

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 22, 2020

Findings Date: April 22, 2020

Project Analyst: Tanya M. Saporito

Assistant Chief: Lisa Pittman

Project ID #: N-11832-19

Facility: Bladenboro Dialysis

FID #: 160065

County: Bladen

Applicant: Total Renal Care of North Carolina, LLC

Project: Relocate 2 dialysis stations from Southeastern Dialysis Center-Whiteville (Columbus County) and 2 stations from Southeastern Dialysis Center-Burgaw (Pender County) to Bladenboro Dialysis, which is a change of scope and cost overrun for Project ID #N-11130-16 (develop a new 10-station facility by relocating 10 stations from Southeastern Dialysis Center-Elizabethtown)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

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The applicant, Total Renal Care of North Carolina, LLC (TRC) proposes a change of scope (COS) and cost overrun (COR) for the approved but undeveloped Project ID #N-11130-16.

Project ID #N-11130-16 authorized the development of a new 10-station facility, Bladenboro Dialysis, by relocating 10 stations from Southeastern Dialysis Center-Elizabethtown. The latest progress report, dated January 17, 2020, indicates that construction is complete, the certificate of occupancy has been issued and the facility is preparing for the initial survey. However, since Project ID #N-11130-16 is not yet developed, this application to relocate 2 dialysis stations from Southeastern Dialysis Center-Whiteville and 2 stations from Southeastern Dialysis Center-Burgaw is a COS. In addition, the certificate of need issued for

Project ID #N-11130-16 approved a capital cost of \$1,664,359. The current application proposes a COR of \$394,858, which results in a total combined capital cost of \$2,059,217, which is 123.7% of the capital cost approved in Project ID #N-11130-16.

### **Need Determination**

The applicant proposes a COS and COR to Project ID #N-11130-16; therefore, neither the county need methodology nor the facility need methodology in the 2019 State Medical Facilities Plan (SMFP) are applicable to this review.

### **Policies**

There are two policies in the 2019 SMFP applicable to this review: Policy ESRD-2: Relocation of Dialysis Stations and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

### **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, TRC, proposes to relocate two existing stations from Southeastern Dialysis Center-Burgaw (SEDC Burgaw) in Pender County and two existing stations from Southeastern Dialysis Center, Inc. (SEDC Whiteville) in Columbus County. Pender County and Columbus County are contiguous to Bladen County.

In Section B, page 15, the applicant explains why it believes its application is conforming to Policy ESRD-2. The applicant provides the following table:

	<b>Columbus County</b>	<b>Pender County</b>
Projected station surplus as reported in Table D of July 2019 SDR.	12	6
Number of stations to be relocated from County.	2	2
Difference between the two.	10	4
Number of residents from County dialyzing at facility.	4	1

Source: application page 15

The applicant proposes to relocate two stations from Columbus County, which reports a surplus of 12 dialysis stations in the July 2019 SDR. Likewise, the applicant proposes to relocate two existing stations from Pender County, which reports a surplus of six dialysis stations in the July 2019 SDR. All four stations will be relocated to Bladenboro dialysis in Bladen County, which reports a deficit of six dialysis stations in the July 2019 SDR. The proposal will decrease the surplus of dialysis stations in both Columbus and Pender counties, and will decrease the existing deficit in Bladen County.

In addition, on page 15, the applicant provides a copy of Table A of the July 2019 SDR, which reports that SEDC-Burgaw and SEDC-Whiteville are currently serving patients from Bladen County, the county to which the stations are proposed to be relocated. Therefore, the application is consistent with Policy ESRD-2.

### **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 based on the following:

- The applicant's proposal will not result in a deficit, nor increase the existing deficit of dialysis stations in Pender County.
- The applicant's proposal will not result in a deficit, nor increase the existing deficit of dialysis stations in Columbus County.
- The applicant's proposal will not result in a surplus, nor increase an existing surplus of dialysis stations in Bladen County.
- The applicant adequately demonstrates that Bladenboro Dialysis currently serves dialysis patients from Pender and Columbus counties.

Therefore, the application is consistent with Policy ESRD-2.

## **Policy GEN-4**

Policy GEN-4 states:

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

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

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

The proposed total capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B.4, pages 13 - 14, the applicant describes the project’s plan to improve energy efficiency and conserve water, including energy efficient lighting, water optimization protocols, sustainable design and building materials, high-performance HVAC systems, and high-efficiency equipment and appliances. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Pursuant to Policy ESRD-2, the applicant proposes to relocate 2 dialysis stations from Southeastern Dialysis Center-Whiteville in Columbus County and 2 stations from Southeastern Dialysis Center-Burgaw in Pender County to Bladenboro Dialysis, which is a change of scope and cost overrun for Project ID #N-11130-16 (develop a new 10-station facility by relocating 10 stations from Southeastern Dialysis Center-Elizabethtown).

