

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 9, 2017

Findings Date: November 9, 2017

Project Analyst: Bernetta Thorne-Williams

Team Leader: Lisa Pittman

Project ID #: J-11372-17

Facility: Fresenius Kidney Care Selma

FID #: 170323

County: Johnston

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

Project: Develop a new 10-station dialysis facility by relocating two dialysis stations from FMC Four Oaks, four stations from Johnston Dialysis Center and four stations from FMC New Hope Dialysis. Upon project completion, FMC Four Oaks will have 16 stations, Johnston Dialysis Center will have 27 stations, and FMC New Hope Dialysis will have 32 stations.

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

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a Fresenius Kidney Care Selma (FKC Selma) proposes to relocate two dialysis stations from FMC Four Oaks, four stations from Johnston Dialysis Center and four dialysis stations from FMC New Hope Dialysis to develop the proposed new 10-station dialysis facility in Johnston County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon project completion, FMC Four Oaks will be certified for 16 dialysis stations following completion of this project and Project I.D. # J-11310-17, Johnston Dialysis Center will be certified for 27 stations following completion of this project and Project

I.D. # J-11230-16, and FMC New Hope Dialysis will be certified for 32 stations following completion of this project, Project I.D. # J-11312-17 and Project I.D. # J-11271-16. Two of the existing facilities are located in Johnston County, (FMC Four Oaks and Johnston Dialysis Center), FMC New Hope Dialysis is located in Wake County.

Need Determination

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

Policies

Policy ESRD-2 is applicable to this review. Policy ESRD-2 of the 2017 SMFP 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 contiguous counties 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 10-station dialysis facility, to be named FKC Selma, in Selma, Johnston County by relocating two dialysis stations from FMC Four Oaks, four stations from Johnston Dialysis Center and four dialysis stations from FMC New Hope Dialysis. Two of the existing facilities (FMC Four Oaks and Johnston Dialysis Center), and the proposed new facility will be located in Johnston County. FMC New Hope Dialysis is located in Wake County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. The July 2017 SDR projects a deficit of 11 stations in Johnston County, however, the applicant projects to relocate dialysis stations within the county and from Wake County, therefore, the projected inventory of dialysis stations within Johnston County will increase by four stations. The same SDR shows a surplus of 12 dialysis stations in Wake County, therefore, the proposed project will decrease the number of surplus stations in Wake County to eight stations ($12 - 4 = 8$) and decrease the deficit in Johnston County to seven stations ($11 - 4 = 7$).

Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with Policy ESRD-2. Therefore, the application is conforming to this criterion.

- (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 10-station dialysis facility in Selma by relocating two dialysis stations from FMC Four Oaks, four stations from Johnston Dialysis Center and four dialysis stations from FMC New Hope Dialysis. Two of the existing facilities (FMC Four Oaks and Johnston Dialysis Center), and the proposed new facility will be located in Johnston County. FMC New Hope Dialysis is located in Wake County.

The following tables, summarized from pages 4-5 of the application, illustrate the proposed FKC Selma dialysis stations, FMC Four Oaks, Johnston Dialysis Center and FMC New Hope Dialysis inventory following completion of the proposed project.

Fresenius Kidney Care Selma

Stations	Description	Project ID #
0	Total existing certified stations as of the July 2017 SDR	
+10	Stations to be added as part of this project	J-11372-17
10	Total stations upon completion of above projects	

FMC Four Oaks

Stations	Description	Project ID #
22	Total existing certified stations as of the July 2017 SDR	
-2	Stations to be deleted as part of this project	J-11372-17
-4	Stations previously approved to be deleted but not yet certified	J-11310-17
16	Total stations upon completion of above projects	

Johnston Dialysis Center

Stations	Description	Project ID #
25	Total existing certified stations as of the July 2017 SDR	
-4	Stations to be deleted as part of this project	J-11372-17
+6	Stations previously approved to be added but not yet certified	J-11230-16
27	Total stations upon completion of above projects	

FMC New Hope Dialysis

Stations	Description	Project ID #
36	Total existing certified stations as of the July 2017 SDR	
-4	Stations to be deleted as part of this project	J-11372-17
+6	Stations previously approved to be added but not yet certified	J-11312-17
-6	Stations previously approved to be deleted but not yet certified	J-11271-16
32	Total stations upon completion of above projects	

As the tables above illustrate, several other projects impact the final number of certified dialysis stations at each facility. Upon completion of this project, FKC Selma will be certified for 10 dialysis stations, FMC Four Oaks will be certified for 16 stations following completion of this project and Project I.D. # J-11310-17, Johnston Dialysis will be certified for 27 stations following completion of this project and Project I.D. # J-11230-16 and FMC New Hope Dialysis will be certified for 32 stations following completion of this project, Project I.D. # J-11312-17 and Project I.D. #J-11271-16. Two of the existing facilities (FMC Four Oaks and Johnston Dialysis Center), and the proposed new facility will be located in Johnston County. FMC New Hope Dialysis is located in Wake County.

