

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 30, 2018

Findings Date: April 30, 2018

Project Analyst: Mike McKillip

Team Leader: Gloria C. Hale

Assistant Chief: Lisa Pittman

Project ID #: J-11449-18

Facility: Carolina Dialysis-Orange County

FID #: 180044

County: Orange

Applicant: Carolina Dialysis, LLC

Project: Develop a new 10-station dialysis facility by relocating seven existing dialysis stations from Carolina Dialysis-Carrboro and three existing dialysis stations from BMA Burlington, and relocate the home training program from Carolina Dialysis-Carrboro to the new facility

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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

Carolina Dialysis, LLC d/b/a Carolina Dialysis-Orange County [**CDO**] proposes to develop a new 10-station dialysis facility in Orange County by relocating seven existing dialysis stations from Carolina Dialysis-Carrboro, in Orange County, and three existing dialysis stations from BMA Burlington in Alamance County. The applicant also proposes to relocate the existing home training program from Carolina Dialysis-Carrboro to the new facility. Upon completion of the proposed relocation, Carolina Dialysis-Carrboro will be certified for 34 dialysis stations and BMA Burlington will be certified for 42 dialysis stations.

Need Determination

The county and facility need methodologies in the January 2018 SDR and the 2018 SMFP are not applicable to this review.

Policies

There are two policies in the 2018 SMFP applicable to this review: Policy ESRD-2: Relocation of Dialysis Stations, on page 27, and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 33.

Policy ESRD-2

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.”*

CDO proposes to develop a new 10-station dialysis facility by relocating seven existing dialysis stations from Carolina Dialysis-Carrboro and three existing dialysis stations from BMA Burlington. Both Carolina Dialysis-Carrboro and the proposed facility location are in Orange County, therefore there is no change in the dialysis station inventory in Orange County associated with that proposed relocation. However, BMA Burlington is located in Alamance County. Alamance and Orange are contiguous counties. In Section B.3, page 9, the applicant states that BMA Burlington and Carolina Dialysis-Carrboro are both currently serving residents of Orange County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

According to Table D of the January 2018 SDR, Alamance County has a projected surplus of 29 dialysis stations. Following the applicant’s proposed relocation of three existing stations from BMA Burlington to Orange County, Alamance County would have a surplus of 26 dialysis stations ($29 - 3 = 26$). Therefore, the proposal will not result in a deficit, or increase

an existing deficit in the number of dialysis stations in the county that would be losing stations.

According to Table D of the January 2018 SDR, Orange County has a projected deficit of nine dialysis stations. Following the applicant's proposed relocation of three existing stations from BMA Burlington to Orange County, Orange County would still have a deficit of six dialysis stations ($9 - 3 = 6$). Therefore, the proposal will not result in a surplus, or increase an existing surplus in the number of dialysis stations in the county that would be gaining stations. Therefore, the application is consistent with Policy ESRD-2.

Policy GEN-4

Policy GEN-4 states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B.5, pages 14-15, the applicant describes the project's plan to improve energy efficiency and conserve water, including energy efficient lighting, water optimization protocols, sustainable design and building materials, high-performance HVAC systems, and high-efficiency equipment and appliances. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

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

CDO proposes to develop a new 10-station dialysis facility in Orange County by relocating seven existing dialysis stations from Carolina Dialysis-Carrboro, in Orange County, and three existing dialysis stations from BMA Burlington in Alamance County. The applicant also proposes to relocate the existing home training program from Carolina Dialysis-Carrboro to the new facility. Upon completion of the proposed relocation, Carolina Dialysis-Carrboro will be certified for 34 dialysis stations and BMA Burlington will be certified for 42 dialysis stations.

In Section A.4, page 2, the applicant states Carolina Dialysis, LLC is a limited liability company comprised of two members: The University of North Carolina Hospitals (UNCH) and Renal Research Institute, LLC (RRI). RRI is a wholly-owned subsidiary of Fresenius Medical Care Holdings, Inc. (FMCH), which is the parent company of Bio-Medical Applications of North Carolina, Inc.

