

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 7, 2019

Findings Date: January 7, 2019

Project Analyst: Celia C. Inman

Assistant Chief: Lisa Pittman

Project ID #: O-11642-18

Facility: Wrightsville Beach Dialysis

FID #: 180569

County: New Hanover

Applicant: Total Renal Care of North Carolina, LLC

Project: Develop a new 10-station facility by relocating 8 stations from Cape Fear Dialysis and 2 stations from Southeastern Dialysis Center-Wilmington

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC (TRC) d/b/a Wrightsville Beach Dialysis (WBD), the applicant, proposes to develop a new 10-station dialysis facility in New Hanover County by relocating eight existing dialysis stations from Cape Fear Dialysis (CFD) and two existing dialysis stations from Southeastern Dialysis Center-Wilmington (SEDC-W). Both existing facilities and the proposed facility are located in New Hanover County. Cape Fear Dialysis will be certified for 32 dialysis stations, upon completion of the project under review and Project ID #O-11260-16 (add eight stations for a total of 40). SEDC-Wilmington will be certified for 30 dialysis stations, upon completion of the project under review, Project ID #O-11257-16 (add four stations for a total of 38), and Project ID #O-11548-18 (relocate six stations).

Need Determination

Neither the county nor the facility need methodologies in the July 2018 SDR and the 2018 SMFP are applicable to this review.

Policies

There is one policy in the 2018 SMFP which is applicable to this review: Policy ESRD-2: Relocation of Dialysis Stations, on page 27.

Policy ESRD-2

Policy ESRD-2 states:

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

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to develop a new 10-station dialysis facility in New Hanover County by relocating eight existing dialysis stations from CFD and two existing dialysis stations from SEDC-Wilmington. The existing and proposed facilities are all located in New Hanover County.

According to Table D of the July 2018 SDR, New Hanover County has a projected surplus of 19 dialysis stations. However, this project proposes a relocation of existing dialysis stations within New Hanover County; thus, the surplus will not be affected. Therefore, the application is conforming to Policy ESRD-2.

Conclusion

The Agency reviewed the:

- application,

- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- (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 New Hanover County by relocating eight existing dialysis stations from CFD and two existing dialysis stations from SEDC-W. The existing and proposed facilities are all located in New Hanover County. CFD will be certified for 32 dialysis stations, upon completion of the project under review and Project ID #O-11260-16 (add eight stations for a total of 40). SEDC-W will be certified for 30 dialysis stations, upon completion of the project under review, Project ID #O-11257-16 (add four stations for a total of 38), and Project ID #O-11548-18 (relocate six stations).

The following tables, summarized from Section A.9, pages 4-5 of the application, and information from the July 2018 SDR, show the total number of stations at the proposed WBD facility, and the existing CFD and SEDC-W facilities from which the applicant plans to relocate 10 stations to develop the proposed new facility, upon project completion.

Wrightsville Beach Dialysis

| # STATIONS | DESCRIPTION | PROJECT ID # |
|------------|--|--------------|
| 0 | Total # existing stations per most recent SDR | |
| 10 | # stations to be added as part of this project | O-11642-18 |
| 10 | Total # stations upon completion of all projects | |

Cape Fear Dialysis

| # STATIONS | DESCRIPTION | PROJECT ID # |
|------------|---|--------------|
| 32 | Total # existing stations per most recent SDR | |
| 8 | # stations previously approved to be added; not certified | O-11260-16 |
| 8 | # stations to be deleted as part of this project | O-11642-18 |
| 32 | Total # stations upon completion of all projects | |

SEDC-Wilmington

| # STATIONS | DESCRIPTION | PROJECT ID # |
|------------|---|--------------|
| 34 | Total # existing stations per most recent SDR | |
| 4 | # stations previously approved to be added; not certified | O-11257-16 |
| 6 | # of stations proposed to be deleted in an application still under review | O-11548-18 |
| 2 | # stations to be deleted as part of this project | O-11642-18 |
| 30 | Total # stations upon completion of all projects | |

As shown in the tables above, upon project completion, WBD will be certified for 10 dialysis stations, CFD will be certified for 32 dialysis stations, assuming completion of this project and Project ID #O-11260-16 (add eight stations at CFD) and SEDC-W will be certified for 30 dialysis stations, assuming completion of this project, Project ID #O-11257-16 (add four stations), and Project ID #O-11548-18 (relocate six stations to New Hanover Dialysis).

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Wrightsville Beach Dialysis is located in New Hanover County; thus, the service area for this facility consists of New Hanover County. Facilities may also serve residents of counties not included in their service area.

