

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: July 27, 2012
PROJECT ANALYST: Gregory F. Yakaboski
CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: N-8801-12/ Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center- Elizabethtown/ Add 3 dialysis stations 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 December 12, 2012. In this application, the applicant proposes to relocate dialysis stations between facilities. Therefore, neither the county need nor facility need methodologies in the 2012 State Medical Facilities Plan (SMFP) are applicable to this review. Additionally, Policy GEN-3 is not applicable because neither need methodology is applicable to the review. 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 January 2012 Semiannual Dialysis Report Columbus County (the county that would be losing stations as a result of the proposed project) has a surplus of 8 dialysis stations and Bladen County (the county that would gain stations as a result of the proposed project) has a deficit of 6 dialysis stations. Columbus County would have a surplus of 5 dialysis stations ($8-3 = 5$) and Bladen County would still have a deficit of 3 dialysis stations ($6-3 = 3$) 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 December 12, 2012. SEDC-Elizabethtown has an agreement with SEDC-Wilmington to provide home training in peritoneal and home hemodialysis.

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: 2013		YEAR TWO: 2014		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	In-center patients	Home dialysis patients	In-center patients	Home dialysis patients	Year 1	Year 2
Bladen	85	0	94	0	91.5%	92.3%
Columbus	2	0	2	0	2.1%	1.9%
Sampson	5	0	5	0	5.3%	4.8%
Cumberland	1	0	1	0	1.1%	1.0%
TOTAL	93	0	102	0	100%	100%

The applicant adequately identified the population proposed to be served.

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 22-24. On page 23, the applicant states

“The Southeastern Dialysis Center-Elizabethtown had 70 in-center patients as of June 30, 2011 based on information included on Page 10 of the January 2012 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 January 2012 SDR indicates in Table B on page 19 that there is a projected six-station deficit in Bladen County and a projected eight-station surplus of stations in Columbus County.

Six patients receiving their daily dialysis treatment at the SEDC-Whiteville facility have signed letters that they will consider transfer to the SEDC-Elizabethtown facility if the transfer of stations is granted. All six of the patients live in Bladen County. In all six cases the patients live closer to the SEDC-Elizabethtown [sic] than to the Whiteville facility.”

In Section III.3, page 20, the applicant states that one station and three in-center patients will be transferred from the Chadbourn Dialysis Center to the SEDC-Elizabethtown facility.

On pages 23-25 the applicant states

Of the 70 in-center patients at SEDC-Elizabethtown, 62 lived in Bladen County as of June 30, 2011. Five patients lived in Sampson County, two patients lived in Columbus County and one patient in Cumberland County. The current year calculations indicating patient growth will be based on the 62 patients living in Bladen County. The nine Bladen County patients indicating an interest in transferring to SEDC-Elizabethtown have been added to the 68 Bladen County patients projected as 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 10.7% Average Annual Change Rate for the Past Five Years as indicated on page 19 of the January 2012 Semiannual Dialysis Report for 71 in-center patients:

January 1, 2012 – December 31, 2012 – 62 patients X 1.107 = 68.634

January 1, 2013 – December 31, 2013 – 77 patients X 1.107 = 85.239

January 1, 2014 – December 31, 2014 – 85.239 patients X 1.107 = 94.359573

Operating Year One is projected to begin January 1, 2013 and end on December 31, 2013

Operating Year Two is projected to begin on January 1, 2014 and end on December 31, 2014.

The SEDC-Elizabethtown facility is projected to have 93 in-center patients (85 Bladen County residents/5 Sampson County patients/ 2 Columbus County patients/ 1 Cumberland County patient) at the end of Operating Year 1 for a utilization rate of 86% or 3.4 patients per station based on 27 dialysis stations.

The SEDC-Elizabethtown facility is projected to have 102 in-center patients (94 Bladen County residents/5 Sampson County patients/ 2 Columbus County patients/ 1 Cumberland County patient) at the end of Operating Year 2 for a utilization rate of 94% or 3.7 patients per station based on 27 dialysis stations.”

