

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 22, 2018

Findings Date: August 22, 2018

Project Analyst: Bernetta Thorne-Williams

Team Leader: Gloria Hale

Project ID #: J-11512-18

Facility: Carolina Dialysis - Siler City

FID #: 955802

County: Chatham

Applicant: Carolina Dialysis, LLC

Project: Relocate one dialysis station from BMA Asheboro for a total of 23 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

The applicant, Carolina Dialysis, LLC (CD) d/b/a Carolina Dialysis - Siler City (CD - Siler City), whose parent company is The University of North Carolina Hospitals and Renal Research Institute, LLC is an affiliated company of Bio-Medical Applications of North Carolina, Inc. Fresenius Medical Care Holdings, Inc, is the parent company of Bio-Medical Applications of North Carolina, Inc. The applicant proposes to relocate one dialysis station from BMA Asheboro for a total of 23 certified dialysis stations at CD - Siler City upon project completion. BMA Asheboro will have 45 certified dialysis stations upon project completion.

Need Determination

The 2018 State Medical Facilities Plan (2018 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D in the January 2018 Semiannual Dialysis Report (SDR) the county need methodology shows there is a deficit of three dialysis stations in Chatham County. However, in Project I.D. # J-11469-18, the applicant was approved to relocate one dialysis station from CD - Sanford in Lee County to CD - Pittsboro in Chatham County, thereby reducing the deficit in Chatham County to two dialysis stations. Therefore, the January 2018 SDR does not indicate a need for additional stations in Chatham County based on the county need methodology, which states that the county deficit must be ten or greater to establish a need for additional stations. An applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The applicant is not eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for CD - Siler City in the January 2018 SDR is 3.1364 patients per station per week, or 78.41% ($3.1364 / 4$ patients per station = 0.7841). This utilization rate was calculated based on 69 in-center dialysis patients and 22 certified dialysis stations (69 patients / 22 stations = 3.1364 patients per station per week). Therefore, neither of the two need determination methodologies in the 2018 SMFP apply to this proposal.

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 the relocation of one dialysis station from BMA Asheboro in Randolph County to CD - Siler City in Chatham County. According to Table D in the January 2018 SDR,

there is a deficit of three dialysis stations in Chatham County and a surplus of nine dialysis stations in Randolph County. Thus, the proposed relocation of one station from Randolph County to Chatham County would reduce the surplus of stations in Randolph County to eight dialysis stations as well as reduce the deficit of stations in Chatham County to one dialysis station. (See Project I.D. # J-11469-18 which also reduced the deficit in Chatham County by one station.)

On page 7, the applicant states that the proposed project, *“Relocation of one station from BMA Asheboro to Carolina Dialysis-Siler City does not create a deficit of stations in Randolph County, nor does this proposal create a surplus of stations in Chatham County.”* Additionally, Randolph County is a contiguous county to Chatham County. On page 22, the applicant states that as of December 31, 2017, two Chatham County residents were receiving services at BMA Asheboro in Randolph County. The applicant adequately demonstrates that the proposed relocation of one dialysis station from Randolph County to Chatham County 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 reasons stated above.

- (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

The applicant proposes to relocate one dialysis station from BMA Asheboro in Randolph County, for a total of 23 certified dialysis stations at CD - Siler City in Chatham County, upon project completion. BMA Asheboro will have 45 certified dialysis stations upon completion.

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 Chatham County. Facilities may serve residents of counties not included in their service area.

In Section C.1, page 14 and Section C.8, page 19, the applicant provides the projected and historical patient origin for CD - Siler City, respectively, as illustrated in the table below.

	CD - Siler City					
	CURRENT AS OF 12/31/2017		OPERATING YEAR 1 CY2019	OPERATING YEAR 2 CY2020	COUNTY PATIENTS AS A PERCENT OF TOTAL IN-CENTER PATIENTS	
	IN-CENTER PATIENTS	% OF TOTAL	IN-CENTER PATIENTS	IN-CENTER PATIENTS	OY1	OY 2
Chatham	65.0	84.4%	71.4	74.8	86.6%	87.1%
Alamance	1.0	1.3%	1.0	1.0	1.2%	1.2%
Randolph	10.0	13.0%	10.0	10.0	12.2%	11.7%
Other States	1.0	1.3%	0.0	0.0	0.0%	0.0%
TOTAL	77.0	100.0%	82.0	85.0	100.0%	100.0%

In the table on page 14, the applicant rounds down to the nearest whole patient for operating years (OYs) 1 and 2, therefore, the applicant projects to serve 82 in-center patients in OY1 and 85 in-center patients in OY2. In Section C, pages 15-16, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 15-16, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services.

