

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 25, 2019

Findings Date: July 25, 2019

Project Analyst: Gregory F. Yakaboski

Team Leader: Fatimah Wilson

Project ID #: P-11710-19

Facility: Richlands Dialysis

FID #: 190217

County: Onslow

Applicant(s): Total Renal Care of North Carolina, LLC

Project: Develop a new 10-station dialysis facility by relocating eight stations from New River Dialysis and two stations from Southeastern Dialysis Center-Jacksonville

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 Richlands Dialysis, the applicant, proposes to develop a new 10-station dialysis facility in Onslow County by relocating eight existing dialysis stations from New River Dialysis and two existing dialysis stations from Southeastern Dialysis Center-Jacksonville (SEDC-Jacksonville).

Upon completion of the proposed project, New River Dialysis will be certified for 17 dialysis stations and SEDC-Jacksonville will be certified for 36 dialysis stations upon completion of this project and Project ID #P-11681-19 (add 5 stations). TRC owns both the New River Dialysis and SEDC-Jacksonville facilities. The parent company of TRC is DaVita, Inc. (DaVita).

Need Determination

Neither the county nor the facility need methodologies in the January 2019 Semiannual Dialysis Report (SDR) and the 2019 State Medical Facilities Plan (SMFP) are applicable to this review.

Policies

There is one policy in the 2019 SMFP which is applicable to this review: Policy ESRD-2: Relocation of Dialysis Stations, on page 25.

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 Onslow County by relocating eight existing dialysis stations from New River Dialysis and two existing dialysis stations from SEDC-Jacksonville. Both the existing facilities and the proposed facility are located in Onslow County.

According to Table D of the July 2019 SDR, Onslow County has a projected deficit of 11 dialysis stations. However, this project proposes a relocation of existing dialysis stations within Onslow County; thus, the deficit will not be affected. Therefore, the application is consistent with 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 Onslow County by relocating eight existing dialysis stations from New River Dialysis and two existing dialysis stations from SEDC-Jacksonville. The applicant does not propose to serve home hemodialysis (HHD) or peritoneal dialysis (PD) patients at the proposed facility.

Patient Origin

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Onslow County. Facilities may also serve residents of counties not included in their service area.

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

| County | OY2 CY2022 | Percent of Total |
|---------------|-------------------|-------------------------|
| Onslow | 32 | 94.1% |
| Duplin | 2 | 5.9% |
| Total | 34 | 100.0% |

Source: Application page 18.

In Section C, pages 18-20, 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.4, page 20, 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 Onslow County, it was determined that DaVita is serving a total of 32 in-center patients who live in or near the northwestern part of Onslow County.

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

The applicant thus proposes to develop a new dialysis facility in Richlands, which is in northwestern Onslow County, by relocating existing dialysis stations from DaVita dialysis facilities in Onslow County to better serve existing patients being served at other DaVita facilities in Onslow 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 (32) who indicated in letters provided in Exhibit C-3, that the proposed location would be more convenient for 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 Richlands, in northwestern Onslow County.

Projected Utilization

In Section C, pages 18-20, the applicant describes its need methodology and assumptions for projected utilization for the proposed facility summarized as follows:

- Operating Year 1 (OY1) = Calendar Year (CY) 2021
- Operating Year 2 (OY2) = Calendar Year (CY) 2022
- A total of 32 patients, 30 Onslow County residents and 2 non-Onslow County residents, who currently receive their dialysis care at DaVita facilities in Onslow County (14 Onslow County patients and 2 non-Onslow County patients from New River Dialysis and 16 Onslow County patients from SEDC-Jacksonville) have signed letters indicating that the proposed Richlands Dialysis facility would be more convenient for them and that they would consider transferring their dialysis care to Richlands Dialysis.

