

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: May 27, 2014

PROJECT ANALYST: Gene DePorter

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: D-10247-14/ Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Watauga County/ Relocate existing 14-station dialysis facility and add 2 dialysis stations for a total of 16 stations upon project completion /Watauga

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 Watauga County (BMA) operates a 14-station dialysis facility located at 337 Deerfield Road, Boone. The applicant proposes to relocate the facility to a site on Route 421 which is three miles from the current dialysis center in Boone and expand by adding two additional dialysis stations for a total of 16 stations upon completion of this project.

The applicant proposes to relocate 14 dialysis stations within Watauga County and based upon the facility need methodology to add two dialysis stations for a total of 16 stations upon project completion. The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for additional dialysis stations. According to the January 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of eight dialysis stations in Watauga County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility

need methodology if the patient per station ratio is 3.2 or greater. The January 2014 SDR shows FMC Watauga County is operating with 3.21 patients per station [$45 / 14 = 3.21$] or 80.25% utilization [$3.21 / 4 = .8025$]. Application of the facility need methodology indicates a need for two additional stations, as illustrated in the following table.

**D-10247-14-FMC Watauga County
ESRD Facility Need Methodology**

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/13		80.36%
Certified Stations		14
Pending Stations		0
Total Existing and Pending Stations		14
In-Center Patients as of 6/30/13 (SDR2)		45
In-Center Patients as of 12/31/12 (SDR1)		39
Step	Description	Result
(i)	Difference (SDR2 – SDR1)	6
	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/12 (SDR1)	0.3077
(ii)	Divide the result of step (i) by 12	0.0256
(iii)	Multiply the result of Step ii by 6 (the number of months from June 30, 2013 until December 31, 2013)	0.1538
(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	51.9231
(v)	Divide the result of step (iv) by 3.2 patients per station	16.2260
	and subtract the number of certified and pending stations as recorded in SDR2 [14] to determine the number of stations needed	2

Based upon the calculations in the above table there is a need for 2 additional dialysis stations. Step (c) of the facility need methodology, page 364 of the 2014 SMFP, states; *“The facility may apply to expand to meet the need established... up to a maximum of 10 stations.”* The applicant is proposing to add 2 dialysis stations, therefore the application is consistent with the facility need determination for dialysis stations.

POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS is applicable to this review. The Policy 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 proposed relocation of 14 existing dialysis stations within Watauga County does not change the inventory of the county. Therefore, the application is consistent with Policy ESRD-2 and is conforming to this criterion.

POLICY GEN-3: Basic Principles, in the 2014 SMFP is also 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 31, the applicant describes how this proposal will promote safety and quality:

“BMA is a high quality health care provider. The Table at II.3 D provides quality indicators for the FMC Watauga County dialysis facility. In addition, 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.A, pages 35-41 the applicant identifies the following programs and methods it uses to insure and maintain quality care:

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 Watauga County’s Quality Improvement Program. The applicant adequately demonstrates the proposal will promote safety and quality of care.

Promote Equitable Access

In Section II, pages 32-33, the applicant describes how the proposal will 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 Watauga County has one operational dialysis center. As the dialysis patient population of Watauga and surrounding counties continues to increase, the need for dialysis stations will continue to increase. BMA will apply to develop new dialysis stations when needed. In this case, BMA is applying to relocate the entire facility and add two dialysis stations. The two new stations are needed to meet a growing need of the ESRD patient population served by BMA in its Watauga County dialysis facility.”

In Section VI.1 (a), page 61 the applicant states:

“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 100 facilities in 42 North Carolina Counties (includes our affiliations with RRI facilities); in addition, BMA has eight 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, and other traditionally underserved persons. The patient population of the FMC Watauga County facility is comprised of the following:

FMC Watauga County Facility Patient Demographics

Facility	Medicaid/ Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
FMC Watauga County	34.6%	57.7%	82.7%	36.5%	3.8%

In Section VI.2, page 64, the applicant states:

“The design of the facility is such that handicapped persons have easy access to the facility; the facility complies with ADA requirements. It was constructed in compliance with applicable sections of the North Carolina State Building Code, 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, pages 65-66, the applicant states:

BMA admission policy states 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 a patient.” See Exhibit 11, for a copy of applicable policies and procedures.

