ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date:	February 26, 2016
Findings Date:	February 26, 2016
Project Analyst:	Tanya S. Rupp
Team Leader:	Lisa Pittman
Project ID #:	F-11099-15
Facility:	Fresenius Medical Care Aldersgate
FID #:	150435
County:	Mecklenburg
Applicant(s):	Bio-Medical Applications of North Carolina, Inc.
Project:	Develop a new 10-station dialysis facility by relocating four dialysis stations from BMA West Charlotte and six dialysis stations from FMC Charlotte.

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a Fresenius Medical Care (FMC) Aldersgate ("the applicant") proposes to develop a new 10-station dialysis facility in Charlotte by relocating four existing stations BMA West Charlotte and six existing stations from FMC Charlotte. All three facilities are located in Mecklenburg County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

Need Determination

The applicant is proposing to relocate existing dialysis stations within Mecklenburg County; therefore, there are no need methodologies in the 2015 State Medical Facilities Plan (2015 SMFP) that are applicable to this review.

Policies

POLICY *ESRD-2: RELOCATION OF DIALYSIS STATIONS* on page 32 of the 2015 SMFP is applicable to this review and states:

> *"Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:*
>
> 1. *Demonstrate that the proposal shall not result in a 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*
>
> 2. *Demonstrate that the proposal shall not result in a 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, Fresenius Medical Care Aldersgate, in Mecklenburg County, by relocating existing Mecklenburg County dialysis stations from two Mecklenburg County facilities. Because all three facilities are located in Mecklenburg County, there is no change in the dialysis station inventory in the county. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the applicable policy in the 2015 SMFP.

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 establish a new 10-station dialysis facility in Charlotte, Mecklenburg County, by relocating four existing dialysis stations from BMA West Charlotte and six existing dialysis stations from FMC Charlotte. The proposed facility will be located on the Aldersgate Continuing Care Retirement Community campus in east-central Charlotte.

Population to be Served

On page 361, the 2015 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 Mecklenburg County. Facilities may serve residents of counties not included in their service area.

FMC Aldersgate will be a new facility in Mecklenburg County and therefore has no existing patient origin. Though the applicant proposes to relocate stations from BMA West Charlotte and FMC Charlotte; in Section C.1, page 20, the applicant states that it assumes the dialysis patients who transfer to the proposed facility are a part of a large number of existing BMA patients who reside in close proximity to the Aldergate community.

In Section C.1, page 19, and in clarifying information provided at the Agency's request, the applicant provides a table showing the projected patient origin of the in-center patients to be served at FMC Aldersgate for Operating Years (OY) 1 and 2 following completion of the project, as shown below.

COUNTY	OY 1	OY 2	% PATIENTS OY 1	% PATIENTS OY 2
Mecklenburg	32.8	34.7	100%	100%
Total	**32**	**35**	**100%**	**100%**

In Exhibit C-1 the applicant provides 39 letters of support signed by existing BMA patients who support the proposed project and state that they live closer to the proposed FMC Aldersgate facility. The applicant adequately identifies the population to be served.

Analysis of Need

In Section C.2, pages 22 - 23, the applicant discusses the need that the population to be served has for the proposed project, stating that patients with End Stage Renal Disease (ESRD) require frequent and regular treatments. Thus it is critical that a patient is able to dialyze conveniently and in close proximity to his or her home. The applicant proposes to develop the facility in leased space on the Aldersgate Continuing Care Retirement Community campus, to serve both residents of that community as well as other dialysis patients who live in close proximity to the Aldersgate community. The applicant identified 39 patients; each of whom currently receives dialysis treatment at another BMA facility in Mecklenburg County, and each of whom indicated that the Aldersgate location is a closer and thus more convenient location. The applicant states the need for the dialysis facility on the Aldersgate campus *"...is a function of the individual patient need for dialysis care and treatment, and the stated desires of the patients to have dialysis at the Aldersgate location."*

In Section C.1, page 20, and in Exhibit C-2, the applicant provides a map depicting the location of dialysis facilities in the Charlotte area as well as residences of patients who currently use those

facilities. The applicant states the map shows that the Aldersgate location is central to a large number of dialysis patients who currently dialyze at BMA facilities in the area.

