ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: January 20, 2012
PROJECT ANALYST: Lisa Pittman
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: C-8732-11/ Dialysis Clinic, Inc. d/b/a DCI Shelby/ Add 4 stations to current dialysis facility / Cleveland County

C-8733-11/ Dialysis Clinic, Inc. d/b/a DCI Boiling Springs/ Add 4 stations to current dialysis facility / Cleveland County

C-8756-11/ Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC Cleveland County/ Relocate 10 existing stations into Cleveland County to develop a new 10-station dialysis facility / Cleveland County

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
DCI Shelby
DCI Boiling Springs
FMC Cleveland

The 2011 State Medical Facilities Plan (SMFP) and the July 2011 Semiannual Dialysis Report (SDR) provide a county need methodology for determining the need for additional dialysis stations. According to the county need methodology, found on page 350 of the 2011 SMFP, *"If a county's December 31, 2011 projected station deficit is 10 or greater and the July SDR shows that utilization of each dialysis facility in the county is 80*

percent or greater, the December 31, 2011 county station need determination is the same as the December 31, 2011 projected station deficit. If a county's December 31, 2011 projected station deficit is less than 10 or if the utilization of any dialysis facility in the county is less than 80 percent, the county's December 31, 2011 station need determination is zero." Although the July 2011 SDR shows a deficit of 11 stations, the county need methodology results in a need determination of zero additional dialysis stations in Cleveland County.

Following is a description of the three proposals submitted in this review:

C-8732-11 Dialysis Clinic, Inc. d/b/a DCI Shelby proposes to add 4 stations to the current DCI Shelby dialysis facility in Cleveland County in response to the facility need methodology. In Section VIII.1, page 83, the applicant states the project will require the addition of dialysis machines, chairs, and patient TVs. DCI Shelby currently has 25 certified dialysis stations, including one station for isolation patients; therefore, after completion of this project, DCI Shelby will have a facility total of 29 dialysis stations, including one isolation station. DCI Shelby is eligible to apply for additional stations in its existing facility based on the facility need methodology.

The utilization rate reported for DCI Shelby in the June 2011 SDR is 3.64 patients per station. This utilization rate was calculated based on 91 in-center dialysis patients and 25 certified dialysis stations as of December 31, 2010 (91 patients / 25 stations = 3.64 patients per station). Therefore, application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

DCI Shelby Utilization and Needs

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/10		91.0%
Certified Stations		25
Pending Stations		0
Total Existing and Pending Stations		**25**
In-Center Patients as of 12/31/10 (SDR2)		91
In-Center Patients as of 06/30/10 (SDR1)		90
Difference (SDR2 - SDR1)		1
Step	Description	
(i)	Multiply the difference by 2 for the projected net in-center change	2
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/10	0.0222
(ii)	Divide the result of Step (i) by 12	0.0019
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the July 2011 SDR (12/31/10) until the end of calendar year 2010 (12 months)	0.0222
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	93.0222
(v)	Divide the result of Step (iv) by 3.2 patients per station	29.0694
	and subtract the number of certified and pending stations as recorded in SDR2 [25] to determine the number of stations needed	4

Step C of the facility need methodology states *"The facility may apply to expand to meet the need established in (2)(B)(v)* [Step (v) in the table above], *up to a maximum of ten stations."* Based on the facility need methodology for dialysis stations, the number of stations needed at DCI Shelby is four and the applicant proposes to add no more than four new stations. Therefore, the DCI Shelby application is consistent with the facility need determination for dialysis stations.

C-8733-11 Dialysis Clinic, Inc. d/b/a DCI Boiling Springs proposes to add 4 stations to the current DCI Boiling Springs dialysis facility in Cleveland County in response to the facility need methodology. In Section VIII.1, page 83, the applicant states the project will require the addition of dialysis machines, chairs, patient TVs and plumbing. DCI Boiling Springs currently has 10 certified dialysis stations, including one station for isolation patients; therefore, after completion of this project, DCI Boiling Springs will have a facility total of 14 dialysis stations, including one isolation station. DCI Boiling Springs is eligible to apply for additional stations in its existing facility based on the facility need methodology.

The utilization rate reported for DCI Boiling Springs in the July 2011 SDR is 3.20 patients per station. This utilization rate was calculated based on 32 in-center dialysis patients and 10 certified dialysis stations as of December 31, 2010 (32 patients / 10 stations = 3.20 patients per station). Therefore, application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

DCI Boiling Springs Utilization and Needs

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/10		80.0%
Certified Stations		10
Pending Stations		0
Total Existing and Pending Stations		**10**
In-Center Patients as of 12/31/10 (SDR2)		32
In-Center Patients as of 6/30/10 (SDR1)		26
Difference (SDR2 - SDR1)		6
Step	Description	
(i)	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/10	0.4615
(ii)	Divide the result of Step (i) by 12	0.0385
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the July 2011 SDR (12/31/10) until the end of calendar year 2011 (12 months)	0.4615
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	46.7692
(v)	Divide the result of Step (iv) by 3.2 patients per station	14.6154
	and subtract the number of certified and pending stations as recorded in SDR2 [10] to determine the number of stations needed	5

Step C of the facility need methodology states *"The facility may apply to expand to meet the need established in (2)(B)(v)* [Step (v) in the table above], *up to a maximum of ten stations."* Based on the facility need methodology for dialysis stations, the number of stations needed at DCI Boiling Springs is five and the applicant proposes to add no more than five new stations. Therefore, the DCI Boiling Springs application is consistent with the facility need determination for dialysis stations.