- The applicant assumes at least 32 patients will transfer their dialysis care to the proposed Richlands Dialysis facility upon certification of that facility which is documented by the signed patient letters of support provided in Exhibit C which state that, *“Since Richlands Dialysis would be more convenient for me and I will have access to the same services that have become so important to me at my current facility, I would be willing to transfer my care to Richlands Dialysis.”*
- The applicant uses the Five-Year AACR for Onslow County which is 3.9%, as published in the January 2019 SDR, to project the Onslow County patient population forward.
- The applicant does not project an increase in the non-Onslow county patients who utilize the facility and live in other counties.

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

| Richlands Dialysis | In-Center Patients |
|---|------------------------------|
| Begin January 1, 2021 with 30 Onslow County IC patients | 30 |
| Project the Onslow County IC patients forward one year to December 31, 2021, using the Five-Year Average Annual Change Rate (AACR) for Onslow County. | $30 \times 1.039 = 31.17$ |
| Add the 2 patients from other counties projected to dialyze at Richlands Dialysis. This is the IC patient census at the end of OY1 | $31.17 + 2 = \mathbf{33.17}$ |
| Project the Onslow County IC patients forward one year to December 31, 2022, using the Five-Year AACR for Onslow County. | $31.17 \times 1.039 = 32.39$ |
| Add the 2 patients from other counties projected to dialyze at Onslow Dialysis. This is the IC patient census at the end of OY2. | $32.39 + 2 = \mathbf{34.39}$ |

The applicant states on page 19 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2021) and OY2 (CY2022) the facility is projected to serve 33 and 34 in-center patients, respectively.

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

- OY1: 3.3 patients per station per week, or 82.5% ($33 \text{ patients} / 10 \text{ stations} = 3.3 / 4 = 0.825$ or 82.5%).
- OY2: 3.4 patients per station per week, or 85.0% ($34 \text{ patients} / 10 \text{ stations} = 3.4 / 4 = 0.85$ or 85.00%).

The projected utilization of 3.3 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 reasonable and adequately supported for the following reasons:

- The applicant projects the starting patient census for the proposed facility based on existing Onslow County patients who currently dialyze at a DaVita facility in Onslow County, each of whom has signed a letter expressing an intent to consider transferring dialysis care to the proposed facility because it would be more convenient for them.
- The applicant's growth projections assume that the dialysis patient census will increase annually by 3.9%, which is consistent with the five-year AACR for Onslow County, as reported in the January 2019 SDR, Table D.
- The applicant projects no growth for patients who are projected to transfer their care to Richlands Dialysis and live in other counties.

Access

In Section C, page 21, the applicant states:

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

We will make every reasonable effort to accommodate all patients, especially those with special needs such as handicapped, patients attending school or patients who work. Dialysis services will be provided six days per week with two patient shifts per day to accommodate patient need.

Payment will not be required upon admission. Therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped, elderly, and other under-served persons”

In Section L, page 48, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

**Richlands Dialysis Payor Mix
FY2**

| Payor Category | Percent of Total Patients |
|-----------------------|----------------------------------|
| Medicaid | 6.4% |
| Medicare | 79.8% |
| Insurance | 6.9% |
| Other | 7.9% |
| Total | 100.0% |

Source: Table on page 48 of the application.

Note: Totals might foot due to rounding.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for the 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 Onslow County by relocating eight existing dialysis stations from New River Dialysis and two existing dialysis stations from SEDC-Jacksonville.

The following tables show the total number of stations upon project completion at the proposed Richlands Dialysis facility and the existing New River Dialysis and SEDC-Jacksonville facilities, from which the applicant plans to relocate 10 stations to develop the facility.