The applicant does not propose to serve home hemodialysis (HH) or peritoneal dialysis (PD) patients at the proposed facility. The applicant shows in Section I.1 that it has made arrangements for home training, hemodialysis, peritoneal dialysis and follow-up to be provided by SEDC-Wilmington (Exhibit I) in New Hanover County.

The following table illustrates the projected in-center (IC) patient origin for WBD for the first two years of operation following project completion, as shown in the following table:

**Wrightsville Beach Dialysis
 Projected In-Center Patient Origin**

| COUNTY | OY 1 CY2021 | OY 2 CY2022 | PERCENT OF TOTAL | |
|--------------|----------------|----------------|------------------|---------------|
| | | | OY 1 | OY 2 |
| New Hanover | 32 | 33 | 100.0% | 100.0% |
| Total | 32 | 33 | 100.0% | 100.0% |

Source: Section C.1, page 13

In Section C, pages 13-15, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.2, page 15, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“In doing an analysis of the patients served by Total Renal Care of North Carolina, LLC in New Hanover County, it was determined that DaVita is serving a total of 39 in-center patients who live in or near the eastern part of New Hanover County.

In order to make the travel to dialysis – three times a week for in- patients and monthly for PD patients – more convenient, it was determined that Total Renal Care of North Carolina, LLC needs to provide a dialysis center nearer to their homes for better access to their dialysis services and support.”

The applicant thus proposes to develop a new dialysis facility in Wilmington, which is in eastern New Hanover County, by relocating existing New Hanover County DaVita dialysis stations, to better serve existing patients being served at other DaVita facilities in New Hanover County who live closer to the proposed facility. The applicant states that the relocation of these stations to develop a new facility would better serve DaVita’s existing patient population (39) who indicated, in letters provided in Exhibit C-1, that the proposed location would be more convenient to them.

The information is reasonable and adequately supported for the following reasons:

- The applicant demonstrates the need to develop a new dialysis facility by relocating existing dialysis stations consistent with Policy ESRD-2. The discussion regarding Policy ESRD-2 found in Criterion (1) is incorporated herein by reference.
- The applicant demonstrates, through signed patient letters, that existing DaVita dialysis patients would be better served by a new facility located in Wilmington, in eastern New Hanover County.

Projected Utilization

In Section C.1, pages 13 – 15, the applicant describes its need methodology and assumptions for projecting utilization of the proposed facility as follows:

- 39 in-center patients who currently live in New Hanover County and receive dialysis care in New Hanover County have signed letters indicating they would consider transferring their care to WBD.
- It is assumed that at least 32 of the patients who signed letters will transfer their care to the new facility.
- It is anticipated that there will be additional ESRD patients who live in the service area who may want to receive their dialysis treatments at WBD.
- Operating Year (OY) 1 is projected to be calendar year (CY) 2021; and OY2 is projected to be CY2022.

- Growth is calculated using the New Hanover County 1.9% average annual change rate (AACR) for the past five years, per Table D of the July 2018 North Carolina Semiannual Dialysis Report (SDR).

The tables below summarize the beginning patient census on January 1, 2021 and its growth through the ending patient census on December 31, 2022.

| | |
|--|---------------------------------|
| Begin January 1, 2021 with 32 New Hanover County patients | 32 |
| Project New Hanover County in-center patient growth forward at 1.9% for one year to December 31, 2021 – Census OY1 | $32 \times 1.019 = 32.6080$ |
| Project New Hanover County in-center patient growth forward at 1.9% for one year to December 31, 2022 – Census OY2 | $32.608 \times 1.019 = 33.2275$ |

WBD Projected Utilization

| Beginning Period | Start Date* | # Patients at Beginning of Year | # Patients at End of Year | Average # Patients In Year | Patients per Station | Utilization Rate |
|------------------|-------------|---------------------------------|---------------------------|----------------------------|----------------------|------------------|
| OY 1 (CY2021) | 1/1/2021 | 32.0 | 32.0 | 32.0 | 3.2 | 80.0% |
| OY 2 (CY2022) | 1/1/2022 | 32.0 | 33.0 | 32.5 | 3.3 | 82.5% |

* The applicant's table on page 15 incorrectly lists the start dates as 1/1/2020 and 1/1/2021 for OY1 and OY2, respectively

The applicant states that projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1, the facility is projected to serve 32 in-center patients and at the end of OY2, the facility is projected to serve 33 in-center patients.