On pages 23-24 the applicant states

“The facility will apply for additional stations as the facility qualifies based on facility based need.

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 93 in-center patients or 3.4 in-center patients per station per week ($93/27 = 3.4$) 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. The applicant’s initial calculation is “*January 1, 2012 – December 31, 2012 – 62 patients X 1.107 = 68.634.*” All of the applicant’s subsequent calculations and projected utilization is based on this initial calculation. The applicant states above that as of June 30, 2011 62 of the 70 in-center patients as SEDC-Elizabethtown lived in Bladen County. This is the basis of the

62 patients in the applicant's initial calculation. The applicant should have provided the actual number of Bladen County residents utilizing SEDC-Elizabethtown as of December 31, 2011. This information was in the applicant's possession at the time this application was filed. The application was not filed until March 15, 2012. Furthermore, according to data from the Southeastern Kidney Council, Network 6, the number of in-center dialysis patients from Bladen County had decreased almost 9% from July 13, 2011 and October 4, 2011 reports [89 in-center and 90 in-center patients, respectively) to January 9, 2012 [81 in-center patients]. Additional data from the Southeastern Kidney Council, Network 6 current as of April 3, 2012 reporting only 82 in-center patients from Bladen County shows that the in-center data from January 9, 2012 was not an anomaly.

The Southeastern Kidney Council (SEKC) Network 6 obtains patient data from the dialysis providers in North Carolina, South Carolina and Georgia including all the North Carolina facilities that serve patients in Bladen and Columbus Counties. The SEKC also provides data to the Medical Facilities Planning Branch, DHSR for preparation of the Semiannual Dialysis Reports. The overall in-center hemodialysis patient data for Bladen and Columbus Counties from July 13, 2011 to April 3, 2012 is illustrated in the table below.

In-Center Hemodialysis patients

	Bladen County	Columbus County
4/3/12	82	122
1/9/12	81	113
10/14/11	90	111
7/13/11	89	113

*Data from Southeastern Kidney Council, Network 6

The number of in-center dialysis patients actually increased by 9 in Columbus County (the county the applicant is requesting to transfer dialysis stations from) while decreasing by 7 in Bladen County (the county the applicant is requesting to transfer dialysis stations to).

The tables below are based on data from the last four Semiannual Dialysis Report's (SDR) and illustrate the number stations and in-center patients for SEDC-Elizabethtown; SEDC-Whiteville; and Chadbourn Dialysis Center as reported by the providers.

SEDC-Elizabethtown (Bladen County)

	Stations	In-Center Patients
July 2012	24	65
January 2012	24	70
July 2011	21	71
January 2011	21	65

SEDC- Whiteville (Columbus County)

	Stations	In-Center Patients
July 2012	26	65
January 2012	26	58
July 2011	27	61
January 2011	27	64

Chadbourn Dialysis Center (Columbus County)

	Stations	In-Center Patients
July 2012	17	45
January 2012	17	41
July 2011	17	41
January 2011	17	44

As shown in the tables the number of in-center patients receiving dialysis in Bladen County at the SEDC-Elizabethtown facility has remained the same while the number of in-center dialysis patients receiving dialysis in Columbus County has increased. 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, the applicant did not provide letters from any patients residing in Bladen County and currently receiving dialysis at either the SEDC-Whiteville facility or 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.

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.

NC

DaVita Inc is the holding company that owns Total Renal Care, Inc and 855 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 January 2012 SDR indicates that SEDC-Whiteville had 58 in-center patients for a station utilization rate of 56%, 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 52 in-center patients. Based on 52 in-center patients, the facility is projected to have a utilization rate of 54%. 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 -1.1%. Table B of the January 2012 SDR states that there is a surplus of 8 dialysis stations in Columbus County. According to Table A of the January 2012 SDR the SEDC-Whiteville facility had 58 in-center patients as of June 30, 2011. The following projects utilization of the SEDC-Whiteville facility for the first two project years:

July 1, 2011 – December 31, 2011 $58 \times -1.0055 = 57.68$

Subtract out the six patients projected to transfer to SEDC-Elizabethtown results in 51.68 in-center patients ($57.68 - 6 = 51.68$).