The following tables, summarized from Section A.9, pages 4-5 of the application, show the proposed CDO facility, and the existing Carolina Dialysis-Carrboro and BMA Burlington facilities from which the applicant plans to relocate 10 stations to develop the proposed new facility.

Carolina Dialysis-Orange County		
Stations	Description	Project ID #
0	Total existing certified stations as of the January 2018 SDR	
+10	Stations to be added as part of this project	J-11449-18
10	Total stations upon completion of above project	
Carolina Dialysis-Carrboro		
Stations	Description	Project ID #
41	Total existing certified stations as of the January 2018 SDR	
-7	Stations to be deleted as part of this project	J-11449-18
34	Total stations upon completion of above project	
BMA Burlington		
Stations	Description	Project ID #
45	Total existing certified stations as of the January 2018 SDR	
-3	Stations to be deleted as part of this project	J-11449-18
42	Total stations upon completion of above project	

As shown in the table above, upon project completion, CDO will be certified for 10 dialysis stations, Carolina Dialysis-Carrboro will be certified for 34 dialysis stations, and BMA Burlington will be certified for 42 dialysis stations.

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 for this facility consists of Orange County. Facilities may also serve residents of counties not included in their service area.

In Section C.1, page 16, the applicant provides the projected patient origin for CDO for in-center (IC), home hemodialysis (HHD) and peritoneal dialysis (PD) patients for the first two years of operation following completion of the project as follows:

County	Operating Year 1 CY2020			Operating Year 2 CY2021			Percent of Total	
	IC	HHD	PD	IC	HHD	PD	OY1	OY2
Orange	34.0	1.2	8.4	36.2	1.3	8.9	65.5%	66.8%
Caswell	0	0	1	0	0	1	1.5%	1.4%
Chatham	0	0	3	0	0	3	4.5%	4.3%
Cumberland	0	1	0	0	1	0	1.5%	1.4%
Durham	0	1	7	0	1	7	12.0%	11.5%
Gaston	0	1	0	0	1	0	1.5%	1.4%
Guilford	0	0	1	0	0	1	1.5%	1.4%
Halifax	0	0	1	0	0	1	1.5%	1.4%
Hoke	0	0	1	0	0	1	1.5%	1.4%
Moore	0	0	1	0	0	1	1.5%	1.4%
New Hanover	0	0	1	0	0	1	1.5%	1.4%
Sampson	0	0	1	0	0	1	1.5%	1.4%
Wake	0	1	2	0	1	2	4.5%	4.3%
Total	34.0	5.2	27.4	36.2	5.3	27.9	100.0%	100.0%

The applicant provides the assumptions and methodology used to project patient origin on pages 16-18. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.1, page 17, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section C.1, pages 16-18, the applicant describes its need methodology assumptions for projecting utilization of the proposed facility as follows:

1. The applicant projects the first two full operating years of the project will be January 1, 2020 – December 31, 2020 (CY2020) and January 1, 2021 – December 31, 2021 (CY2021).
2. The applicant states that 32 in-center dialysis patients who are currently being treated at Carolina Dialysis-Carrboro and one in-center dialysis patient currently being treated at BMA Burlington have signed letters indicating they would consider transferring to CDO. Exhibit C-1 contains copies of the letters.
3. CDO assumes that 32 of the 33 patients identified above will transfer their care to the proposed facility. The applicant assumes that the Orange County patient population will increase by 6.3 percent per year through the first two operating years of the project. On page 17, the applicant states,

“Carolina Dialysis-Orange County assumes that 32 patients will complete the transfer of care to the new facility upon completion of the project. ... The applicant

does not project in-center patients from other counties will transfer their care to the new facility. This is not say that the new facility will restrict admissions. Rather, this is simply a statement that based on the letters of support, the applicant is not projecting to serve patients from other counties. ... The applicant will demonstrate growth of the home patient population who are residents of Orange County in the same manner as the in-center patient population. The applicant will apply the Orange County Five Year Average Annual Change Rate to the Orange County patients. Patients of other counties are assumed to be dialyzing with Carolina Dialysis-Orange County by patient choice. The applicant will not apply any growth factor to these patients (residing in other counties) but does assume they will continue dialysis with Carolina Dialysis at the new facility. These patients will be added to the projected census at appropriate points in time.”

