

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 19, 2018

Findings Date: December 19, 2018

Project Analyst: Jane Rhoe-Jones

Team Leader: Fatimah Wilson

Project ID #: O-11548-18

Facility: New Hanover Dialysis

FID #: 140333

County: New Hanover

Applicant: Total Renal Care of North Carolina

Project: Relocate six stations from Southeastern Dialysis Center-Wilmington and the home hemodialysis training and support program for a total of 18 dialysis stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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 New Hanover Dialysis proposes to relocate six dialysis stations and transfer the home hemodialysis (HHD) training and support program from Southeastern Dialysis Center-Wilmington (SEDC–Wilmington) to New Hanover Dialysis for a total of 18 stations at New Hanover Dialysis. Two of the six dialysis stations being relocated will be used for HHD training and support and the other four stations will be used for in-center (IC) hemodialysis.

Upon completion of this project and Project I.D.# O-11257-16 (add four stations), SEDC-Wilmington will be certified for 32 dialysis stations and will only be providing peritoneal dialysis training and support.

Policies

There is one policy in the 2018 SMFP which is applicable to this review. *Policy ESRD-2: Relocation of Dialysis Stations*. Policy ESRD-2 states:

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

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

The applicant proposes to relocate six dialysis stations from SEDC–Wilmington to New Hanover Dialysis. Both the dialysis facility relocating the stations and the facility receiving the stations are located in New Hanover County.

According to Table D in the July 2018 Semiannual Dialysis Report (SDR), there is a surplus of 19 dialysis stations in New Hanover County. The proposed relocation of six stations from SEDC–Wilmington to New Hanover County Dialysis would not result in a deficit or increase an existing deficit nor would it result in a surplus or increase an existing surplus of stations in New Hanover County.

The applicant adequately demonstrates that the proposed relocation of six dialysis stations from SEDC–Wilmington to New Hanover County Dialysis is consistent with Policy ESRD-2.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the above stated reasons.

- (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

TRC proposes to relocate six dialysis stations and transfer the home hemodialysis (HHD) training and support program from SEDC–Wilmington to New Hanover Dialysis for a total of 18 stations at New Hanover Dialysis. Two of the six dialysis stations being relocated will be used for HHD training and support and the other four stations will be used for in-center hemodialysis.

Upon project completion of this project and Project I.D.# O-11257-16 (add four stations), SEDC-Wilmington will be certified for 32 dialysis stations and will only be providing peritoneal dialysis training and support.

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations as, “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is New Hanover County. Facilities may serve residents of counties not included in their service area.

The following table illustrates the current and projected patient origin for IC patients and HHD patients for operating year one (OY1) and OY2.

NEW HANOVER DIALYSIS Current and Projected Patient Origin							
County	Current 6/30/2018	OY1 7/1/2019-6/30/2020		OY2 7/1/2020-6/30/2021		County Patients as Percent of Total	
	IC Patients	IC Patients	HHD Patients	IC Patients	HHD Patients	OY1	OY2
New Hanover	38	52	6	55	7	78.3%	79.4%
Pender	1	1	1	1	1	2.6%	2.6%
Alamance	1	1	0	1	0	1.4%	1.3%
Wake	1	1	0	1	0	1.4%	1.3%
Brunswick	0	0	3	0	3	4.1%	3.8%
Onslow	0	0	2	0	2	2.6%	2.6%
Bladen	0	0	1	0	1	1.4%	1.3%
Sampson	0	0	1	0	1	1.4%	1.3%
Duplin	0	0	1	0	1	1.4%	1.3%
Other States	3	3	1	3	1	5.4%	5.1%
Total*	44	58	16	61	17	100.0%	100.0%

Source: Section C, pages 12 and 18

*The applicant has used 2019-2020 in different places in the application for its first two OYs. However, in Section R, the pro formas, the applicant uses 2021-2022 for its first two OYs. In clarifying information received by the Agency on November 21, 2018, the applicant states that OY1 is 7/1/2019-6/30/2020 and OY2 is 7/1/2020-6/30/2021. Therefore, the project analyst uses the last made representation of the applicant.