**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 for this facility consists of Bladen County. Facilities may also serve residents of counties not included in their service area.

As of January 2020, Bladenboro Dialysis was not operating. Thus, there is no historical patient origin to report.

In Section C.3, page 17, and clarifying information, the applicant projects patient origin for in-center (IC) and peritoneal dialysis (PD) patients, as illustrated in the tables below:

Bladenboro Dialysis Center (CY 2022)

COUNTY	# IN-CTR. PATIENTS	% OF TOTAL	# PD PATIENTS	% OF TOTAL
Bladen	51	98.1%	3	100.0%
Columbus	1	1.9%	0	0.00%
<b>Total</b>	<b>52</b>	<b>100.0%</b>	<b>3</b>	<b>100.0%</b>

\*Note: Totals may not foot due to rounding

The applicant does not propose to offer home hemodialysis (HHD) training support services at Bladenboro Dialysis.

In Section C, pages 17 - 19, the applicant provides the assumptions and methodology used to project patient origin for in-center patients. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C, page 20, the applicant states:

*“At 10 stations, Bladenboro Dialysis could reasonably project to serve up to 40 in-center dialysis patients on traditional shifts. However, since approval of Bladenboro Dialysis, the number of dialysis patients residing near the proposed facility has increased. Total Renal Care of North Carolina, LLC has identified 26 new dialysis patients who have signed letters of support for this proposal. Each of these patients began dialysis after submission of the original CON application for Bladenboro Dialysis, and therefore could not have been projected to receive dialysis care at the facility.”*

In Section C, pages 17 - 18, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, which is summarized below:

- The applicant begins its projections with the 31 patients originally projected to be served at Bladenboro Dialysis in Project ID# N-11130-16. That project proposed to relocate 10 existing dialysis stations from SEDC Elizabethtown, and transfer 31 patients from two existing DaVita dialysis facilities.
- With this application, the applicant provides 26 letters of support from existing DaVita patients who indicate a willingness to transfer their care to Bladenboro Dialysis. See the following table to illustrate the breakdown of the patient residence ZIP codes, from page 18:

PATIENT RESIDENCE		DAVITA FACILITY				
ZIP CODE	COUNTY	ELIZABETHTOWN	WHITEVILLE	CHADBOURN	BURGAW	TOTAL
28320	Bladen	8	0	2	0	10
28433	Columbus	0	1	0	0	1
28433	Bladen	2	2	0	0	4
28448	Bladen	0	0	0	1	1
28337	Bladen	10	0	0	0	10
<b>Total</b>		<b>20</b>	<b>3</b>	<b>2</b>	<b>1</b>	<b>26</b>

- The applicant states it cannot determine how many of the 26 patients who signed letters indicating a willingness to transfer their care to Bladenboro Dialysis will actually transfer; consequently, the applicant projects that 15 of the 26 patients will in fact transfer their care to Bladenboro Dialysis following the relocation of four stations as proposed in this application. The applicant states 14 of those 15 patients reside in Bladen County and one patient resides in Columbus County.
- The applicant projects growth of the Bladen County in-center patient population using the Bladen County Five Year Average Annual Change Rate (AACR) of 6.9%, published in the July 2019 SDR.

- The applicant states Operating Year 1 (OY 1) is Calendar Year (CY) 2021.
- The applicant states Operating Year 2 (OY 2) is Calendar Year (CY) 2022.

**Projected Utilization**

In-Center Patients

In Section C, page 19, the applicant provides the methodology used to project in-center utilization, as illustrated in the following table:

**Projected Patients, Bladenboro Dialysis**

	# STATIONS	# PATIENTS/CALCULATIONS
Begin with the 31 patients identified in Project ID #N-11130-16 projected to transfer their care to Bladenboro Dialysis as of January 1, 2021.	10	31
Add 15 patients who signed letters of support for this application to transfer their care to Bladenboro Dialysis as of January 1, 2021. Add four stations to be relocated as proposed in this application. This is the beginning census for this project.	$10 + 4 = 14$	$31 + 15 = 46$
Project Bladen County patient population forward one year to December 31, 2021, using the Bladen County Five Year AACR of 6.9%.		$45 \times 1.069 = 48.105$
Add one patient from Columbus County. This is the ending census for OY 1 (12/31/21).		$48.105 + 1 = 49.105$
Project Bladen County patient population forward one year to December 31, 2022, using the Bladen County Five Year AACR of 6.9%.		$48.105 \times 1.069 = 51.424$
Add one patient from Columbus County. This is the ending census for OY 2 (12/31/22).		$51.424 + 1 = 52.424$

