

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 11, 2017

Findings Date: May 11, 2017

Project Analyst: Celia C. Inman

Team Leader: Fatimah Wilson

Project ID #: Q-11304-17

Facility: Fresenius Kidney Care Captains Cove

FID #: 170125

County: Pitt

Applicant(s): Bio-Medical Applications of North Carolina, Inc.

Project: Develop a new 12-station dialysis facility by relocating 6 stations from FMC Care of Ayden, 3 stations from FMC Dialysis Services East Carolina University, and 3 stations from Greenville Dialysis Center

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, Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a Fresenius Kidney Care Captains Cove (FKC Captains Cove), proposes to develop a new 12-station dialysis facility in Winterville by relocating six stations from FMC Care of Ayden (FMC Ayden), three stations from FMC Dialysis Services East Carolina University (FMC East Carolina), and three stations from Greenville Dialysis Center. All four facility locations are in Pitt County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, FKC Captains Cove will be certified for 12 dialysis stations, FMC Ayden will be certified for 10 dialysis stations, FMC East Carolina will be certified for 38 dialysis stations, and Greenville Dialysis Center will be

certified for 48 dialysis stations following completion of this project, Project ID #L-11011-15 (relocate four stations to FMC Tarboro), and Project ID #Q-11141-16 (add 10 stations).

Need Determination

The applicant is proposing to relocate existing dialysis stations within Pitt County, therefore there are no need methodologies in the 2017 State Medical Facilities Plan (2017 SMFP) applicable to this review.

Policies

There is one policy in the 2017 SMFP that is applicable to this review: *Policy ESRD-2 Relocation of Dialysis Stations*, on page 27.

Policy ESRD-2: Relocation of Dialysis Stations states:

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

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

The applicant proposes to develop a new 12-station dialysis facility in Winterville by relocating six stations from FMC Ayden, three stations from FMC East Carolina, and three stations from Greenville Dialysis Center. All four facility locations are in Pitt County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the applicable policy in the 2017 SMFP.

- (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 develop a new 12-station dialysis facility in Winterville by relocating six stations from FMC Ayden, three stations from FMC East Carolina, and three stations from Greenville Dialysis Center. All four facility locations are in Pitt County.

The following tables, summarized from pages 4-5 of the application, illustrate the proposed FKC Captains Cove stations, and the current projects under development which impact the number of dialysis stations at FMC Ayden, FMC East Carolina, and Greenville Dialysis Center, the three facilities from which the applicant plans to relocate stations to develop the proposed new facility.

Fresenius Kidney Care Captains Cove

Stations	Description	Project ID #
0	Total existing certified stations as of the January 2017 SDR	
+12	Stations to be added as part of this project	Q-11304-17
12	Total stations upon completion of above projects	

FMC Ayden

Stations	Description	Project ID #
16	Total existing certified stations as of the January 2017 SDR	
-6	Stations to be deleted as part of this project	Q-11304-17
10	Total stations upon completion of above projects	

FMC Dialysis Services East Carolina University

Stations	Description	Project ID #
41	Total existing certified stations as of the January 2017 SDR	
-3	Stations to be deleted as part of this project	Q-11304-17
38	Total stations upon completion of above projects	

Greenville Dialysis Center

Stations	Description	Project ID #
45	Total existing certified stations as of the January 2017 SDR	
-3	Stations to be deleted as part of this project	Q-11304-17
+10	Stations previously approved to be added but not yet certified	Q-11141-16
-4	Stations previously approved to be deleted but not yet certified	L-11011-15
48	Total stations upon completion of above projects	

As the tables above illustrate, upon project completion, FKC Captains Cove will be certified for 12 dialysis stations, FMC Ayden will be certified for 10 dialysis stations and FMC East Carolina will be certified for 38 stations: Greenville Dialysis Center will be certified for 48 dialysis stations following completion of this project, Project ID #L-11011-15 (relocate four stations to FMC Tarboro), and Project ID #Q-110141-16 (add 10 stations),

Patient Origin

On page 373, the 2017 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.”* The proposed new facility, FKC Captains Cove, will be located in Pitt County; thus, the service area for this facility consists of Pitt County. Facilities may also serve residents of counties not included in their service area.

FKC Captains Cove will be a new facility in Pitt County and therefore has no existing patient origin.

In Section C.1, page 19, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table:

**Fresenius Kidney Care Captains Cove
 Projected Patient Origin by County**

County	Operating Year 1 1/1/19 –12/31/19	Operating Year 2 1/1/20-12/31/20	County Patients as Percent of Total	
	In-Center Patients	In-Center Patients	Year 1	Year 2
Pitt	42.8	45.7	100.0%	100.0%
Total*	42	45	100.0%	100.0%

*Rounded down to the whole patient

The applicant does not propose to serve home hemodialysis or peritoneal dialysis patients. On page 19, the applicant states that patients who might be candidates for home dialysis will be referred to Greenville Dialysis Center.

In Section C.1, pages 19-21, the applicant provides the assumptions and methodology used to project patient origin. The applicant states that projected patient origin is based on the existing 49 Pitt County patients living in close proximity to the proposed facility who signed letters stating their willingness to transfer their care to the proposed facility. Exhibit C-1 contains copies of the 49 signed letters.

The applicant adequately identifies the population to be served.

