

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: December 20, 2013

PROJECT ANALYST: Gregory F. Yakaboski

CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: N-10200-13/ Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center- Elizabethtown/ Add 3 dialysis stations (transfer of one station from Chadbourn Dialysis Center and two dialysis stations from Southeastern Dialysis Center-Whiteville) to the existing facility for a total of 27 stations / Bladen County

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 d/b/a Southeastern Dialysis Center- Elizabethtown/ proposes to relocate a total of 3 existing dialysis stations from two facilities in Columbus County (2 existing dialysis stations from SEDC-Whiteville and 1 existing dialysis station from the Chadbourn Dialysis Center) to the existing 24 station SEDC-Elizabethtown facility in Bladen County for a total of 27 dialysis stations at SEDC-Elizabethtown. This project is scheduled for completion on July 1, 2014. In this application, the applicant proposes to relocate dialysis stations between facilities. Therefore, neither the county need nor facility need methodologies in the 2013 State Medical Facilities Plan (SMFP) are applicable to this review. Additionally, Policy GEN-3: *Basic Principles* is not applicable because neither need methodology is applicable to the review and Policy GEN-4: *Energy Efficiency and Sustainability for Health Service Facilities* is not applicable because the capital expenditure of the proposed project is less than \$2.0 million.

However, Policy ESRD-2 is applicable to this review. Policy ESRD-2 states:

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

1. demonstrate that the proposal shall not result in a 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 Dialysis Report, and

2. demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent Dialysis Report.

The applicant proposes to relocate 3 existing certified dialysis stations from Columbus County to Bladen County. Columbus County is contiguous to Bladen County. Per Table B of the July 2013 Semiannual Dialysis Report Columbus County (the county that would be losing stations as a result of the proposed project) has a surplus of 11 dialysis stations and Bladen County (the county that would gain stations as a result of the proposed project) has a deficit of 5 dialysis stations. Columbus County would have a surplus of 8 dialysis stations ($11-3 = 8$) and Bladen County would still have a deficit of 2 dialysis stations ($5-3 = 2$) as a result of the proposed project. Therefore, the application is consistent with Policy ESRD-2 and 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.

NC

Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center- Elizabethtown/ proposes to relocate a total of 3 existing dialysis stations from two facilities in Columbus County (2 existing dialysis stations from SEDC-Whiteville and 1 existing dialysis station from the Chadbourn Dialysis Center) to the existing 24 station SEDC-Elizabethtown facility in Bladen County for a total of 27 dialysis stations at SEDC-Elizabethtown. This project is scheduled for completion on July 1, 2014.

Population to be Served

In Section III.7, page 22, the applicant provides projected patient origin for the first two years of operation following completion of the proposed project, as illustrated in the following table:

SEDC-Elizabethtown Dialysis Center -Projected Patient Origin

| COUNTY | YEAR ONE: 2014/2015 | | YEAR TWO: 2015/2016 | | COUNTY PATIENTS AS A PERCENT OF TOTAL | |
|--------|------------------------|------------------------------|------------------------|------------------------------|--|--------|
| | In-center patients | Home dialysis patients | In-center patients | Home dialysis patients | Year 1 | Year 2 |
| Bladen | 87 | 14 | 91 | 14 | 100% | 100% |
| TOTAL | 87 | 14 | 91 | 14 | 100% | 100% |

The applicant adequately identified the population proposed to be served. See discussion in the need analysis below regarding the reasonableness of the projections.

Need Analysis

The assumptions and methodology used to project in-center utilization are provided in Section II, pages 12-14, and Section III.7, pages 22-23. On page 23, the applicant states

“The Southeastern Dialysis Center-Elizabethtown had 71 in-center patients as of December 31, 2012 based on information included on Page 1 [sic] of the July 2013 Semiannual Dialysis Report (SDR). Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center- Elizabethtown is requesting a three-station expansion to the facility. Two of the stations will be transferred from the Southeastern Dialysis Center- Whiteville facility in Columbus County. One dialysis station will be transferred fro the Chadbourn Dialysis Center in Columbus County. The July 2013 SDR indicates in Table B on page 1 that there is a projected five-station deficit in Bladen County and a projected eleven-station surplus of stations in Columbus County.

