

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 31, 2015

Findings Date: July 31, 2015

Project Analyst: Julie Halatek

Team Leader: Lisa Pittman

Project ID #: O-11018-15

Facility: Southeastern Dialysis Center – Wilmington

FID #: 956055

County: New Hanover

Applicant: Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center – Wilmington

Project: Add three dialysis stations for a total of 32 stations upon completion of this project, Project I.D. #O-10324-14 (relocate 10 stations to New Hanover Dialysis), and Project I.D. #O-10346-14 (add ten dialysis stations)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC (TRC) d/b/a Southeastern Dialysis Center – Wilmington (SEDC – Wilmington) proposes to add three dialysis stations to its existing facility for a total of 32 stations upon completion of this project, Project I.D. #O-10324-14 (relocate 10 stations to New Hanover Dialysis), and Project I.D. #O-10346-14 (add ten dialysis stations). Project I.D. #O-10324-14 is still under development. Project ID #O-10346-14 was approved and a certificate of need was issued effective March 28, 2015.

Need Determination

The 2015 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility in New Hanover County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate reported for SEDC – Wilmington in the January 2015 SDR is 4.8621 patients per station. This utilization rate was calculated based on 141 in-center dialysis patients and 29 certified dialysis stations as of June 30, 2014 (141 patients / 29 stations = 4.8621 patients per station). Application of the facility need methodology indicates that up to eight additional stations are potentially needed at this facility, as illustrated in the following table:

2015 SMFP Facility Need Methodology		
Required SDR Utilization		80%
SEDC – Wilmington Utilization Rate as of 6/30/2014		121.55%
Certified Stations		29
Pending Stations		10
Total Existing and Pending Stations		39
In-Center Patients as of 6/30/2014 (SDR2, January 2015 SDR)		141
In-Center Patients as of 12/31/2013 (SDR1, July 2014 SDR)		131
Step	Description	
(i)	Difference (SDR2 - SDR1)	10
	Multiply the difference by 2 for the projected net in-center change	20
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/2013	0.1527
(ii)	Divide the result of Step (i) by 12	0.0127
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/2014 until 12/31/2014) for the January 2015 SDR	0.0763
(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	151.7634
(v)	Divide the result of Step (iv) by 3.2 patients per station	47.4260
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	8

As shown in the table above, based on the facility need methodology for dialysis stations, SEDC – Wilmington potentially has a need for an additional eight stations. 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.*” The applicant proposes to add only three new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

POLICY GEN-3: BASIC PRINCIPLES, on page 38 of the 2015 SMFP, is applicable to this review. 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 its proposal will promote safety and quality in Section I.13(c), pages 6-10; Section II.3, pages 22-23; Section V.2, pages 37-38; Section V.6, pages 39-40; Sections VII.2 and VII.3, pages 48-49; Section XI.6(g), pages 69-70; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how its proposal will promote equitable access in Section II, page 14; Section VI, pages 41-46; and referenced exhibits. The applicant states in Sections VI.1(b) and VI.1(c), pages 41-42, that 86.67 percent of its in-center dialysis patients and 66.66 percent of its home dialysis patients have coverage through Medicare and/or Medicaid and projects that the same percentages of in-center patients and home patients will be covered by Medicare or Medicaid after the completion of the proposed project. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how its proposal will maximize healthcare value for resources expended in Section III.9, pages 32-33; Section V.6, pages 39-40; Section VIII, pages 51-55; Sections XI.6(d)-(e) and XI.6(g), pages 69-70; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will maximize healthcare value.

Conclusion

The applicant adequately demonstrates that the application is consistent with the facility need determination in the January 2015 SDR and with POLICY GEN-3: BASIC PRINCIPLES. 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

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county where they are located. Thus, the service area for this facility consists of New Hanover County. Dialysis facilities may also serve residents of counties not included in their service area.