Analysis of Need

The applicant proposes to develop a new 12-station dialysis facility in Winterville by relocating six stations from FMC Ayden, three stations from FMC East Carolina, and three stations from Greenville Dialysis Center. All four facility locations are in Pitt County.

In Section C.2, page 21, the applicant states:

“The need methodology for dialysis stations is focused on four patient shifts per week and recognizes that patients will dialyze on a Monday-Wednesday-Friday, morning or afternoon shift schedule, or on a Tuesday-Thursday-Saturday, morning or afternoon shift schedule. Failure to receive dialysis care will ultimately lead to the patient’s demise.”

The applicant has included 49 in-center patient letters of support, which state the patient would consider transferring their care to the new facility. The applicant states that each of these patients resides in close proximity to the proposed facility location, is currently receiving dialysis care at a Fresenius-affiliated dialysis facility in Pitt County, and has expressed a willingness to transfer to the proposed location because it is more convenient and closer to their homes. The applicant provides a table on page 20 of the application showing at which Fresenius-affiliated facility the Pitt County patients who are expected to transfer are currently dialyzing, as summarized below.

Facility	Number of Patients Projected to Transfer
FMC Ayden	15
FMC East Carolina	13
Greenville Dialysis Center	12
Total	40

The applicant further states that the need this population has for the proposed service is a function of the individual patient need for dialysis care, and the stated desire of the patients to have dialysis at the proposed facility.

Projected Utilization

In Section C.1, pages 19-21, the applicant provides the following assumptions used to project utilization:

- The applicant plotted the residence location of patients dialyzing at BMA facilities within Pitt County. The applicant includes 49 letters (Exhibit C-1) from patients who reside in close proximity to the proposed facility, who could be better served by the proposed location.
- The applicant projects based on the patient letters that 40 in-center dialysis patients will transfer their care to the new facility upon project certification. This is 81% of the patients who signed letters stating willingness to consider transferring their care to the proposed facility.
- The applicant states that the project will be completed on December 31, 2018. Operating Year 1 (OY1) is the period from January 1 through December 31, 2019. Operating Year 2 (OY2) is the period from January 1 through December 31, 2020.
- The applicant assumes that the Pitt County dialysis patients transferring to the new facility are part of the Pitt County ESRD patient population as a whole, and that this population will increase at a rate commensurate with the Pitt County Five Year Average Annual Change Rate (AACR) of 6.9%, as published in the January 2017 Semiannual Dialysis Report (SDR).

In Section C.1, page 20, the applicant provides the following methodology used to project utilization:

FKC Captains Cove	In-Center
Begin with 40 in-center dialysis patients projected to transfer their care to the new facility upon certification of the project, December 31, 2018.	40
The applicant projects the patient population forward to December 31, 2019 (end of OY1), using the Pitt County Five Year AACR of 6.9%.	$(40 \times 0.069) + 40 = 42.8$
The applicant projects the patient population forward to December 31, 2020 (end of OY2), using the Pitt County Five Year AACR of 6.9%.	$(42.8 \times 0.069) + 42.8 = 45.7$

The applicant states on page 19, that it rounds down to the whole patient in this calculation. Therefore, the applicant projects that at the end of OY1, 42 patients will be dialyzing on 12 stations for a projected utilization rate of 3.5 patients per station per week (42 in-center patients / 12 stations = 3.5) which exceeds the minimum standard of 3.2 patients per station per week as required by 10A NCAC 14C.2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need that population has for the proposed facility.

Access

In Section L.1, page 71, the applicant states:

“It is policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

In Section L.1, page 72, the applicant projects that 90% of its in-center patients will be covered by some combination of Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population projected to be served has for the proposed services based on reasonable and supported utilization projections and assumptions, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to develop a new 12-station dialysis facility in Winterville by relocating six stations from FMC Ayden, three stations from FMC East Carolina, and three stations from Greenville Dialysis Center. All four facility locations are in Pitt County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, FKC Captains Cove will be certified for 12 stations, FMC Ayden will be certified for 10 dialysis stations ($16 - 6 = 10$) and FMC East Carolina will be certified for 38 stations ($41 - 3 = 38$); and Greenville Dialysis Center will be certified for 48 dialysis stations ($45 - 3 + 10 - 4 = 48$), upon completion of this project, Project ID # L-11011-15 and Project ID # Q-11141-16.

The following table shows the proposed relocation of stations and transfer of Pitt County dialysis patients projected in the proposed FKC Captains Cove project.

Facility	Number of Stations to be Relocated	Number of Patients Transferring
FMC Ayden	6	15
FMC East Carolina	3	13
Greenville Dialysis Center	3	12
Total	12	40

FMC Ayden

In Section D.1, pages 29-31, the applicant states that as of December 31, 2016, as reported to DHSR Healthcare Planning as part of the ESRD Data Collection reporting for the period ended December 31, 2016, there were 64 patients dialyzing at FMC Ayden on 16 dialysis stations, for a utilization rate of 100% ($64 / 16 = 4.0 / 4 = 1.00$). In addition, the applicant states that 60 of the 64 in-center patients live in Pitt County.