The July 2017 SDR projects a deficit of 11 stations in Johnston County, however, the applicant projects to relocate dialysis stations within the county and from Wake County, therefore, the projected inventory of dialysis stations within Johnston County will increase by four stations. The same SDR shows a surplus of 12 dialysis stations in Wake County, therefore, the proposed project will decrease the number of surplus stations in Wake County to eight stations (12 – 4 = 8) and decrease the deficit in Johnston County to seven stations (11 – 4 = 7).

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Johnston County. Facilities may serve residents of counties not included in their service area.

FKC Selma will be a new facility in Johnston County and therefore has no existing patient origin.

In Section C.1, page 20, 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:

**FKC Selma
 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
Johnston	34.0	36.2	100.0%	100.0%
Total*	34	36	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 20, the applicant states that patients who might be candidates for home dialysis will be referred to FMC South Selma.

The applicant provides the assumptions and methodology used to project patient origin on pages 20-22. The applicant adequately identifies the population to be served.

Analysis of Need

In Section C-2, page 22, the applicant describes the need for the proposed project as follows:

“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.”

In Section C, pages 20-22, the applicant states the need for the proposed new FKC Selma Dialysis facility is based on the following factors:

- The applicant plotted the residence of patients currently being served in BMA facilities in Johnston and Wake counties and noted a significant number of patients who reside in Selma and in Johnston County, north and east of Selma. The applicant concluded that this group of residents who reside in Selma and in the northern and eastern areas of Johnston County could be better served by the proposed facility which would provide a more convenient location. (page 20).
- In Exhibit C.1 the applicant provides 40 letters of support from in-center patients who reside in close proximity to the proposed facility. (page 20)

The applicant provides a table on page 21, which depicts the patients by residence Zip Code along with the facility that they are currently receiving dialysis services, as illustrated below.

BMA Facility	FKC Selma Letters of Support					
	ZIP Code of Residence					
	27520	27555	27576	27568	27569	Totals
Johnston Dialysis		2	22	1	3	28
FMC Four Oaks			8		3	11
FMC New Hope	1					1
Totals	1	2	30	1	6	40

- The applicant assumes that 32 of the 40 patients who provided letters of support will transfer their care to the proposed FKC Selma facility based upon a reduction in travel time to receive services. (page 21)
- The applicant assumes the Johnston County dialysis patients transferring to the proposed facility will grow at a rate commensurate with the Johnston County Five Year Average Annual Change Rate as published in the July 2017 SDR of 6.3%. (page 21)

Projected In-center Utilization

The applicant projects that Operating Year One (OY1) and Operating Year Two (OY2) for the proposed project will be Calendar Year (CY) 2019 and CY2020, respectively. In Section C.1, page 20, the applicant provides its methodology for projecting in-center (IC) utilization as follows:

FKC Selma IN-CENTER	
In-center Methodology:	
BMA begins 32 Johnston County IC dialysis patients upon project certification December 31, 2018.	32
BMA projects this census forward one year using the Johnston County Five Year Average Annual Change Rate of 4.0% to December 31, 2019. This is the end of OY1.	$32 \times 1.063 = 34.01$
BMA projects this Johnston County patient population forward to December 31, 2020. This is the ending census for Operating Year 2.	$34.01 \times 1.063 = 36.15$

The applicant rounds down to the nearest whole number. Therefore, 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 OY1 with a utilization rate of 85% ($3.4/4 = 0.85$ or 85%) and 36 in-center patients or 3.6 patients per station per week ($36/10 = 3.6$) with a utilization rate of 90% ($3.6/4 = 0.9$ or 90%) by the end of OY2 for the proposed 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).