On page 16, the applicant states,

“Carolina Dialysis - Siler City is operating at a high utilization rate. Growth of the facility census has been steady for many months. As of December 31, 2017 the facility census was 77 dialysis patients, on 22 dialysis stations. This is a utilization rate of 3.5 patients per station, or 87.5% [77 patients / 22 stations = 3.5; 3.5 / 4 = 0.875].”

Table B of the July 2018 SDR confirms the utilization rate mentioned above at CD - Siler City.

On page 15, the applicant provides the following assumptions:

- The applicant begins the projections for the future patient population of CD - Siler City by using the ending in-center patient census of 65 patients from Chatham County, as of December 31, 2017.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Chatham County which is 4.8% to project the Chatham County patient population forward. The applicant states that growth at CD - Siler City has been steady for several months.
- The applicant assumed the one patient served from “*other*” state was transient and that this patient population will not be projected forward.
- The applicant does not project an increase in the patient population from Alamance or Randolph counties.
- Operating Year 1 (OY1) = Calendar Year (CY) 2019.
Operating Year 2 (OY2) = Calendar Year (CY) 2020.

The information 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 CD - Siler City on December 31, 2017; and
- the applicant grows the Chatham County patient population by the January 2018 SDR Chatham County five-year AACR of 4.8% and holds utilization constant for patients from outside Chatham County.

Projected Utilization

In Section C, page 15, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

Begin with Chatham County patients dialyzing at CD - Siler City as of December 31, 2017.	65
Project the Chatham County patient population forward one year to December 31, 2018 using the Five-Year Average Annual Change Rate for Chatham County of 4.8%	$65 \times 1.048 = 68.1$
Add patients from Alamance and Randolph counties. This is the starting census for the project.	$68.1 + 11 = 79.1$
Project the Chatham County population forward one year to December 31, 2019 using the Five-Year Average Annual Change Rate for Chatham County of 4.8%.	$68.1 \times 1.048 = 71.4$
OY1: Add patients from Alamance and Randolph counties. This is the projected census for OY 1.	$71.4 + 11 = 82.4$
Project the Chatham County population forward one year to December 31, 2020 using the Five-Year Average Annual Change Rate for Chatham County of 4.8%.	$71.4 \times 1.048 = 74.8$
OY2: Add patients from Alamance and Randolph counties. This is the projected census for OY 2.	$74.8 + 11 = 85.8$

The applicant provides the assumptions for the projected in-center utilization on pages 15-16, as summarized below:

- Beginning census, December 31, 2017, is as listed in the ESRD Data Collection Forms submitted to DHSR Healthcare Planning in February 2018.
- OY1 is the period from January 1 through December 31, 2019.
- OY2 is the period from January 1 through December 31, 2020.
- The 65 in-center patients from Chatham County and the 11 patients from Alamance and Randolph counties will continue to dialyze at CD - Siler City.
- The Chatham County patient census will grow at the Chatham County Five Year AACR of 4.8%, as reported in the January 2018 SDR, and the Alamance and Randolph counties patient census will be held constant.

On page 14, the applicant rounds down to the nearest whole patient for operating years (OY) 1 and 2, therefore, the applicant projects to serve 82 in-center patients in OY1 and 85 in-center patients in OY2. Thus, the applicant projects that CD - Siler City will have a utilization rate of 89.1% or 3.5 patients per station per week ($82 \text{ patients} / 23 \text{ stations} = 3.5652 / 4 = 0.891$ or 89.1%) in OY1. The projected utilization of 3.5 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- the applicant begins its utilization projection with the existing patients of CD - Siler City,

- the applicant grows the Chatham County patient population by the January 2018 SDR Chatham County Five Year AACR and holds the patient population from outside Chatham County constant, and
- the resulting utilization rate at CD - Siler City by the end of the first year is above the minimum standard of 3.2 patients per station per week.

