

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

FINDINGS: June 7, 2013

PROJECT ANALYST: Gene DePorter

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: J-10094-13/ Bio-Medical Applications of North Carolina Inc. d/b/a FMC-Stallings Station Dialysis, add 4 dialysis stations for a total of 24 certified dialysis stations upon completion of this project /Johnston

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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

Bio-Medical Applications [BMA] of North Carolina, Inc. d/b/a FMC Stallings Station [Stallings Station], whose parent company is Fresenius Medical Care Holdings, Inc; was opened in January 2010. The applicant proposes to add four dialysis stations to its existing dialysis facility located at 5420 Barber Road, Clayton, for a total of 24 dialysis stations upon completion of this project.

The 2013 State Medical Facilities Plan [2013 SMFP] provides a county need methodology and a facility need methodology for determining the need for additional dialysis stations. According to the January 2013 Semiannual Dialysis Report (SDR) the county need methodology shows there is a deficit of 2 stations and thus no need for an additional facility in Johnston County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for FMC Stallings Station in the January 2013 SDR is 6.50 patients per station and a utilization percentage of 162.50%.

However, the January 2013 SDR incorrectly shows 10 stations being certified as of 6/30/12. The correct number of certified stations is 20 as of 6/30/12. Therefore utilization of Stallings Station

was 3.25 patients per station or 81.25% ($65/20 = 3.25$; $3.25/4 = 0.8125$ or 81.25%). Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

Table 1
FMC Stallings Station
 ESRD Facility Need Methodology
 Semiannual Dialysis Facility Need

| Required SDR Utilization | | 80% |
|--|--|----------|
| Center Utilization Rate as of 6/30/12 | | 81.25% |
| Certified Stations | | 20 |
| Pending Stations | | 0 |
| Total Existing and Pending Stations | | 20 |
| In-Center Patients as of 6/30/12 (SDR2) | | 65 |
| In-Center Patients as of 12/31/11 (SDR1) | | 39 |
| Step | Description | Result |
| (i) | Difference (SDR2 – SDR1) | 26 |
| | Multiply the difference by 2 for the projected net in-center change | 52 |
| | Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/11 | 133.3% |
| (ii) | Divide the result of step (i) by 12 | 0.1111 |
| (iii) | Multiply the result of step (ii) by the number of months from the most recent month reported in the June 30, 2012 SDR (6) (6/30/12) until the end of calendar year 12/31/2012) for the January 2, 2013 | 0.6667 |
| (iv) | Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2 | 108.3333 |
| (v) | Divide the result of step (iv) by 3.2 patients per station | 13.8542 |
| | and subtract the number of certified and pending stations as recorded in SDR2 [27] to determine the number of stations needed | 14 |

As shown in the above table, based on the facility need methodology for dialysis stations the potential number of stations needed is 14 stations. However, Step (c) of the facility need methodology, page 381 of the 2013 SMFP, states; “*The facility may apply to expand to meet the need established... up to a maximum of 10 stations.*”

The applicant proposes to add four dialysis stations and therefore is consistent with the facility need determination for dialysis stations.

POLICY GEN-3: Basic Principles, in the 2013 SMFP is applicable to this review. Policy GEN-3 states:

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

Promote Safety and Quality

In Section II., page 26, the applicant describes how this proposal will promote safety and quality:

“BMA is a high quality health care provider. BMA’s parent company, Fresenius Medical Care encourages all BMA facilities to attain the FMC UltraCare certification. This is not a one time test, but rather is an ongoing process aimed at encouraging all staff, vendors, physicians, and even patients to be a part of the quality care program. Facilities are evaluated annually for UltraCare certification.”

In Section II.3, page 36-37, the applicant provides BMA goals for quality that the applicant states are more stringent than national averages. Reference the following table;

Table 2
BMA Core Indicators of Quality

| Core Indicator | Measuring | FMC Stallings Station |
|-----------------------|----------------------------------|------------------------------|
| Dialysis Adequacy | % of patients with EKT/> 1.2 | 91.8% |
| Nutrition | % of Patients with Albumin > 3.5 | 68.5% |
| Vascular Access | % of Patients with AV Fistula | 60.0% |
| | % of Patients with Catheter | 22.2% |

The applicant identifies the following programs and methods it uses to insure and maintain quality care:

Table 3

Maintaining Quality Care Programs

| Corporate Programs | Facility Programs |
|--|--------------------------------|
| Technical Audits | Quality Improvement Program |
| Continuous Quality Improvement | Staff Orientation and Training |
| External Surveys-DFS Certification Surveys | In-Service Education |
| Core Indicators of Quality | |
| Single Use Dialyzers | |

Exhibit 13 includes FMC’s Quality Improvement Program.

The applicant adequately demonstrates the proposal will promote safety and quality of care.

Promote Equitable Access

In Section II, pages 28-29, the applicant describes how the proposal would promote equitable access for medically underserved groups, as follows:

“10A NCAC .2202 (b)(8), requires a commitment by BMA ‘to admit and provide services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.’ BMA provides such assurances within Section VI of this application.