The applicant projects to serve 49 in-center patients at the end of OY 1 and 52 in-center patients at the end of OY 2. Thus, the applicant projects that Bladenboro Dialysis will have a utilization rate of 87.5% or 3.5 patients per station per week ( $49 \text{ patients} / 14 \text{ stations} = 3.5$ ;  $3.5 / 4 = 0.875$  or 87.5%) at the end of OY 1. 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 begins the projections with the patient population originally approved in Project ID #N-11130-16 to transfer their care to Bladenboro Dialysis.
- The applicant projects the Bladen County patient census will increase by the Bladen County Five Year AACR of 6.9%, as reported in the July 2019 SDR.
- The utilization rate by the end of OY 1 is above the minimum standard of 3.2 patients per station per week.

### Peritoneal Dialysis Patients

In clarifying information provided to the Agency, the applicant provided the methodology used to project PD patient utilization, summarized as follows:

- The applicant states nine PD patients who reside in Bladen County and who currently receive PD support at SEDC Elizabethtown, a DaVita facility in Bladen County, have signed letters indicating they would consider transferring their care to Bladenboro Dialysis because it would be a more convenient location for them.
- The applicant states eight PD patients who reside in Columbus County and who currently receive PD support at SEDC Elizabethtown have signed letters indicating they would consider transferring their care to Bladenboro Dialysis because it would be a more convenient location for them.
- The applicant states one PD patients who resides in Robeson County and who currently receives PD support at SEDC Elizabethtown has signed a letter indicating he or she would consider transferring PD care to Bladenboro Dialysis because it would be a more convenient location.
- The applicant assumes at least one of the 18 patients who signed letters will transfer PD care to Bladenboro Dialysis.
- The applicant states OY 1 is CY 2021, and OY 2 is CY 2022.
- The applicant projects the PD patient census to grow by at least one patient per year, as shown in the following table:

PD PATIENT PROJECTIONS	START DATE	# PTS. BEGIN YEAR	# PTS. END YEAR	AVERAGE # PTS. / YEAR
OY 1 (CY 2021)	1/1/2021	1	2	1.5
OY 2 (CY 2022)	1/1/2022	2	3	2.5

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

- The applicant begins the projections with less than the number of PD patients who stated they would consider transferring their care to Bladenboro Dialysis.
- The applicant projects the PD patient census will increase by only one PD patient per year.

### Access

In Section C.3, page 21, the applicant states that by policy, the proposed services will be made available “to all residents in its service area without qualifications. The facility will serve



*patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.”* In Section L, page 48, and in clarifying information, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project (CY 2022) illustrated below.

**Projected Payor Mix, Bladenboro Dialysis, OY 2 (CY 2022)**

PAYOR SOURCE	# IN-CTR. PATIENTS	% OF TOTAL REVENUE	# PD PATIENTS	% OF TOTAL REVENUE
Self Pay	0.0	0.0%	0.0	0.0%
Insurance*	2.6	5.1%	0.6	21.1%
Medicare*	41.9	80.5%	2.0	68.4%
Medicaid*	4.4	8.5%	0.2	5.1%
Misc. (VA)	3.1	5.9%	0.2	5.1%
<b>Total</b>	<b>52.0</b>	<b>100.0%</b>	<b>3.0</b>	<b>100.0%</b>

Numbers may not sum due to rounding by Project Analyst

As illustrated in the table above, the applicant projects that 89.0% of all IC patients will be Medicare or Medicaid recipients in CY 2022. On page 49, the applicant states its projected payor mix in Operating Year 2 is based on the originally approved payor mix in Project ID #N-11130-16.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Clarifying information provided to the Agency
- 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

Pursuant to Policy ESRD-2, the applicant proposes to relocate 2 dialysis stations from Southeastern Dialysis Center-Whiteville in Columbus County and 2 stations from Southeastern Dialysis Center-Burgaw in Pender County to Bladenboro Dialysis, which is a change of scope and cost overrun for Project ID #N-11130-16.

In Section D, pages 25 - 28, the applicant explains why it believes the needs of the population presently being served at SEDC-Whiteville and SEDC-Burgaw will be adequately met following the relocation of two dialysis stations from each facility to Bladenboro Dialysis.