In Section C, pages 12-14, the applicant provides the assumptions and methodology it used to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, page 14, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services.

On page 14 the applicant states the following in regards to the need for additional in-center dialysis stations,

“Section B-2 clearly outlines the need that the population to be served, the in-center patients of New Hanover Dialysis, has for the six-station expansion via transfer of six stations from SEDC-Wilmington proposed in this application.”

In Section B.2, page 7, the applicant states that the application was filed pursuant to Policy ESRD-2. The application is consistent with Policy ESRD-2.

The applicant also proposes to relocate the HHD training and support program from SEDC-Wilmington to New Hanover Dialysis. On page 17 the applicant states the following,

“... The training and support area at SEDC-Wilmington is not large enough to support both the Peritoneal Dialysis and Home Hemodialysis Programs. New Hanover Dialysis is a new facility with sufficient space to support the Home Hemodialysis training and support program.”

The applicant is proposing to use 2 of the 18 stations at New Hanover Dialysis for HHD training support.

SEDC-Wilmington currently and will continue to provide peritoneal dialysis (PD) training and support to New Hanover Dialysis patients.

On pages 12-14, the applicant describes its need methodology assumptions for projecting utilization of the facility as follows:

1. The applicant projects the first two full operating years of the project will be July 1, 2019 - June 30, 2020 and July 1, 2020 - June 30, 2021.
2. As of June 30, 2018, the current patient census of New Hanover County residents at New Hanover Dialysis was 38 in-center patients.
3. As of June 30, 2018, the patient census of non-New Hanover County residents at New Hanover Dialysis was a total of six patients from other NC counties and other states, as follows:
 - a. Three in-center patients from other states. No growth calculations were performed for the out of state patients.
 - b. Three patients were from other North Carolina counties. No growth calculations were performed for the patients outside of New Hanover County.
4. The New Hanover County Five Year Average Annual Change Rate (5-Year AACR) as published in the July 2018 SDR was 1.9%. However, the facility has experienced a 41.9% growth rate over the past six months [44 patients – 31 patients = 13 patients; $13/31=0.419$ or 41.9%] based on the June 30, 2018 ESRD Data Collection Form and July 2018 SDR data. The applicant utilized a 5% growth rate to project utilization at the facility which is higher than the New Hanover County 5-Year AACR but lower than the facility's historical growth rate.
5. TRC adds 10 in-center patients to the census of New Hanover Dialysis because it states that 10 patients currently being served at SEDC-Wilmington signed letters of support and indicated they would transfer their care to New Hanover Dialysis

upon project completion. The Project Analyst notes that one letter was signed by the patient, however, support letters are not required by any statutory or regulatory review criteria.

The information above is reasonable and adequately supported.

Projected Utilization

In Section C, pages 12-14, the applicant provides the methodology used to project in-center utilization, as illustrated in the following table.

NEW HANOVER DIALYSIS	In-Center
The applicant begins with a facility census of New Hanover County in-center patients as of 7/1/2018.	38
The census of New Hanover County in-center patients is increased by 5% (1.05) to project the census forward one year to 7/1/2019.	$38 \times 1.05 = 39.9$
The applicant adds the 6 patients from outside New Hanover County. This is the projected ending census for 6/30/2019.	$39.9 + 6 = 45.9$
The applicant adds the 10 New Hanover County in-center patients who have indicated they will transfer their care to New Hanover Dialysis.	$39.9 + 10 = 49.9$
The census of New Hanover County in-center patients is increased by 5% (1.05) to project the beginning census forward one year.	$49.9 \times 1.05 = 52.395$
The applicant adds the 6 patients from outside New Hanover County. This is the projected ending census for Operating Year 1 (6/30/2020).	$52.395 + 6 = \mathbf{58.395}$
The census of 52 in-center New Hanover patients is increased by 5% (1.05) to project the beginning census forward to 7/1/2021.	$52.395 \times 1.05 = 55.015$
The applicant adds the 6 patients from outside New Hanover County. This is the projected ending census for Operating Year 2 (6/30/2021).	$55.015 + 6 = \mathbf{61.015}$

Note: One of the 10 patient support letters provided in the Exhibits is not signed, however support letters are not required by any statutory or regulatory review Criteria. The facility has had a 41.9% growth rate over the last six months so even if no patients relocated from SEDC-Wilmington, the historical growth rate of the facility would be sufficient enough to project future utilization.