The applicant assumes that the number of in-center patients at FMC Ayden who live in Pitt County will increase at 6.9% per year based on the Five Year AACR for Pitt County, as reported in Table B of the January 2017 SDR. The applicant assumes that no growth will occur for the four in-center patients from outside Pitt County. In Section D.1, page 30, the applicant calculates the in-center patient census for FMC Ayden starting December 31, 2016 through OY1 (CY2019) and OY2 (CY2020), summarized as follows:

FMC Ayden	In-Center Patients
Begin with the ESRD patient population of Pitt County, as of December 31, 2016.	60
Project this population forward for 12 months to December 31, 2017, using the Five Year AACR for Pitt County.	$(60 \times 0.069) + 60 = 64.1$
Project this population forward for 12 months to December 31, 2018, using the Five Year AACR for Pitt County	$(64.14 \times 0.069) + 64.1 = 68.6$
Subtract 15 Pitt County patients projected to transfer their care to FKC Captains Cove.	$68.6 - 15 = 53.6$
Add 4 patients from outside Pitt County.	$53.6 + 4.0 = 57.6$

Thus, on December 31, 2018, FMC Ayden is projected to have 10 certified dialysis stations with a patient population of 58 (rounded). Utilization is calculated to be 5.8 patients per station ($57.6 / 10 = 5.76$, rounded to 5.8), or 145% utilization ($5.8 / 4 = 1.45$).

The applicant states that utilization rates greater than four patients per station means the facility will operate a third, or evening dialysis shift unless additional stations can be added. FMC Ayden had a December 31, 2016 census of 64 patients. Thus, the facility will qualify for additional stations based on the facility need methodology in the July 2017 SDR. In the facility need methodology table provided by the applicant on page 31, the applicant demonstrates that FMC Ayden will qualify to apply for up to seven stations. The applicant states that BMA will file an application for six additional stations at FMC Ayden in

September 2017 for an October 2017 review. Assuming approval of the application to add six stations, the facility would have a census of 58 patients dialyzing on 16 stations, a utilization rate of 3.625 patients per station or 90.6% ($3.625 / 4 = 0.906$).

Therefore, the applicant states that no FMC Ayden patients will be adversely impacted by this application to relocate 6 stations and transfer 15 patients to FKC Captains Cove.

FMC East Carolina

In Section D.1, pages 32-34, the applicant states that as of December 31, 2016, as reported to DHSR Healthcare Planning as part of the ESRD Data Collection reporting for the period ended December 31, 2016, there were 141 patients dialyzing at FMC East Carolina on 41 dialysis stations, for a utilization rate of 86%. In addition, the applicant states that 117 of the 141 in-center patients live in Pitt County.

In Project ID #L-11011-15, BMA projected that one patient, a resident of Edgecombe County would transfer from FMC East Carolina to FMC Tarboro by mid-year 2017. Based on letters of support, the applicant assumes 13 Pitt County patients will transfer from FMC East Carolina to the proposed facility.

The applicant assumes that the number of in-center patients at FMC East Carolina who live in Pitt County will increase at 6.9% per year based on the Five Year AACR for Pitt County, as reported in Table B of the January 2017 SDR. The applicant assumes that no growth will occur for the 24 in-center patients residing outside of Pitt County, which includes the one Edgecombe County patient transferring to FMC Tarboro. In Section D.1, page 33, the applicant calculates the in-center patient census for FMC East Carolina starting December 31, 2016 through OY1 and OY2, as summarized below:

FMC East Carolina	In-Center Patients
Begin with the ESRD patient population of Pitt County, as of December 31, 2016.	117
Project this population forward for 12 months to December 31, 2017, using the Five Year AACR for Pitt County.	$(117 \times 0.069) + 117 = 125.1$
Project this population forward for 12 months to December 31, 2018, using the Five Year AACR for Pitt County	$(125.1 \times 0.069) + 125.1 = 133.7$
Subtract 13 Pitt County patients projected to transfer their care to FKC Captains Cove.	$133.7 - 13 = 120.7$
Add 23 patients from outside Pitt County. (24 -1 Edgecombe County FMC Tarboro patient transfer in Project ID #L-11011-15	$120.7 + 23 = 143.7$

Thus, at December 31, 2018, FMC East Carolina is projected to have 38 certified dialysis stations with a patient population of 144 (rounded). Utilization is calculated to be 3.8 patients per station ($143.7 / 38 = 3.78$).

The applicant states that FMC East Carolina had a December 31, 2016 census of 141 patients. Thus, the facility will qualify to add stations based on the facility need methodology in the July 2017 SDR. In the facility need methodology table provided by the applicant on page 34, the applicant demonstrates that FMC East Carolina will qualify to apply for one station. The applicant states that BMA will file an application for one additional station at FMC East Carolina in September 2017 for an October 2017 review. Assuming approval of the application to add one station, the facility would have a census of 144 patients dialyzing on 39 stations, a utilization rate of 3.69 patients per station ($144 / 39 = 3.692$) or 92.3%.

Therefore, the applicant states that no FMC East Carolina patients will be adversely impacted by this application to relocate 3 stations and transfer 13 patients to FKC Captains Cove.

Greenville Dialysis Center

The applicant assumes that Project ID #L-11011-15 and Q-11141-16 will be completed and certified prior to the decision on this review. Thus, prior to this decision, the facility will be operating 51 stations ($45 - 4 + 10$). This project will be relocating three stations, leaving a net of 48 stations ($51 - 3$), effective December 31, 2018.