#### SEDC Whiteville

On page 25 and in clarifying information provided to the Agency, the applicant states SEDC-Whiteville in Columbus County was dialyzing 66 in-center patients, 62 of whom were Columbus County residents and four of whom lived outside of Columbus County. The applicant's assumptions for projected utilization of SEDC-Whiteville are summarized as follows:

- The applicant projects growth in the Columbus County in-center patients using the Columbus County 5-year AACR as published in the January 2019 SDR, which is a negative growth rate (-2.2%).
- The applicant does not project growth in the patients who reside outside of Columbus County.
- The applicant proposes to relocate two stations from SEDC-Whiteville to Bladenboro Dialysis as of January 1, 2021.
- The applicant projects that one patient from Columbus County and two patients from Bladen County who dialyze at SEDC-Whiteville will transfer their care to Bladenboro Dialysis.
- The period of growth begins January 1, 2019 and projects forward to December 31, 2022, the end of the second project year following completion of this project.

The following table, summarized from information on page 26 and clarifying information provided to the Agency, illustrates projected utilization of SEDC-Whiteville:

**Projected Patients, SEDC-Whiteville**

	# STATIONS	# PATIENTS/CALCULATIONS
Begin with the facility census as of January 1, 2019.	26	66
Project Columbus County patients forward one year to December 31, 2019 using the Columbus County Five Year AACR of -2.2%.	--	$62 - (62 \times .022) = 60.636$
Add four patients from outside Columbus County.	--	$60.636 + 4 = 64.636$
Project Columbus County patients forward one year to December 31, 2020 using the Columbus County Five Year AACR of -2.2%	--	$60.636 - (60.636 \times .022) = 59.302$
Add four patients from outside Columbus County. This is the ending census as of 12/31/2020.	--	$59.302 + 4 = 63.302$
Bladenboro Dialysis is projected to be certified as of 1/1/2021: <ul style="list-style-type: none"> <li>• 2 stations are projected to relocate to Bladenboro Dialysis from SEDC Whiteville</li> <li>• 3 patients are projected to transfer to Bladenboro Dialysis from SEDC Whiteville (1 patient from Columbus County and 2 patients from Bladen County).</li> </ul>	$26 - 2 = 24$	$63.302 - 3 = 60.302$
SEDC Whiteville stations and patients as of 1/1/2021.	24	60
Project Columbus County patients forward one year to December 31, 2021 using the Columbus County Five Year AACR of -2.2%.	--	$58.302 - (58.302 \times .022) = 57.019$
Add two patients from outside Columbus County (four minus the two to transfer to Bladenboro Dialysis). This is the ending census for CY 2021 and the end of OY 1.	--	$57.019 + 2 = 59.019$
Project Columbus County patients forward one year to December 31, 2022 using the Columbus County Five Year AACR of -2.2%.	--	$57.019 - (57.019 \times .022) = 55.765$
Add two patients from outside Columbus County (four minus the two to transfer to Bladenboro Dialysis). This is the ending census for CY 2022 and the end of OY 2.	--	$55.765 + 2 = 57.765$

Thus, as of December 31, 2021, the applicant projects that SEDC-Whiteville will dialyze 59 patients on 24 in-center stations, which is a utilization rate of 61.5%, or 2.46 patients per station per week [ $58 / 24 = 2.46$ ;  $2.46 / 4 = 0.615$ ]. The needs of the patients currently served at SEDC-Whiteville will continue to be adequately met following the relocation of two stations to Bladenboro Dialysis.

SEDC Burgaw

On page 27 the applicant states SEDC-Burgaw in Pender County was dialyzing 52 in-center patients, 46 of whom were Pender County residents and six of whom lived outside of Pender County. The applicant's assumptions for projected utilization of SEDC-Burgaw are summarized as follows:

- The applicant projects growth in the Pender County in-center patients using the Pender County 5-year AACR as published in the January 2019 SDR, which is a negative growth rate (-3.1%).
- The applicant does not project growth in the patients who reside outside of Pender County.

- The applicant proposes to relocate two stations from SEDC-Burgaw to Bladenboro Dialysis as of January 1, 2021.
- The applicant projects that one patient from Bladen County who dialyzes at SEDC-Burgaw will transfer their care to Bladenboro Dialysis.
- The period of growth begins January 1, 2019 and projects forward to December 31, 2022, the end of the second project year following completion of this project.