- OY1: 32 in-center patients = 3.2 patients per station per week, a utilization rate of 80.0% ($32 \text{ patients} / 10 \text{ stations} = 3.20 / 4 = 0.800$ or 80.0%).
- OY2: 33 in-center patients = 3.3 patients per station per week, a utilization rate of 82.5% ($33 \text{ patients} / 10 \text{ stations} = 3.30 / 4 = 0.825$ or 82.5%).

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

Projected utilization for in-center dialysis patients at WBD is reasonable and adequately supported for the following reasons:

- The applicant projects the starting patient census for the proposed facility based on existing New Hanover County patients who currently dialyze at a DaVita facility in New Hanover County, each of whom has signed a letter expressing an intent to consider transferring dialysis care to the proposed facility.

- The applicant’s growth projections are based on an assumption that the dialysis patient census will increase annually by 1.9%, which is consistent with the five-year AACR for New Hanover County, reported in the July 2018 SDR, Table D.

Access

In Section C.3, page 15, 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.”

The applicant projects payor mix for the second operating year following completion of the project in Section L.1(b), page 50, by percent, as summarized below:

**Projected Payor Mix
OY2**

| Payor Source | Total Patients | In-center Patients | HH Patients | PD Patients |
|-----------------------|-----------------------|---------------------------|--------------------|--------------------|
| Private Pay | 0.0% | 0.0% | 0.0% | 0.0% |
| Medicare | 19.8% | 19.8% | 0.0% | 0.0% |
| Medicaid | 7.3% | 7.3% | 0.0% | 0.0% |
| Commercial Insurance | 9.5% | 9.5% | 0.0% | 0.0% |
| Medicare / Commercial | 29.3% | 29.3% | 0.0% | 0.0% |
| Medicare / Medicaid | 30.8% | 30.8% | 0.0% | 0.0% |
| VA | 3.3% | 3.3% | 0.0% | 0.0% |
| Other | 0.0% | 0.0% | 0.0% | 0.0% |
| Total | 100.0% | 100.0% | 0.0% | 0.0% |

Totals may not sum due to rounding

In Section L.1(b), page 50, the applicant states that the projected payor mix is based upon sources of patient payments received by CFD and SEDC-W during the last full operating year. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- The applicant adequately identifies the population to be served.

- The applicant adequately explains why the population to be served needs the services proposed in this application.
 - Projected utilization is reasonable and adequately supported.
 - The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to develop a new 10-station dialysis facility in New Hanover County by relocating eight existing dialysis stations from CFD and two existing dialysis stations from SEDC-W. The existing and proposed facilities are all located in New Hanover County. CFD will be certified for 32 dialysis stations, upon completion of the project under review and Project ID #O-11260-16 (add eight stations for a total of 40). SEDC-W will be certified for 30 dialysis stations, upon completion of the project under review, Project ID #O-11257-16 (add four stations for a total of 38), and Project ID #O-11548-18 (relocate six stations).

In Section D.1, pages 22-25, the applicant explains why it believes the needs of the population presently utilizing the dialysis services to be relocated will be adequately met following completion of the project.

Cape Fear Dialysis

According to the July 2018 SDR, there were 113 in-center patients dialyzing at CFD on 32 certified dialysis stations for a utilization rate of 88.28%, or 3.5 patients per station per week ($113 / 32 = 3.53$) as of December 31, 2017. The proposed relocation of stations will leave CFD with 32 certified stations, upon completion of this project and Project ID #O-11260-16 (add eight stations). The applicant states that of the 113 patients, 99 live in New Hanover County. The applicant assumes the New Hanover County patients will grow at the 1.9% New Hanover County five-year AACR in the July 2018 SDR. The applicant projects that a total of 29 in-center patients will transfer their care from CFD to the new facility with the results summarized in the table below.

CFD Projected Utilization

| Beginning Period | Start Date | # New Hanover County Patients | Five-Year New Hanover AACR | # County Patients End of Year | # Out of County Patients | Ending Patient Census 12/31 |
|-------------------------|-------------------|--------------------------------------|-----------------------------------|--------------------------------------|---------------------------------|------------------------------------|
| Current | 1/1/2018 | 99.000 | 1.019 | 100.881 | 14 | 114.881 |
| Interim Period | 1/1/2019 | 100.881 | 1.019 | 102.798 | 14 | 116.798 |
| Interim Period | 1/2/2020 | 102.798 | 1.019 | 104.751 | 14 | 118.751 |
| OY 1 (CY2021)* | 1/1/2021 | 104-29=75.000 | 1.019 | 76.425 | 14 | 90.425 |
| OY 2 (CY2022) | 1/1/2022 | 76.425 | 1.019 | 77.877 | 14 | 91.877 |

*Transfer of 10 patients to the proposed facility

The applicant rounds projected utilization down to the whole patient. CFD is projected to have 90 in-center patients at the end of operating year one for a utilization rate of 70.3% or 2.81 patients per station per week on its 32 certified stations ($90/32 = 2.81$). At the end of operating year two, CFD will have a utilization rate of 71.0% or 2.84 patients per station per week on its 32 certified stations ($91/32 = 2.84$). The applicant states that additional CON applications will be submitted based on facility need as the facility approaches full capacity to ensure that the needs of the facility's patients will continue to be met.