C-8759-11 Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC Cleveland County proposes to establish a 10-station dialysis facility by relocating two stations from BMA Burke County, an existing 25-station dialysis facility in Burke County; six stations from BMA Hickory, an existing 33-station dialysis facility in Catawba County; one station from BMA Lincolnton, an existing 25-station dialysis facility in Lincoln County; and one station from BMA Kings Mountain, an existing 14-station facility in Gaston County. Therefore, neither of the need methodologies in the 2011 SMFP is applicable to the review of this application. However, 2011 SMFP Policy ESRD-2: Relocation of Dialysis Stations is applicable in this review to FMC Cleveland. Policy ESRD-2: Relocation of Dialysis Stations, found on page 33 of the SMFP, states:

> *"Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:*
>
> 1. *demonstrate that the proposal shall not result in a deficit in the number of Dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
>
> 2. *demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report."*

The following table reflects the projected station deficit/surplus for the four counties from which BMA proposes to relocate stations.

	Current Projected Station Surplus (Deficit)	Proposed # Stations to be Relocated Out of County	Projected Station Surplus (Deficit) After Proposed Relocation
Burke County	2	2	0
Catawba County	6	6	0
Gaston County	2	1	1
Lincoln County	1	1	0

Source: July 2011 SDR for 12/30/10.

Cleveland County, the county into which the applicant proposes to move stations, has a projected station deficit of 11, as of the July 2011 SDR. Therefore, because the proposed relocation will not leave counties loosing stations with a deficit and will not create a surplus in the county where the relocated stations move, BMA is eligible to apply to relocate 10 existing stations into Cleveland County and develop a new 10 station dialysis facility based on Policy ESRD-2: Relocation of Dialysis Stations.

Additionally, Policy GEN-3: Basic Principles in the 2011 SMFP is applicable in this review to DCI Shelby and DCI Boiling Springs because their proposals are based on the facility need determination of the SMFP. BMA's application is not based on a need

determination in the SMFP therefore Policy GEN-3 is not applicable to its review. Policy GEN-3 Basic Principles states:

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

The applicants respond to Policy GEN-3 as follows:

DCI Shelby

Promote Equitable Access
In Section VI.1(a), page 73, **DCI Shelby** states:

> *"As discussed throughout this application, DCI is a not-for-profit corporation that was created solely to meet the needs of dialysis patients. This commitment to patient need has remained strong not only at the corporate level but also at the clinic level. Because of this commitment, DCI willingly serves* ***any and all population groups*** *without regard to income, race or ethnic minority, sex, ability, age, or any perceived underserved status. ... Locally, during FY 2010, DCI Shelby incurred more than $635,000 in bad debt and charity care. The amount is approximately 10 percent of the Shelby clinic's gross revenue. DCI's commitment to its patients is exemplified in its admission policy and its equal treatment policy. Please see Exhibit 6 for copies of these policies."* [Emphasis in original.]

In Section VI.1(b), page 73, DCI Shelby reports that 86.5% of the patients who received treatment at DCI Shelby had some or all of their services paid for by Medicare or Medicaid. The applicant demonstrates that it currently provides adequate access to medically underserved populations.

In Section VI.2, page 76, the applicant states

> *"As an existing Medicare approved facility, DCI Shelby is in full compliance with all Americans with Disabilities Act requirements as well as Section 11.X of the North Carolina building code."*

In Section VI.7, page 78, the applicant states

> *"The equal treatment policy of DCI states, 'No patient will be denied services or be otherwise treated in a discriminatory manner because of any disease, illness or disability.' DCI treats all patients deemed appropriate for dialysis care by the nephrologists who refer to the dialysis center. DCI's acceptance of patients includes behavioral issues as well. ... DCI is willing to accept* ***any*** *patient that is in need of dialysis care."* [Emphasis in original.]

The applicant adequately demonstrates how the proposal will promote equitable access to the proposed services.

