

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: August 28, 2014
FINDINGS DATE: September 2, 2014
PROJECT ANALYST: Kim Randolph
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBERS: G-10254-14/ Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Asheboro/ Relocate two stations from BMA South Greensboro in Guilford County to BMA Asheboro for a total of 48 dialysis stations upon completion/ Randolph County (**BMA Asheboro**)

G-10262-14/ Wake Forest University Health Sciences and North Randolph Dialysis Center of Wake Forest University/ Develop a 10-station dialysis facility by relocating 10 dialysis stations from High Point Kidney Center in Guilford County/ Randolph County (**North Randolph Dialysis**)

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- All Applications

ESRD dialysis station need determinations are published semiannually, in the January and July North Carolina Semiannual Dialysis Report (SDR), by the State Health Coordinating Council and the Medical Facilities Planning Branch, Division of Health Service Regulation, Department of Health and Human Services, pursuant to Chapter 14 of the 2014 North Carolina State Medical Facilities Plan (2014 SMFP). The January 2014 SDR is the applicable SDR for applications submitted in 2014 prior to July 1, 2014. The July 2014 SDR is the applicable SDR for applications submitted in 2014 after July 1, 2014.

Two applications were submitted to the Certificate of Need Section (CON) on March 17, 2014, for the review cycle beginning April 1, 2014, based on a 10-station deficit projected in the January 2014 SDR for Randolph County. The two applicants applied for a total of 12 dialysis stations. Both applications propose to relocate existing dialysis stations from Guilford County to Randolph County, pursuant to Policy ESRD-2. However, pursuant to Policy ESRD-2 and the 10-station deficit in the January 2014 SDR, 10 dialysis stations is the maximum number of dialysis stations that may be approved in this review.

BMA Asheboro. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Asheboro proposes to relocate two certified dialysis stations from BMA South Greensboro in Guilford County to BMA Asheboro in Randolph County in response to the 10-station deficit in Randolph County. Exhibit 18 contains a copy of the applicant's Medicare Certification Letter documenting the facility is certified for a total of 46 stations as of July 21, 2013. Exhibit 28 contains a line drawing of the facility and the applicant will have a total of 48 dialysis stations, including an isolation station and home hemodialysis training stations, at BMA Asheboro upon project completion. The applicant does not propose to relocate more than 10 dialysis stations.

North Randolph Dialysis. Wake Forest University Health Sciences and North Randolph Dialysis Center of Wake Forest University propose to relocate 10 certified dialysis stations from High Point Kidney Center of Wake Forest University (HPKC) in Guilford County to Randolph County to develop a 10-station dialysis facility. Attachment T contains a line drawing of the facility and the applicant will have a total of 10 dialysis stations, including an isolation station and home hemodialysis training stations, at North Randolph Dialysis upon project completion. The applicant does not propose to relocate more than 10 dialysis stations.

Since both applications are proposing to relocate existing dialysis stations, and are not proposing to add new dialysis stations to an existing facility or to establish new dialysis stations, the county and facility need methodologies in the January 2014 SDR and the 2014 SMFP are not applicable to this review. However, there are two policies in the 2014 SMFP applicable to this review: *Policy ESRD-2: Relocation of Dialysis Stations* and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*. Policy ESRD-2 is applicable to both applications and Policy GEN-4 is applicable only to the North Randolph Dialysis application. Each proposal and its conformity with these policies is discussed below.

Policy ESRD-2 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.”*

BMA Asheboro proposes to relocate two existing dialysis stations from BMA South Greensboro (Guilford County) to its existing dialysis facility in Asheboro (Randolph County).

Randolph and Guilford counties are contiguous to each other. Relocating two dialysis stations from Guilford County to Randolph County will decrease the Guilford County dialysis station inventory by two stations and increase the Randolph County inventory by two stations. *Table B: ESRD Dialysis Station Need Determinations by Planning Area*, in the January 2014 SDR, indicates a 21-station surplus in Guilford County and a 10-station deficit in Randolph County.

Since Randolph County has a deficit of 10 stations, relocating two dialysis stations from Guilford County will not result in a surplus in the number of dialysis stations in Randolph County. Since Guilford County has a surplus of 21 stations, relocating two dialysis stations from Guilford County will not result in a deficit in the number of dialysis stations in Guilford County.

The application is consistent with Policy ESRD-2. Therefore, the application is conforming to this criterion.

North Randolph Dialysis proposes to develop a 10-station dialysis facility in Randolph County by relocating 10 existing dialysis stations from High Point Kidney Center of Wake Forest University (HPKC) (Guilford County), in response to the 10-station deficit in Randolph County. The applicant states the facility will be located in the northwest corner of Randolph County, near the towns of Trinity or Archdale, and the primary site is located at 1449 E. Sunrise Avenue, Thomasville.

Randolph and Guilford counties are contiguous to each other. Relocating 10 dialysis stations from Guilford County to Randolph County will decrease the Guilford County dialysis station inventory by 10 stations and increase the Randolph County inventory by 10 stations. Table B in the January 2014 SDR, indicates a 21-station surplus in Guilford County and a 10-station deficit in Randolph County.

Since Randolph County has a deficit of 10 stations, relocating 10 dialysis stations from Guilford County will not result in a surplus in the number of dialysis stations in Randolph County. Since Guilford County has a surplus of 21 stations, relocating 10 dialysis stations from Guilford County will not result in a deficit in the number of dialysis stations in Guilford County. Therefore, this application is consistent with Policy ESRD-2.

Policy GEN-4 states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

North Randolph Dialysis proposes to develop a 10-station dialysis facility in Randolph County, for a total capital cost of \$3,295,700. In Attachment T, the applicant includes a written statement, dated February 17, 2014, from the manager of Greensboro Engineering describing the plans to assure improved energy efficiency and water conservation. The letter states the building will meet the requirements for energy conservation as set out in the North Carolina State Building Code: Energy Conservation Code 2012. The applicant includes a written statement describing the project’s plan to assure improved energy efficiency, sustainability and water conservation. The application is consistent with Policy GEN-4.

The application is consistent with Policy ESRD-2 and Policy GEN-4. Therefore, the application is conforming to this criterion.

Summary

Two applications were received by the CON Section to relocate dialysis stations to Randolph County based on a 10-station deficit projected in the January 2014 SDR. The two applicants applied for a total of 12 dialysis stations; however pursuant to the deficit in the January 2014 SDR and Policy ESRD-2, 10 dialysis stations is the maximum number of dialysis stations that may be approved in this review. Therefore, even if both applications are conforming or conditionally conforming to all statutory and regulatory review criteria, both applications cannot be approved. See the Conclusion following the Comparative Analysis for the decision.

- (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.

NC- BMA Asheboro
C- North Randolph Dialysis

BMA currently operates the only dialysis facility in Randolph County, BMA Asheboro, a 46-station facility located in Asheboro. The January 2014 SDR *Table A: Inventory of Dialysis Stations and Calculation of Utilization Rates* indicates that as of June 30, 2013, BMA Asheboro was operating at a 99.07% utilization rate with 107 in-center patients dialyzing on 27 stations [$107 / 27 = 3.96$; $3.96 / 4 = 99\%$]. The January 2014 SDR also indicates that BMA Asheboro had a total of 46 certified dialysis stations, as of December 16, 2013. Table B, in the January 2014 SDR, projects there will be 18 Randolph County residents in need of home care dialysis treatments and 179 Randolph County residents in need of in-center dialysis treatments for a total need of 56 in-center dialysis stations, as of June 30, 2014. Since the total number of stations in Randolph County is currently 46 stations, the January 2014 SDR identified a deficit of 10 in-center dialysis stations [$179 / 56 = 3.19$; $3.19 / 4 = 79.8\%$] in Randolph County.

Both applications propose to relocate existing stations to Randolph County from facilities located in Guilford County as discussed below.

BMA Asheboro proposes to relocate two existing dialysis stations from BMA South Greensboro (Guilford County) to BMA Asheboro (Randolph County) for a total of 48 stations at BMA Asheboro and 57 stations at BMA South Greensboro upon project completion. In Section II.1, page 11, the applicant states that it recently relocated and expanded the BMA Asheboro facility by 19 stations. The applicant provides documentation in Exhibit 18 indicating BMA Asheboro had 46 certified dialysis stations as of July 21, 2013. The applicant also stated it started offering and will continue to offer home dialysis therapies including home peritoneal dialysis and home hemodialysis.

In Section III.7, page 43, and Section IV, page 47, the applicant states that as of December 31, 2013, BMA Asheboro had 46 stations with 101 total patients, operating at a 54.89% utilization rate [$101 / 46 = 2.1957$; $2.2 / 4 = 55\%$]. Of those 101 total patients, 98 patients were residents of Randolph County. The applicant also indicates that as of December 31, 2013, BMA Asheboro was serving six home patients from Randolph County.

Population to be Served

In Section III.7, page 40, the applicant provides projected patient origin for the first two years of operation following completion of the proposed project, as illustrated in the following table.

BMA Asheboro - Projected Patient Origin

County	OY1 CY 2017		OY2 CY 2018		County Patients as a Percent of Total	
	In-Center	Home	In-Center	Home	Year 1	Year 2
Randolph	151.70	11.30	166.10	15.60	98.19%	98.38%
Davidson	1.00	0.00	1.00	0.00	0.60%	0.54%
Guilford	2.00	0.00	2.00	0.00	1.21%	1.08%
Total	154.70	11.30	169.10	15.60	100.00%	100.00%

Exhibit 22 of the application contains 90 dialysis patient signatures of support for the addition of two stations at BMA Asheboro. Exhibit 22 also contains two patient letters from patients living in Randolph County and one patient letter from a patient living in Davidson County indicating the patients' plans to transfer their care from BMA South Greensboro to BMA Asheboro.

After the proposed relocation of stations and transfer of patients, the applicant projects BMA Asheboro will have 154 in-center ESRD patients, consisting of residents from Randolph, Davidson, and Guilford counties. The applicant adequately identifies the population to be served.

Demonstration of Need

The above patient origin is based on the following assumptions and methodology provided by the applicant in Section II, pages 13-16, and Section III.7, pages 40-44.

Assumptions:

1. *The January 2014 SDR reports that BMA Asheboro was operating at 99.07% utilization with a census of 107 in-center patients dialyzing on 27 certified dialysis stations as of June 30, 2013.*
2. *The Randolph County Five Year Average Annual Change Rate as published in the January 2014 SDR is 11.5%. The SDR further reports a 10 station deficit in Randolph County.*
3. *This project is scheduled to be completed December 31, 2016. BMA will utilize the time between CON issuance and completion of the project to develop internal plans for expansion, and to complete development of the project.*

*Operating Year 1 is the period from January 1, 2017- December 31, 2017.
Operating Year 2 is the period from January 1, 2018 - December 31, 2018.*

4. *BMA Asheboro facility census as of December 31, 2013 include two Guilford County residents and one Davidson County resident. BMA assumes these patients will continue to dialyze at BMA Asheboro as a function of patient choice. Obviously there are dialysis facilities in both Guilford and Davidson Counties. BMA will not demonstrate any increase in this segment of the BMA Asheboro facility census but will add these three patients to projections of future patient census at appropriate points in time.*
5. *BMA assumes that at least two patients currently dialyzing in the BMA South Greensboro facility, will transfer their care to the BMA Asheboro facility as this project is completed.*
6. *BMA is also projecting to serve home training patients at the facility. BMA will assume that two Randolph County patients per year, in Operating Year 1, and three patients in Operating Year 2 will convert to home dialysis.*

Within the most recent years, the growth of the home patient population has increased at a rate greater than the ESRD patient population as a whole. For example, based upon SEKC zip code reports for the periods indicated below, BMA has calculated changes within the ESRD patient population.

	<i>IC</i>	<i>Home HD</i>	<i>Home PD</i>	<i>IC PD</i>	<i>Other</i>	<i>Total</i>
<i>03/31/2012</i>	<i>12836</i>	<i>277</i>	<i>1420</i>	<i>2</i>		<i>14535</i>
<i>12/31/2009</i>	<i>12128</i>	<i>123</i>	<i>1186</i>	<i>1</i>	<i>6</i>	<i>13444</i>
<i>12/31/2007</i>	<i>11704</i>	<i>59</i>	<i>1115</i>		<i>6</i>	<i>12884</i>
<i>Raw Change 2007 - 2012</i>	<i>1132</i>	<i>218</i>	<i>305</i>	<i>NA</i>	<i>NA</i>	<i>1651</i>
<i>% of Change 2007 - 2012</i>	<i>0.096719 or, 9.67%</i>	<i>3.694915 or, 369.49%</i>	<i>0.273543 or, 27.35%</i>	<i>NA</i>	<i>NA</i>	<i>0.128143 or, 12.81%</i>
<i>Annualized Change</i>	<i>0.022757 or, 2.28%</i>	<i>0.869392 or, 86.94%</i>	<i>0.064363 or, 6.44%</i>	<i>NA</i>	<i>NA</i>	<i>0.030151 or, 3.02%</i>

- a. *The overall growth of the ESRD patient population from December 31, 2007 through March 31, 2012 averaged slightly over 3% annual growth. This figure is calculated by dividing the percentage of change for the period (51 months) by 51 and then multiplying by 12 to annualize.*
- b. *During this time, the in-center hemodialysis patient population increased by an average of 2.28% annually. This figure is calculated in the same manner as the annualized change discussed in a) above.*
- c. *During the same period of time, the PD patient population grew at a rate of 6.44% annual. This figure is calculated in the same manner as the annualized change discussed in a) above.*
- d. *However, the home hemodialysis patient population increased at significantly higher rate of 86.94%. This figure is calculated in the same manner as the annualized change discussed in a) above.*
- e. *BMA assumes the growth in the HH patient population during this time is largely attributable to changes in technology (i.e. NxStg home hemodialysis),*

increased nephrology physician support, and a more educated dialysis patient and family.