Total Renal Care of North Carolina, LLC (TRC) d/b/a Southeastern Dialysis Center – Wilmington (SEDC – Wilmington) proposes to add three dialysis stations to the existing facility for a total of 32 stations upon completion of this project, Project I.D. #O-10324-14 (relocate 10 stations to New Hanover Dialysis), and Project I.D. #O-10346-14 (add ten dialysis stations). Project I.D. #O-10324-14 is still under development. Project ID #O-10346-14 was approved and a certificate of need was issued effective March 28, 2015.

Population to be Served

In Section IV.1, page 34, the applicant identifies the patient population as of June 30, 2014, as illustrated in the table below.

SEDC – Wilmington Patient Population as of June 30, 2014		
County/State	In-Center Patients	Home Patients
New Hanover	121	46
Brunswick	19	15
Columbus	0	1
Pender	1	14
Bladen	0	3
South Carolina	0	1
TOTAL	141	80

In Section III.7, page 27, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table.

SEDC – Wilmington Projected Patient Origin						
County/State	OY 1 – 2016		OY 2 – 2017		County/State Patients as a % of Total	
	In-Center Patients	Home Patients	In-Center Patients	Home Patients	OY 1	OY 2
New Hanover	108	39	114	41	84.0%	84.8%
Brunswick	1	8	1	8	5.1%	4.9%
Pender	1	14	1	14	8.6%	8.2%
Bladen	0	3	0	3	1.7%	1.6%
South Carolina	0	1	0	1	0.6%	0.5%
TOTAL	110	65	116	67	100.0%	100.0%

The applicant adequately identifies the population to be served.

Need Analysis

The applicant states that need for the proposed expansion is based on the following factors:

- As of June 30, 2014, SEDC – Wilmington had 141 in-center patients and 29 certified stations, which is a utilization rate of 121.55 percent. See Table A in the January 2015 SDR and page 27 of the application.
- SEDC – Wilmington is experiencing growth and expanding will help meet the growing demand for services at SEDC – Wilmington. See page 32 of the application.
- The applicant projects that SEDC – Wilmington will have 110 in-center patients and 32 certified stations at the end of Operating Year One (ending December 31, 2016), which is a utilization rate of 86 percent ($110 / 32 = 3.44$; $3.44 / 4 = .86$ or 86%). See page 30 of the application.

Projected Utilization

In Section III.7, page 27, the applicant provides projected utilization for Operating Years One and Two, as shown in the table below:

SEDC – Wilmington Projected Utilization – Operating Years One and Two						
County/State	OY 1 – 2016		OY 2 – 2017		County/State Patients as a % of Total	
	In-Center Patients	Home Patients	In-Center Patients	Home Patients	OY 1	OY 2
New Hanover	108	39	114	41	84.0%	84.8%
Brunswick	1	8	1	8	5.1%	4.9%
Pender	1	14	1	14	8.6%	8.2%
Bladen	0	3	0	3	1.7%	1.6%
South Carolina	0	1	0	1	0.6%	0.5%
TOTAL	110	65	116	67	100.0%	100.0%

As shown in the table above, at the end of Operating Year 1, the applicant projects to serve 110 in-center dialysis patients on 32 certified dialysis stations, or 3.44 patients per station per week, which is a utilization rate of 86 percent [$110 / 32 = 3.44$; $3.44 / 4 = 0.86$ or 86%]. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

Assumptions and Methodology Used

In Section III.7, pages 27-32, the applicant states it uses the following assumptions to project utilization:

- As of June 30, 2014, SEDC – Wilmington had 141 in-center patients; 121 live in New Hanover County, 19 live in Brunswick County, and one lives in Pender County. (See page 34.)
- The Average Annual Change Rate for New Hanover County, as published in Table B of the January 2015 SDR, is 5.5 percent, and the New Hanover County in-center patient population will continue to grow at an annual rate of 5.5 percent.
- The Average Annual Change Rate for Brunswick County, as published in Table B of the January 2015 SDR, is 5.6 percent, and the Brunswick County in-center patient population will continue to grow at an annual rate of 5.6 percent.
- In Project I.D. #O-10305-14, TRC projects 19 SEDC – Wilmington patients will transfer to Leland Dialysis.
- In Project I.D. #O-10324-14, TRC was approved to transfer 10 stations and 28 SEDC – Wilmington patients to New Hanover Dialysis.
- In Project I.D. #O-10346-14, TRC was approved to add 10 stations to SEDC – Wilmington.