Promote Safety and Quality

In Section II.3, pages 42-43, the applicant states:

> *"DCI has exceptionally high quality standards which are not only obvious in the clinics themselves but are recognized nationally by quality organizations. For example, the most recent annual report from the United States Renal Data System (URDS) found that DCI clinics consistently rank at the top in many of the important ESRD categories related to outpatient care. Specifically, the data indicate that:*
>
> - *DCI has lower mortality rates than other providers;*
> - *DCI has lower hospitalization rates than other providers;*
> - *DCI is most consistent at meeting target hemoglobin levels/* [sic]
> - *DCI is best at maintaining hemoglobin levels for three months or more;*
> - *DCI patients are staying at hemoglobin levels longer than patients with other providers;*
> - *DCI has a higher percentage of patients in their target hemoglobin range of 10-12 grams/deciliter;*
> - *DCI has fewer patient*[s] *likely to exceed hemoglobin levels of 12, 13, 14; and*
> - *DCI is the national provider with the lowest monthly cost to CMS at $1,366 per patient per month compared to a national average of $1,425 per patient per month.*
>
> ...
>
> *Locally, DCI utilizes a team approach to the quality improvement process. ... Realistic goals, which promote safe, therapeutically effective and individualized care for each patient, are defined in the patient care plan."*

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

Maximize Healthcare Value

In Section III.9, pages 54-55, DCI Shelby discusses how this was its most effective alternative:

"As described throughout this application, DCI's primary focus and commitment is to its patients. Meeting their needs is DCI's first priority. ... This project is the result of a careful evaluation of patient needs at DCI Shelby.

The 'July 2011 Semiannual Dialysis Report' indicates a facility need of four stations for DCI Shelby. In order to determine the appropriateness of adding four stations, DCI considered other alternatives."

The applicant states that it considered maintaining the status quo, operating a third shift and the current proposal adding stations in the existing facility.

The applicant adequately demonstrates the proposal will maximize healthcare value. Additionally, the applicant demonstrates projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. See Criteria (3) and (13c) for additional discussion.

The application is consistent with Policy GEN-3 and is conforming to this criterion.

DCI Boiling Springs

Promote Equitable Access
In Section VI.1(a), page 73, **DCI Boiling Springs** states:

"As discussed throughout this application, DCI is a not-for-profit corporation that was created solely to meet the needs of dialysis patients. This commitment to patient need has remained strong not only at the corporate level but also at the clinic level. Because of this commitment, DCI willingly serves ***any and all population groups*** *without regard to income, race or ethnic minority, sex, ability, age, or any perceived underserved status. ... Locally, DCI Boiling Springs has incurred more than $49,486 in bad debt and charity care during FY 2010. DCI's commitment to its patients is exemplified in its admission policy and its equal treatment policy. Please see Exhibit 5 for copies of these policies."* [Emphasis in original.]

In Section VI.1(b), page 73, DCI Boiling Springs reports that 85.3% of the patients who received treatment at DCI Boiling Springs had some or all of their services paid for by Medicare or Medicaid. The applicant demonstrates that it currently provides adequate access to medically underserved populations.

In Section VI.2, page 76, the applicant states:

"As an existing Medicare approved facility, DCI Boiling Springs is in full compliance with all Americans with Disabilities Act requirements as well as Section 11.X of the

North Carolina building code. Because the Boiling Springs clinic was constructed specifically for dialysis use, the building is fully accessible, with no barriers to any patient, even those with physical disabilities or with visual impairments."

In Section VI.7, page 78, the applicant states

"The equal treatment policy of DCI states, 'No patient will be denied services or be otherwise treated in a discriminatory manner because of any disease, illness or disability.' DCI treats all patients deemed appropriate for dialysis care by the nephrologists who refer to the dialysis center. DCI's acceptance of patients includes behavioral issues as well. ... Clearly, DCI is willing to accept ***any*** *patient that is in need of dialysis care."* [Emphasis in original.]

The applicant adequately demonstrates how the proposal will promote equitable access to the proposed services.

Promote Safety and Quality

In Section II.3, pages 40-41, the applicant states:

"DCI has exceptionally high quality standards which are not only obvious in the clinics themselves but are recognized nationally by quality organizations. For example, the most recent annual report from the United States Renal Data System (URDS) found that DCI clinics consistently rank at the top in many of the important ESRD categories related to outpatient care. Specifically, the data indicate that:

- *DCI has lower mortality rates than other providers;*
- *DCI has lower hospitalization rates than other providers;*
- *DCI is most consistent at meeting target hemoglobin levels/* [sic]
- *DCI is best at maintaining hemoglobin levels for three months or more;*
- *DCI patients are staying at hemoglobin levels longer than patients with other providers;*
- *DCI has a higher percentage of patients in their target hemoglobin range of 10-12 grams/deciliter;*
- *DCI has fewer patient*[s] *likely to exceed hemoglobin levels of 12, 13, 14; and*
- *DCI is the national provider with the lowest monthly cost to CMS at $1,366 per patient per month compared to a national average of $1,425 per patient per month.*

...

Locally, DCI uses a team approach to the quality improvement process. ... Realistic goals, which promote safe, therapeutically effective and individualized care for each patient, are defined in the patient care plan."