The following table, from page 27, illustrates projected utilization of SEDC-Burgaw:

**Projected Patients, SEDC-Burgaw**

	# STATIONS	# PATIENTS/CALCULATIONS
Begin with the facility census as of January 1, 2019.	18	52
Project Pender County patients forward one year to December 31, 2019, using the Pender County -3.1% AACR.		$46 - (46 \times 0.031) = 44.574$
Add six patients from outside Pender County.		$44.574 + 6 = 50.574$
Project ID #O-11689-19 to add one station is certified on 1/1/2020.	$18 + 1 = 19$	
Project Pender County patients forward one year to December 31, 2020, using the Pender County -3.1% AACR.		$44.574 - (44.574 \times 0.031) = 43.192$
Add six patients from outside Pender County. This is the ending census as of 12/31/2020.	--	$43.192 + 6 = 49.192$
Bladenboro Dialysis' projected certification date is 1/1/2021. <ul style="list-style-type: none"> <li>• Two stations are projected to relocate to Bladenboro Dialysis from SEDC-Burgaw</li> <li>• One Bladen County patient is projected to transfer to Bladenboro Dialysis from SEDC-Burgaw.</li> </ul>	$19 - 2 = 17$	$49.192 - 1 = 48.192$
Station count and patient census as of January 1, 2021.	17	48
Project Pender County patients forward one year to December 31, 2021, using the Pender County -3.1% AACR.		$43.192 - (43.192 \times 0.031) = 41.853$
Add five patients from outside Pender County (one was subtracted to transfer to Bladenboro Dialysis). This is the ending census as of 12/31/2021.		$41.853 + 5 = 46.853$
Project Pender County patients forward one year to December 31, 2022, using the Pender County -3.1% AACR.		$41.853 - (41.853 \times 0.031) = 40.556$
Add five patients from outside Pender County. This is the ending census as of 12/31/2022.		$40.556 + 5 = 45.556$

Numbers may not sum due to rounding by Project Analyst.

Thus, on December 31, 2021, the applicant projects that SEDC-Burgaw will dialyze 46 patients on 17 in-center stations, which is a utilization rate of 67.6%, or 2.7 patients per station per week [ $46 / 17 = 2.7$ ;  $2.7 / 4 = 0.676$ ]. The needs of the patients currently served at SEDC-Burgaw will continue to be adequately met following the relocation of two stations to Bladenboro Dialysis.

Projected utilization of SEDC-Whiteville and SEDC-Burgaw is reasonable and adequately supported based on the following:

- The applicant utilizes the -2.2% Columbus County 5-year AACR as published in the January 2019 SDR to project in-center patient utilization at each of the facilities from which stations will relocate.
- The applicant utilizes the -3.1% Pender County 5-year AACR as published in the January 2019 SDR to project in-center patient utilization at each of the facilities from which stations will relocate.
- The applicant projects growth (decrease) only of the in-center county patient population dialyzing at each of SEDC-Burgaw and SEDC-Whiteville, and then adds patients who reside in other counties who choose to dialyze at each facility at the end of the growth projections.

In Section D.2, on page 28, the applicant states the relocation of stations as proposed in this application will have no effect on the ability of low-income persons, racial and ethnic minorities, women, handicapped, elderly and other groups to obtain needed health care.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Clarifying information provided to the Agency
- 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 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

Pursuant to Policy ESRD-2, the applicant proposes to relocate 2 dialysis stations from Southeastern Dialysis Center-Whiteville in Columbus County and 2 stations from Southeastern Dialysis Center-Burgaw in Pender County to Bladenboro Dialysis, which is a change of scope and cost overrun for Project ID #N-11130-16.

In Section E.1, 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 the Status Quo - the applicant dismissed this alternative because the Five Year AACR for Bladen County is 6.9%.
- Relocate existing stations from another DaVita facility – the applicant states the only other DaVita facility in Bladen County (SEDC-Elizabethtown) was operating at less than 80% capacity; however, that facility is already relocating stations to Bladenboro Dialysis (Project ID #O-11130-16). The applicant states that this facility cannot relocate additional dialysis stations without adversely affecting the patient population.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative for the reasons stated above.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. 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, the applicant shall materially comply with the last made representation.**
- 2. Pursuant to Policy ESRD-2, Total Renal Care of North Carolina, LLC shall relocate two existing dialysis station from SEDC-Whiteville and two dialysis stations from SEDC-Burgaw to Bladenboro Dialysis, for a total of no more than 14 dialysis stations at Bladenboro Dialysis upon completion of this project and Project ID #O-11130-16.**
- 3. Total Renal Care of North Carolina, LLC shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations which shall include any isolation 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 SEDC-Whiteville and two dialysis stations from SEDC-Burgaw for a total of no more than 24 dialysis stations at SEDC-Whiteville and 17 stations at SEDC-Burgaw.**

**5. Total Renal Care of North Carolina, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to the 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 relocate 2 dialysis stations from Southeastern Dialysis Center-Whiteville in Columbus County and 2 stations from Southeastern Dialysis Center-Burgaw in Pender County to Bladenboro Dialysis, which is a change of scope and cost overrun for Project ID #N-11130-16 (develop a new 10-station facility by relocating 10 stations from Southeastern Dialysis Center-Elizabethtown). The certificate of need issued for Project ID #N-11130-16 authorized a capital cost of \$1,664,359. The current application proposes a COR of \$394,858, which results in a total combined capital cost of \$2,059,217, which is 123.7% of the capital cost approved in Project ID #N-11130-16.