- When the three projects above (Project I.D. #s O-10305-14, O-10324-14, and O-10346-14) are complete (projected completion date of January 1, 2016), SEDC – Wilmington will have 94 in-center patients and 29 certified stations.
- No growth is projected for the one patient living in Pender County.
- Operating Year One = January 1, 2016 through December 31, 2016.
- Operating Year Two = January 1, 2017 through December 31, 2017.

The applicant calculated growth starting on July 1, 2014 with 121 patients from New Hanover County and 19 patients from Brunswick County. In Section III.7, pages 27-29, the applicant uses the following calculations to project growth of patient populations from New Hanover County and Brunswick County through December 31, 2015:

New Hanover County

- July 1, 2014 – December 31, 2014: 121 patients X 1.0275 = 124.3275
- January 1, 2015 – December 31, 2015: 124.3275 patients X 1.055 = 131.1655125

Brunswick County

- July 1, 2014 – December 31, 2014: 19 patients X 1.028 = 19.532
- January 1, 2015 – December 31, 2015: 19.532 patients X 1.056 = 20.625792

The applicant projects that on December 31, 2015, SEDC – Wilmington will have a total of 152 in-center patients (131 New Hanover County patients, 20 Brunswick County patients, and one Pender County patient). On pages 28-29, the applicant provides information about how the completion of Project I.D. #s O-10324-14 and O-10346-14 will impact the patient population of SEDC – Wilmington. On page 29, the applicant states:

“The result of the transfer of dialysis stations and patients to New Hanover Dialysis and the transfer of patients to Leland Dialysis is that SEDC-Wilmington will have 19 dialysis stations and 105 in-center patients as of January 1, 2016. Please review the chart below for clarification.”

Impact of Other Projects on the Number of Patients at SEDC – Wilmington		
Breakdown of patients by county projected for December 31, 2015 based on growth calculated above:	131 New Hanover County patients + 20 Brunswick County patients + 1 Pender County patient +	152
# of Brunswick County patients projected for January 1, 2016 after transfer of patients to Leland Dialysis:	20 – 19 =	1
# of New Hanover County patients projected for January 1, 2016 after transfer of patients to New Hanover Dialysis	131 – 28 =	103
Total # of SEDC Wilmington patients projected for January 1, 2016	103 New Hanover County patients + 1 Brunswick County patient + 1 Pender County patient =	105

The Project Analyst prepared the table below to show the results of the completion of Project I.D. #s O-10324-14 and O-10346-14 on the number of certified stations at SEDC – Wilmington.

Impact of Other Projects on the Number of Stations at SEDC – Wilmington		
# of stations at SEDC – Wilmington – January 2015 SDR		29 stations
Results of Completion of Projects – January 1, 2016		
Project I.D. #O-10324-14	Develop New Hanover Dialysis by transferring 10 stations from SEDC – Wilmington	- 10 stations
Project I.D. #O-10346-14	Add 10 stations to SEDC – Wilmington	+ 10 stations
Total # of stations at SEDC – Wilmington – January 1, 2016		29 stations

As shown above, the applicant projects to be serving 103 New Hanover County patients, one Brunswick County patient, and one Pender County patient on 29 certified stations on January 1, 2016.

On pages 29-30, the applicant states it projects growth from January 1, 2016 through December 31, 2017. The following are the in-center patient projections using a 5.5% growth rate for New Hanover County patients and no growth for Brunswick and Pender County patients.

January 1, 2016 – December 31, 2016 – 103 patients X 1.055 = 108.665

- Plus one Brunswick County patient and one Pender County patient for a total of 110 patients by December 31, 2016.