...BMA is also keenly sensitive to the second element of ‘equitable access’ – time and distance barriers. ...At this time, Johnston County has three operational dialysis facilities. The January 2013 SDR reports that Johnston County ESRD patient population is growing at an Average Annual Change Rate of 4.5%. FMC Stallings Station census is increasing at a far higher rate. As the dialysis patient population of Johnson County continues to increase, the need for dialysis stations will continue to increase. ...Over the years, BMA has sought to develop new facilities and new dialysis stations in an effort to make dialysis convenient to the patient. This application to add four dialysis stations to FMC Stallings Station is another example of BMA efforts to meet the needs of the ESRD patient population of Johnston County. BMA is planning to add four stations so that an adequate supply of necessary health resources remains in closer proximity to the residence location of patients residing in this are of Johnston County.”

As noted in Section VI.1 (a), page 54 of this application:

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. ...Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, and other traditionally underserved persons.”

In Section II, page 29; BMA has projected that the facility will have the following demographic profile:

Table 4

FMC Stallings Station Facility Demographics

| Facility | Medicaid/ Low Income | Elderly (65+) | Medicare | Women | Racial Minorities |
|----------------------------------|---------------------------------|--------------------------|-----------------|--------------|------------------------------|
| FMC Stallings Station | 23.3% | 61.7% | 85.0% | 43.3% | 43.3% |

In Section VI.2, page 56-57, the applicant states:

“The design of the facility is such that handicapped persons will have easy access to the facility; the facility will comply with ADA requirements. It will be constructed in compliance with Section XIIX of the North Carolina applicable State Building Code, Vol. #1-General Construction, which lists minimum requirements for the handicapped applicable to institutional and residential structures. In addition, wheelchairs are always available for transporting patients who are unable to stand or walk.”

In Section VI.7, page 58, the applicant states:

“BMA admission policy state’s that patients shall be accepted for treatment at BMA when such treatment is deemed indicated and appropriate according to the clinical judgment of the patients’ attending physician. No arbitrary criteria with respect to the patient’s age or magnitude of complicating medical problems are established.

BMA also has an AIDS policy that states: a diagnosis of AIDS or HIV-positive status (absent other contraindications) is not an acceptable reason to refuse referral of a patient. Established referral patterns should be followed without regard to AIDS status of patients.” (Reference Exhibit 8 FMC Business and Admission Policy and Exhibit 9, HIV/HBV Policy & Procedure)

The applicant adequately demonstrates the proposal will promote equitable access to medically underserved groups. See Criteria (13c) for additional discussion.

Maximize Healthcare Value

In Section II., page 28, the applicant states:

“BMA is projecting a capital expenditure of \$52,008 for this project. BMA does not seek State or Federal monies to accomplish routine expansions or relocations; BMA does not seek charitable contributions to accomplish expansions. Rather, BMA through its parent company, FMC assumes the financial burden to complete addition of stations in an effort to ensure an adequate number of stations are available for the patients choosing to dialyze at FMC Stallings Station. As an additional consideration, BMA notes that the overwhelming majority of dialysis treatments are reimbursed through Medicare, Medicaid, or other government payor sources. For example, within this application, BMA projects that 84.2% of the treatments are covered by Medicare and Medicaid, and an additional 5.0% are covered by VA. The point here is that government payors are

working from a fixed payment schedule, often at significantly lower reimbursement rates than the posted charges. As a consequence, BMA must work diligently to control costs of delivery of dialysis. BMA does.”

The applicant adequately demonstrates the proposal will maximize healthcare value. Consequently, the applicant demonstrates that projected volumes for the proposed services incorporate the basic principles in meeting the needs of the patients to be served. The application is consistent with the facility need determination in the January 2013 SDR and Policy GEN-3. 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 FMC Stallings Station proposes to add four dialysis stations to its existing facility for a total of 24 stations upon completion of the project.

Population to Be Served

In Section IV. 1, page 47, the applicant identifies the population it serves, as illustrated in the following table:

**Table 5
FMC Stallings Station
March 15, 2013 Patient Origin**

| County | In-Center | Home PD |
|--------------|-----------|-----------|
| Johnston | 41 | 8 |
| Wake | 8 | 2 |
| Wayne | 1 | 0 |
| TOTAL | 50 | 10 |

In application Section II, pages 16-17, the applicant identifies the in-center population it proposes to serve during the first two operating years following project completion, as illustrated in the following table:

**Table 6
FMC Stallings Station-In-Center Patient Projections
Operating Years 1 and 2**

| County | Operating YR 1 7/1/14-6-30/15 | | Operating YR 2 7/1/15-6/30/16 | | County Patients as a Percentage of Total | |
|----------|----------------------------------|--------------|----------------------------------|--------------|---|---------|
| | In- Center | Home Hemo | In- Center | Home Hemo | Year 1 | Year 2 |
| Johnston | 64.6 | 2.0 | 67.8 | 4.2 | 84.80% | 85.10% |
| Wake | 12.6 | | 13.2 | | 13.50% | 13.20% |
| Wayne | 1.6 | | 1.7 | | 1.70% | 1.70% |
| Total | 78.7 | 2.0 | 82.7 | 4.2 | 100.00% | 100.00% |

Note: Operating Year 1-July 1, 2014 through June 30, 2015
Operating Year 2-July 1, 2015 through June 30, 2016.