Thea applicant states that projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (2020) the facility is projected to serve 58 in-center patients and at the end of OY2 (2021), the facility is projected to serve 61 in-center patients.

The projected utilization rates for the first two operating years are as follows:

OY1: 3.2 patients per station per week or 80% (58 patients / 18 stations = 3.22 or 3.2 / 4 = 0.805 or 80.5%)

OY2: 3.2777 patients per station per week or 82% (61 patients / 18 stations = 3.38 / 4 = 0.847 or 84.7%)

The projected utilization of 3.2 patients per station per week at the end of OY1 meets the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected Home Hemodialysis Utilization

In Section C, page 14, the applicant provides the methodology used to project home hemodialysis utilization, as illustrated in the following table.

Patient Projections	NEW HANOVER DIALYSIS			
	# Patients – Year Begins	# Patient-Year Beginning	# Patients – Year Ends	Average # Patients per Year
Current Year	7/1/2018	14	15	14.5
OY1	7/1/2019	15	16	15.5
OY2	7/1/2020	16	17	16.5

Note: The table reads PD patient projections but the applicant is not proposing to provide PD services at this facility. PD patients for New Hanover Dialysis are referred to SEDC-Wilmington. The beginning patient census in the table matches the HHD patient census provided on the most recent ESRD Data Collection Forms for SEDC-Wilmington.

On page 14, the applicant states,

It is reasonable to assume that the HHD patient population being served will increase by one patient in the current operating year and operating years one and two.”

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant begins its projections of the patient population to be served with the existing patient census of New Hanover Dialysis as of July 1, 2018.
- The applicant grows the New Hanover County patient population by a growth rate of 5% which is more than the 1.9% New Hanover County 5-Year AACR but less than the 41.9% growth rate the facility experienced over the past six months.
- The 5% growth rate is held constant over the first two project years 2019-2021.
- The applicant projects no growth for patients who reside outside of New Hanover County.

- The HHD patient population currently being served at SEDC-Wilmington is the basis for the projected HHD patient utilization for New Hanover Dialysis.
- The resulting utilization rate at New Hanover Dialysis by the end of the first year meets the minimum standard of 3.2 patients per station per week.

Access

In Section L.1(a), pages 44-45, the applicant states that New Hanover Dialysis has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons regardless of their ability to pay. In Section L.1(b), page 45, the applicant provides the projected payor mix for OY2 (2021) for New Hanover Dialysis, illustrated as follows.

NEW HANOVER DIALYSIS	
Payor Source	Percent of Total Patients
Private Pay	0.0%
Medicare	22.4%
Medicaid	3.4%
Commercial Insurance	5.3%
Medicare / Commercial	36.2%
Medicare / Medicaid	31.0%
VA	1.7%
Total	100.00%

As illustrated in the above table, in OY2021, 93% of all New Hanover Dialysis patients are projected Medicare and Medicaid recipients. On page 45, the applicant states that “projected *payor mix is based on sources of patient payment that have been received by the existing facility in the last full operating year.*”

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

(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

TRC proposes to relocate six dialysis stations and transfer the HHD training and support program from SEDC–Wilmington to New Hanover Dialysis for a total of 18 stations at New Hanover Dialysis.

The following table shows the projected addition and deletion of stations at SEDC-Wilmington.