[Year 1] January 1, 2012 – December 31, 2012: $51.68 \times -1.011 = 51.11$

[Year 2] January 1, 2013 – December 31, 2013: $51.11 \times -1.011 = 50.55$

For Year 1 SEDC-Whiteville would have 24 stations and 51 in-center patients for a utilization rate of 47% or 2.12 patients per station ($51 / 24 = 2.12$).

For Year 2 SEDC-Whiteville would have 24 stations and 50 in-center patients for a utilization rate of 48% ($24 / 50 = 0.48$ or 2.08 patients per station ($50/24 = 2.08$)).

Chadbourn Dialysis Center currently has 17 certified dialysis stations. The facility has never used more than 16 stations. The January 2012 SDR indicates that Chadbourn Dialysis Center had 41 in-center patients for a station utilization rate of 60%, 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 38 in-center patients. Based on the 38 in-center patients, the facility is projected to have a utilization rate of 59%. 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 January 2012 SDR the Chadbourn Dialysis Center had 41 in-center patients as of June 30, 2011. The following projects utilization of the Chadbourn Dialysis Center for the first two project years:

July 1, 2011 – December 31, 2011 $41 \times -1.0055 = 40.77$

Subtract out the three patients projected to transfer to SEDC-Elizabethtown results in 37.77 in-center patients ($40.77 - 3 = 37.77$).

[Year 1] January 1, 2012 – December 31, 2012: $37.77 \times -1.011 = 37.35$

[Year 2] January 1, 2013 – December 31, 2013: $37.35 \times -1.011 = 36.94$

For Year 1 Chadbourn Dialysis Center would have 16 stations and 37.35 in-center patients for a utilization rate of 43.24% ($16/37 = 0.43$) or 2.31 patients per station ($37 / 16 = 2.31$)

For Year 2 Chadbourn Dialysis Center would have 16 stations and 36.94 in-center patients for a utilization rate of 44.4% ($16/36 = 0.44$) or 2.25 patients per station ($36 / 16 = 2.25$).

However, the applicant does not adequately demonstrate the need for the proposed transfer of stations from Columbus County to Bladen County. Furthermore, the applicant did not provide letters from any patients residing in Bladen County and currently receiving dialysis in Columbus County at either the SEDC-Whiteville facility or 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. See Criterion (3) for discussion which is hereby incorporated as if fully set forth herein.

The applicant does not 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 not 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, pages 24-25, 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), (7), (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 41-42, the applicant states the capital cost is projected to be \$64,962. In Section IX, page 46, the applicant states that no working capital will be needed.

In Section VIII, page 42, 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 March 10, 2011 [sic], 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 by transferring one dialysis station from Chadbourn Dialysis Center and two dialysis stations from SEDC-Whiteville. The project calls for a capital expenditure of \$64,962. 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, Inc. which document that DaVita, Inc. had \$393,752,000 in cash and cash equivalents as of December 31, 2011. The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

In Section X, pages 48-51, 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 48, 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 proposed 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 5 dialysis stations in Columbus County and there will still be a deficit of 3 dialysis stations in Bladen County. However, the applicant does not adequately demonstrate the need to add three dialysis stations to the existing facility for a total of 27 stations upon completion of this project.

The Southeastern Kidney Council (SEKC) Network 6 obtains patient data form the dialysis providers in North Carolina, South Carolina and Georgia including all the North Carolina facilities that serve patients in Bladen and Columbus Counties. The SEKC also provides data to the Medical Facilities Planning Branch, DHSR for preparation of the Semiannual Dialysis Reports. The overall in-center hemodialysis patient data for Bladen and Columbus Counties from July 13, 2011 to April 3, 2012 is illustrated in the table below.