January 1, 2017 – December 31, 2017 – 108.665 patients X 1.055 = 114.641575

- Plus one Brunswick County patient and one Pender County patient for a total of 116 patients by December 31, 2017.

By the end of Operating Year One, the applicant projects to serve 110 in-center patients dialyzing on 32 stations for a utilization rate of 86 percent or 3.44 patients per station [110 / 32 = 3.44 / 4 = 0.86 or 86%]. The applicant projects 116 in-center patients will be

dialyzing on 32 stations at the end of Operating Year Two for a utilization rate of 91 percent or 3.63 patients per station [$116 / 32 = 3.63 / 4 = 0.9075$ or 91%]. This meets the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

In Section III.7, pages 30-32, the applicant discusses the projected growth of home-trained dialysis patients at SEDC – Wilmington. As of June 30, 2014, SEDC – Wilmington served 80 home-trained patients (46 patients from New Hanover County and the remaining 34 from surrounding counties and states). The applicant projects growth of only the New Hanover County patients by the 5.5 Average Annual Change Rate for New Hanover County as published in Table B of the January 2015 SDR:

- July 1, 2014 – December 31, 2014: 46 patients X 1.0275 = 47.265
- January 1, 2015 – December 31, 2015: 47.265 patients X 1.055 = 49.864575

As of December 31, 2015, SEDC – Wilmington projects to serve 83 home-trained patients (49 from New Hanover County and the remaining 34 from surrounding counties and states). After the completion of Project I.D. #s O-10324-14 and O-10346-14 on January 1, 2016, SEDC – Wilmington projects to serve 63 home-trained patients, as shown in the table below, reproduced from page 31 of the application.

Home-trained patients by county/state projected from growth calculations as of December 31, 2015	49 New Hanover County patients + 15 Brunswick County patients + 1 Columbus County patient + 14 Pender County patients + 3 Bladen County patients + 1 South Carolina patient =	83
# Brunswick County patients projected after opening of Leland Dialysis (Project I.D. #O-10305-14) on January 1, 2016	15 – 7 =	8
# Columbus County patients projected after opening of Leland Dialysis (Project I.D. #O-10305-14) on January 1, 2016	1 – 1 =	0
# New Hanover County patients projected after opening of New Hanover Dialysis (Project I.D. #O-10324-14) on January 1, 2016	49 – 12 =	37
Total # SEDC – Wilmington home-trained patients projected on January 1, 2016	37 New Hanover County patients + 8 Brunswick County patients + 0 Columbus County patients + 14 Pender County patients + 3 Bladen County patients + 1 South Carolina patient =	63

On page 32, the applicant projects growth of only the New Hanover County patients by the 5.5 Average Annual Change Rate for New Hanover County as published in Table B of the January 2015 SDR:

- January 1, 2016 – December 31, 2016: 37 patients X 1.055 = 39.035
- January 1, 2017 – December 31, 2017: 39.035 patients X 1.181925

The applicant projects that SEDC – Wilmington will be serving 65 home-trained patients (39 New Hanover County patients and 26 patients from surrounding counties and states) at the end of Operating Year One and 67 home-trained patients (41 New Hanover County patients and 26 patients from surrounding counties and states) at the end of Operating Year Two.

The applicant adequately demonstrates the need this population has for three additional dialysis stations at SEDC – Wilmington.

Access to Services

In Sections VI.1(b) and VI.1(c), pages 41-42, the applicant provides the current and projected payor mix for the proposed services at SEDC – Wilmington, as shown in the table below. The applicant projects no change from the current payor mix upon project completion:

SEDC – Wilmington Current / Projected Payor Mix		
Payor Source	% In-Center Patients	% Home-Trained Patients
Medicare	22.22%	13.33%
Medicaid	5.56%	0.00%
Medicare/Medicaid	30.00%	20.00%
Commercial Insurance	8.89%	26.67%
VA	4.44%	6.67%
Medicare/Commercial	28.89%	33.33%
Total	100.00%	100.00%

The applicant adequately demonstrates 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 proposed services.