Methodology:

The next table represents BMA calculations of future patient population at BMA Asheboro.

<i>BMA Asheboro</i>	<i>In-Center</i>	<i>Home</i>
<i>BMA begins with facility census of Randolph County patients as of December</i>	98	6

<i>31, 2013.</i>		
<i>The census is increased by the Randolph County Five Year Average Annual Change Rate of 11.5% for one year to December 31, 2014.</i>	$(98 \times .115) + 98 = 109.3$	$(6 \times .115) + 6 = 6.7$
<i>The census is increased by the Randolph County Five Year Average Annual Change Rate of 11.5% for one year to December 31, 2015.</i>	$(109.3 \times .115) + 109.3 = 121.8$	$(6.7 \times .115) + 6.7 = 7.5$
<i>The census is increased by the Randolph County Five Year Average Annual Change Rate of 11.5% for one year to December 31, 2016. This is the projected completion date for this project.</i>	$(121.8 \times .115) + 121.8 = 135.8$	$(7.5 \times .115) + 7.5 = 8.3$
<i>BMA adds two Randolph County residents projected to transfer their care to the facility from BMA South Greensboro.</i>	$135.8 + 2 = 137.8$	8.3
<i>BMA adds the 3 patients from Davidson and Guilford Counties. This is the beginning census for this project, December 31, 2016.</i>	$137.8 + 3 = 140.8$	8.3
<i>The Randolph County census is again increased by the Randolph County Five Year Average Annual Change Rate of 11.5% for one year to December 31, 2017.</i>	$(137.8 \times .115) + 137.8 = 153.7$	$(8.3 \times .115) + 8.3 = 9.3$
<i>BMA projects two patients projected to convert to home dialysis modality.</i>	$153.7 - 2 = 151.7$	$9.3 + 2 = 11.3$
<i>BMA adds 3 in-center patients from Davidson and Guilford Counties. This is the ending census for Operating Year 1.</i>	$151.7 + 3 = 154.7$	11.3
<i>The Randolph County census is increased by the Randolph County Five Year Average Annual Change Rate of 11.5% for one year to December 31, 2018.</i>	$(151.7 \times .115) + 151.7 = 169.1$	$(11.3 \times .115) + 11.3 = 12.6$
<i>BMA projects three patients projected to convert to home dialysis modality.</i>	$169.1 - 3 = 166.1$	$12.6 + 3 = 15.6$
<i>BMA adds 3 in-center patients from Davidson and Guilford Counties. This is the ending census for Operating Year 2.</i>	$166.1 + 3 = 169.1$	15.6"

The applicant proposes to relocate two certified dialysis stations from BMA South Greensboro, an existing facility in Guilford County, to BMA Asheboro, an existing facility in Randolph County. In Section III.7, page 43, and Section IV, page 47, the applicant indicates that as of December 31, 2013, BMA Asheboro had 46 stations with 101 total patients operating at a 54.89% utilization rate [$101 / 46 = 2.1957$; $2.2 / 4 = 55\%$]. Of those 101 total patients, 98 patients were residents of Randolph County. The applicant also indicates that as of December 31, 2013, BMA Asheboro was serving six home trained dialysis patients from Randolph County but did not have home training capacity prior to completion of the recent relocation and

expansion. The applicant indicates that it expects the home patient population to continue to increase.

The Performance Standards for dialysis facilities, as promulgated in 10A NCAC 14C .2203(b), requires an applicant proposing to increase the number of dialysis stations in an existing facility to “... *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... .*” As shown above, and in Section II, page 17, the applicant projects BMA Asheboro will serve 154 in-center patients on 48 stations or 3.2083 in-center patients per station per week ($154 / 48 = 3.2083$; $3.2083 / 4 = 80.21\%$) by the end of OY1, which exceeds the 3.2 patients per station required by 10A NCAC 14C .2203(b).

However, the projected utilization is not based on reasonable and adequately supported assumptions. Therefore, the applicant does not adequately demonstrate it will serve 154 in-center patients by the end of OY1.

In Section II.1, page 11, the applicant states BMA Asheboro recently relocated to a new facility and added 19 new stations, expanding from 27 stations to 46 stations on July 21, 2013. The applicant provided BMA Asheboro’s utilization rates for the last three years which indicates the average number of in-center and home patients has declined each year, as shown below.

BMA Asheboro	Beginning Patients	Ending Patients	Average
2011	107	116	111.5
2012	116	103	109.5
2013	103	107	105.0

The project analyst reviewed the number of in-center patients listed in the January and July SDR’s for the last three years and confirmed the number of in-center patients served at BMA Asheboro has declined since June 30, 2011, as shown below.

BMA Asheboro

Data Source	As of Date	In-Center Patients
January 2012 SDR	06/30/2011	113
July 2012 SDR	12/31/2011	105
January 2013 SDR	06/30/2012	106
July 2013 SDR	12/31/2012	104
January 2014 SDR	06/30/2013	107
Applicant Supplied Data	12/31/2013	101

As of June 30, 2013, according to the January 2014 SDR, there were 107 in-center patients at BMA Asheboro. On page 15, the applicant indicates that after the 19 new stations were added to BMA Asheboro, the number of in-center patients at BMA Asheboro declined to 101 patients (98 Randolph County patients + 3 patients from Davidson and Guilford

counties) as of December 31, 2013, yielding a 5.9% decline in the number of in-center patients since the addition of the 19 new stations.

The applicant did not provide an explanation for the declining in-center population. Additionally, the applicant did not provide an explanation for how it was going to achieve or sustain an 11.5% annual growth rate, at a current utilization rate of only 55%, after reporting a historical decline in the in-center patient population. Note: If the applicant serves even four fewer patients than projected in OY1, the facility would be operating at only a 78.13% utilization rate ($150 / 48 = 3.125$; $3.125 / 4 = 78.13\%$).

Furthermore, in Chapter 14, page 360, of the 2014 SMFP, Basic Principle 6 states “*No existing facility may expand unless its utilization is 80 percent or greater. Any facility at 80 percent utilization or greater may apply to expand.*” BMA Asheboro is an existing facility proposing to expand by relocating two existing dialysis stations from BMA South Greensboro to BMA Asheboro. BMA Asheboro is not at 80% utilization and according to the applicant on page 43, is not projected to achieve an 80% utilization rate for four years, until December 31, 2017, even with a projected 11.5% increase of in-center patients per year. Therefore, approval of BMA Asheboro’s application would not be consistent with Basic Principle 6.

Access to Services

In Section VI, page 55, the applicant states

“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.

BMA of North Carolina has historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”

The applicant projects that 72.9% of its patients will be covered by Medicare and 6.5% will be covered by Medicaid. The applicant states the Medicare percentage “... represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 72.9% of the facility treatment reimbursement is from Medicare.” The applicant adequately demonstrates adequate access for the medically underserved to its services.

In summary, the applicant adequately identifies the population to be served and demonstrates all residents of the service area, and in particular, underserved groups, are likely to have access to the services proposed. However, the applicant does not demonstrate the need the population has for relocating two existing dialysis stations to BMA Asheboro. Therefore, the application is nonconforming to this criterion.

North Randolph Dialysis proposes to develop a new 10-station dialysis facility in northwestern Randolph County by relocating 10 existing in-center dialysis stations from High Point Kidney Center of Wake Forest University (Guilford County) to North Randolph Dialysis (Randolph County). The applicant proposes that the new dialysis facility will offer in-center dialysis and home dialysis training and support. Health Systems Management (HSM) will operate the facility on behalf of Wake Forest University Health Services (WFUHS).

WFUHS operates a 42-station dialysis facility in Guilford County, High Point Kidney Center. The January 2014 SDR does not show a utilization rate for High Point Kidney Center since High Point Kidney Center was renovating its facility from March 2013 through February 2014 (CON Project I.D. #'s G-10028-12 and G-10029-12). However, in Section IV.1, page 28, WFUHS indicates that High Point Kidney Center was operating at 75% utilization with 126 in-center patients dialyzing on 42 stations as of March 1, 2014 [$126 / 42 = 3.0$; $3.0 / 4 = 75\%$]. WFUHS indicates High Point Kidney Center was also serving 48 home dialysis patients, 8 of whom are residents of Randolph County.

Population to be Served

In Section III.7, page 25, the applicant provides projected patient origin for the first two years of operation following completion of the proposed project, as illustrated in the following table.

North Randolph Dialysis - Projected Patient Origin

County	OY1 CY 2016		OY2 CY 2017		County Patients as a Percent of Total	
	In-Center	Home	In-Center	Home	Year 1	Year 2
Randolph	54.06	18	60.28	20	100.00%	100.00%
Total	54.06	18	60.28	20	100.00%	100.00%

In Section III.3, page 22, the applicant provides the Randolph County dialysis patients currently being served at WFUHS facilities as of June 30, 2013, as shown in the table below.

Randolph County Residents Currently Served by WFUHS

Facility County	WFUHS Facility	In-Center Patients	Home Patients
Davidson	Thomasville Dialysis Center (TVDC)	15	0
Davidson	Lexington Dialysis Center (LXDC)	0	4
Forsyth	Piedmont Dialysis Center (PDC)	0	1
Guilford	High Point Kidney Center (HPKC)	23	8
Guilford	Triad Dialysis Center (TDC)	1	0
	Total	39	13

Attachment W of the application contains letters of support from 50 WFUHS dialysis patients living in Randolph County. Attachment O contains 8 community letters of support and Attachment R contains 29 physician letters of support for the creation of a new facility

in Randolph County.

The applicant's projections for North Randolph Dialysis start with the 39 in-center ESRD patients WFUHS is currently serving from Randolph County. The applicant projects to serve a total of 54 in-center patients in OY1. The applicant adequately identifies the population to be served.

Demonstration of Need

The above patient origin is based on the following assumptions and methodology provided by the applicant in Section III, pages 25-27.

Assumptions

- 1. The current patient population as of publication of the most recent SDR (January 2014) shall increase by the 5-year AACR by county of origin for at least the period of project development, OY1, and OY2.*
- 2. The 5-year AACR accounts for patient deaths, and by design it indicates net average patient growth.*
- 3. There are no outside indicators to suggest uncalculated growth or deaths shall occur.*
- 4. Ending OY1 projected patient numbers were increased by the 5-year AACR by county of origin in order to project the ending OY2 patient population."*

Methodology

1. Beginning patient population identified as of 12/31/2013 (39 ICH patients).
2. The census is increased by the Randolph County Five Year Average Annual Change Rate of 11.5% for one year to December 31, 2014 $(39 \times 1.115) = 43.485$ patients.
3. The census is increased by the Randolph County Five Year Average Annual Change Rate of 11.5% for one year to December 31, 2015 $(43.485 \times 1.115) = 48.4858$ patients. The project completed and certified by 12/31/2015.
4. The census is increased by the Randolph County Five Year Average Annual Change Rate of 11.5% for one year to December 31, 2016 $(48.4858 \times 1.115) = 54.0617$ patients. OY1 begins 01/01/2016 and ends 12/31/2016.
5. The census is increased by the Randolph County Five Year Average Annual Change Rate of 11.5% for one year to December 31, 2016 $(54.0617 \times 1.115) = 60.2787$ patients. OY1 begins 01/01/2017 and ends 12/31/2017.

The applicant proposes to relocate 10 certified dialysis stations from High Point Kidney Center, an existing facility in Guilford County, to create North Randolph Dialysis in Randolph County. On pages 23-26, the applicant indicates WFUHS is currently serving 39 in-center patients and 13 home dialysis patients who are residents of Randolph County. Of the 39 in-center patients and 13 home dialysis WFUHS patients, High Point Kidney Center serves 23 in-center patients and 8 home dialysis patients living in Randolph County. Attachment W of the application shows the residence locations of the WFUHS dialysis patients living in Randolph County, primarily clustered in the northwest quadrant of Randolph County.

