

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 20, 2018

Findings Date: December 20, 2018

Project Analyst: Bernetta Thorne-Williams

Team Leader: Fatimah Wilson

Project ID #: J-11567-18

Facility: Carolina Dialysis - Siler City

FID #: 955802

County: Chatham

Applicant: Carolina Dialysis, LLC

Project: Add three dialysis stations for a total of 26 dialysis stations upon completion of this project and Project I.D. # J-11512-18 (relocate one dialysis station from BMA Asheboro)

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 is Carolina Dialysis, LLC (CD) d/b/a Carolina Dialysis - Pittsboro (CD - Pittsboro). The parents are The University of North Carolina Hospitals and Renal Research Institute, LLC, an affiliate of Bio-Medical Applications of North Carolina, Inc. (BMA). Fresenius Medical Care Holdings, Inc, is the parent company of BMA.

The proposes to add three dialysis stations for a total of 26 dialysis stations upon completion of this project and Project I.D. # J-11512-18 (relocate one dialysis station from BMA Asheboro).

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 July 2018 Semiannual Dialysis Report (SDR) the county need methodology shows there is a deficit of eight dialysis stations in Chatham County. Therefore, the July 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 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 July 2018 SDR is 3.5 patients per station per week, or 87.50% ($3.5 / 4 \text{ patients per station} = 0.875$). This utilization rate was calculated based on 77 in-center dialysis patients and 22 certified dialysis stations ($77 \text{ patients} / 22 \text{ stations} = 3.5 \text{ patients per station per week}$).

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table:

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/17		87.5%
Certified Stations		22
Pending Stations		1
Total Existing and Pending Stations		23
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2)		77
In-Center Patients as of 6/30/17 (Jan 2018 SDR) (SDR1)		69
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	8
	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/17	0.2319
(ii)	Divide the result of Step (i) by 12	0.0193
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/16 until 12/31/17)	0.2319
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	94.8551
(v)	Divide the result of Step (iv) by 3.2 patients per station	29.6422
	and subtract the number of certified and pending stations to determine the number of stations needed	6.6422

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is seven (rounded) stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add three new stations, therefore the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2018 SMFP which is applicable to this review. Policy GEN-3 on page 33 of the 2018 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

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

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4, page 9, Section K.1(g), page 44, Section N.1, page 54, Section O, pages 55-58, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4, pages 10-11, Section C, page 16, Section L, pages 48-49, Section N.1, page 54, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4, pages 10-11, Section C.1, pages 14-16, Section F, pages 24-30, Section K, pages 42-44, Section N, page 54, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

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 add three dialysis stations for a total of 26 dialysis stations upon completion of this project and Project I.D. # J-11512-18 (relocate one dialysis station from BMA Asheboro).

The applicant does not propose to serve home hemodialysis (HHD) or peritoneal dialysis patients.

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 18, the applicant provides the historical and projected 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 CY2020	OPERATING YEAR 2 CY2021	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	64.0	87.7%	82.6	91.5	90.2%	91.0%
Alamance	1.0	1.4%	1.0	1.0	1.1%	1.0%
Randolph	8.0	10.9%	8.0	8.0	8.7%	8.0%
TOTAL	73.0	100.0%	91.0	100.0	100.0%	100.0%

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 14-16, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section B, page 7, the applicant states the application is filed pursuant to the facility need methodology in the 2018 SMFP utilizing data from the July 2018 SDR.

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 June 30, 2018 the facility census was 77 dialysis patients, on 22 dialysis stations. This is a utilization rate of 3.3 patients per station, or 82.95% .”

The applicant made an error in its calculation on page 15. The application states Carolina Dialysis - Siler City had an in-center census of 77 patients dialyzing on 22 stations, as of June 30, 2018, 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.

Projected Utilization

On page 15, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant starts with the number of Chatham County patients (64), as of June 30, 2018.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Chatham County as published in the July 2018 SDR (10.7%) to project the Chatham County patient population forward.
- The applicant does not project an increase in the patient population from Alamance or Randolph counties using the facility.
- Operating Year 1 (OY1) = Calendar Year (CY) 2020.
Operating Year 2 (OY2) = Calendar Year (CY) 2021.