Stations	Description	Project ID #
34	Total existing certified stations as of the July 2018 SDR	
-6	Stations to be deleted as part of this project	O-11548-18
+4	Stations to be added but not yet certified	O-11257-16
32	Total stations upon completion of proposed projects	

In Section D, page 21, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 21, the applicant states,

“The fourteen Home Hemodialysis patients have signed letters that they enthusiastically support the relocation of the program from SEDC-Wilmington to New Hanover Dialysis. Two of the six stations being transferred will be used for HHD training and support (those two stations are currently being used at SEDC-Wilmington to support the HHD program).

SEDC-Wilmington has a CON to add four stations. These stations will replace four of the stations being transferred to New Hanover Dialysis. SEDC-Wilmington had 102 in-center patients as of June 30, 2018. Based on the 32 stations on the treatment floor, the

facility had a utilization rate of 79.7% or 3.19 patients per station. This does not include the projected transfer of the nine in-center patients who signed letters of support to consider transfer to New Hanover Dialysis.”

The Project Analyst notes that the applicant did not provide any support letters from HHD patients in any of the Exhibits to the application. The applicant did provide support letters from 10 in-center patients (only nine were signed) who are interested in transferring their care to New Hanover Dialysis upon project completion. The Project Analyst notes that support letters are not required by any statutory or regulatory review criteria.

As shown in the above table, four of the six stations to be relocated in this application will be replaced upon completion of Project I.D. #O-11257-16 (add four stations).

In Section D.2, page 21, regarding how the proposed relocation or elimination of HHD from SEDC-Wilmington to New Hanover Dialysis would affect the ability of low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care, the applicant states,

“The relocation of the Home Hemodialysis Program from SEDC-Wilmington to New Hanover Dialysis and the transfer of six dialysis stations will have no effect on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care.”

The two facilities are approximately 1.9 miles and 5 minutes apart according to Google Maps, thus the existing HHD patient population at SEDC-Wilmington will still have adequate access to HHD services upon relocation of the HHD training program to New Hanover Dialysis.

SEDC-Wilmington

According to the July 2018 SDR, there were 108 in-center patients dialyzing at SEDC-Wilmington and 34 certified dialysis stations for a utilization rate of 79.41%, or 3.1765 patients per station per week ($108/34 = 3.1765/4 = .7941$ or 79.41%) as of December 31, 2017.

In addition to the 34 certified stations as of December 31, 2017, SEDC-Wilmington was approved for a four station expansion in Project I.D. #O-11257-16 for a total of 38 dialysis stations. The proposed project is to relocate six existing dialysis stations to New Hanover Dialysis leaving SEDC-Wilmington with a total of 32 dialysis stations upon completion of both projects.

As of December 31, 2017, of the 108 in-center patients 88 were residents of New Hanover County and 20 were not residents of New Hanover County. Per the letters of support found in Exhibit C, 10 in-center patients currently being served at SEDC-Wilmington are projected to

transfer their care to New Hanover Dialysis upon relocation of six stations which is projected to happen on or about July 1, 2019.

The applicant did not provide projected utilization for SEDC-Wilmington upon completion of this project and Project ID.# O-11257-16. In the table below, the Project Analyst provides utilization data for the facility based on the last two SDRs (January and July 2018) and the June 30, 2018 ESRD Data Collection Form.

SEDC-Wilmington				
Utilization Dates	# of Certified Stations	# In-center Patients	Percent Utilization	Patients per Station
June 30, 2017	32	113	88.28%	3.5313
December 31, 2017	34	108	79.41%	3.1765
June 30, 2018	34	102	75.00%	3.0000

Note: Per Project I.D.# O-11257-16, SEDC-Wilmington was approved to add four stations to the facility for a total of 38 stations, however those stations are not yet certified.

As shown in the table above, the facility has been experiencing negative growth. If the proposed project to relocate six stations to New Hanover Dialysis and Project I.D.# O-11257-16 (add four stations) are factored into the most recent utilization data and assuming no growth at the facility, the facility's utilization would be as follows:

2.875 patients per station per week or 71.875% [92 patients (102-10) / 32 stations (34+4-6) = 2.875 / 4 = 0.71875 or 71.875%]

Thus, the applicant demonstrates that the needs of the population presently served at SEDC-Wilmington would be adequately met upon the proposed relocation of six stations to New Hanover Dialysis.