The applicant adequately identified the population FMC Stallings Station proposes to serve.

Need Analysis

In Section III.7, pages 39-42, the applicant states the application is filed pursuant to the Facility Need Methodology utilizing data from the January 2013 SDR and it proposes to add four dialysis stations to Stallings Station for a total of 24 stations at that facility.

- The FMC Stallings Station census has grown at a rate far exceeding the Johnston County Five Year Average Change Rate of 4.5% for dialysis services (as published in the January 2013 SDR). Since opening in 2010 the facility census at FMC Stallings Station has grown from “0” patients to “65” patients as reported in the January 2013 SDR.
- The Facility Need Methodology indicated a potential need for 14 additional stations at FMC Stallings Station. The applicant has only requested 4 dialysis stations.
- Calculations in this application are based upon completion and certification of stations as of June 30, 2014.
- BMA does not believe it appropriate to use Johnston County’s Five Year Average Annual Change Rate of ESRD population growth. (4.5%) when the community of Clayton (within Johnston County) has experienced an average annual total population growth rate from 2000 to 2010 of 13.1%.
- The population in the Clayton area around FMC Stallings Station is increasing at a significantly higher rate (13.1%) per year than the county ESRD population as a whole (4.5%) per year.
- BMA proposes that one of the four requested dialysis stations be dedicated to home hemodialysis training which BMA states it conservatively projects at 2 patients per year. Currently, FMC Stallings Station is serving 10 home PD patients but is not currently certified for the provision of home hemodialysis at FMC Stallings Station.

The applicant assumes the patient population of the facility will continue to increase at a rate faster than that of the county. Therefore, the applicant has decided to use a rate of 7.5% for projecting future dialysis station need in the Stallings Station service area. BMA noted that in the approval of CON Project ID J-10038-12, the CON Section accepted a growth factor significantly exceeding the County Five Year Average Annual Change Rate.

The applicant's methodology is provided in the following table:

Table 7
BMA In-Center Methodology for Projected Patient Volume
June 30, 2013 through June 30, 2016

| | |
|---|------------------------------------|
| BMA begins with the in-center patient population for FMC Stallings Station as reported in the January 2013 SDR for June 30, 2012. | 65 |
| BMA projects this population forward to June 30, 2013 | $(65 \times .075) + 65 = 69.9$ |
| BMA projects this population forward to June 30, 2014. This is the beginning census for this proposal. | $(69.9 \times .075) + 69.9 = 75.1$ |
| BMA projects this population forward to June 30, 2015 | $(75.1 \times .075) + 75.1 = 80.7$ |
| BMA subtracts two patients projected to change dialysis modality to HH. This is the projected ending census for Operating Year 1. | $80.7 - 2 = 78.7$ |
| BMA projects this population forward to June 30, 2016. | $(78.7 \times .075) + 78.7 = 84.7$ |
| BMA subtracts two patients projected to change dialysis modality to HH. This is the projected ending census for Operating Year 2. | $84.7 - 2 = 82.7$ |

BMA projects the home peritoneal dialysis (PD) patient population will also increase by 7.5%. BMA indicates that it has been serving 10 PD patients at FMC Stallings Station since June 30, 2012. In Section II, page 15, the following table illustrates the calculation of the peritoneal dialysis projected patient population.

Table 8
BMA Peritoneal Dialysis Methodology for Projected Patient Volume
June 30, 2013 through June 30, 2016

| | |
|---|----|
| BMA begins with the PD patient population for FMC Stallings Station as of June 30, 2012 | 10 |
|---|----|

| | |
|---|------------------------------------|
| BMA projects this population forward to June 30, 2013 | $(10 \times .075) + 10 = 10.8$ |
| BMA projects this population forward to June 30, 2014. This is the beginning census for this proposal. | $(10.8 \times .075) + 10.8 = 11.6$ |
| BMA projects this population forwards to June 30, 2015 This is the projected ending census of PD patients for Operating Year 1. | $(11.6 \times .075) + 11.6 = 12.4$ |
| BMA projects the patient population forwards to June 30, 2016. This is the projected ending census of PD patients for Operating Year 2. | $(12.4 \times .075) + 12.4 = 13.4$ |

FMC Stallings Station is not currently certified to provide home hemodialysis training. In this proposal Stallings Station proposes to dedicate one of the four requested stations for home hemodialysis. In Section II., page 16, the applicant provides a three step methodology to determine home hemodialysis patient census;

Table 9
BMA Home Hemodialysis Methodology for Projected Patient Volume
June 30, 2014 through June 30, 2016

| | |
|--|------------------------------------|
| BMA begins with the HH patient population for FMC Stallings Station as of June 30, 2014 | 0 |
| BMA projects two patients to change modality in the first year of operations. This is the projected ending census of HH patients for Operating Year One. | 2 |
| BMA projects the patient population forward for 12 months to June 30, 2016 and adds two patients projected to change dialysis modality. | $[(2 \times .075) + 2] + 2 = 4.15$ |

Consequently, the applicant projects it will serve 78 in-center patients or 3.25 patients per station ($78/24 = 3.25$) by the end of Year 1 and 87 in-center patients or 3.42 in-center dialysis patients per station per week by the end of Year 2 [$82 \text{ patients}/24 \text{ stations} = 3.42 \text{ patients per station}$]. This exceeds the 3.2 patients per station per week required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth.