In Exhibit C-3, the applicant provides a September 14, 2015 letter signed by the President and CEO of Aldersgate that states:

> *"Aldersgate is a Continuing Care Retirement Community dedicated to meeting the individual and unique needs of all our residents .... Our vision includes the ability to provide the full spectrum of care which may be needed by our residents. We are very pleased that on-site hospice services will soon be available for our residents. Another key service which we would like to see developed on our campus is in-center dialysis.*
>
> *On-site dialysis care will be a tremendous benefit for our resident population which may have need for these services. Dialysis services on campus will eliminate the need for our patients to travel off campus three days week for their care. This will obviously reduce the financial burden associated with travel to and from dialysis care.*
>
> *We are also pleased that the dialysis facility will be available to provide care for dialysis patients residing near our campus, which supports our strategic goal to build even stronger connections with the surrounding community."*

Thus, while the facility will be located on the Aldersgate campus, it will be available to dialysis patients in the area as well.

In Section C.1, pages 20 – 21, the applicant provides assumptions and methodology it used to determine the need to develop a new facility in the Aldersgate area. Those assumptions and methodology are summarized below:

- BMA mapped existing dialysis patients residing in the Charlotte area of Mecklenburg County and determined that there are a significant number of patients residing in east-central Charlotte in the general area of Aldersgate.
- The applicant provides 39 letters signed by current BMA patients who prefer the Aldersgate location.
- As demonstrated by the letter from the CEO of Aldersgate, the community supports a dialysis facility on its campus to serve both residents of that community and residents from the area.
- The applicant projects growth for the dialysis patients using the 5.8% Mecklenburg County Five Year Average Annual Change Rate (AACR) as published in the July 2015 SDR.
- Although the applicant received 39 patient letters expressing a willingness to transfer to the proposed Aldersgate location, the applicant projects growth of only 32, or 80% of those 39 patients, as shown in the table below, from page 21 and clarifying information:

Calculated 80% of Patient Letters

CURRENT DIALYSIS FACILITY	# PATIENT LETTERS	X 80%	END # PATIENT LETTERS
BMA North Charlotte	17	X 0.8	13.6
BMA East Charlotte	13	X 0.8	10.4
FMC Charlotte	8	X 0.8	6.4
BMA Nations Ford	1	X 0.8	0.8
Total	**39**		**31.2**

- The applicant projects the facility will be complete on June 30, 2017; therefore, OY 1 will be FY 2018, and OY 2 will be FY 2019.

Projected Utilization

In Section C.1, page 22 and clarifying information, the applicant provides the calculations used to project the in-center patient census for the proposed Aldersgate facility for OYs 1 and 2, as shown in the table below:

Begin with 31 in-center dialysis patients projected to transfer their care to FMC Aldersgate as of June 30, 2017	31
Project growth of 32 in-center patients utilizing the 5.8% Mecklenburg County Five Year AACR, to June 30, 2018, the end of OY 1	31 x 1.058 = 32.8
Project growth of those in-center patients utilizing the 5.8% Mecklenburg County Five Year AACR, to June 30, 2019, the end of OY 2	32.8 x 1.058 = 34.7

As shown in the table, by the end of OY 1, the applicant projects to serve 32 in-center patients on 10 dialysis stations, which is a utilization rate of 80% [32 patients / 10 stations = 3.2 patients per station; 3.2 / 4 = 0.80]. At the end of OY 2, the applicant projects to serve 35 in-center patients on 10 stations, which is a utilization rate of 86% [35 / 10 = 3.5; 3.5 / 4 = 0.875]. The projected utilization of 3.2 patients per station per week for Operating Year 1 satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth, particularly since the projected growth is based on a beginning census of 32 patients, rather than the 39 patients who signed a letter indicating a willingness to transfer dialysis care to the proposed FMC Aldersgate location.

Access

In Section C.3, page 23, the applicant states:

> *"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 applicant states that the patient population of the proposed facility is expected to be comprised of the following:

FACILITY	MEDICAID	ELDERLY (65+)	MEDICARE	WOMEN	RACIAL MINORITIES
FMC Aldersgate	8.20%	31.86%	77.88%	47.91%	79.80%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 77.88% of the facility treatment reimbursement is from Medicare.

The applicant states that Medicare and Medicaid represented 82.54% and 4.63%, respectively, of dialysis treatments in BMA facilities in North Carolina in fiscal year 2014. The applicant confirms that low income and medically underinsured persons will continue to have access to all services provided by BMA and that the facility will conform to all applicable codes and standards.

