

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: May 10, 2016
Findings Date: May 10, 2016

Project Analyst: Julie Halatek
Team Leader: Lisa Pittman

Project ID #: N-11130-16
Facility: Bladenboro Dialysis
FID #: 160065
County: Bladen
Applicant: Total Renal Care of North Carolina, LLC
Project: Develop a new 10-station dialysis facility by relocating 10 dialysis stations from Southeastern Dialysis Center - Elizabethtown

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC (TRC) d/b/a Bladenboro Dialysis (BD) proposes to develop a new 10-station dialysis facility in Bladenboro by relocating 10 dialysis stations from Southeastern Dialysis Center - Elizabethtown (SEDC-E). Both facilities are located in Bladen County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2016 State Medical Facilities Plan (SMFP).

Policies

Policy ESRD-2: Relocation of Dialysis Stations is the only policy in the 2016 SMFP applicable to this review.

Policy ESRD-2: Relocation of Dialysis Stations states:

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

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

The applicant proposes to develop a new 10-station dialysis facility in Bladen County by relocating existing Bladen County dialysis stations from SEDC-E. Because both facilities are located in Bladen County, there is no change in dialysis station inventory in Bladen County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant demonstrates that the proposal is conforming to all applicable policies in the 2016 SMFP. Therefore, the application is conforming to this criterion.

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

C

Total Renal Care of North Carolina, LLC (TRC) d/b/a Bladenboro Dialysis (BD) proposes to develop a new 10-station dialysis facility in Bladenboro by relocating 10 dialysis stations

from Southeastern Dialysis Center - Elizabethtown (SEDC-E). The January 2016 Semiannual Dialysis Report (SDR) reports SEDC-E as having 24 certified dialysis stations. In Section D.1, page 25, the applicant states that two additional stations associated with Project I.D. #N-11021-15 were certified after the project was completed on December 18, 2015, bringing the current total to 26 certified stations. At completion of this project, BD will be certified for 10 dialysis stations and SEDC-E will be certified for 16 dialysis stations.

Population to be Served

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

In Section C.1, page 14, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, including in-center (IC) patients and home peritoneal dialysis (PD) patients, as illustrated in the following table:

BD Projected Patients by County of Residence – OYs 1&2						
County	OY 1		OY 2		County Patients as	
	CY 2018		CY 2019		% of Total	
	IC	PD	IC	PD	OY 1	OY2
Bladen	32	2	33	3	100%	100%
Total	32	2	33	3	100%	100%

In Section C.2, page 18, and Exhibit C, the applicant states that the location of the proposed facility was based upon analysis showing that existing DaVita facilities in Bladen County and Columbus County serve 35 in-center patients that reside in or around ZIP code 28320 in Bladenboro. The applicant also states that analysis showed SEDC-E serving 18 home PD patients who live in Bladen, Columbus, or Robeson counties and who have indicated the proposed facility would better serve them or be more convenient for them. On page 14, and in Exhibit C, the applicant states that it has letters from 35 in-center patients residing in Bladen County, nine home PD patients residing in Bladen County, eight home PD patients residing in Columbus County, and one home PD patient residing in Robeson County who express support for the project and who state they could be better served by dialyzing at the proposed facility. The applicant provides tables identifying the patient residence ZIP code and current dialysis facility of the 53 in-center and home PD patients providing the support letters and expressing a willingness to transfer their care.

The applicant adequately identifies the population to be served.

Analysis of Need

The applicant proposes to develop a new 10-station dialysis facility by relocating 10 dialysis stations from SEDC-E. In Section C, pages 14-24, the applicant states that the need the population to be served has for the proposed project is based on the following factors:

In-Center Dialysis

- The applicant states that analysis of the patients served by DaVita facilities in Bladen County and Columbus County shows that 35 in-center patients live in or around ZIP code 28320 in southwestern Bladen County.
- The applicant states that in order to provide better support and access to dialysis services, a new facility is needed closer to the homes of those patients residing in or around ZIP code 28320.
- The first two full OYs of the project are expected to be CY 2018 and CY 2019.
- The applicant assumes that 31 out of 35 patients who express support for the proposed project and a willingness to transfer care to the new facility will do so and that all will be Bladen County residents.
- The Five Year Average Annual Change Rate (AACR) for Bladen County, as published in the January 2016 SDR, is -1.0 percent. However, the applicant states that the growth rate for DaVita patients in Bladen County (SEDC-E) has been 4.7 percent over the five year period from 2011 to 2015. On page 15, the applicant provides the following information (which the Project Analyst verified from the July 2012, July 2013, July 2014, and July 2015 SDRs):