Richlands Dialysis

| # STATIONS | DESCRIPTION | PROJECT ID # |
|------------|--|--------------|
| 0 | Total # existing stations per most recent SDR | |
| 10 | # stations to be added as part of this project | P-11710-19 |
| 10 | Total # stations upon completion of all projects | |

New River Dialysis

| # STATIONS | DESCRIPTION | PROJECT ID # |
|------------|--|--------------|
| 25 | Total # existing stations per most recent SDR | |
| 8 | # stations to be deleted as part of this project | P-11710-19 |
| 17 | Total # stations upon completion of all projects | |

SEDC-Jacksonville

| # STATIONS | DESCRIPTION | PROJECT ID # |
|------------|---|--------------|
| 33 | Total # existing stations per most recent SDR | |
| 5 | # stations previously approved to be added; not certified | P-11681-19 |
| 2 | # stations to be deleted as part of this project | P-11710-19 |
| 36 | Total # stations upon completion of all projects | |

As shown in the tables above, upon project completion, Richlands Dialysis will be certified for 10 dialysis stations, New River Dialysis will be certified for 17 dialysis stations and SEDC-Jacksonville will be certified for 36 dialysis stations upon completion of this project and Project ID #P-11681-19 (add five stations).

In Section D, page 25-27, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated or relocated will be adequately met following completion of the project.

New River Dialysis: Projected Utilization

In Section D, page 25, the applicant describes its need methodology and assumptions for projected utilization for IC patients for New River Dialysis summarized as follows:

- The ESRD Data Collection Form show that New River Dialysis operated at a utilization rate of 96.0 percent (3.84 patients per station per week) as of December 31, 2018 and had 96 in-center patients. The applicant states, based on the ESRD Data Collection form, that 89 of the 96 patients were residents of Onslow County with 7 patients residing in other counties.
- The applicant accounts for the 8 dialysis stations and 16 IC patients (14 Onslow County patients and 2 non-Onslow County patients) that are projected to transfer to Richlands

Dialysis as of January 1, 2021, the projected date of certification for the Richlands Dialysis facility.

- The applicant begins the projections for the future patient population of New River Dialysis by using the ending in-center patient census of 89 patients from Onslow County, as of December 31, 2019.
- The applicant uses the Five-Year AACR for Onslow County which is 3.9%, as published in the January 2019 SDR, to project the Onslow County patient population forward.
- The applicant does not project an increase in the non-Onslow county patients who utilize the facility and live in other counties.

The table below summarizes the beginning patient census on January 1, 2019 and its growth through the ending patient census on December 31, 2022.

| New River Dialysis | In-Center Patients |
|--|------------------------------|
| Begin January 1, 2019 with 89 Onslow County IC patients | 89 |
| Project the Onslow County IC patients forward one year to December 31, 2019, using the Five-Year AACR for Onslow County. | $89 \times 1.039 = 92.47$ |
| Project the Onslow County IC patients forward one year to December 31, 2020, using the Five-Year AACR for Onslow County. | $92.47 \times 1.039 = 96.08$ |
| Add the 7 non-Onslow County patients. This is the projected patient census at New River Dialysis as of December 31, 2020. | $96 + 7 = 103$ |
| Richlands Dialysis is projected to be certified as of January 1, 2021. *14 Onslow County patients are projected to transfer their care from New River Dialysis to Richlands Dialysis. $96 - 14 = 82$. *2 non-Onslow County patients are projected to transfer their care from New River Dialysis to Richlands Dialysis. $7 - 2 = 5$ Total patients projecting to transfer from New River Dialysis is 16. | |
| This is the patient census at New River Dialysis as of January 1, 2021. | $103 - 16 = 87$ |
| Project the Onslow County IC patients forward one year to December 31, 2021, using the Five-Year AACR for Onslow County. | $82 \times 1.039 = 85.20$ |
| Add the 5 non-Onslow county patients projected to dialyze at Richlands Dialysis. This is the IC patient census at the end of OY1. | $85.20 + 5 = \mathbf{90.20}$ |
| Project the Onslow County IC patients forward one year to December 31, 2022, using the Five-Year AACR for Onslow County. | $85.20 \times 1.039 = 88.52$ |
| Add the 5 non-Onslow county patients projected to dialyze at Richlands Dialysis. This is the IC patient census at the end of OY2. | $88.52 + 5 = \mathbf{93.52}$ |

The applicant states on page 19 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2021) and OY2 (CY2022) the facility is projected to serve 90 and 93 in-center patients, respectively.