Conclusion

In summary, the applicant adequately identifies the population it proposes to serve, demonstrates the need this population has for the proposed services, and demonstrates 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 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.

NA

- (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 32-33, the applicant discusses the alternative it considered prior to submitting this application.

Maintain the Status Quo – the applicant states: *“This alternative was dismissed given the growth rate of the facility.”*

The applicant states that adding three stations to SEDC – Wilmington is the most effective alternative because it will meet the growing need for dialysis services at SEDC – Wilmington.

The applicant adequately demonstrates the need for three additional dialysis stations based on the facility’s projected utilization. The discussions regarding need and projected utilization found in Criterion (3) are incorporated herein by reference.

The application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable. An application that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the need. Consequently, 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 – Wilmington 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 – Wilmington shall develop and operate no more than three additional dialysis stations for a total of no more than 32 certified dialysis stations upon completion of this project, completion of Project I.D. #O-10324-14 (relocate 10 stations to develop New Hanover Dialysis), and completion of Project I.D. #O-10346-14 (add ten dialysis stations).**
 - 3. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center – Wilmington shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations for a total of no more than 32 dialysis stations upon completion of this project, Project I.D. #O-10324-14, and Project I.D. #O-10346-14, which shall include any home hemodialysis or isolation stations.**
 - 4. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center – Wilmington 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(d), page 53, the applicant projects a capital cost of \$11,493 for the proposed project, funded through accumulated cash reserves. In Section IX.1(a), page 56, the applicant states there will be no start-up or initial operating expenses associated with the proposed project because it is an existing facility.

In Section VIII.2, page 53, and Section VIII.5, page 54, the applicant states the entire capital cost of the project will be funded with accumulated reserves of DaVita HealthCare Partners, Inc. Exhibit 18 contains a letter dated March 10, 2015, signed by the Vice President of Tax for DaVita HealthCare Partners, Inc., the parent company of Total Renal Care, Inc., which states that DaVita HealthCare Partners, Inc. is authorizing the use of \$11,493 from cash reserves to add three stations to SEDC – Wilmington.

In Exhibit 19, the applicant provides the audited financial statements for DaVita HealthCare Partners, Inc. for the years ending December 31, 2014 and December 31, 2013. As of December 31, 2014, DaVita HealthCare Partners, Inc. had \$965,241,000 in cash and cash equivalents, \$17,942,715,000 in total assets, and \$6,190,276,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In Section X.1, page 58, the applicant provides the allowable charges per treatment for each payor source for SEDC – Wilmington as follows:

SEDC – Wilmington	
Payor Source	Allowable Charge Per Treatment
Medicare	\$239.02
Medicaid	\$143.00
Medicare/Medicaid	\$239.02
Commercial Insurance	\$1,275.00
VA	\$193.00
Medicare/Commercial	\$239.02

In Sections X.2, page 58, and X.4, page 62, the applicant projects revenues and expenses for SEDC – Wilmington as follows:

SEDC – Wilmington Revenue/Expenses/Profit		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$9,092,281	\$9,425,144
Total Expenses	\$7,285,928	\$7,543,429
Net Profit	\$1,806,353	\$1,881,715

The applicant projects that revenue will exceed operating expenses in each of the first two operating years of the project. Projected charges, reimbursement rates, and contractual adjustments are based on reasonable assumptions. See Section X, pages 58-64, for the applicant’s assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and operating expenses of the project, and that the financial feasibility of the proposal is based on reasonable projections of revenues and operating expenses. 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

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county where they are located. Thus, the service area for this facility consists of New Hanover County. Dialysis facilities may also serve residents of counties not included in their service area.