Bladen County ESRD Patient Population Growth Rate 12/31/2010 – 12/31/2015					
DaVita Patients			All Patients		
Date	# Patients	Growth Rate	Date	# Patients	Growth Rate
12/31/2011	65	--	12/31/2010	95	--
12/31/2012	71	9.2%	12/31/2011	95	0.0%
12/31/2013	73	2.8%	12/31/2012	106	11.6%
12/31/2014	74	1.4%	12/31/2013	87	-17.9%
12/31/2015	78	5.4%	12/31/2014	89	-2.3%
5 Year AACR		4.7%	5 Year AACR		-1.0%

The applicant states that it will use the 4.7 percent five year AACR for SEDC-E to project the increase in the Bladen County ESRD patient population utilizing the facility.

Projected Utilization

In Section C.1, pages 14-16, the applicant provides the assumptions and methodology it uses to determine the need for a new facility developed by relocating stations from an existing facility. The applicant’s assumptions and methodology are summarized below:

- The starting in-center patient population at the proposed facility will consist of 31 Bladen County patients currently dialyzing at other DaVita facilities who have expressed a willingness to transfer care to the proposed facility.
- The Bladen County patient population will grow at a rate of 4.7 percent (the five year AACR for the SEDC-E facility) through the end of the second year of operation.
- The project is scheduled for completion on January 1, 2018. OY1 is CY 2018. OY2 is CY 2019.

In Section C.1, pages 14-16, the applicant provides the calculations used to arrive at the projected in-center patient census for OY1 and OY2 as summarized in the table below.

BD	In-Center Dialysis
Starting point of calculations is Bladen County patients dialyzing at other DaVita facilities but who are willing to transfer care to BD. This is the projected census on January 1, 2018.	31
Bladen County patient population is projected forward by one year to December 31, 2018. Projection is based on the five year AACR for SEDC-E in Bladen County (4.7%). This is the projected census on December 31, 2018 (OY1).	$31 \times 1.047 = 32.457$
Bladen County patient population is projected forward by one year to December 31, 2019, using the five year AACR (4.7%) referenced above. This is the projected census on December 31, 2019 (OY2).	$32.457 \times 1.047 = 33.98248$

The applicant projects to serve 32 in-center patients on 10 stations, which is 3.2 patients per station (32 patients / 10 stations = 3.2), by the end of OY1 and 33 in-center patients on 10 stations, which is 3.3 patients per station (33 patients / 10 stations = 3.3), by the end of OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Peritoneal Dialysis

- The applicant states that analysis of the patients served by DaVita facilities in Bladen County, Columbus County, and Robeson County shows that 18 home PD patients live in or around ZIP code 28320 in southwestern Bladen County.
- The applicant states that in order to provide better support and access to dialysis services, a new facility is needed closer to the homes of those patients residing in or around ZIP code 28320.
- The first two full OYs of the project are expected to be CY 2018 and CY 2019.

- The applicant assumes that one out of the 18 patients who express support for the proposed project and a willingness to transfer care to the new facility will do so and that it will be a Bladen County resident.
- The applicant assumes that the home PD program will grow at a rate of at least one patient per year.

Projected Utilization

In Section C.1, pages 16-17, the applicant provides the assumptions and methodology it uses to determine the need for a new facility developed by relocating stations from an existing facility. The applicant’s assumptions and methodology are summarized below:

- The starting home PD patient population at the proposed facility will consist of one Bladen County patient currently dialyzing at another DaVita facility who has expressed a willingness to transfer care to the proposed facility.
- The Bladen County patient population will grow at a rate of one patient per year through the end of the second year of operation.
- The project is scheduled for completion on January 1, 2018. OY1 is CY 2018. OY2 is CY 2019.