Access

In Section VI, page 55, the applicant states that each of BMA's 93 facilities in 40 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. The applicant projects that 89.2% of the patients at FMC Stallings Station will be covered by Medicare, Medicaid, and VA. The applicant demonstrates adequate access for medically underserved groups at FMC Stallings Station.

In summary, the applicant adequately identifies the population to be served and demonstrates the need the population has for four additional dialysis stations at FMC Stallings Station and demonstrates all residents of the area, and in particular, 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.

NA

- (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 III.9, page 45 of the application, the applicant describes the alternatives it considered to meet the need for the proposed services, stating:

“Basically there are only three options: apply, apply for fewer stations, or not apply.”

In Section III. 9, page 45, the applicant states that developing additional stations is the only way to serve the growing ESRD population choosing to dialyze at Stallings Station. Developing fewer than 4 stations is also not a reasonable alternative considering the utilization of this facility, according to the applicant.

The applicant adequately demonstrated the need for four additional stations based on the number of in-center patients it now serves and proposes to serve. See Criterion (3) for discussion on need which is hereby incorporated by reference as if fully set forth herein. The application is conforming to all other applicable statutory and regulatory review criteria and is thus approvable. The applicant adequately demonstrates that this project is its least costly or most effective alternative to meet the need for additional dialysis stations at this facility. 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 FMC Stallings Station shall materially comply with all representations made in its certificate of need application.**
2. **Bio-Medical Applications of North Carolina, Inc., d/b/a FMC Stallings Station shall develop and operate no more than four additional dialysis stations for a total of no more than 24 stations, which shall include any home hemodialysis training or isolation stations upon completion of this project.**
3. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Stallings Station shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations for a total of 24 stations, which shall include any home hemodialysis training or isolation stations.**

4. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Stallings Station shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section 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

In Section VIII. 1(b), page 62, Table VIII. 1; the applicant shows that the total capital costs of this project are \$52,008. The applicant further indicates that FMC Stallings Station facility is an operational facility. Consequently, there is no associated “start-up” expense involved and further indicates the following:

“Exhibit 10 is a copy of the most recent FMC audited financial reports. The 2011 Consolidated Balance Sheet reflects more than \$204 million in cash, and current assets exceeding \$13 billion. It is obvious that FMC has the resources necessary for all projects.”

In Exhibit 24 of the application, the applicant states the following in a letter dated March 15, 2013:

“BMA proposes to add four dialysis stations to FMC Stallings Station dialysis facility. The project calls [for] the following capital expenditures on behalf of BMA:

BMA Capital Expenditure \$52,008

As Vice President, I am authorized and do hereby authorize addition of four new dialysis stations for a total capital cost of \$52,008. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$52,008.”

The applicant adequately demonstrates availability of sufficient funds for the capital needs of the project.

The rates in the following table were provided by the applicant in application Section X.1, page 68 and are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services. ❶

**Table 10
In-Center Medicare/Medicaid Rates**

| | In-Center |
|----------------------|-------------|
| Commercial Insurance | \$ 1,375.00 |
| Medicare | \$ 234.00 |
| Medicaid | \$ 137.29 |

| | |
|-------------|-------------|
| VA | \$ 146.79 |
| Private Pay | \$ 1,375.00 |

In the revenue and expense statements in Section X. 2, page 69 and Section X.4, page 77, the applicant projects that revenues will exceed operating costs in each of the first two years of operation. The following table illustrates projected revenues and expenses during the first two years after project completion.

**Table 11
Revenue, Costs and Profit**

| | Operating Year 1 7/1/14-6/30/15 | Operating Year 2 7/1/15-6/30/16 |
|-----------------------|------------------------------------|------------------------------------|
| Total Net Revenue | \$4,257,330 | \$4,613,229 |
| Total Operating Costs | \$3,871,505 | \$4,167,927 |
| Net Profit | \$ 385,825 | \$ 445,302 |

The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Section X, pages 69-78, for the applicant’s assumptions.