The applicant’s methodology is illustrated in the following table,

Carolina Dialysis - Siler City
J-11567-18
Page 7

The applicant begins with Chatham County patients dialyzing at CD - Siler City as of June 30, 2018.	64
The applicant projects the Chatham County patients forward 6 months to December 31, 2018 using one half the Chatham County 5-year AACR, which is 5.35%.	$64 \times 1.0535 = 67.4$
The applicant projects the Chatham County in-center patients forward one year to December 31, 2019 at the 5-year AACR, which is 10.7%.	$67.4 \times 1.107 = 74.6$
The applicant adds the 9 patients from outside Chatham County. This is the projected starting census for Operating Year 1.	$74.6 + 9 = 83.6$
The applicant projects the Chatham County in-center patients forward one year to December 31, 2020 at the 5-year AACR, which is 10.7%.	$83.6 \times 1.107 = 92.6$
The applicant adds the 9 patients from outside Chatham County. This is the projected ending census for Operating Year 1 (12/ 31/ 2020).	$92.6 + 9 = 101.6$
The census of Chatham County in-center patients is increased by 10.7% (0.107) to project the census forward one year to December 31, 2021.	$101.6 \times 1.107 = 112.5$
The applicant adds the 9 patients from outside Chatham County. This is the projected ending census for Operating Year 2 (12/ 31/ 2021).	$112.5 + 9 = 121.5$

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 91 in-center patients in OY1 and 100 in-center patients in OY2. Thus, the applicant projects that CD - Siler City will have a utilization rate of 98.9% or 3.5 patients per station per week ($91 \text{ patients} / 26 \text{ stations} = 3.5 / 4 = 0.875$ or 87.5%) 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 with the existing patients,
- the applicant grows the Chatham County in-center patients using the Chatham County 5-year AACR and holds the patient population from Alamance and Randolph counties constant,
- the growth rate for CD - Siler City was 23.19% as measured between 6/30/2017 and 12/31/17, and
- the utilization rate by the end of OY1 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 37, 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), page 48, the applicant states that each of Fresenius Medical Care’s (FMC) 114 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, page 49, 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 Source	Percent of Total Revenue
Self Pay/ Indigent/ Charity	2.10%
Medicare	47.59%
Medicaid	19.87%
Commercial Insurance	3.89%
Medicare / Commercial	20.97%
Misc. (VA)	5.58%
Total	100.00%

As shown in the table above during OY2, the applicant projects its payor source will consist of 68.56% Medicare patients (includes Medicare and Medicare/Commercial) and 19.87% Medicaid patients.

On pages 49-50, the applicant provides the assumptions and methodology used to project payor mix during OY2. On page 49, the applicant states that projected, “*payor mix is based upon the facility [sic] 2017 historical performance*”. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization at CD - Siler City.

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.

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.

NA

The applicant does not propose to:

- reduce a service
- eliminate a service
- relocate a facility or service

Therefore, Criterion (3a) is not applicable to this review.

(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 add three dialysis stations for a total of 26 dialysis stations upon completion of this project and Project I.D. # J-11512-18 (relocate one dialysis station from BMA Asheboro).

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 the utilization at CD - Siler City will be greater than 80% by the end of OY1. Although, the applicant used the five year AACR of 10.7 percent for Chatham County, as published in the July 2018 SDR, to project future growth at CD-Siler City. The applicant states the facility need methodology calculates a growth rate of 23.19 percent. Therefore, this alternative was rejected.

- Add more stations - The applicant states the facility need methodology indicated a potential need for seven (rounded) stations. The applicant stated adding more than three stations would require significant construction and was not considered to be a cost effective alternative. Therefore, this alternative was rejected.
- Add additional stations and home hemodialysis and peritoneal dialysis training - The applicant states this is a more expensive alternative. Additionally, the applicant has a concurrent application to relocate, expand and add home training services to CD - Pittsboro (see Project J-11571-18). The applicant concluded that adding home training services to the proposed project would not be cost effective.

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 facility need methodology indicates a need for additional stations at the facility, and
- 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.

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 to the facility need determination in the July 2018 SDR, Carolina Dialysis, LLC, shall develop no more than three additional dialysis stations for a total of no more than 26 dialysis stations upon completion of this project and Project I.D. # J-11512-18 (relocate one dialysis station from BMA Asheboro), which shall include any home hemodialysis training or isolation stations.**

3. **Carolina Dialysis, LLC d/b/a Carolina Dialysis - Siler City shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations, which shall include any isolation or home hemodialysis training stations.**
 4. **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 add three dialysis stations for a total of 26 dialysis stations upon completion of this project and Project I.D. # J-11512-18 (relocate one dialysis station from BMA Asheboro).

Capital and Working Capital Costs

In Section F, pages 24, the applicant projects the total capital cost of the project as shown in the table below.

Construction Costs	\$227,216
Dialysis Machines	\$45,000
Water Treatment Equipment	\$7,600
Miscellaneous Costs	\$42,600
Total	\$322,416

In Section F, page 27, 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 *	\$322,416	\$322,416
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$322,416	\$322,416

* OE = Owner's Equity

Exhibit F.1 contains a letter dated September 17, 2018, from the Chairman of the Board of Managers for Carolina Dialysis, which states,

“I am authorized and do hereby authorize the addition of three dialysis stations at Carolina Dialysis-Siler City, Further, I am authorized and do hereby authorize and commit case reserves for the capital cost of \$322,416 as may be needed for this project.”