In Project ID #L-11011-15, BMA projected that two patients from Greenville Dialysis Center would transfer to FMC Tarboro. Those two patients were projected to be residents of Edgecombe and Martin Counties. FMC Tarboro is expected to be certified by mid-year 2017 and will be deducted from the number of patients dialyzing at Greenville Dialysis Center and living outside Pitt County. The applicant assumes 12 of the 19 Pitt County resident patients who signed letters of support (Exhibit C-1) will transfer their care from Greenville Dialysis Center to the proposed facility.

In Section D.1, pages 35-38, the applicant states that as of December 31, 2016, as reported to DHSR Healthcare Planning as part of the ESRD Data Collection reporting for the period ended December 31, 2016, there were 170 patients dialyzing at Greenville Dialysis Center on 45 dialysis stations, for a utilization rate of 94.5%. In addition, the applicant states that 144 of the 170 in-center patients live in Pitt County.

The applicant assumes that the number of in-center patients at Greenville Dialysis Center who live in Pitt County will increase at 6.9% per year based on the Five Year AACR for Pitt County, as reported in Table B of the January 2017 SDR. The applicant assumes that no growth will occur for the four in-center patients living outside of Pitt County. In Section D.1, page 36, the applicant calculates the in-center patient census for Greenville Dialysis Center starting December 31, 2016 through OY1 and OY2, illustrated as follows:

Greenville Dialysis Center	In-Center Patients
Begin with the ESRD patient population of Pitt County, as of December 31, 2016.	144
Project this population forward for 12 months to December 31, 2017, using the Five Year AACR for Pitt County.	$(144 \times 0.069) + 144 = 153.9$
Project this population forward for 12 months to December 31, 2018, using the Five Year AACR for Pitt County	$(153.93 \times 0.069) + 153.9 = 164.6$
Subtract 12 Pitt County patients projected to transfer their care to FKC Captains Cove.	$164.6 - 12 = 152.6$
Add 24 (26 – 2 patients transferring to FMC Tarboro in Project ID #L-11011-15) patients from outside Pitt County.	$152.6 + 24 = 176.6$

Thus, at December 31, 2018, Greenville Dialysis Center is projected to have 48 certified dialysis stations with a patient population of 177 (rounded) in-center dialysis patients. Utilization is calculated to be 3.7 patients per station ($176.6 / 48 = 3.67$) or 91.98% ($3.7 / 4 = 0.9198$).

The applicant states that Greenville Dialysis Center had a December 31, 2016 census of 170 patients. Thus, the facility will qualify for addition of stations based on the facility need methodology in the July 2017 SDR. In the facility need methodology table provided by the applicant on page 37, the applicant demonstrates that Greenville Dialysis Center will qualify to apply for one station. The applicant states that BMA will file an application for one additional station at Greenville Dialysis Center in September 2017 for an October 2017 review. Assuming approval of the application to add one station, the facility would have a census of 177 patients dialyzing on 49 stations, a utilization rate of 3.61 patients per station ($177 / 49 = 3.61$) or 90.1% ($3.6 / 4 = 0.901$).

Therefore, the applicant states that no Greenville Dialysis Center patients will be adversely impacted by this application to relocate 3 stations and transfer 12 patients to FKC Captains Cove.

In Section L.1(b), page 72, the applicant states that the projected payor mix at the proposed facility is based on the payor mix of the three facilities which are relocating stations and transferring patients to the proposed facility. Thus, the applicant states that the proposed relocation of stations and transfer of patients will not have an adverse impact 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.

Thus, the applicant demonstrates that the needs of the populations presently served at FMC Ayden, FMC East Carolina and Greenville Dialysis Center will continue to be adequately met following the proposed relocation of dialysis stations and transfer of patients from each facility to FKC Captains Cove; and that access for medically underserved groups will not be negatively impacted.

Therefore, the application is conforming to this criterion.

- (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.1, pages 39-40, the applicant discusses the alternatives considered prior to the submission of this application, summarized as follows:

1. Maintain the Status Quo – the applicant states that it dismissed this alternative because there is a significant number of patients dialyzing in Fresenius-affiliated facilities and residing in close proximity to the proposed FKC Captains Cove facility, who can be more conveniently served by the development of the proposed facility. Therefore, the applicant determined the status quo would not be the most effective alternative.
2. Develop Facility in Another Area in Pitt County – the applicant states that based on its evaluation of existing patients served by Fresenius related facilities, coupled with projections of future patient populations, there is not a patient population of sufficient size to warrant development of a facility in another area of the county at this time. Thus, the applicant determined any other location would be less effective.
3. Develop a Larger Facility with More Stations – after evaluation of the patient letters, the patient population served, and the effects upon existing facilities when stations are relocated, the applicant states that it determined that FKC Captains Cove should not apply for more than 12 stations. The applicant projects that 40 patients will transfer to the facility upon certification, sufficient to meet Performance Standard 10A NCAC 14C .2203. Thus, the applicant determined a larger facility would be more costly.
4. Expand Existing Facilities - the applicant states that existing Fresenius related facilities have little opportunity for physical plant expansion. Three of the four facilities are at physical plant capacity and the fourth is not proximate to the proposed patient residence location to be served by that facility. Thus, in order to serve patients of the proposed area in a convenient setting, the applicant states a new facility is required; therefore, this alternative was rejected.
5. Apply to Offer Home Therapies – the applicant states that it could have proposed to provide home therapies at this location, however Fresenius has two home therapies programs in Pitt County: FMC East Carolina and Greenville Dialysis Center. The applicant states that the cost of the home training area is not insignificant; therefore, by utilizing existing home therapies programs, Fresenius is able to reduce development costs for the proposed facility. Therefore, the applicant rejected this alternative as more costly.