**Capital and Working Capital Costs**

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

	PREVIOUSLY APPROVED COST PROJECT ID #N-11130-16	CAPITAL COST THIS PROJECT PROJECT ID #N-11832-19	DIFFERENCE
Site Preparation	\$97,777	\$97,016	-\$761
Construction/Renovation Contract	\$955,000	\$1,113,688	\$158,688
Architect/Engineering Fees	\$80,395	\$125,500	\$45,105
Medical Equipment	\$152,400	\$208,000	\$55,600
Non-Medical Equipment	\$283,787	\$293,251	\$9,464
Furniture	\$95,000	\$160,115	\$65,115
Interest During Construction	\$0	\$61,647	\$61,647
<b>Total</b>	<b>\$1,664,359</b>	<b>\$2,059,217</b>	<b>\$394,858</b>

In Section F, page 33, the applicant projects \$201,470 in start-up expenses and \$806,215 in initial operating expenses, for a total working capital of \$1,007,685

**Availability of Funds**

In Section F.2 and F.3, pages 32 and 34, the applicant states that the capital cost and working capital, respectively, will be funded as shown in the table below.

**Sources of Capital Cost and Working Capital Financing**

TYPE	DAVITA INC.		TOTAL
	CAPITAL COST	WORKING CAPITAL	
Accumulated reserves or OE *	\$394,858	\$1,007,685	<b>\$1,402,543</b>
<b>Total Financing</b>	<b>\$394,848</b>	<b>\$1,007,685</b>	<b>\$1,402,543</b>

\* OE = Owner's Equity

Exhibit F contains a letter dated November 15, 2019 from the Chief Accounting Officer for DaVita Inc., authorizing the use of accumulated reserves for the capital needs of the project. Exhibit F also contains 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 cost of the proposed project.

**Financial Feasibility**

The applicant provides pro forma financial statements for the first three 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 full fiscal years of operation of the project, as shown in the table below.

	1 <sup>ST</sup> FULL FISCAL YEAR (CY 2021)	2 <sup>ND</sup> FULL FISCAL YEAR (CY 2022)
Total Treatments	7,188	7,862
Total Gross Revenues (Charges)	\$2,165,369	\$2,839,827
Total Net Revenue	\$2,029,377	\$2,241,071
Average Net Revenue per Treatment	\$ 282.33	\$ 285.05
Total Operating Expenses (Costs)	\$1,684,160	\$1,778,452
Average Operating Expense per Treatment	\$ 234.30	\$ 226.21
Net Income	\$ 345,218	\$ 462,619

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 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

Pursuant to Policy ESRD-2, the applicant proposes to relocate 2 dialysis stations from Southeastern Dialysis Center-Whiteville in Columbus County and 2 stations from Southeastern Dialysis Center-Burgaw in Pender County to Bladenboro Dialysis, which is a change of scope and cost overrun for Project ID #N-11130-16 (develop a new 10-station facility by relocating 10 stations from Southeastern Dialysis Center-Elizabethtown).

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 for this facility consists of Bladen County. Facilities may also serve residents of counties not included in their service area.

According to the July 2019 SDR, there is one operational dialysis facility and one approved, but not yet operational facility in Bladen County, both of which are or will be operated by DaVita, Inc., the parent company of TRC, as shown in the table below.

BLADEN COUNTY DIALYSIS FACILITIES					
FACILITY	OWNER	LOCATION	# PATIENTS	# CERTIFIED STATIONS AS OF 12/31/18	UTILIZATION AS OF 12/31/18
Southeastern Dialysis Center - Elizabethtown	DaVita	Elizabethtown	82	26	3.15%
Bladenboro Dialysis*	DaVita	Bladenboro	0	0	0.00%
<b>Totals</b>			<b>82</b>	<b>26</b>	<b>3.15%</b>

Source: Table B, January 2019 SDR.  
 \*Projected to be operational in 2020

As illustrated in the table above, SEDC-Elizabethtown’s utilization was 78.8%,  $[82 / 26 = 3.153; 3.153 / 4 = 0.788]$ , as reported on Table B of the July 2019 SDR.