The Performance Standards for dialysis facilities, as promulgated in 10A NCAC 14C .2203(a), requires an applicant proposing to establish a new facility to “*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... .*” As shown above, and in Section III.7, pages 25-26, the applicant projects North Randolph Dialysis will serve 54 in-center patients on 10 stations or 5.4 in-center patients per station per week ($54 / 10 = 5.4$; $5.4 / 4 = 135\%$) by the end of the first operating year, which exceeds the 3.2 patients per station per week required. Note: Since the applicant stated it is currently serving 39 Randolph County patients in sister facilities, the applicant has documented the need for at least 10 stations based on utilization of 3.2 patients per station per week by the end of the first operating year without projecting any patient population growth in Randolph County ($39 / 10 = 3.9$; $3.9 / 4 = 97.5\%$). Projected utilization is based on reasonable, credible, and supported assumptions. Therefore, the applicant adequately demonstrates that the proposed Randolph County facility would serve 3.2 patients per station per week as required by 10A NCAC 14C .2203(a).

Access to Services

In Section VI, page 37, the applicant states

“The WFUHS dialysis centers accept patients based on medically defined admission criteria. There is no discrimination based on race, sex, national origin, nor disability. Services are available to all area residents with ESRD. Further, WFUHS dialysis facilities also accept the needy and the homeless, through its referral system, and assists those patients in obtaining the medical care they need. WFUHS’ dialysis clinic Referral / Admissions Policy can be found at Attachment S.”

The applicant projects that 81% of its in-center and home patients will be covered by Medicare and 4% will be covered by Medicaid based on the current payor mix for existing Randolph County patients at other WFUHS facilities. The applicant states it anticipates the payor mix for OY1 and OY2 will “... emulate historical payor mix for Randolph County dialysis patients“. The applicant adequately demonstrates adequate access for the medically underserved to its services.

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for developing a new 10-station dialysis facility in Randolph County, and demonstrates all residents of the service area, and in particular, underserved groups, are

likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

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

C- All Applications

BMA Asheboro proposes to relocate two dialysis stations from BMA South Greensboro in Guilford County to its existing dialysis facility in Asheboro, Randolph County. In Section III, pages 39-40, the applicant describes the impact of the proposed relocation of stations on BMA South Greensboro.

BMA South Greensboro (Guilford County)

In Section III.6, page 39, the applicant states BMA South Greensboro has 59 certified dialysis stations. According to the January 2014 SDR, the facility was operating at 72.88% capacity, as of June 30, 2013, with 172 in-center patients utilizing 59 certified dialysis stations. The January 2014 SDR shows a projected surplus of 21 dialysis stations in Guilford County.

The applicant states that relocating two dialysis stations and transferring two in-center patients from BMA South Greensboro to BMA Asheboro will result in BMA South Greensboro having 57 certified stations [$59 - 2 = 57$] and 170 in-center patients [$172 - 2 = 170$]. To account for potential growth, the applicant states it used the Guilford County five-year AACR of 1.4%. However, the applicant begins its projections with 178 Guilford County patients being served as of December 31, 2013, as shown in the table below.

BMA South Greensboro	In-Center
BMA begins with the Guilford County residents dialyzing	178

at BMA South Greensboro as of December 31, 2013.	
BMA projects this population forward for one year to December 31, 2014.	$178 \times 1.014 = 180.5$
BMA projects this population forward for one year to December 31, 2015.	$180.5 \times 1.014 = 183$
BMA projects this population forward for one year to December 31, 2016.	$183 \times 1.014 = 185.6$
BMA adds the five patients from Randolph, Rockingham and Chatham counties. This is the projected census for the first day after completion of this relocation project.	$185.6 + 5 = 190.6$
BMA subtracts the two Randolph County patients projected to transfer to BMA Asheboro.	$190.6 - 2 = 188.6$

On page 40, the applicant projects BMA South Greensboro will operate at 82.9% capacity as of December 31, 2016, with 189 patients dialyzing on 57 stations or 3.316 in-center patients per station per week ($189 / 57 = 3.316$; $3.316 / 4 = 82.9\%$).

The applicant demonstrates that the needs of the population presently served at BMA South Greensboro will continue to be adequately met following the proposed relocation of two dialysis stations from BMA South Greensboro to BMA Asheboro and that access for medically underserved groups will not be negatively impacted.

North Randolph Dialysis proposes to develop a new 10-station dialysis facility in northwest Randolph County, by relocating 10 existing dialysis stations from High Point Kidney Center of Wake Forest University in Guilford County. In Section III, page 24, the applicant describes the impact of the proposed relocation of stations from High Point Kidney Center of Wake Forest University.

High Point Kidney Center of Wake Forest University (Guilford County)

In Section III.6, page 24, the applicant states High Point Kidney Center has 42 certified dialysis stations. According to the applicant, the facility was operating at 74.4% capacity with 125 in-center patients utilizing the 42 certified dialysis stations as of June 30, 2013. The January 2014 SDR shows a projected station surplus in Guilford County of 21 dialysis stations.

The applicant states that relocating 10 dialysis stations and transferring the 23 in-center patients living in Randolph County from High Point Kidney Center to North Randolph Dialysis will result in High Point Kidney Center having 32 certified stations [$42 - 10 = 32$] and 102 in-center patients [$125 - 23 = 102$]. To account for potential growth, the applicant states it used the appropriate five-year AACR of 1.4% for Guilford County, 2.7% for Davidson County, and 0.9% for Forsyth County, as shown in the table below.

High Point Kidney Center - Projected Patient Origin

County	OY1 CY 2016	OY2 CY 2017	County Patients as a Percent of Total
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	In-Center	Home	In-Center	Home	Year 1	Year 2
Guilford	96.96	27.11	98.32	27.49	90.86%	90.76%
Davidson	9.75	13.00	10.01	13.35	9.14%	9.24%
Forsyth	0.00	2.05	0.00	2.07	0.00%	0.00%
Total	106.71	42.16	108.33	42.91	100.00%	100.00%

The applicant projects High Point Kidney center will operate at 83.37% capacity as of December 31, 2016, with 106.71 patients dialyzing on 32 stations or 3.335 in-center patients per station per week ($106.71 / 32 = 3.335$; $3.335 / 4 = 83.37\%$).

The applicant demonstrates that the needs of the population presently served at High Point Kidney Center will continue to be adequately met following the proposed relocation of 10 dialysis stations from High Point Kidney Center to North Randolph Dialysis and that access for medically underserved groups will not be negatively impacted.

- (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.

NC- BMA Asheboro
C- North Randolph Dialysis

BMA Asheboro. In Section III.9, pages 45-46, the applicant discusses the alternatives considered prior to the submission of the application, which include

- 1) Relocate one station. The applicant could have chosen to relocate only one station to BMA Asheboro, but states this alternative is not as effective because this option would not meet the growing patient census in Randolph County.
- 2) Relocate more than two stations. The applicant could have chosen to relocate more than two stations to BMA Asheboro, but states this alternative is not as effective because the facility is new and almost at physical capacity. There is no additional space at the facility to add more than two stations without expanding the facility.
- 3) Develop a new facility. The applicant could have chosen to develop a new facility, but states this alternative is not as effective because it just built BMA Asheboro. The applicant stated there is no another area in Randolph County with a patient population to support another facility in Randolph County.
- 4) Maintain the status quo. The applicant states this alternative is not as effective because the applicant projects BMA Asheboro will exceed 80% utilization by the end of the first operating year for the proposed project and expects the patient population will continue to increase. The applicant states failure to expand would deny patients choice of dialysis at BMA Asheboro.

- 5) Relocate two stations. The applicant states that relocating two stations from BMA South Greensboro in Guilford County to BMA Asheboro in Randolph County is the most effective alternative. According to the January 2014 SDR, Guilford County has a five year AARC of 1.4% and a surplus of 21 stations compared to Randolph County which has a five year AARC of 11.5% and a deficit of 10 stations.

However, the application is not conforming to all applicable statutory and regulatory review criteria, and thus, the application is not approvable. An application that cannot be approved is not an effective alternative. See discussion on demonstration of need in Criterion (3) which is incorporated hereby as if set forth fully herein.

BMA failed to adequately demonstrate that the proposal is the least costly or most effective alternative to meet the need for relocating two dialysis stations to Randolph County. Consequently, the application is not conforming to this criterion.

North Randolph Dialysis. In Section III.9, pages 26-27, the applicant discusses the alternatives considered prior to the submission of the application, which include

- 1) Maintain the status quo. The applicant states WFUHS is currently serving a large percentage of Randolph County residents without a facility located in Randolph County. The applicant states this alternative is not as effective of an option because it would not meet the growing patient census in Randolph County.
- 2) Wait for a 10-station county need determination. The applicant states this alternative is not as effective of an option for its patients who reside in northwest Randolph County. The applicant states that choosing to delay development for even six months to a year could result in utilization issues at existing facilities currently serving these Randolph County patients.
- 3) Develop a new facility. The applicant states that relocating 10 stations from High Point Kidney Center in Guilford County to North Randolph Dialysis in the northwest corner of Randolph County is the most effective alternative. According to the January 2014 SDR, Guilford County has a five year AARC of 1.4% and a surplus of 21 stations compared to Randolph County which has a five year AARC of 11.5% and a deficit of 10 stations. The applicant states the most effective alternative to serve its current Randolph County patients is to provide access to care geographically convenient to their residences.

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.

The applicant adequately demonstrates that the North Randolph Dialysis proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion.

- (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.

NC- BMA Asheboro
C- North Randolph Dialysis

BMA Asheboro. In Section VIII.1, page 63, the applicant projects the total capital cost of the project will be \$15,750, as shown in the table below.

Miscellaneous Project Costs*	\$15,750
Total Capital Cost	\$15,750

* Includes water treatment equipment costs of \$9,000, television costs of \$4,500, and patient chair costs of \$2,250.

On page 65, the applicant states it will fund the project from the cash reserves of Fresenius Medical Care Holdings, Inc. In Section IX, page 67, the applicant states there will be no start-up costs or initial operating expenses since BMA Asheboro is an existing facility.

Exhibit 24 contains a letter dated March 17, 2014, from the Vice President of Fresenius Medical Care Holdings, Inc., the parent company of Bio-Medical Applications of North Carolina, Inc., which states in part

“The project calls for the following capital expenditure:

Capital Expense \$15,750

...I am authorized and do hereby authorize the relocation of two dialysis stations to BMA Asheboro, for capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$15,750 as may be needed for this project.”

In Exhibit 4, the applicant provides audited consolidated financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the fiscal years ending December 31, 2012, and 2011. As of December 31, 2012, Fresenius Medical Care Holdings, Inc. and Subsidiaries had \$341,071,000 in cash and cash equivalents, \$17,841,509,000 in total assets and \$8,738,771,000 in total equity. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of this project.

In Section X.1, page 68, the applicant projects the allowable charges per treatment for each payment source, as shown below.

Payment Source	BMA Asheboro’s Allowable Charges Per Treatment
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Private Pay	\$1,425.00
Commercial Insurance*	\$1,425.00
Medicare	\$234.00
Medicaid	\$137.29
Medicare/Medicaid	\$234.00
Medicare/Commercial	\$234.00
State Kidney Program	\$100.00
VA	\$146.79
Other: Self/Indigent	\$1,425.00

* The applicant states the commercial charges above do not reflect actual reimbursement rates. The applicant states it is an industry standard for providers to have contractual relationships with various payors resulting in less reimbursement than the stated charge.

On page 69, the applicant states that in November 2013, Medicare announced cuts in reimbursement for dialysis treatment to be phased in over the next five years, as shown below.

Calendar Year	Anticipated Medicare Reimbursement Rates
2014	\$239.02
2015	\$239.02
2016	\$229.46
2017	\$220.28
2018	\$211.47
2019	\$211.47

The applicant states it used the anticipated Medicare reimbursement rates above to project revenue in the table below. In Sections X.2 - X.4, pages 70-77, the applicant reported projected revenues and expenses for the first two operating years, as shown below.

	Current Year 01/01/14 - 12/31/14	OY1 01/01/17 - 12/31/17	OY2 01/01/18 - 12/31/18
Projected Gross Revenue*	\$6,580,357	\$8,862,799	\$9,810,850
Projected Contractual Adjustments	\$1,281,539	\$1,801,102	\$2,054,503
Projected Net Revenue	\$5,298,818	\$7,061,697	\$7,756,347
Projected Operating Costs	\$4,669,699	\$5,873,438	\$6,377,763
Projected Net Profit	\$629,119	\$1,188,259	\$1,378,584

* Projected gross revenue includes: in-center revenue, page 72; home revenue, page 74; and ancillary revenue, page 75.

As illustrated in the table above, the applicant projects revenues will exceed operating expenses in each of the first two operating years following completion of the project. In Table X.5, Budgeted Salary on page 78, the applicant states that “BMA hourly rates are increased three percent (3%) annually to reflect average annual salary increases in BMA facilities.” However, the applicant did not actually calculate a 3% increase for the interim years 2015 and 2016. If the applicant had included a 3% increase for 2015 and 2016, the proposed project would still be financially feasible.

