

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 30, 2015

Project Analyst: Bernetta Thorne-Williams
Team Leader: Lisa Pittman

Project ID #: P-10351-14
Facility: Southeastern Dialysis Center-Jacksonville
FID #: 956056
County: Onslow
Applicant(s): Total Renal Care of North Carolina, LLC
Project: Add five dialysis stations and relocate three existing dialysis stations from SEDC-Kenansville for a total of 33 stations upon completion of Project I.D. # P-10266-14 (add 1 station), Project I.D. # P-10123-13 (relocate 18 stations) and this project

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-Jacksonville (SEDC-Jacksonville) is currently certified for 42 in-center dialysis stations. In this application, the applicant proposes to add five dialysis station and to relocate three existing stations from SEDC-Kenansville for a total of 33 stations upon completion of Project I.D. # P-10266-14 (add one station to the facility), Project I.D. # P-10123-13 (relocate 18 stations to New River Dialysis to develop a new facility), and this project.

Need Determination

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of eight dialysis stations in Onslow County, however, because the deficit identified in the SDR is less than ten stations, a new dialysis facility cannot be considered, but new dialysis stations can be added to an existing facility. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology because the utilization rate reported for SEDC-Jacksonville in the July 2014 SDR is 3.4 patients per station, or 85.12%. This utilization rate was calculated based on 143 in-center dialysis patients and 42 certified dialysis stations as of December 31, 2013 (143 patients / 42 stations = 3.40 patients per station). Application of the facility need methodology indicates additional stations are needed for the facility, as illustrated in the following table

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/13		85.1%
Certified Stations		42
Pending Stations		1
Total Existing and Pending Stations		43
In-Center Patients as of 12/31/13(SDR2)		143
In-Center Patients as of 6/30/13 (SDR1)		138
Step	Description	
(i)	Difference (SDR2 - SDR1)	5
	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/13	0.0725
(ii)	Divide the result of Step (i) by 12	0.0060
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/12 until 12/31/13)	0.0725
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	153.3623
(v)	Divide the result of Step (iv) by 3.2 patients per station	47.9257
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	4.9257

Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established, [...] up to a maximum of ten stations.*” As shown in the table above, based on the facility need methodology for dialysis stations, SEDC-Jacksonville has a need for five additional stations. However, the applicant is applying for a total of eight additional stations, three of those stations, are based on Policy ESRD-2. The applicant proposes to add a total of eight stations and therefore, the application is consistent with both the facility and county need determinations for dialysis stations.

Policies

Additionally, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, is not applicable to this review as the applicant proposes no capital cost associated with the proposed project. However, Policy ESRD-2: Relocation of Dialysis Stations and Policy GEN-3: Basic Principles, are both 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:

- (A) 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 North Carolina Semiannual Dialysis Report, and*
- (B) 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 North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate three existing dialysis stations from SEDC-Kenansville in Duplin County, which is contiguous to Onslow County. In Section IV.1, page 31, the applicant reports that SEDC-Jacksonville was serving one patient from Duplin County as of December 31, 2013. The July 2014 SDR showed a surplus of 12 dialysis stations in Duplin County and a deficit of eight dialysis stations in Onslow County. Additionally, the utilization rate reported for SEDC-Kenansville in the same SDR is 2.88 patients per station, or 72.06%. This utilization rate was calculated based on 49 in-center dialysis patients and 17 certified dialysis stations as of December 31, 2013 (49 patients / 17 stations = 2.88 patients per station). The transfer of three existing dialysis stations from Duplin County to Onslow County will decrease the number of surplus stations in Duplin County to nine and decrease the deficit of stations in Onslow County to five. Consequently, the application is consistent with Policy ESRD-2.

Policy GEN-3 states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these

concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section II.1, pages 19-20, Section II.3, pages 21-22, Section V.7, page 36, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section VI.1, pages 37-40 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section III.9, pages 29-30, Section V.7, page 36, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need. Therefore, the application is consistent with Policy GEN-3.

Conclusion

In summary, the application is consistent with the facility and county need determinations in the July 2014 SDR. The application is also consistent with Policy ESRD-2 and Policy GEN-3. Therefore, the application is conforming to this criterion.