Projected Utilization

The applicant’s methodology for in-center patients is shown in the following table.

	In-Center
The applicant begins with the 32 Orange County residents currently dialyzing at Carolina Dialysis-Carrboro and BMA Burlington who expressed their intention to transfer to CDO upon certification of the new facility on December 31, 2019.	32
The census of Orange County in-center patients is increased by 6.3% to project the census forward one year to December 31, 2020. This is the projected ending census for Operating Year 1.	$[32 \times 0.063] + 32 = 34.0$
The census of Orange County in-center patients is increased by 6.3% to project the census forward one year to December 31, 2021. This is the projected ending census for Operating Year 2.	$[34.0 \times 0.063] + 34.0 = 36.2$

The applicant projects to serve 34 in-center patients or 3.4 patients per station per week ($34/10 = 3.4$) by the end of Operating Year 1 and 36 in-center patients or 3.6 patients per station per week ($36/10 = 3.6$) by the end of Operating Year 2 for the proposed 10-station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). In this application, the applicant assumes a projected annual rate of growth of 6.3 percent for the in-center patient census at CDO, which is equal to the Orange County Five Year Average Annual Change Rate as published in the January 2018 SDR. Projected in-center utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Home Therapy Programs

On page 18, the applicant provides the following tables showing its projections of home hemodialysis (HHD) and peritoneal dialysis (PD) patients through the first two operating years of the project.

	Peritoneal Dialysis
The applicant begins with 7 Orange County patients currently on the peritoneal dialysis program at Carolina Dialysis-Carrboro as of December 31, 2017.	10 PD patients
The applicant projects growth based on 6.3% annual rate of increase to December 31, 2018.	$7 \times 1.063 = 7.4$
The applicant projects growth based on 6.3% annual rate of increase to December 31, 2019.	$7.4 \times 1.063 = 7.9$
The applicant projects growth based on 6.3% annual rate of increase to December 31, 2020.	$7.9 \times 1.063 = 8.4$
The applicant adds 19 patients who reside out-of-county. This is the projected ending census for Operating Year 1.	$8.4 + 19 = 27.4$
The census of Orange County PD is increased by 6.3% to project the census forward one year to December 31, 2021.	$8.4 \times 1.063 = 8.9$
The applicant adds 19 PD patients who reside out-of-county. This is the projected ending census for Operating Year 2.	$8.9 + 19 = 27.9$

	Home Hemodialysis
The applicant begins with 1 Orange County patient currently on the home hemodialysis program at Carolina Dialysis-Carrboro as of December 31, 2017.	1 HHD patient
The applicant projects growth based on 6.3% annual rate of increase to December 31, 2018.	$1 \times 1.063 = 1.1$
The applicant projects growth based on 6.3% annual rate of increase to December 31, 2019.	$1.1 \times 1.063 = 1.1$
The applicant projects growth based on 6.3% annual rate of increase to December 31, 2020.	$1.2 \times 1.063 = 1.2$
The applicant adds four HHD patients who reside out-of-county. This is the projected ending census for Operating Year 1.	$1.2 + 4 = 5.2$
The census of Orange County HHD patients is increased by 6.3% to project the census forward one year to December 31, 2021.	$1.2 \times 1.063 = 1.3$
The applicant adds four HHD patients who reside out-of-county. This is the projected ending census for Operating Year 2.	$1.3 + 4 = 5.3$

On page 17, the applicant describes its assumptions as follows:

“Carolina Dialysis-Orange County is planning to develop a new contemporary and spacious home therapies suite in the new location. Carolina Dialysis intends to relocate the entire home therapies program of Carolina Dialysis-Carrboro to the new location. ... The applicant will demonstrate growth of the home patient population who are residents of Orange County in the same manner as the in-center patient population. The applicant will apply the Orange County Five Year Average Annual Change Rate to the Orange County patients. Patients of other counties are assumed to be dialyzing with Carolina Dialysis-Orange County by patient choice. The applicant will not apply any growth factor to these patients (residing in other counties) but does assume they will continue dialysis with Carolina Dialysis at the new facility. These patients will be added to the projected census at appropriate points in time.”