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(a), pages 67-68, the applicant states that each of BMA's 109 facilities in 48 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons. In Section L, page 68, the applicant projects that 88.1% of its in-center patients will be covered by some combination of Medicare or Medicaid at the proposed FKC Selma facility. Additionally, in Section L.7, pages 71-72, the applicant provides the historical payor mix for Johnston Dialysis, FMC Four Oaks, and FMC New Hope. In FY 2016, the applicant reports that 88.1% of its total patients at Johnston Dialysis, 94.2% of FMC Four Oaks, and 84.8% (rounded) of FMC New Hope, respectively, had some or all of their services paid for by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the projected population has for the proposed services, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. 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 10-station dialysis facility, to be named FKC Selma, in Selma, Johnston County by relocating two dialysis stations from FMC Four Oaks, four stations from Johnston Dialysis Center and four dialysis stations from FMC New Hope Dialysis. Two of the existing facilities (FMC Four Oaks and Johnston Dialysis Center), and the proposed new facility will be located in Johnston County. FMC New Hope Dialysis is located in Wake 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, FMC Four Oaks will be certified for 16 dialysis stations ($22 - 2 - 4 = 16$), Johnston Dialysis will be certified for 27 stations ($25 - 4 + 6 = 27$), and FMC New Hope will also be certified for 32 dialysis stations ($36 - 4 + 6 - 6 = 32$).

The following table shows the proposed relocation of stations and transfer of Johnston County dialysis patients projected in the proposed project.

Facility	Number of Stations to be Relocated	Number of Patients Transferring
FMC Four Oaks	2	10
Johnston Dialysis	4	21
FMC New Hope	4	1
Total	10	32

FMC Four Oaks

In Section D-1, pages 32-33, the applicant provides the assumptions used to project FMC Four Oaks utilization as of December 31, 2018. The applicant discusses how it will continue to meet the needs of dialysis patients at FMC Four Oaks after the relocation of two stations to the proposed FKC Selma facility and the four stations previously approved in Project I.D. # J-11310-17 to be relocated to FMC Stallings Station. The applicant did not project any patients to transfer to the FMC Stallings Station facility. The July 2017 SDR reported as of December 31, 2016, 58 patients dialyzing at FMC Four Oaks on 22 dialysis stations, for a utilization rate of 65.91% ($58 / 22 = 2.636 / 4 = 0.65909$). On pages 32-33, the applicant states that as of June 30, 2017 there were 65 patients dialyzing at FMC Four Oaks and that 64 of those patients were residents of Johnston County. The applicant provides a table on page 33, which illustrates the county of residence for the in-center patients at FMC Four Oaks as of June 30, 2017, as shown below.

FMC Four Oaks	Number of Patients by County
Johnston	64
Other States	1
Total	65

The applicant assumes that the number of in-center patients at FMC Four Oaks who live in Johnston County will increase at 6.3% per year based on the Five Year AACR for Johnston County, as reported in Table D of the July 2017 SDR. The applicant assumes that the out of state patient was transient and therefore no growth is projected forward. In Section D.1, page 33, the applicant calculates the in-center patient census for FMC Four Oaks starting June 30, 2017 through December 31, 2018 (projected certification date of FKC Selma facility), summarized as follows:

FMC Four Oaks	
BMA begins with the Johnston County patient census as of June 30, 2017.	64
BMA projects this census forward for six months using the Johnston County Five Year Average Change Rate to December 31, 2017.	$[64 \times (.063 / 12 \times 6)] + 64 = 66.02$
BMA projects this census forward for one year to December 31, 2018.	$66.02 \times 1.063 = 70.17$
Subtract 10 Johnston County residents projected to transfer their care to FKC Selma.	$70.17 - 10 = 60.17$

On page 33, the applicant states that BMA rounds the patient population of 60.2 up to 61 in-center patients for a utilization of 95.3% or 3.81 patients per station, per week. This is based on 61 in-center patients dialyzing on 16 certified dialysis stations ($61 / 16 = 3.8125$; $3.8125 / 4 = 0.9531$ or 95.31%). However, throughout the application and historically, the patient census is typically rounded down not up, thus the project analyst calculated the utilization based on 60 in-center patients dialyzing on 16 certified stations for a utilization of 93.8% or 3.75 patients per stations per week ($60 / 16 = 3.75$; $3.75 / 4 = 0.9375$ or 93.8%).