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*Data from Southeastern Kidney Council, Network 6

The number of in-center dialysis patients actually increased by 9 in Columbus County (the county the applicant is requesting to transfer dialysis stations from) while decreasing by 7 in Bladen County (the county the applicant is requesting to transfer dialysis stations to).

The tables below are based on data from the last four Semiannual Dialysis Report's (SDR) and illustrate the number stations and in-center patients for SEDC-Elizabethtown; SEDC-Whiteville; and Chadbourn Dialysis Center as reported by the providers.

SEDC-Elizabethtown (Bladen County)

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Chadbourn Dialysis Center (Columbus County)

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As shown in the tables the number of in-center patients receiving dialysis in Bladen County at the SEDC-Elizabethtown facility has remained the same while the number of in-center dialysis patients receiving dialysis in Columbus County has increased. 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.

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 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 VII.1, page 37, the applicant projects the following staffing during the first two operating years.

POSITION	TOTAL FTES YEARS 1 AND 2
RN (dc)	3.0
Pt. Care Technician (dc)	11
Bio-Med Tech	0.7
Admin (dc)	1.0
Dietician	0.7
Social Worker	0.7
Unit Secretary	1.0
Other-reuse	1.0

TOTAL	19.1
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*dc: direct care staff

As shown in the above table, the applicant proposes a total of 19.1 full-time equivalent (FTE) positions, 15 of which will be direct care positions. In Section VII.4, page 38, the applicant states that it does not anticipate having any difficulty staffing the facility.

The following table shows hours of operation as proposed by the applicant in Section VII, on page 39:

WEEKLY HOURS OF OPERATION				
DAY	MORNING	AFTERNOON	EVENING	TOTAL
Monday	7	7	0	14
Tuesday	7	7	0	14
Wednesday	7	7	0	14
Thursday	7	7	0	14
Friday	7	7	0	14
Saturday	7	7	0	14
Sunday	0	0	0	0
Total	42	42	0	84
Total Hours Operation per Year (weekly hours x 52) 4,368				

The following table shows the number of FTE direct care staff positions the applicant proposes based on the number of hours the facility will operate, as reported by the applicant in Section VII, page 39:

	# FTEs	Hrs/Yr/FTE	TOTAL FTE HOURS (ANNUAL)	TOTAL HRS OF OPERATION (ANNUAL)	FTE HRS/HRS OF OPERATION
RN	3	2,080	6,240	4,368	1.4
Techs	11	2,080	22,880	4,368	5.2
Admin	1	2,080	2,080	4,368	0.5
Total	15	2,080	31,200	4,368	7.1

Based on the proposed operating hours for the facility, it will be open 4,368 hours a year. In Section VII, page 37, the applicant projects 15 total direct care FTEs. Assuming one FTE works 2,080 hours annually, 15 FTEs would work a total of 31,200 hours annually, which is sufficient to cover the 4,368 hours of operation. The applicant proposes more than sufficient direct care staff to provide the proposed services.

In addition, the facility projects to serve 93 in-center patients in Year One on 27 stations in 2 shifts, per day, Monday through Saturday. The following table illustrates the maximum number of in-center patients per shift.

TIME/SHIFT	M/W/F PATIENTS	T/TH/SA PATIENTS
Morning (27 stations)	27	27
Afternoon (27 Stations)	27	27

As shown in the table above, the facility would be able to dialyze up to a maximum of 108 in-center patients on 27 dialysis stations, assuming one patient per station per shift and two shifts per day, Monday through Saturday. On page 23, the applicant states it projects to serve 102 in-center patients in Year Two on 27 stations.

In Section V.4(c), page 36, the applicant states that John Herion, MD, the current Medical Director of the facility has indicated his willingness to continue to serve.