In Section III.3, page 20, the applicant states that it projects transferring two stations and six in-center patients from the SEDC-Whiteville facility to the SEDC-Elizabethtown facility and one station and three in-center patients from the Chadbourn Dialysis Center.

On pages 23 the applicant states

Of the 71 in-center patients at SEDC-Elizabethtown, all of the patients lived in Bladen County as of December 31, 2012. The current year calculations indicating patient growth will be based on the 71 patients living in Bladen County. The nine [sic] Bladen County patients indicating an interest in transferring to SEDC-Elizabethtown have been added to the 71 Bladen County patients projected at the end of the current year for the purpose of calculating the utilization projections for the first two years of operation after the expansion.”

The following are the in-center utilization projections using the 4.6% Average Annual Change Rate for the Past Five Years as indicated on page 1 [sic] of the July 2013 Semiannual Dialysis Report for 71 in-center patients:

January 1, 2013 – June 30, 2013 – 71 patients X 1.1023 [sic] = 72.633

July 1, 2013 – June 30, 2014 -72.633 X 1.046 = 75.974118

July 1, 2014 = 75 Elizabethtown in-center patients + 6 Whiteville transfer in-center patients + 3 Chadbourn transfer in-center patients = 84 in-center patients.

July 1, 2014 – June 30, 2015 – 84 x 1.046 = 87.864

July 1, 2015 – June 30, 2016 – 87.864 x 1.046 = 91.905744

Operating Year One is projected to begin July 1, 2014 and end on June 30, 2015

Operating Year Two is projected to begin July 1, 2015 and end on June 30, 2016.

The SEDC-Elizabethtown facility is projected to have 87 in-center at the end of Operating Year 1 for a utilization rate of 80% or 3.2 patients per station based on 27 dialysis stations.

The SEDC-Elizabethtown is projected to have 91 in-center patients at the end of Operating Year 2 for a utilization rate of 84% or 3.3 patients per station based on 27 dialysis stations.”

On pages 23 the applicant states

“NOTE: The patient numbers for operating year 1 and 2 will be used to determine the number of treatments, operating revenue and operating expenses.”

The applicant projects the facility will serve 87 in-center patients or 3.22 in-center patients per station per week ($87/27 = 3.22$) by the end of Year One, which exceeds the 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

However, the applicant did not base its calculations on reasonable and supported assumptions:

In the first step in its methodology, set forth above, the applicant started with the 71 in-center patients it had as of December 31, 2012 and grew those 71 patients the five year average annual change rate for Bladen County for six months to determine the number of in-center patients for the SEDC-Elizabethtown facility as of June 30, 2013. See “*January 1, 2013 – June 30, 2013 – 71 patients X 1.1023 [sic] = 72.633*” Based on this calculation the applicant determined that there would be 72.633 or 72 in-center patients as of June 30, 2012. However, based on data submitted by the applicant the actual number of in-center patients

utilizing the SEDC-Elizabethtown facility as of June 30, 2013 was 68 patients (66 Bladen County residents, 1 Columbus County resident and 1 Sampson County resident). The actual number of patients dialyzing as of June 30, 2013 at SEDC-Elizabethtown was available to the applicant two and a half months prior to the application being submitted. Starting with the 68 in-center patients (which, to be conservative, includes the 2 out-of-county in-center patients cited above) as of June 30, 2013 the project analyst projected the number of in-center patients as of June 30, 2015, the end of Project Year 1.

July 1, 2013 to June 30, 2014: $68 \times 1.046 = 71.128$

July 1, 2014 = 71 Elizabethtown in-center patients + 6 Whiteville transfer in-center patients + 3 Chadbourn transfer in-center patients = 80 in-center patients.