Home Hemodialysis and Peritoneal Dialysis

On page 14, the applicant states CD - Siler City does not currently provide home hemodialysis (HH) or peritoneal dialysis (PD) training nor does the applicant propose adding a home training program in the proposed project. On page 39, the applicant states that those patients who desire HH and PD training will be referred to either CD - Sanford or CD - Carrboro.

Access

In Section L-1(a), pages 50-51, the applicant states that each of Fresenius Medical Care’s (FMC) 112 facilities in 48 North Carolina counties 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.7, page 54, the applicant provides the historical payor mix for calendar year (CY) 2017 for CD - Siler City, as illustrated below.

Payor Category	Percent of Total Patients
Self Pay/ Indigent/ Charity	1.14%
Medicare	47.49%
Medicaid	18.53%
Commercial Insurance	4.47%
Medicare / Commercial	21.70%
Misc. (VA)	6.66%
Total	100.00%

As illustrated in the table above, in CY2017 87.72% of all CD - Siler City patients were Medicare or Medicaid recipients. On page 51, the applicant states that projected, “*payor mix is based upon the facility [sic] 2017 historical performance*”. On page 51, the applicant projects to serve 86.94% Medicare or Medicaid recipients in OY2.

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

The applicant proposes to relocate one dialysis station from BMA Asheboro for a total of 23 certified dialysis stations at CD - Siler City upon project completion. BMA Asheboro will have 45 certified dialysis stations upon completion.

In Section D, page 22, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated or relocated will be adequately met following completion of the project. On pages 22-23, the applicant states:

- The applicant identifies an in-center patient population at BMA Asheboro that consists of patients from Randolph, Chatham, Davidson, Guilford, Montgomery and Moore counties. (page 22)
- As of December 31, 2017, BMA Asheboro was certified for 46 dialysis stations. (page 22)
- As of December 31, 2017, BMA Asheboro served two patients from Chatham County. The applicant does not project that those two patients will transfer their care to CD - Siler City. (pages 22-23)
- The applicant projects the Randolph County patient population forward using the Five-Year Average Annual Change Rate for Randolph County of 1.2%. (page 23)

- The applicant does not project growth in the patient population from Chatham, Davidson, Guilford, Montgomery or Moore counties. (page 23)

In Section D, page 23, the applicant projects to serve 113 patients on 45 dialysis stations CY2019 (OY1) of the proposed project, as illustrated below.

Begin with Randolph County patients dialyzing at BMA Asheboro as of December 31, 2017.	102
Project the Randolph County patient population forward one year to December 31, 2018 using the Five-Year Average Annual Change Rate for Randolph County of 1.2%	$102 \times 1.020 = 104$
Add the 9 patients from other counties. This is the starting census for the project.	$104 + 9 = 113$

Thus, the applicant projects that BMA Asheboro will serve a total of 113 in-center patients at the end of OY1 for a utilization rate of 62.8% or 2.5 patients per station per week (113 patients / 45 stations = 2.5111 / 4 = 0.6277 or 62.8%).

In Section D, page 23, the applicant states,

“This relocation of one station will not alter or 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.

Those patients dialyzing with BMA Asheboro will continue to have access to dialysis care.”

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

- the applicant begins its utilization projection with the existing patients of BMA Asheboro,
- the applicant grows the Randolph County patient population by the January 2018 SDR Randolph County Five Year AACR and holds the patient population from outside Randolph County constant, and
- the resulting utilization rate at BMA Asheboro by the end of the first year remains underutilized. On page 15, the applicant states, *“Utilization at BMA Asheboro has been less than 80% for several years”*.

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 reduced, eliminated or 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 one dialysis station from BMA Asheboro for a total of 23 certified dialysis stations at CD - Siler City upon project completion.