The information regarding the availability of resources, including health manpower and management personnel, for the provision of the services provided in Section VII is reasonable and credible and supports a finding of conformity with 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, pages 28-29, the applicant lists the providers of the necessary ancillary and support services. SEDC-Elizabethtown has an agreement with SEDC-Wilmington to provide home training in peritoneal and home hemodialysis. 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(b), page 33, the applicant reports that 93.2% of the patients who received treatments at the SEDC-Elizabethtown facility had some or all of their services paid for by Medicare or Medicaid 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	13.5%
Medicaid	1.4%
Medicare/Medicaid	45.9%
Commercial Insurance	4.1%
VA	2.7%
Medicare/Commercial	32.4%
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 as of June 2010 and CY2008-CY 2009, respectively. The data in the table were obtained on May 24, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	Total # of Medicaid Eligible as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
Bladen	25%	12.4%	19.4%
Columbus	28%	13.1%	20.4%
Sampson	25%	10.1%	24.0%
Cumberland	18%	7.4%	20.3%
Statewide	17%	6.7%	19.7%

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 the SEDC-Elizabethtown facility.

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 or 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. Also, 9% are dually eligible for Medicare/Medicaid. About 25% of the Medicare-covered patients had employer group health plans as primary insurance, with Medicare as the secondary payer. Also, the CMS website states:

“Although the ESRD population is 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.”

The applicant demonstrates that medically underserved populations currently have adequate access to the dialysis 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 36, the applicant states there have been no civil rights 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 34, 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 36-36, 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 26, the applicant states that it has “*offered the facility as a clinical learning site for nursing students from Bladen Community College.*” Exhibit 10 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

See Sections II, III, V, VI and VII. In particular, see Section V.7, pages 31-32, 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. The information provided by the applicant in those sections 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, quality and access to dialysis services 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;

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 26, and Exhibit 7 (copy of the January 2012 SDR).

.2202(a)(2) Mortality rates;

-C- In Section IV.2, page 26, the applicant reports the 2009, 2010, and 2011 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 26, the applicant states “*SEDC-Wilmington provides home training for patients living in Bladen County under an agreement with SEDC-Wilmington.*”

.2202(a)(4) The number of transplants performed or referred;

-C- In Section IV.4, page 27, the applicant states that 12 patients were referred for transplant evaluation and that no patients received at transplant in 2011.

.2202(a)(5) The number of patients currently on the transplant waiting list;

-C- In Section IV.5, page 27, the applicant states there are 5 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 27.

.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 27.

(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, pages 37-38 and, XI.6(e) and (g), pages 56-57.*
- .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 18-24.*
- .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 22-24, the applicant projects to serve 93 in-center patients by the end of Year 1, which is 3.4 patients per station ($93 / 27 = 3.4$). However, projected utilization is not based on reasonable, credible and supported assumptions. See Criterion (3) for additional discussion.

.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 20-24, 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 additional discussion.

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 28.
- .2204(2) *Maintenance dialysis;*
 - C- See Section V.1, page 28.
- .2204(3) *Accessible self-care training;*
 - C- See Section V.1, page 28 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 28.
- .2204(5) *X-ray services;*
 - C- See Section V.1, page 28.
- .2204(6) *Laboratory services;*
 - C- See Section V.1, page 28.
- .2204(7) *Blood bank services;*
 - C- See Section V.1, page 28.
- .2204(8) *Emergency care;*
 - C- See Section V.1, page 28.
- .2204(9) *Acute dialysis in an acute care setting;*
 - C- See Section V.1, page 28.
- .2204(10) *Vascular surgery for dialysis treatment patients*
 - C- See Section V.1, page 28.
- .2204(11) *Transplantation services;*
 - C- See Section V.1, page 28.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
 - C- See Section V.1, page 28.
- .2204(13) *Transportation*
 - C- See Section V.1, page 28.

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 37, the applicant provides the proposed staffing. In Section VII.2, pages 37-38, 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 38, and Exhibits 15, 21 and 22.