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

- OY1: 5.29 patients per station per week, or 132.3% ($90 \text{ patients} / 17 \text{ stations} = 5.29 / 4 = 1.323$ or 132.3%).
- OY2: 5.47 patients per station per week, or 136.8% ($93 \text{ patients} / 17 \text{ stations} = 5.47 / 4 = 1.3675$ or 136.8%).

The projected utilization of 5.29 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).

On page 26, the applicant states *“Given this projected growth of the in-center patient population, additional Certificate of Need application(s) will be submitted based on facility need as the facility approaches full capacity of stations to ensure that the needs of the facility’s patients will continue to be met. The first opportunity will be in the October 1, 2019 review period.”*

SEDC-Jacksonville: Projected Utilization

In Section D, page 25, the applicant describes its need methodology and assumptions for projected utilization for IC patients for SEDC-Jacksonville summarized as follows:

In Section D, pages 26-27, the applicant provides the assumptions and methodology used to project IC patient utilization at SEDC-Jacksonville, which is summarized below.

- The ESRD Data Collection Forms shows that SEDC-Jacksonville operated at a utilization rate of 81.06 percent (3.24 patients per station per week) as of December 31, 2018 and had 107 in-center patients. The applicant states, based on the ESRD Data Collection form, 101 of the 107 patients were residents of Onslow County with 6 patients residing in other counties.
- The applicant accounts for the 2 dialysis stations and 16 Onslow County IC patients that are projected to transfer to Richlands Dialysis as of January 1, 2021, the projected date of certification for the Richlands Dialysis facility.
- The applicant accounts for the 5 stations to be added to SEDC-Jacksonville pursuant to Project ID #P-11681-19 and the 2 stations to be transferred to Richlands Dialysis pursuant to this application.
- The applicant begins the projections for the future patient population of SEDC-Jacksonville by using the ending in-center patient census of 101 patients from Onslow County, as of December 31, 2019.
- The applicant uses the Five-Year AACR for Onslow County which is 3.9%, as published in the January 2019 SDR, to project the Onslow County patient population forward.
- The applicant does not project an increase in the non-Onslow county patients who utilize the facility and live in other counties.

The table below summarizes the beginning patient census on January 1, 2019 and its growth through the ending patient census on December 31, 2022.

| SEDC-Jacksonville | In-Center Patients |
|--|--------------------------------|
| Begin January 1, 2019 with 101 Onslow County IC patients | 101 |
| Project the Onslow County IC patients forward one year to December 31, 2019, using the Five-Year AACR for Onslow County. | $101 \times 1.039 = 104.94$ |
| Project the Onslow County IC patients forward one year to December 31, 2020, using the Five-Year AACR for Onslow County. | $104.94 \times 1.039 = 109.03$ |
| Add the 6 non-Onslow County patients. This is the projected patient census at SEDC-Jacksonville as of December 31, 2020. | $109.03 + 6 = 115.03$ |
| Richland Dialysis is projected to be certified as of January 1, 2021. *16 Onslow County patients are projected to transfer their care from SEDC-Jacksonville to Richlands Dialysis. $109 - 16 = 93$. | |
| This is the patient census at SEDC-Jacksonville as of January 1, 2021. | $93 + 6 = 99$ |
| Project the Onslow County IC patients forward one year to December 31, 2021, using the Five-Year AACR for Onslow County. | $93 \times 1.039 = 96.63$ |
| Add the 6 non-Onslow county patients projected to dialyze at Richlands Dialysis. This is the IC patient census at the end of OY1. | $96.63 + 6 = \mathbf{102.63}$ |
| Project the Onslow County IC patients forward one year to December 31, 2022, using the Five-Year AACR for Onslow County. | $96.63 \times 1.039 = 100.40$ |
| Add the 5 non-Onslow county patients projected to dialyze at Richlands Dialysis. This is the IC patient census at the end of OY2. | $100.40 + 6 = \mathbf{106.40}$ |

The applicant states on page 19 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2021) and OY2 (CY2022) the facility is projected to serve 102 and 106 in-center patients, respectively.