The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed project and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to relocate four existing dialysis stations from BMA West Charlotte and six dialysis stations from FMC Charlotte to develop the proposed 10-station FMC Aldersgate, also in Charlotte. All three facilities are located in the Charlotte area of Mecklenburg County.

In Section D, pages 37 – 40, and in clarifying information provided at the Agency's request, the applicant discusses how the needs of the dialysis patients dialyzing at BMA West Charlotte will continue to be adequately met following the relocation of four stations to FMC Aldersgate.

The applicant states that no patients currently dialyzing at BMA West Charlotte signed letters indicating an intent to transfer to FMC Aldersgate. The applicant states that all of the patients currently dialyzing at BMA West Charlotte are residents of Mecklenburg County, and thus growth projections are based on the 5.8% Mecklenburg County AACR. The census of BMA West Charlotte as of June 30, 2015 was 95 patients. See the following table:

BMA West Charlotte Projected In-Center Utilization

Begin with the in-center patient population of BMA West Charlotte as of June 30, 2015	95
Project forward one year to June 30, 2016	95 x 1.058 = 100.5
Project forward one year to June 30, 2017 (certification date for FMC Aldersgate)	100.5 x 1.058 = 106.3

Therefore, as of June 30, 2017, the projected certification date for FMC Aldersgate, BMA West Charlotte will have 106 patients dialyzing on 25 in-center stations, which is a utilization rate of 4.24 patients per station per week, or 106% [106 / 25 = 4.24; 4.24 / 4 = 1.06]. The applicant states:

> *"BMA is aware that utilization rates exceeding four patients per station necessarily result in operation of a third shift. BMA can begin a third shift at BMA West Charlotte if it becomes necessary.*
>
> *However, BMA routinely applies for additional dialysis stations to meet the need of the patient population dialyzing with BMA. In this case, the BMA West Charlotte facility will be reported at 81.9% utilization in the January 2016 SDR. Thus, the facility will qualify for additional stations via the Facility Need Methodology. BMA will apply for additional stations at BMA West Charlotte in March 2016."*

The applicant states that applying the facility need methodology based on the data projected to be reported in the January 2016 SDR would result in a need for two additional dialysis stations at BMA West Charlotte. The applicant states that, based on 27 stations, utilization at BMA West Charlotte would be 3.93 patients per station per week, or 98% [106 / 27 = 3.92; 3.92 / 4 = 0.9815].

With regard to FMC Charlotte, the applicant states that in a separate application, Project ID #F-10052-12, FMC Charlotte was approved to relocate four stations to develop a new facility (FMC Southwest Charlotte). In addition, in Project ID #F-10186-13, BMA was approved to add seven station to FMC Charlotte, for a total of 43 dialysis stations upon project completion. That project is scheduled for certification on June 30, 2017, the proposed certification date for FMC Aldersgate. Therefore, following the relocation of six of the 43 stations to FMC Aldersgate, FMC Charlotte will be left with 37 dialysis stations as of June 30, 2017. See the following table:

FMC Charlotte Projected In-Center Utilization

Begin with the in-center patient population of FMC Charlotte as of June 30, 2015	133
Project forward one year to June 30, 2016	133 x 1.058 = 140.7
Project forward one year to June 30, 2017 (certification date for FMC Aldersgate)	140.7 x 1.058 = 148.9
Subtract 8 patients projected to transfer to FMC Aldersgate	148.9 – 8 = 140.9

Thus, as of June 30, 2017, FMC Charlotte will have 37 certified dialysis stations and 141 in-center patients, which is a utilization of 95.3%, or 3.8 patients per station per week [141 / 37 = 3.81; 3.81 / 4 = 0.9527].