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

C

SEDC-Jacksonville currently operates a 42-station dialysis facility located in Jacksonville, in Onslow County. The applicant proposes to add five dialysis stations and to relocate three existing dialysis from SEDC-Kenansville to the existing SEDC-Jacksonville facility for a total of 33 certified dialysis stations upon completion of this project, Project I. D. # P-10266-14 (add one station) and Project I.D. # P-10123-13 (relocate 18 stations to New River Dialysis to develop a new facility). The applicant provided home hemodialysis training and support at SEDC-Jacksonville, however, the home training program was relocated to the New River Dialysis facility effective, January 1, 2015. The July 2014 SDR reports SEDC-Jacksonville operated with 42 certified in-center dialysis stations and 143 in-center patients as of December 31, 2013.

Population to be Served

In Section IV.1, page 31, the applicant identifies the population it served, as of December 31, 2013, as illustrated in the table below.

SEDC-JACKSONVILLE		
COUNTY OF RESIDENCE	IN-CENTER PATIENTS	HOME-TRAINED PATIENTS
Onslow	141	28
Jones	1	0
Duplin	1	0
Carteret	0	2
Craven	0	3
Total	143	33

In Section III.7, page 27, the applicant projects the number of in-center patients to be served in the first two years of operation following project completion, as illustrated in the following table:

SEDC-Jacksonville				
County	Operating Year 1 2016	Operating Year 2 2017	County In-Center Patients as % of Total	
	In-Center	In-Center	Year 1	Year 2
Onslow	111	121	98.2%	98.4%
Jones	1	1	0.9%	0.8%
Duplin	1	1	0.9%	0.8%
Total	113	123	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section III.7, pages 27-29, the applicant provides the assumptions and methodology used to project the number of patients expected to utilize SEDC-Jacksonville. The projections are based on the following assumptions:

The majority of patients projected to utilize SEDC-Jacksonville will be Onslow County residents. The projections are based on the following assumptions:

- The SEDC-Jacksonville had 143 in-center patients dialyzing on 42 certified stations as of December 31, 2013.
- The applicant transferred 18 certified stations and its home hemodialysis training program to New River Dialysis effective January 1, 2015 (see Project I. D # P-10123-13)
- The applicant was approved for one additional station (see Project I.D. # P-10266-14).
- The applicant assumes there is a need for eight additional stations in Onslow County according to Table B of the July 2014 SDR which indicates an eight station deficit within the county.
- Based on the facility need methodology, SEDC-Jacksonville could add up to five stations at the existing facility.
- The applicant proposes to transfer three existing stations from SEDC-Kenansville, which is located in the contiguous county of Duplin, to SEDC-Jacksonville.
- It is assumed that the number of dialysis patients living in Onslow County is projected to grow at a rate of 8.7% based on the Onslow County Five Year Average Annual Change Rate (AACR) as indicated in Table B of the July 2014 Semiannual Dialysis Report.

In Section III.7, pages 27-29, the applicant states in-center utilization projections begin with 141 in-center patients living in Onslow County and are increased by the Onslow County five year AACR of 8.7%. No growth was added for the patients that reside within other counties, as shown below.

$$\textit{"January 1, 2014-December 31, 2014 - 141 in-center patients X 1.087 = 153.267"}$$

The applicant then adds in the two patients from other counties (Jones and Duplin) for a beginning census of 155 patients as of December 31, 2014. The applicant then subtracts the 58 patients that will transfer to the New River Dialysis Center, as of January 1, 2015, which

leaves 97 in-center patients ($155-58=97$). The applicant then subtracts the two patients from other counties for a beginning census of 95 ($97-2=95$) Onslow County patients projected to utilize SEDC-Jacksonville as of January 1, 2015. Using the projected growth rate of 8.7 % the applicant projects the following utilization at SEDC-Jacksonville, as illustrated below:

*“January 1, 2015-December 31, 2015 – 95 in-center patients X 1.087 = 103.265
January 1, 2016-December 31, 2016 – 103 in-center patients X 1.087 = 111.961*