Projected utilization for the in-center, HHD and PD dialysis programs at CDO is reasonable and adequately supported for the following reasons:

- The applicant projects the starting patient census for the proposed facility based on existing Carolina Dialysis-Carrboro and BMA Burlington patients who have signed letters expressing their intention to transfer their care to the proposed CDO facility.
- The applicant's growth projections are based on an assumption that patient census will increase at an annual rate of 6.3%, which is consistent with the Five Year Average Annual Change Rate (AACR) for Orange County, as reported in Table D of the January 2018 SDR.

Access

In Section C.3, pages 19-20, the applicant states that each of BMA's 112 facilities in 48 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. In Section L.1, page 60, the applicant projects the following payor mix during the second full fiscal year of operation (CY2021) following completion of the project, as illustrated in the following table.

Payment Source	Total Patients by Percent of Total
Self Pay/Indigent/Charity	2.90%
Medicare	46.38%
Medicaid	17.39%
Commercial Insurance	11.59%
Medicare/Commercial Insurance	20.29%
Miscellaneous (including VA)	1.45%
Total	100.00%

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

CDO proposes to develop a new 10-station dialysis facility in Orange County by relocating seven existing dialysis stations from Carolina Dialysis-Carrboro, in Orange County, and three existing dialysis stations from BMA Burlington in Alamance County. The applicant also proposes to relocate the existing home training program from Carolina Dialysis-Carrboro to the new facility. Upon completion of the proposed relocation, Carolina Dialysis-Carrboro will be certified for 34 dialysis stations and BMA Burlington will be certified for 42 dialysis stations.

The following table shows the projected relocation of stations from BMA Burlington and Carolina Dialysis-Carrboro to the proposed CDO facility and identifies the number of patients projected to transfer from the existing facility to the proposed new facility.

Proposed Carolina Dialysis-Orange County Project		
Facility	Number of Stations to be Relocated	Number of Patients Transferring
Carolina Dialysis-Carrboro	7	32
BMA Burlington	3	1
Total Relocated and Transferred	10	33

In Section D.1, pages 27-30, the applicant explains why it believes the needs of the population presently utilizing the dialysis services to be relocated will be adequately met following completion of the project.

Carolina Dialysis-Carrboro

According to the January 2018 Semiannual Dialysis Report (SDR), there were 120 patients dialyzing at Carolina Dialysis-Carrboro and 41 certified dialysis stations for a utilization rate of 73.17%, or 2.93 patients per station per week ($120/41 = 2.93$) as of June 30, 2017. In Section D.1, page 28, the applicant states that 95 of the 120 in-center patients reside in Orange County, and the remaining patients originate from Durham County (13 patients), Chatham County (6 patients), Granville County (2 patients), Bladen (1 patient), Alamance (1 patient), Wake (1 patient), and Wilson County (1 patient).

The applicant assumes that the number of in-center patients at Carolina Dialysis-Carrboro who reside in Orange County will increase at a rate of 6.3% per year through the first two operating years of the project based on the Five Year Average Annual Change Rate (AACR) for Orange County, as reported in Table D of the January 2018 SDR. The applicant assumes that there will be no increase in the number of patients from the other counties. The applicant projects that 32 Carolina Dialysis-Carrboro patients, all of whom will reside in Orange County, will transfer their care to CDO upon certification of that facility on December 31, 2019.