In summary, the applicant adequately demonstrated that the financial feasibility of the proposal is based on reasonable projections regarding revenues and operating costs. 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 add four dialysis stations to the existing FMC Stallings Station facility for a total 24 dialysis stations upon completion of this project. The applicant adequately demonstrates the need for four additional stations based on the number of in-center patients it proposes to serve. As of June 30, 2012, the 20 station Stallings Station was operating at 81.25% capacity ($65/20 = 3.25$; $3.25/4 = .8125$). The target utilization is 80%. The applicant therefore is eligible to expand its facility and may apply for additional stations. Upon completion of this project, the facility will have 24 stations serving 78 patients in Year 1 which is a utilization rate of 81.25% ($78/24 = 3.25$; $3.25/4 = .8125$). Therefore, the applicant is conforming with the requirement in 10A NCAC 14C .2203.

① http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/End_Stage_Renal_Disease_Pro prospective_Payment_System_INC905143.pdf

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

There are three dialysis facilities in Johnston County, two at the eastern county line and FMC Stallings Station at the western end of the county in Clayton. The following table shows the distribution of ESRD facilities in Johnston County and utilization of dialysis stations based upon data in the January 2013 North Carolina Semiannual Dialysis Report.

Table 12
Johnston County Dialysis Facilities

| Facility (Stations) | Community | Pts. Per Station | % Utilized | Site |
|----------------------------|------------------|-------------------------|-------------------|---|
| FMC Stallings Station (20) | Clayton | 3.25 | 81.25% | Western End of Johnston County. |
| Johnston Dialysis (25) | Smithfield | 3.36 | 84.00% | Eastern end of Johnston County |
| FMC Four Oaks (22) | Four Oaks | 3.05 | 76.32% | Eastern end of Johnston County. South of Smithfield |

Source: 2013 North Carolina Semiannual Dialysis Report Table A, page 5 Johnston County.
 Note: Data adjusted for Stallings Station to reflect 20 certified stations as of 6/30/12.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities. 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 VII.1, page 59, the applicant provides the current and projected staffing for FMC Stallings Station as shown in the following table:

Table 13
FMC Stallings Station Current and Projected Staffing

| | # of Current (FTE) Positions | # of (FTE) Positions to be added | # of Projected (FTE) Positions |
|-------|-------------------------------------|---|---------------------------------------|
| RN | 2.00 | 0.00 | 2.00 |
| LPN | 1.00 | 0.00 | 1.00 |
| Tech. | 4.00 | 1.00 | 5.00 |

| | | | |
|------------------|---------------------------------------|-------------|--------------|
| Clinical Manager | 1.00 | 0.00 | 1.00 |
| Medical Director | Contract Position not a facility FTE. | | |
| Administrator | 0.15 | 0.00 | 0.15 |
| Dietitian | 0.50 | 0.00 | 0.50 |
| Social Worker | 0.50 | 0.00 | 0.50 |
| Home Training | 1.50 | 0.00 | 1.50 |
| Chief Tech | 0.10 | 0.10 | 0.10 |
| Equipment Tech | 0.70 | 0.00 | 0.70 |
| In-Service | 0.15 | 0.00 | 0.15 |
| Clerical | 1.00 | 0.00 | 1.00 |
| Total | 12.60 | 1.00 | 13.60 |

The applicant indicates a total of 12.60 FTE current staff and projects staffing of 13.60 which includes 1.00 FTE of additional staff, upon project completion. The applicant indicates in Section VII.4, page 60; that it does not expect any difficulty in recruiting staff. The information regarding staffing provided in application Section VII and the estimated annual salaries and revenues are reasonable and credible.

In Exhibit 21, Dr. Sejan Patel indicates that he will continue as Medical Director of Stallings Station. The applicant adequately documents the availability of resources, including health manpower and management personnel, for the provision of the services to be provided. 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

FMC Stallings Stations is an existing kidney disease treatment center certified by the Centers for Medicare and Medicaid. According to the records in Aspen, the facility meets all conditions of participation, including any requirements for the provision of ancillary and support services. In Section V. 1, page 49, the applicant includes a list of providers for the necessary ancillary and support services. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be available and coordinated with the existing health system. Therefore, the application is conforming to this criterion.

In application Section V.1, page 49, the applicant lists providers of the necessary ancillary and support services. Exhibit 16 contains a copy of a “*Transplant Services Agreement*” between WakeMed Health and Hospitals and FMC Stallings Station. Exhibit 17 includes an agreement between Duke University Medical Center and FMC Stallings Station for “*Transplant Center Evaluation Services.*” Section V.4 (b), pages 51-52 contains two tables listing physicians a) by specialty who support this application and b) who have expressed a willingness to provide medical coverage for ESRD patients. Exhibit 21 contains a letter from

Dr. Sejan Patel, M.D. who is and will continue to serve, as the Medical Director for the facility. The information provided in Section V is reasonable and credible and supports a finding of conformity with this criterion. See also 10A NCAC 14C .2200 in these findings.

- (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.