Thus, after considering the above alternatives, the applicant concludes that its proposal to develop a new 12-station dialysis center in Winterville by relocating stations from FMC

Ayden, FMC East Carolina and Greenville Dialysis Center is the most cost effective alternative.

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

In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the need. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Captains Cove shall materially comply with all representations made in the certificate of need application.**
 - 2. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Captains Cove shall relocate no more than six dialysis stations from FMC Care of Ayden, no more than three dialysis stations from FMC Dialysis Services East Carolina University and no more than three dialysis stations from Greenville Dialysis Center.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Captains Cove shall install plumbing and electrical wiring through the walls for no more than 12 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 - 4. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 6 dialysis stations from FMC Care of Ayden for a total of 10 certified dialysis stations, 3 dialysis stations from FMC Dialysis Services East Carolina University for a total of 38 and 3 dialysis stations from Greenville Dialysis Center for a total of 48 upon completion of this project, Project ID # Q-11141-16 (add 10 dialysis stations) and Project ID # L-11011-15 (relocate four stations to FMC Tarboro).**
 - 5. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Captains Cove 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 develop a new 12-station dialysis facility in Winterville, Pitt County by relocating six stations from FMC Ayden, three stations from FMC East Carolina, and three stations from Greenville Dialysis Center.

Capital and Working Capital Costs

In Section F.1, page 42, the applicant provides the capital cost of the project as summarized in the following table:

**FKC Captains Cove
Project Capital Costs**

		Total Capital Costs
Construction Project Costs		
Construction Contract	\$1,194,537	
Sub-Total Construction Costs		\$1,194,537
Miscellaneous Project Costs		
Water Treatment Equipment	\$210,000	
Equipment/Furniture	\$214,343	
Architect & Engineering Fees	\$107,508	
Other: Contingency	\$65,102	
Sub-Total Miscellaneous Costs		\$596,953
Total Capital Cost		\$1,791,490

Totals may not sum due to rounding

In Section F.10, pages 45-46, and Section F.11, page 46, the applicant estimates start-up expenses of \$138,710 and initial operating expenses of \$1,192,899, respectively, for a total working capital of \$1,331,609 (Section F.12, page 47).

Availability of Funds

In Exhibit F-1, the applicant provides a letter dated March 15, 2017 from the Senior Vice President & Treasurer of the parent company, Fresenius Medical Care Holdings, Inc. (FMC), authorizing the project and committing cash reserves for the capital expenditure in the amount of \$1,791,490. The letter also authorizes additional funds as necessary for start-up costs. Exhibit F-2 contains the FMC and Subsidiaries Consolidated Financial Statements, as of December 31, 2015, showing cash and cash equivalents of \$249,300,000, total assets of \$19,332,539,000 and net assets (total assets less total liabilities) of \$8,915,722,000. The applicant adequately demonstrates the availability of funds for the capital, working capital, and operating needs of the project.

Financial Feasibility

In Section R, Form C, page 92, the applicant provides the allowable charges per treatment for each payment source, as illustrated in the table below:

Allowable Charges

Payor	In-Center Charge
Self Pay/Indigent/ Charity	\$194.83
Medicare	\$253.36
Medicaid	\$176.06
Commercial Insurance	\$1,071.46
Medicare/Commercial	\$305.00
Miscellaneous, including VA	\$329.01

In Section R, page 93, the applicant states that it calculates an average number of in-center patients (number of patients at the beginning of the year + number of patients at the end of the year / 2), rounded down to the nearest whole number, to calculate its revenues for the first and second operating years of the project. Therefore, the number of in-center patients used in operating year one was 41, and the number of in-center patients used in operating year two was 44.

In Section R, page 91, the applicant projects operating expenses and revenues, summarized as follows:

FKC Captains Cove

	Operating Year 1	Operating Year 2
Average # of In-Center Patients	41	44
Projected Treatments ((156 / Pt) - 5%)	6,076	6,520
Projected Average Charge (Gross Patient Revenue / Projected # Treatments)	\$3,988	\$3,988
Gross Patient Revenue	\$24,231,088	\$ 26,001,760
Deductions from Gross Patient Revenue	\$22,390,023	\$ 24,026,160
Net Patient Revenue	\$1,841,065	\$ 1,975,600
Total Expenses	\$1,675,423	\$ 1,738,534
Net Income	\$165,642	\$ 237,066

Totals may not sum due to rounding

The applicant projects that revenues will exceed operating expenses in each of the first two operating years of the project. The assumptions used in preparation of the pro forma financial statements are reasonable, including projected utilization, cost and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for operating needs and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital, working capital, and operating needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to develop a new 12-station dialysis facility in Winterville by relocating six stations from FMC Ayden, three stations from FMC Dialysis Services East Carolina University, and three stations from Greenville Dialysis Center. All four facilities are in Pitt County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, FKC Captains Cove will be certified for 12 dialysis stations, FMC Ayden will be certified for 10 dialysis stations, FMC Dialysis Services East Carolina University will be certified for 38 stations, and Greenville Dialysis Center will be certified for 48 dialysis stations following completion of this project, Project ID #L-11011-15 (relocate four stations to FMC Tarboro), and Project ID #Q-110141-16 (add 10 stations),

On page 373, the 2017 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.*” The proposed new facility, FKC Captains Cove, will be located in Pitt County; thus, the service area for this facility consists of Pitt County. Facilities may also serve residents of counties not included in their service area.