In Section G, page 37, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Bladen County. The applicant states:

*“As has been discussed within this application, the July 2019 SDR indicates that Bladen County has a deficit of 6 dialysis stations. The relocation of two stations from SEDC Whiteville and [sic] SEDC Burgaw will serve to reduce this deficit. In addition to the station deficit, Total Renal Care of North Carolina, LLC has identified 26 new dialysis patients who reside in the area of Bladenboro Dialysis. Each of the patients was not a dialysis patient at the time of the original application for Bladenboro Dialysis and therefore could not have signed a letter of support for the proposal. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates the need to relocate two existing stations from each SEDC-Whiteville and SEDC-Burgaw.

### **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 Form H in supplemental information, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

<b>POSITION</b>	<b>PROJECTED FTE STAFF YEAR 2</b>
Administrator	1.00
Registered Nurse	2.00
Home Training Nurse	0.50
Patient Care Technician	6.00
Dietician	0.50
Social Worker	0.50
Administration/Business Office	1.00
Bio-Medical Technician	0.50
<b>Total</b>	<b>11.50</b>

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 supplemental information, Form F.4. In Section H, page 40, the applicant refers to the methods used to recruit or fill new positions and its existing training and continuing education programs in the original application and states nothing has changed in this COS/COR.

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section I.1, page 41, the applicant states there are no changes from the information provided in the original application.

The applicant adequately demonstrated that the proposed services will be coordinated with the existing health care system in Project ID #N-11130-16, and there are no changes proposed in this application that would affect that determination.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

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

### C

This application represents a COS/COR of the originally approved application, Project ID #N-11130-16, which proposed to develop a new 10-station dialysis facility by relocating existing stations. In Section K, page 45, the applicant states it provides an updated line drawing to reflect the addition of four stations to the original line drawing submitted in Project ID# N-11130-16. In addition, the United States Postal Service provided the applicant with a different address than what was identified in the originally approved application because of a change in the facility orientation on the lot. The Agency granted a material compliance determination with respect to the address change on October 16, 2019.

The application was conforming to this criterion in Project ID #N-11130-16 and the applicant proposes no changes in this application that would affect that determination.

### **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

In Section L.1, page 47, the applicant provides the historical payor mix during CY 2018 for both SEDC Whiteville and SEDC Burgaw, as shown below.

**SEDC Whiteville, CY 2018 Payor Mix**

PAYOR SOURCE	# IN-CENTER PATIENTS	% OF TOTAL
Self Pay	0.0	0.0%
Insurance*	4.0	6.1%
Medicare*	51.0	77.3%
Medicaid*	6.0	9.1%
Other (VA)	5.0	7.6%
<b>Total</b>	<b>66.0</b>	<b>100.0%</b>

Totals may not foot due to rounding

**SEDC Burgaw, CY 2018 Payor Mix**

PAYOR SOURCE	# IN-CENTER PATIENTS	% OF TOTAL
Self Pay	0.0	0.0%
Insurance*	2.0	3.8%
Medicare*	44.0	84.6%
Medicaid*	4.0	7.7%
Other (VA)	2.0	3.8%
<b>Total</b>	<b>52.0</b>	<b>100.0%</b>

Totals may not foot due to rounding

In Section L.1, pages 46 and 47, the applicant compares demographic information on SEDC Whiteville and SEDC Burgaw patients and service area patients during CY 2018 as summarized below:

**SEDC Whiteville**

	Percentage of Total Patients Served by Mt. Olive Dialysis during CY2018	Percentage of the Population of Service Area
Female	37.5%	52.3%
Male	62.5%	47.7%
Unknown	0.0%	0.0%
64 and Younger	50.0%	78.2%
65 and Older	50.0%	21.8%
American Indian	4.7%	3.0%
Asian	0.0%	0.3%
Black or African-American	79.7%	34.2%
Native Hawaiian or Pacific Islander	0.0%	0.0%
White or Caucasian	12.5%	60.8%
Other Race	3.1%	1.6%
Declined / Unavailable	0.0%	0.0%

Source: application page 46

**SEDC Burgaw**

	<b>Percentage of Total Patients Served by Mt. Olive Dialysis during CY2018</b>	<b>Percentage of the Population of Service Area</b>
Female	40.4%	52.3%
Male	59.6%	47.7%
Unknown	0.0%	0.0%
64 and Younger	53.8%	78.2%
65 and Older	46.2%	21.8%
American Indian	0.0%	3.0%
Asian	0.0%	0.3%
Black or African-American	63.5%	34.2%
Native Hawaiian or Pacific Islander	0.0%	0.0%
White or Caucasian	28.8%	60.8%
Other Race	7.7%	1.6%
Declined / Unavailable	0.0%	0.0%

Source: application page 47

The Agency reviewed the:

- Application
- Exhibits to the application

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, page 48, the applicant states it is not obligated 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 either SEDC Whiteville and SEDC Burgaw in the last five years.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 48, and in clarifying information requested by the Agency, the applicant projects the following in-center and PD 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.