July 2014 to June 30, 2015: $80 \times 1.046 = 83.68$

The Project Analyst projects the facility will serve 83 in-center patients or 3.074 in-center patients per station per week ($83/27 = 3.074$) by the end of Year One (even accepting that 9 in-center patients who currently reside in Bladen County but receive in-center dialysis treatment at a facility in Columbus County. See below) which does not meet the 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

Please note that the SEDC-Elizabethtown facility is the only dialysis facility in Bladen County and the SEDC-Whiteville and Chadbourn Dialysis Center are the only dialysis centers in Columbus County.

In addition, while the applicant did provide four letters from any patients residing in Bladen County and currently receiving dialysis at either the SEDC-Whiteville facility and three letters from patients currently receiving dialysis at the Chadbourn Dialysis Center indicating that they would consider or be willing to transfer to the SEDC-Elizabethtown facility if the proposed transfer of stations was granted the letters were all dated in either February or March of 2012. The application was filed on September 16, 2013. Furthermore, while the applicant projects 6 patients transferring from SEDC-Whiteville facility the applicant only provides letters from 4 patients currently receiving dialysis at the SEDC-Whiteville facility. See Exhibit 11. Further calling into doubt the relevance of letters dated approximately sixteen months prior to the submittal of the application, based on data supplied by the SEDC-Whiteville facility as of June 30, 2013 there were only 3 Bladen County residents receiving dialysis treatment at the SEDC-Whiteville facility and as of June 30, 2012 there were only 2 Bladen County residents receiving in-center dialysis treatment at the Chadbourn Dialysis Center. The data utilized is available to the applicant. Below, the project analyst projects patients per station as if all 5 of the Bladen County residents receiving treatment SEDC-Whiteville and Chadbourn Dialysis Center transferred to SEDC-Elizabethtown.

July 1, 2013 to June 30, 2014: $68 \times 1.046 = 71.128$

July 1, 2014 = 71 Elizabethtown in-center patients + 3 Whiteville transfer in-center patients + 2 Chadbourn transfer in-center patients = 76 in-center patients.

July 2014 to June 30, 2015: $76 \times 1.046 = 79.496$

At the end of Project Year 1 there are projected to be 79 patients / 27 stations = 2.925 patients per station / 4 = 0.731 or 73.15 % utilization

The Project Analyst projects the facility will serve 79 in-center patients or 2.93 in-center patients per station per week ($79/27 = 2.925$) by the end of Year One which does not meet the 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is not based on reasonable, credible and supported assumptions. The applicant does not adequately demonstrate the need for the proposed stations. Therefore, the application is not 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

DaVita HealthCare Partners Inc is the holding company that owns Total Renal Care, Inc and 85% of Total Renal Care of North Carolina, LLC. Total Renal Care of North Carolina, LLC owns all three of the facilities which are part of this application: 1) SEDC-Elizabethtown (Bladen County); 2) SEDC-Whiteville (Columbus County); and the Chadbourn Dialysis Center (Columbus County)

In Section III.3, (c) page 20, the applicant states

“SEDC-Whiteville currently has 26 certified dialysis stations. The facility has never used more than 24 stations. The July 2013 SDR indicates that SEDC-Whiteville had 64 in-center patients for a station utilization rate of 61%, based on 26 certified dialysis stations. By transferring two stations and six in-center patients to the SEDC- Elizabethtown facility, SEDC-Whiteville will have 24 certified stations and 58 in-center patients. Based on 58 in-center patients, the facility is projected to have a utilization rate of 60%. Therefore, the number of stations remaining as the SEDC-Whiteville facility will be adequate to meet the needs of the patient population.”

The Average Annual Change Rate for the Past Five Years in Columbus County is -3.3%. Table B of the July 2013 SDR states that there is a surplus of 11 dialysis stations in Columbus County.

