38 patient letters of support which state:

*“I fully support this new dialysis facility ... to be built in Durham. ... I could travel between home and that location more easily and quickly, which would save me time and money.”*

### Projected Utilization

In Section C.1, pages 14-15, the applicant provides the assumptions and methodology used to project utilization for the proposed facility. The assumptions and methodology are summarized as follows:

- The applicant states that it received 38 letters of support from in-center patients utilizing DVA dialysis facilities in Durham County indicating their willingness to consider transferring their care to the proposed facility.
- The applicant assumes that the in-center patients who are residents of Durham County will increase at a rate commensurate with Durham County’s Five Year Average Annual Change Rate (AACR) of 3.4%, as published in Table B of the July 2016 Semi-Annual Dialysis Report (SDR), through the second operating year.
- The applicant states that all 38 in-center patients who have expressed an interest in transferring their care to the proposed new facility are residents of Durham County and reside within the 27704 ZIP Code Area.
- The applicant states that 29 of those patients currently receive dialysis care/services at Durham Dialysis and 9 patients currently receive dialysis care/services at Durham West Dialysis.

- The applicant assumes that at least 34 of the 38 patients that provided letters of support for the proposed facility will actually transfer to the proposed Durham Regional Dialysis facility.

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

<b>Durham Regional Dialysis</b>	<b>In-Center Patients</b>
January 1, 2018, the beginning of Operating Year 1, will begin with 34 in-center patients who have transferred their care from other DVA dialysis facilities.	34
Growth is projected during OY1 by multiplying the beginning census by the Durham County Five Year AACR of 3.4% to arrive at the end of year census for December 31, 2018	$34 \times 1.034 = 35.156$
Growth is projected again for OY2 by multiplying the beginning census for January 1, 2019 by the Durham County Five Year AACR of 3.4% to arrive at the end of year census for December 31, 2019.	$35.156 \times 1.034 = 36.351$

The applicant states on page 15 that the number of projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2018) the facility is projected to serve 35 in-center patients and at the end of OY2 (CY2019) the facility is projected to serve 36 in-center patients.

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

- OY1: 3.5 patients per station per week, or 87.5% ( $35 \text{ patients} / 10 \text{ stations} = 3.5/4 = .875$  or 87.5%).
- OY2: 3.6 patients per station per week, or 90.0% ( $36 \text{ patients} / 10 \text{ stations} = 3.6/4 = .9$  or 90.0%).

The projected utilization of 3.5 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

### Access to Services

In Section C.3, page 16, the applicant states,

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

In addition, the applicant projects, in Section L.1, page 51, that 88.6% of its patients at Durham Regional Dialysis will be covered by either Medicare or Medicaid. The applicant states that the projected payor mix for the proposed facility is based on sources of payment for its DVA facilities in Durham County for the last full operating year. The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to have access to the proposed services.

### Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed project and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

### C

DVA proposes to develop a new 10-station dialysis facility in Durham by relocating three dialysis stations from Durham Dialysis and seven dialysis stations from Durham West Dialysis. The two existing facilities and the proposed facility 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 Regional Dialysis will be certified for 10 dialysis stations, Durham Dialysis will be certified for 22 dialysis stations following completion of Project I.D. # J-11084-15 (add three stations) and Project I.D. # J-10319) (relocate seven stations) ( $29-3+3-7= 22$ ) and Durham West Dialysis will be certified for 23 dialysis stations following completion of Project I.D. # J-10350-14 (add four stations) and Project I.D. # J-10319-14 (relocate three stations) ( $29-7+ 4-3= 23$ ).

Durham Dialysis

In Section D.1, pages 24-25, the applicant states that as of December 31, 2015, as reported in the July 2016 SDR, there were 103 in-center dialysis patients at Durham Dialysis dialyzing on 29 dialysis stations, for a utilization rate of 88.79%. In addition, the applicant states that 93 of the 103 in-center patients lived in Durham County and that 10 lived outside Durham County.