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

- OY1: 2.83 patients per station per week, or 70.75% ($102 \text{ patients} / 36 \text{ stations} = 2.83 / 4 = 0.7075$ or 70.75%).
- OY2: 2.94patients per station per week, or 73.5% ($106 \text{ patients} / 36 \text{ stations} = 2.94 / 4 = 0.735$ or 73.50%).

On page 27, the applicant states, “Given this projected growth of the in-center patient population, the needs of the facility’s patients will continue to be met. Additional Certificate of Need applications will be submitted based on the facility need as the facility approaches full capacity of stations.”

Projected utilization for New River Dialysis and SEDC-Jacksonville is reasonable and adequately supported based on the following:

- The applicant projects a reasonable patient census for New River Dialysis and SEDC-Jacksonville 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 assume that Onslow County patient census will increase at an annual rate of 3.9%, which is consistent with the five-year AACR for Onslow County, as reported in Table D of the January 2019 SDR.

Furthermore, in Section D, page 28, the applicant states that the proposed relocation of stations from New River Dialysis and SEDC-Jacksonville will not adversely affect the ability of low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

Conclusion

The Agency reviewed the:

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

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

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

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

CA

The applicant proposes to develop a new 10-station dialysis facility in Onslow County by relocating eight existing dialysis stations from New River Dialysis and two existing dialysis stations from SEDC-Jacksonville.

In Section E, page 30, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain 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 Onslow County.
- Locating a facility in another area of Onslow County – the applicant states that based on the location of the in-center patients identified in the patient letters in Exhibit C-3, locating the facility in another area would not address the geographic needs of the identified patients.

On page 30, the applicant states that the alternative proposed in this application is the most effective alternative to meet the need because the proposed project offers the best geographic access to the identified patient population.

The applicant provides supporting documentation in Exhibit C-3.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

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 shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Total Renal Care of North Carolina, LLC shall materially comply with the last made representation.**
- 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 Richlands Dialysis by relocating eight dialysis stations from New River Dialysis and two dialysis stations from Southeastern Dialysis Center - Jacksonville.**
- 3. Upon completion of this project, Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify eight dialysis stations at New River Dialysis for a total of no more than 17 dialysis stations at New River Dialysis.**

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-Jacksonville for a total of no more than 36 dialysis stations at Southeastern Dialysis Center-Jacksonville following completion of this project and Project ID #P-11681-19 (add five stations).**
 5. **Total Renal Care of North Carolina, LLC 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 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 Onslow County by relocating eight existing dialysis stations from New River Dialysis and two existing dialysis stations from SEDC-Jacksonville.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects the total capital cost of the project as shown in the table below.

| | |
|---------------------|--------------------|
| Site Costs | \$68,944 |
| Construction Costs | \$875,120 |
| Miscellaneous Costs | \$602,302 |
| Total | \$1,546,366 |

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, page 32, the applicant projects that start-up costs will be \$176,059 and initial operating expenses will be \$629,170 for a total working capital of \$805,228. On pages 32-33, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F, page 31, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

| Type | DaVita Inc. | Total |
|------------------------------|--------------------|--------------------|
| Accumulated reserves or OE * | \$1,546,366 | \$1,546,366 |
| Total Financing | \$1,546,366 | \$1,546,366 |

* OE = Owner's Equity

In Section F, page 33, the applicant states that the working capital needs of the project will be funded as shown in the table below.

| Sources of Financing for Working Capital | | Amount |
|--|--|------------------|
| (a) | Loans | \$ |
| (b) | Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity | \$805,228 |
| (c) | Lines of credit | \$ |
| (d) | Bonds | \$ |
| (e) | Total * | \$805,228 |