In Section C.1, pages 16-17, the applicant provides the calculations used to arrive at the projected home PD patient census for OY1 and OY2 as summarized in the table below.

BD	Home PD Dialysis
Starting point of calculations is a Bladen County patient dialyzing at another DaVita facility but who is willing to transfer care to BD. This is the projected census on January 1, 2018.	1
Bladen County patient population is projected forward by one year to December 31, 2018. Projection is based on a growth rate of one patient per year. This is the projected census on December 31, 2018 (OY1).	1 + 1 = 2
Bladen County patient population is projected forward by one year to December 31, 2019, again assuming growth of one patient per year. This is the projected census on December 31, 2019 (OY2).	2 + 1 = 3

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

Access

In Section L.1, page 50, the applicant states that BD will provide dialysis services to all residents in its service area without qualifications and serves patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability. The

applicant also states that it will make every reasonable effort to accommodate those with special needs and helps uninsured and underinsured patients with applying for assistance so it can serve low-income persons, racial and ethnic minorities, women, handicapped persons, elderly persons, and other underserved persons. The applicant projects 85.3 percent of its patients will have some or all of their services paid for by Medicare or Medicaid and bases its projected payor mix on the sources of patient payment received by the patients utilizing SEDC-E in the last full operating year. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the proposed 10-station facility, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to develop a new 10-station dialysis facility in Bladen County by relocating 10 dialysis stations from SEDC-E, also in Bladen County. In Section D.1, page 25, the applicant states that the January 2016 SDR shows SEDC-E serving 77 in-center patients on 24 stations as of June 30, 2015, for a utilization rate of 80.21 percent. The applicant states that the facility has 26 certified stations as of December 18, 2015 (see page 25 and Exhibit A-9).

In Section D, pages 25-26, the applicant discusses how the needs of dialysis patients at SEDC-E will continue to be met after the relocation of stations to the proposed facility. The applicant states that after the development of the proposed facility SEDC-E will have 16 certified stations. The applicant further states that it projects at least 31 patients to transfer from SEDC-E to the proposed facility.

On pages 25-26 of the application, the applicant provides the assumptions used to project SEDC-E's utilization through the end of OY2 (December 31, 2019). The assumptions are summarized below:

- As of December 31, 2014, SEDC-E was serving 77 patients – 68 Bladen County residents and nine patients residing outside Bladen County.

- The applicant projects growth of the Bladen County patient population using the 4.7 percent five year Average Annual Change Rate for SEDC-E discussed previously. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.
- The applicant does not project any growth in the patient population that resides outside of Bladen County.
- The applicant states that it expects 31 patients residing in Bladen County to transfer from SEDC-E to BD upon completion of the current project (on January 1, 2018).

Based on the above assumptions, the applicant projects utilization at SEDC-E as follows:

SEDC-E	In-Center Dialysis
Starting point of calculations is Bladen County patients dialyzing at SEDC-E on July 1, 2015.	68
Bladen County patient population is projected forward by six months to December 31, 2015. Projection is based on the 4.7% five year AACR for SEDC-E.	$68 \times 1.0235 = 69.598$
Bladen County patient population is projected forward by one year to December 31, 2016, using the 4.7% five year AACR for SEDC-E.	$69.598 \times 1.047 = 72.86911$
The nine patients residing outside Bladen County are added. This is the projected census on December 31, 2016.	$72.86911 + 9 = 81.86911$
Bladen County patient population is projected forward by one year to December 31, 2017, using the 4.7% five year AACR for SEDC-E.	$72.86911 \times 1.047 = 76.29395$
The 31 patients projected to transfer from SEDC-E to the new UCD facility are subtracted from the Bladen County patient population.	$76 - 31 = 45$
The nine patients residing outside Bladen County are added. This is the projected census on December 31, 2017.	$45 + 9 = 54$
Bladen County patient population is projected forward by one year to December 31, 2018, using the 4.7% five year AACR for SEDC-E.	$45 \times 1.047 = 47.115$
The nine patients residing outside Bladen County are added. This is the projected census on December 31, 2018 (OY1).	$47.115 + 9 = 56.115 (56)$
Bladen County patient population is projected forward by one year to December 31, 2019, using the 4.7% five year AACR for SEDC-E.	$47.115 \times 1.047 = 49.3294$
The nine patients residing outside Bladen County are added. This is the projected census on December 31, 2019 (OY2).	$49.3294 + 9 = 58.3294 (58)$