In Section D.1, page 29, the applicant calculates the in-center patient census for Carolina Dialysis-Carrboro starting December 31, 2017 through the first two operating years (CY2020 and CY2021), summarized as follows:

Carolina Dialysis-Carrboro	In-Center Patients
Begin with the ESRD patient population of Orange County, as of December 31, 2017.	95
Project the Orange County population forward one year to December 31, 2018, using the Five Year AACR for Orange County.	$95 \times 1.063 = 101.0$
Project the Orange County population forward one year to December 31, 2019, using the Five Year AACR for Orange County.	$101.0 \times 1.063 = 107.3$
Subtract 32 Orange County patients projected to transfer their care to CDO.	$107.3 - 32 = 75.3$
Add the out-of-county patients expected to remain at Carolina Dialysis-Carrboro	$75.3 + 25 = 100.3$

Thus, on December 31, 2019, Carolina Dialysis-Carrboro is projected to have 34 certified dialysis stations with an in-center patient population of 100, which is equivalent to a utilization rate of 2.94 patients per station per week ($100 / 34 = 2.94$) or 73.5% ($2.94 / 4 = 0.735$). In Section D.1, page 30, the applicant states that the needs of Carolina Dialysis-Carrboro’s patients will continue to be met following the proposed relocation of seven stations to CDO.

Projected utilization for Carolina Dialysis-Carrboro is reasonable and adequately supported for the following reasons:

- The applicant projects the patient census for Carolina Dialysis-Carrboro based on existing Carolina Dialysis-Carrboro patients, and those patients who have signed letters expressing their intention to transfer their care to the proposed CDO facility.
- The applicant’s growth projections are based on an assumption that the Orange County patient census will increase at an annual rate of 6.3%, which is consistent with the Five Year Average Annual Change Rate (AACR) for Orange County, as reported in Table D of the January 2018 SDR.

According to the January 2018 Semiannual Dialysis Report (SDR), there were 96 patients dialyzing at BMA Burlington and 45 certified dialysis stations for a utilization rate of 53.33%, or 2.13 patients per station per week ($96/45 = 2.13$) as of June 30, 2017. In Section D.1, page 30, the applicant states that on December 31, 2017, 74 of the 98 in-center patients reside in Alamance County, and the remaining patients originate from Guilford County (19 patients), Caswell County (3 patients), Orange County (1 patients), and Virginia (1 patient).

The applicant assumes that the number of in-center patients at BMA Burlington who reside in Alamance County will increase at a rate of 4.1% per year through the first two operating years of the project based on the Five Year Average Annual Change Rate (AACR) for Alamance County, as reported in Table D of the January 2018 SDR. The applicant assumes that there will be no increase in the number of patients from the other counties. The applicant projects that one BMA Burlington patient, who resides in Orange County, will transfer their care to CDO upon certification of that facility on December 31, 2019.

In Section D.1, page 30, the applicant calculates the in-center patient census for BMA Burlington starting December 31, 2017 through the first two operating years (CY2020 and CY2021), summarized as follows:

BMA Burlington	In-Center Patients
Begin with the ESRD patient population of Alamance County, as of December 31, 2017.	74
Project the Alamance County population forward one year to December 31, 2018, using the Five Year AACR for Alamance County.	$74 \times 1.041 = 77.0$
Project the Alamance County population forward one year to December 31, 2019, using the Five Year AACR for Alamance County.	$77.0 \times 1.041 = 80.2$
Subtract one Orange County patient projected to transfer their care to CDO.	$80.2 - 1 = 79.2$
Add the remaining out-of-county patients expected to remain at BMA Burlington.	$79.2 + 24 = 103.2$

Thus, on December 31, 2019, BMA Burlington is projected to have 42 certified dialysis stations with an in-center patient population of 103, which is equivalent to a utilization rate of 2.45 patients per station per week ($103 / 42 = 2.45$) or 61.3% ($2.45 / 4 = 0.613$). In Section D.1, page 30, the applicant states that the needs of BMA Burlington’s patients will continue to be met following the proposed relocation of three stations to CDO.

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

- The applicant projects the patient census for BMA Burlington based on existing BMA Burlington patients, and those patients who have signed letters expressing their intention to transfer their care to the proposed CDO facility.