Projected charges, reimbursement rates, and contractual adjustments are based on reasonable assumptions. However, to the extent that the projected revenues and operating costs are based on utilization, including the projected number of patients and treatments, the projected revenues and operating cost are not based on reasonable and adequately supported assumptions. In Section X.3, page 71, the applicant indicates “*Current year treatment numbers are derived from the information within the response to III.7.*” The applicant did not provide an explanation of how it was going to achieve or sustain an 11.5% annual growth rate after reporting a historical decline in the in-center patient population. Therefore, projected in-center revenues and operating costs are not based on reasonable assumptions regarding projected utilization. See Section X.3, pages 71-72, for the applicant’s assumptions. See Criterion (3) for discussion regarding utilization which is incorporated hereby as if set forth fully herein.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital needs of this project. However, to the extent that the projected revenues and operating costs are based on utilization, the applicant does not adequately demonstrate that the financial feasibility of the proposal is based on reasonable and adequately supported projections of revenue and operating costs. Therefore, the application is not conforming with this criterion.

North Randolph Dialysis. In Section VIII.1, pages 51-52, the applicant projects the total capital cost of the project will be \$3,295,700, as shown in the table below.

Site Costs	\$727,000
Construction Contract	\$1,952,000
Miscellaneous Project Costs*	\$616,700
Total Capital Cost	\$3,295,700

* Includes, in part, water treatment equipment costs of \$125,000 and equipment and furniture costs of \$455,000.

On page 50, the applicant indicates the dialysis machines and chairs will transfer from HPKC when the dialysis stations are transferred to North Randolph Dialysis. WFUHS is not acquiring additional dialysis machines, but is transferring the machines from one facility to another.

In Section IX.3, page 56, the applicant states there will be start-up and initial operating expenses of \$204,300, for a total project cost of \$3,500,000. The applicant states it will fund the project and the start-up and initial operating expenses from the cash reserves of WFUHS.

Attachment D contains a letter dated March 6, 2014, from the co-applicant, WFUHS, signed by Terry L. Hales, Jr., which states in part

“The project has been budgeted to cost approximately \$3,500,000. North Randolph Dialysis Center is a non-profit subordinate of Wake Forest University Health Sciences. Wake Forest University Health Sciences commits to provide monies to its subordinates in order to fund these costs”

In Attachment D, the applicant provides audited consolidated financial statements for Wake Forest University Health Sciences and Affiliates for the fiscal years ending June 30, 2013, and 2012. As of June 30, 2013, Wake Forest University Health Sciences and Affiliates had \$17,882,000 in cash and cash equivalents, \$1,220,166,000 in total assets and \$470,270,000 in net unrestricted assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of this project.

In Section X.1, page 57, the applicant states the billable charge is \$1,397.00 for in-center and \$540.00 for home treatment, which is the same for all payors. The applicant projects the allowable charges per treatment for each payment source, based on amounts in effect for WFUHS dialysis facilities as of March 17, 2014, as shown below.

Payment Source	North Randolph Dialysis' Projected In-Center Allowable Charges Per Treatment	North Randolph Dialysis' Projected Home Treatment Allowable Charges Per Treatment
Private Pay	\$1,173.00	\$453.60
Commercial Insurance	\$1,173.00	\$453.60
Medicare	\$245.00	\$105.00
Medicaid	\$180.00	\$77.00
Medicare/Medicaid	\$245.00	\$105.00
Medicare/Commercial	\$245.00	\$105.00
State Kidney Program	\$0.00	\$0.00
VA	\$252.00	\$107.70
Medicare Advantage	\$245.00	\$105.00

In Sections X.2 - X.4, pages 57-63, the applicant reported projected revenues and expenses for in-center and home treatment for the first two operating years, as shown below.

	OY1 01/01/16 - 12/31/16	OY2 01/01/17 - 12/31/17
Projected Gross Revenue*	\$14,428,212	\$16,365,946
Projected Deductions**	\$11,854,647	\$13,524,060
Projected Net Revenue	\$2,573,565	\$2,841,886
Projected Operating Costs	\$2,502,890	\$2,678,921
Projected Net Profit	\$70,675	\$162,965

* WFUHS dialysis facilities' billable revenue, which is used to calculate gross revenue, is increased by 3% in OY1 and OY2.

** Projected deductions include Indigent/Charity Care, Bad Debt, and Contractual Allowances on page 58 of the application.

As illustrated in the table above, the applicant projects revenues will exceed operating expenses in each of the first two operating years following completion of the project. However, the Centers for Medicare and Medicaid Services (CMS) published a final rule indicating a Medicare rate of \$239.02 for CY 2014 in the December 2013 Federal Register. CMS also published a proposed Medicare rate of \$239.33 for CY 2015 in the July 2014 Federal Register and is accepting comments about that proposed rule until September 2014.

Since the Medicare rate can change annually, the following table illustrates the project analyst's re-calculations using the most recent \$239.02 Medicare rate published by CMS.

North Randolph Dialysis Projected Revenue

	OY1 01/01/16 - 12/31/16	OY2 01/01/17 - 12/31/17
Revised Projected Net Revenue*	\$2,536,539	\$2,801,300
Projected Operating Costs	\$2,502,890	\$2,678,921
Revised Projected Net Profit*	\$33,649	\$122,379

** Recalculated based on the Medicare rate published in the Federal Register on December 2, 2013.

Using the Medicare rate of \$239.02, North Randolph Dialysis' projected revenue will still exceed operating expenses in both the first and second operating years following completion of the project.

In Section I.12, page 7, the applicant indicates it is a non-profit subordinate of WFUHS, which is a non-profit corporation. The applicant states it did not report any property tax since it is a non-profit and exempt from property taxes. Projected revenues and operating costs are based on reasonable, credible and supported assumptions, including the projected number of treatments, charges, reimbursement rates, and contractual adjustments.

Operating costs and revenues are based on reasonable assumptions including projected utilization. See Section X.3, pages 60-62, for the applicant's assumptions. See Criterion (3) for discussion regarding utilization which is incorporated hereby as if set forth fully herein.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital needs of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming with 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.

NC- BMA Asheboro
C- North Randolph Dialysis

BMA currently operates the only dialysis facility located in Randolph County, BMA Asheboro, a 46-station facility located in Asheboro. Two applications were received by the CON Section to relocate a total of 12 dialysis stations from Guilford County to Randolph County, based on a projected 10-station deficit in Randolph County listed in the January 2014 SDR. However, pursuant to the 10-station deficit in the January 2014 SDR, 10 dialysis stations is the maximum number of dialysis stations that may be approved in this review.

BMA Asheboro proposes to relocate two existing dialysis stations from BMA South Greensboro (Guilford County) to BMA Asheboro (Randolph County) for a total of 48

stations at BMA Asheboro upon project completion. In Section II.1, page 11, the applicant states that it recently relocated and expanded the BMA Asheboro facility by 19 stations. The applicant provides documentation in Exhibit 18 indicating BMA Asheboro had 46 certified dialysis stations as of July 21, 2013. In Section III.7, page 43, and Section IV, page 47, the applicant states that as of December 31, 2013, BMA Asheboro had 46 stations with 101 total patients and was operating at a 54.89% utilization rate [$101 / 46 = 2.1957$; $2.2 / 4 = 55\%$].

The Performance Standards for dialysis facilities, as promulgated in 10A NCAC 14C .2203(b), requires an applicant proposing to increase the number of dialysis stations in an existing facility to “... *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... .*” In Section II, page 17, the applicant projects BMA Asheboro will serve 154 in-center patients on 48 stations or 3.2083 in-center patients per station per week ($154 / 48 = 3.2083$; $3.2083 / 4 = 80.21\%$) by the end of OY1, which meets the 3.2 patients per station per week required.

However, the applicant did not base its calculations on reasonable and adequately supported assumptions. The applicant did not provide an explanation for how it was going to achieve or sustain an 11.5% annual growth rate after reporting a historical decline in the in-center patient population.

Furthermore, in Chapter 14, page 360, of the 2014 SMFP, Basic Principle 6 states “*No existing facility may expand unless its utilization is 80 percent or greater. Any facility at 80 percent utilization or greater may apply to expand.*” BMA Asheboro is proposing to expand by relocating two existing dialysis stations from BMA South Greensboro to BMA Asheboro. As of December 31, 2013, the applicant reported BMA Asheboro had a utilization rate of 55%, not 80% or greater. According to the applicant in Section III.7, page 43, even with a projected 11.5% increase of in-center patients per year starting in 2014, the applicant is not projected to be at an 80% utilization rate for four years, until December 31, 2017, which is the end of OY1. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein.

Therefore, the applicant does not adequately demonstrate that relocating two stations from Guilford County to Randolph County will not result in the unnecessary duplication of existing or approved in-center dialysis stations in Randolph County. Consequently, the application is not conforming to this criterion.

North Randolph Dialysis proposes to develop a 10-station dialysis facility in northwest Randolph County, by relocating 10 certified dialysis stations from HPKC in Guilford County, based on a projected 10-station deficit in Randolph County listed in the January 2014 SDR.

The Performance Standards for dialysis facilities, as promulgated in 10A NCAC 14C .2203(a), requires an applicant to “*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... .*” The applicant adequately demonstrates the need to develop 10 stations as a new

facility. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein.

Therefore, the applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved in-center dialysis stations in Randolph County. Consequently, the application is conforming to this criterion.

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

C- All Applications

BMA Asheboro. In Section VII.1, page 60, the applicant provides the current and projected number of full-time equivalent (FTE) positions, as shown in the table below.

POSITION	CURRENT # OF FTEs	PROJECTED # OF NEW FTEs	TOTAL # OF FTEs
RN	5.00	0.00	5.00
Patient Care Tech (PCT)	11.00	0.00	11.00
Clinical Manager (DON)	1.00	0.00	1.00
Admin (FMC Dir. Ops)	0.15	0.00	0.15
Dietitian	1.00	0.00	1.00
Social Worker	1.00	0.00	1.00
Home Training Nurse	0.50	0.00	0.50
Chief Tech	0.50	0.00	0.50
Equipment Tech	1.00	0.00	1.00
In-Service	0.50	0.00	0.50
Clerical/Medical Records	1.00	0.00	1.00
Total	22.65	0.00	22.65

As shown in the above table, the applicant proposes to maintain the current staffing level of 22.65 FTE positions, 16 of which are direct care positions (RNs and PCTs), upon completion of the proposed project. In Section VII.4, page 61, the applicant states it does not anticipate any difficulty filling staff positions. BMA Asheboro currently has 46 certified dialysis stations and reasonably projects the same staffing levels for the proposed 48 certified dialysis stations.

The applicant states on page 61, it will comply with all staffing requirements as stated in 42 C.F.R. Section 494.

The applicant proposes a total of 10 hours of operation per day, 60 hours of operation per week and 3,120 hours of operation per year at the facility, as shown in the table below.

Weekly Hours of Operation

Day	Morning 7 am to 12 pm	Afternoon 12 pm to 5 pm	Evening 5 pm to 10 pm	Total
Monday	5	5	0	10
Tuesday	5	5	0	10
Wednesday	5	5	0	10
Thursday	5	5	0	10
Friday	5	5	0	10
Saturday	5	5	0	10
Sunday	0	0	0	10
Total	30	30	0	60

The following table shows the number of full-time equivalent (FTE) direct care staff positions the applicant proposes, based on the number of hours of operation, as reported by the applicant in Section VII.10, page 62.

	FTE's	Hours/Year per FTE (40 hrs x 52 wks)	Total Direct Care Hours (FTE's x Hrs/Year)	Total Hours of Operation per Year (60 hrs/wk x 52 wks)	Total Direct Care Hours / Hours of Operation
RN	5	2080	10,400	3,120	3.33
Tech	11	2080	22,880	3,120	7.33
Total	16	2080	33,280	3,120	10.66

Based on the above table, the applicant proposes sufficient direct care staff to provide the proposed services.

In Section II.1, page 17, the applicant projects to serve 154 in-center patients in OY1 (CY 2017) on 48 stations in 2 shifts, per day, Monday through Saturday. The following table illustrates the maximum number of in-center patients per shift.

Shift	Number of Stations	Monday/Wednesday/Friday Patients	Tuesday/Thursday/Saturday Patients
Morning	48	48	48
Afternoon	48	48	48

As shown in the table above, the proposed 48 station facility would be able to dialyze up to a maximum of 192 in-center patients on 48 dialysis stations, assuming one patient per station per shift and two shifts per day, Monday through Saturday. On page 17, the applicant states it projects to serve 154 in-center patients in OY1 and 169 in-center patients in OY2.