The applicant adequately demonstrates how the proposal will promote equitable access to medically underserved groups.

Maximize Healthcare Value

In Section II., page 33, the applicant states:

“BMA is projecting a capital expenditure of \$1,997,121 for this project. BMA is not seeking State or Federal monies to develop the CON application, relocation of the facility or the addition of these two dialysis stations to the FMC Watauga County facility; BMA is not seeking charitable contributions. Rather, BMA, through its parent company, FMC is taking on the burden to complete this facility relocation and expansion in an effort to continue delivering dialysis treatment close to patient homes. 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 83.6% of the treatments are covered by Medicare and Medicaid, and an additional 1.59% 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 for dialysis. BMA does.”

The applicant adequately demonstrates how 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 patients to be served. In summary, the application is consistent with the facility need methodology, Policy ESRD-2 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.

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Population to Be Served

In Section III. 3, page 45, the applicant identifies the in-center dialysis patient population it served as of June 30, 2013 as 20 Watauga, 14 Ashe, 7 Avery, 2 Wilkes and 2 patients from Johnson, Tn. for a total of 45 in-center patients. On page 44, 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:

FMC Watauga County, In-Center Patient Projections

County	Operating YR 1	Operating YR 2	County Patients as a	
	CY17	CY18	Percentage of Total	
	In-Center Pts.	In-Center Pts.	Year 1	Year 2
Watauga	23.6	23.7	43.5%	43.5%
Ashe	17.2	17.0	32.3%	32.3%
Avery	8.6	9.0	16.1%	16.1%
Wilkes	2.5	2.6	3.2%	3.2%
Johnson, TN	2.5	2.6	4.8%	4.8%
Total	54.3	54.8	100.0%	100.0%

The applicant adequately identified the population FMC Watauga County proposes to serve.

Need Analysis

In Section III.7, pages 44-51, the applicant states the application is filed pursuant to the Facility Need Methodology utilization data from the January 2014 SDR. The applicant

provides the assumptions and methodology it used to project need for two additional dialysis stations at FMC Watauga County.

Assumptions

- Project completion date is projected for December 31, 2016.
Operating Year 1 is January 1, 2017 to December 31, 2017
Operating Year 2 is January 1, 2018 to December 31, 2018
- The January 2014 SDR reports FMC Watauga County operating at 80.36% utilization with a census of 45 in-center patients dialyzing on 14 certified dialysis stations as of June 30, 2013.
- FMC Watauga County provides dialysis care for four counties in North Carolina (Watauga, Ashe, Avery, Wilkes), and (2) patients from Johnson (TN). As of June 30, 2013 FMC Watauga County was providing dialysis services for 45 patients. The dialysis patients from Watauga, Ashe and Avery are the source of 92% of BMA patients.
- According to the 2014 State Medical Facilities Plan, both Watauga and Ashe are in separate and distinct health service planning areas. Ashe has no dialysis stations within the county boundaries. Avery County is part of the Avery-Mitchell-Yancey multicounty planning area,
- As of the July 2013 SDR, FMC Watauga County had 39 in-center patients dialyzing on 14 stations for a utilization rate of 69.64%. As of the January 2014 SDR FMC Watauga County had 45 in-center patients dialyzing on 14 stations for a utilization percentage of 80.36%. Over the six month period 12/31/12-6/30/13 FMC Watauga County experienced a growth rate of 15.38% or an annualized rate of 30.77%. BMA considered using a facility growth rate of 30.77%, but rejected it based on the assumption that this rate is too high to justify.
- Based on the four year average annual change rate for Watauga, Ashe and Avery counties combined, BMA decided to utilize a growth rate of 4.66% and apply this to the FMC Watauga County patient population as of June 30, 2013.
- From June 30, 2013 - December 31, 2013, FMC Watauga County in-center patient census grew at a rate exceeding the Watauga County Five Year Average Change Rate of -0.052% (as published in the January 2014 SDR).
- In Operating Years 1 and 2, FMC Watauga County assumes 1 patient per year from Watauga County will change dialysis modality to home hemodialysis, and in Operating Year 2, one patient from Ashe County will convert to home hemodialysis.