NA

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.1 (a), page 54, the applicant states the following;

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. Fresenius Medical Care Holdings, Inc. parent company to BMA, currently operates 93 facilities in 40 North Carolina Counties (includes our affiliations with RRI facilities); in addition, BMA has seven facilities under development or pending CON approval. Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly or other traditionally underserved persons. The following is indicative of the FMC Stallings Station facility and the expected patient population for the facility:

Table 14
FMC Stallings Station Patient Profile

| <i>Facility</i> | <i>Medicaid/Low Income</i> | <i>Elderly (65+)</i> | <i>Medicare</i> | <i>Women</i> | <i>Racial Minorities</i> |
|------------------------------|----------------------------|----------------------|-----------------|--------------|--------------------------|
| <i>FMC Stallings Station</i> | 23.3% | 61.7% | 85.0% | 43.3% | 43.3% |

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 76.3% of the facility treatment reimbursement is from Medicare.

It is clear that BMA projects to provide service to historically underserved populations. It is BMA 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...For example, Medicare represented 84.8% of North Carolina dialysis treatments in BMA facilities in FY 2012. Medicaid treatments represented an additional 4.5% of treatments in BMA facilities in FY 2012, low income and medically underinsured persons will continue to have access to all services provided by BMA.

The facility will conform to the North Carolina Building Code, the National Fire Protection Association 101 Life Safety Code, the Americans with Disabilities Act, ANSI Standards for Handicapped Access, and any other requirement of federal, state, and local bodies.”

As shown in the following table, 89.2% of FMC Stallings Station current in-center patients have some or all of their care paid for by Medicare, Medicaid or VA. In Section VI.1 (b), pages 54-55, the applicant provides the current and projected payer mix for FMC Stallings Station. The applicant projects no change in reimbursement, between current and projected reimbursement, as shown in the following table:

Table 15

**FMC Stallings Station
Current and Projected Payor Mix**

| Payor Source | Current & Projected Percent of Total |
|--------------------------|---|
| Private | 0.0% |
| Commercial Insurance | 10.8% |
| Medicare | 82.4% |
| Medicaid | 1.8% |
| Medicare/Medicaid | 0.0% |
| Medicare/Commercial | 0.0% |
| State Kidney Program | 0.0% |
| VA | 5.0% |
| Other: Self Pay/Indigent | 0.0% |
| Total | 100.0% |

The applicant demonstrated that medically underserved populations currently have adequate access to dialysis services provided at FMC Stallings Station. Therefore, the application is conforming to this criterion.

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Johnston County and Statewide. More current data, particularly with regard to the estimated uninsured percentages, was not available.

**Table 16
Percent of Medicaid Eligible
By County and State**

| County | Total # of Medicaid Eligible as % of Total Population^① | Total # of Medicaid Eligible Age 21 and older as % of Total Population^② | % Uninsured CY 08-09 (Estimate by Cecil G. Sheps Center) |
|---------------|--|---|---|
| Johnston | 17.0% | 6.7% | 20.0% |
| Statewide | 17.0% | 6.7% | 19.7% |

Source: www.ncdhhs.gov/dema-Medicaid-Eligible-Johnston-County June 2010.

① Medicaid Eligible by Age for Johnston County and State, June 2010.

② Medicaid Eligible Age 21+ for Johnston County and State, June 2010.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by FMC Stallings Station. In fact, in 2011 only 5.8 of all newly diagnosed ESRD patients (Incident ESRD patients) in North Carolina's Network 6 were under the age of 35. ③

The Office of Budget and Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition data are available by race, age or gender. However, a direct comparison to the applicant's current payor mix would

be of little value. The population data by age, race or gender do not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM’s website does not include information on the number of handicapped persons.

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. About 25% of Medicare-covered patients had employer group health plans as primary insurance, with Medicare as the secondary payer. Also, the CMS website states:

“Although the ESRD population is less than 1% of the entire U.S. population, it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standing. ...

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.”

In addition, the United States Renal Data System, in its 2012 USRDS Annual Data Report provides the following national statistics for FY 2010:

Table 17
The 2012 United States Renal Data System
Selected National Statistics as of December 31, 2010

| Patients Receiving Hemodialysis Nationally- 376,000 | | | |
|---|--------|------|--------|
| African American | 38.23% | Male | 55.65% |
| White | 55.38% | 65+ | 44.35% |

④ Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 340.

⑤ <http://www.cms.gov/Medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf>

④ <http://www.cms.gov/Medicare/End-Stage-Renal-Disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf>.

“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39% covered solely by Medicare, and 32% covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients respectively.”

The report provides 2010 ESRD spending, by payor as follows:

Table 18
ESRD Spending Nationally by Payor

| Payor | Spending in Billions | % of Total Spending |
|-------|----------------------|---------------------|
|-------|----------------------|---------------------|

| | | |
|-----------------------------|--------|---------|
| Medicare Paid | \$29.6 | 62.32% |
| Medicare Patient Obligation | \$4.7 | 9.89% |
| Medicare HMO | \$3.4 | 7.16% |
| Non-Medicare | \$9.8 | 20.63% |
| Total ESRD Expenditures | \$47.5 | 100.00% |

⑤ Source: 2012 United States Renal Data System (USRDS) Annual Data Report, Chapter 11, page 340.