January 1, 2017-December 31, 2017– 111.961 in-center patients X 1.087 = 121.701”

The applicant reports that Operating Year 1 (OY1) is projected to be January 1 – December 31, 2016 and Operating Year 2 (OY2) is January 1 – December 31, 2017. The applicant projects to have 111 Onslow County residents dialyzing on 33 in-center dialysis stations at SEDC-Jacksonville in OY1. The applicant then adds back in the two patients from Jones and Duplin County for a projected ending census in OY1 of 113 in-center patients for a utilization rate of 85.6% or 3.42 patients per station which is based on ($113 \text{ patients} / 33 \text{ dialysis stations} = 3.42/4 = 85.6\%$). The applicant projects to have 121 Onslow County residents dialyzing at SEDC-Jacksonville in OY2. The applicant then adds back in the two patients from Jones and Duplin County for a projected ending census in OY2 of 123 in-center patients for a utilization rate of 93.2% or 3.73 patients per station which is based on ($123 \text{ patients} / 33 \text{ dialysis stations} = 3.727/4 = 93.18\%$).

The applicant’s projected in-center patient utilization at the end of Operating Year One exceeds the 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Home Training

In Section II.1, page 16 and Section III.7, page 29, the applicant discusses its relocating of its home training program from SEDC-Jacksonville to the New River Dialysis Center on or about January 1, 2015. As of December 31, 2013, the applicant reports that the home training program had 33 patients (28 from Onslow County, 3 from Craven County and 2 from Carteret County). The applicant states that the facility experienced a 10% increase in its home training population from December 31, 2012 to December 31, 2013. The applicant projects that the relocated training program will continue to grow at roughly the same rate.

Access to Services

In Section VI.1, page 37, the applicant states:

“SEDC-Jacksonville, by policy, has always made dialysis services available to all residents in its service area without qualifications. 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.”

The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identified the population to be served, demonstrated the need the population has for the project and the demonstrated extent to which all residents of the area, in particular underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to relocate three existing certified dialysis stations from SEDC-Kenansville and to add five dialysis stations, based on the facility need methodology, for a total of 33 stations upon completion of Project I.D. # P-10123-13 (relocate 18 stations to New River Dialysis to develop a new facility), Project I.D. # P-10266-14 (add one station to the facility) and this project.

The July SDR reported SEDC-Kenansville had 49 in-center patients dialyzing on 17 dialysis stations for a utilization rate of 72.06% as of December 31, 2013. The applicant states on page 20 that three dialysis stations are proposed to transfer to SEDC-Jacksonville. This would leave 14 dialysis stations and 49 in-center patients at SEDC-Kenansville. Based on the proposed reduction of dialysis station and the in-center patient population remaining consistent, SEDC-Kenansville has the potential of having 3.5 patients per station with a utilization rate of 87.5% ($49/14 = 3.5/4 = 87.5\%$).

The Duplin County Average Annual Change Rate for the past 5 years, as reported in the July 2014 SDR, is 1.0%. The same SDR also reports a surplus of 12 dialysis stations in Duplin County. The surplus would be reduced to nine stations.

The applicant states the medically underserved population will continue to have access to services provided by DVA as stated in Section VI.1, pages 38-39. Therefore, the applicant demonstrates that the needs of the population presently served at SEDC-Kenansville will be adequately met following the relocation of three stations from SEDC-Kenansville to SEDC-Jacksonville. Additional discussion relating to promoting equitable access in Criterion (13) is incorporated herein by reference.

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

CA

In Section III.9, pages 29-30, the applicant states the following two alternatives were considered:

- Maintaining the Status Quo – The applicant concluded that this was not the best option because the patient population of Onslow County continues to grow, as is evident by the County Need Determination which indicates a deficit of eight stations in Onslow County, as reported in the July 2014 SDR.
- Develop the Facility as Proposed – The applicant concluded that the development of the project, as proposed, to relocate three existing stations based on the Policy ESRD-2 and to add five stations based on the facility need determination was the best alternative to meet the growing need for dialysis services in Onslow County.