According to Table A of the July 2013 SDR the SEDC-Whiteville facility had 64 in-center patients as of December 31, 2012. The following projects utilization of the SEDC-Whiteville facility for the first two project years:

January 1, 2013 – June 30, 2013: $64 \times -1.0165 = 62.944$

July 1, 2013 – June 30, 2014: $62.944 \times -1.033 = 60.867$

Subtract out the six patients projected to transfer to SEDC-Elizabethtown results in 51.687 in-center patients ($60.867 - 6 = 54.867$).

[Year 1] July 1, 2014 – June 30, 2015: $54.867 \times -1.033 = 53.056$

[Year 2] July 1, 2015 – June 30, 2016: $53.056 \times -1.033 = 51.305$

For Year 1 SEDC-Whiteville would have 24 stations (26 – 2 stations to be transferred) and 53 in-center patients for a utilization rate of 55.2% or 2.2 patients per station ($53 / 24 = 2.208$).

For Year 2 SEDC-Whiteville would have 24 stations and 51 in-center patients for a utilization rate of 53.1% or 2.1 patients per station ($51/24 = 2.125$).

Chadbourn Dialysis Center currently has 17 certified dialysis stations. The facility has never used more than 16 stations. The July 2013 SDR indicates that Chadbourn Dialysis Center had 48 in-center patients for a station utilization rate of 70%, based on 17 certified dialysis stations. By transferring one station and three in-center patients to the SEDC-Elizabethtown facility, Chadbourn Dialysis Center will have 16 certified stations and 45 in-center patients. Based on the 45 in-center patients, the facility is projected to have a utilization rate of 70%. Therefore, the number of stations remaining at the Chadbourn Dialysis Center will be adequate to meet the needs of the patient population.”

According to Table A of the July 2013 SDR the Chadbourn Dialysis Center had 48 in-center patients as of December 31, 2012. The following projects utilization of the Chadbourn Dialysis Center for the first two project years:

January 1, 2013 – June 30, 2013: $48 \times -1.0165 = 47.208$

July 1, 2013 – June 30, 2014: $47.208 \times -1.033 = 45.65$

Subtract out the three patients projected to transfer to Chadbourn Dialysis Center results in 42.65 in-center patients ($45.65 - 3 = 42.65$).

[Year 1] July 1, 2014 – June 30, 2015: $42.65 \times -1.033 = 41.24$

[Year 2] July 1, 2015 – June 30, 2016: $41.24 \times -1.033 = 39.879$

For Year 1 Chadbourn Dialysis Center would have 16 stations (16 – 1 stations to be transferred) and 41 in-center patients for a utilization rate of 64% or 2.562 patients per station ($41 / 16 = 2.562$).

For Year 2 Chadbourn Dialysis Center would have 16 stations and 39 in-center patients for a utilization rate of 60.9% or 2.4 patients per station ($39/16 = 2.437$).

The applicant adequately demonstrates that the needs of the population presently served will be met adequately by the proposed relocation and that the relocation of the three dialysis stations from Columbus County to Bladen County will have no negative effect on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain dialysis service in Columbus County. 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.

NC

In Section III.9, page 24, the applicant describes the alternatives considered prior to the submission of its application, which were to either maintain the status quo or increase the number of dialysis stations at the facility. The application is not conforming or conditionally conforming to all other applicable statutory and regulatory review criteria. See Criteria (3), (5), (6), (18a) and the Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. Therefore, applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative.

- (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.

NC

In Section VIII.1, pages 40-41, the applicant states the capital cost is projected to be \$76,784. In Section IX, page 44, the applicant states that no working capital will be needed.