DVA proposes to relocate three stations from Durham Dialysis to the proposed Durham Regional Dialysis. The applicant projects that 29 in-center patients currently receiving care/services at Durham Dialysis will opt to transfer those services to Durham Regional Dialysis. The applicant states on page 24, that DVA was approved in Project I.D. # J-10319-14 to develop East Durham Dialysis by relocating seven dialysis stations from Durham Dialysis. In Project I.D. # J-10319-14, the applicant also projected that 17 in-center patients would transfer their care/services to East Durham Dialysis. The applicant states on page 24, that none of the 38 letters of support provided for the proposed project are from those patients projected to transfer their care/services to East Durham Dialysis. Additionally, DVA was approved in Project I.D. # J-11084-15 to add three dialysis stations to Durham Dialysis following the relocation of seven dialysis stations from Durham Dialysis to East Durham Dialysis leaving Durham Dialysis with a total of 22 dialysis stations [ $29 - 3 + 3 - 7 = 22$ ].

The applicant assumes that the number of in-center patients at Durham Dialysis who live in Durham County will increase at 3.4% per year based on the Five Year AACR for Durham County, as reported in Table B of the July 2016 SDR. The applicant assumes that no growth will occur for the 10 in-center patients living outside of Durham County. In Section D.1, page 25, the applicant calculates the in-center patient census for Durham Dialysis starting January 1, 2016 through OY1 (CY2018) and OY2 (CY2019), illustrated follows:



Durham Dialysis	In-Center Patients
Beginning census for January 1, 2016 for Durham County patients only, increased by the Five Year AACR for Durham County of 3.4%. Add 10 patients from outside Durham County to arrive at the ending census for December 31, 2016.	$93 \times 1.034 = 96.162 + 10 = 106.162$
Durham County patient census for CY2017 increased by 3.4% Five Year AACR for Durham County. Reduce the in-center patient population by 17 patients per Project I.D. # J-10319-14. Add 10 patients from outside Durham County to arrive at ending census for December 31, 2017.	$96.162 - 17 = 79.162 \times 1.034 = 81.853 + 10 = 91.853$
<b>OY1 (CY2018)</b> Durham County patient census for CY2018 increased by 3.4% Five Year AACR for Durham County. (After subtracting out 29 Durham County patients who are projected to transfer to the proposed Durham Regional Dialysis facility). Add 10 patients from outside Durham County to arrive at ending census for December 31, 2018.	$81.853 - 29 = 52 \times 1.034 = 53.768 + 10 = 63.768$
<b>OY2 (CY2019)</b> Durham County patient census for CY2019 increased 3.4% Five Year AACR for Durham County. Add 10 patients from outside Durham County to arrive at ending census for December 31, 2019.	$53.768 \times 1.034 = 55.596 + 10 = 65.596$

The applicant rounds down the ending census numbers for OY1 and OY2. (See page 25) Durham Dialysis is projected to have 63 in-center patients at the end of OY1 dialyzing on 22 stations for a utilization rate of 71.6%, or 2.86 patients per station (63 patients/ 22 stations = 2.86/4 = 0.715 or 71.5%). The applicant states the following on page 25:

*“Given this projected growth of the in-center patient population, the needs of the facility’s patients will continue to be met. Should growth exceed these projections, additional Certificate of Need applications 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.”*

Durham West Dialysis

In Section D.1, pages 25-27, the applicant states that as of December 31, 2015, as reported in the July 2016 SDR, there were 90 in-center dialysis patients at Durham West Dialysis dialyzing on 29 dialysis stations, for a utilization rate of 77.59%. In addition, the applicant states that 68 of the 90 in-center patients lived in Durham County and that 22 lived outside Durham County.