Exhibit F-2 contains a letter dated May 15, 2019 from the Chief Accounting Officer for DaVita Inc., parent company to Total Renal Care, Inc., authorizing the use of accumulated reserves for the capital needs of the project. In supplemental information the applicant provided a copy of the Consolidated Balance Sheets from DaVita, Inc., for year ending December 31, 2018. DaVita, Inc. had adequate cash and assets to fund the capital and working capital cost of the proposed project.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Section Q, Form F.2, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

| | 1 st Full Fiscal Year | 2 nd Full Fiscal Year |
|---|----------------------------------|----------------------------------|
| Total Treatments | 4,817 | 4,977 |
| Total Gross Revenues (Charges) | \$1,562,373 | \$1,614,532 |
| Total Net Revenue | \$1,480,492 | \$1,529,918 |
| Average Net Revenue per Treatment | \$307 | \$307 |
| Total Operating Expenses (Costs) | \$1,245,928 | \$1,302,521 |
| Average Operating Expense per Treatment | \$258 | \$261 |
| Net Income | \$234,565 | \$227,397 |

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital 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 Onslow County by relocating eight existing dialysis stations from New River Dialysis and two existing dialysis stations from SEDC-Jacksonville.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Onslow County. Facilities may also serve residents of counties not included in their service area.

According to the January 2019 SDR, there are two existing dialysis facilities in Onslow County, both of which are operated by DaVita, Inc., as shown in the table below.

| ONSLow COUNTY DIALYSIS FACILITIES | | | | |
|---|--------|--------------|------------------------------------|---------------------------|
| FACILITY | OWNER | LOCATION | # CERTIFIED STATIONS AS OF 6/30/18 | UTILIZATION AS OF 6/30/18 |
| New River Dialysis* | DaVita | Jacksonville | 22 | 80.68% |
| Southeastern Dialysis Center – Jacksonville** | DaVita | Jacksonville | 31 | 88.71% |

Source: Table B, January 2019 SDR.

*Project I.D.# P-11493-18/ Add three dialysis stations for a total of 25 stations upon completion of this project, Project I.D. #P-11416-17 (add two stations) and Project I.D. #P-11325-17 (add two stations) was certified on 8/19/2018.

**Project I.D. #P-11415-17/ Add 2 dialysis stations for a total of 33 stations upon completion of this project, Project ID# P-10351-14 (add 5 stations), and Project ID# P-11326-17 (add 1 station) was certified on 8/19/2018 and Project I.D. #P-11681-19/ Add no more than 5 stations for a total of no more than 38 stations upon completion of this project and Project ID #P-11415-17 (add two stations) has been approved but not yet developed.

In Section G, page 36, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Onslow. The applicant states:

“This certificate of need application does not propose to increase the number of stations in Onslow County. Relocating ten stations from New River dialysis and SEDD Jacksonville 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 proposal would not result in an increase in the number of dialysis stations in Onslow County.
- The applicant adequately demonstrates that the proposed new dialysis facility is needed in addition to the existing or approved dialysis facilities in Onslow County.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section Q, Form H Staffing, the applicant provides current and projected OY2 staffing for the proposed services in full-time equivalents (FTEs) as summarized in the following table.

| POSITION | OY2 PROJECTED FTE POSITIONS |
|--------------------------------|------------------------------------|
| RN | 2.0 |
| Technician (Patient Care) | 4.0 |
| Administrator | 1.0 |
| Dietician | 0.5 |
| Social Worker | 0.5 |
| Administration/Business Office | 1.0 |
| Biomed Technician | 0.5 |
| Total | 9.5 |

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

The assumptions and methodology used to project staffing are provided in Sections H and Q). Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section Q. In Section H.2 and H.3, pages 37 and 38, respectively, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section H, page 38, the applicant identifies the proposed medical director. In Exhibit H-4, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. In Exhibit H-4 the applicant provides supporting documentation.