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

Maximize Healthcare Value

In Section III.9, pages 54-55, DCI Boiling Springs discusses how this was its most effective alternative:

> *"As described throughout this application, DCI's primary focus and commitment is to its patients. Meeting their needs is DCI's first priority. ... This project is the result of a careful evaluation of patient needs at DCI Boiling Springs.*
>
> *The July 2011 Semiannual Dialysis Report indicates a facility need of five stations for DCI Boiling Springs. In order to determine the appropriateness of adding four or five stations, DCI considered these alternatives."*

The applicant states that it considered maintaining the status quo, operating a third shift, adding five additional stations and the current proposal of adding four stations in the existing facility.

The applicant adequately demonstrates the proposal will maximize healthcare value. Additionally, the applicant demonstrates projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. See Criteria (3) and (13c) for additional discussion.

The application is consistent with Policy GEN-3 and is conforming to this criterion.

In this review, 2011 SMFP Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities is not applicable to any of the three applicants.

Policy Gen-4 states in part *"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."*

The capital costs of the **DCI Shelby** and **DCI Boiling Springs** proposed projects are $66,000 and $70,000, respectively; therefore Policy Gen-4 is not applicable to either project. **FMC Cleveland**'s proposed project involves a new health service facility; however the capital cost of the proposed project is less than $2 million ($857,751); therefore, Policy Gen-4 is not applicable to the FMC Cleveland project.

Three applications were received by the Certificate of Need Section, proposing to develop a total of 18 new dialysis stations. However, pursuant to facility need determination, Policy ESRD-2 and an 11-station county station deficit, 11 is the limit on the number of new dialysis stations that may be approved in this review for Cleveland County. A competitive review of these applications began on October 1, 2011.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C
DCI Shelby

CA
DCI Boiling Springs

NC
FMC Cleveland

DCI Shelby, located at 1610 North Lafayette Street in Shelby, proposes to add four additional stations for a total of 29 stations following completion of the project. The June 2011 SDR indicates a total of 25 certified station at DCI Shelby, as of December 31, 2010.

Population to be Served
The following table illustrates the current patient origin at DCI Shelby, as reported in Section IV.1, page 59.

DCI Shelby - Patient Origin as of 6/30/11

County of Residence	# Patients Dialyzing In-Center	# Patients Dialyzing at Home
Cleveland	85	13
Gaston	12	2
Lincoln	1	2
Cherokee, SC	0	2
Total	**98**	**19**

In Section III.7, page 54, the applicant provides the projected patient origin for the first two years of operation following completion of the proposed project, as illustrated in the following table:

DCI Shelby - Projected Patient Origin

County	Year One FFY12		Year Two FFY13		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis Patients	In-Center Patients	Home Dialysis Patients	Year 1	Year 2
Cleveland	80	16	82	16	83.7%	83.7%
Gaston	12	2	12	2	12.0%	12.0%
Lincoln	3	1	3	1	2.6%	2.6%
Cherokee, SC	1	0	1	0	1.7%	1.7%
TOTAL	**96**	**19**	**98**	**19**	100.0%	100.0%

The applicant adequately identified the population proposed to be served.

Need for the Proposed Stations

The applicant proposes to add four stations to the DCI Shelby facility. The DCI Shelby facility is currently certified for 25 stations. In Section III.2, pages 47-51, the applicant describes the need methodology and assumptions it used to project the number of patients to be served in each of the first two operating years following project completion. The July 2011 SDR states that the Five Year Average Annual Change Rate for Cleveland County is 4.1%. However, based on the ESRD Facility Need Methodology, DCI Shelby used its current in-center patient growth rate of 2.2% to project utilization through Year 2. The growth rate was only applied to in-center patients. DCI Shelby's current low growth rate reflects the patients who transferred to the DCI Shelby South facility which opened in June 2010.

In Section III.2, pages 48-51, the applicant provides its methodology, including the projected utilization for the first two project years:

"As demonstrated in the table above, DCI currently needs 4.0 additional stations in order to meet the facility need....total patients were projected using the State [sic] *need methodology as defined in the 'July 2011 Semiannual Dialysis Report.' As shown in the table above, DCI is expected to care for 93 in-center patients by the end of 2011, which is a conservative methodology as DCI Shelby is currently providing care to 98 in-center patients at DCI Shelby. ... Based on this same methodology (Step 2), the growth rate of 2.2 percent has been projected forward through 2014, as shown in the table below.*

Year	*Total In-Center Patients*	*Annual Growth Rate^*
2010	*90*	*2.2%*
2011	*93*	*2.2%*
2012	*95*	*2.2%*
2013	*97*	*2.2%*
2014	*99*	*2.2%*

^Based on Step 2 of the methodology table.

... Since the project is expected to begin July 1, 2012, DCI converted the calendar year projections above to project years. Patient volume for PY 1 is calculated as the sum of one-half of the patient volume for 2012 and one-half of the patient volume for 2013; volume for PY 2 is the sum of one-half of the volume for 2013 and one-half of the patient volume for 2014, as shown in the following table.