DVA proposes to relocate seven stations from Durham West Dialysis to the proposed Durham Regional Dialysis. And projects that nine in-center patients currently receiving care/services at Durham West Dialysis will opt to transfer those services to Durham Regional Dialysis. The applicant states on page 25, that DVA was approved in Project I.D. # J-10319-14 to develop East Durham Dialysis by relocating three dialysis stations from Durham West Dialysis. In Project I.D. # J-10319-14, the applicant also projected

that 27 in-center patients would transfer their care/services to East Durham Dialysis. The applicant states on pages 25-26, that none of the 38 letters of support provided for the proposed project are from those patients projected to transfer their care/services to East Durham Dialysis. Additionally, DVA was approved in Project I.D. # J-10350-15 to add four dialysis stations to Durham West Dialysis following the relocation of three dialysis stations from Durham West Dialysis to East Durham Dialysis leaving Durham West Dialysis with a total of 23 dialysis stations [29 -7 +4 - 3 = 23].

The applicant assumes that the number of in-center patients at Durham West Dialysis who live in Durham County will increase at 3.4% per year based on the Five Year AACR for Durham County, as reported in Table B of the July 2016 SDR. The applicant assumes that no growth will occur for the 22 in-center patients living outside of Durham County. In Section D.1, page 27, the applicant calculates the in-center patient census for Durham West Dialysis starting January 1, 2016 through OY1 (CY2018) and OY2 (CY2019), illustrated follows:

<b>Durham West Dialysis</b>	<b>In-Center Patients</b>
Beginning census for January 1, 2016 for Durham County patients only, increased by the Five Year AACR for Durham County of 3.4%. Add 22 patients from outside Durham County to arrive at the ending census for December 31, 2016.	$68 \times 1.034 = 70.312 + 22 = 92.312$
Durham County patient census for CY2017 increased by 3.4% Five Year AACR for Durham County. Reduce the in-center patient population by 7 patients per Project I.D. # J-10319-14. Add 22 patients from outside Durham County to arrive at ending census for December 31, 2017.	$70.312 - 7 = 63 \times 1.034 = 65.142 + 22 = 87.142$
<b>OY1 (CY2018)</b> Durham County patient census for CY2018 increased by 3.4% Five Year AACR for Durham County. (After subtracting out 9 Durham County patients who are projected to transfer to the proposed Durham Regional Dialysis facility). Add 22 patients from outside Durham County to arrive at ending census for December 31, 2018.	$65.142 - 9 = 56 \times 1.034 = 57.904 + 22 = 79.904$
<b>OY2 (CY2019)</b> Durham County patient census for CY2019 increased 3.4% Five Year AACR for Durham County. Add 22 patients from outside Durham County to arrive at ending census for December 31, 2019.	$57.904 \times 1.034 = 59.872 + 22 = 81.872$

The applicant rounds down the ending census numbers for OY1 and OY2. (See page 27) Durham West Dialysis is projected to have 79 in-center patients at the end of OY1 for a utilization rate of 85.9%, or 3.52 patients per station (79 patients/ 23 stations = 3.43/4 = .8586 or 85.9%). The applicant states the following on page 27:

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

The applicant demonstrates that the needs of the populations presently served at Durham Dialysis and Durham West Dialysis will continue to be adequately met following the proposed relocation of three dialysis stations from Durham Dialysis and seven dialysis stations from Durham West Dialysis to Durham Regional Dialysis and that access for medically underserved groups will not be negatively impacted.

Therefore, the application is conforming to this criterion.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section E.1, page 28, the applicant discusses the alternatives considered prior to submitting this application, which include maintaining the status quo or developing the new facility in another area of Durham County. The applicant discusses the fact that dialysis can be a time consuming and physically demanding process and that the proposed location in northern Durham County would place the facility in close proximity to existing dialysis patients who currently utilize other existing DVA owned facilities in Durham County and the fact that these patients residing in northern Durham County have signed letters of support for the proposed project.