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, page 39, the applicant provides a list of the necessary ancillary and support services, as illustrated below.

| Richlands Dialysis Ancillary and Support Services | |
|--|--|
| Services | Provider |
| In-center dialysis/maintenance | To be available on premises |
| Self-care training (in-center) | To be available on premises |
| Home training: Home hemodialysis Peritoneal dialysis Accessible follow-up program | New River Dialysis |
| Psychological counseling | To be available on premises |
| Isolation – hepatitis | To be available on premises |
| Nutritional counseling | To be available on premises |
| Social Work services | To be available on premises |
| Acute dialysis in an acute care setting | Onslow Memorial Hospital |
| Emergency care | Onslow Memorial Hospital |
| Blood bank services | Onslow Memorial Hospital |
| Diagnostic and evaluation services | Onslow Memorial Hospital |
| X-ray services | Onslow Memorial Hospital |
| Laboratory services | DaVita Laboratories Services, Inc. |
| Pediatric nephrology | Onslow Memorial Hospital |
| Vascular surgery | Onslow Memorial Hospital |
| Transplantation services | Vidant Medical Center |
| Vocational rehabilitation & counseling | NC Division of Vocational Rehab Services |
| Transportation | Onslow United Transit System |

In Section I.2, pages 39-40, and Exhibits I-1 and I-2, the applicant describes its existing and proposed relationships with other local health care and social services providers. The applicant provides supporting documentation in Exhibit I. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

NA

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

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

NA

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

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

C

In Section K, page 42, the applicant states that the project involves upfitting 7,000 square feet of leased space at 9103 Richlands Highway in Richlands. Line drawings are provided in Exhibit K-1.

On page 42, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 43, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

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

On pages 44-45, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Exhibit K-4 documents the location of the site, the availability of the site and the zoning for permitted uses.

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.

- (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

Richlands Dialysis is not an existing facility. In Section L.1, page 46, the applicant provides the historical payor mix percentages for New River Dialysis and SEDC-Jacksonville, the two facilities from which stations are to be relocated and patients are to be transferred, for the last full operating year, CY2018, as shown in the tables below.

**New River Dialysis
 Payor Mix CY2018**

| Payor Source | In-center Patients | HHD Patients | PD Patients |
|---------------------|---------------------------|---------------------|--------------------|
| Medicaid | 5.2% | 0.0% | 5.3% |
| Medicare | 79.2% | 100.0% | 73.7% |
| Insurance | 8.3% | 0.0% | 21.1% |
| Other | 7.3% | 0.0% | 0.0% |
| Total | 100.0% | 100.0% | 100.0% |

Source: Table on page 47 of the application.
 Totals may not sum due to rounding

**SEDC-Jacksonville
 Payor Mix CY2018**

| Payor Source | In-center Patients | HHD Patients | PD Patients |
|---------------------|---------------------------|---------------------|--------------------|
| Medicaid | 7.5% | 0.0% | 0.0% |
| Medicare | 78.5% | 0.0% | 0.0% |
| Insurance | 5.6% | 0.0% | 0.0% |
| Other | 8.4% | 0.0% | 0.0% |
| Total | 100.0% | 100.0% | 100.0% |

Source: Table on page 47 of the application.
 Totals may not sum due to rounding

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 |
| Onslow | 9% | 45% | 34% | 14% | 13% | 10% |
| Duplin | 18% | 51% | 49% | 21% | 13% | 20% |
| Statewide | 16% | 51% | 37% | 15% | 10% | 12% |

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

* Excludes "White alone, not Hispanic or Latino"

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

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report

which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

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

The Agency reviewed the:

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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, page 48, the applicant states that the facility has no obligation under any applicable federal regulations to provide uncompensated care, community service or access by minorities and handicapped persons

In Section L.2, page 48, the applicant states that during the last five years no patient civil rights access complaints have been filed against any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application

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

- Exhibits to the application

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

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

C

In Section L, page 48, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

**Richlands Dialysis Payor Mix
FY2**

| Payor Category | Percent of Total Patients |
|-----------------------|----------------------------------|
| Medicaid | 6.4% |
| Medicare | 79.8% |
| Insurance | 6.9% |
| Other | 7.9% |
| Total | 100.0% |

Source: Table on page 48 of the application.