Year	*Total In-Center Patients*
PY 1	*96*
PY 2	*98*

DCI Shelby is the clinic that cares for all the in-home patients served by DCI, even those that originate at one of the other DCI clinics. As shown in the table below, during the past twelve months, the number of DCI patients home trained and on peritoneal dialysis has not changed. Typically peritoneal dialysis patients are far less in number than in-center patients and the total number home trained and on peritoneal dialysis does not fluctuate a great deal. For this reason, DCI is projecting a flat in-home growth rate through project year two.

Year	*Total In-Home Patients*	*% Change from Prior Year*
2010	*19*	*0%*
2011	*19*	*0%*
PY 1	*19*	*0%*
PY 2	*19*	*0%*

The following table summarizes the estimated volume at the DCI Shelby location through the second project year.

Year	*Total In-Center Patients*	*Total In-Home Patients*	*Total*
2010	*91*	*19*	*110*
2011	*93*	*19*	*112*
PY 1	*96*	*19*	*115*
PY 2	*98*	*19*	*117*

In order to determine the need for additional stations based on utilization of 3.2 patients per station per week as of the end of the second project year, DCI used the SDR methodology (Step #6) and the total in-center patients as projected above.

Year	*Total In-Center Patients*	*Patients per Station*	*# Existing Stations*	*Total Stations Needed*	*Additional Stations Needed*
2010	*91*	*3.2*	*25*	*28*	*3*
2011	*93*	*3.2*	*25*	*29*	*4*
PY 1	*96*	*3.2*	*29*	*30*	*1*
PY 2	*98*	*3.2*	*29*	*31*	*2*

As shown in the table above, DCI currently needs four additional stations and, even with the proposed increase of four stations is expected to need an additional station by the end of the first project year."

The following table illustrates the applicant's projected number of patients based on the above stated assumptions and utilizing a 2.2% average annual increase for DCI Shelby.

Existing DCI Shelby In-Center Patients as of 12/31/10	91
Jan. 2011 - Dec. 2011	91 x 1.022 = 93.0020
Jan. 2012 - Dec. 2012	93.0020 x 1.022 = 95.0480 80 Cleveland County in-center patients + 11 Gaston County in-center patients + 2 Lincoln County in-center patients + 2 Cherokee, SC in-center patients for a total of 95 projected patients.
Jan. 2013 – Dec. 2013	95.0480 x 1.022 = 97.1390 81 Cleveland County in-center patients + 12 Gaston County in-center patients + 2 Lincoln County in-center patients + 2 Cherokee, SC in-center patients for a total of 97 projected patients.
Jan. 2014 – Dec 2014	97.1390 x 1.022 = 99.2760 83 Cleveland County in-center patients + 12 Gaston County in-center patients + 2 Lincoln County in-center patients + 2 Cherokee, SC in-center patients for a total of 99 projected patients.

[To convert calendar years to project years:
Project Year 1 = ½ x CY12 + ½ x CY13 = 95/2 + 97/2 = 47.5 + 48.5 = 96
Project Year 2 = ½ x CY13 + ½ x CY14 = 97/2 + 99/2 = 48.5 + 49.5 = 98]

The following shows the number of in-center patients per station per week and the utilization rate for each of the first two operating years following completion of the project.

Year 1 (July 1, 2012- June 30, 2012)
Patients/Station/Week: 96 in-center patients dialyzing on 29 stations = 3.31
Utilization Rate: 96 patients / (4 shift-cycles per week x 29 stations) = 96 / 116 = .8276 or 83% utilization.

Year 2 (July 1, 2013- June 30, 2013)
Patients/Station/Week: 98 in-center patients dialyzing on 29 stations = 3.38
Utilization Rate: 98 patients/ (4 shift-cycles per week x 29 stations) = 98 / 116 = .8448 or 84% utilization.

Projected utilization at the end of Year 1 equals at least 3.2 in-center patients per station per week as required by 10A NCAC 14C .2203(b). The number of in-center patients projected to be served is based on reasonable and supported assumptions regarding future growth.

In summary, the applicant adequately identified the population to be served and demonstrated the need this population has for four additional dialysis stations. Therefore, the application is conforming to this criterion.

DCI Boiling Springs, located at 108 Creekside Drive in Shelby, proposes to add four additional stations for a total of 14 stations following completion of the project. The July 2011 SDR indicates a total of 10 certified station at DCI Boiling Springs, as of December 31, 2010.

Population to be Served

The following table illustrates the current patient origin at DCI Boiling Springs, as reported in Section IV.1, page 58.

DCI Boiling Springs - Patient Origin as of 6/30/11

County of Residence	# Patients Dialyzing In-Center	# Patients Dialyzing at Home
Cleveland	25	NA
Rutherford	9	NA
Cherokee, SC	1	NA
Total*	**35**	**NA**

*Source: Application.