According to the January 2017 SDR, there are four dialysis facilities in Pitt County, as follows:

Pitt County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
FMC Care of Ayden (FMC)	16	93.75%	3.7500
FMC Dialysis Services East Carolina (FMC)	41	88.41%	3.5366
FMC Farmville (FMC)*	10	40.00%	1.6000
Greenville Dialysis Center (FMC)	45	92.22%	3.6889

Source: January 2017 SDR, Table A.

* Project ID #Q-10315-14 approved the development of new 10-station facility. Stations were certified February 29, 2016.

As illustrated above, FMC or Fresenius related entities own and operate the dialysis facilities in Pitt County. One of the facilities, FMC Farmville, was developed during the previous year, being certified at the end of February 2016; therefore, it's utilization represents only four months of data based on the June 30, 2016 data in the January 2017 SDR. The other three FMC dialysis facilities are reasonably well-utilized, operating above 88% utilization and 3.5 patients per station.

According to Table B in the January 2017 SDR, there is a surplus of one dialysis station in Pitt County. However, the applicant is not increasing the number of dialysis stations in Pitt County, rather it is relocating 12 existing Pitt County stations to develop a new facility that the applicant states is closer to patients living in the area where the new facility will be located. Therefore, it is not duplicating services, rather it is proposing to create a new facility to better serve existing patients using existing stations.

In Section C.1, page 20, the applicant demonstrates that FKC Captains Cove will serve a total of 42 in-center patients on 12 stations at the end of the first operating year, which is 3.5 patients per station per week, or a utilization rate of 87.5% ($42 / 12 = 3.5$; $3.5 / 4 = 0.875$). The applicant provides documentation in Exhibit C-1 from 49 Pitt County in-center patients dialyzing at Fresenius-affiliated facilities stating their willingness to consider transferring to FKC Captains Cove because its location would be more convenient. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates the need to relocate existing Pitt County Fresenius-affiliated dialysis stations to develop a new Fresenius dialysis facility in Pitt County. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on the need of the populations presently served at FMC Ayden, FMC East Carolina, and Greenville Dialysis Center, found in Criterion (3a), is incorporated herein by reference.

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

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

C

In Section H.1, pages 55-56, the applicant provides the projected staffing for FKC Captains Cove in OY2 by full-time equivalent (FTE) positions, as shown in the table below:

FKC Captains Cove Proposed FTE Positions OY2	
Position	Total
Registered Nurse	2.00
Patient Care Technician	4.50
Clinical Manager	1.00
Administrator	0.15
Dietitian	0.40
Social Worker	0.40
Chief Tech	0.15
Equipment Tech	0.50
In-Service	0.15
Clerical	1.00
Total FTEs	10.25

Note: The Medical Director is an independent contractor, not an employee.

In Exhibit I.5, the applicant provides a letter from M. Carney Taylor, MD, dated March 8, 2017, indicating support for the project and a willingness to serve as Medical Director of the facility. In Section H.3, page 56, the applicant states it does not anticipate any difficulties in filling staff positions as it provides a range of benefits and competitive salaries to attract qualified staff. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I.1, page 59, the applicant lists the providers of the necessary ancillary and support services for the proposed project. The table states that acute dialysis in an acute care setting, blood bank services, diagnostic/evaluation, X-ray, and pediatric nephrology services will be referred to Vidant Medical Center. Exhibit I-3 includes a letter of support from Vidant Health affirming a willingness to provide those services to FKC Captains Cove patients. Exhibit I-4 contains a letter from Vidant Health agreeing to enter in to an agreement with FKC Captains

Cove to provide its patients with transplant services. Exhibit I-1 contains an agreement for home training services at Greenville Dialysis Center. Exhibit I-2 contains an agreement for lab services between Spectra and FMC. The applicant discusses coordination with the existing health care system in Sections I.3 and I.4, pages 60-62, stating that Fresenius has relationships with the medical community in the area, including area physicians and hospitals. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Section K.2, page 66, the applicant states that the proposed facility will have 3,412 square feet of treatment area, which includes isolation space. The applicant provides the proposed

facility's line drawings in Exhibit K-1. The drawing depicts a 7,776 square foot facility, with 11 main floor dialysis stations and one isolation dialysis station, for a total of 12 stations. In Section F.1, page 41, the applicant states that it relies upon the Fresenius Facility Design and Maintenance Department to develop anticipated project development costs. On page 42, the applicant provides the proposed costs, including \$1,194,537 for construction, \$596,953 in miscellaneous costs, including water treatment equipment, furniture, architect/engineering fees, and contingency for a total project cost of \$1,791,490. In Section K.1, pages 64-66, the applicant describes its plans for energy-efficiency, including water conservation. The applicant states its plans for implementing applicable energy saving features and water conservation methods, include the following:

- The building plumbing systems will be designed to ensure conservation of water.
- The exterior roof, walls and glass systems will meet current requirements for energy conservation.
- HVAC system operating efficiency "will equal current industry standards for high seasonal efficiency." In addition, the system will be controlled via 7 day/24 hour set back time clock and maintained and serviced quarterly.
- Energy efficient exit signs, water flow restrictors at sink faucets, water conserving flush toilets, optical sensor water switches and external insulation wrap for hot water heaters will be used for energy and water conservation.
- Water treatment system will allow for a percentage of the concentrate water to be re-circulated into the supply feed water, thus lowering water discharge quantity; and will use three-phase electric motors which run cooler and use less amperage.

Costs and charges are described by the applicant in Section F, pages 42-51, and in Section R proforma financial statements. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans and that the construction cost will not unduly increase costs and charges for health services. Therefore, 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

FKC Captains Cove is not an existing facility, thus, it has no historical payor mix. However, in Section L.7, pages 74-76, the applicant provides the payor mix for FMC Ayden, FMC East Carolina and Greenville Dialysis Center for CY2016. These are the facilities that will be contributing 12 dialysis stations, in total, to develop the proposed 12-station facility and from which the patients will transfer (See Exhibit C-1 for patients' letters of support). The historical payor mix is illustrated as follows:

Payor Source	Percentage of In-Center Patients		
	FMC Ayden	FMC East Carolina	Greenville Dialysis Center
Private Pay/Indigent/ Charity	0.40%	1.39%	1.10%
Medicare	91.96%	75.74%	71.61%
Medicaid	1.79%	9.88%	5.43%
Commercial Insurance	3.40%	5.34%	7.65%
Medicare/Commercial	0.56%	6.12%	10.02%
Miscellaneous, including VA	1.90%	1.53%	4.19%
Total	100.00%	100.00%	100.00%

Totals may not sum due to rounding

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**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Pitt	11%	53%	44%	23%	8%	18%
Statewide	15%	51%	36%	17%	10%	15%

Source: http://www.census.gov/quickfacts/table_2014_Estimate_as_of_December_22_2015.

*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., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 provides prevalence data on ESRD Network 6 dialysis patients by age, race, and gender on pages 27-28¹. The

¹http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

ESRD Network 6 service area contract, previously managed by Alliant Healthcare Solutions' Southeastern Kidney Council, was awarded to IPRO in April 2016 and is now called the IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6). IPRO SA Network 6 is still comprised of North Carolina, South Carolina and Georgia. The 2015 Annual Report, submitted in November 2016 by IPRO differs somewhat from the reports submitted in the past by The Southeastern Kidney Council.

The statistics on number and percent of dialysis patients by age, gender and race are now shown only in total for Network 6; the statistics are no longer separately shown for North Carolina in the report. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*² percentages for North Carolina and the total Network shows very little variance; therefore the statistics for the total Network 6 are representative of North Carolina's statistics. One would also assume the 2015 percentages for the total Network 6 should also very closely reflect North Carolina percentages by age, gender and race. The following table shows the North Carolina and total Network data for 2014 as provided by the Southeastern Kidney Council, and compared with the IPRO 2015 Network totals.

²<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014 and 2015						
	2014 Patients and Percentages*				2015 Patients and Percentages**	
	NC Patients	NC Percentage	Total Network 6 Patients	Total Network 6 Percentage	Total Network 6 Patients	Total Network 6 Percentage
Age						
0-19	52	0.3%	137	0.3%	137	0.3%
20-34	770	4.8%	2,173	4.9%	2,142	4.7%
35-44	1,547	9.7%	4,385	9.9%	4,493	9.8%
45-54	2,853	17.8%	8,070	18.3%	8,422	18.3%
55-64	4,175	26.1%	11,706	26.5%	12,024	26.1%
65+	6,601	41.3%	17,716	40.1%	18,817	40.9%
Gender						
Female	7,064	44.2%	19,923	45.1%	20,805	45.2%
Male	8,934	55.8%	24,264	54.9%	25,230	54.8%
Race						
African-American	9,855	61.6%	29,191	66.1%	30,092	65.4%
White	5,778	36.1%	14,222	32.2%	15,049	32.7%
Other	365	2.3%	774	1.8%	894	1.9%

*2014 Calendar Year data from the Southeastern Kidney Council Network 6 2014 annual Report at <http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

**2015 Calendar Year data from the IPRO ESRD Network of the South Atlantic at http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian comparing with 85% of Network 6 patients being 45 and over and 69% being non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*). In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older and over 67% were non-Caucasian. (IPRO SA Network 6).

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

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

C

In Section L.3(e), page 74, the applicant states,

“Fresenius related facilities in North Carolina do 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 BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

In Section L.6, page 74, the applicant states that no civil rights complaints have been lodged against any BMA North Carolina facilities in the past five years.