In summary, the applicant adequately demonstrates that the needs of the dialysis population presently served at BMA West Charlotte and FMC Charlotte will continue to be adequately met following the relocation of stations and the transfer of patients from FMC Charlotte to FMC Aldersgate. Therefore, the application is conforming to this criterion.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section E.1, pages 41 - 42, the applicant discusses the alternatives considered prior to submitting this application, which include:

- Maintain the Status Quo - the applicant states that this option ignores the need in Mecklenburg County for additional dialysis stations, and the current inability of existing facilities to provide that need. The applicant states that six of the seven BMA dialysis facilities with certified stations are at physical plant capacity and cannot expand.
- Development of the new facility in northern Mecklenburg County - BMA states that it evaluated its existing patient populations and projections of future patient populations and determined the BMA patient population in the Aldersgate area could be better served by a new facility in that area.
- The development of a larger facility with more in-center dialysis stations -BMA determined the proposed facility size is optimal for the demonstrated need for its patients in and near Aldersgate at this time.
- Relocation of stations into BMA facilities under development in Mecklenburg County -the applicant states that an application of this nature ignores the patients dialyzing with BMA but residing in or near Aldersgate, and would impose a significant delay in the development of those approved projects.

After considering the above alternatives, the applicant states that given the residence location of the existing patients projected to be served at the Aldersgate facility and the other Mecklenburg County physical plant capacity issues, BMA believes developing the new FMC Aldersgate facility is the most effective alternative to meet the needs of the dialysis patient population in the area.

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 this 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 Medical Care Aldersgate shall materially comply with all representations made in the certificate of need application and supplemental responses. In those instances where representations conflict, Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Aldersgate shall materially comply with the last-made representation.**

2. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Aldersgate shall relocate no more than four dialysis stations from BMA West Charlotte and six dialysis stations from FMC Charlotte for a total of no more than 10 certified stations, which shall include any home hemodialysis or isolation stations, upon completion of this project.**

3. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Aldersgate 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. **Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify four dialysis stations at BMA West Charlotte and six stations at FMC Charlotte, for a total of no more than 25 dialysis stations at BMA West Charlotte and 37 stations at FMC Charlotte upon project completion.**

5. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Aldersgate 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 relocate four existing dialysis stations from BMA West Charlotte and six dialysis stations from FMC Charlotte to develop the proposed 10-station FMC Aldersgate, also in Charlotte.

Capital and Working Capital Costs

In Section F.1, page 44, the applicant provides the following table to illustrate the capital cost for the project:

Item	Cost
Construction Contract	$1,033,458
Water Treatment Equipment	$ 230,000
Equipment/Furniture	$ 221,783
Architect & Engineering Fees	$ 93,011
Other: Contingency	$ 56,323
Total	**$1,634,575**

In Section F.10, pages 47 – 49, the applicant projects the working capital cost will be $1,558,281, which includes start-up expenses (clinical supplies and staff salaries for four weeks) in the amount of $136,572. The amount also includes an estimated eight month initial operating period, for which clinical and staff salaries are projected to be $1,421,709.

Availability of Funds

In Section F.5, page 45, the applicant states it will use accumulated reserves to finance the project. In Exhibit F-1, the applicant provides a September 15, 2015 letter signed by the Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., which confirms the availability of sufficient funds for the completion of the project, and confirms the commitment of those funds for the development of the project.

In F.8, page 47, the applicant states:

> *"This application will not interfere with the financing of any other projects currently filed, or being filed by BMA. The amount shown in the financial statements is more than adequate to finance all CON projects proposed, and under development."*

In Section F.7, page 46, the applicant refers to Exhibit F-2 for a copy of the most recent audited FMC Holdings, Inc, financial statements (years ended December 31, 2013 and 2014). As of December 31, 2014, Fresenius Medical Care Holdings, Inc. and Subsidiaries had $195,280,000 in cash and cash equivalents with $18,507,042,000 in total equity and $8,428,400,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

Financial Feasibility

In Section R, page 103, the applicant provides the following allowable charges per treatment for each payor source in the first and second years of operation:

PAYOR	IN-CENTER CHARGE
Self-Pay/Indigent/Charity	$473.57
Medicare	$245.09
Medicaid	$153.60
Medicare Commercial	$303.76
Commercial Insurance	$1,098.82
VA	$317.19

In Section R, page 104, the applicant states it used an average number of in-center patients, rounded down to the nearest whole number, to calculate revenues for the first and second operating years. The applicant states it reduces that figure by 5% for a missed treatment allowance. In Section R, page 102, he applicant projects revenues and expenses, as summarized in the table below:

FMC ALDERSGATE	OY 1 FY 2018	OY 2 FY 2019
Total Revenue	$1,414,295	$1,502,875
Total Operating Expenses	$1,404,437	$1,485,907
Net Profit	$ 9,858	$ 16,967

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The applicant's projections of treatments and revenues are reasonable based on the number of in-center patients projected for the first two operating years. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

In Section H, page 59, the applicant provides projected staffing and salaries. Form A in Section R, page one, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the proposal and adequately demonstrates that the financial feasibility of the project is based on 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 establish a new 10-station dialysis facility in Charlotte, Mecklenburg County, by relocating four existing dialysis stations from BMA West Charlotte and six existing dialysis stations from FMC Charlotte. The proposed facility will be located on the Aldersgate Continuing Care Retirement Community campus in east-central Charlotte.