- The applicant's growth projections are based on an assumption that the Alamance County patient census will increase at an annual rate of 4.1%, which is consistent with the Five Year Average Annual Change Rate (AACR) for Alamance County, as reported in Table D of the January 2018 SDR.

Further, in Section D.2, page 31, the applicant states that the proposed relocation of stations will not will not adversely affect 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.

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

In Section E, pages 32-33, 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 due to the fact that Carolina Dialysis is projected to exceed 80 percent of capacity in the next few years.
- Relocate 10 Stations from Carolina Dialysis-Carrboro Only – The applicant states it considered relocating ten stations from Carolina Dialysis-Carrboro and none from BMA Burlington but rejected that alternative because Carolina Dialysis-Carrboro is projected to have higher utilization, and BMA Burlington is projected to have lower utilization. Also, Alamance County has a surplus of 29 dialysis stations and Orange County has a deficit of nine stations, according to the January 2018 SDR.
- Develop a Larger Facility – The applicant states that it considered developing a larger facility but rejected that alternative because the utilization projections did not support the larger facility.

- Leave Home Therapy Program at Carolina Dialysis-Carrboro – The applicant states it considered leaving the home therapy program at Carolina Dialysis-Carrboro but rejected that alternative because the existing space at Carolina Dialysis-Carrboro is suboptimal in terms of providing a “home like” environment that encourages and supports home therapy treatment.

On page 33, the applicant states that its proposal is the most effective alternative because the proposed facility is convenient to the patients currently served and will be large enough to accommodate the projected need for both in-center and home therapy programs for the community.

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-Orange County shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, Carolina Dialysis, LLC d/b/a Carolina Dialysis-Orange County shall develop a new kidney disease treatment center to be known as Carolina Dialysis-Orange County by relocating seven dialysis stations from Carolina Dialysis-Carrboro and three dialysis stations from BMA Burlington.**
- 3. Upon completion of this project, Carolina Dialysis, LLC shall take the necessary steps to decertify seven dialysis stations at Carolina Dialysis-Carrboro for a total of no more than 34 dialysis stations at Carolina Dialysis-Carrboro.**
- 4. Upon completion of this project, Carolina Dialysis, LLC shall take the necessary steps to decertify three dialysis stations at BMA Burlington for a total of no more than 42 dialysis stations at BMA Burlington.**
- 5. Carolina Dialysis, LLC d/b/a Carolina Dialysis-Orange County shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations which shall include any isolation stations.**
- 6. Carolina Dialysis, LLC d/b/a Carolina Dialysis-Orange County 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

CDO proposes to develop a new 10-station dialysis facility in Orange County by relocating seven existing dialysis stations from Carolina Dialysis-Carrboro, in Orange County, and three existing dialysis stations from BMA Burlington in Alamance County.

Capital and Working Capital Costs

In Section F.1, page 35, the applicant projects the total capital cost of the project as shown in the table below.

Construction Costs	\$1,998,204
Miscellaneous Costs	\$1,110,906
Total	\$3,109,110

In Section F.1, page 35, the applicant provides the assumptions used to project the capital cost.

In Section F.10, pages 38-39, the applicant projects that start-up costs will be \$190,937 and initial operating expenses will be \$2,070,444 for a total working capital of \$2,261,381. On pages 38-39, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F.2, page 36, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Carolina Dialysis	Total
Loans	\$	\$
Accumulated reserves or OE *	\$3,109,110	\$3,109,110
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$3,109,110	\$3,109,110

* OE = Owner's Equity

In Section F.13, page 39, the applicant states that the working capital needs of the project will be funded as shown in the table below.

Sources of Financing for Working Capital		Amount
(a)	Loans	\$
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$2,261,381
(c)	Lines of credit	\$
(d)	Bonds	\$
(e)	Total	\$2,261,381

Exhibit F-1 contains a letter dated January 16, 2018 from the Executive Vice President and Chief Financial Officer for UNCH, and Board Member for Carolina Dialysis, LLC, authorizing and committing accumulated reserves of Carolina Dialysis for the capital and working capital costs of the project. Exhibit F-2 contains a copy of the balance sheet for Carolina Dialysis, LLC for the year ending December 31, 2017. The report indicates that as of December 31, 2017, Carolina Dialysis had \$23.6 million in cash and cash equivalents, \$38.7 million in total assets and \$34.8 million in net assets (total assets less total liabilities).