Johnston Dialysis Center

In Section D.1, pages 34-35, the applicant provides the assumptions used to project Johnston Dialysis utilization as of December 31, 2018. The applicant discusses how it will continue to meet the needs of dialysis patients at Johnston Dialysis after the relocation of four stations to the FKC Selma facility. The July 2017 SDR reported as of December 31, 2016, 94 patients dialyzing at Johnston Dialysis on 25 dialysis stations, for a utilization rate of 94.0% ($94 / 25 = 3.76 / 4 = 0.94$). On page 34, the applicant states that as of June 30, 2017 there were 95 patients dialyzing at Johnston Dialysis and that 91 of those patients were residents of Johnston County. The applicant provides a table on page 34, which the applicant refers to as “*the in-center patient population at FMC Four Oaks,*” however, in the narrative the applicant states it’s the in-center population for Johnston Dialysis. Therefore, the project analyst assumed the heading in the table to be a typographical error. The applicant provides a table which illustrates the county of residence for the in-center patients at Johnston Dialysis (not FMC Four Oaks), as of June 30, 2017, as shown below.

Johnston Dialysis	Number of Patients by County
Johnston	91
Wake	1
Wayne	3
Total	95

The applicant assumes that the number of in-center patients at Johnston Dialysis who live in Johnston County will increase at 6.3% per year based on the Five Year AACR for Johnston County, as reported in Table D of the July 2017 SDR. The applicant assumes that no growth will occur for the in-center patients residing in Wake and Wayne counties. In Section D.1, page 35, the applicant calculates the in-center patient census for Johnston Dialysis starting June

30, 2017 through December 31, 2018 (projected certification date of FKC Selma facility), summarized as follows:

Johnston Dialysis	
BMA begins with the Johnston County patient census as of June 30, 2017.	91
BMA projects this census forward for six months using the Johnston County Five Year Average Change Rate to December 31, 2017.	$[91 \times (.063 / 12 \times 6)] + 63 = 93.87$
BMA projects this census forward for one year to December 31, 2018.	$93.87 \times 1.063 = 99.78$
Subtract 4 Johnston County residents projected to transfer their care to FMC Stallings (Project I.D. # J-11310-17).	$99.78 - 4 = 95.0$ [95.78]
Subtract 21 Johnston County residents projected to transfer their care to FKC Selma.*	95.0 [95.78] – 21 = 78.8 [74.78]
Add the 4 patients from outside Johnston County (one patient from Wake County and four patient from Wayne County) – this is the projected census for December 31, 2018	78.8 [74.78] + 4 = 82.8 [78.78]

*Reflects analyst calculations based on the data provided. The information on page 35 reflects two mathematical errors that the analyst assumes to be typographical errors.

On page 35, the applicant states that BMA rounds the patient population of 82.8 up to 83 in-center patients. The applicant projects a utilization of 76.85% or 3.1 patient per station per week. The actual projected number of in-center patients is 78.78 rounded down to 78 patients, thus, calculating the utilization on 83 in-center patients is inaccurate. Therefore, a utilization of 72.22% or 2.88 patients per station per week is projected for the Johnston Dialysis. This is based on 78 in-center patients dialyzing on 27 certified dialysis stations ($78 / 27 = 2.88$; $2.88 / 4 = 0.7222$ or 72.22%).

FMC New Hope Dialysis

In Section D.1, pages 35-36, the applicant provides the assumptions used to project FMC New Hope Dialysis utilization as of December 31, 2018. The applicant discusses how it will continue to meet the needs of dialysis patients at FMC New Hope Dialysis after the relocation of four stations to the FKC Selma facility. The July 2017 SDR reported as of December 31, 2016, 119 patients dialyzing at FMC New Hope Dialysis on 36 dialysis stations, for a utilization rate of 82.64% ($119 / 36 = 3.3056 / 4 = 0.82638$). On page 36, the applicant states that as of June 30, 2017 there were 124 patients dialyzing at FMC New Hope Dialysis and that 3 of those patients were residents of Johnston County. As FMC New Hope Dialysis is located in Wake County, the majority of its patients (120) are residents of Wake County. The applicant provides a table on page 36, which illustrates the county of residence for the in-center patients at FMC New Hope Dialysis, as of June 30, 2017, as shown below.

FMC New Hope Dialysis	Number of Patients by County
Wake	120
Johnston	3
Wilson	1
Total	124

The applicant states that one of the three patients who live in Johnston County and are currently dialyzing at FMC New Hope has expressed a willingness in considering transferring their care to the proposed FKC Selma facility. The applicant assumes that the number of in-center patients at FMC New Hope who live in Wake County will increase at 5.6% per year based on the Five Year AACR for Wake County, as reported in Table D of the July 2017 SDR. The applicant assumes that no growth will occur for the in-center patients residing in Johnston and Wilson counties. In Section D.1, page 37, the applicant calculates the in-center patient census for FMC New Hope Dialysis starting June 30, 2017 through December 31, 2018 (projected certification date of FKC Selma facility), summarized as follows:

FMC New Hope Dialysis	
BMA begins with the Johnston County patient census as of June 30, 2017.	120
BMA projects this census forward for six months using the Wake County Five Year Average Change Rate to December 31, 2017.	$[120 \times (.056 / 12 \times 6)] + 120 = 123.36$
BMA projects this census forward for six months to June 30, 2018.	$[123.36 \times (.056 / 12 \times 6)] + 123.36 = 126.8$
Subtract 1 Wake County residents projected to transfer their care to FMC White Oak (Project I.D. # J-11312-17).	$126.8 - 1 = 125.8$
BMA projects this census forward for six months to December 31, 2018.	$[125.8 \times (.056 / 12 \times 6)] + 125.8 = 129.3$
Subtract 8 Wake County residents projected to transfer their care to FMC Rock Quarry (Project I.D. # J-11220-16).	$129.3 - 8 = 121.3$
Add the 1 patients from outside Wilson County – this is the projected census for December 31, 2018	$121.3 + 1 = 122.3$

On page 37, the applicant states that BMA rounds the patient population of 122.3 up to 123 in-center patients. Thus, the applicant projects to serve 3.84 patients per station per week for a utilization of 96.09%. However, the applicant should have rounded down to 122 in-center patients for a utilization 95.3% or 3.81 patients per station per week which is based on 122 patients dialyzing on 32 dialysis stations ($122/32 = 3.8125$; $3.8125 / 4 = 0.9531$)

In Section L.1(b), page 68, the applicant states that the projected payor mix at the proposed new facility is based on the historical payor mix of Johnston Dialysis. 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

Conclusion

The applicant demonstrates that the needs of the population presently served at FMC Four Oaks, Johnston Dialysis and FMC New Hope will continue to be adequately met following the proposed relocation of two dialysis stations from FMC Four Oaks, four dialysis stations from Johnston Dialysis, and four dialysis stations from FMC New Hope to FKC Selma 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, page 38, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the status quo - The applicant states that maintaining the status quo is not an effective alternative because of the number of people currently dialyzing at a BMA facility in Johnston and Wake counties who live in closer proximity to the proposed FKC Selma facility. Therefore, this alternative was rejected.
- Develop a facility in another area of Johnston County - After an evaluation of the current patient population served at BMA facilities in Johnston County and an analysis of projected population growth, the applicant concluded that the proposed area north and east of Selma would be best served by a new facility. Therefore, development of a facility in another area of Johnston County was not considered to be an effective alternative.
- Development of a larger facility - After evaluation of the current patient population and the projected population growth, the applicant concluded that a larger facility was not needed and therefore would not be an effective alternative.
- Inclusion of home hemodialysis and peritoneal dialysis services - The applicant concluded that the current home patient population is well served by the FMC Stallings Station facility. The applicant will save money by not adding home hemodialysis services to the proposed facility. Therefore, this alternative was rejected.

Thus, after considering the above alternatives, the applicant states that its proposal to develop a new 10-station facility in Selma by relocating two dialysis stations from FMC Four Oaks, four dialysis stations from Johnston Dialysis and four dialysis stations from FMC New Hope is the most efficient or cost effective alternative.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project 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 identified need. Therefore, 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 Selma shall materially comply with all representations made in the certificate of need application.**
 2. **Pursuant to Policy ESRD 2, Bio-Medical Applications of North Carolina, Inc. shall develop a new kidney disease treatment center to be known as Fresenius Kidney Care Selma by relocating two dialysis stations from FMC Four Oaks, four dialysis stations from Johnston Dialysis and four dialysis stations from FMC New Hope.**
 3. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Selma shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 4. **Upon completion of this project and Project I.D. # J-11310-17, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify two dialysis stations (proposed project) and four dialysis stations (Project I.D. # J-11310-17) for a total of six dialysis stations to be decertified at FMC Four Oaks for a total of no more than sixteen dialysis stations at FMC Four Oaks.**
 5. **Upon completion of this project and Project I.D. # J-11230-16, Bio-Medical Applications of North Carolina, Inc., shall add six stations and decertify four dialysis stations from Johnston Dialysis for a total of no more than twenty-seven dialysis stations at Johnston Dialysis.**
 6. **Upon completion of this project, Project I.D. # J-11312-17 and Project I.D. # J-11271-16, Bio-Medical Applications of North Carolina, Inc., shall decertify four stations (proposed project) and six stations (Project I.D. # J-11271-16) for a total of ten dialysis stations to be decertified and add six stations (Project I.D. # J-11312-17) for a total of no more than thirty-two dialysis stations at FMC New Hope.**
 7. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Selma 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 10-station dialysis facility in Selma by relocating two dialysis stations from FMC Four Oaks, four stations from Johnston Dialysis Center and four dialysis stations from FMC New Hope Dialysis. Two of the existing facilities (FMC Four Oaks and Johnston Dialysis Center), and the proposed new facility will be located in Johnston County. FMC New Hope Dialysis is located in Wake County.