On page 361, the 2015 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 Mecklenburg County. Facilities may serve residents of counties not included in their service area.

The applicant currently operates eight dialysis centers in Mecklenburg County, and has been approved to develop two facilities (FMC of Southwest Charlotte and FMC Regal Oaks). In addition, there are two other providers of dialysis services in Mecklenburg County, as shown in the table below.

DIALYSIS FACILITY	PROVIDER	# CERTIFIED STATIONS AS OF 12/31/14	% UTILIZATION	# PATIENTS PER STATION
BMA Beatties Ford	BMA	32	88.28%	3.53
BMA Nations Ford	BMA	24	114.58%	4.58
BMA of East Charlotte	BMA	25	84.00%	3.36
BMA of North Charlotte	BMA	28	104.46%	4.17
BMA West Charlotte	BMA	29	78.45%	3.14
FMC Charlotte	BMA	40	82.50%	3.30
FMC Matthews	BMA	21	114.29%	4.57
FMC of Southwest Charlotte*	BMA	0	--	--
FMC Regal Oaks*	BMA	0	--	--
Huntersville Dialysis*	DaVita	0	--	--
Mint Hill Dialysis	DaVita	10	100.00%	4.00
North Charlotte Dialysis Center	DaVita	35	99.29%	3.97
Carolinas Medical Center	CMC	9	0.00%	0.00
Charlotte Dialysis	DaVita	36	78.47%	3.13
Charlotte East Dialysis	DaVita	26	92.31%	3.69
DSI Charlotte Latrobe Dialysis	DSI	24	66.67%	2.67
DSI Glenwater Dialysis	DSI	42	77.38%	3.10
South Charlotte Dialysis	DaVita	20	82.50%	3.30

Source: July 2015 SDR, Table A
*CON approved; facilities not yet developed

As shown in the table above, 10 of the 14 operational Mecklenburg County dialysis facilities are operating above 80% utilization (3.2 patients per station), and 13 facilities are operating at or above 75% utilization (3.0 patients per station). This is based on the assumption that dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station per week.

The applicant proposes to develop a new facility in the Aldersgate community by relocating existing dialysis stations within Mecklenburg County. In Section C.1, pages 19-22, the applicant provides reasonable projections for the in-center patient population it proposes to serve. The applicant's growth projections are based on Mecklenburg County's Five Year Average Annual Change Rate (AACR) in the July 2015 SDR. The applicant adequately demonstrates the need to develop a new 10-station dialysis facility in Aldersgate based on the number of in-center patients it proposes to serve.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities in Mecklenburg County. Therefore, 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 59, the applicant provides proposed staffing for the facility, as shown in the following table:

POSITION	# FTE POSITIONS TO BE ADDED	TOTAL FTE POSITIONS
Registered Nurse	1.50	1.50
Patient Care Technician	4.50	4.50
Clinical Manager	1.00	1.00
Administrator	0.15	0.15
Dietician	0.33	0.33
Social Worker	0.33	0.33
Chief Technician	0.15	0.15
Equipment Technician	0.50	0.50
In-Service	0.15	0.15
Clerical	1.00	1.00
Total	**9.61**	**9.61**

In Sections H.3 and H.4, page 60, the applicant describes its experience in and processes for recruiting, training and retaining staff. On page 64, the applicant identifies George Hart, M.D. as the Medical Director for the proposed facility. Exhibit I-6 contains a copy of a letter from Dr. Hart, expressing his interest in serving as the Medical Director for the proposed facility. 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 63, the applicant includes a list of providers of the necessary ancillary and support services for the patients who dialyze at the facility. 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 70, the applicant provides a table that shows the proposed facility will have 2,456 square feet of treatment area, and 134 square feet of isolation space, for a total of 2,590 square feet. In Section F.1, page 44, the applicant lists its project costs, including $1,033,458 for construction, $451,783 in miscellaneous costs that include but are not limited to water treatment equipment and furniture for the facility, and $149,334 for other fees and contingency, for a total of $1,634,578. In Section K.1, pages 68 - 69, the applicant describes its plans for energy-efficiency, including water conservation. The applicant states its plans for implementing applicable energy saving features and water conservation methods include the following:

- The building plumbing systems will be designed to ensure conservation of water.
- The exterior roof, walls and glass systems will meet current requirements for energy conservation.