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

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

- 1. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville shall materially comply with all representations made in the certificate of need application.**
- 2. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville shall add no more than five additional dialysis stations at SEDC-Jacksonville and relocate no more than three dialysis stations from SEDC-Kenansville to SEDC-Jacksonville for a total of no more than 33 dialysis stations upon completion of this project, Project I.D. # P-10266-14 and Project I.D. # P-10123-13; including any home hemodialysis or isolation stations.**
- 3. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville shall install plumbing and electrical wiring through the walls for no more than 33 stations upon projection completion.**
- 4. Prior to issuance of the certificate of need, Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville shall submit documentation of an invitation to a professional training program in the Jacksonville area to use the facility for training students.**

5. **After certification of the three stations relocated to Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville, Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Kenansville shall take the necessary steps to decertify three stations at SEDC-Kenansville for a total of no more than 14 dialysis stations.**
 6. **Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, page 48 and Section IX.1 page 52, the applicant states that there will be no capital cost or working capital expenses associated with the proposed project. Exhibit 19 of the application contains the audited financial statements for DaVita HealthCare Partners Inc. for the fiscal year ended December 31, 2013. As of December 31, 2013, DaVita HealthCare Partners Inc. had \$946,249,000 in cash and cash equivalents, \$17,098,877,000 in total assets and \$5,302,841,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project, should a need arise.

In Section X.1, page 54, the applicant provides the allowable charges, per treatment, for each payment source for SEDC-Jacksonville, as illustrated in the table below:

Payor Source	Charge per Treatment
Medicare	\$239.02
Medicaid	\$143.00
Medicare/Medicaid	\$239.02
Commercial Insurance	\$1,175.00
VA	\$193.00
Medicare/Commercial	\$239.02

The applicant projects revenues in Section X.2, page 55 and operating expenses in Section X.4, page 59, of the application. In Section X.2-X.4, pages 55-59, the applicant reports projected revenues and expenses for SEDC-Jacksonville, as illustrated in the table below:

SEDC-Jacksonville		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$4,733,900	\$5,125,355

Total Operating Costs	\$4,111,634	\$4,374,822
Net Profit	\$622,266	\$750,533

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable, credible and supported. See Section X of the application for the applicant's assumptions.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of this project shall any arise. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville proposes to add five dialysis stations and to relocate three existing stations from SEDC-Kenansville to the existing facility for a total of 33 certified dialysis stations upon project completion and completion of Project I.D. # P-10266-14 (add one station to the existing facility) and Project I.D. # P-10123-13 (relocate 18 stations to New River Dialysis).

The July 2014 SDR reports that there are two ESRD facilities in Onslow County; SEDC-Jacksonville and New River Dialysis. New River Dialysis is projected to be operational effective January 1, 2015. Both facilities are owned and operated by DaVita HealthCare Partners, Inc.

As reported in the July 2014 SDR, the SEDC-Jacksonville operated with 42 certified stations and 143 in-center patients with a utilization rate of 85.12% as of December 31, 2013. Additionally, the July SDR identified a deficit of eight dialysis stations in Onslow County.

Consequently, the applicant adequately demonstrates the proposal would not result in the unnecessary duplication of existing health service capabilities or facilities. 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 43, the applicant provides projected staffing for SEDC-Jacksonville, which includes a reduction in the number of Full-Time Equivalent (FTE) Positions, upon completion of Project I.D. # P-10266-14 (add one station), Project I.D. # P-10123-13 (relocate

18 stations to develop New Rive Dialysis), and this project, as illustrated in the following table:

SEDC-JACKSONVILLE		
POSITION	CURRENT FTES	PROJECTED FTES
Registered Nurse	5.0	4.0
Home-training RN	2.0	0
Patient Care Technician	17.0	14.0
Bio-Medical Technician	1.0	1.0
Administrative	1.0	1.0
Dietician	1.5	1.0
Social Worker	1.5	1.0
Unit Secretary	2.0	1.0
Reuse	2.0	2.0
TOTAL	33.0	25.0