Note: Totals might foot due to rounding.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 79.8% of total services will be provided to Medicare patients and 6.6% to Medicaid patients.

On page 48, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the applicant's proposed payor mix is comparable to the last full year of the facilities from which the stations and patients are being relocated.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.4, page 49, 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

In Section M, page 50, 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop a new 10-station dialysis facility in Onslow County by relocating eight existing dialysis stations from New River Dialysis and two existing dialysis stations from SEDC-Jacksonville.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Onslow County. Facilities may also serve residents of counties not included in their service area.

According to the January 2019 SDR, there are two existing dialysis facilities in Onslow County, both of which are operated by DaVita, Inc., as shown in the table below.

| ONSLow COUNTY DIALYSIS FACILITIES | | | | |
|---|--------|--------------|------------------------------------|---------------------------|
| FACILITY | OWNER | LOCATION | # CERTIFIED STATIONS AS OF 6/30/18 | UTILIZATION AS OF 6/30/18 |
| New River Dialysis* | DaVita | Jacksonville | 22 | 80.68% |
| Southeastern Dialysis Center – Jacksonville** | DaVita | Jacksonville | 31 | 88.71% |

Source: Table B, January 2019 SDR.

*Project I.D.# P-11493-18/ Add three dialysis stations for a total of 25 stations upon completion of this project, Project I.D. #P-11416-17 (add two stations) and Project I.D. #P-11325-17 (add two stations) was certified on 8/19/2018.

**Project I.D. #P-11415-17/ Add 2 dialysis stations for a total of 33 stations upon completion of this project, Project ID# P-10351-14 (add 5 stations), and Project ID# P-11326-17 (add 1 station) was certified on 8/19/2018 and Project I.D. #P-11681-19/ Add no more than 5 stations for a total of no more than 38 stations upon completion of this project and Project ID #P-11415-17 (add two stations) has been approved but not yet developed.

In Section N, page 51, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 51, the applicant states:

“DaVita operates the other two facilities in the county. We do not expect that the development of Richlands Dialysis will have an effect on any dialysis facilities located in Onslow County since the patients already being served by DaVita will be transferring their care from one DaVita facility to another DaVita facility. ... There are no other dialysis facilities in the proposed service area; therefore, there can be no effect on the competition.”

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 Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

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

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

- (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 Q, Form A Facilities, the applicant provides a list of the over 90 dialysis facilities in North Carolina owned and operated by DaVita.

In Section O.2, page 52, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two of these facilities, Southeastern Dialysis Center-Wilmington and Waynesville Dialysis Center. The applicant provides documentation regarding the deficiencies and subsequent measures taken by those facilities to ensure compliance with CMS Conditions for Coverage. In Section O, pages 52-53, in Exhibit O-3, and in supplemental information the applicant states that all the problems at Southeastern Dialysis Center-Wilmington and Waynesville Dialysis Center have been corrected and that Southeastern Dialysis Center-Wilmington was back in compliance as of March 21, 2018 and Waynesville Dialysis Center was back in compliance as of June 7, 2019. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may

vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- (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, pages 17-20, the applicant demonstrates that Richlands Dialysis will serve a total of 33 in-center patients at the end of OY1 (CY 2021) for a utilization rate of 82.5% or 3.3 patients per station per week (33 patients / 10 stations = 3.3/ 4 = 0.825 or 82.5%). 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 Section C, pages 17-20, the applicant provides the assumptions and methodology used to project utilization of the facility.