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

Costs and charges are described by the applicant in Section F, pages 43 - 53, and in Section R proforma financial statements. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

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

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

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

C

In Section L.7, page 79, the applicant reports that 85.7% of the in-center patients who received treatments at FMC Charlotte, the facility that will donate six stations, had some or all of their services paid for by Medicare or Medicaid in the past year. In addition, the applicant reports that 84.04% of the in-center patients who received treatments at BMA West Charlotte, the facility that will donate four stations, had some or all of their services paid for by Medicare or Medicaid in the past year. The tables below shows the historical (CY2014) payment sources for each facility for in-center patients:

FMC Charlotte Payor Mix CY 2014

PAYMENT SOURCE	IN-CENTER
Private Pay	2.24%
Commercial Insurance	11.90%
Medicare	75.37%
Medicaid	7.37%
VA	0.11%
Medicare/Commercial Insurance	3.02%
Total	**100.00%**

BMA West Charlotte Payor Mix CY 2014

PAYMENT SOURCE	IN-CENTER
Private Pay	2.93%
Commercial Insurance	5.61%
Medicare	74.19%
Medicaid	2.82%
VA	7.41%
Medicare/Commercial Insurance	7.03%
Total	**100.00%**

The *Southeastern Kidney Council Network 6 Inc. Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	**% of Dialysis Population**
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).[1]

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

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

C

In Section L.3(e), page 78, the applicant states:

> *"BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. ... The applicant will treat all patients the same regardless of race or handicap status."*

In Section L.6, page 78, the applicant states there have been no civil rights access complaints filed within the last five years. 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(b), page 76, the applicant projects that 86.1% of the in-center patients who will receive treatments at FMC Aldersgate in the second operating year (FY 2019) will have some or all of their services paid for by Medicare or Medicaid. The applicant states this projection is *"a weighted payor mix based upon the patient letters of support and the payor mix for the patient*[s'] *existing dialysis center."* The table below shows the projected OY 2 payment source for the facility for in-center patients:

[1] *See* http://www.esrdnetweork6.org/utils/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf.

FMC Aldersgate Projected Payor Mix OY 2

PAYMENT SOURCE	IN-CENTER
Private Pay	2.8%
Commercial Insurance	8.3%
Medicare	72.2%
Medicaid	8.3%
VA	2.8%
Medicare/Commercial Insurance	5.6%
Total	**100.0%**

In Section L3.1(b), pages 76 - 77, the applicant provides the assumptions used to project payor mix. The applicant's projected payment sources are consistent with the applicant's historical payment sources as reported in Section L.7, page 79. The applicant demonstrates that medically underserved groups will have adequate access to the dialysis services proposed at FMC Aldersgate. 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 78, the applicant describes the range of means by which a person will have access to the dialysis services at FMC Aldersgate, including referrals from nephrologists, other physicians, or hospital emergency rooms. 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 80, the applicant states that it has communicated with local student nursing programs to offer the facility as a clinical training site for nursing students. Exhibit M-1 contains a copy of correspondence to Central Piedmont Community College documenting the offer of the facility as clinical training site. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

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

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

C

The applicant proposes to establish a new 10-station dialysis facility in Charlotte, Mecklenburg County, by relocating four existing dialysis stations from BMA West Charlotte and six existing dialysis stations from FMC Charlotte. The proposed facility will be located on the Aldersgate Continuing Care Retirement Community campus in east-central Charlotte.

On page 361, the 2015 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 Mecklenburg County. Facilities may serve residents of counties not included in their service area.

The applicant currently operates eight dialysis centers in Mecklenburg County, and has been approved to develop two facilities (FMC of Southwest Charlotte and FMC Regal Oaks). In addition, there are two other providers of dialysis services in Mecklenburg County, as shown in the table below.