The applicant projects a total of 25 FTE positions upon completion of this project, Project I.D. # 10266-14 and Project I.D. # P-10123-13, which is a reduction of eight FTE positions. The applicant indicates that along with the 18 stations relocated to New River Dialysis Center that existing FTE's were also relocated to establish the new dialysis facility. On pages 44-45, the applicant discusses DaVita HealthCare Partners' recruitment policy and states that they do not anticipate difficulty in recruiting and retaining qualified staff because of their aggressive recruiting practice and their competitive salary structure. In Section V.4, page 35, the applicant identifies the Medical Director for SEDC-Jacksonville as Dr. George Thomas. In Exhibit 13 the applicant provides a letter from Dr. Thomas indicating his support for the project. Additionally, in Section VII.10, page 46, the applicant states SEDC-Jacksonville will operate two shifts, six days a week from 6:00 a.m. to 4:00 p.m., with nine direct care staff and two RNs each shift.

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, page 33, the applicant lists the proposed providers of the necessary ancillary and support services. Onslow Memorial Hospital provides the following services: emergency, acute hemodialysis, diagnostic evaluation, X-ray, blood bank, and vascular surgery. The

other services are provided by the individual providers listed in the table provided on page 33. The applicant discusses coordination with the existing health care system in Section V.2-V.6, pages 34-36. See Exhibit 14 for a copy of DVA's Dialysis Regulatory and Ancillary Policies and Procedures. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

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

NA

- (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 37, the applicant reports that 85.1% of the patients who received treatments at SEDC-Jacksonville had some or all of their services paid for by Medicare or Medicaid in the past year. The tables below illustrate the historical payment source for the facility:

2013 SEDC-JACKSONVILLE PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	19.6%
Medicaid	3.4%
Medicare/Medicaid	21.6%
Commercial Insurance	6.8%
VA	8.1%
Medicare/Commercial	40.5%
Total	100.0%

The applicant also includes its historical payor mix for its home training component on page 38 of the application. The home training program is being relocated to the New River Dialysis Center, effective January 1, 2015.

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Durham County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Onslow County	11%	4.2%	23.4%
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 dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/21/2013, page 99*).¹

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

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis”*² (p. 216)

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender and race, which show that 65.4% were white, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p.218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 216). The report further states:

“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.” (p. 216).

The *2013 USRDS Annual Data Report* provides 2011 ESRD spending by payor, as follows:

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

² www.usrds.org/adr.aspx

ESRD Spending by Payor		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
Total	\$49.2	100.0%

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2013		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
Gender		
Female	6,845	44.5%
Male	8,544	55.5%
Race		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.³

The applicant demonstrates that medically underserved populations currently have adequate access to services available at SEDC-Jacksonville. 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;

³<http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

C

In Section VI.1(f), page 40, the applicant states, “*SEDC-Jacksonville has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons...*”

In Section VI.6(a), page 41, the applicant states there have been no civil rights access complaints filed against the facility or its parent company within the past five years. The application is conforming to this criterion.

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

C

In Section VI.1(c), page 38, the applicant provides the projected payor mix for the proposed dialysis services at the facility. The applicant projects no change from the current payor mix, as illustrated in the table below.

2013 SEDC-JACKSONVILLE PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	19.6%
Medicaid	3.4%
Medicare/Medicaid	21.6%
Commercial Insurance	6.8%
VA	8.1%
Medicare/Commercial	40.5%
Total	100.0%

The applicant demonstrates that the elderly and medically underserved populations will continue to have adequate access to the proposed dialysis services at SEDC-Jacksonville. 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 40-41, the applicant describes the range of means by which patients will have access to the proposed dialysis services. The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity to this criterion.

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

CA

In Section V.3, page 35, the applicant states that SEDC-Jacksonville has an existing clinical training agreement with Education Corporation of America. See Exhibit 12 for a copy of the clinical service agreement with Education Corporation of America d/b/a Virginia College.

However, the training program specified does not appear to have a program “in the area” of Jacksonville, NC. The application is conditionally conforming to this criterion subject to Condition #5 in Criterion (4).