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

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

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

- 1. DVA Renal Healthcare, Inc. d/b/a Durham Regional Dialysis shall materially comply with all representations made in the certificate of need application.**
- 2. DVA Renal Healthcare, Inc. d/b/a Durham Regional Dialysis shall relocate no more than three dialysis stations from Durham Dialysis and no more than seven dialysis stations from Durham West Dialysis.**

3. **DVA Renal Healthcare, Inc. d/b/a Durham Regional 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 three dialysis stations at Durham Dialysis for a total of no more than 22 dialysis stations at Durham Dialysis upon completion of this project and Project J-11084-15 (add three stations) and Project I.D. # J-10319-14 (relocate seven stations) and to decertify seven dialysis stations at Durham Dialysis for a total of no more than 23 dialysis stations at Durham West Dialysis upon completion of this project and Project I.D. # J-10350-14 (add four stations) and Project I.D. # J-10319-14 (relocate three stations).**
  5. **DVA Renal Healthcare, Inc. d/b/a Durham Regional 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 by relocating three dialysis stations from Durham Dialysis and seven dialysis stations from Durham West Dialysis.

**Capital and Working Capital Costs**

In Section F.1, page 29, the applicant provides the capital cost of the project as summarized in the following table:

**Durham Regional Dialysis  
Project Capital Costs**

Site Costs	\$58,000
Construction Contract	\$1,461,600
Dialysis Machines	\$152,400
Water Treatment Equipment	\$105,000
Equipment/Furniture	\$315,944
Architect & Engineering Fees	\$114,000
<b>Total Capital Cost</b>	<b>\$2,206,944</b>

In Section F.10, pages 31-32, and Section F.11, page 32, the applicant estimates start-up expenses of \$191,529 and initial operating expenses of \$765,555, respectively, for a total working capital \$957,084.

**Availability of Funds**

In Section F.2, page 30, the applicant states that accumulated reserves/owner's equity will be used to finance the project's capital costs. In Section F.13, page 33, the applicant states that the working capital costs will be financed with cash reserves. Exhibit F-5 contains a letter from DVA's Chief Accounting Officer, dated August 11, 2016, confirming DVA's commitment to funding the project's capital costs and working capital costs with cash reserves.

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

**Financial Feasibility**

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

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

<b>Durham Regional Dialysis</b>	<b>Operating Year 1 CY2018</b>	<b>Operating Year 2 CY2019</b>
Total Net Revenue	\$1,604,734	\$1,651,760
Total Operating Expenses	\$1,531,109	\$1,572,681
<b>Net Profit</b>	<b>\$73,625</b>	<b>\$79,079</b>

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected utilization, costs and charges are reasonable and adequately supported. See Section R, pro formas, for the applicant's assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In Section H.1, page 36, the applicant provides projected staffing and salaries. Form A in Section R, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

## **Conclusion**

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project. The applicant also adequately demonstrates that the financial feasibility of the project is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming to this criterion.

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

### C

DVA proposes to develop a new 10-station dialysis facility in Durham by relocating three dialysis stations from Durham Dialysis and seven dialysis stations from Durham West Dialysis. The two existing facilities and the proposed facility 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 Regional Dialysis will be certified for 10 dialysis stations, Durham Dialysis will be certified for 22 dialysis stations following completion of Project I.D. # J-11084-15 (add three stations) and Project I.D. # J-10319) (relocate seven stations) ( $29-3+3-7= 22$ ) and Durham West Dialysis will be certified for 23 dialysis stations following completion of Project I.D. # J-10350-14 (add four stations) and Project I.D. # J-10319-14 (relocate three stations) ( $29-7+ 4-3= 23$ ).

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Durham County. Facilities may also serve residents of counties not included in their service area.

The July 2016 SDR indicates there are nine dialysis facilities in Durham County, as follows:

**Durham County Dialysis Facilities  
December 31, 2015**

<b>Dialysis Facilities</b>	<b>Owner</b>	<b># of Patients</b>	<b>Location</b>	<b># of Certified Stations</b>	<b># of Approved Stations</b>	<b>Percent Utilization</b>
Duke Hospital Dialysis	Duke	52	Durham	16	0	81.25%
Durham Dialysis	DVA	103	Durham	29	-4	88.79%
Durham West	DVA	90	Durham	29	1	77.59%
Est Durham Dialysis	DVA	Under development – New 10 stations facility				
FMC Briggs Avenue	Fresenius	82	Durham	29	0	70.69%
FMC West Pettigrew	Fresenius	63	Durham	24	0	65.63%
FMC South Durham	Fresenius	49	Durham	18	0	68.06%
Freedom Lake Dialysis	Fresenius	84	Durham	26	0	80.77%
Southpoint Dialysis	Fresenius	65	Durham	16	0	101.56%