The applicant proposes to add three dialysis stations to the existing SEDC – Wilmington facility for a total of 32 stations upon completion of this project, completion of Project I.D. #O-10324-14 (relocate 10 stations to develop New Hanover Dialysis), and

completion of Project I.D. #O-10346-14 (add ten dialysis stations). The January 2015 SDR indicates there is one other operational dialysis facility and one dialysis facility under development in New Hanover County, as shown below:

New Hanover County Dialysis Facilities			
Dialysis Facility	Certified Stations 6/30/14	% Utilization	Patients Per Station
Cape Fear Dialysis	32	89.84%	3.59
SEDC – Wilmington	29	121.55%	4.86
New Hanover Dialysis*	0	0.00%	0.00

Source: January 2015 SDR, Table A.

*New site – no data reported

The applicant operates all three dialysis facilities in New Hanover County. The two operational dialysis facilities are operating above 80 percent utilization. In Section V.6, pages 39-40, the applicant discusses the impact of this project on existing ESRD services in the area.

The applicant adequately demonstrates the need to add three additional stations to its existing facility based on the facility need methodology and the number of in-center patients it proposes to serve. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

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

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

C

The following table illustrates current and projected staffing for SEDC – Wilmington, as provided by the applicant in Section VII.1, page 47:

SEDC – Wilmington Full-Time Equivalent (FTE) Positions			
Position	Current	Additional	Total
RN	5	1	6
HT RN	2	0	2
Patient Care Technician	12	1	13
Bio-Med Technician	1	0	1
Medical Director*	-	-	-
Administrative	1	0	1
Dietician	1	0	1
Social Worker	1	0	1
Unit Secretary	1	0	1
Reuse	1	0	1
Total FTEs	25	2	27

*The applicant states on page 48 that the Medical Director is not an employee of the facility. There is a contract between the facility and the Medical Director for \$150,000 per year to carry out the responsibilities of Medical Director.

As shown in the above table, the applicant proposes to employ a total of 27 full-time equivalent positions to staff SEDC – Wilmington upon completion of the proposed project. Exhibit 13 contains a letter from Dr. Jonathan Woods, the current Medical Director, stating his support for the expansion of SEDC – Wilmington.

The applicant documents the availability of adequate health manpower and management personnel, including the medical director, for the 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 36, the applicant lists the providers of the necessary ancillary and support services. See Exhibits 9 and 10 for documentation of service agreements. The applicant discusses coordination with the existing health care system on page 39, stating that it has been providing dialysis services to many of the patients residing in New Hanover County at SEDC – Wilmington, and that “...over the years [it has] established relationships with other agencies in New Hanover County and surrounding counties.” The applicant adequately demonstrates the necessary ancillary and support services will be 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 41, the applicant reports that 86.67 percent of the in-center patients and 66.66 percent of the home-trained patients who received treatments at SEDC – Wilmington had some or all of their services paid for by Medicare and/or Medicaid in the past year. The table below illustrates the current payor mix for the facility:

SEDC – Wilmington Current Payor Mix		
Payor Source	% In-Center Patients	% Home-Trained Patients
Medicare	22.22%	13.33%
Medicaid	5.56%	0.00%
Medicare/Medicaid	30.00%	20.00%
Commercial Insurance	8.89%	26.67%
VA	4.44%	6.67%
Medicare/Commercial	28.89%	33.33%
Total	100.00%	100.00%

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 New Hanover 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)*
New Hanover County	13.1%	5.7%	20.4%
Statewide	16.5%	6.7%	19.7%

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

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).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. But it does not include information on the number of elderly, handicapped, minorities, or women utilizing health services.

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

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

Source: Southeastern Kidney Council Network 6 Inc. 2014 Annual Report.²

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

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

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service, and access by minorities and handicapped persons. In Section VI.1(f), page 44, the applicant states that SEDC – Wilmington has no obligations under any applicable federal regulation to fulfill.