The applicant projects to serve 56 in-center patients on 16 stations, which is 3.5 patients per station ($56 \text{ patients} / 16 \text{ stations} = 3.5$), by the end of OY1 and 58 in-center patients on 16 stations, which is 3.63 patients per station ($58 \text{ patients} / 16 \text{ stations} = 3.63$), by the end of OY2 at SEDC-E. 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 applicant demonstrates that the needs of the population presently served at SEDC-E will continue to be adequately met following the proposed relocation of 10 dialysis stations from SEDC-E to the proposed new facility and that access for medically underserved groups will not be negatively impacted.

Therefore, the application is conforming to this criterion.

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

CA

In Section E.1, page 27, the applicant discusses the alternatives considered prior to submitting this application, which include:

- Maintain the Status Quo – The applicant states that this alternative was dismissed because the facility will eventually be at patient capacity and there is no room for expansion. The applicant also states that the home training space at SEDC-E is currently inadequate.
- Develop a Facility in Another Area of Bladen County – The applicant states that this alternative was dismissed due to the geographic location of the patient population proposed to be served.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

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

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

- 1. Total Renal Care of North Carolina, LLC d/b/a Bladenboro Dialysis shall materially comply with all representations made in the certificate of need application.**
- 2. Total Renal Care of North Carolina, LLC d/b/a Bladenboro Dialysis shall relocate no more than 10 dialysis stations from Southeastern Dialysis Center – Elizabethtown.**

3. **Total Renal Care of North Carolina, LLC d/b/a Bladenboro Dialysis shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 4. **Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify 10 dialysis stations at Southeastern Dialysis Center – Elizabethtown for a total of no more than 16 dialysis stations at Southeastern Dialysis Center – Elizabethtown upon project completion.**
 5. **Total Renal Care of North Carolina, LLC d/b/a Bladenboro Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new 10-station dialysis facility by relocating 10 dialysis stations from Southeastern Dialysis Center – Elizabethtown.

Capital and Working Capital Costs

In Section F.1, page 28, the applicant states that the projected capital cost is \$1,664,359, which includes \$1,052,777 in site and construction costs, \$152,400 for dialysis machines, \$95,000 for water treatment equipment, and \$364,182 for other equipment and costs.

In Sections F.10-12, page 31, the applicant projects \$191,283 in start-up expenses and \$701,227 in initial operating costs for the first six months of operations for a total projected working capital cost of \$892,510.

Availability of Funds

In Sections F.2, page 29, and F.13, pages 32-33, the applicant states that cash reserves/owner's equity is being used to finance the proposed project.

Exhibit F-5 contains a February 15, 2016 letter from the Chief Accounting Officer of DaVita HealthCare Partners, stating that DaVita HealthCare Partners has committed cash reserves in the amount of \$2,556,869 for the project's capital and working capital expenditures.

In Section F.8(b), page 30, the applicant states:

“The financial strength of the company precludes any financial impact upon the operation and performance of the expansion that this application proposes. Therefore, there is no appreciable impact on either this application or from any that has been approved previously or is currently under review.”

Exhibit F-7 contains the most recent audited financial statements for DaVita HealthCare Partners, Inc. for years ended December 31, 2013 and 2014. As of December 31, 2014, DaVita HealthCare Partners, Inc. had \$965,241,000 in cash and cash equivalents, \$17,942,715,000 in total assets and \$5,360,311,000 in total equity. The applicant adequately demonstrates the availability of funds for the capital needs of the project.