As illustrated above, there are eight existing dialysis facilities located in Durham and one facility under development. Of those nine facilities, three facilities are operated by DVA, one by Duke University Hospital and the remaining five facilities are owned Fresenius. The proposed site for Durham Regional Dialysis is in the northern part of Durham. Three of the facilities operate with a utilization rate over 80.0%, two with a utilization over 70.0%, two with a utilization of over 65.0% and one of the Fresenius facilities operates with a utilization of over 100.0%. Thus, all of the operational dialysis facilities in the county are reasonably well utilized.

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 the area where the new facility will be located. Therefore, it is not duplicating services, rather it is proposing to create a new facility to better serve existing patients using existing stations.

In Section C.1, page 14, the applicant demonstrates that Durham Regional Dialysis will serve a total of 35 in-center patients on 10 stations at the end of the first operating year, which is 3.5 patients per station per week, or a utilization rate of 87.5% ( $35/10 = 3.5$ ;  $3.5/4 = 0.875$  or 87.5%). The applicant provides documentation in Exhibit C-1 from 38 in-center patients at its Durham County facilities indicating their willingness to consider transferring to Durham Regional Dialysis upon completion because its location would be more convenient. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Durham County. Consequently, the application is conforming to this criterion.

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

C

The applicant provides the projected staffing for Durham Regional Dialysis in Section H.1, page 36, illustrated as follows:

<b>Position</b>	<b>Projected Number of FTEs</b>
Medical Director*	
Registered Nurse	2.0
Patient Care Technician (PCT)	4.0
Administrator	1.0
Dietitian	0.5
Social Worker	0.5
Administrative Assistant	1.0
Biomedical Technician	0.3
<b>Total</b>	<b>9.3</b>

\*The Medical Director is an independent contractor, not an employee of the facility.

In Section H.3, pages 37-38, the applicant states that it will fill positions by using a DVA Teammate Recruiter, the Teammate Referral Program, and its Student Internship Program. In addition, the applicant states that it provides a wide range of benefits and competitive salaries to attract candidates for positions.

In Section H.7, page 39, the applicant provides the projected Direct Care Staff Hours for OY2, as follows:



**Projected Direct Care Staff Hours – OY2**

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

In Section H.2, page 37, the applicant states that the Medical Director for Durham Regional Dialysis will be Dr. Stephen Smith. In Exhibit I-3, the applicant provides a letter signed by Dr. Smith, dated August 9, 2016, confirming his commitment to serve as Medical Director. Additionally, Dr. Smith states in his letter that his Nephrology practice (Duke University Medical Center Division of Nephrology), “*will refer, admit and round End Stage Renal in-center ... patients to the facility.*” In Exhibit I-3, the applicant provides letters signed by other doctors from Duke University Medical Center Division of Nephrology, also dated August 9, 2016, stating that their Nephrology practice, will “*secure admission privileges and make referrals to the facility.*”

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I, pages 40-41, the applicant discusses the provision of necessary ancillary and support services to be provided for the proposed facility and provides a list of service providers on page 40. The applicant provides documentation regarding coordination with the existing health care system in Exhibits I-1, I-2 and I-3 including letters from several providers such as Durham West Dialysis agreeing to provide home training in home hemodialysis and peritoneal dialysis, DaVita Laboratory Services, Inc., Duke Vascular Surgery, the NC Division of Vocational Rehabilitation Services, transportation services, and Duke University Hospital. The information in Section I and Exhibits I-1, I-2 and I-3 is reasonable and adequately supports a finding of conformity with this criterion.