²<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

In Section VI.6(a), page 45, the applicant states there have been no patient civil rights access complaints filed in 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 42, the applicant provides the projected payor mix for the proposed services at SEDC – Wilmington as shown in the table below:

SEDC – Wilmington Projected Payor Mix		
Payor Source	% In-Center Patients	% Home-Trained Patients
Medicare	22.22%	13.33%
Medicaid	5.56%	0.00%
Medicare/Medicaid	30.00%	20.00%
Commercial Insurance	8.89%	26.67%
VA	4.44%	6.67%
Medicare/Commercial	28.89%	33.33%
Total	100.00%	100.00%

As shown in the table above, the applicant projects that 86.67 percent of the in-center patients and 66.66 percent of the home-trained patients who received treatments at SEDC – Wilmington will have some or all of their services paid for by Medicare and/or Medicaid. The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5, pages 44-45, 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

On page 38, the applicant states it has an established Student Training Agreement with Cape Fear Community College. Exhibit 12 contains a copy of the Student Training Agreement. The information provided in Section V.3 and Exhibit 12 is reasonable and supports a finding of conformity to this criterion.

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

C

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county where they are located. Thus, the service area for this facility consists of New Hanover County. Dialysis facilities may also serve residents of counties not included in their service area.

The applicant proposes to add three dialysis stations to the existing SEDC – Wilmington facility for a total of 32 stations upon completion of this project, completion of Project I.D. #O-10324-14 (relocate 10 stations to develop New Hanover Dialysis), and completion of Project I.D. #O-10346-14 (add ten dialysis stations). The January 2015 SDR indicates there is one other operational dialysis facility and one dialysis facility under development in New Hanover County, as shown below:

New Hanover County Dialysis Facilities			
Dialysis Facility	Certified Stations 6/30/14	% Utilization	Patients Per Station
Cape Fear Dialysis	32	89.84%	3.59
SEDC – Wilmington	29	121.55%	4.86
New Hanover Dialysis*	0	0.00%	0.00

Source: January 2015 SDR, Table A.

*New site – no data reported

The applicant operates all three dialysis facilities in New Hanover County. The two operational dialysis facilities are operating above 80 percent utilization.

In Section V.7 (labeled as Section V.6), pages 39-40, the applicant discusses how any enhanced competition in the service area will promote 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 is not intended to be a competitive venture. There are no other dialysis facilities in the proposed service area; therefore, there can be no effect on the competition.

The effect upon competition is unknown. However, patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs. SEDC - Wilmington provides access to all qualified Nephrologists to admit his or her patients.

We view this project as having no impact, positive or negative, on the cost effectiveness or quality of our services. Our costs are low and our quality superior. However, we do feel that accessibility to our services by the patients living in the service area identified will be enhanced.”

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 includes a positive impact on cost-effectiveness, quality, and access to the proposed services. This determination is based on the information in the application, and the following analysis:

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

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

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

C

In Section I.13 and referenced exhibits, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The 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 dialysis stations in an existing certified facility or relocate stations must provide the following information:*

- (1) *Utilization rates;*

-C- In Section III.7, page 27, the applicant states that SEDC – Wilmington had 141 in-center patients dialyzing on 29 certified stations, for a utilization rate of 121.55 percent, as of June 30, 2014.

- (2) *Mortality rates;*

- C- In Section IV.2, page 34, the applicant reports 2012, 2013, and 2014 facility mortality rates of 12.8 percent, 11.8 percent, and 9.3 percent, respectively.
 - (3) *The number of patients that are home trained and the number of patients on home dialysis;*
 - C- In Section IV.3, page 35, the applicant states that SEDC – Wilmington had 18 home hemodialysis patients and 67 peritoneal dialysis patients as of December 31, 2014.
 - (4) *The number of transplants performed or referred;*
 - C- In Section IV.4, page 35, the applicant states SEDC – Wilmington referred 37 patients for transplant evaluation in 2014. SEDC – Wilmington had one patient receive a transplant in 2014.
 - (5) *The number of patients currently on the transplant waiting list;*
 - C- In Section IV.5, page 35, the applicant states SEDC – Wilmington has 17 patients on the transplant waiting list.
 - (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
 - C- In Section IV.6, page 35, the applicant reports a total of 311 hospital admissions in 2014; 273 (87.8 percent) were non-dialysis related and 38 (12.2 percent) were dialysis related.
 - (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
 - C- In Section IV.7, page 35, the applicant reports that as of December 31, 2014, there were three patients with AIDS and six patients with hepatitis B dialyzing at SEDC – Wilmington. Two patients converted to infectious status in 2014.
- (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:*
- (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 – Wilmington is an existing facility.