Financial Feasibility

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

Projected Revenues and Operating Expenses		
BD	Operating Year 1 CY 2018	Operating Year 2 CY 2019
Gross Patient Revenue	\$1,446,698	\$1,555,531
Deductions from Gross Patient Revenue	(\$60,528)	(\$63,497)
Net Patient Revenue	\$1,386,170	\$1,492,035
Total Operating Expenses	\$1,402,453	\$1,445,387
Net Income/Profit	(\$16,283)	\$46,648

The applicant's projections of treatments and revenues are reasonable based on the number of patients projected for the first two operating years. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

In Section H.1, page 35, the applicant provides projected staffing and salaries. Form A in Section R shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

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from Southeastern Dialysis Center - Elizabethtown (SEDC-E). The January 2016 Semiannual Dialysis Report (SDR) reports SEDC-E as having 24 certified dialysis stations. In Section D.1, page 25, the applicant states that two additional stations associated with Project I.D. #N-11021-15 were certified after the project was completed on December 18, 2015, bringing the current total to 26 certified stations. At completion of this project, BD will be certified for 10 dialysis stations and SEDC-E will be certified for 16 dialysis stations.

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

According to the January 2016 SDR, Bladen County has a surplus of one station. The Five Year AACR for Bladen County as published in the January 2016 SDR is -1.0 percent. However, the applicant states that the growth rate for DaVita patients in Bladen County (SEDC-E) has been 4.7 percent over the five year period from 2011 to 2015. On page 15, the applicant provides the following information (which the Project Analyst verified from the July 2012, July 2013, July 2014, and July 2015 SDRs):

Bladen County ESRD Patient Population Growth Rate 12/31/2010 – 12/31/2015					
DaVita Patients			All Patients		
Date	# Patients	Growth Rate	Date	# Patients	Growth Rate
12/31/2011	65	--	12/31/2010	95	--
12/31/2012	71	9.2%	12/31/2011	95	0.0%
12/31/2013	73	2.8%	12/31/2012	106	11.6%
12/31/2014	74	1.4%	12/31/2013	87	-17.9%
12/31/2015	78	5.4%	12/31/2014	89	-2.3%
5 Year AACR		4.7%	5 Year AACR		-1.0%

The applicant operates the only existing dialysis facility in Bladen County and there are no other approved facilities. As of June 30, 2015, SEDC-E was serving 77 patients weekly on 24 stations, which is 3.21 patients per station or 80.21 percent of capacity (77 patients / 24 stations = 3.21; 3.21 / 4 = 0.8021 or 80.21%). At the end of Operating Year One, the applicant projects that BD will be serving 32 patients weekly on 10 stations, which is 3.2 in-center patients per station or 80 percent of capacity (32 patients / 10 stations = 3.2; 3.2 / 4 = 0.80 or 80%). This meets the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b). Additionally, the applicant projects that at the end of Operating Year one, SEDC-E will be serving 56 in-center patients on 16 stations, which is 3.5 patients per station or 87.5 percent of capacity (56 patients / 16 stations = 3.5; 3.5 / 4 = 0.875 or 87.5%).

The applicant adequately demonstrates the need to develop a new facility by relocating 10 stations from SEDC-E based on the number of in-center patients it currently serves and

proposes to serve. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

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

C

In Section H.1, page 35, the applicant provides the following table to illustrate the projected staffing for BD at completion of the project.

BD – Proposed Facility Staffing	
Position	Projected # of FTEs
Medical Director*	
RN	2.0
Technician	4.0
Administrator	1.0
Dietitian	0.5
Social Worker	0.5
Home Training RN	0.5
Admin. Assistant	1.0
Biomed Technician	0.3
Total	9.8

*The Medical Director is a contract position and is not an employee of the facility.

The following table shows the applicant’s projected number of direct care staff FTEs at BD for OY2, as shown on page 38 of the application.

BD – Projected Direct Care Staff Hours – OY2					
Direct Care Positions	# FTEs* [a]	Hours / Year / FTE [b]	Total Annual FTE Hours [c] = [a] x [b]	Total Annual Hours of Operation ** [d]	FTE Hours / Hours of Operation [e] = [c] ÷ [d]
RN	2.0	2,080	4,160	3,120	1.3
Technician (PCT)	4.0	2,080	8,320	3,120	2.7
Total	6.0	2,080	12,480	3,120	4.0

* FTEs should match the direct care Total FTE Positions [a + c] listed in the Facility Staffing table in Section H, Question 1.