Capital and Working Capital Costs

In Section F.1, page 41, the applicant projects \$1,528,746 in capital costs to develop the proposed project as summarized below:

Projected Capital Costs		Total Capital Costs
Construction Project Costs		
Construction Contract	\$1,019,282	
Sub-Total Construction Costs		\$1,019,282
Miscellaneous Project Costs		
Water Treatment Equipment	\$225,000	
Equipment/Furniture	\$137,177	
Architect & Engineering Fees	\$91,735	
Other: Contingency	\$55,552	
Sub-Total Miscellaneous Costs		\$509,464
Total Capital Cost		\$1,528,746

In Sections F.10 - F.12, pages 44-45, the applicant estimates start-up expenses of \$122,667 and initial operating expenses of \$972,422, for a total working capital of \$1,095,089.

Availability of Funds

In Section F.2, page 42, the applicant states it will finance the capital costs with accumulated reserves/owner's equity of Fresenius Medical Care Holdings, Inc. (FMC). In Section F.13, page 46, the applicant states the working costs will be financed by the accumulated reserves of FMC.

Exhibit F.1 contains a letter dated July 17, 2017, from the Senior Vice President and Treasurer for FMCH, the parent company of BMA, which authorizes and commits cash reserves for the capital costs of the proposed project in the amount of \$1,528,746. Additionally the letter states,

“Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$1,528,746 as may be needed for this project. I am also authorized, and authorize an additional funds as may be necessary for the start-up costs in the new location.”

The letter contained in Exhibit F-1, does not specifically list the total working capital of the project as \$1,095,089, however, it is clear from the intent of the letter that the working capital needs of the project will be financed by FMC.

Exhibit F-2 contains the Subsidiaries Consolidated Financial Statements for FMC which indicates that it had \$357.9 million in cash and cash equivalents as of December 31, 2016, \$20.1 billion in total assets and \$10.5 billion in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital, working capital, and operating needs of the project.

Financial Feasibility

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

	Operating Year 1 CY2019	Operating Year 2 CY2020
Total Treatments	4,890	5,187
Total Gross Revenues (Charges)	\$19,501,320	\$20,685,756
Total Net Revenue	\$1,479,484	\$1,569,342
Total Operating Expenses (Costs)	\$1,458,632	\$1,507,223
Net Income	\$20,852	\$62,119

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. 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.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital 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 10-station dialysis facility in Selma by relocating two dialysis stations from FMC Four Oaks, four stations from Johnston Dialysis Center and four dialysis stations from FMC New Hope Dialysis. Two of the existing facilities (FMC Four Oaks and Johnston Dialysis Center), and the proposed new facility will be located in Johnston County. FMC New Hope Dialysis is located in Wake County.

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Johnston County. Facilities may serve residents of counties not included in their service area.

According to the July 2017 SDR, there are currently three dialysis facilities in Johnston County, as illustrated below.

JOHNSTON COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of DECEMBER 31, 2016				
Dialysis Facility/Owner	Certified Stations 12/31/16	# In-center Patients	Percent Utilization	Patients per Station
FMC Four Oaks	22	58	65.91%	2.6364
FMC Stallings Station	24	78	81.25%	3.2500
Johnston Dialysis Center	25	94	94.00%	3.7600

Source: July 2017 SDR.

As shown in the table above, all three of the facilities in Johnston County are operated by Fresenius Medical Care. Two of those facilities, FMC Stallings Station and Johnston Dialysis Center operated with a utilization of over 80% and FMC Four Oaks operated with a utilization of 65.91%.