Projected utilization is reasonable and adequately supported based on the following:

- The current patient census for SEDC-Wilmington as reported in the June 30, 2018 ESRD Data Collection Form;
- Historical utilization data from the January and July 2018 SDR;
- The proposed project and Project I.D.# O-11257-16 (add four stations); and
- No projected growth at the facility

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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

The applicant proposes to relocate six stations from SEDC-Wilmington and HHD training and support program for a total of 18 dialysis stations upon project completion.

In Section E.1, page 22, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo - The applicant states that maintaining the status quo is not an effective alternative because of the growth rate at the facility. Therefore, this alternative was rejected.
- Apply for a Station Expansion - The applicant states that the facility is not eligible for station expansion utilizing the Facility Need Methodology. In the past six months, the applicant states that the facility has been at 100% utilization based on operating two shifts six days a week. Therefore, this alternative was rejected.

On page 22, the applicant states that its proposal to relocate stations from another DaVita facility, the parent company for the applicant, is the most effective alternative because of growth and access issues at the facility. The applicant states that a third shift would be inconvenient for patients and a facility at maximum capacity would eliminate patient choice.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- the facility has had a 41.9% growth rate over the past six months,

- maintaining the status quo does not address the need for additional stations and will result in higher utilization rates and potentially restrict patient admissions,
- relocation of stations from another DaVita facility in New Hanover County would result in higher utilization levels at that facility,
- relocation of the HHD training and support program from SEDC-Wilmington to New Hanover Dialysis would help to relieve space restraints at SEDC-Wilmington

Conclusion

The Agency reviewed the:

- Application
- Clarifying information requested by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC d/b/a New Hanover Dialysis shall materially comply with all representations made in the certificate of need application and any clarifying responses. In the event that representations conflict, Total Renal Care of North Carolina, LLC d/b/a New Hanover Dialysis shall materially comply with the last made representation.**
 - 2. Pursuant Policy ESRD-2, Total Renal Care of North Carolina, LLC, d/b/a New Hanover Dialysis shall relocate no more than six dialysis stations from Southeastern Dialysis Center-Wilmington for a total of no more than 18 certified stations at New Hanover Dialysis upon project completion which shall include any home hemodialysis training or isolation stations.**
 - 3. Upon completion of this project, Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify six dialysis stations at Southeastern Dialysis Center-Wilmington for a total of no more than 32 dialysis stations at Southeastern Dialysis Center-Wilmington and completion of Project ID #O-11257-16.**
 - 4. Total Renal Care of North Carolina, LLC d/b/a New Hanover Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of

the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to relocate six stations from SEDC-Wilmington and HHD training and support program for a total of 18 dialysis stations upon project completion.

Capital and Working Capital Costs

In Section F, page 23, the applicant projects the total capital cost of the project as shown below in the table.

NEW HANOVER DIALYSIS	
Site Costs	\$0
Construction Costs	\$0
Dialysis Machines	\$59,400
Equipment/Furniture (not included above)	\$8,480
Total	\$67,880

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 26-27, the applicant states that there will be no start-up costs or initial operating expenses because New Hanover Dialysis is an existing facility.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full operating years of following completion of the project. In Section R, Form B, the applicant projects that revenues will exceed operating expenses in the first and second operating years of the project, as shown below in the table.

NEW HANOVER DIALYSIS		
	OY1 CY2020	OY2 CY2021
Total Treatments (adjusted for 5% missed treatments)	2,297	2,445
Total Gross Revenues (Charges)	\$3,014,679	\$3,180,056
Total Net Revenue	\$2,906,626	\$3,065,874
Average Net Revenue per Treatment	\$1,265	\$1,254
Total Operating Expenses (Costs)	\$2,688,256	\$2,814,327
Average Operating Expense per Treatment	\$1,170	\$1,151
Net Income	\$218,369	\$251,548

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital cost is based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (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

The applicant proposes to relocate six stations from SEDC-Wilmington and HHD training and support program for a total of 18 dialysis stations upon project completion.