In Section E.1, page 24, 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 the utilization at CD - Siler City will be greater than 80% by the end of OY1. Therefore, this alternative was rejected.
- Relocate stations from CD - Pittsboro - The applicant states that the utilization for CD - Pittsboro, as reported in the January 2018 SDR, is 82.5%. Therefore, the facility was over capacity. In Project I.D. # J-11469-18, the applicant was approved to relocate one dialysis station from CD - Sanford to CD - Pittsboro to address this need. Therefore, this alternative was rejected.
- Relocate more than one station from BMA Asheboro - The applicant states that to add additional stations would require construction. The applicant rejected this alternative because CD - Siler City needs "*immediate additional capacity*" and can accommodate one additional dialysis station.

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 operated above 80% capacity as of December 31, 2017, as reported in Table B of the July 2018 SDR and referenced throughout this application.
- the applicant's need methodology indicates a need for additional stations at the facility,

- to maintain the status quo does not address the need for additional stations at the facility and would result in higher utilization and potentially restrict patient admissions, and
- considering the growth experienced at CD - Siler City since December 31, 2017, failure to relocate one station pursuant to Policy ESRD-2 would result in a higher utilization of 3.7 patients per station per week based on 82 patients dialyzing on 22 stations instead of the proposed 23 stations in CY2019.

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 reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Carolina Dialysis, LLC d/b/a Carolina Dialysis - Siler City shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant Policy ESRD-2, Carolina Dialysis, LLC shall relocate no more than one dialysis station from BMA Asheboro for a total of no more than 23 certified stations at Carolina Dialysis - Siler City upon project completion which shall include any home hemodialysis training or isolation stations.**
 - 3. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify one dialysis station at BMA Asheboro for a total of no more than forty-five dialysis stations at BMA Asheboro upon project completion.**
 - 4. Carolina Dialysis, LLC d/b/a Carolina Dialysis - Siler City shall install plumbing and electrical wiring through the walls for no more than one additional dialysis station, which shall include any isolation or home hemodialysis training stations.**
 - 5. Carolina Dialysis, LLC d/b/a Carolina Dialysis - Siler City 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 one dialysis station from BMA Asheboro for a total of 23 certified dialysis stations at CD - Siler City upon project completion.

Capital and Working Capital Costs

In Section F, pages 26, the applicant projects the total capital cost of the project as shown in the table below.

Miscellaneous Costs:	
Dialysis Machines	\$15,000
Water Treatment Equipment	\$750
Other Equipment/Furniture	\$3,000
Total	\$18,750

In Section R, the applicant provides the assumptions used to project the capital cost. In Section F, page 29, the applicant states that there will be no start-up costs or initial operating expenses associated with the proposed project as CD - Siler City is an existing facility.

Availability of Funds

In Section F, page 27, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Carolina Dialysis, LLC	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$18,750	\$18,750
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$18,750	\$18,750

* OE = Owner's Equity

Exhibit F.1 contains a letter dated May 15, 2018, from the President of UNC Health Care Networks Hospital, Executive VP and CFO of UNC Hospitals at Chapel Hill and Carolina Dialysis, LLC Board Member, which states,

“As a member of the Board of Directors, I am authorized and do hereby authorize the addition of one dialysis station at Carolina Dialysis--Siler City. Further, I am authorized

and do hereby authorize and commit cash reserves for the capital cost of \$18,750 as may be needed for this project.”

Exhibit F.2 contains the Balance Sheet for Carolina Dialysis, LLC which indicates that it had \$23,627,675 in cash and investments as of December 31, 2017, \$38,680,436 in total assets and \$34,831,752 in retained earnings (total assets less total liabilities). The applicant adequately demonstrates the availability of funds, should there be a need.

Financial Feasibility

The applicant provided pro forma financial statements for the first two fiscal years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	Operating Year 1 CY2019	Operating Year 2 CY2020
Total Treatments	11,856	12,448
Total Gross Revenues (Charges)	\$47,281,728	\$49,642,624
Total Net Revenue	\$3,361,420	\$3,529,264
Average Net Revenue per Treatment	\$283.52	\$283.52
Total Operating Expenses (Costs)	\$2,851,042	\$2,955,754
Average Operating Expense per Treatment	\$240.47	\$237.45
Net Income	\$510,378	\$573,510

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
- 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 demonstrates that the capital costs are 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 one dialysis station from BMA Asheboro for a total of 23 certified dialysis stations at CD - Siler City 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 Chatham County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, there are currently two dialysis facilities in Chatham County, both of which are operated by Carolina Dialysis, LLC, as illustrated below.