- Using a growth factor of 4.66%, BMA has projected the patient population of the facility forward from June 30, 2013 until December 31, 2018. The results are indicated in the following table found in Section III. 7, on pages 44-48.

The applicant's projections are shown in the following table and described from pages 44-50.

<i>FMC Watauga County</i>	<i>In-Center Patient Growth</i>
<i>BMA begins with the patient population of the facility as of June 30, 2013.</i>	<i>45 In-center patients</i>
<i>BMA projects the census forward for 12 months to June 30, 2014.</i>	<i>(45 X .0466) + 45 = 47.1</i>
<i>BMA Projects the census forward for 12 months to June 30, 2015.</i>	<i>(47.1 X .0466) + 47.1 = 49.3</i>
<i>BMA projects the census forward for 12 months to June 30, 2016.</i>	<i>(49.3 X .0466) + 49.3 = 51.6</i>
<i>BMA projects the census forward for 6 months to December 31, 2016.</i>	<i>(51.6 X .0233) + 51.6 = 52.8</i>
<i>BMA projects the census forward for 12 months to December 31, 2017. This is the ending census of Operating Year 1.</i>	<i>(52.8 X .0466) + 52.8 = 55.3</i>
<i>BMA projects the census forward for 12 months to December 31, 2018. This is the ending census for Operating Year 2.</i>	<i>(55.3 X .0466) + 55.3 = 57.8</i>

The following table summarizes the BMA projections of patients to be served at FMC Watauga County upon completion of this project.

County	Operating Year 1			Operating Year 2			County Patients as a Percent of TOTAL	
	In-Center	PD	HH	In-Center	PD	HH	Year 1	Year 2
Watauga	23.6	8.6	1.0	23.7	9.0	2.0	43.5%	43.5%
Ashe	17.2	7.4	0.0	17.0	7.7	1.0	32.3%	32.3%
Avery	8.6	3.7	0.0	9.0	3.9	0.0	16.1%	16.1%
Wilkes	2.5	0.0	0.0	2.6	0.0	0.0	3.2%	3.2%
Johnson (TN)	2.5	1.2	0.0	2.6	1.3	0.0	4.8%	4.8%
TOTAL	54.3	20.9	1.0	54.8	21.8	3.0	100.0%	100.0%

The applicant projects utilization of FMC Watauga County to be the following;

Operating Year 1: 54 patients dialyzing on 16 stations = 3.375 patients per station
 $3.375 / 4.0 = 0.844$, or 84.4%

Operating Year 2: 54 patients dialyzing on 16 stations = 3.375 patients per station
 $3.375 / 4.0 = 0.844$ or 84.4%

Access

In Section VI, page 61, the applicant states that as of this application BMA operates 100 facilities in 42 North Carolina counties with another 8 facilities under development or pending CON approval. The patient population includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. The applicant projects that 88.9% of the in-center patients at FMC Watauga County will be covered by Medicare or Medicaid. The applicant demonstrates adequate access for medically underserved groups at FMC Watauga County.

In summary, the applicant adequately identifies the population to be served and demonstrates all residents of the area, and in particular, underserved groups are likely to have access to the services proposed. The applicant adequately demonstrates the need the proposed population has for two additional dialysis stations at FMC Watauga County. Therefore, the application is conforming with 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.

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The applicant's current lease is expiring and the facility must be relocated.

In Exhibit 27 the applicant proposes to enter into a 10 year lease at a site approximately three miles from the current location of FMC Watauga County. The applicant anticipates no changes in service to the patient population.

- (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 53 of the application, the applicant indicates that there is only one alternative available; relocation to another site in Boone due to the following:

- The lease is expiring.
- The existing space is not large enough to accommodate additional dialysis stations.
- Boone is a central location in the tri-county area which is the source of approximately 92% of FMC Watauga County patients.

- Indicators point to continued growth rate. The facility is already exceeding 80% utilization.

The applicant states the following on page 53:

“Considering the alternatives, BMA has only one viable option: apply to relocate two stations to FMC Watauga County.”