On page 365, the 2018 SMFP defines the service area for dialysis stations as *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is New Hanover County. Facilities may serve residents of counties not included in their service area.

According to the July 2018 SDR, there are three dialysis facilities in New Hanover County, all operated by DaVita, Inc., illustrated as follows:

NEW HANOVER COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of December 31, 2017				
Dialysis Facility	Certified Stations	# In-center Patients	Percent Utilization	Patients per Station
	12/31/2017	12/31/2017	12/31/2017	12/31/2017
New Hanover Dialysis	12	31	64.58%	2.5833
Cape Fear Dialysis	32	113	88.28%	3.5313
Southeastern Dialysis Center-Wilmington	34	108	79.41%	3.1765

Source: July 2018 SDR.

In Section G, page 29, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved Dialysis services in the New Hanover County service area. The applicant states:

“Section G-1 lists all the existing and approved dialysis facilities in the proposed service area, New Hanover County. All three are operated by subsidiaries of the applicant’s parent company, DaVita.

We are not applying for any new stations, just the relocation of stations from one facility to another. The relocation of stations within the same county will not result in an unnecessary duplication of the existing and approved facilities in the service area.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The proposal would not result in an increase in an increase or deficit of dialysis stations.
- The applicant adequately demonstrates that the proposed relocation of dialysis stations is needed in addition to the existing or approved services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

In Section H, page 30, the applicant provides current and projected staffing in full-time equivalents (FTE) for the proposed services at New Hanover Dialysis, as illustrated in the following table.

NEW HANOVER DIALYSIS		
POSITION	CURRENT # FTEs CY2017	PROJECTED # FTEs OY2 (CY2021)
Registered Nurse	2.0	3.0
Home Training RN	0.0	2.0
Technician (PCT)	6.0	8.0
Dietician	1.0	1.0
Social Worker	1.0	1.0
Administrator	1.0	1.0
Administrative Assistant	1.0	1.0
Biomed Tech	1.0	1.0
Total	13.0	18.0

The assumptions and methodology used to project staffing are provided in Section H and Section R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H, pages 31-32, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit I.3, the applicant provides a letter from the medical director indicating his interest in continuing to serve as the medical director of New Hanover Dialysis.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

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

C

In Section I, page 34, the applicant provides a list of the necessary ancillary and support services for the proposed services, as illustrated below.

NEW HANOVER DIALYSIS Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	New Hanover Dialysis (on site)
Self-care training (in-center)	New Hanover Dialysis (on site)
Home training HH PD Accessible follow-up program	New Hanover Dialysis (to add). Currently provided at SEDC-Wilmington Provided at SEDC-Wilmington New Hanover Dialysis (to add). Currently provided at SEDC-Wilmington
Psychological counseling	New Hanover Dialysis (on site)
Isolation – hepatitis	New Hanover Dialysis (on site)
Nutritional counseling	New Hanover Dialysis (on site)
Social Work services	New Hanover Dialysis (on site)
Acute dialysis in an acute care setting	New Hanover Medical Center
Emergency care	New Hanover Medical Center
Blood bank services	New Hanover Medical Center
Diagnostic and evaluation services	New Hanover Medical Center
X-ray services	New Hanover Medical Center
Laboratory services	DaVita Laboratory Services
Pediatric nephrology	New Hanover Medical Center
Vascular surgery	New Hanover Medical Center
Transplantation services	Vidant Medical Center
Vocational rehabilitation & counseling	NC Division of Vocational Rehab.
Transportation	Dept of Social Services

The applicant provides supporting documentation in Exhibit I. for home training services with SEDC-Wilmington, DaVita laboratories services, Vidant Medical Center and New Hanover Medical Center.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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

The applicant does not propose to construct new space nor renovate the existing space. Therefore, Criterion (12) is not applicable to this review.

- (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 L, page 48, the applicant provides the historical payor mix during Calendar Year (CY) 2017 for the existing services, as shown below in the table.