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

NA

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

NA

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

C

In Section K.2, page 45, the applicant states there will be 3,252 square feet of treatment area, which will include space for an isolation room. The applicant provides line drawings of the proposed facility in Exhibit K-1(a). The drawing depicts a 9,695 square foot facility, including office space, nine dialysis stations located in open space and one isolation dialysis station in an enclosed room, for a total of 10 stations. In Section F.1, page 29, the applicant lists its project costs, including \$58,000 for site work and \$1,461,600 for construction and \$687,344 for miscellaneous costs including dialysis machines, water treatment equipment, furniture, and architect/engineering fees for a total project cost of \$2,206,944. In Section B.5, pages 11-13, the applicant describes its plans to assure improved energy-efficiency and water conservation, including the following:

- The use of full LED lighting packages with occupancy and vacancy sensors, dimmers, and a full lighting control system that will provide 28% energy reduction.

- Adopt water optimization protocols to reduce the volume of water required to provide patient care, including adjusting the recovery rate for reverse osmosis devices and utilizing water-conserving plumbing fixtures.
- Interior finishes and materials will be used based on sustainable design and *“Indoor Environmental Quality criteria...defined in the US Green Building Council’s LEED Rating system.”*
- The HVAC system will be selected for its high performance and energy efficiency.
- All appliances, when possible, and most information technology equipment will be Energy Star rated.

Costs and charges are described by the applicant in Section F, pages 29-33, and in Section R pro forma financial statements. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

Durham Regional Dialysis would be a new facility, thus, it has no historical payor mix. In Section L.7, page 54, the applicant provides the payor mix for both Durham Dialysis and Durham West Dialysis for CY2015. These are the facilities that will be contributing three dialysis stations (Durham Dialysis) and seven dialysis stations (Durham West Dialysis) to develop the proposed facility and from which at least some patients will transfer (See Exhibit C-1 for patients’ letters of support). The historical payer mix is illustrated as follows:

**Durham Dialysis  
 Payor Mix CY2015**

Payor Type	Percent of Total Patients
Medicare	41.0%
Medicaid	15.2%
Commercial Insurance	6.7%
Medicare/Commercial	16.1%
Medicare/Medicaid	21.0%
<b>Total</b>	<b>100.0%</b>

**Durham West Dialysis  
 Payor Mix CY2015**

Payor Type	Percent of Total Patients	Percent of In-Center Patients	Percent of HH Patients	Percent of PD Patients
Medicare	22.8%	25.3%	17.6%	15.8%
Medicaid	4.1%	5.7%	0.0%	0.0%
Commercial Insurance	23.6%	14.9%	47.1%	42.1%
Medicare/Commercial	39.8%	40.2%	35.3%	42.1%
Medicare/Medicaid	8.1%	11.5%	0.0%	0.0%
VA	1.6%	2.3%	0.0%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

As the tables above indicate, 93.3% of Durham Dialysis' patients and 74.8% of Durham West Dialysis' patients are covered by Medicare or Medicaid. The applicant provides a copy of DVA's policy on acceptance of patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability in Exhibit L-3.

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

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
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.

\*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:

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

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

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

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

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

C

In Section L.3(e) page 53, the applicant states:

*“Durham Regional Dialysis has no obligation under any applicable federal regulation to provide uncompensated care, community service or*

*access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993. The facility has no obligation under the Hill Burton Act.”*

In Section L.6, page 53, the applicant states, in reference to any facilities owned by DVA in the state, that there have been no civil rights equal access complaints filed within the last five years.

The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L.1, page 51, the applicant states that the projected payor mix for Durham Regional Dialysis is based on sources of payment for its DVA facilities in Durham County for the last full operating year, and the projected payor mix is illustrated as follows:

**Durham Regional Dialysis  
Projected Payor Mix OY2**

<b>Payor Source</b>	<b>Percent of Total Patients</b>
Medicare	33.9%
Medicaid	10.9%
Commercial Insurance	10.4%
Medicare/Commercial	27.1%
Medicare/Medicaid	16.7%
VA	1.0%
<b>Total</b>	<b>100.0%</b>

The applicant projects that 88.6% of Durham Regional Dialysis' patients will be covered by Medicare or Medicaid.