Southeastern Dialysis Center-Wilmington

According to the July 2018 SDR, there were 108 in-center patients dialyzing at SEDC-W on 34 certified dialysis stations for a utilization rate of 79.41%, or 3.17 patients per station per week ($108 / 34 = 3.17$) as of December 31, 2017. The proposed addition of four stations (Project ID #O-11257-16) and the relocation of six stations to New Hanover Dialysis (Project ID #O-11548-18) will leave SEDC-W with 32 certified stations, prior to the completion of the proposed project. The applicant states that of the 108 patients listed in the July 2018 SDR, 88 live in New Hanover County. The applicant assumes the New Hanover County patients will grow at the 1.9% New Hanover County AACR in the July 2018 SDR. The applicant projects that a total of 10 in-center patients will transfer their care from SEDC-W to the new facility with the proposed relocation of two stations, as summarized in the table below.

SEDC-Wilmington Projected Utilization

| Beginning Period | Start Date | # New Hanover County Patients | Five-Year New Hanover AACR | # County Patients End of Year | # Out of County Patients | Ending Patient Census 12/31 |
|-------------------------|-------------------|--------------------------------------|-----------------------------------|--------------------------------------|---------------------------------|------------------------------------|
| Current | 1/1/2018 | 88.000 | 1.019 | 89.672 | 20 | 109.672 |
| Interim Period* | 1/1/2019 | 89-10=79.000 | 1.019 | 80.501 | 20 | 100.501 |
| Interim Period | 1/2/2020 | 80.501 | 1.019 | 82.031 | 20 | 102.031 |
| OY 1 (CY2021)** | 1/1/2021 | 82-10=72.000 | 1.019 | 73.368 | 20 | 93.368 |
| OY 2 (CY2022) | 1/1/2022 | 73.368 | 1.019 | 74.762 | 20 | 94.762 |

*Transfer of 10 patients to New Hanover Dialysis (Project ID #O-11548-18)

** Transfer of 10 patients to the proposed facility

SEDC-W is projected to have 93 in-center patients at the end of the proposed facility's first operating year for a utilization rate of 77.5% or 3.1 patients per station per week on its 30 certified stations ($93/30 = 3.1$). The applicant states that additional CON applications will be submitted based on facility need as the facility approaches full capacity to ensure that the needs of the facility's patients will continue to be met.

Projected utilization for CFD and SEDC-W is reasonable and adequately supported for the following reasons:

- The applicant projects a reasonable patient census for CFD and SEDC-W based on existing patients who will remain at each facility, after the relocation of stations and transfer of the patients who have signed letters expressing their intention to transfer their care to the proposed facility.
- The applicant's growth projections are based on an assumption that New Hanover County patient census will increase at an annual rate of 1.9%, which is consistent with the five-year AACR for New Hanover County, as reported in Table D of the July 2018 SDR.

Further, in Section D.2, page 25, the applicant states that the proposed relocation of stations will not adversely affect the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- (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

The applicant proposes to develop a new 10-station dialysis facility in New Hanover County by relocating eight existing dialysis stations from CFD and two existing dialysis stations from SEDC-W. The existing and proposed facilities are all located in New Hanover County.

CFD will be certified for 32 dialysis stations upon completion of this project and previously approved Project ID #O-11260-16 (add eight stations for a total of 40 stations). SEDC-W

will be certified for 30 dialysis stations, upon completion of this project, and previously approved Project ID #O-11257-16 (add four stations), and Project ID #O-11548-18 (relocate six stations).

In Section E, page 26, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain status quo – the applicant states that this alternative is not effective because it does not address the needs of the growing patient population identified in New Hanover County.
- Locating a facility in another area of New Hanover County – the applicant states that based on the location of the in-center patients identified in the patient letters in Exhibit C-1, locating the facility in another area would not address the geographic needs of the identified patients.