Financial Feasibility

The applicant provided pro forma financial statements in Section R for the first two full fiscal years of operation following completion of the project. In 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.

	1st Full Fiscal Year CY2020	2nd Full Fiscal Year CY2021
Total Treatments*	9,632	9,929
Total Gross Revenues (Charges)	\$44,193,687	\$45,378,123
Total Net Revenue	\$6,141,234	\$6,205,760
Average Net Revenue per Treatment	\$637.59	\$625.01
Total Operating Expenses (Costs)	\$3,105,666	\$3,182,779
Average Operating Expense per Treatment	\$322.43	\$320.55
Net Income	\$3,035,568	\$3,022,981

*Includes in-center, home hemodialysis and peritoneal dialysis treatments.

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 and working capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working 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

CDO proposes to develop a new 10-station dialysis facility in Orange County by relocating seven existing dialysis stations from Carolina Dialysis-Carrboro, in Orange County, and three existing dialysis stations from BMA Burlington in Alamance County. The applicant also proposes to relocate the existing home training program from Carolina Dialysis-Carrboro to the new facility. Upon completion of the proposed relocation, Carolina Dialysis-Carrboro will be certified for 34 dialysis stations and BMA Burlington will be certified for 42 dialysis stations.

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 for this facility consists of Orange County. Facilities may also serve residents of counties not included in their service area.

The applicant operates the only dialysis center in Orange County. The existing and approved Orange County dialysis facilities are shown below:

Existing and Approved Orange County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/17	CON Issued Not Certified	% Utilization	Patients Per Station
Caroline Dialysis-Carrboro	41	0	73.17%	2.9

Source: January 2018 SDR, Table B.

In Section G.2, pages 44-45, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Orange County. The applicant states:

“This application does create a new dialysis facility in Orange County. Approval of this application will result in three additional stations in the Service Area. ... The January 2018 SDR reports that Orange County has a deficit of nine dialysis stations. Addition of three stations in the county will not create a duplication or a surplus of dialysis stations.”

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

- Although the proposal will result in an increase in the number of dialysis stations in Orange County, it will reduce the projected deficit of dialysis stations in Orange County reported in the January 2018 SDR from nine to six.
- The applicant adequately demonstrates that the proposed facility is needed in addition to the existing or approved facilities in Orange County.

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.1, page 45, the applicant provides projected staffing for the proposed facility in the second year of operation (CY2021) as shown in the following table.

Carolina Dialysis-Orange County Projected Staffing CY2021	
Position	Total FTE Positions
Medical Director	NA*
Registered Nurse	2.00
Home Training Nurse	2.00
Technician	4.00
Dietitian	1.00
Social Worker	1.00
Clinical Manager	1.00
Administrator	0.15
In-Service	0.20
Clerical	1.00
Chief Technician	0.15
Equipment Technician	0.75
Total FTEs	13.25

*Medical Director is an independent contractor, not an employee.

The assumptions and methodology used to project staffing are provided in Section H.1, page 45, and Sections H.6 and H.7, page 47. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Sections H.3 and H.4, page 46, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I.3, page 49, the applicant identifies the proposed medical director. In Exhibit I-5, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services.

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.1, page 48, the applicant provides a table showing the ancillary and support services necessary for the proposed services. On page 48, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.

In Section I, pages 48-51, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.

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.

C

In Section K.2, page 55, the applicant states that the project involves construction and up-fitting of 5,056 square feet in leased space in a building to be constructed by a developer at 1165 Weaver Dairy Road in Chapel Hill. A line drawing of the proposed facility is provided in Exhibit K-1.