In Section V.4, page 53, the applicant states that Joseph Coladonato, MD has agreed to continue to serve as the Medical Director of the existing facility. Exhibit 21 contains a letter from Dr. Coladonato which states

“I am writing as the Medical Director of BMA Asheboro to wholeheartedly endorse the application by Bio-Medical Applications of North Carolina, Inc. to relocate two dialysis

stations from BMA South Greensboro to the BMA Asheboro facility for a total of 48 dialysis stations. I have agreed to continue serving as the Medical Director for this facility.”

The information regarding staffing provided in Section VII is reasonable and credible and supports a finding of conformity with this criterion.

North Randolph Dialysis. In Section VII.1, page 44, the applicant provides the current and projected number of FTE positions, as shown in the table below.

POSITION*	CURRENT # OF FTEs*	PROJECTED # OF NEW FTEs	TOTAL # OF FTEs
RN	1.00	1.00	2.00
LPN	1.00	0.00	1.00
Patient Care Tech (PCT)	4.00	1.00	5.00
CNM (DON)	1.00	0.00	1.00
Dietitian	0.50	0.25	0.75
Social Worker	0.50	0.25	0.75
Home Training RN	0.50	0.00	0.50
BioMed Tech	1.00	0.00	1.00
Dialysis Tech	2.00	0.00	2.00
Clerical	1.00	1.00	2.00
Total	12.50	3.50	16.00

* Current FTEs represent staff at the host facility currently supporting the existing patient base.

As shown in the above table, the applicant proposes a total of 16 FTE positions, 9.5 of which are direct care positions (RNs, LPNs, PCTs, CNMs and Home Training RNs), upon completion of the proposed project. In Section VII.4, page 47, the applicant states the current staff at the host facility supporting the existing patient base will transfer with the 10 dialysis stations. The applicant states if openings occur, it does not anticipate any difficulty filling staff positions and in addition, staff members from sister facilities can fill any vacancies until employees are hired.

The applicant proposes a total of 15.5 hours of operation per day, 93 hours of operation per week and 4,836 hours of operation per year at the facility, as shown in the table below.

Weekly Hours of Operation

Day	Morning 6:30 am to 12 pm	Afternoon 12:01 pm to 5 pm	Evening 5:01 pm to 10 pm	Total
Monday	5.5	5.0	5.0	15.5
Tuesday	5.5	5.0	5.0	15.5
Wednesday	5.5	5.0	5.0	15.5
Thursday	5.5	5.0	5.0	15.5
Friday	5.5	5.0	5.0	15.5
Saturday	5.5	5.0	5.0	15.5
Sunday	0.0	0.0	0.0	0.0
Total	33.0	30.0	30.0	93.0

The following tables show the number of direct care staff for each shift currently offered at High Point Kidney Center in Guilford County and how that will change after the proposed relocation of stations and transfer of patients.

Current High Point Kidney Center Direct Care Staff by Shift				
42 Stations and 126 Patients				
Day	Morning 6:30 am to 12 pm	Afternoon 12:01 pm to 5 pm	Evening 5:01 pm to 10 pm	Total
Monday	14	14	0	28
Tuesday	14	0	0	14
Wednesday	14	14	0	28
Thursday	14	0	0	14
Friday	14	14	0	28
Saturday	14	0	0	14
Sunday	0	0	0	0
Total	84	42	0	126

Source: Section VII.10, page 48 of the application.

Anticipated Change - High Point Kidney Direct Care Staff by Shift				
32 Stations and 107 Patients				
Day	Morning 6:30 am to 12 pm	Afternoon 12:01 pm to 5 pm	Evening 5:01 pm to 10 pm	Total
Monday	11	11	0	22
Tuesday	11	4	0	15
Wednesday	11	11	0	22
Thursday	11	4	0	15
Friday	11	11	0	22
Saturday	11	4	0	15
Sunday	0	0	0	0
Total	66	45	0	111

Source: Section VII.10, page 48 of the application.

The following table shows the number of direct care staff FTEs the applicant proposes based on the number of hours the facility operates, as reported by the applicant in Section VII, page 49.

	FTE's	Hours/Year per FTE (40 hrs x 52 wks)	Total Direct Care Hours (FTE's x Hrs/Year)	Total Hours of Operation per Year (93 hrs/wk x 52 wks)	Total Direct Care / Hours of Operation
RN*	3.5	2080	7,280	4,836	1.50
LPN	1.0	2080	2,080	4,836	0.43
Tech	5.0	2080	10,400	4,836	2.15
Total	9.5	2080	19,760	4,836	4.08

* Includes RN, CNM, and HT RN.

Based on the above table, the applicant proposes sufficient direct care staff to provide the proposed services.

In Section VII.10, page 49, the applicant projects to serve an average of 52 in-center patients in OY1 (CY 2016) on 10 stations in 3 shifts, per day, Monday through Saturday. The following table illustrates the maximum number of in-center patients per shift.

Shift	Number of Stations	Monday/Wednesday/Friday Patients	Tuesday/Thursday/Saturday Patients
Morning	10	10	10
Afternoon	10	10	10
Evening	10	10	10

As shown in the table above, the proposed 10-station dialysis facility would be able to dialyze up to a maximum of 60 in-center patients on 10 dialysis stations, assuming one patient per station per shift and three shifts per day, Monday through Saturday. On page 49, the applicant states it projects to serve an average of 52 in-center patients in OY1.

In Section V.4, page 34, the applicant states that John M. Burkart, MD will serve as the initial Medical Director for North Randolph Dialysis. Attachment R contains a letter from Dr. Burkart which states

“... I will provide Medical Director Services for the facility.”

The information regarding staffing provided in Section VII is reasonable and credible and supports a finding of conformity with 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- All Applications

BMA Asheboro. In Section V, pages 50-51, the applicant lists the providers of the necessary ancillary and support services. Exhibit 15 contains a copy of a Spectra Lab agreement. Exhibit 25 contains a copy of an affiliation agreement with The Moses H. Cone

Memorial Hospital, even though this is not a new facility. On page 51, the applicant states a dialysis patient in need of emergency services would be transferred to Randolph Hospital to be stabilized, then transferred to The Moses H. Cone Memorial Hospital for admission. Exhibit 26 contains a copy of the transplant agreement. The applicant discusses coordination with the existing health care system in Section V, pages 51-53. The information provided in Section V and the referenced exhibits is reasonable and credible and supports a finding of conformity with this criterion.

North Randolph Dialysis. In Section V, pages 30-31, the applicant lists the proposed providers of the necessary ancillary and support services. Attachment K contains a copy of a Meridian Lab agreement. Attachment E contains a copy of an affiliation agreement with North Carolina Baptist Hospital. Attachment F contains a copy of the transplant agreement. The applicant discusses coordination with the existing health care system in Section V, pages 32-35. The information provided in Section V and the referenced attachments is reasonable and credible and supports a finding of conformity with 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- All Applications

- (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- All Applications

- (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- BMA Asheboro
C- North Randolph Dialysis

North Randolph Dialysis. In Section XI, pages 65-73, the applicant states WFUHS will construct a 10,286 square foot building in northwest Randolph County near Trinity or Archdale on one of the following three sites: 1449 E. Sunrise Avenue, Thomasville; 5948 Mendenhall Road Ext, High Point; or 5940 Tom Hill Road, High Point. In Section XI.6, page 70, the applicant states each dialysis station will have 120 square feet per station. The applicant indicates *“The facility has been engineered and will be constructed utilizing the most modern technology and operations to maintain energy efficient operations and to control the operating costs.”* See Attachment T, page 461, for the Energy Efficiency and Water Conservation Plan provided by Greensboro Engineering. On pages 70-71, the applicant states The Piedmont Triad Regional Water Authority provides water to all of the proposed sites and discusses its procedures for modifying the water quality and providing for power outages. See Attachments H and P for supporting documentation and Attachment T, page 460, for a line drawing of the floor plan of the facility.

In Section X, pages 57-64, the applicant describes the costs and charges. See Criterion (5) for discussion of costs and charges which is incorporated hereby as if set forth fully herein.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction costs 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- All Applications

BMA Asheboro. In Section VI.1, pages 55-58, the applicant discusses BMA's history of providing dialysis services to the underserved populations of North

Carolina. Exhibit 7 contains FMC’s Patient Admission Policy. On page 55, 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, or other traditionally underserved persons. The patient population of the BMA Asheboro facility is comprised of the following:

Facility	Medicaid/Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
BMA Asheboro	6.5%	47.4%	72.9%	47.7%	37.4%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 72.9% of the facility treatment reimbursement is from Medicare.

... 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.”

In Section VI.1, page 56, the applicant reports that 86.23% of in-center patients who received treatment at BMA Asheboro had some or all of the services paid for by Medicare or Medicaid in the past year. The applicant provides the following table illustrating the historical payor mix, which the applicant also used to project the payor mix for BMA Asheboro.

BMA Asheboro Payor Source	Percent of Total	
	In-Center	Home
Commercial	7.94%	17.17%
Medicare	65.24%	57.13%
Medicaid	6.16%	0.00%
VA	5.10%	0.00%
Medicare/Commercial	14.83%	25.70%
Other: Self/Indigent	0.73%	0.00%
Total	100.00%	100.00%

North Randolph Dialysis. In Section VI.1, pages 37-40, the applicant discusses WFUHS’ history of providing dialysis services to the underserved populations of North Carolina. Attachment S contains the applicant’s New Patient Policy. On page 37, the applicant states

“The WFUHS dialysis centers accept patients based on medically defined admission criteria. There is no discrimination based on race, sex, national origin nor disability. Services are available to all area residents with ESRD. Further,

WFUHS dialysis facilities also accept the needy and the homeless, through its referral system, and assists those patients in obtaining the medical care they need.”

In Section VI.1, page 37, the applicant reports that 85% of Randolph County patients who received treatment at a WFUHS facility had some or all of the services paid for by Medicare or Medicaid in the past year. The applicant provides the following table illustrating the historical payor mix, which the applicant states it also used to project the payor mix for North Randolph Dialysis.

Existing Randolph County Patients Payor Source	Percent of Total
	In-Center and Home
Commercial	4%
Medicare	11%
Medicaid	4%
Medicare/Medicaid	27%
VA	11%
Medicare/Commercial	36%
Medicare Advantage	7%
Total	100%

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 Randolph County and statewide.

	June 2010 Total # of Medicaid Eligibles as % of Total Population*	June 2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population*	2008-2009 % Uninsured CY (Estimate by Cecil G. Sheps Center)
Randolph County	18.6%	7.2%	19.5%
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 with respect to dialysis services.

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 applicants’ 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.

The United States Renal Data System, in its *2013 USRDS Annual Data Report* (page 216) provides the following national statistics for FY 2011:

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

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. 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. 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.”

The report states, on page 118, that the overall Medicare expenditures for chronic kidney disease for 2011 were \$45.5 billion, including Medicare Part D.

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender 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%

¹ www.usrds.org/adr.aspx

20-34	751	5.0%
35-44	1,442	9.7%
45-54	2,644	17.7%
55-64	4,013	26.9%
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

BMA Asheboro and North Randolph Dialysis demonstrate they provide adequate access to medically underserved populations. Therefore, the applications are 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– All Applications

BMA Asheboro. In Section VI.1, page 58, 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, page 59, the applicant states “*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.*” Therefore the application is conforming to this criteria.

North Randolph Dialysis. In Section VI.1, page 40, the applicant states “*The facility has no obligation to provide uncompensated care or community service.*” In Section VI.6, page 43, the applicant states “*There have been no civil rights or equal access complaints filed against the host facility and/or any facilities owned by the parent company in North Carolina in the last five years.*” Therefore the application is conforming to this criteria.

- 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- All Applications

BMA Asheboro. In Section VI.1, page 56, the applicant provides the projected payor mix for in-center and home dialysis patients.

BMA Asheboro Payor Source	Percent of Total	
	In-Center	Home
Commercial	7.94%	17.17%
Medicare	65.24%	57.13%
Medicaid	6.16%	0.00%
VA	5.10%	0.00%
Medicare/Commercial	14.83%	25.70%
Other: Self/Indigent	0.73%	0.00%
Total	100.00%	100.00%

The applicant projects 86.23% of its in-center patients will have some or all of their care paid for by Medicare or Medicaid (80.07% Medicare + 6.16% Medicaid). In Section VI.1, page 55, the applicant states

“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.”

BMA of North Carolina has historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. 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 applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

North Randolph Dialysis. In Section VI.1, page 37, the applicant provides the projected payor mix for in-center and home dialysis patients.

North Randolph Dialysis Payor Source	Percent of Total
	In-Center and Home
Commercial	4%
Medicare	11%
Medicaid	4%
Medicare/Medicaid	27%
VA	11%

Medicare/Commercial	36%
Medicare Advantage	7%
Total	100%

The applicant projects 85% of its in-center patients will have some or all of their care paid for by Medicare or Medicaid (81% Medicare + 4% Medicaid). On page 37, the applicant states

“The WFUHS dialysis centers accept patients based on medically defined admission criteria. There is no discrimination based on race, sex, national origin nor disability. Services are available to all area residents with ESRD. Further, WFUHS dialysis facilities also accept the needy and the homeless, through its referral system, and assists those patients in obtaining the medical care they need.”