The applicant adequately explains why it chose the selected alternative over the status quo. Furthermore, the applicant is conforming to all other applicable statutory review criteria. Therefore, 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. Consequently, the application is conforming to this criterion and is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Watauga County 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 Watauga County shall develop and operate no more than 2 additional stations for a total of 16 certified stations upon completion of this project, including any isolation or home hemodialysis stations.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Watauga County shall install plumbing and electrical wiring through the walls for no more than 2 additional dialysis stations for a total of no more than 16 dialysis stations at the replacement facility which shall include any isolation or home hemodialysis stations.**
 - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Watauga County, 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 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(9), page 70, the applicant shows that the total capital cost of this project is \$1,997,121. The applicant’s capital budget is the following;

Construction Contract

\$1,376,942

RO Water Treatment Equipment	\$ 214,175
Equipment/Furniture	\$ 130,422
A & E Fees	\$ 123,925
Other	\$ 76,614
Subtotal Capital Costs	\$1,922,078
Contingency	\$ 75,043
Total Capital Costs	\$1,997,121

There is no associated “start-up” expense involved because this proposal is to relocate an existing facility. The applicant states the following in Section VIII. 7(b), page 72:

“Exhibit 4 is a copy of the most recent FMC audited financial reports. Audited financials for 2013 have not been released. The 2012 Consolidated Balance Sheet reflects more than \$341 million in cash, and total assets exceeding \$17 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 17, 2014:

“BMA is submitting a Certificate of Need Application to relocate the entire facility and add two dialysis stations to its FMC Watauga County facility in Watauga County. The project calls for the following capital expenditure:

Capital Expense \$1,997,121

As Vice President, I am authorized and do hereby authorize the relocation of the entire facility and addition of two dialysis stations, for the capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital costs of \$1,997,121 as may be needed by this project. I am also authorized and do hereby authorize any additional funds as may be necessary for the start-up costs in the new location.

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 Section X.1, page 75 and are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services.

In-Center Medicare/Medicaid Allowable Charges

Payor	In-Center
Commercial Insurance	\$1,425.00
Private Pay	\$1,425.00
Medicare	\$ 239.00
Medicaid	\$ 137.29

VA	\$ 146.79
Medicare/Medicaid	\$ 239.00
Medicare/Commercial	\$ 239.00
State Kidney Program	\$ 100.00
Other: Self/Indigent	\$1,425.00

In the revenue and expense statements in Section X. 2, page 77 and Section X.4, page 84, the applicant projects that revenues will exceed operating costs in each of the first two years of operation as shown in the following table:

**FMC Watauga County
Revenue, Costs and Profit**

	Operating Year 1 FY17	Operating Year 2 FY18
Total Net Revenue	\$3,686,177	\$3,998,165
Total Operating Costs	\$3,241,420	\$3,444,053
Net Profit	\$ 444,757	\$ 554,112

The assumptions used in preparation of the pro formas, including the number of projected treatments, are based on reasonable, credible and supported assumptions. See Section X, pages 75-85 for the applicant's projections.

In summary, the applicant adequately demonstrates 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.

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FMC Watauga County is the only dialysis facility in Watauga County and currently has 14 certified stations. The applicant proposes to relocate the entire facility to a new location approximately 3 miles from the current facility in Boone and add 2 stations for a total of 16 stations upon project completion. The applicant adequately demonstrates the need to relocate the facility and to add 2 stations based upon the number of in-center patients it proposes to serve. As of June 30, 2013, the 14 station FMC Watauga County facility was operating at 80.36% ($45/14= 3.21$; $3.21 / 4= .8036$). The target utilization is 80%. Upon completion of this project, the facility will have 16 stations serving 54 patients in Year 1, which is a utilization rate of 84.38% ($54/16=3.375$; $3.375 / 4 = .84375$). Therefore, the applicant is conforming with the requirement in 10A NCAC 14C .2204.

The applicant's projections are based on reasonable, credible and supported assumptions therefore; 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.