In Section VIII, page 41, the applicant states it will fund the capital needs of the proposed project from the cash reserves of DaVita Inc., the parent company of Total Renal Care, Inc. and Total Renal Care of North Carolina, LLC. Exhibit 16 contains a letter, dated September 6, 2013, from the Chief Accounting Officer of DaVita, Inc. which states:

“I am the Chief Accounting Officer of DaVita, Inc., the parent and 100% owner of Total Renal Care, Inc. I also serve as the Chief Accounting Officer of Total Renal Care, Inc. which owns 85% of the ownership interests in Total Renal Care of North Carolina, LLC (“TRC”).

We are submitting a Certificate of Need Application to expand our SEDC-Elizabethtown ESRD facility by three dialysis stations. This will involve the transfer of two dialysis stations from Southeastern Dialysis Center-Whiteville and one dialysis station from the Chadbourn Dialysis Center.

The project calls for a capital expenditure of \$64,962 [sic]. This letter will confirm that DaVita, Inc. has committed cash reserves in the total sum of \$64,962. [sic] for the project capital expenditure. DaVita Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to Total Renal Care of North Carolina, LLC.”

In Exhibit 17, the applicant provides audited financial statements for DaVita Healthcare Partners Inc. (DaVita) which document that DaVita had \$533,748,000 in cash and cash equivalents as of December 31, 2012. (See page F-6 of Exhibit 17) The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

In Section X, pages 46-49, the applicant projects revenues will exceed expenses in the first three years of operation after completion of the project. The rates in Section X.1, page 46, are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services. However, the applicant does not adequately demonstrate that projected revenues and expenses are based on reasonable and supported projected utilization of the facility. See Criterion (3) for discussion which is hereby incorporated as if fully set forth herein.

Therefore, the applicant does not adequately demonstrate that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Consequently, the application is not conforming with 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.

NC

Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center- Elizabethtown proposes to relocate a total of 3 dialysis stations from Columbus County to the existing SEDC-Elizabethtown facility in Bladen County, the counties are contiguous. Upon project completion there will be a surplus of 8 dialysis stations in Columbus County and there will still be a deficit of 2 dialysis stations in Bladen County.

According to Table A of the July 2013 SDR as of December 31, 2012, the SEDC-Elizabethton facility had 24 certified stations and 71 in-center patients for a utilization of 73.96% or 2.958 patients per station [$71 / 24 = 2.958$; $2.958 / 4 = 0.73958$].

Further, based on data submitted to the Division of Health Service Regulation by the SEDC-Elizabethtown facility, as of June 30, 2013 the number of in-center patients had decreased by 3

patients from December 31, 2012 to June 30, 2013 [71 – 68 = 3]. Therefore, as of June 30, 2013, the only ESRD facility in Bladen County, the SEDC-Elizabethtown facility, was operating at only 70.8% or 2.833 patients per station [68/24 = 2.833; 2.833 / 4 = 0.7083] as of June 30, 2013. The facility does not currently meet the 3.2 patients per station per week required by 10A NCAC 14C .2203(b). The applicant projected: 1) that as of June 30, 2013 SEDC-Elizabethtown would have 72 in-center patients; and 2) that 9 Bladen County residents who currently receive in-center dialysis treatment outside the county would transfer to SEDC-Elizabethtown at the start of Project Year 1 (July 1, 2014). However, as discussed in Criterion 3, these assumptions and projections were not based on reasonable, credible and supported facts. See Criterion (3) for discussion which is hereby incorporated as if fully set forth herein.

Thus, the applicant does not adequately demonstrate that the proposed project will not result in the unnecessary duplication of existing in-center dialysis services. Therefore, the application is nonconforming 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 VII.1, page 35, the applicant states that the SEDC-Elizabethtown facility currently employs 18.1 full time equivalent staff (FTEs). The applicant further states on page 35, that the SEDC-Elizabethtown facility proposes to hire 2.0 additional FTEs upon project completion. Those FTE positions for which the applicant will hire are illustrated in the table below.

| SEDC-Elizabethtown facility Proposed New(FTE) Positions | |
|--|-------------|
| PCT | 2.00 |
| Total Proposed FTEs | 2.00 |