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

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

C- All Applications

BMA Asheboro. In Section VI.5, pages 58-59, and Exhibit 7, the applicant describes the range of means by which patients will have access to the proposed services. The information provided in Section VI.5 and the referenced exhibit is reasonable and credible and supports a finding of conformity with this criterion.

North Randolph Dialysis. In Section VI.5, pages 41-42, and Attachment S, the applicant describes the range of means by which patients will have access to the proposed services. The information provided in Section VI.5 and the referenced attachment is reasonable and credible and supports a finding of conformity with 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- All Applications

BMA Asheboro. In Section V.3, page 51, the applicant states FMC encourages colleges, nursing programs, and health related education and training programs to include BMA Asheboro in their clinical student rotations. Exhibit 19 contains a letter from the FMC Director of Operations to Randolph Community College discussing a prior project, CON Project I.D.# G-008594-10. In BMA’s Public Hearing Comments, number 6, received at the

public hearing on May 19, 2014, the applicant states “*BMA may have inadvertently used old information within the letter, but a new letter to the school was sent.*” The information provided in Section V.3, the referenced exhibit, and the public hearing comments is reasonable and credible and supports a finding of conformity with this criterion.

North Randolph Dialysis. In Section V.3, pages 32-33, the applicant states the Wake Forest Outpatient Dialysis Program participates with community college and university systems in North Carolina to provide clinical observation and hands-on learning experiences for students. The applicant states it does not have an existing relationship with college or university systems in Randolph County, so it contacted Randolph Community College and received a favorable response. See Attachment Y for a draft Clinical Education Affiliation Agreement between North Randolph Dialysis Center and Randolph Community College. The information provided in Section V.3 and the referenced attachment is reasonable and credible and support a finding of conformity with this criterion.

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

NC- BMA Asheboro
C- North Randolph Dialysis

BMA currently operates the only dialysis facility located in Randolph County, BMA Asheboro, a 46-station facility located in Asheboro. Two applications were received by the CON Section to relocate a total of 12 dialysis stations from Guilford County to Randolph County, based on a projected 10-station deficit in Randolph County listed in the January 2014 SDR. The applicants are not applying for stations due to a facility or county need methodology. Both applicants propose to relocate existing certified dialysis stations from Guilford County to Randolph County pursuant to Policy ESRD-2. However, based on the 10-station deficit in the January 2014 SDR, 10 dialysis stations is the maximum number of dialysis stations that may be approved in this review.

BMA Asheboro. In Section V.7, page 54, the applicant discusses how any enhanced competition in the service area will have a positive impact on 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 Randolph County. According to the January 2014 SDR there is only one dialysis facility operating within Randolph County: BMA Asheboro. BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area.

...

This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients’ lives.”

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access. The information provided by the applicant regarding quality and access in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on quality and access to the proposed services.

However, the applicant does not adequately demonstrate that any enhanced competition will have a positive impact on the cost-effectiveness of the proposed services. This determination is based on the information in the application regarding projected utilization and projected revenue based on the utilization proposed for this project. The applicant does not adequately demonstrate that projected revenues are reliable. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. See Criterion (5) for discussion of costs and charges which is incorporated hereby as if set forth fully herein. Therefore, the application is not conforming to this criterion.

North Randolph Dialysis. In Section V.7, page 36, the applicant discusses how any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality and access to the proposed services. The applicant states

“The existing facility in Randolph County is located in Asheboro. The WFUHS Randolph County dialysis patients do not travel to that facility due to the fact it is geographically inconvenient for them to do so and/or they prefer the location of and care given by their current WFUHS dialysis facility, staff and physician(s). WFUHS does not propose in its patient projects [sic] that any patients from the existing provider will transfer their care to NRDC. WFUHS does not propose additional Randolph County patients will utilize NRDC due to any reason aside from transfer of existing WFUHS Randolph County dialysis patients and growth projected from that base number of patients based on the Randolph County 5-year AACR of 11.5%. However, any Randolph County dialysis patient existing or future will be welcome and will have access to NRDC’s services. Thus, while this project will introduce an additional provider into a county where there is currently a sole provider of dialysis services, it will not pose a direct competitive threat to the dialysis facility in Asheboro due to its geographical location, existing WFUHS patient base, and existing relationships with community resources and local physicians who support this endeavor.

... By locating NRDC in northwestern Randolph County, in the Trinity / Archdale area, a favorable impact on cost-effectiveness, quality of life, and additional access to care is anticipated. NRDC does not anticipate any unfavorable consequences related to competition as a result of this project."

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area will have a positive impact on 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 demonstrates the need to develop a 10-station dialysis facility in northwest Randolph County, by relocating existing dialysis stations from HPKC, Guilford County, and that it is a cost-effective alternative;
- The applicant adequately demonstrates that it will continue to provide quality services; and
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations.

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- BMA Asheboro
NA- North Randolph Dialysis

BMA Asheboro. BMA has an existing facility in Randolph County, BMA Asheboro. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation (DHSR), the BMA Asheboro facility has operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision.

BMA also provides dialysis services at BMA South Greensboro, Guilford County. BMA is proposing to transfer two existing certified stations from BMA South Greensboro, Guilford County, to BMA Asheboro, Randolph County. According to the Acute and Home Care Licensure and Certification Section's survey on June 6, 2014, there were three condition level deficiencies identified which is within the 18 months immediately preceding the date of this decision. The Acute and Home Care Licensure and Certification Section's follow-up survey on July 30, 2014 indicated the condition level deficiencies were corrected and the facility is

currently in compliance with Medicare's Conditions of Coverage for ESRD facilities. After reviewing and considering the information provided by the applicant and by the Acute Care Licensure and Certification Section, the applicant has provided evidence that quality care was provided in the past. Therefore, the application is conforming to this criterion.

North Randolph Dialysis. WFUHS does not have an existing facility in Randolph County. However, WFUHS provides dialysis services at High Point Kidney Center, Guilford County. WFUHS is proposing to transfer 10 existing certified stations from High Point Kidney Center, Guilford County, to North Randolph Dialysis, Randolph County. According to the Acute and Home Care Licensure and Certification Section, DHSR, the High Point Kidney Center facility operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

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

NC- BMA Asheboro
C- North Randolph Dialysis

BMA Asheboro's application is not conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as promulgated in 10A NCAC 14C .2200. See discussion below.

North Randolph Dialysis' application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as promulgated in 10A NCAC 14C .2200. See discussion below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

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- **BMA Asheboro.** In Section II.1, page 11, the applicant states it has a utilization rate

of 99.07% reported in the January 2014 SDR, as of June 30, 2013, (107 patients dialyzing on 27 stations). However, the applicant states as of July 21, 2013, this facility was relocated and expanded (Project I.D.# G-008594-10), and currently has 46 dialysis stations. In Section III.7, page 43 and Section IV, page 47, the applicant indicates that as of December 31, 2013, BMA Asheboro had 46 stations with 101 total patients operating at a 54.89% utilization rate [$101 / 46 = 2.1957$; $2.2 / 4 = 55\%$]. Of those 101 total patients, 98 patients were residents of Randolph County.

- C- **North Randolph Dialysis.** In Section IV.1, page 28, the applicant states that as of March 1, 2014, High Point Kidney Center had a utilization rate of 75% with 126 patients dialyzing on 42 stations. High Point Kidney Center has a utilization rate of 0.00% listed in the January 2014 SDR because the facility was being renovated (Project I.D.#'s G-10028-12 and G-10029-12). The patients from High Point Kidney Center were not transferred back from local sister facilities until December 2013.

.2202(a)(2) *Mortality rates;*

- C- **BMA Asheboro.** In Section II.1, page 11, the applicant reports the 2011, 2012, and 2013 facility mortality rates, as 9.9%, 12.8% and 11.4% respectively.
- C- **North Randolph Dialysis.** In Section IV.2, page 28, the applicant reports High Point Kidney Center's 2010, 2011, 2012, and 2013 facility mortality rates, as 17.68%, 17.32%, 15.4%, and 5.98% respectively.

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

- C- **BMA Asheboro.** In Section II.1, page 11, the applicant states that it had six home trained dialysis patients as of December 31, 2013. The applicant states the facility did not have home training capacity until after the relocation and expansion in 2013.
- C- **North Randolph Dialysis.** In Section IV.3, page 28, the applicant states that High Point Kidney Center provided home dialysis training and support to 48 home dialysis patients and completed home dialysis training for 19 patients in 2013. The applicant states that of those 48 home dialysis patients, 8 are residents of Randolph County.

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

- C- **BMA Asheboro.** In Section II.1, page 11, the applicant reports the 2012 and 2013 number of transplants performed as 2 and 4, respectively and referred as 4 and 5, respectively.
- C- **North Randolph Dialysis.** In Section IV.4, page 28, the applicant reports High Point Kidney Center's 2012 and 2013 number of transplants performed as 10 and 5, respectively.

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

- C- **BMA Asheboro.** In Section II.1, page 11, the applicant states that it has 13 patients on the transplant waiting list.

- C- **North Randolph Dialysis.** In Section IV.5, page 29, the applicant states that High Point Kidney Center has 26 patients on the transplant waiting list.

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

- C- **BMA Asheboro.** In Section II.1, page 12, the applicant reports a total of 160 hospital admissions in 2013, 8 (5%) were dialysis-related admissions and 152 (95%) were non-dialysis related admissions.

- C- **North Randolph Dialysis.** In Section IV.6, page 29, the applicant reports that High Point Kidney Center had a total of 107 hospital admissions in 2013; 27 (25.2%) were dialysis-related admissions and 80 (74.8%) were non-dialysis related admissions.

.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- **BMA Asheboro.** In Section II.1, page 12, the applicant reports that in 2013 there were zero patients with AIDS and zero patients with Hepatitis B. Zero patients converted to infectious status in 2013.

- C- **North Randolph Dialysis.** In Section IV.7, page 29, the applicant reports that in 2013, High Point Kidney Center had 3 patients with AIDS, 1 patient with Hepatitis B, and 16 patients with Hepatitis C. Zero patients converted to infectious status in 2013.

(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 (Replaced with 42 CFR Part 494).*

- NA- **BMA Asheboro.** The applicant does not propose a new facility. BMA Asheboro is an existing facility.
- C- **North Randolph Dialysis.** Attachment E contains an Affiliation Agreement between North Carolina Baptist Hospital and North Randolph Dialysis, which includes the information required by 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.*

-NA- **BMA Asheboro.** The applicant does not propose a new facility. BMA Asheboro is an existing facility.

-C- **North Randolph Dialysis.** Attachment F contains a Renal Transplant Facility Agreement between North Carolina Baptist Hospital and North Randolph Dialysis, which includes the information required by this rule.

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

-NA- **BMA Asheboro.** The applicant does not propose a new facility. BMA Asheboro is an existing facility.

-C- **North Randolph Dialysis.** Attachment I contains letters of site availability for each of the three proposed sites, including documentation that power and water are available at the proposed sites.

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

-C- **BMA Asheboro.** Exhibit 12 contains a copy of the Fresenius Medical Care Clinical Services Integrated Policy and Procedure Manual, Emergency Management & Disaster Planning Section, which includes written policies and procedures for back up of electrical service in the event of a power outage.

-C- **North Randolph Dialysis.** Attachment H, page 177, contains generator specifications for back up electrical service in the event of a power outage. Attachment P contains a copy of the Dialysis Planning Guide for Emergency/Disaster Situations for staff and the Emergency Preparedness Guide for Dialysis Patients which includes written procedures for back up of 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.*

-NA- **BMA Asheboro.** The applicant does not propose a new facility. BMA Asheboro is an existing facility.

-C- **North Randolph Dialysis.** Section II.1, page 15 contains a written commitment by WFUHS to pursue acquiring the primary or one of the secondary sites listed in Section XI, pages 66-68. Attachment I contains the letters of site availability for each of the three proposed sites.

.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- **BMA Asheboro.** See Sections II.1, page 13; VII.2, page 61; and XI.6, page 83.

-C- **North Randolph Dialysis.** See Sections II.1, page 15; VII.2, page 45; and XI.6, page 71.

.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- **BMA Asheboro.** In Section II.1, pages 13-16, the applicant provides the assumptions and methodology it used to project patient origin. See Criterion (3) for further discussion on patient origin which is incorporated hereby as if set forth fully herein.

-C- **North Randolph Dialysis.** In Section III.7, pages 25-26, the applicant provides the assumptions and methodology it used to project patient origin. See Criterion (3) for further discussion on patient origin which is incorporated hereby as if set forth fully herein.