The Southeastern Kidney Council (SKC) provides Network 6, 2011 Incident ESRD patient data by age, race and gender, as shown below:

Table 19
Number and 2011 Percent of Dialysis Patients
By Age, Race, and Gender ⑥

| Age | # of ESRD Patients | % of Dialysis Population |
|------------------|--------------------|--------------------------|
| 0-19 | 89 | 1.0% |
| 20-34 | 451 | 4.8% |
| 35-44 | 773 | 8.3% |
| 45-54 | 1,529 | 16.4% |
| 55-64 | 2,370 | 25.4% |
| 65-74 | 2,258 | 24.2% |
| 75+ | 1,872 | 20.0% |
| Gender | | |
| Female | 4,237 | 45.35% |
| Male | 5,105 | 54.65% |
| Race | | |
| African-American | 5,096 | 54.55% |
| White | 4,027 | 43.11% |
| Other | 219 | 2.3% |
| Total | 9,342 | 100% |

⑤ Source: 2012 United States Renal Data System (USRDS) Annual Data Report, Chapter 11, page 340.

⑥ Source: Southeastern Kidney Council ESRD Network 6 2011 Annual Report; Table 3, page 16.

The applicant demonstrates that it 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;

In application Section VI.1 (f), page 56, the applicant states, “*BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations.*” In Section VI.6 (a), page 58, the applicant states, “*There has been no Civil Rights access complaints lodged against any BMA North Carolina facility 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 VI.1(c), page 55, the applicant provides the projected payor mix for the proposed services at FMC Stallings Station. The applicant projects no change from the current payor mix for dialysis visits as shown in the table in Criteria (13a) above. The applicant projects that 84.2% of the patients will be Medicare or Medicaid beneficiaries. 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 VI.5 (a), page 57, the applicant states, “*FMC Stallings Station has an open policy, which means that any Nephrologist may apply to admit patients at the facility.*” Further, in Section VI.5 (b), page 57, the applicant states, “*... all patients will be admitted to the facility through one of the Nephrologists on the staff of FMC Stallings Station. Referrals for treatment will continue to come from Johnston Memorial Hospital, Wake Med [sic] Hospital, and practicing physicians in the area as patients demonstrate a need for nephrology physician services.*”

The applicant adequately demonstrates that FMC Stallings Station offers a range of means by which a person can access 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 application Section V.3 (a), page 50, the applicant states:

“Exhibit 19 is a letter from ...the FMC Area Manager to Johnston Community College inviting the school to include the new facility in its clinical rotations for nursing students. Further, the letter seeks to establish a formal affiliation agreement

with the school for this program. This type of agreement is typical for all BMA facilities. Students are provided tours through the facilities and discussions regarding the different aspects of dialysis and facility operations.

All health related education and training programs are welcomed to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment...”

The information provided in application Section V is reasonable and credible and supports a finding of conformity with this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add four dialysis stations for a total of 24 stations upon completion of the project.

The following table provides a profile of the three dialysis providers in Johnston County.

**Table 20
 Johnston County Dialysis Facilities**

| Facility (Stations) | Community | Pts. Per Station | % Utilized | Site |
|----------------------------|------------------|-------------------------|-------------------|---------------------------------|
| FMC Stallings Station (20) | Clayton | 3.25 | 81.25% | Western End of Johnston County. |
| Johnston Dialysis (25) | Smithfield | 3.36 | 84.00% | Eastern end of Johnston County |

| | | | | |
|--------------------------|-----------|------|--------|--|
| FMC of Four Oaks (22) | Four Oaks | 3.05 | 76.32% | Eastern end of Johnston County. South of Smithfield |
|--------------------------|-----------|------|--------|--|

The other two facilities are operating at or close to the operating measures of 80% utilization or 3.2 patients per station. FMC Stallings Station is operating at 81.25% or 3.25 patients per station.

In Section V.7 the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states that this proposal will not have any effect on competition in Johnston County. FMC owns all three facilities in Johnston County and believes it has done an exceptional job of containing operating cost while continuing to provide outstanding care and treatment for patients. See Sections II, III, V, VI and VII 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 credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality, and access to services in Johnston County. This determination is base on information in the application and the following analysis:

- The applicant adequately demonstrates the need to add four dialysis, and that it is a cost-effective alternative to meet the patient volume at FMC Stallings Station dialysis center;
- The applicant adequately demonstrated that it will continue to provide quality services;
- The applicant adequately demonstrated that it will continue to provide adequate access to medically underserved populations.

Therefore, the application is conforming to this application.

⑦ Source: 2013 North Carolina Semiannual Dialysis Report Table A, page 5 Johnston County.
Note: Data adjusted for Stallings Station to reflect 20 certified stations as of 6/30/12.

(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

The applicant currently provides dialysis services at several facilities in North Carolina. According to files of the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, FMC Stallings Station operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this 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, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C .2200. The specific findings are discussed below.