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, page 53, the applicant states that patients will have access to the facility for dialysis services upon referral from a Nephrologist with admitting privileges at the facility. Patients, family, and friends who contact the facility seeking access to services will be referred to “*a qualified nephrologist for evaluation and subsequent admission...*”

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M.1, page 55, the applicant states that it has offered Durham Regional Dialysis as a clinical training site for nursing students from Durham Technical Community College. A copy of a letter sent by the applicant to the college, dated August 15, 2016, is included in Exhibit M-2.

The information provided in Section M.1 and Exhibit M-2 is reasonable and adequately supports a finding of conformity with this criterion.

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

C

DVA proposes to develop a new 10-station dialysis facility in Durham by relocating three dialysis stations from Durham Dialysis and seven dialysis stations from Durham West Dialysis. The two existing facilities and the proposed facility 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 Regional

Dialysis will be certified for 10 dialysis stations, Durham Dialysis will be certified for 22 dialysis stations following completion of Project I.D. # J-11084-15 (add three stations) and Project I.D. # J-10319) (relocate seven stations) (29-3+3-7= 22) and Durham West Dialysis will be certified for 23 dialysis stations following completion of Project I.D. # J-10350-14 (add four stations) and Project I.D. # J-10319-14 (relocate three stations) (29-7+ 4-3= 23).

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Durham County. Facilities may also serve residents of counties not included in their service area.

The July 2016 SDR indicates there are nine dialysis facilities in Durham County, as follows:

**Durham County Dialysis Facilities  
 December 31, 2015**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Duke Hospital Dialysis	Duke	52	Durham	16	0	81.25%
Durham Dialysis	DVA	103	Durham	29	-4	88.79%
Durham West	DVA	90	Durham	29	1	77.59%
Est Durham Dialysis	DVA	Under development – New 10 stations facility				
FMC Briggs Avenue	Fresenius	82	Durham	29	0	70.69%
FMC West Pettigrew	Fresenius	63	Durham	24	0	65.63%
FMC South Durham	Fresenius	49	Durham	18	0	68.06%
Freedom Lake Dialysis	Fresenius	84	Durham	26	0	80.77%
Southpoint Dialysis	Fresenius	65	Durham	16	0	101.56%

As illustrated above, there are eight existing dialysis facilities located in Durham and one facility under development. Of those nine facilities, three facilities are operated by DVA, one by Duke University Hospital and the remaining five facilities are owned Fresenius. The proposed site for Durham Regional Dialysis is in the southern part of Durham. Three of the facilities operate with a utilization rate over 80.0%, two with a utilization over 70.0%, two with a utilization of over 65.0% and one of the Fresenius facilities operates with a utilization of over 100.0%. Thus, all of the operational dialysis facilities in the county are reasonably well utilized.

In Section N.1, page 56, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states:



*“The development of Durham Regional Dialysis will have no effect on any dialysis facilities located in Durham County or in counties contiguous to it. DaVita operates three other facilities in the county. Fresenius Medical Care operates four dialysis facilities in Durham County. Duke University operates one facility in the county.*

*The proposed facility will not have an adverse effect on competition since the patients already being served by DaVita will be transferring their care from one DaVita facility to another DaVita facility, which will be more convenient for the patients who have indicated this in the letters they signed.*

*... Durham Regional Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and other [sic] involved in the dialysis process to receive services.”*

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

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

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that DVA will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that DVA will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3), (3a) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

In Section B, pages 8-9, the applicant discusses the methods it uses to insure and maintain quality. In Exhibit O-3, the applicant provides a listing of four dialysis facilities that were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application. However, each facility is back in compliance as of the date of this decision.

Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

## C

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

### **10 NCAC 14C .2203 PERFORMANCE STANDARDS**

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

-C- In Section C.1, page 15, the applicant adequately demonstrates that Durham Regional Dialysis will serve at least 35 in-center patients on 10 stations at the end of the first operating year, which is 3.5 patients per station per week, or a utilization rate of 87.5% ( $35/10 = 3.5$ ;  $3.5/4 = 0.875$ ). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

*.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the*

*beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-NA- The applicant is seeking to develop a new 10-station dialysis facility.

*.2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section C.1, pages 14-16, 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.