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

-NA- **BMA Asheboro.** The applicant does not propose a new facility. BMA Asheboro is an existing facility.

-C- **North Randolph Dialysis.** In Section III.8, page 26, the applicant states that 100% of anticipated patients will travel less than 30 miles one way for dialysis treatment.

.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- **BMA Asheboro.** In Section II.1, page 17, 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.“

- C- **North Randolph Dialysis.** In Section II.1, page 16, the applicant states, *“The facility is committed to admitting and providing dialysis services to patients who have no insurance or other source of payment, but for who 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.

- NA- **BMA Asheboro.** The applicant does not propose a new facility. BMA Asheboro is an existing facility.

- C- **North Randolph Dialysis.** In Section II.1, page 16, and Section III.7, page 25, the applicant adequately demonstrates it will serve a total of 54 in-center patients on 10 dialysis stations at the end of OY1, which is 5.4 patients per station per week [$54 / 10 = 5.4$], or a utilization rate of 135%. The utilization rate of 3.2 patients per station per week assumes only two shift per day. However, the applicant is proposing an evening shift. See Criterion (3) for discussion of need which is incorporated hereby as if set forth fully herein.

.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.

- NC- **BMA Asheboro.** In Sections II.1, pages 17-18, the applicant proposes to increase the number of dialysis stations in an existing facility by two stations and states it will serve 154 in-center patients on 48 stations by the end of OY1, which is 3.21 patients per station [$154 / 48 = 3.21$]. However, the applicant’s projected utilization is not based on reasonable, credible and adequately supported assumptions. See Criterion (3) for discussion of need which is incorporated hereby as if set forth fully herein.

- N/A- **North Randolph Dialysis.** The applicant is not 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.

- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- **BMA Asheboro.** In Section II.1, pages 18-21, the applicant provides the assumptions and methodology used to project patient utilization. The applicant projects an annual increase in its current Randolph County patient utilization using the Randolph County five-year AACR of 11.5% from the January 2014 SDR. The applicant also makes assumptions about patients who have expressed an interest in transferring to the facility. Additionally, the applicant projects to serve home training patients, stating it assumes two Randolph County patients in OY1 and three patients in OY2 will convert to home dialysis. See Criterion (3) for discussion of the reasonableness of the assumptions and methodology which is incorporated hereby as if set forth fully herein.
 - C- **North Randolph Dialysis.** In Section III.7, pages 25-26, the applicant provides the assumptions and methodology used to project patient utilization. The applicant projects an annual increase in its current Randolph County patient utilization using the Randolph County five-year AACR of 11.5% from the January 2014 SDR. The applicant also makes assumptions about patients who have expressed an interest in transferring to the proposed facility.

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- **BMA Asheboro.** See Section II.1, page 21, and Section V.1, page 50. The applicant states Randolph Hospital will provide diagnostic and evaluation services.
 - C- **North Randolph Dialysis.** See Section V.1, page 30. The applicant states it will provide diagnostic and evaluation services.
- .2204(2) *Maintenance dialysis;*
- C- **BMA Asheboro.** See Section II.1, page 21, and Section V.1, page 50. The applicant states it will provide maintenance dialysis.
 - C- **North Randolph Dialysis.** See Section V.1, page 30. The applicant states it will provide maintenance dialysis.
- .2204(3) *Accessible self-care training;*
- C- **BMA Asheboro.** See Section II.1, page 21, and Section V.1, page 50. The applicant states it will provide self-care training.
 - C- **North Randolph Dialysis.** See Section V.1, page 30. The applicant states it will provide self-care training.

- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
- C- **BMA Asheboro.** See Section II.1, page 21, and Section V.1, page 51. The applicant states patients who are candidates for home dialysis are trained and followed by the facility home training program.
 - C- **North Randolph Dialysis.** See Section V.1, page 32. The applicant states “*NRDC will provide ICH services as well as home dialysis training and support services for all modalities of dialysis, offering a full range of dialysis options to its patients.*”
- .2204(5) *X-ray services;*
- C- **BMA Asheboro.** See Section II.1, page 22, and Section V.1, page 50. The applicant states Randolph Hospital will provide X-ray services.
 - C- **North Randolph Dialysis.** See Section V.1, page 30, and Attachment E. The applicant states North Carolina Baptist Hospital will provide X-ray services based on its Affiliation Agreement in Attachment E.
- .2204(6) *Laboratory services;*
- C- **BMA Asheboro.** See Section II.1, page 22, Section V.1, page 50, and Exhibit 15. The applicant states Spectra Labs will provide laboratory services.
 - C- **North Randolph Dialysis.** See Section V.1, page 30, and Attachments E and K. The applicant states North Carolina Baptist Hospital and Meridian Laboratory Corporation will provide laboratory services as indicated on page 30.
- .2204(7) *Blood bank services;*
- C- **BMA Asheboro.** See Section II.1, page 22, and Section V.1, page 50. The applicant states Randolph Hospital will provide blood bank services.
 - C- **North Randolph Dialysis.** See Section V.1, page 30, and Attachment E. The applicant states North Carolina Baptist Hospital will provide blood bank services.
- .2204(8) *Emergency care;*
- C- **BMA Asheboro.** See Section II.1, page 22, and Section V.1, page 50. The applicant states BMA’s staff are fully trained to respond and a fully stocked crash cart is maintained at the facility. The applicant states emergency services requiring transportation to a hospital will be “*summoned via phone call to 911.*”
 - C- **North Randolph Dialysis.** See Section V.1, page 30, and Attachment E. The applicant states North Carolina Baptist Hospital will provide emergency care.
- .2204(9) *Acute dialysis in an acute care setting;*
- C- **BMA Asheboro.** See Section II.1, page 22, and Section V.1, page 50. The applicant states Moses Cone Hospital in Greensboro will provide acute dialysis in an acute care setting.

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 (Replaced with 42 C.F.R. Part 494).*
- C- **BMA Asheboro.** In Section VII.1, pages 60-61, the applicant provides the proposed staffing and states it complies with all staffing requirements set forth in 42 C.F.R., Part 494 (formerly 42 C.F.R., Section 405.2100). See Criterion (7) for further discussion on staffing which is incorporated hereby as if set forth fully herein.
 - C- **North Randolph Dialysis.** In Section VII, pages 44-45, the applicant provides the proposed staffing and states it complies with all staffing requirements set forth in 42 C.F.R. Part 494 (formerly 42 C.F.R., Section 405.2100). See Criterion (7) for further discussion on staffing which is incorporated hereby as if set forth fully herein.
- .2205(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
- C- **BMA Asheboro.** See Section II.1, page 23, Section VII.5, page 61, and Exhibits 9-10.
 - C- **North Randolph Dialysis.** See Section VII.3, pages 45-46, and Attachment M.

COMPARATIVE ANALYSIS

The 2014 State Medical Facilities Plan (2014 SMFP) and the January 2014 Semiannual Dialysis Report (January 2014 SDR) identify a 10-station deficit for Randolph County. Two applicants applied to the CON Section for a total of 12 dialysis stations based on the projected 10-station deficit. Both applications propose to relocate existing dialysis stations from Guilford County to Randolph County, pursuant to Policy ESRD-2. Since both applications are proposing to relocate existing dialysis stations, the county and facility need methodologies in the January 2014 SDR and the 2014 SMFP are not applicable to this review.

Pursuant to Policy ESRD-2 and 10A NCAC 14C .0202(f), 10 dialysis stations is the limit on the number of dialysis stations that may be approved in this review. Policy ESRD-2 indicates proposals cannot create a surplus of dialysis stations in a county gaining stations or create a deficit of dialysis stations in a county losing stations. 10A NCAC 14C .0202(f) states *“Applications are competitive if they, in whole or in part, are for the same or similar services and the agency determines that the approval of one or more of the applications may result in the denial of another application reviewed in the same review period.”*

The analyst considered all of the information in each application and reviewed each application individually against all applicable review criteria. Then the analyst conducted a comparative analysis of the proposals. Based on that review and for the reasons set forth below and in the rest of the findings, the application submitted by Wake Forest University Health Sciences and North Randolph Dialysis Center of Wake Forest University (**North Randolph Dialysis**), Project I.D. # G-10262-14 is approved and the application submitted by Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Asheboro (**BMA Asheboro**), Project I.D. # G-10254-14, is denied.

SMFP Principles

Basic Principle 2

Basic Principle 2 regarding the projection of need for additional dialysis stations as outlined in Chapter 14, page 359, of the 2014 SMFP states

“New facilities must have a projected need for at least 10 stations (or 32 patients at 3.2 patients per station) to be cost effective and to assure quality of care.”

See also 10A NCAC 14C .2203(a).

BMA Asheboro. BMA Asheboro is an existing dialysis care facility, not a new facility; therefore, Basic Principle 2 is not applicable to the review of this application.

North Randolph Dialysis. North Randolph dialysis proposes to develop a 10-station dialysis facility in Randolph County, pursuant to Policy ESRD-2 and a projected 10-station deficit in Randolph County in the 2014 SMFP and the January 2014 SDR. Basic Principle 2 regarding the projection of need for additional dialysis stations is applicable to the review of this application. North Randolph Dialysis proposes a projected need for at least 10 stations in its application and is consistent with Basic Principle 2. However, approval of only a portion of North Randolph Dialysis’ application (less than 10 stations) would not be consistent with Basic Principle 2 or the Performance Standards for dialysis facilities, as promulgated in 10A NCAC 14C .2203(a).

Basic Principle 6

Basic Principle 6 regarding expanding an existing facility as outlined in Chapter 14, page 360, of the 2014 SMFP states

“No existing facility may expand unless its utilization is 80 percent or greater. Any facility at 80 percent utilization or greater may apply to expand.”

BMA Asheboro. BMA Asheboro proposes to relocate two dialysis stations from BMA South Greensboro (Guilford County) to BMA Asheboro (Randolph County), pursuant to Policy ESRD-2 and a projected 10-station deficit in Randolph County. Basic Principle 6 regarding expanding an existing facility is applicable to the review of this application. In Section III.7, page 43, and Section IV, page 47, the applicant indicates that as of December 31, 2013, BMA Asheboro had 46 stations with 101 total in-center patients and was operating at a 54.89% utilization rate [$101 / 46 = 2.1957$; $2.2 / 4 = 55\%$]. BMA Asheboro is not at 80% or greater utilization and according to the applicant on page 43, is not projected to be at 80% utilization, for four years, until December 31, 2017, which is the end of OY1. Therefore, BMA Asheboro’s application is not consistent with Basic Principle 6.

North Randolph Dialysis. North Randolph Dialysis is not an existing dialysis care facility; therefore, Basic Principle 6 is not applicable to the review of this application.

Basic Principle 12

Basic Principle 12 regarding the availability of dialysis care as contained in Chapter 14, page 361, of the 2014 SMFP states

“The North Carolina State Health Coordinating Council encourages applicants for dialysis stations to provide or arrange for:

- a. Home training and backup for patients suitable for home dialysis in the ESRD dialysis facility or in a facility that is a reasonable distance from the patient’s residence;*
- b. ESRD dialysis service availability at times that do not interfere with ESRD patients’ work schedules;*
- c. Services in rural, remote areas.”*

a. Home Training

BMA Asheboro. In Section II.2, page 29, the applicant states, *“Patients who wish to perform dialysis at home, and have both the capability and supportive home environment, will be referred to the facility Home Training department. There the patient will be trained in either peritoneal dialysis (CAPD or CCPD) or hemodialysis.”* In Section V.2, page 51, the applicant states

“Currently, patients who desire to perform home dialysis will be trained and followed by the facility home training program. Patients who are candidates for home dialysis are referred by their attending nephrologists to facility Home Training Clinic. The

applicant will provide back-up hemo-dialysis treatments to any home patient in need of temporary hemo-dialysis.

Services offered to home patients include home visitation, assistance with problems that patients have with catheters; diagnosis of infections and assistance with placing orders of needed supplies. Social work and dietary assessments are provided for those patients on an ongoing basis. Patients are given EPO at the facility or taught to administer it to themselves at home. Laboratory testing of blood samples may be provided by the facility as prescribed by the physician.”

In Section II.2, page 29, the applicant states the home training program will be backed up by the home training program of BMA Greensboro and as a result can offer many cost containment advantages.

North Randolph Dialysis. In Section V.2, page 32, the applicant states

“WFUHS has an extensive home training (“HT”) and support program available in every county it serves. In counties where WFUHS does not offer home training or at WFUHS facilities where home training is not offered on site, sister facility agreements are in place, which allow patients who qualify to receive HT services at another “sister” WFUHS dialysis facility. Through the home training agreement, patients are provided medical services, nurse directed training and support services, social work counseling services, dietetic teaching and counseling, and telephone access 24 hours per day, 7 days per week.

Training and support for home dialysis patients is developed, conducted, and managed by registered nurses in consultation with the Medical Director who is a Board Certified Nephrologist.

...