On page 26, the applicant states that the project as proposed (relocating stations from CFD and SEDC-W to a new location that will better serve a large patient population that is currently receiving services at these two facilities) is the most effective alternative because it deals with the significant growth over the past several years of these two facilities in New Hanover County and offers better access to DaVita dialysis services in New Hanover County to the existing DaVita patients. The applicant states:

“This action will provide Cape Fear Dialysis, New Hanover Dialysis, and SEDC Wilmington space for future growth.”

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- 1. Total Renal Care of North Carolina, LLC d/b/a Wrightsville Beach Dialysis shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, Total Renal Care of North Carolina, LLC shall develop a new 10-station kidney disease treatment center to be known as Wrightsville Beach Dialysis by relocating eight dialysis stations from Cape Fear Dialysis and two dialysis stations from Southeastern Dialysis Center - Wilmington.**

3. **Upon completion of this project, Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify eight dialysis stations at Cape Fear Dialysis for a total of no more than 32 dialysis stations at Cape Fear Dialysis, following completion of this project and Project ID #O-11260-16 (add eight stations).**
 4. **Upon completion of this project, Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify two dialysis stations at Southeastern Dialysis Center-Wilmington for a total of no more than 30 dialysis stations at Southeastern Dialysis Center-Wilmington following completion of this project, Project ID #O-11257-16 (add four stations) and Project ID #O-11548-18 (relocate six stations).**
 5. **Total Renal Care of North Carolina, LLC d/b/a Wrightsville Beach Dialysis shall install plumbing and electrical wiring through the walls for no more than ten dialysis stations, which shall include any home training and isolation stations.**
 6. **Total Renal Care of North Carolina, LLC d/b/a Wrightsville Beach 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 New Hanover County by relocating eight existing dialysis stations from CFD and two existing dialysis stations from SEDC-Wilmington.

Capital and Working Capital Costs

In Section F.1, the applicant states that the capital costs for the project will total \$1,801,834 and provides a table with the estimated capital costs on page 28, as summarized below.

Projected Capital Costs

| | Total Costs |
|----------------------------|--------------------|
| Site Costs | \$26,920 |
| Construction Costs | \$1,088,936 |
| Miscellaneous Costs | \$685,978 |
| Total Capital Costs | \$1,801,834 |

Totals may not sum due to rounding

In Section F.10, pages 30-31, the applicant projects that start-up costs will be \$177,154 and initial operating expenses will be \$724,048 for a total working capital of \$901,203. On page 31, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F.2, page 29, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

| Type | Total |
|------------------------------|--------------------|
| Loans | |
| Accumulated reserves or OE * | \$1,801,834 |
| Other (Specify) | |
| Total Financing | \$1,801,834 |

* OE = Owner's Equity

In Section F.13, page 32, the applicant states that the working capital needs of the project will be funded as shown in the table below.

Sources of Working Capital Financing

| TYPE | TOTAL |
|------------------------------|------------------|
| Loans | 0\$ |
| Accumulated reserves or OE * | \$0 |
| Bonds | \$0 |
| Other (Cash Reserves) | \$901,203 |
| Total Financing | \$901,203 |

*OE = Owner's Equity

In Exhibit F-5, the applicant provides a letter dated November 15, 2018, from the DaVita Chief Accounting Officer, signed by Esther Fleming, through procurement, authorizing the project and committing \$2,703,036 (\$1,801,834 + \$177,154 + \$724,048) for the development of the project.

Exhibit F-7 contains the Form 10-K for Davita, Inc. for the fiscal year ended December 31, 2017, showing DaVita, Inc. consolidated figures of \$508,234,000 in cash and cash equivalents, \$18.9 billion in total assets and \$4.9 billion in total equity.

The applicant adequately demonstrates the availability of funds for the capital needs of the project.

Financial Feasibility

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

| Wrightsville Beach Dialysis Revenue and Expenses | | |
|---|---------------------|---------------------|
| | OY1 (CY2020) | OY2 (CY2021) |
| In-Center Patients* | 32 | 32.5 |
| In-Center Treatments | 4,742 | 4,817 |
| Gross Patient Revenue | \$1,529,313 | \$1,552,701 |
| Medicare Adjustment from Gross | \$43,267 | \$43,912 |
| Net Patient Revenue | 1,486,045 | 1,508,789 |
| Average Net Revenue per Patient | \$46,439 | \$46,424 |
| Total Operating Expenses | \$1,448,097 | \$1,475,692 |
| Average Operating Expense per Patient | \$45,253 | \$45,406 |
| Net Income | \$37,949 | \$33,097 |

Totals may not sum due to rounding

*In-Center patients is an average of the beginning and ending patient census for the year

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

C

The applicant proposes to develop a new 10-station dialysis facility in New Hanover County by relocating eight existing dialysis stations from CFD and two existing dialysis stations from SEDC-W.