The applicant projects a total of 20.1 positions upon project completion and states on page 36 that there is no difficulty expected in recruiting staff. In Section VII.10, page 37, the applicant states provides a chart showing the shifts and the projected number of direct care staff per shift. In Section V.4(c), page 29, and Exhibit 21 the applicant identifies the Medical Director for the SEDC-Elizabethtown facility as Dr. John Herion. In Exhibit 10 the applicant provides a letter from Dr. Herion stating that he was the Medical Director of the facility. The applicant adequately documents the availability of resources, including health manpower and management personnel, for provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and

support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section V.1-2, page 27, the applicant lists the providers of the necessary ancillary and support services. Also see the applicant's response to 10A NCAC 14C .2204, Section II, pages 14-15. The information provided in Section V is reasonable and credible 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.

NA

- (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 VI.1, page 31 the applicant states:

“SEDC-Elizabethtown, by policy, has always made dialysis services available to all residents in its service area without qualification. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.”

In Section VI.1(b), page 31, the applicant reports that 95.3% of the patients who received treatments at the SEDC-Elizabethtown facility had some or all of their services paid for by Medicare, Medicaid or the VA in the past year. The table below illustrates the historical payment source of the facility:

| DIALYSIS CARE OF HOKE COUNTY | |
|-------------------------------------|-------------------|
| SOURCE OF PAYMENT | PERCENTAGE |
| Medicare | 14.1% |
| Medicaid | 2.4% |
| Medicare/Medicaid | 42.3% |
| Commercial Insurance | 4.7% |
| VA | 5.9% |
| Medicare/Commercial | 30.6% |
| Total | 100.0% |

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Bladen County and statewide.

| | CY 2009 Total # of Medicaid Eligibles as % of Total Population * | CY 2009 Total # of Medicaid Eligibles Age 21 and older as % of Total Population * | CY 2009 % Uninsured (Estimate by Cecil G. Sheps Center)* |
|---------------|---|--|---|
| Bladen County | 25% | 12.4% | 19.4% |
| Statewide | 17% | 6.7% | 19.7% |

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by SEDC-Elizabethtown. In fact, only 5.8% of all newly diagnosed ESRD patients (incident ESRD patients) in North Carolina's Network 6 were under the age of 35.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race and gender. However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. About 25% of the Medicare-covered patients had employer group plans as primary insurance, with Medicare as the secondary payer. Also, the CMS website states:

“Although the ESRD population in less than 1% of the entire U.S. population it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings. ...

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9) populations.”

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report (page 225) provides these national statistics for FY 2010: *“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy.”* Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”

The report provides 2010 ESRD spending, by payor as follows:

| |
|-------------------------------|
| ESRD Spending by Payor |
|-------------------------------|

| Payor | Spending in Billions | % of Total Spending |
|-----------------------------|-----------------------------|----------------------------|
| Medicare Paid | \$29.6 | 62.32% |
| Medicare Patient Obligation | \$4.7 | 9.89% |
| Medicare HMO | \$3.4 | 7.16% |
| Non-Medicare | \$9.8 | 20.63% |

Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 340.

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender as shown below:

| Number and Percent of Dialysis Patients by Age, Race and Gender | | |
|--|---------------------------|---------------------------------|
| | # of ESRD Patients | % of Dialysis Population |
| Ages | | |
| 0-19 | 89 | 1.0% |
| 20-34 | 451 | 4.8% |
| 35-44 | 773 | 8.3% |
| 45-54 | 1,529 | 16.4% |
| 55-64 | 2,370 | 25.4% |
| 65-74 | 2,258 | 24.2% |
| 75+ | 1,872 | 20.0% |
| Gender | | |
| Female | 4,237 | 45.35% |
| Male | 5,105 | 54.65% |
| Race | | |
| African American | 5,096 | 54.55% |
| White/Caucasian | 4,027 | 43.11% |
| Other | 219 | 2.3% |