NRDC will provide ICH services as well as home dialysis training and support services for all modalities of dialysis, offering a full range of dialysis options to its patients.”

With respect to home training, both applications are equally effective alternatives, since both applicants are providing or proposing to provide home dialysis training and support services.

b. Hours of Availability

BMA Asheboro. In Section VII.10, page 62, the applicant states dialysis services will be available from 7:00 a.m. to 5:00 p.m., Monday through Saturday, for a total of 10 hours per day and 60 hours per week. BMA Asheboro does not propose a third or evening shift.

North Randolph Dialysis. In Section VII.10, page 49, the applicant states dialysis services will be available from 6:30 a.m. to 10:00 p.m., Monday through Saturday, for a total of 15.5 hours per day and 93 hours per week. This schedule includes an evening shift.

With respect to hours of availability, **North Randolph Dialysis** is the most effective alternative because it proposes to offer three shifts for a total of 15.5 hours per day and is scheduled to be open 6 days a week. **BMA Asheboro** is an effective alternative because it proposes to offer a first and second shift for a total of 10 hours per day and is scheduled to be open 6 days a week. BMA Asheboro is not proposing a third shift.

c. Services in Rural, Remote Areas

Both applicants are proposing to provide services to Randolph County residents. Both applications are equally effective with regard to providing services in Randolph County.

Facility Location

BMA Asheboro is an existing facility located in Asheboro.

North Randolph Dialysis is proposing locations in northwest Randolph County near Trinity or Archdale. All three sites identified by the applicant are adequate for the proposed facility. The applicant states the proposed locations provide better geographic access for its current Randolph County patients.

Both applications are equally effective alternatives based on facility location.

Access by Underserved Groups

BMA Asheboro. In Section VI.1, page 56, the applicant states that 86.23% of its in-center patients (80.07% Medicare + 6.16% Medicaid) and 82.83% of its home care patients (82.83% Medicare + 0.00% Medicaid) will have some or all of their services covered by Medicare or Medicaid. In Section VI.1, page 55, the applicant states “... *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.*” Since North Randolph Dialysis combined both in-center and home patients in its projections, the project analyst combined the in-center and home Medicare/Medicaid patients projected by BMA Asheboro in OY1 and determined 86% of its in-center and home patients will have some or all of their services covered by Medicare or Medicaid as shown below.

	(# of patients X % of patients = % In-Center Medicare patients)
Medicare:	
In-Center	(154 X 0.8007 = 123.31);
Home	(11 X 0.8283 = 9.11);
Total Medicare	(123.31 + 9.11 = 132.42); 132.42 / 165 = 0.8025 or 80.25%

Medicaid:

In-Center (154 X 0.0616 = 9.49);

Total Medicaid (9.49 / 154 = 0.0616) or 6.16% Medicaid patients

Total projected Medicare and Medicaid patients at BMA Asheboro: 86%
(80.25% + 6.16% = 86.41%)

North Randolph Dialysis. In Section VI.1, page 37, the applicant states that 85% of its in-center and home patients will have some or all of their services covered by Medicare or Medicaid (81% Medicare and 4% Medicaid). The applicant states *“The total percentage of services delivered to Medicare primary payors (Medicare, Medicare/Medicaid, Medicare/Commercial, and Medicare Advantage) represent 81% of all services provided to Randolph County dialysis patients.”*

Generally, the application proposing the highest Medicare/Medicaid percentage is the most effective alternative with regard to this comparative factor. Since BMA Asheboro’s combined Medicare and Medicaid payor mix is 86% and North Randolph Dialysis’ combined Medicare and Medicaid payor mix is 85%, **BMA Asheboro** is the more effective application with regard to access by underserved groups.

Access to Ancillary and Support Services

BMA Asheboro. In Section V.1-2, pages 50-51, the applicant lists the providers of the necessary ancillary and support services. In Exhibits 15, 19, 21, and 25-26, the applicant documents how the project will be coordinated with the existing health care system. In Section V.5, page 53, the applicant states

“BMA Asheboro has been serving the needs of dialysis patients for many years. These years of experience have included forged relationships with physicians, local hospitals, and other health professionals within the community. The BMA Asheboro facility enjoys a warm relationship with the medical community of Randolph County.”

North Randolph Dialysis. In Section V.1-2, pages 30-31, the applicant lists the providers of the necessary ancillary and support services. In Attachments E-F, K-L, O, R, R-2, and S the applicant documents how the project will be coordinated with the existing health care system. On page 31, the applicant states

“The patients of NRDC are fortunate to have access to Wake Forest Baptist Medical Center (“WFBMC”), Winston-Salem, North Carolina. WFBMC is well equipped to provide care for the ESRD patients of NRDC. ... In Nephrology, WFBMC is ranked #9 nationally.”

With regard to access to ancillary and support services, both applications are equally effective alternatives.

Service to Randolph County Residents

BMA Asheboro. In Section II.1, page 15, the applicant states that as of December 31, 2013, BMA Asheboro served 98 in-center dialysis patients and 6 home dialysis patients who are residents of Randolph County. In Section V.4, page 62, the applicant states Carolina Kidney Associates is a group of nephrologists practicing in the Greensboro Triad area providing care for patients dialyzing at BMA Asheboro. Exhibit 21 contains physician letters of support.

North Randolph Dialysis. In Section II.1, pages 15-16 the applicant states that WFUHS currently serves 39 in-center dialysis patients and 13 home dialysis patients who are residents of Randolph County. All of the WFUHS Randolph County dialysis patients reside within 30 miles of the proposed facility, in northwest Randolph County.

In Attachment R, North Randolph Dialysis provides a signed letter from Dr. John M. Burkart, confirming interest and willingness to serve as the Medical Director for the proposed North Randolph Dialysis facility. In Section V.4, page 34, the applicant states,

“Due to the history of quality care provided by WFUHS dialysis facilities, and their relationship with WFUHS, local physicians routinely refer patients to nephrologists on staff at WFBMC. The facility has developed relationships with these physicians to coordinate the care of the patient and routinely work with these local physicians for transfer of medical information to ensure a continuum of care. Due to WFUHS’ existing patient base, there are long-standing working relationships in place with local physicians and healthcare organizations.”

Attachment R contains physician letters of support.

With regard to service to Randolph County residents, both applications are equally effective alternatives.

Access to Alternative Providers

Fresenius Medical Care Holdings, Inc., the parent company of BMA Asheboro operates the only dialysis facility in Randolph County. Therefore, with regard to providing dialysis patients with access to an alternative provider, the proposal submitted by **North Randolph Dialysis** is the more effective alternative.

Revenues and Operating Costs

In Section X of the application, each applicant projects the revenues and operating costs for the first two operating years of the proposed project. Generally, the application proposing the lowest average net revenue per treatment and the lowest average operating cost per treatment is the most effective alternative.

Average Net Revenue per Treatment

In order to consider the same calendar year for both applications, calendar year 2017 was compared for both applicants.

BMA Asheboro In-Center Treatment	OY1 CY 2017
Projected Net Revenue	\$6,772,839.00
# In-Center	21,441
Average Net Revenue per Treatment	\$315.88

North Randolph Dialysis In-Center Treatment	OY2 CY 2017
Projected Net Revenue	\$2,372,494.00
# In-Center Treatments	8,379
Average Net Revenue per Treatment	\$283.15

BMA Asheboro Home Treatment	OY1 CY 2017
Projected Net Revenue	\$553,561.00
Home Treatments	1,296
Average Net Revenue per Treatment	\$427.13

North Randolph Dialysis Home Treatment	OY2 CY 2017
Projected Net Revenue	\$754,160.00
Home Treatments*	2,671
Average Net Revenue per Treatment	\$282.35

*Source: Section X.3, page 62, of application.

North Randolph Dialysis projects the lowest average net revenue per treatment. With regard to average net revenue per treatment, **North Randolph Dialysis** is the most effective alternative.

Average Operating Cost per Treatment

In order to consider the same calendar year for both applications, calendar year 2017 was compared for both applicants.

BMA Asheboro	OY1 CY 2017
Projected Operating Costs	\$5,873,438.00
# In-Center + Home Treatments	22,738
Average Operating Cost per Treatment	\$258.31

North Randolph Dialysis	OY2 CY 2017
Projected Operating Costs	\$2,678,921.00
# In-Center + Home Treatments	11,050
Average Operating Cost per Treatment	\$242.44

North Randolph Dialysis projects the lowest average operating cost per treatment. With regard to average operating cost per treatment, **North Randolph Dialysis** is the most effective alternative.

Staffing

Direct Care Staff Salaries

The following table illustrates projected annual salaries during 2017 for direct care staff (registered nurses and technicians) as reported in Section VII.1 of the respective applications.

Position	BMA Asheboro	North Randolph Dialysis
Registered Nurse	\$58,787	\$59,904.80
Home Training Nurse	\$61,058	\$59,904.80
Technicians	\$27,894	\$28,817.34

North Randolph Dialysis projects the higher annual salary for registered nurses, however BMA Asheboro projects the higher annual salary for home training nurses. Therefore, both applications are equally effective alternatives with respect to nurses. North Randolph Dialysis projects a higher annual salary for technicians. Therefore **North Randolph Dialysis** is the more effective alternative with respect to technician salaries. Note: If BMA Asheboro had included a 3% increase for 2015 and 2016, as stated on page 78, BMA Asheboro would have projected the higher annual salary for RN's, home training nurses, and technicians.

Availability of Staff and Medical Director

Both applicants projected sufficient shifts and a sufficient number of direct care staff for the projected number of patients to be served in Year Two. Each has budgeted sufficient staff salaries. See discussion in Criterion (7).

BMA Asheboro identified Joseph Coladonato, MD as its medical director. Dr. Coladonato is currently the medical director and has agreed to continue serving as the medical director of BMA Asheboro.

North Randolph Dialysis identified John M. Burkart, MD as its initial Medical Director.

The two applications are comparable with regard to the availability of staff and medical director.

SUMMARY

Conformity with Review Criteria

The application submitted by **North Randolph Dialysis** is conforming to all applicable statutory and regulatory review criteria. However, the application submitted by **BMA Asheboro** is not conforming to all statutory and regulatory review criteria. See Criteria (3), (4), (5), (6), (18a) and 10 NCAC 14C .2203 for discussion.

For each of the comparative analysis factors listed below, the applications were determined to be equally effective:

- Facility Location
- Access to Ancillary and Support Services
- Service to Randolph County Residents
- Nurses Salary (RN + Home Training)
- Availability of Staff and Medical Director

For each of the comparative analysis factors listed below, the application submitted by North Randolph Dialysis was determined to be the more effective alternative. Note: The comparative factors are listed in the same order they are discussed in the Comparative Analysis, which should not be construed to indicate an order of importance.

Comparative Factors	BMA Asheboro	North Randolph Dialysis
SMFP Principles	Nonconforming	Conforming
Access by Underserved Groups	More Effective	Effective
Access to Alternative Providers	Effective	More Effective
Average Net Revenue per Treatment	Effective	More Effective
Average Operating Cost per Treatment	Effective	More Effective
Technician Salary	Effective	More Effective
Conforming to all Review Criteria	No	Yes

CONCLUSION

The 2014 State Medical Facilities Plan (2014 SMFP) and the January 2014 Semiannual Dialysis Report (January 2014 SDR) identify a 10-station deficit for Randolph County. Pursuant to Policy ESRD-2 and 10A NCAC 14C .0202(f), 10 dialysis stations is the limit on the number of dialysis stations that may be approved in this review. The CON Section determined that the application submitted by North Randolph Dialysis is the more effective alternative proposed in this review. Approval of only a portion of North Randolph Dialysis' application (less than 10 stations) would not be consistent with the Performance Standards for dialysis facilities, as promulgated in 10A NCAC 14C .2203(a), which requires an applicant to document the need for at least 10 stations. Therefore, the application submitted by North Randolph Dialysis is approved as conditioned below.

- 1. Wake Forest University Health Sciences and North Randolph Dialysis Center of Wake Forest University shall materially comply with all representations made in its certificate of need application.**
- 2. Wake Forest University Health Sciences and North Randolph Dialysis Center of Wake Forest University shall develop and operate no more than 10 dialysis stations at North Randolph Dialysis Center, which shall include any isolation stations and home hemodialysis training stations.**
- 3. Wake Forest University Health Sciences and North Randolph Dialysis Center of Wake Forest University shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation stations and home hemodialysis training stations.**
- 4. Wake Forest University Health Sciences shall take the necessary steps to decertify 10 dialysis stations at High Point Kidney Center of Wake Forest University for a total of no more than 32 dialysis stations at High Point Kidney Center of Wake Forest University.**
- 5. Wake Forest University Health Sciences and North Randolph Dialysis Center of Wake Forest University shall provide the site location address chosen for the new facility, based on the three potential site locations proposed in the application.**
- 6. Wake Forest University Health Sciences and North Randolph Dialysis Center of Wake Forest University shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**