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” WBD is proposed to be located in New Hanover County; thus, the service area for this facility consists of New Hanover County. Facilities may also serve residents of counties not included in their service area.

TRC (DaVita owned and operated) is the only provider of dialysis services in New Hanover County. According to the July 2018 SDR, New Hanover County has the following dialysis facilities.

New Hanover County Dialysis Facilities

| Dialysis Facility | Certified Stations | Percent Utilization | Patients Per Station |
|--|---------------------------|----------------------------|-----------------------------|
| Cape Fear Dialysis (DaVita) | 32 | 88.28% | 3.5313 |
| New Hanover Dialysis (DaVita) | 12 | 64.58% | 2.5833 |
| SEDC-Wilmington(DaVita) | 34 | 79.41% | 3.1765 |
| Total Dialysis Stations in New Hanover County | 78 | | |

Source: July 2018 SDR, Table B.

In Section G, page 34, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in New Hanover County. The applicant states:

“As of December 31, 2017 there were three dialysis facilities in New Hanover County with a total of 78 certified stations. This certificate of need application does not propose to increase the number of stations in New Hanover County. Transferring ten stations from SEDC Wilmington and Cape Fear Dialysis will create a new facility at a different location to better serve patients living in the area of the new facility, but it will not result in the duplication of existing services.”

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

- The applicant demonstrates the need for the stations based on the New Hanover County DaVita facilities’ patients’ needs.
- The applicant adequately demonstrates that the relocated stations are needed in a different location from its existing or approved stations in New Hanover County.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

C

The applicant proposes to develop a new 10-station dialysis facility in New Hanover County by relocating eight existing dialysis stations from CFD and two existing dialysis stations from SEDC-Wilmington.

In Section H.1, page 35, the applicant provides current and projected OY2 staffing for the proposed services as summarized in the following table.

| POSITION | Current FTE Positions (Proposed/Not Operational) | OY2 PROJECTED FTE POSITIONS |
|---------------------------|---|--------------------------------|
| RN | 0.0 | 2.0 |
| LPN | 0.0 | 0.0 |
| Technician (Patient Care) | 0.0 | 4.0 |
| Medical Records | 0.0 | 0.0 |
| Administrator | 0.0 | 1.0 |
| Dietician | 0.0 | 0.5 |
| Social Worker | 0.0 | 0.5 |
| Home Training RN | 0.0 | 0.0 |
| Administrative Assistant | 0.0 | 0.5 |
| Biomed Technician | 0.0 | 0.5 |
| Total | 0.0 | 9.0 |

Source: Sections H and R of the application.
 Totals may not sum due to rounding

The Medical Director is a contract service, not an FTE position. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the

pro forma financials found in Section R. The assumptions and methodology used to project staffing are provided in Sections H and R. In Section H, pages 36-37, the applicant describes the methods used to recruit or fill new positions and DaVita's existing training and continuing education programs. Exhibit H contains DaVita training documentation. In Section H.2, page 36, and Section I.3, page 40, the applicant identifies the Medical Director as Brian Donner, MD. In Exhibit I-3, the applicant provides a letter from Dr. Donner, indicating a commitment to serve as Medical Director for the facility.

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

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section I.1, pages 39-40, the applicant identifies the necessary ancillary and support services and explains how they will be made available. The applicant provides a table on page 39, as summarized below.

**Wrightsville Beach Dialysis
 Ancillary and Support Services**

| Services | Provider |
|---|---|
| (a) In-center dialysis/maintenance | To be available on Premises |
| (b) Self-care training (performed in-center) | To be available on Premises |
| (c) Home training | |
| (1) Hemodialysis | SEDC-Wilmington |
| (2) Peritoneal dialysis | SEDC-Wilmington |
| (3) Accessible follow-up program | SEDC-Wilmington |
| (d) Psychological counseling | To be available on Premises |
| (e) Isolation-hepatitis | To be available on Premises |
| (f) Nutritional counseling | To be available on Premises |
| (g) Social work services | To be available on Premises |
| (h) Acute dialysis in an acute care setting | New Hanover Regional Medical Center |
| (i) Emergency care | New Hanover Regional Medical Center |
| (j) Blood bank services | New Hanover Regional Medical Center |
| (k) Diagnostic and evaluation services | New Hanover Regional Medical Center |
| (l) X-ray services | New Hanover Regional Medical Center |
| (m) Laboratory services | DaVita Laboratory Services, Inc. |
| (n) Pediatric nephrology | New Hanover Regional Medical Center |
| (o) Vascular surgery | Wilmington Surgical Association |
| (p) Transplantation services | Vidant Medical Center |
| (q) Vocational rehabilitation counseling & services | NC Division of Vocational Rehabilitation Services |
| (r) Transportation | Wave Transit |

In Section I, pages 39-41, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation for services in Exhibit I.