Source: Southeastern Kidney Council (SKC) Network 6. Includes North Carolina, South Carolina and Georgia

The applicant demonstrates the medically underserved populations have adequate access to the services provided at the SEDC-Elizabethtown facility. 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

In Section VI.6 (a), page 34, the applicant states there have been no civil rights equal access complaints filed within the last five years. Therefore, 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 VI.1(c), page 32, the applicant provides the projected payor mix for the proposed services at the facility. The applicant projects no change from the current payor mix for dialysis visits as stated in Criterion (13a) above. The applicant demonstrates that medically underserved populations would 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 VI.5, pages 33-34, the applicant describes the range of means by which patients will have access to the proposed services. The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity with 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 V.3(c), page 29, the applicant states that it has "*offered the facility as a clinical learning site for nursing students from Bladen Community College.*" Exhibit 9 contains a copy of the agreement. The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion.

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

NC

Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center- Elizabethtown/ proposes to relocate a total of 3 existing dialysis stations from two facilities in Columbus County (2 existing dialysis stations from SEDC-Whiteville and 1 existing dialysis station from the Chadbourn Dialysis Center) to the existing 24 station SEDC-Elizabethtown facility in Bladen County for a total of 27 dialysis stations at SEDC-Elizabethtown.

Columbus County is contiguous to Bladen County. Per Table B of the July 2013 Semiannual Dialysis Report Columbus County (the county that would be losing stations as a result of the proposed project) has a surplus of 11 dialysis stations and Bladen County (the county that would gain stations as a result of the proposed project) has a deficit of 5 dialysis stations. Columbus County would have a surplus of 8 dialysis stations ($11-3 = 8$) and Bladen County would still have a deficit of 2 dialysis stations ($5-3 = 2$) as a result of the proposed project.

See Sections II, III, V, VI and VII. In particular, see Section V.7, pages 30, in which SEDC-Elizabethtown discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access.

In Section V.7, page 30, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states:

“The proposed expansion of the facility is an effort to provide dialysis services to this community and is not intended to be a competitive venture. There are no facilities operated by another provider in Bladen County.

There are five counties contiguous to Bladen County. DaVita HealthCare Partners, Inc., operating as Total Renal Care of North Carolina, LLC, operates the only dialysis facilities in Pender and Columbus Counties. Total Renal Care of North Carolina, LLC operates the St Pauls Dialysis Center in Robeson County. Fresenius Medical Care operates five facilities in Robeson County, four facilities in Cumberland County and two facilities in Sampson County. SEDC- Elizabethtown is not treating any patients who live in the counties were Fresenius operates facilities. Therefore, any expansion of this facility in order to meet the needs of ESRD patients living in Bladen County will have no effect on the competition in contiguous counties.”

The information provided by the applicant in the sections listed above is not reasonable or credible and does not adequately demonstrate that the expected effects of the proposal on competition include a positive impact on cost-effectiveness in Bladen County. This determination is based on the information in the application, and the following:

- The applicant does not adequately demonstrate the need to develop three additional dialysis stations at SEDC-Elizabethtown and that it is a cost-effective alternative. See discussion in Criterion (3) and (6), which are incorporated hereby as if fully set forth herein,

Therefore, the application is not 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

The applicant currently provides dialysis services as SEDC-Elizabethtown in Elizabethtown, NC. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen months immediately preceding the date of this decision. 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.

NC

The Criteria and Standards for End Stage Renal Disease Services, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The proposal is not conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C Section .2200. The specific findings are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes to increase stations in an existing certified facility or relocate stations must provide the following information:

.2202(a)(1) Utilization rates;

-C- See Section IV.1, page 25, and Exhibit 7 (copy of the July 2013 SDR).