BLADENBORO DIALYSIS PROJECTED PAYOR MIX OY 2 (CY 2022)		
PAYMENT CATEGORY	IN -CENTER PTS.	PD PTS.
	% OF TOTAL REVENUE	% OF TOTAL REVENUE
Medicare	80.5%	68.4%
Medicaid	8.5%	5.1%
Commercial Insurance	5.1%	21.1%
Other (VA)	5.9%	5.1%
<b>Total*</b>	<b>100.0%</b>	<b>100.0%</b>

\*Note: Totals may not foot due to rounding

As shown in the table above, OY 2, the applicant projects 80.5% of total services will be provided to Medicare in-center patients and 8.5% to Medicaid in-center patients.

On page 49, the applicant provides the assumptions and methodology used to project payor mix during OY 2. The projected payor mix is reasonable and adequately supported.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Clarifying information requested by the Agency

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 Project ID #N-11130-16 the application was found conforming to this criterion. There are no changes proposed in this application that would affect that determination.

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 Project ID #N-11130-16 the application was found conforming to this criterion. There are no changes proposed in this application that would affect that determination.

**Conclusion**

The Agency reviewed the:

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

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

Pursuant to Policy ESRD-2, the applicant proposes to relocate 2 dialysis stations from Southeastern Dialysis Center-Whiteville in Columbus County and 2 stations from Southeastern Dialysis Center-Burgaw in Pender County to Bladenboro Dialysis, which is a change of scope and cost overrun for Project ID #N-11130-16 (develop a new 10-station facility by relocating 10 stations from Southeastern Dialysis Center-Elizabethtown).

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 for this facility consists of Bladen County. Facilities may also serve residents of counties not included in their service area.

According to the July 2019 SDR, there is one operational dialysis facility and one approved, but not yet operational facility in Bladen County, both of which are or will be operated by DaVita, Inc., the parent company of TRC, as shown in the table below.

BLADEN COUNTY DIALYSIS FACILITIES					
FACILITY	OWNER	LOCATION	# PATIENTS	# CERTIFIED STATIONS AS OF 12/31/18	UTILIZATION AS OF 12/31/18
Southeastern Dialysis Center - Elizabethtown	DaVita	Elizabethtown	82	26	3.15%
Bladenboro Dialysis*	DaVita	Bladenboro	0	0	0.00%
<b>Totals</b>			<b>82</b>	<b>26</b>	<b>3.15%</b>

Source: Table B, January 2019 SDR.  
 \*Projected to be operational in 2020

As illustrated in the table above, SEDC-Elizabethtown’s utilization was 78.8%, [ $82 / 26 = 3.153$ ;  $3.153 / 4 = 0.788$ ], as reported on Table B of the July 2019 SDR.

In Section N.1, page 51, the applicant states this project will have no effect on competition in the service area. The applicant states: “*There are no other dialysis facilities in Bladen County; therefore, there can be no effect on the competition.*”

The applicant adequately demonstrates:

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

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 Form A, Section Q, the applicant provides a table that shows the North Carolina dialysis facilities that DaVita Inc. owns and operates.

In Section O.3, 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 one of these facilities, Waynesville Dialysis Center. The applicant provides documentation regarding the deficiencies and subsequent measures taken by that facility to ensure compliance with CMS Conditions for Coverage in Exhibit O-3. In Section O, page 53, the applicant states that the problems in Waynesville Dialysis were corrected, and the facility is currently in compliance. 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 Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

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

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

-NA- The applicant was approved pursuant to Project ID #N-11130-16 to develop Bladenboro Dialysis, a ten-station dialysis facility. This is a cost overrun / change of scope application to relocate four additional stations to Bladenboro Dialysis.

*.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section C, pages 17 - 20, the applicant demonstrates that Bladenboro Dialysis will serve a total of 49 in-center patients at the end of OY 1 (CY 2021) for a utilization rate of 87.5% or 3.5 patients per station per week ( $49 \text{ patients} / 14 \text{ stations} = 3.5$ ;  $3.5 / 4 = 0.875$  or 87.5%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 17 – 19 and in supplemental information, 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.