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.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in

adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

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

NA

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

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

C

The applicant proposes to develop a new 10-station dialysis facility in New Hanover County by relocating eight existing dialysis stations from CFD and two existing dialysis stations from SEDC-W.

In Section K, pages 43-45, the applicant states that the project involves construction of 3,123 square feet of treatment space in leased building space to be constructed at 6930 Market Street in Wilmington. A line drawing of the proposed facility is provided in Exhibit K-1.

On pages 43-44, and Exhibit K, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On pages 44-47, and the applicant identifies the proposed primary and secondary sites and provides information about the availability of the sites and zoning and special use permits. Exhibit K-4 documents the location of the sites, the availability of the sites and the zoning for permitted uses.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

The applicant proposes to develop a new 10-station dialysis facility in New Hanover County by relocating eight existing dialysis stations from CFD and two existing dialysis stations from SEDC-W.

Wrightsville Beach Dialysis is not an existing facility. In Section L.7, page 53, the applicant provides the historical payor mix percentages for CFD and SEDC-W, the two facilities from which stations are to be relocated and patients are to be transferred, for the last full operating year, CY2017, as shown in the tables below.

**Cape Fear Dialysis
 Payor Mix CY2017**

| Payor Source | Total Patients | In-center Patients | HH Patients | PD Patients |
|-----------------------|-----------------------|---------------------------|--------------------|--------------------|
| Private Pay | 0.0% | 0.0% | 0.0% | 0.0% |
| Medicare | 15.8% | 15.8% | 0.0% | 0.0% |
| Medicaid | 8.9% | 8.9% | 0.0% | 0.0% |
| Commercial Insurance | 6.8% | 6.8% | 0.0% | 0.0% |
| Medicare / Commercial | 29.5% | 29.5% | 0.0% | 0.0% |
| Medicare / Medicaid | 36.3% | 36.3% | 0.0% | 0.0% |
| VA | 2.7% | 2.7% | 0.0% | 0.0% |
| Other | 0.0% | 0.0% | 0.0% | 0.0% |
| Total | 100.0% | 100.0% | 100.0% | 100.0% |

Totals may not sum due to rounding

**SEDC-Wilmington
 Payor Mix CY2017**

| Payor Source | Total Patients | In-center Patients | HH Patients | PD Patients |
|-----------------------|-----------------------|---------------------------|--------------------|--------------------|
| Private Pay | 0.0% | 0.0% | 0.0% | 0.0% |
| Medicare | 23.1% | 24.4% | 31.3% | 17.9% |
| Medicaid | 4.5% | 5.5% | 0.0% | 3.6% |
| Commercial Insurance | 11.1% | 12.6% | 12.5% | 7.1% |
| Medicare / Commercial | 35.7% | 29.1% | 31.3% | 51.8% |
| Medicare / Medicaid | 22.1% | 24.4% | 18.8% | 17.9% |
| VA | 3.5% | 3.9% | 6.3% | 1.8% |
| Other | 0.0% | 0.0% | 0.0% | 0.0% |
| Total | 100.0% | 100.0% | 100.0% | 100.0% |

Totals may not sum due to rounding

As shown in the tables above, the applicant reports that 91% and 85% of the total patients at CFD and SEDC-W, respectively, had some or all of their services paid for by Medicare or Medicaid in CY2017.

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

| Percent of Population | | | | | | |
|-----------------------|---------------|---------------|-------------------------------|------------------------|------------------------------|---------------------------------------|
| County | % 65+ | % Female | % Racial and Ethnic Minority* | % Persons in Poverty** | % < Age 65 with a Disability | % < Age 65 without Health Insurance** |
| 2017 Estimate | 2017 Estimate | 2017 Estimate | 2017 Estimate | 2017 Estimate | 2017 Estimate | 2017 Estimate |
| New Hanover | 17% | 52% | 23% | 17% | 9% | 11% |
| Statewide | 16% | 51% | 37% | 15% | 10% | 12% |

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

* Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

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

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (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

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

assistance, including the existence of any civil rights access complaints against the applicant;

C

The applicant proposes to develop a new 10-station dialysis facility in New Hanover County by relocating eight existing dialysis stations from CFD and two existing dialysis stations from SEDC-W.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3(d), page 52, the applicant states:

“Wrightsville Beach 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 52, the applicant states that there have been no civil rights access complaints filed against any similar facilities owned by the applicant or a related entity and located in North Carolina within the last five years.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

The applicant proposes to develop a new 10-station dialysis facility in New Hanover County by relocating eight existing dialysis stations from CFD and two existing dialysis stations from SEDC-W.