On pages 53-54, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On pages 56-57, and Exhibit K-5, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

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

- (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.1, page 60, and Section L.7, page 63, the applicant reports that 84% of the patients who received treatments at Carolina Dialysis-Carrboro had some or all of their services paid for by Medicare or Medicaid, and that 88% of the patients who received treatments at BMA Burlington had some or all of their services paid for by Medicare or Medicaid, in CY2017. The table below shows the historical (CY2017) payment source for Carolina Dialysis-Carrboro and BMA Burlington:

Payment Sources CY2014 [CY2017]*	Carolina Dialysis- Carrboro Patients as Percent of Total	BMA Burlington Patients as Percent of Total
Self Pay/Indigent/Charity	2.90%	2.59%
Medicare	46.38%	55.50%
Medicaid	17.39%	4.50%
Commercial Insurance	11.59%	6.20%
Medicare/Commercial Insurance	20.29%	28.25%
Miscellaneous (VA)	1.45%	2.96%
Total	100.00%	100.00%

*The applicant's table on page 63 which shows the last full operating year payor mix appears to be mislabeled "CY2014". On page 60, the states, "Payor mix projections are based on the Carolina Dialysis-Carrboro historical performance through 2017."

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Orange	12%	52%	31%	14%	6%	10%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. 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., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

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.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by

¹<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

²http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

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.3, page 62, the applicant states:

“Carolina Dialysis facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. ... The CDO facility will be responsible to provide care to both minorities and handicapped people.”

In Section L.6, page 62, 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.

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.1, page 60, 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.

Payment Source	Patients as Percent of Total
Self Pay/Indigent/Charity	2.90%
Medicare	46.38%
Medicaid	17.39%
Commercial Insurance	11.59%
Medicare/Commercial Insurance	20.29%
Miscellaneous (VA)	1.45%
Total	100.00%

Source: Table on page 60 of the application.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.9% of total services will be provided to self-pay patients and charity care patients, 66.67% to Medicare patients and 17.39% to Medicaid patients.

On page 60, 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 payor mix for Carolina Dialysis-Carrboro.

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 62, 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.1, page 64, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

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

CDO proposes to develop a new 10-station dialysis facility in Orange County by relocating seven existing dialysis stations from Carolina Dialysis-Carrboro, in Orange County, and three existing dialysis stations from BMA Burlington in Alamance County.

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 for this facility consists of Orange County. Facilities may also serve residents of counties not included in their service area.

The applicant operates the only dialysis center in Orange County. The existing and approved Orange County dialysis facilities are shown below:

Existing and Approved Orange County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/17	CON Issued Not Certified	% Utilization	Patients Per Station
Carolina Dialysis-Carrboro	41	0	73.17%	2.9

Source: January 2018 SDR, Table B.

In Section N.1, page 65, 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 65, the applicant states:

“Carolina Dialysis does not expect this proposal to have effect on the competitive climate in Orange County. At the present time, Carolina Dialysis is the only provider of dialysis services in the county. CDO does not propose to serve dialysis patients currently being served by another provider.”

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 O.3, page 69, the applicant states Fresenius owns more than 100 dialysis facilities located in North Carolina. Exhibit A-4 contains a list of the Fresenius dialysis facilities located in North Carolina.

In Section O.3, page 69, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities, BMA East Rocky Mount. The applicant states that BMA East Rocky Mount is currently back in full compliance with all CMS requirements. The applicant provides documentation regarding the deficiencies and subsequent compliance with CMS Conditions for Coverage for the BMA East Rocky Mount facility in Exhibit O-3. After reviewing and considering information provided by the applicant and considering the quality of care provided at all Fresenius facilities, 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 application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are 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.

-C- In Section C.1, page 15, the applicant projects to serve 34 in-center patients by the end of Operating Year 1, which is 3.4 patients per station per week (34 / 10 =

3.4). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

.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.*

-NA- The applicant is not proposing to increase the number of dialysis stations in an existing facility or one that was not operational prior to the beginning of the review period.

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

-C- In Section C.1, pages 16-19, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.