DIALYSIS FACILITY	PROVIDER	# CERTIFIED STATIONS AS OF 12/31/14	% UTILIZATION	# PATIENTS PER STATION
BMA Beatties Ford	BMA	32	88.28%	3.53
BMA Nations Ford	BMA	24	114.58%	4.58
BMA of East Charlotte	BMA	25	84.00%	3.36
BMA of North Charlotte	BMA	28	104.46%	4.17
BMA West Charlotte	BMA	29	78.45%	3.14
FMC Charlotte	BMA	40	82.50%	3.30
FMC Matthews	BMA	21	114.29%	4.57
FMC of Southwest Charlotte*	BMA	0	--	--
FMC Regal Oaks*	BMA	0	--	--
Huntersville Dialysis*	DaVita	0	--	--
Mint Hill Dialysis	DaVita	10	100.00%	4.00
North Charlotte Dialysis Center	DaVita	35	99.29%	3.97
Carolinas Medical Center	CMC	9	0.00%	0.00
Charlotte Dialysis	DaVita	36	78.47%	3.13
Charlotte East Dialysis	DaVita	26	92.31%	3.69
DSI Charlotte Latrobe Dialysis	DSI	24	66.67%	2.67
DSI Glenwater Dialysis	DSI	42	77.38%	3.10
South Charlotte Dialysis	DaVita	20	82.50%	3.30

Source: July 2015 SDR, Table A
*CON approved; facilities not yet developed

As shown in the table above, 10 of the 14 operational Mecklenburg County dialysis facilities are operating above 80% utilization (3.2 patients per station), and 13 facilities are operating at or above 75% utilization (3.0 patients per station). This is based on the assumption that dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station per week.

In Section N.1, pages 81 - 82, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

> *"BMA does not expect this proposal to have effect on the competitive climate in Mecklenburg County. BMA does not project to serve dialysis patients currently being served by another provider. The projected population for the FMC Aldersgate facility begins with patients currently served by BMA at other BMA locations within the county, and a growth of that patient population consistent with the Mecklenburg County five year average annual change rate of 5.8% as published within the July 2015 SDR.*
>
> ...
>
> *BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 84% of the In-center patients will be relying upon government payors (Medicare/Medicaid/VA). The facility must capitalize upon every opportunity for efficiency.*
>
> *BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. ... This proposal will certainly not adversely affect quality, but rather, 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, G, H and L in which 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 provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.

- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is 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 Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. In Section O.3, pages 86 - 88, the applicant identifies two of its North Carolina facilities, BMA Lumberton and BMA East Charlotte, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. On page 88, the applicant states both facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. 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:

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) *Utilization Rates;*
-C- In Section P, page 90, the applicant reports utilization for FMC Charlotte and BMA West Charlotte, the facilities that will donate stations to develop FMC Aldersgate.

.2202(a)(2) *Mortality Rates;*
-C- In Section P, pages 90 - 91, the applicant reports 2012, 2013 and 2014 facility mortality rates of 4.6%, 5.1% and 5.8%, respectively, for FMC Charlotte; and 7.7%, 3.0% and 8.2% for BMA West Charlotte.

.2202(a)(3) *The number of patients that are home trained and the number of patients on Home Dialysis;*
-NA- In Section P, page 91, the applicant reports that FMC Charlotte had 8 home hemodialysis patients and 52 peritoneal dialysis patients as of June 30, 2015. The applicant states BMA West Charlotte does not have a home training program.

.2202(a)(4) *The number of transplants performed or referred;*
-C- In Section P, page 91, the applicant states FMC Charlotte referred 18 patients for transplant evaluation in 2015, and BMA West Charlotte referred four patients for transplant evaluation in 2015.

..2202(a)(5) *The number of patients currently on the transplant waiting list;*
-C- In Section P, page 91, the applicant states FMC Charlotte has six patients on the transplant waiting list, and BMA West Charlotte has four patients on the transplant waiting list.

.2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
-C- In Section P, page 91, the applicant states there were 107 total admissions, 24 of which (22.4%) were dialysis related and 83 of which (77.6%) were non-dialysis related reported for FMC Charlotte. The applicant states there were 147 total admissions, 34 of which (23.1%) were dialysis related and 113 of which (76.9%) were non-dialysis related reported for BMA West Charlotte.