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

C

The applicant proposes to add five dialysis stations and to relocate three existing stations from SEDC-Kenansville to the existing facility for a total of 33 certified dialysis stations upon completion of Project I.D. # P-10266-14 (add one station), Project I.D. # P-10123-13, New River Dialysis (relocate 18 stations to develop a new facility) and this project. The applicant does not propose to establish a new facility in this project. The applicant adequately demonstrates the need for five additional stations based on the number of in-center patients it proposes to serve and an additional three stations based on Policy ESRD-2 in the July 2014 SDR.

The July 2014 SDR reports that there are two ESRD facilities in Onslow County; SEDC-Jacksonville and New River Dialysis. New River Dialysis is projected to be operational effective January 1, 2015. Both facilities are owned and operated by DaVita HealthCare Partners, Inc.

As reported in the July 2014 SDR, the SEDC-Jacksonville facility operated with 42 certified stations and 143 in-center patients with a utilization rate of 85.12% as of December 31, 2013. Additionally, the July SDR identified a deficit of eight dialysis stations in Onslow County.

In Section V.7, page 36, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

“The proposed expansion of the facility is an effort to provide dialysis services to this community and not intended to be a competitive venture. ... SEDC-Jacksonville provides access to all qualified Nephrologists to admit his or her patients.”

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area would have a positive impact on quality and access to the proposed services. This determination is based on the information in the application and following analysis:

- The applicant adequately demonstrates the need to add five stations and to relocate three existing dialysis stations from SEDC-Kenansville to SEDC-Jacksonville. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access for Onslow County dialysis patients. The discussion regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference;
- The applicant adequately demonstrates it will continue to provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference; and
- The applicant adequately demonstrates that it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, SEDC-Jacksonville operated in compliance with the Medicare

Conditions of Participation within the past 18 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.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .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, page 31, and Exhibit 7 (copy of the July 2014 SDR, Tables A and B). As of December 31, 2013, the utilization rate for SEDC-Jacksonville was 85.12%.

.2202(a)(2) Mortality rates;

- C- In Section IV.2, page 31, the applicant states mortality rates for SEDC-Jacksonville were 8.0% in 2011, 16.8% in 2012, and 13.5% in 2013.

.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 31, the applicant reports as of December 31, 2013, SEDC-Jacksonville had 33 home hemodialysis patients.

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

-C- In Section IV.4, page 32, the applicant states SEDC-Jacksonville referred 11 patients for transplant evaluation and four transplants were performed in 2013.

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

-C- In Section IV.5, page 32, the applicant states there are currently 25 patients on the transplant waiting list at SEDC-Jacksonville.

.2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

-C- In Section IV.6, page 32, the applicant provides the hospital admissions rates, by admission diagnosis, as illustrated in the tables below.

SEDC-Jacksonville Patient Hospital Admissions

<i>1/13-12/13 Hospital Admissions</i>	<i>Total</i>
<i>Number dialysis related</i>	20
<i>Percent Dialysis related</i>	7.6%
<i>Number non-dialysis related</i>	244
<i>Percent non-dialysis related</i>	92.4%
<i>Total number Admissions</i>	<i>264</i>

.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 32, the applicant reported as of December 31, 2013 there were three patients dialyzing at SEDC-Jacksonville with AIDS and one person with Hepatitis B. Additionally, the applicant reports that none of the patients with infectious disease at the facility converted to infectious status during the past year.

(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-Jacksonville 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-Jacksonville 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-Jacksonville 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- See Exhibit 8 for copies of the applicant's policies, procedures and guidelines; which includes a section on power failure.

.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-Jacksonville is an existing facility.

.2202(b)(6) *Documentation that the services will be provided in conformity to applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- See Section VII.2, page 44 and Section XI.6, pages 64-67. In Section X1.6(g), page 65, the applicant states, “*SEDC-Jacksonville has and will continue to operate within the applicable laws and regulations pertaining to staffing, and fire safety equipment, physical environment and other relevant health safety requirements.*”

.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.7, pages 27-29, for all assumptions, including the methodology by which patient origin is projected. The applicant provides projected patient origin which is based on the historical utilization of SEDC-Jacksonville facility, as shown in the below table.