The July 2017 SDR projects a deficit of 11 stations in Johnston County, however, the applicant projects to relocate dialysis stations within the county and add four stations from Wake County, therefore, the projected inventory of dialysis stations within Johnston County will increase by four stations which will decrease the deficit in Johnston County to seven stations (11 – 4 = 7). The same SDR shows a surplus of 12 dialysis stations in Wake County, therefore, the proposed project will decrease the number of surplus stations in Wake County to eight stations (12 – 4 = 8). Thus, the applicant proposes to relocate six dialysis stations in Johnston County and to relocate four stations from Wake County, which is a contiguous county to Johnston County, to develop the proposed 10 new station facility. The applicant states the proposed FKC Selma 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 Selma will serve 34 in-center patients or 3.4 patients per station per week ($34/10 = 3.4$) by the end of OY1 with a utilization rate of 85% ($3.4/4 = 0.85$ or 85%) and 36 in-center patients or 3.6 patients per station per week ($36/10 = 3.6$) with a utilization rate of 90% ($3.6/4 = 0.9$ or 90%) by the end of OY2.

The applicant provides documentation in Exhibit C-1 from 40 Johnston County in-center patients dialyzing at Fresenius-affiliated facilities stating their willingness to consider transferring to FKC Selma because its location would be more convenient. The applicant assumes that at least 32 of those patients who submitted letters of support will transfer their care to the proposed FKC Selma facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates the need to relocate existing six Johnston County Fresenius-affiliated dialysis stations and four Wake County dialysis stations to develop a new

Fresenius dialysis facility in Johnston 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 Four Oaks, Johnston Dialysis and FMC New Hope, 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 Johnston 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, page 51, the applicant provides the projected staffing for FKC Selma in OY2 by full-time equivalent (FTE) staff, as shown below:

FKC Selma Proposed FTE Positions OY2	
Position	Total
Registered Nurse	1.50
Patient Care Technician	4.00
Clinical Manager	1.00
Administrator	0.15
Dietitian	0.40
Social Worker	0.40
Chief Tech	0.15
Equipment Tech	0.60
In-Service	0.15
Clerical	0.75
Total FTEs	9.10

Note: The Medical Director is a contracted position.

In Section H.3, page 52, the applicant describes its experience and process for recruiting and retaining staff. In Section I.3, page 56, the applicant identifies the medical director for the proposed facility as Michael Casey, M.D. Exhibit I.5 contains a copy of a letter dated June 29, 2017 from Dr. Casey expressing support for the proposed project and a willingness to serve as the Medical Director. Exhibit I.6 contains a copy of Dr. Casey's curriculum vitae. 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 55, the applicant includes a list of providers of the necessary ancillary and support services for the proposed project. Exhibits I.1-4 contain documentation for home dialysis training, laboratory, hospital and transplant services, respectively. Exhibit I-5 contains a letter from the proposed medical director of the facility describing Nephrology services that will be offered by North Carolina Nephrology, P.A. The applicant discusses coordination with the existing health care system on page 57. 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 health care 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 62, the applicant states that the proposed facility will have 2,790 square feet of treatment area, which includes an isolation room. The applicant provides the proposed facility's line drawings in Exhibit K.1. The drawing depicts a 6,287 square foot facility, with nine main floor dialysis stations and one isolation dialysis station, for a total of 10 dialysis stations. In Section F.1, page 40, the applicant states that it relies upon the Fresenius Facility Design and Maintenance Department to develop anticipated project development costs. On page 41, the applicant provides the proposed costs, including \$1,019,282 for construction, \$509,464 in miscellaneous costs, including water treatment equipment, furniture, architect/engineering fees, and contingency for a total project cost of \$1,528,746. In Section K.1, pages 60-61, the applicant describes its plans for energy-efficiency, including water conservation.

Costs and charges are described by the applicant in Section F, pages 41-42, and in Section R pro forma 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 Selma is not an existing facility, therefore, it has no historical payor mix. However, in Section L.7, pages 71-72, the applicant provides the historical payor mix for FMC Four Oaks, Johnston Dialysis and FMC New Hope for CY2016. These are the three facilities from which the applicant proposes to relocate the ten existing dialysis stations to develop the proposed new FKC Selma facility. Their payor mix is illustrated below:

	Percentage of In-Center Patients		
	FMC Four Oaks	Johnston Dialysis	FMC New Hope
Self Pay/Idigent/Charity	0.38%	2.93%	1.95%
Medicare	73.24%	60.25%	48.67%
Medicaid	12.26%	16.15%	9.44%
Commercial Insurance	3.0%	6.72%	10.18%
Medicare/Commercial	8.73%	11.70%	26.64%
Miscellaneous Including VA)	2.40%	2.25%	3.11%
Total	100.0%	100.0%	100.0%

Note: The applicant states on page 71 that 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**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Johnston	13%	51%	31%	13%	10%	14%
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 applicant adequately demonstrates that it currently provides access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