.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- In Section P, page 92, the applicant reports that FMC Charlotte currently has one patient with an infectious disease, and no patients were converted to infectious status in the last calendar year. BMA West Charlotte currently has

no patients with an infectious disease and there were no conversions to infectious status in the last calendar year.

(b) An applicant that proposes to develop a new facility, 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*

-C- Exhibit I-4 provides a letter of intent executed by Carolinas Medical Center that specifies the relationship with the proposed facility as described in this rule.

.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.*

-C- Exhibit I-5 provides a transplant agreement with Carolinas Medical Center as described in this rule.

.2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-C- Exhibit K-5 provides documentation of power and water availability at the proposed site, as described in this rule.

.2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- Exhibit K-3 contains a copy of written policies and procedures for back up for electrical service in the event of a power outage.

.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.*

-C- Exhibit K-5 provides site information for the primary site. The exhibit also includes a letter of intent to lease the property located on the Aldergate campus, signed by both the applicant and Aldersgate.

.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, water supply, and other relevant health and safety requirements.*

-C- In Section P, page 93, the applicant states that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.

.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- In Section C.1, page 19, the applicant projects patient origin for the first two years of operation following completion of the project. The discussion regarding patient origin assumptions found in Criterion (3) is incorporated herein by reference.

.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.*

-C- In Section P, page 93, the applicant states 100% of the anticipated patient population will reside within 30 miles of the proposed 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 for such services.*

-C- In Section P, page 93, the applicant states, *"BMA will 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."*

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 P, page 94 and Section C-1, pages 20 – 22 and clarifying information, the applicant demonstrates that when the proposed facility is certified and begins accepting patients, it will have an in-center utilization of 3.2 patients per station per week. At the end of the first operating year, the applicant projects 3.28 patients per station per week. The discussion regarding utilization projections 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- This is an application for a new facility.

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

-C- In Section C.1, pages 19-22 and clarifying information, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding utilization assumptions found in Criterion (3) is incorporated herein by reference.

10 NCAC 14C .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- These services are provided by Carolinas Medical Center (CMC). See Section P, page 94.

.2204(2) *Maintenance dialysis;*

-C- Will be provided at FMC Aldersgate. See Section P, page 94.

.2204(3) *Accessible self-care training;*

-C- These services will be provided by FMC Charlotte. See Section P, page 94.

.2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
-C- Patients who are candidates for home training will be referred to FMC Charlotte. See Section P, page 95.

.2204(5) *X-ray services;*
-C- These services will be provided by CMC. See Section P, page 95.

.2204(6) *Laboratory services;*
-C- These services will be provided by Spectra Labs. See Section P, page 95 and a copy of the agreement with Spectra Labs in Exhibit I-3.

.2204(7) *Blood bank services;*
-C- Patients in need of blood bank services will be referred to CMC or Mercy Hospital. See Section P, page 95.

.2204(8) *Emergency care;*
-C- Emergency services will be provided by staff on-site and by local hospitals via phone call to 911. See Section P, page 95.

.2204(9) *Acute dialysis in an acute care setting;*
-C- Patients requiring admission for acute dialysis in an acute care setting will be referred to CMC. See Section P, page 95.

.2204(10) *Vascular surgery for dialysis treatment patients*
-C- Patients requiring vascular surgical services will be referred to CMC, Sanger Heart and Vascular, or MNA Vascular Access Center. See Section P, page 95.

.2204(11) *Transplantation services;*
-C- Patients in need of transplantation services will be referred to CMC. See Section P, page 95. The applicant provides a copy of a letter of intent to CMC in Exhibit I-5.

.2204(12) *Vocational rehabilitation counseling and services; and,*
-C- Patients in need of vocational rehabilitation services will be referred to the North Carolina Division of Vocational Rehabilitation in Charlotte. See Section P, page 95.

.2204(13) *Transportation*
-C- Transportation services will be provided by Charlotte Area Transportation, A-1 Wheelchair Transport, or area taxi services. See Section P, page 96.

10 NCAC 14C .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 405.2100.*

-C- In Section H.1, page 59, the applicant provides the proposed staffing. In Section H.2, page 60, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 494 (formerly 405.2100). The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

.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 P, page 96. In addition, the applicant provides a copy of the training program outline for BMA in Exhibit H-1. In Exhibit H-2, the applicant provides a copy of the continuing education programs for BMA staff members.