.2202 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes to increase stations in an existing certified facility or relocated stations must provide the following information:

.2202(a)(1) Utilization rates;

-C- Utilization-2013 SDR-81.25% or .3.25 patients per station
(Note: Data adjusted to reflect 20 certified stations as of 6/30/12. $(65/20 = 3.25; 3.25/4 = .8125)$)

.2202(a)(2) Mortality rates;

-C- In Section IV.2, page 47 the applicant provides the following mortality rates-Year 2010-0.0%, 2011-15.7%, and 2012-9.5%.

.2202(a)(3) The number of patients that are home trained and the number of patients on home dialysis;

-C- See Section IV.3, page 47, 10-Home Dialysis Patients.

.2202(a)(4) The number of transplants performed or referred;

-C- See Section IV.4, page 47, Transplants referred-10 and Transplant performed-1, in 2012.

.2202(a)(5) The number of patients currently on the transplant waiting list;

-C- See Section IV.5, page 47, 10 patients on the waiting list.

.2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related-65.

-C- See Section IV.6, page 48.-Dialysis related-7 and non-dialysis related-58.

.2202(a)(7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.

-C- See Section IV.7, page 48-0.

(b) An applicant that proposed develop a new facility, to increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

- .2202(b)(1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*
-NA- FMC Stallings Station is an existing facility.
- .2202(b)(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) timeframe for initial assessment and evaluation of patients for transplantation,*
 - (B) composition of the assessment/evaluation team at the transplant center,*
 - (C) method for periodic re-evaluation,*
 - (D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
 - (E) signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- NA- FMC Stallings Station is an existing facility.*
- .2202(b)(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.*
-NA- FMC Stallings Station is an existing facility.
- .2202(b)(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
-C- See Section XI.6 (f), page 81 and Exhibit 12 regarding back-up capabilities.
- .2202(b)(5) For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
-NA- FMC Stallings Station is an existing facility.
- .2202(b)(6) Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, and other relevant health and safety requirements.*
-C- See Section XI.6 (g), page 81 and Exhibits 11 and 12.

.2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- See Section III.7, pages 39-40, and discussion in Criterion (3).

.2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- FMC Stallings Station is an existing facility.

.2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*

-C- See Section II, 10A NCAC 14C .2202 (9) page 17.

.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 week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- FMC Stallings Station is an existing facility.

.2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section III.7, pages 43-45 the applicant projects to serve 78 in-center patients by the end of Year 1, which equates to 3.25 patients per station per week [78 / 24 = 3.25]. Further, the applicant projects to serve 82 in-center patients by the end of Year 2, which equates to 3.42 patients per station per week [82 / 24 = 3.42]. See Criterion (3) for discussion which is hereby incorporated by reference as if fully set forth herein.

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

-C- See Section II.1, pages 12-22, In Section III.7, pages 39-46, the applicant provides the assumptions and methodology used to project utilization of the additional stations. See Criterion (3) for discussion which is hereby incorporated by reference as if fully set forth herein.

.2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

- .2204(1) *Diagnostic and evaluation services;*
 - C- See Section V.1 (e), page 49. Johnston Memorial Hospital
- .2204(2) *Maintenance dialysis;*
 - C- See Section V.1 (c), page 49. On Site
- .2204(3) *Accessible self-care training;*
 - C- See Section V.1 (d), page 49. On Site
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
 - C- Provided by the applicant. See Section V.1 (d), page 49.
- .2204(5) *X-ray services;*
 - C- See Section V.1 (g), page 49. Johnston Memorial Hospital and WakeMed.
- .2204(6) *Laboratory services;*
 - C- See Section V.1 (h), page 49. Spectra (Exhibit 18).
- .2204(7) *Blood bank services;*
 - C- See Section V.1, page 49. Johnston Memorial Hospital
- .2204(8) *Emergency care;*
 - C- See Section V.1 (b), page 49. All staff is trained to respond, a fully stocked crash cart is maintained, and ambulance transport to hospital is accessible.
- .2204(9) *Acute dialysis in an acute care setting;*
 - C- See Section V.1 (a), page 49. WakeMed Hospital.
- .2204(10) *Vascular surgery for dialysis treatment patients;*
 - C- See Section V.1 (p), page 49. Referral to Premier Surgical, Rex Vascular Surgical Specialists and Duke Vascular Surgery.
- .2204(11) *Transplantation services;*
 - C- See Section V.1 (f), page 49. Duke UMC
- .2204(12) *Vocational rehabilitation counseling and services; and*
 - C- See Section V. 1 (o), page 49. Johnston County Vocational Rehabilitation Services.
- .2204(13) *Transportation*
 - C- See Section V.1 (q), page 49. Johnston Area Transit.

.2205 STAFFING AND STAFF TRAINING

.2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 494 (formerly 405.2100)*

- C- See Section VII.1, page 59 the applicant provides the proposed staffing. In Section VII, 2, page 60 the applicant states, the proposed facility will comply with all staffing requirements set forth in the Federal code. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7)

for discussion which is incorporated hereby as if set forth fully herein.

.2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*

-C- See Section VII.5, page 60 and Exhibits 14 and 15 for outline of continuing education programs.