- (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), pages 69-70, 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 70, the applicant states there have been no civil rights access complaints filed within the last five years against any BMA North Carolina facility. Therefore, 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 68, the applicant projects that 88.1% of the patients who will receive in-center treatments at FKC Selma will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected OY2 (CY2020) payor sources for the facility for in-center patients

FKC Selma	
PROJECTED PAYOR SOURCE (OY2) (CY2020)	PERCENT OF TOTAL IN-CENTER PATIENTS
Self Pay/Indigent/Charity	2.93%
Medicare	60.25%
Medicaid	16.15%
Commercial Insurance	6.72%
Medicare/Commercial	11.70%
Miscellaneous (Includes VA)	2.25%
Total	100.00%

In Section L1, page 68, the applicant states the projected payor mix is calculated based on the payor mix of BMA facilities in Johnston County as of April 30, 2017. The

projected payor mix mirrors the payor mix of Johnston Dialysis. The applicant demonstrates that medically underserved groups will 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 70, the applicant describes the range of means by which a person will have access to the dialysis services at the proposed FKC Selma facility, including referrals from nephrologists and hospital emergency departments. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis 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 73, 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 Director of Nursing Education Programs for Johnston Community College, dated July 17, 2017, inviting the school to include FKC Selma 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 10-station dialysis facility in Selma by relocating two dialysis stations from FMC Four Oaks, four stations from Johnston Dialysis Center and four dialysis stations from FMC New Hope Dialysis. Two of the existing facilities (FMC Four Oaks

and Johnston Dialysis Center), and the proposed new facility will be located in Johnston County. FMC New Hope Dialysis is located in Wake County.

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Johnston County. Facilities may serve residents of counties not included in their service area.

According to the July 2017 SDR, there are currently three dialysis facilities in Johnston County, as illustrated below.

JOHNSTON COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of DECEMBER 31, 2016				
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Source: July 2017 SDR.

As shown in the table above, all three of the facilities in Johnston County are operated by Fresenius Medical Care. Two of those facilities, FMC Stallings Station and Johnston Dialysis Center operated with a utilization of over 80% and FMC Four Oaks operated with a utilization of 65.91%.

The July 2017 SDR projects a deficit of 11 stations in Johnston County, however, the applicant projects to relocate dialysis stations within the county and add four stations from Wake County, therefore, the projected inventory of dialysis stations within Johnston County will increase by four stations which will decrease the deficit in Johnston County to seven stations (11 – 4 = 7). The same SDR shows a surplus of 12 dialysis stations in Wake County, therefore, the proposed project will decrease the number of surplus stations in Wake County to eight stations (12 – 4 = 8). Thus, the applicant proposes to relocate six dialysis stations in Johnston County and to relocate four stations from Wake County, which is a contiguous county to Johnston County, to develop the proposed 10 new station facility. The applicant states the proposed FKC Selma is closer to patients living in the area where the new facility will be located.

In Section N-1, page 74, the applicant discusses how any enhanced competition would have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

“The applicant does not expect this proposal to have effect on the competitive climate in Johnston County. At this time, BMA is the only provider of dialysis services in the county.”

The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FKC Selma facility begins with patients currently served by BMA at other nearby BMA locations, and a growth of that patient population consistent with the Johnston County five year average annual change rate of 6.3% as published within the July 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 88% of the patients at FKC Selma will have their services covered by Medicare or Medicaid. Moreover, the applicant states, on page 74, 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 in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will continue providing quality services. The discussions regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will 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. On page 67, the applicant states, Fresenius operates 109 facilities in 48 North Carolina counties In Section O, pages 75-79 and referenced Exhibits, the applicant identifies the two kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation during the 18 month look-back period. Those two facilities had immediate jeopardy citations: RAI West

College-Warsaw and BMA East Rocky Mount. Both facilities are back in compliance with the Medicare conditions of participation. 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. 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 to 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, pages 20-22, the applicant states the need for the proposed project. 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 OY1 with a utilization rate of 85% ($3.4/4 = 0.85$ or 85%) and 36 in-center patients or 3.6 patients per station per week ($36/10 = 3.6$) with a utilization rate of 90% ($3.6/4 = 0.9$ or 90%) by the end of OY2 for the proposed facility. The discussion regarding analysis of need 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 application is for the development of a new 10-station facility.

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

-C- The applicant provides its assumptions, including the methodology by which patient utilization is projected in Section C-1, pages 20-22, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.