Exhibit F.2 contains a balance sheet for Carolina Dialysis, LLC which indicates that, as of June 30, 2018, it had \$23,046,729 in cash and investments, \$41,798,706 in total assets and \$37,917,505 in retained earnings (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the project.

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 CY2020	Operating Year 2 CY2021
Total Treatments	12,893	14,227
Total Gross Revenues (Charges)	\$51,417,284	\$56,737,276
Total Net Revenue	\$3,928,210	\$4,334,650
Average Net Revenue per Treatment	\$304.68	\$304.68
Total Operating Expenses (Costs)	\$3,254,233	\$3,458,414
Average Operating Expense per Treatment	\$252.40	\$242.24
Net Income	\$673,977	\$876,236

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 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 add three dialysis stations for a total of 26 dialysis stations upon completion of this project and Project I.D. # J-11512-18 (relocate one dialysis station from BMA Asheboro).

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 July 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 CERTIFIED STATIONS & UTILIZATION as of December 31, 2017				
Dialysis Facility	Certified Stations 12/31/17	# In-center Patients 12/31/17	Percent Utilization 12/31/17	Patients per Station 12/31/17
CD – Pittsboro*	10	36	90.00%	3.6000
CD - Siler City**	22	77	87.50%	3.5000
Total	32	113	88.28%	3.5312

Source: July 2018 SDR.

*approved to add 2 stations

**approved to add 1 station

As illustrated in the table above, the existing facilities in Chatham County are well utilized. Even with the three approved stations, the average utilization rate would be 3.22 patients per station per week [$113/35=3.22$] or 80.7% [$3.22/4=0.807$].

In Section G, page 32, 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, “*Based solely on the growth of the census within the Carolina Dialysis facilities in both Pittsboro and Siler City, the applicant suggests that adding three stations is not duplicating existing capacity.*”

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 three new dialysis stations 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

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.

In Section H, page 33, the applicant provides current and projected staffing for the proposed services. The applicant projects an increase of 1.50 FTE positions at CD - Siler City with the addition of the one dialysis station, as illustrated in the following table.

POSITION	CURRENT # FTEs CY2017	PROJECTED # FTEs OY2 (CY2021)
Registered Nurse	4.00	4.50
Technician (PCT)	9.00	10.00
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	20.05

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, page 73, which is found in Section R. In Section H, pages 33-34, 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

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.

In Section I, page 37, the applicant provides a list of the necessary ancillary and support services for the proposed services, as illustrated below.

CD - Siler City 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	Referred to CD - Sanford or CD - Carrboro
HH	
PD	
Accessible follow-up program	
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 - Sanford, 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

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 52, the applicant provides the historical payor mix during CY 2017, as shown in the table below.

Payor Source	Percent of Total Revenue
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 51, 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 52, 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

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 49, 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 Source	Percent of Total Revenue
Self Pay/ Indigent/ Charity	2.10%
Medicare	47.59%
Medicaid	19.87%
Commercial Insurance	3.89%
Medicare / Commercial	20.97%
Misc. (VA)	5.58%
Total	100.00%

As shown in the table above during OY2, the applicant projects its payor source will be 68.56% Medicare patients (includes Medicare and Medicare/Commercial) and 19.87% 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 49-50, 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

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.

In Section L.4, page 51, 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 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

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 add three dialysis stations for a total of 26 dialysis stations upon completion of this project and Project I.D. # J-11512-18 (relocate one dialysis station from BMA Asheboro).

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 July 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 CERTIFIED STATIONS & UTILIZATION as of December 31, 2017				
Dialysis Facility	Certified Stations 12/31/17	# In-center Patients 12/31/17	Percent Utilization 12/31/17	Patients per Station 12/31/17
CD – Pittsboro*	10	36	90.00%	3.6000
CD - Siler City**	22	77	87.50%	3.5000
Total	32	113	88.28%	3.5312

Source: July 2018 SDR.

*approved to add 2 stations

**approved to add 1 station

As illustrated in the table above, the existing facilities in Chatham County are well utilized. Even with the three approved stations, the average utilization rate would be 3.22 patients per station per week [$113/35=3.22$] or 80.7% [$3.22/4=0.807$].

In Section N.1, page 54, 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 54, 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.2, page 58.

In supplemental information received from the applicant on December 6, 2018, the applicant states that, during the 18 months immediately preceding the submittal of the application, zero incident related to quality of care occurred in any of these facilities. In Exhibit O-2, the applicant provides a copy of the most recent survey for CD-Siler City. 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

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 91 in-center patients in OY1 for a utilization rate of 87.5% or 3.5 patients per station per week ($91 \text{ patients} / 26 \text{ stations} = 3.5 / 4 = 0.875$ or 87.5). 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.