In Section III.7, page 53, the applicant provides the projected patient origin for the first two years of operation following completion of the proposed project, as illustrated in the following table:

DCI Boiling Springs - Projected Patient Origin

County	Year One FFY12		Year Two FFY13		County Patients as a Percent of Total	
	In-center Patients	Home Dialysis Patients	In-center Patients	Home Dialysis Patients	Year 1	Year 2
Cleveland	34	0	40	0	71%	71%
Rutherford	13	0	14	0	26%	26%
Cherokee, SC	1	0	2	0	3%	3%
TOTAL	**48**	**0**	**56**	**0**	100%	100%

The applicant adequately identified the population proposed to be served.

Need for the Proposed Stations

The applicant proposes to add four stations to the DCI Boiling Springs facility. The DCI Boiling Springs facility is currently certified for 10 stations.

In Section III.2, pages 45-51, the applicant describes the need methodology and assumptions it used to project the number of patients to be served in each of the first two operating years following project completion.

"As demonstrated in the table above, DCI Boiling Springs currently needs 4.6 or 5 additional stations in order to meet the facility need. Because of the space that is

currently available in the dialysis room that can be converted to additional stations without extensive upfit, DCI is applying for four additional stations rather than five.

...

total patients were projected using the State [sic] *need methodology as defined in the 'July 2011 Semiannual Dialysis Report.' As shown in the table above, DCI is expected to care for 47 in-center patients by the end of 2011, which is seven patients more than the clinic's capacity and, if the projections become a reality, would require the operation of a third shift. (See Section III.9 for a discussion of the difficulties associated with operating a third shift.) Based on this same SDR methodology (Step 2), the growth rate of 46.2 percent has been projected forward through 2014, as shown in the table below.*

Year	*Total In-Center Patients*	*Annual Growth Rate^*
2010	*32*	*46.2%*
2011	*47*	*46.2%*
2012	*69*	*46.2%*
2013	*100*	*46.2%*
2014	*147*	*46.2%*

^Based on Step 2 of the methodology table.

While this methodology is consistent with the methodology typically used to project dialysis need, DCI Boiling Springs believes it is unreasonable to use to project need for additional stations in this project. This position is based on the fact that the Boiling Springs clinic has limited capacity and, by the end of the current year would be well above capacity, which would require the operation of a third shift in order to meet patient needs. As explained in Section III.9, operating a third shift is used only as a short-term means of providing dialysis to a limited number of patients until additional stations can be approved and become operational. Thus, using a third shift as part of general dialysis operations is not optimal and certainly would not be used on a routine basis by DCI clinics, primarily due to the negative attitude of patients toward third shift dialysis treatments. Furthermore, while DCI does anticipate steady growth in the coming years, the clinic does not believe it will continue to grow consistently at a rate of 46.2 percent.

Consequently, DCI believes a more conservative growth rate must be used to project need for this project. Please note, if the SDR growth rate does continue at 46.2 percent, at its earliest opportunity, DCI Boiling Springs will submit a certificate of need application to increase the number of stations at the Boiling Springs clinic so that the dialysis needs of patients referred to the clinic can be met without the need to operate a third shift on an ongoing basis.

DCI believes that its growth rate will be limited by the capacity available during the AM and PM shifts at the clinic rather than a consistent growth rate percentage that would require routine operation of a third shift. With the addition of four stations,

capacity will increase from 40 patients to 56 patients as shown in the Existing and Proposed capacity tables below."

Capacity with 10 Dialysis Stations (Existing)		
	Monday/Wednesday/Friday	**Tuesday/Thursday/Saturday**
AM	10	10
PM	10	10
Night	10	10
AM/PM Capacity	20	20
Capacity with 3rd Shift	30	30
Total Capacity with 2 Shifts = 40 patients		
Total Capacity with 3 Shifts = 60 patients		

Capacity with 14 Dialysis Stations (Proposed)		
	Monday/Wednesday/Friday	**Tuesday/Thursday/Saturday**
AM	14	14
PM	14	14
Night	14	14
AM/PM Capacity	28	28
Capacity with 3rd Shift	42	42
Total Capacity with 2 Shifts = 56 patients		
Total Capacity with 3 Shifts = 84 patients		

Continuing on page 49, the applicant states:

"Based on the two-shift capacity of the Boiling Springs clinic, DCI projects that its patient volume will be limited to a total of 40 patients in 2011 through the first six months of 2012, with a capacity of no more than 56 patients thereafter (the clinic's AM/PM capacity with four additional stations). To calculate projected patients for the project years, which begins July 12, 2012, DCI assumed a capacity of 20 patients for the first half of 2012 (one-half of the total annual capacity with 10 stations) and a capacity of 28 patients for the second half of 2012 (one-half of the total annual capacity with 14 stations). Patient volume for 2013 and 2014 is projected to be the full annual capacity of 14 stations, or 56 patients. These projections are shown in the table below.