CHATHAM COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of June 30, 2017				
Dialysis Facility	Certified Stations 6/30/17	# In-center Patients	Percent Utilization	Patients per Station
CD - Pittsboro	10	33	82.50%	3.3000
CD - Siler City	22	69	78.41%	3.1364
Total	32	102	79.68%	3.1875

Source: January 2018 SDR.

As shown in the table above, CD-Pittsboro operated with the highest utilization rate of 82.50%. With regard to the utilization at CD - Siler City, on page 15, the applicant states,

“Carolina Dialysis - Siler City is operating at a high utilization rate. Growth of the facility census has been steady for many months. As of December 31, 2017 the facility census was 77

dialysis patients, on 22 dialysis stations. This is a utilization rate of 3.5 patients per station, or 87.5% .”

Additionally, in Section C, page 16, the applicant states, *“The facility will qualify for up to eight additional stations by the application of the Facility Need Methodology based on the July 2018 SDR.”*

On page 34, the applicant provides the following table which illustrates an increase in utilization at the two facilities between June 30, 2017 and December 31, 2017, as reported in Table B of the January and the July 2018 SDR.

	# of Stations	As of June 30, 2017		As of December 31, 2017	
		# of Patients	Percent Utilization	# of Patients	Percent Utilization
CD - Pittsboro	10	33	82.50%	36	90.0%
CD - Siler City	22	69	78.41%	77	87.5%
Total	32	102	79.68%	113	88.3%

As illustrated above, the applicant reports that CD - Siler City had a utilization of 87.5% and CD - Pittsboro had a utilization of 90.0% as of December 31, 2017. The overall utilization for those two facilities as of December 31, 2017 was 88.3%, thus the facilities in Chatham County are well utilized.

In Section G, page 34, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Chatham County. The applicant states, *“CD-Siler City is actually taking a proactive step to ensure adequate access to care by the patients of the area who choose to dialyze at the facility.”*

The January 2018 SDR reports a deficit of three dialysis station in Chatham County and a surplus of nine dialysis stations in Randolph County. Therefore, the relocation of one dialysis station from BMA Asheboro in Randolph County to CD - Siler City in Chatham County will reduce the deficit of dialysis stations in Chatham County to one station and reduce the surplus of dialysis stations in Randolph County to eight dialysis stations. (See Project I.D. # J-11469-18 which also reduced the deficit in Chatham County by one station.)

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed addition of one dialysis station at CD - Siler City is needed in addition to the existing or approved dialysis stations.

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 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 35, the applicant provides current and projected staffing for the proposed services. The applicant does not project a change in the staffing of CD - Siler City with the addition of the one dialysis station, as illustrated in the following table.

POSITION	CURRENT # FTES CY2017	PROJECTED # FTES OY2 (CY2020)
Registered Nurse	4.00	4.00
Technician (PCT)	9.00	9.00
Dietician	1.00	1.00
Social Worker	1.00	1.00
Clinical Manager	1.00	1.00
Admin. (FMC Dir. Ops)	0.15	0.15
In-Service	0.20	0.20
Clerical	1.00	1.00
Chief Tech	0.20	0.20
Equipment Tech	1.00	1.00
Total	18.55	18.55

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, page 66, which is found in Section R. In Section H, pages 35-36, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit I.5, the applicant provides a letter from the medical director indicating his interest in continuing to serve as the medical director of CD - Siler City.

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
- 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 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 39, the applicant provides a list of the necessary ancillary and support services for the proposed services, as illustrated below.

Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	CD - Siler City (on site)
Self-care training (in-center)	Referred to CD - Sanford or CD - Carrboro
Home training HH PD Accessible follow-up program	Referred to CD - Sanford or CD - Carrboro
Psychological counseling	UNC Hospitals
Isolation – hepatitis	CD - Siler City (on site)
Nutritional counseling	CD - Siler City (on site)
Social Work services	CD - Siler City (on site)
Acute dialysis in an acute care setting	UNC Hospitals
Emergency care	Chatham Hospitals
Blood bank services	UNC Hospitals
Diagnostic and evaluation services	Chatham Hospital or UNC Hospitals
X-ray services	Chatham Hospital or UNC Hospitals
Laboratory services	Spectra
Pediatric nephrology	UNC Hospitals
Vascular surgery	UNC Hospital
Transplantation services	UNC Hospitals
Vocational rehabilitation & counseling	Chatham County Vocational Rehab.
Transportation	Chatham Transportation

The applicant provides supporting documentation in Exhibit I.1-5. Exhibits I-1 through I-4, respectively, contain copies of agreements for home training services with CD - Carrboro, Spectra for laboratories services, UNC Hospitals and Chatham Hospital for hospital transfer and UNC Hospitals for transplant services.

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
- 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.

- (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.7, page 54, the applicant provides the historical payor mix during CY 2017, as shown in the table below.

Payor Category	Percent of Total Patients
Self Pay/ Indigent/ Charity	1.14%
Medicare	47.49%
Medicaid	18.53%
Commercial Insurance	4.47%
Medicare / Commercial	21.70%
Misc. (VA)	6.66%
Total	100.00%

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
Chatham	24%	52%	28%	12%	10%	14%
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.

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 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, page 53, the applicant states:

“CD-Siler City does not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all CD-Siler City is obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

In Section L, page 54, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

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.

- (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 51, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Projected Payor Mix OY2

Payor Category	Percent of Total Patients
Self Pay/ Indigent/ Charity	1.87%
Medicare	45.70%
Medicaid	19.61%
Commercial Insurance	4.62%
Medicare / Commercial	21.63%
Misc. (VA)	6.56%
Total	100.00%

As shown in the table above, during the second full fiscal year of operation, the applicant projects its payor source will consist of 67.33% Medicare patients (includes Medicare and Medicare/Commercial) and 19.61% Medicaid patients. The projected payor mix for OY2 differs slightly from, but is roughly within the same range, as the facility's 2017 historical payor mix of 69.19% Medicare patients (includes Medicare and Medicare/Commercial) and 18.53% Medicaid patients.

On pages 51-52, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year 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 at CD - Siler City.

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.

- (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.4, page 53, 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
- 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.

- (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 55, 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-1.

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 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

The applicant proposes to relocate one dialysis station from BMA Asheboro for a total of 23 certified dialysis stations at CD - Siler City 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 Chatham County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, there are currently two dialysis facilities in Chatham County, both of which are operated by Carolina Dialysis, LLC, as illustrated below.

CHATHAM COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of June 30, 2017				
Dialysis Facility	Certified Stations 6/30/17	# In-center Patients	Percent Utilization	Patients per Station
CD - Pittsboro	10	33	82.50%	3.3000
CD - Siler City	22	69	78.41%	3.1364
Total	32	102	79.68%	3.1875

Source: January 2018 SDR.

In Section N.1, page 56, 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 56, the applicant states:

“CD-Siler City does not expect this proposal to have an effect on the competitive climate in Chatham County. At the present time, there are two operational facilities to serve the ESRD patients in Chatham County, both are operated by Carolina Dialysis, LLC. CD-Siler City does not project to serve dialysis patients currently being served by another provider. The projected patient population for the Carolina Dialysis--Siler City facility begins with patients currently served by CD-Siler City, and a growth of that patient population at the Chatham County Five Year Average Annual Change Rate.”

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 R 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 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 reasons stated above.

- (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, pages 4-5, the applicant states that Carolina Dialysis, LLC operates six dialysis facilities in North Carolina and has a seventh dialysis facility under development (Project I.D. # J-11449-18). In Exhibit A.3, the applicant provides a list of its affiliates which includes over 100 Fresenius-related facilities operating in North Carolina, as stated in Section O.3, page 60.

In Section O.3, pages 60-61, the applicant states that, during the 18 months immediately preceding the submittal of the application, one incident related to quality of care occurred in one

of these facilities (BMA East Rocky Mount). The applicant states that the problem has 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- CD - Siler City 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 14-16, the applicant demonstrates that CD - Siler City will serve a total of 82 in-center patients in OY1 for a utilization rate of 89.1% or 3.5 patients per

station per week (82 patients / 23 stations = 3.5652 / 4 = 0.891 or 89.1. 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 14-16, 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.