- (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 67, the applicant provides the current and projected staffing for FMC Watauga County as shown in the following table:

FMC Watauga County Current and Projected Staffing

Position	# of Current FTE Positions	# of FTE Positions to be added	# of Projected FTE Positions
RN	2.00	0.50	2.50
PCT.	4.50	1.00	5.50
Clinical Manager	1.00	0	1.00
Medical Director	Contract Position not a facility FTE.		
Administrator	0.15	0	0.15
Dietitian	0.40	0.10	0.50
Social Worker	0.40	0.10	0.50
Home Training	1.20	0.50	1.70
Chief Tech	0.15	0	0.15
Equipment Tech	0.50	0	0.50
In-Service	0.25	0	0.25
Clerical	0.80	0.20	1.00
Total	11.35	2.40	13.75

The applicant indicates 11.35 current FTEs and is projecting an additional 2.40 FTEs for a total of 13.75 FTEs upon project completion. The applicant indicates in Section VII.4, page 68; that it does not expect any difficulty in recruiting staff. The information regarding staff provided in Section VII and the pro forma financial statements regarding projected staffing are reasonable and credible.

In Section VII.10, page 69, the applicant provides the projected direct care staff upon project completion for each shift offered in the facility as shown in the following table:

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	7A – 12N	4	4	4	4	4	4
Afternoon	12N-5P	4	4	4	4	4	4
Evening							

Exhibit 21 contains a letter dated January 27, 2014 from the current medical director Richard Benson, MD, (a certified Nephrologist) indicating he will continue in the role of medical director for FMC Watauga County.

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.

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In Section V. 1, page 56, the applicant lists the providers of necessary ancillary and support services. The applicant states that Watauga Medical Center will provide acute dialysis in an acute care setting, diagnostic evaluation services, x-ray services and blood bank services and how the facility will coordinate services with the existing healthcare system. The following exhibits contain agreements for the indicated support relationships:

Exhibit 15 - Spectra Laboratory Services Agreement

Exhibit 19 - Invitation to Appalachian State University to utilize
FMC Watauga County as a training site

Exhibit 25 - Watauga Hospital Affiliation Agreement

Exhibit 26 - Transplant Agreement with Wake Forest Baptist Hospital

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 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.

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;

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In Section VI.1 (a), page 61, 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 100 facilities in 42 North Carolina Counties (includes our affiliations with RRI facilities); in addition BMA has eight 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 patient population of the FMC Watauga County facility is comprised of the following:

Facility	Medicaid / Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
<i>FMC Watauga County</i>	34.6%	57.7%	82.7%	36.5%	3.8%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 82.7% of the facility treatment reimbursement is from Medicare.

It is clear that FMC Watauga County provides 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 83.97% of North Carolina dialysis treatments in BMA facilities in FY 2013. Medicaid treatments represented an additional 4.82% of treatments in BMA facilities for FY 2013, 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, and ANSI Standards for Handicapped Access, and any other requirement of federal, state, and local bodies.”

As shown in the following table from page 62, 90.5% of FMC Watauga County current in-center dialysis patients have some or all of their services paid for by some form of government reimbursement.

**FMC Watauga County
Current Payor Mix**

Payor Source	Current & Projected Percent of Total
Commercial Insurance	9.20%
Medicare	80.21%
Medicaid	3.41%
Medicare/Commercial	5.30%
VA	1.59%
Self-Pay/Indigent	0.29%
Total	100.00%

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 Watauga County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Watauga County	7.6%	3.5%	24.2%
Statewide	16.5%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

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 dialysis services offered by FMC Watauga County. In fact, in 2012 only 6.5% of all newly-diagnosed ESRD patients in North Carolina’s

Network 6 were under the age of 35 (*ESRD Network 6 2012 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2012 – 12/21/2012*, page 74).

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race 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 does 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.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides the following national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ...”*¹ (p. 216)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were White, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p. 218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states:

“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.”(p. 216)

The Southeastern Kidney Council (SKC) Network 6 2012 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 76, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race and Gender 2012		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	73	0.5%
20-34	751	5.0%
35-44	1,442	9.7%
45-54	2,644	17.7%
55-64	4,013	26.9%

¹ www.usrds.org/adr.aspx

65+	5,995	40.2%
Gender		
Female	6,692	44.9%
Male	8,226	55.1%
Race		
African American	9,346	62.7%
White/Caucasian	5,191	34.8%
Other	380	2.6%

Source: Southeastern Kidney Council (SKC) Network 6. Table includes North Carolina statistics only.²

The 2013 United States Renal Data System (USRDS) Annual Data Report provides 2011 ESRD spending by payor, as follows:

ESRD SPENDING BY PAYOR*		
PAYOR	SPENDING IN BILLIONS	% OF TOTAL SPENDING
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
TOTAL	\$49.2	100.0%

*Source: 2013 United States Renal Data System (USRDS) Annual Data Report, page 332.