(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with 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 – Wilmington is an existing facility.

(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- SEDC – Wilmington is an existing facility.

(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.

(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 – Wilmington is an existing facility.

- (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 Section II.1, pages 12-21; Section VII.2, page 48, Section XI.6(g), pages 69-70, and Exhibits 1, 23, and 24 for documentation of conformity with the applicable laws and regulations.
- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- In Section III.7, page 27, SEDC – Wilmington provides projected patient origin based on historical experience for the first two years of operation following completion of the project, as presented in the following table:

SEDC – Wilmington Projected Patient Origin						
County/State	OY 1 – 2016		OY 2 – 2017		County/State Patients as a % of Total	
	In-Center Patients	Home Patients	In-Center Patients	Home Patients	OY 1	OY 2
New Hanover	108	39	114	41	84.0%	84.8%
Brunswick	1	8	1	8	5.1%	4.9%
Pender	1	14	1	14	8.6%	8.2%
Bladen	0	3	0	3	1.7%	1.6%
South Carolina	0	1	0	1	0.6%	0.5%
TOTAL	110	65	116	67	100.0%	100.0%

- (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 – Wilmington is an existing facility.
- (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 rate for such services.*
- C- In Section II.1, page 14, the applicant states:

“Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center – Wilmington admits and provides dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another

healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- SEDC – Wilmington is an existing facility.

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

-C- In Section III.7, pages 27-30, the applicant projects to serve 110 in-center patients on 32 certified stations by the end of Operating Year One, which is 3.44 patients per station ($110 / 32 = 3.44$). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section II.1, pages 15-20, and Section III.7, pages 27-32.

10A NCAC 14C .2204 SCOPE OF SERVICES

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

(1) *diagnostic and evaluation services;*

-C- These services are provided by New Hanover Regional Medical Center. See Section V.1, page 36.

(2) *maintenance dialysis;*

-C- These services are provided by SEDC – Wilmington. See Section V.1, page 36.

(3) *accessible self-care training;*

-C- These services are provided by SEDC – Wilmington. See Section V.1, page 36.

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

-C- These services are provided by SEDC – Wilmington. See Section V.1, page 36.

(5) *x-ray services;*

-C- These services are provided by New Hanover Regional Medical Center. See Section V.1, page 36.

(6) *laboratory services;*

-C- These services are provided by Dialysis Laboratories. See Section V.1, page 36.

(7) *blood bank services;*

-C- These services are provided by New Hanover Regional Medical Center. See Section V.1, page 36.

(8) *emergency care;*

-C- These services are provided by New Hanover Regional Medical Center. See Section V.1, page 36.

(9) *acute dialysis in an acute care setting;*

-C- These services are provided by New Hanover Regional Medical Center. See Section V.1, page 36.

(10) *vascular surgery for dialysis treatment patients;*

-C- These services are provided by New Hanover Regional Medical Center. See Section V.1, page 36.

(11) *transplantation services;*

-C- These services are provided by Duke University Medical Center and East Carolina University. See Section V.1, page 36.

(12) *vocational rehabilitation counseling and services; and*

-C- These services are provided by Vocational Rehabilitation. See Section V.1, page 36.

(13) *transportation.*

-C- This service is provided by Cape Fear Public Transportation Authority. See Section V.1, page 36.

10A NCAC 14C .2205 STAFFING AND STAFF TRAINING

(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 [494].*

-C- In Section VII.1, page 47, the applicant provides the proposed staffing after completion of the proposed project. In Section VII.2, page 48, the applicant states that staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

(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 49, and Exhibit 24 for documentation of ongoing training for staff at SEDC – Wilmington.