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(b), page 72, the applicant provides the projected payor mix for the proposed services at FKC Captains Cove as shown in the table below:

**Projected Payor Mix, OY2
1/1/20-12/31/20**

Payor Source	Percentage
Private Pay/Indigent/Charity	1.10%
Medicare	76.49%
Medicaid	6.57%
Commercial Insurance	6.07%
Medicare/Commercial	6.98%
Miscellaneous, including VA	2.79%
Total	100.00%

Totals may not sum due to rounding

As shown in the table above, the applicant projects that over 90% of in-center patients will have some or all of their services paid for by Medicare or Medicaid. In Section L.1(b), page 72, the applicant states that the projected payor mix is calculated based upon the current payor mix of FMC Ayden, FMC East Carolina, and Greenville Dialysis Center, the three facilities contributing the 12 relocated stations and the patient transfers for the development of the proposed facility. The applicant

demonstrates that medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, page 74, the applicant states,

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FKC Captains Cove will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”

The applicant adequately demonstrates that FKC Captains Cove will provide a range of means by which a person can access its services. Therefore, 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 77, the applicant states that health related education programs will be welcomed at the facility. Exhibit M-1 includes a letter from the applicant to the nursing program at The College of Nursing at East Carolina University, dated March 14, 2017, inviting the school to include FKC Captains Cove in its clinical rotations for its nursing students. The information provided in Section M.1 and Exhibit M-1 is reasonable and supports a finding of conformity to this criterion.

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

applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to develop a new 12-station dialysis facility in Winterville by relocating six stations from FMC Ayden, three stations from FMC East Carolina, and three stations from Greenville Dialysis Center. All four facility locations are in Pitt County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, FKC Captains Cove will be certified for 12 stations, FMC Ayden will be certified for 10 dialysis stations, FMC East Carolina will be certified for 38 stations; and Greenville Dialysis Center will be certified for 48 dialysis stations following completion of this project and Project ID #L-11011-15 (relocate four stations to FMC Tarboro) and Project ID #Q-11141-16 (add 10 stations).

On page 373, the 2017 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.*” The proposed new facility, FKC Captains Cove, will be located in Pitt County; thus, the service area for this facility consists of Pitt County. Facilities may also serve residents of counties not included in their service area.

According to the January 2017 SDR, there are four dialysis facilities in Pitt County, as follows:

Pitt County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
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Source: January 2017 SDR, Table A.

* Project ID #Q-10315-14 approved the development of new 10-station facility. Stations were certified February 29, 2016.

As illustrated above, FMC or Fresenius related entities own and operate the dialysis facilities in Pitt County. One of the facilities, FMC Farmville, was developed during the previous year, being certified at the end of February 2016; therefore, it's utilization represents only four months of data based on the June 30, 2016 data in the January 2017 SDR. The other three FMC dialysis facilities are reasonably well-utilized, operating above 88% utilization and above 3.5 patients per station.

According to Table B in the January 2017 SDR, there is a surplus of one dialysis station in Pitt County. However, the applicant is not increasing the number of dialysis stations in Pitt County, rather it is relocating 12 existing Pitt County stations to develop a new facility which the applicant states is closer to patients living in the area where the new facility will be located. Therefore, it is not duplicating services, rather it is proposing to create a new facility to better serve existing patients using existing stations.

In Section N.1, page 78, the applicant discusses the expected effects of the proposed project on competition, including cost-effectiveness, quality and access, stating,

“The applicant does not expect this proposal to have effect on the competitive climate in Pitt County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FKC Captains Cove facility begins with patients currently served by BMA at other BMA locations within the county, and a growth of that patient population consistent with the Pitt County five year average annual change rate of 6.9% as published within the January 2017 SDR.”

In addition, the applicant states that it must operate efficiently as a result of fixed Medicare and Medicaid reimbursement rates and projects that greater than 90% of the patients at FKC Captains Cove will have their services covered by Medicare or Medicaid. Moreover, the applicant states, on page 78, that its proposal will *“enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.”*

See also Sections B, C, E, F, H, L, N and O where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and adequately demonstrates that any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality and access to the proposed dialysis services. This determination is based on the information in the application and the following analysis:

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

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section A.11, page 6, the applicant states that Bio-Medical Applications of North Carolina, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc., which owns and operates 108 existing kidney disease treatment centers in North Carolina. In Exhibit A-4, the applicant provides a listing of the FMC-affiliated ESRD facilities owned and operated in North Carolina. In Section O, pages 82-83, the applicant provides information on quality of care provided at its sister facilities, including citations received during the 18 months immediately preceding the submittal of the application, and their resolution. Two FMC-affiliated facilities had immediate jeopardy citations: RAI West College-Warsaw and BMA East Rocky Mount. The applicant summarizes the deficiencies cited, the resolutions, and provides documentation in Exhibits O-3, including correspondence from Licensure and the Centers for Medicare and Medicaid Services. On page 83, the applicant states that both facilities were back in full compliance with all CMS Guidelines upon the submittal of the application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. Therefore, the application is conforming to this criterion.

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

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C.2200 are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C.2200. The specific findings are discussed below.

(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, pages 19-21, the applicant documents the need for the project and demonstrates that it will serve a total of 42 in-center patients on 12 stations at the end of the first operating year, which is 3.5 patients per station per week, or a utilization rate of 87.5% (42 patients / 12 stations = 3.5; $3.5 / 4 = 0.875$). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

(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 seeking to develop a new 12-station dialysis facility.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section C.1, pages 19-21. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.