Year	*Total In-Center Patients*
2010	*32*
2011	*40*
2012	*48*
2013	*56*
2014	*56*

The first two project years are July 2012 through June 2013 and July 2013 through June 2014. Since DCI Boiling Springs will have all 14 proposed stations operational for this time period, it assumes that the patient volume for the first two project years will reach the capacity of 56 patients.

...

In order to determine the need for additional stations based on utilization of 3.2 patients per station per week as of the end of the second project year, DCI used the SDR methodology (Step #6) and the total in-center patients as projected above using the SDR methodology.

Year	*Total In-Center Patients*	*Patients per Station*	*# Existing Stations*	*Total Stations Needed*	*Additional Stations Needed*
2010	*32*	*3.2*	*10*	*10*	*0*
2011	*47*	*3.2*	*10*	*15*	*5*
2012	*69*	*3.2*	*12**	*22*	*10*
2013	*100*	*3.2*	*14*	*31*	*17*
2014	*147*	*3.2*	*14*	*46*	*32*

**The 12 existing stations are based on the average of 10 stations for the first six months and 14 stations for the last six months of the calendar year.*

As shown in the table above, using the SDR methodology, DCI Boiling Springs currently needs five additional stations and is expected to need an additional 32 by the end of the second project year. However, because DCI used a more conservative methodology to project need for the Boiling Springs clinic, it is also reasonable to calculate the utilization of 3.2 patients per stations on the DCI modified need methodology, as shown in the table below.

Year	*Total In-Center Patients*	*Patients per Station*	*# Existing Stations*	*Total Stations Needed*	*Additional Stations Needed*
2010	*32*	*3.2*	*10*	*10*	*0*
2011	*40*	*3.2*	*10*	*13*	*3*
*2012**	*48*	*3.2*	*12*	*15*	*3*
PY 1	*56*	*3.2*	*14*	*18*	*4*
PY 2	*56*	*3.2*	*14*	*18*	*4*

Using the more conservative methodology, even after the proposed increase of four stations, DCI Boiling Springs will need an additional four stations by the end of the first year."

The following table illustrates the applicant's projected number of patients based on the above stated assumptions which utilize decreasing growth rates that are much lower than the actual increase per year of 46.2% based on the ESRD Facility Need Method.

Existing DCI Boiling Springs In-Center Patients as of 12/31/10	32
Jan 2011-Dec 2011	32 x 1.25 = 40.0000
Jan 2012- Dec 2012	40.0000 x 1.20 = 48.0000 34 Cleveland County patients + 13 Rutherford County patients + 1 Cherokee, SC patient for a total of 48 projected patients.
Jan 2013 – Dec 2013	48.0000 x 1.167 = 56.0000 40 Cleveland County patients + 14 Rutherford County patients + 2 Cherokee, SC patients for a total of 56 projected patients.
Jan. 2014 – Dec. 2014	56.0000 x 1.0 = 56.0000 40 Cleveland County patients + 14 Rutherford County patients + 2 Cherokee, SC patients for a total of 56 projected patients

[To convert calendar years to project years:
Project Year 1 = ½ x CY12 + ½ x CY13 = 48/2 + 56/2 = 24 + 28 = 52
Project Year 2 = ½ x CY13 + ½ x CY14 = 56/2 + 56/2 = 28 + 28 = 56]

The following shows the average number of in-center patients per station per week and the utilization rate for each of the first two operating years following completion of the project.

Year 1 (July 1, 2012- June 30, 2013)
Patients/Station/Week: 56 in-center patients dialyzing on 14 stations = 4.0
Utilization Rate: 56 patients/ (4 shift-cycles x 14 stations) = 1.0 or 100% utilization

Year 2 (July 1, 2013- June 30, 2014)
Patients/Station/Week: 56 in-center patients dialyzing on 14 stations = 4.0
Utilization Rate: 56 patients/ (4 shift-cycles x 14 stations) = 1.0 or 100% utilization

Analysis of Methodology
Currently there are four dialysis facilities in Cleveland County. The number of stations and patients for the past four years for each facility is shown in the tables below.

Number of Stations

	12/31/07	12/31/08	6/30/09	12/31/09	6/30/10	12/31/10
DCI Boiling Springs	-	10	10	10	10	10
DCI Kings Mt.	12	12	12	12	12	14
DCI Shelby	36	35	35	35	35	25
DCI Shelby South	-	-	-	-	1	10

Source: SDR Reports

Number of Patients

	12/31/07	12/31/08	6/30/09	12/31/09	6/30/10	12/31/10
DCI Boiling Springs	-	22	21	20	26	32
DCI Kings Mt.	44	50	48	46	44	42
DCI Shelby	130	127	116	121	90	91
DCI Shelby South	-	-	-	-	0	35

Source: SDR Reports

Utilization (Patients per Station)

	12/31/10
DCI Boiling Springs	32/10 = 3.2
DCI Kings Mt.	42/14 = 3.0
DCI Shelby	91/25 = 3.6
DCI Shelby South	35/10 = 3.5

Although DCI Boiling Springs had an actual facility increase of 46.2% per year based on the ESRD Facility Need Method as of the June 30, 2011 SDR, its growth has been based on patient referrals from DCI, not from growth in the overall number of patients dialyzing in Cleveland and Rutherford Counties. Cleveland County's Five Year Average Annual Change Rate is 4.1%, while Rutherford County's is 1.5%. Therefore it is unrealistic that DCI Boiling Springs' growth rate would be four – five times the county average [25% vs. 4.1%].