SEDC-Jacksonville				
County	Operating Year 1 2016	Operating Year 2 2017	County In-Center Patients as % of Total	
	In-Center	In-Center	Year 1	Year 2
Onslow	111	121	98.2%	98.4%
Jones	1	1	0.9%	0.8%
Duplin	1	1	0.9%	0.8%
Total	113	123	100.0%	100.0%

.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-Jacksonville 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 14, the applicant states, “*Total Renal Care of North Carolina. d/b/a Southeastern Dialysis Center- Jacksonville 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-Jacksonville 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.*

-C- See Section II, pages 14-16 and Section III.7, pages 27-29, for the assumptions used by the applicant in determining its utilization for SEDC-Jacksonville. The applicant states the facility would have 3.4 patients per station per week as of the end of the first operating year of this project ($113/33 = 3.42$) which includes completion of Project I.D. # P-10266-14; (add one station) and Project I.D. # 10123-13; (relocate 18 stations to New River Dialysis).

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

-C- In Section II, pages 14-19 and Section III.7, pages 27-29, the applicant provides the assumptions and methodology used to project in-center utilization for the existing facility. The applicant states that its home hemodialysis training program was relocated to the New River Dialysis Center as of January 1, 2015.

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- In Section V.1(e), page 33, the applicant states that diagnostic and evaluation services will be provided by Onslow Memorial Hospital.

.2204(2) *Maintenance dialysis;*

-C- In Section V.1(c), page 33, the applicant states that maintenance dialysis will be provided at SEDC-Jacksonville.

.2204(3) *Accessible self-care training;*

-C- In Section V.1(d), page 33, the applicant states that accessible self-care training will be provided by the applicant at the New River Dialysis location effective January 1, 2015.

.2204(4) *Accessible follow-up program for support of patients dialyzing at home;*

-C- In Section V.1, page 33, the applicant states that an accessible follow-up program for support of peritoneal patients dialyzing at home will be provided by the applicant at the New River Dialysis location effective January 1, 2015.

.2204(5) *X-ray services;*

-C- In Section V.1(g), page 33, the applicant states that X-ray services will be provided by Onslow Memorial Hospital.

.2204(6) *Laboratory services;*

-C- In Section V.1(h), page 33, the applicant states that routine, special and immunological laboratory services will be provided by Dialysis Laboratories.

.2204(7) *Blood bank services;*

-C- In Section V.1(i), page 33, the applicant states that blood bank services will be provided by Onslow Memorial Hospital.

.2204(8) *Emergency care;*

-C- In Section V.1(b), page 33, the applicant states emergency care will be provided by Onslow Memorial Hospital.

.2204(9) *Acute dialysis in an acute care setting;*

-C- In Section V.1(a), page 33, the applicant states that acute dialysis in an acute care setting will be provided by Onslow Memorial Hospital.

.2204(10) *Vascular surgery for dialysis treatment patients*

-C- See Section V.1(p), page 33, the applicant states vascular surgery for dialysis treatment patients will be provided by Onslow Memorial Hospital.

.2204(11) *Transplantation services;*

-C- In Section V.1(F), page 33, the applicant indicates that transplantation services will be provided by Duke University Medical Center and East Carolina University.

.2204(12) *Vocational rehabilitation counseling and services; and,*

-C- In Section V.1(o), page 33, the applicant states that referrals will be made to NC Department of Vocational Rehabilitation for vocational rehabilitation counseling and services.

.2204(13) *Transportation*

-C- In Section V.1(q), page 33, the applicant states that transportation will be provided by Onslow Transit Company.

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, page 43, the applicant provides the current and proposed staffing for SEDC-Jacksonville and states that the facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100. The applicant states no new full time equivalent staff (FTEs) will be hired for the proposed addition of five dialysis stations and the relocation of three stations for a total of eight stations to the facility. The applicant actually proposes a reduction/transfer of eight FTE positions. The applicant reports that those staff were relocated to the New River Dialysis Center along with 18 dialysis stations (see Project I.D. # Project I.D. # P-10123-13). See discussion of staffing in Criterion (7) incorporated herein by reference.

- .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 Exhibit 17 for a copy of DVA's training program description/outline for patient care teammates.