** Total annual hours of operation from the Proposed Hours of Operation table in Section H, Question 6.

The applicant states that the Medical Director is not directly employed by the facility but provides services on a contractual basis. In Section H.2, page 36, the applicant identifies Dr. James McCabe, a board certified nephrologist, as the prospective Medical Director for the proposed facility. Exhibit I-3 contains a copy of a letter from Dr. McCabe supporting the proposed facility and agreeing to serve as Medical Director.

In Section H.3, pages 36-37, the applicant describes its experience and process for recruiting and retaining staff. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section I, pages 39-41, the applicant discusses the providers of the necessary ancillary and support services for the proposed facility. The applicant discusses coordination with the existing health care system on pages 40-41. Exhibits I-1 and I-2 contain documents from DaVita Laboratory Services, the NC Division of Vocational and Rehabilitation Services, a vascular surgeon, a local transportation company, Cape Fear Valley Bladen County Hospital, and Carolinas Medical Center, which demonstrate that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information found in Section I and referenced Exhibits is reasonable and supports a finding of conformity with this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
 - (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;

- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

C

In Section K.2, page 45, the applicant states there will be 4,100 square feet of treatment area, which includes isolation space. The applicant provides the proposed facility's line drawings in Exhibit K-1. The drawing depicts an 8,269 square foot facility, which includes space for home PD patient support, with nine main floor dialysis stations and an isolation dialysis station for a total of 10 stations. In Section F.1, page 28, the applicant lists its projected costs, including \$1,030,000 for construction, \$22,777 in site costs, and \$611,582 in miscellaneous costs (which includes dialysis machines, water treatment equipment, other equipment and furniture not previously specified, and architect/engineering fees) for a total project cost of \$1,664,359. In Section K.1, pages 44-45, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design, and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

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

C

The dialysis facility proposed in this application is a new facility and as such has no history of service. In Section L.7, page 54, the applicant provides the CY 2015 payor mix for SEDC-E, as illustrated in the table below.

CY 2015 Payor Mix - SEDC-E			
Payor Type	% of Patients – Total	% of Patients – IC	% of Patients - PD
Medicare	24.2%	26.3%	15.6%
Medicaid	3.2%	2.5%	5.3%
Commercial Insurance	8.4%	5.3%	21.1%
Medicare/Commercial	23.2%	21.1%	31.6%
Medicare/Medicaid	34.7%	38.2%	21.1%
VA	6.3%	6.6%	5.3%
Total	100.0%	100.0%	100.0%

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

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Bladen	19%	52%	45%	26%	16%	20%
Statewide	15%	51%	36%	17%	10%	15%

Source: http://www.census.gov/quickfacts/table_2014 Estimate as of December 22, 2015.

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The *Southeastern Kidney Council Network 6 Inc. Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

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

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

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

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

C

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

“Bladenboro Dialysis has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993. The facility has no obligation under the Hill Burton Act.”

In Section L.6, pages 53-54, the applicant states that there have been no civil rights equal access complaints filed against any of the facilities owned by DaVita within the last five years.

The application is conforming to this criterion.

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

C

In Section L.1(b), page 51, the applicant provides the projected payor mix for Project Year 2, as shown in the table below.

Project Year 2 Payor Mix - BD			
Payor Type	% of Patients – Total	% of Patients – IC	% of Patients - PD
Medicare	24.2%	26.3%	15.6%
Medicaid	3.2%	2.5%	5.3%
Commercial Insurance	8.4%	5.3%	21.1%
Medicare/Commercial	23.2%	21.1%	31.6%
Medicare/Medicaid	34.7%	38.2%	21.1%
VA	6.3%	6.6%	5.3%
Total	100.0%	100.0%	100.0%

On page 50, the applicant states that the projected payor mix is based on the sources of patient payment that have been received by SEDC-E for the last full operating year.