In Section L.1(b), page 50, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as summarized in the table below.

**Projected Payor Mix
 OY2 (CY2022)**

| Payor Source | Total Patients | In-center Patients | HH Patients | PD Patients |
|-----------------------|-----------------------|---------------------------|--------------------|--------------------|
| Private Pay | 0.0% | 0.0% | 0.0% | 0.0% |
| Medicare | 19.8% | 19.8% | 0.0% | 31.6% |
| Medicaid | 7.3% | 7.3% | 0.0% | 5.3% |
| Commercial Insurance | 9.5% | 9.5% | 0.0% | 31.6% |
| Medicare / Commercial | 29.3% | 29.3% | 0.0% | 10.5% |
| Medicare / Medicaid | 30.8% | 30.8% | 0.0% | 10.5% |
| VA | 3.3% | 3.3% | 0.0% | 10.5% |
| Other | 0.0% | 0.0% | 0.0% | 0.0% |
| Total | 100.0% | 100.0% | 0.0% | 100.0% |

Totals may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 87.2% of the total dialysis patients will have all or part of their services paid for by Medicare and/or Medicaid.

On page 50, the applicant states that the projected payor mix is based on the sources of patient payments that have been received by CFD and SEDC-W in the last full operating year. The projected payor mix is reasonable and adequately supported for the following reasons:

- the applicant bases the projected payor mix on DaVita’s historical payor mix for the facilities relocating stations and transferring patients, and
- the applicant’s proposed patient origin is comparable to DaVita’s historical patient origin in New Hanover County.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

The applicant proposes to develop a new 10-station dialysis facility in New Hanover County by relocating eight existing dialysis stations from CFD and two existing dialysis stations from SEDC-W.

In Section L.4, page 52, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

The applicant proposes to develop a new 10-station dialysis facility in New Hanover County by relocating eight existing dialysis stations from CFD and two existing dialysis stations from SEDC-W.

In Section M, page 54, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

The applicant proposes to develop a new 10-station dialysis facility in New Hanover County by relocating eight existing dialysis stations from CFD and two existing dialysis stations from SEDC-W. Both existing facilities and the proposed WBD facility are located in New Hanover County. CFD will be certified for 32 dialysis stations, upon completion of the project under review and Project ID #O-11260-16 (add eight stations for a total of 40). SEDC-W will be certified for 30 dialysis stations, upon completion of the project under review, Project ID #O-11257-16 (add four stations for a total of 38), and Project ID #O-11548-18 (relocate six stations).

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” WBD is proposed to be located in New Hanover County; thus, the service area for this facility consists of New Hanover County. Facilities may also serve residents of counties not included in their service area.

TRC (DaVita) is the only provider of dialysis services in New Hanover County. According to the July 2018 SDR, New Hanover County has the following dialysis facilities.

New Hanover County Dialysis Facilities

| Dialysis Facility | Certified Stations | Percent Utilization | Patients Per Station |
|---|--------------------|---------------------|----------------------|
| Cape Fear Dialysis (DaVita) | 32 | 88.28% | 3.5313 |
| New Hanover Dialysis (DaVita) | 12 | 64.58% | 2.5833 |
| SEDC-Wilmington(DaVita) | 34 | 79.41% | 3.1765 |
| Total Dialysis Stations in New Hanover County | 78 | | |

Source: July 2018 SDR, Table B.

In Section N, page 55, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. 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 Wrightsville Beach 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 others involved in the dialysis process to receive services.”

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

- the cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits),
- quality services will be provided (see Sections B and O of the application and any exhibits), and
- access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

C

In Section A.11, page 5, the applicant states that DaVita operates over 85 dialysis facilities located in North Carolina. Exhibit A-11 contains a list of the facilities.

In Section O.3, page 56, and Exhibit O-3, the applicant states that during the 18-months immediately preceding the submittal of the application, incidents related to quality of care occurred in two of the 85 facilities. The applicant states that all of the deficiencies have been corrected and provides documentation in Exhibit O. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 85 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an

academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-C- In Section C.1, page 13, the applicant projects to serve 32 in-center patients by the end of Operating Year 1, which is 3.2 patients per station per week ($32 / 10 = 3.2$). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(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 application is to develop a new facility.

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

-C- In Sections C.1, pages 13-15, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.