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;

C

In application Section VI.1 (f), page 64, 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 65, the applicant states, “There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.”

The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

² www.esrdnetwork6.org/publications/reports.html

C

In Section VI.1(c), page 62, the applicant provides the projected payor mix for the proposed services at FMC Watauga County. The applicant projects no change from the current payor mix for dialysis visits as shown in the table below.

**FMC Watauga County
Current and Projected Payor Mix**

Payor Source	Current & Projected Percent of Total
Commercial Insurance	9.20%
Medicare	80.21%
Medicaid	3.41%
Medicare/Commercial	5.30%
VA	1.59%
Self-Pay/Indigent	0.29%
Total	100.00%

The applicant projects that 90.5% of the patients will have some or all of their dialysis costs paid through a government source. The applicant demonstrates that medically underserved populations will continue to 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 65, the applicant states, *“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC Watauga County will have an open policy, which means that any Nephrologist may apply to admit patients at the facility.”* Further, in Section VI.5 (b), page 65, the applicant states, *“... all patients will be admitted to the facility through one of the Nephrologists on the staff of FMC Watauga County. The Nephrologists expect to continue receiving referrals from the local physician community, home health agencies and acute care facilities.”*

The applicant adequately demonstrates that FMC Watauga County 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 57, the applicant references a letter in Exhibit 19 from Jim Whichard, FMC Director of Operations, to Appalachian State University encouraging the school to include the FMC Watauga County facility in their clinical rotation for nursing students. The applicant states that 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 applicant adequately demonstrates that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. Therefore, the application is conforming to this criterion.

(15) Repealed effective July 1, 1987.

(16) Repealed effective July 1, 1987.

(17) Repealed effective July 1, 1987.

(18) Repealed effective July 1, 1987.

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

C

The applicant proposes to relocate 14 dialysis stations within Watauga County and based upon the facility need methodology to add two dialysis stations for a total of 16 stations upon project completion. FMC Watauga County is the only dialysis facility in Watauga County, according to the January 2014 SDR.

See Sections II, III, V, VI and VII. In particular, reference Section V.7, page 59 in which the applicant discusses the impact of the project on competition in the area as it relates to promoting cost-effectiveness, quality and access. On page 59, the applicant states;

“BMA does not expect this proposal to have effect on the competitive climate in Watauga County. According to the January 2014 SDR there is only one dialysis facility operating within Watauga County: FMC Watauga County. BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area.”

The information provided by the applicant in those sections is reasonable, creditable and adequately demonstrates that relocating 14 existing stations and adding two more stations will have a positive impact on cost-effectiveness, quality and access to the proposed service in Watauga County.

This determination is based on the information in the application, and the following:

- The applicant adequately demonstrates the need to add 2 dialysis stations,
- The applicant adequately demonstrates the need to relocate the 14 station facility,
- The applicant adequately demonstrates that its proposal is a cost-effective alternative to meet projected patient volume at FMC Watauga County dialysis center,
- The applicant adequately demonstrates that it has and will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 and VII, and referenced exhibits is reasonable and credible and demonstrates the provision of quality care; and
- The applicant adequately demonstrates that it will continue to provide adequate access to medically underserved populations.

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

According to files of the Adult and Home Care Licensure and Certification Section, Division of Health Service Regulation, FMC Watauga County operated in compliance with the Medicare and 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 applicant is found to be 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- See Exhibit 5 (copy of the January 2014 SDR), which indicates the facility has an 80.36% utilization rate as of June 30, 2013.

.2202(a)(2) Mortality rates;

-C- In Section IV.2, page 54 the applicant provides the following mortality rates: Year 2011-22.6%, 2012-20.3%, and 2013-19.6%.

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

-C- In Section IV.3, page 54, the applicant indicates that there were 14 home trained dialysis patients dialyzing with FMC Watauga County, as of June 30, 2013.

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

-C- In Section IV.4, page 54, the applicant states that in 2013 FMC Watauga County had 11 transplants referred and 3 transplants performed.