In Section L.3(c), page 52, the applicant states:

“Bladenboro Dialysis admits and provides dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

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

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

C

In Section L.4, page 53, the applicant describes the range of means by which a person will have access to the dialysis services at BD, including referrals from other providers, family, and friends, which will result in a referral to a qualified nephrologist for evaluation as to medical necessity. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section M.1, page 55, the applicant states that it has offered the proposed facility as a clinical learning site for nursing students attending Bladen Community College. Exhibit M-2 contains a copy of a letter from the applicant to the president of Bladen Community College, offering the proposed facility as a clinical learning site for the school's nursing students. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

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

C

Total Renal Care of North Carolina, LLC (TRC) d/b/a Bladenboro Dialysis (BD) proposes to develop a new 10-station dialysis facility in Bladenboro by relocating 10 dialysis stations from Southeastern Dialysis Center - Elizabethtown (SEDC-E). The January 2016 Semiannual Dialysis Report (SDR) reports SEDC-E as having 24 certified dialysis stations. In Section D.1, page 25, the applicant states that two additional stations associated with Project I.D. #N-11021-15 were certified after the project was completed on December 18, 2015, bringing the current total to 26 certified stations. At completion of this project, BD will be certified for 10 dialysis stations and SEDC-E will be certified for 16 dialysis stations.

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

According to the January 2016 SDR, Bladen County has a surplus of one station. The Five Year AACR for Bladen County as published in the January 2016 SDR is -1.0 percent. However, the applicant states that the growth rate for DaVita patients in Bladen County (SEDC-E) has been 4.7 percent over the five year period from 2011 to 2015. On page 15, the applicant provides the following information (which the Project Analyst verified from the July 2012, July 2013, July 2014, and July 2015 SDRs):

Bladen County ESRD Patient Population Growth Rate 12/31/2010 – 12/31/2015					
DaVita Patients			All Patients		
Date	# Patients	Growth Rate	Date	# Patients	Growth Rate
12/31/2011	65	--	12/31/2010	95	--
12/31/2012	71	9.2%	12/31/2011	95	0.0%
12/31/2013	73	2.8%	12/31/2012	106	11.6%
12/31/2014	74	1.4%	12/31/2013	87	-17.9%
12/31/2015	78	5.4%	12/31/2014	89	-2.3%
5 Year AACR		4.7%	5 Year AACR		-1.0%

The applicant operates the only existing dialysis facility in Bladen County and there are no other approved facilities. As of June 30, 2015, SEDC-E was serving 77 patients weekly on 24 stations, which is 3.21 patients per station or 80.21 percent of capacity (77 patients / 24 stations = 3.21; 3.21 / 4 = 0.8021 or 80.21%). At the end of Operating Year One, the applicant projects that BD will be serving 32 patients weekly on 10 stations, which is 3.2 in-center patients per station or 80 percent of capacity (32 patients / 10 stations = 3.2; 3.2 / 4 = 0.80 or 80%). This meets the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b). Additionally, the applicant projects that at the end of Operating Year one, SEDC-E will be serving 56 in-center patients on 16 stations, which is 3.5 patients per station or 87.5 percent of capacity (56 patients / 16 stations = 3.5; 3.5 / 4 = 0.875 or 87.5%).

In Section N.1, page 56, the applicant discusses how the proposed project would have a positive impact on the cost-effectiveness, quality, and access to the proposed services. The applicant states:

“The development of Bladenboro Dialysis will have no effect on any dialysis facilities located in Bladen County or in counties contiguous to it. DaVita operates the other facility in the county.

The proposed facility will not have an adverse effect on competition since the patients already being served by DaVita will be transferring their care from one DaVita

facility to another DaVita facility, which will be more convenient for the patients who have indicated this in the letters they signed.”

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

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

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

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

C

In Exhibit O-3, the applicant identifies three kidney disease treatment centers located in North Carolina, owned and operated by the applicant, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. In Section O.3, page 57, the applicant states all three facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Exhibit O-3 contains copies of letters documenting that the facilities were determined to be back in compliance by CMS and the Division of Health Service Regulation. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- C- In Section C, pages 14-24, the applicant documents the need for the project and demonstrates that it will serve a total of 32 in-center patients on 10 stations at the end of the first operating year, which is 3.2 patients per station per week, or a utilization rate of 80 percent. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.
- (b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- NA- The applicant is not 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. The applicant is seeking to develop a new 10-station dialysis facility.
- (b) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 14-17, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.