NEW HANOVER DIALYSIS Historical Payor Mix for CY2017	
Payor Source	In-center Dialysis Services as Percent of Total
Medicare	18.2%
Medicaid	4.5%
Commercial Insurance	6.8%
Medicare Commercial	34.1%
Medicare/Medicaid	34.1%
VA	2.3%
Total	100.0%

In clarifying information received from the applicant on 12/16/2018, the applicant states that the CY referenced on page 28 should read 1/1/2017-12/31/2017.

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
New Hanover	17%	52%	23%	17%	9%	11%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217> Latest Data 7/1/17 as of 7/17/18

Excludes "White alone, not Hispanic or Latino" Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina’s based on the Network’s recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency
- Clarifying information received by the Agency

Based on that review, the Agency concludes that the applicant adequately documents 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.

Therefore, the application is conforming to this criterion.

¹ <https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

- (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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.D, page 47, the applicant states,

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

In Section L.6, page 47, the applicant states that during the last five years no patient civil rights access complaints have been filed.

The Agency reviewed the application. Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section L, page 45, the applicant projects the following payor mix for the proposed services during the second full calendar year of operation following completion of the project, as shown below in the table.

NEW HANOVER DIALYSIS Projected Payor Mix OY2	
Payor Category	In-center Dialysis Services as Percent of Total
Medicare	22.4%
Medicaid	3.4%
Commercial Insurance	5.3%
Medicare /Commercial	36.2%
Medicare/Medicaid	31.0%
VA	1.7%
Total	100.0%

As shown in the table above, during the second full calendar year of operation, the applicant projects that 93% of in-center services will be provided to Medicare patients and Medicaid patients.

On page 45, the applicant provides the assumptions and methodology used to project payor mix during the two full calendar years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization by payor mix at New Hanover Dialysis.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section L, page 47, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section M, page 49, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

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

C

TRC proposes to relocate six dialysis stations and transfer the HHD training and support program from SEDC-Wilmington to New Hanover Dialysis for a total of 18 stations at New Hanover Dialysis.

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is New Hanover County. Facilities may serve residents of counties not included in their service area.

According to the June 30, 2017 SDR, there are three dialysis facilities in New Hanover County, and all are operated by DaVita, Inc, illustrated as follows.

NEW HANOVER COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of December 31, 2017				
Dialysis Facility	Certified Stations 12/31/2017	# In-center Patients 12/31/2017	Percent Utilization 12/31/2017	Patients per Station 12/31/2017
New Hanover Dialysis	12	31	64.58%	2.5833
Cape Fear Dialysis	32	113	88.28%	3.5313
Southeastern Dialysis Center-Wilmington	34	108	79.41%	3.1765

Source: July 2018 SDR.

In Section N, page 50, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 50, the applicant states,

“The expansion of New Hanover Dialysis will have no effect on competition in New Hanover County. Total Renal Care of North Carolina, LLC operates all of the dialysis facilities located in New Hanover County.

The expansion of New Hanover Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for our patients, family members and others involved in the dialysis process to receive services.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)

- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the above stated reasons.

- (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 A.11, page 5, the applicant states that DaVita, Inc. operates more than 80 dialysis facilities in North Carolina. In Exhibit A.11, the applicant provides a list of its affiliates.

In Section O.3, pages 51, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were facilities with incidents related to quality of care occurred. There were two facilities and the applicant states that the problems have been corrected as documented in Exhibit O-3. After reviewing and considering information provided by the applicant and considering the quality of care provided at all facilities, including those related or affiliated with the applicant, the applicant provided sufficient evidence that quality care has been provided in the past. 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 application is conforming to all applicable criteria, as discussed below.

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- New Hanover Dialysis 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- In Section C, pages 13-14, the applicant demonstrates that New Hanover Dialysis will serve a total of 57 in-center patients in OY1 for a utilization rate of 80% or 3.2 patients per station per week ($57 \text{ patients} / 18 \text{ stations} = 3.1666$ or $3.2 / 4 = 0.8$ or 80%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 12-14, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.