- .2202(a)(2) *Mortality rates;*
-C- In Section IV.2, page 25, the applicant reports the 2010, 2011 and 2012 facility mortality rates.
- .2202(a)(3) *The number of patients that are home trained and the number of patients on home dialysis;*
-C- In Section IV.3, page 25, the applicant states “*SEDC-Wilmington had 14 home-trained patients in peritoneal dialysis and no patients on home hemodialysis.*”
- .2202(a)(4) *The number of transplants performed or referred;*
-C- In Section IV.4, page 25, the applicant states that 8 patients were referred for transplant evaluation and that 2 patients received a transplant in 2012.
- .2202(a)(5) *The number of patients currently on the transplant waiting list;*
-C- In Section IV.5, page 25, the applicant states there are 10 patients on the transplant waiting list.
- .2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
-C- See Section IV.6, page 26.
- .2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*
-C- In Section IV.7, page 26.

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

- .2202(b)(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100*
-NA- SEDC-Elizabethtown is an existing facility.
- .2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) timeframe for initial assessment and evaluation of patients for transplantation,*
 - (B) composition of the assessment/evaluation team at the transplant center,*
 - (C) method for periodic re-evaluation,*
 - (D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*
 - (E) Signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- NA- SEDC-Elizabethtown is an existing facility.

- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- SEDC-Elizabethtown is an existing facility
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- Exhibit 8 contains a copy of written policies and procedures for back up for electrical service in the event of a power outage.
- .2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- NA- SEDC-Elizabethtown is an existing facility
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- See Sections II.1, page 12; VII.2-3, pages 35-37 and, XI.6(e) and (g), pages 54-55.
- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- See Section III., pages 20-23.
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- SEDC-Elizabethtown is an existing facility
- .2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*
- C- In Section II, page 12, the applicant states, “Total Renal Care of North Carolina d/b/a Southeastern Dialysis Center-Elizabethtown will admit and provide 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.”

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- SEDC-Elizabethtown is an existing facility
- .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.*

- NC- In Section III.7, pages 22-23, the applicant projects to serve 87 in-center patients by the end of Year 1, which is 3.22 patients per station ($87 / 27 = 3.4$). However, projected utilization is not based on reasonable, credible and supported assumptions. See Criterion (3) for discussion which is hereby incorporated as if fully set forth herein. The project analyst projects the facility will serve 79 in-center patients or 2.93 in-center patients per station per week ($79/27 = 2.925$) by the end of Year One which does not meet the 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

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

- NC- In Section II, pages 12-14 and Section III.7, pages 21-23, the applicant provides the assumptions and methodology used to project utilization of the proposed facility. The assumptions and methodology are not reasonable and credible. See Criterion (3) for discussion which is hereby incorporated as if fully set forth herein.

10 NCAC 14C .2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

- .2204(1) *Diagnostic and evaluation services;*
 - C- See Section V.1, page 27.
- .2204(2) *Maintenance dialysis;*
 - C- See Section V.1, page 27.
- .2204(3) *Accessible self-care training;*
 - C- See Section V.1, page 27 and Section IV.3, page 26.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
 - C- See Section V.1, page 27 and Section V.2(d), page 28.
- .2204(5) *X-ray services;*
 - C- See Section V.1, page 27.
- .2204(6) *Laboratory services;*
 - C- See Section V.1, page 27.
- .2204(7) *Blood bank services;*
 - C- See Section V.1, page 27.
- .2204(8) *Emergency care;*
 - C- See Section V.1, page 27.
- .2204(9) *Acute dialysis in an acute care setting;*
 - C- See Section V.1, page 27.
- .2204(10) *Vascular surgery for dialysis treatment patients*
 - C- See Section V.1, page 27.
- .2204(11) *Transplantation services;*
 - C- See Section V.1, page 27.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
 - C- See Section V.1, page 27.
- .2204(13) *Transportation*
 - C- See Section V.1, page 27.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

- .2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100.*
- C- In Section VII.1, page 35, the applicant provides the proposed staffing. In Section VII.2, pages 35-36, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion.
- .2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
- C- See Section VII.5, page 36, and Exhibits 15, 21 and 22.