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

-C- In Section IV.5, page 54, the applicant states that 4 patients are on the waiting list as of December 31, 2013.

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

-C- In Section IV.6, page 55, the applicant states that there were 8 dialysis related hospital admissions and 66 non-dialysis hospital related admissions during 2013.

.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 IV.7, page 55 the applicant indicates there were no Hepatitis B patients and no Hepatitis B conversions.

(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.*

-C- FMC Watauga County proposes to relocate the current facility. Reference Exhibit 25, FMC Watauga County / Watauga Medical Center Affiliation Agreement.

.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- FMC Watauga County proposes to relocate the current facility. Reference Exhibit 26-FMC Watauga County/Wake Forest University Baptist Renal Transplant Facility Agreement.

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

-C- Exhibits 30 and 31 document that power and water will be available at either of the proposed relocation sites.

.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 91 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.*

-C- FMC Watauga County is an existing facility proposing to relocate the facility within Watauga County. Exhibit 16 contains a letter from Health Property Services (HPS), Inc. and Exhibit 30 includes a letter from Weber, Hodges & Godwin Commercial Real Estate Services, LLC to provide site acquisition services for FMC Watauga County. As of this application a primary site has been identified 135 Innovation Drive in Boone. This site is zoned for medical use. A second site has been identified at 610 State Farm Road, Boone. The secondary site is also properly zoned. The Town of Boone, Department of Public Utilities has stated that Water and sanitary sewer services are accessible to the primary site. Negotiation of site size and price is under negotiation. Exhibit 31 contains information in reference to the secondary site option with existing building and water, electricity and sewer connected.

.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 II.1, page 12, Section XI.6 (g), page 91 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 44-50.

.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 III. 8, page 50 the applicant states that the anticipated travel distance for patients from their homes to the applicant's facility will be 30 miles or less for 100% of existing patients.

.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- In Section II. 9, page 21 the applicant states the following;

“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.”

.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 Watauga County is relocating existing stations and adding 2 in-center stations to the 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 44-50 the applicant projects to serve 54 in-center patients by the end of Year 1, which equates to 3.75 patients per station per week [54 / 16 = 3.375]. Further, the applicant projects to serve 54 in-center patients by the end of Year 2, which equates to 3.375 patients per station per week [54 / 16 = 3.375]. The applicant adequately demonstrates the need for two additional stations based on the number of in-center patients currently and projected to be served. See Criterion (3) for discussion of the reasonableness of the applicant’s methodology 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 (7), pages 12-21, In Section III.7, pages 44-50, 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 56, Watauga Medical Center.

.2204(2) *Maintenance dialysis;*

-C- See Section V.1 (c), page 56, On Site

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

-C- See Section V.1 (d), page 56, On Site

.2204(4) *Accessible follow-up program for support of patients dialyzing at home;*

-C- See Section V.1 (d), page 56, On Site

.2204(5) *X-ray services;*

-C- See Section V.1 (g), page 56, Watauga Medical Center

.2204(6) *Laboratory services;*

-C- See Section V.1 (h), page 56, Spectra (Exhibit 15).

.2204(7) *Blood bank services;*

-C- See Section V.1, (i), page 56, Watauga Medical Center

.2204(8) *Emergency care;*

-C- See Section V.1 (b), page 56, 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 56, Watauga Medical Center.

.2204(10) *Vascular surgery for dialysis treatment patients;*

-C- See Section V.1 (p), page 56, Referral to Dr. Randall Bast, Horizon Surgical.

- .2204(11) *Transplantation services;*
-C- See Section V.1 (f), page 56, Wake Forest Baptist. See Exhibit 26 for copy of agreement.
- .2204(12) *Vocational rehabilitation counseling and services; and*
-C- In Section V. 1 (o), page 56, the applicant states that referrals will be made to Division of Vocational Rehabilitation, Boone.
- .2204(13) *Transportation*
-C- See Section V.1 (q), page 56, Appal CART.

.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- In Section VII.1 and VII.2, pages 67-68, the applicant provides the proposed staffing. In Section VII, 2, page 68 the applicant states, the proposed facility will comply with all staffing requirements set forth in the 42 C.F.R. Section 494. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis service to be provided.
- .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 68 and Exhibits 9 and 10 for an outline of continuing education programs.