If DCI Boiling Springs' current utilization is projected forward based on the current, published Five Year Average Annual Change Rate of 4.1% for Cleveland County, its growth through FY 2014 would be as follows:

Existing DCI Boiling Springs In-Center Patients as of 6/30/11	35
July 2011-June 2012	35 x 1.041 = 36.4350
July 2012 – June 2013 (PY1)	36.4350 x 1.041 = 37.9288
July 2013 – June 2014 (PY2)	37.9288 x 1.041 = 39.4839

To determine the actual number of stations needed based on the projections resulting from using the Five Year Average Annual Change Rate (FYAACR) of 4.1%; divide the number of projected in-center patients by 3.2, the regulatory standard for the end of PY1, as shown in the following table.

Number of Stations Needed

Year	Total In-Center Patients	Patients per Station	# Existing Stations	Total Stations Needed	Additional Stations Needed
CY10	32	3.2	10	10.00	0
FY11	35	3.2	10	10.94	1
FY12	36	3.2	10	11.25	1
FY13 (PY1)	37	3.2	10	11.56	1
FY14 (PY2)	39	3.2	10	12.19	2

Therefore, projected utilization at the end of Year 1 equals at least 3.2 in-center patients per station per week as required by 10A NCAC 14C .2203(b). The number of in-center patients projected to be served is based on reasonable and supported assumptions regarding future growth.

In summary, the applicant adequately identified the population to be served, however it did not demonstrate the need this population has for four additional stations. It did demonstrate the need for one additional dialysis station. Therefore, the application is conforming to this criterion, subject to the limitation on additional stations to one. See Criterion (4), Condition 2.

BMA d/b/a FMC Cleveland County, proposes to establish a 10-station dialysis facility by relocating two stations from BMA Burke County, an existing 25-station dialysis facility in Burke County; six stations from BMA Hickory, an existing 33-station dialysis facility in Catawba County; one station from BMA Lincolnton, an existing 25-station dialysis facility in Lincoln County; and one station from BMA Kings Mountain, an existing 14-station facility in Gaston County. The proposed facility will be located on Kennedy Street in Shelby, in Cleveland County. The applicant does not propose to add dialysis stations to existing facilities or increase the total number of dialysis stations in the contiguous five-county area. However the applicant is proposing to add 10 dialysis stations in Cleveland County.

Further, in Section III.3, pages 43-54, the applicant states that 26 in-center patients for the proposed 10-station facility will originate from the four facilities identified above: 1 patient from BMA Burke County, 1 patient from BMA Hickory, 1 patient from BMA Lincolnton, and 23 patients from BMA Kings Mountain. Exhibit 22 contains 19 letters from in-center patients and 7 letters from home hemodialysis patients who have indicated an interest in transferring because the proposed facility would be closer to their home. The table below illustrates the number of patients transferred and dialysis stations relocated from the four existing facilities to the proposed facility.

Existing BMA Dialysis Facilities 12/31/10				Proposed Facility
	Beginning	Relocate / Transfer	Remaining	Totals
BMA Burke County				
Stations	25	2	23	2
Patients	73	1	72	1
BMA Hickory				
Stations	33	6	27	6
Patients	112	1	111	1
BMA Lincolnton				
Stations	25	1	24	1
Patients	73	1	72	1
BMA Kings Mountain				
Stations	14	1	13	1
Patients	45	23	22	23
			Total Stations	**10**
			Total In-Center Patients	**26**

Population to be Served

From Section III.3, pages 45-54, the applicant provides the current (June 30, 2011) patient origin for the four BMA facilities contributing stations to the proposed project, as shown in the following tables.

BMA Burke County Census: 6/30/11	# In-Center Patients	# Home Patients
Burke	70	7
Cleveland	1	0
Lincoln	1	0
Caldwell	2	1
McDowell	2	1
Total	**76**	**9**

BMA Hickory Census: 6/30/11	# In-Center Patients	# Home Patients
Catawba	95	18
Caldwell	6	6
Burke	6	4
Alexander	4	2
Lincoln	2	4
Iredell	1	0
Cleveland	1	0
Total	**115**	**34**

BMA Lincolnton Census: 6/30/11	# In-Center Patients	# Home Patients
Lincoln	54	NA, BMA Lincolnton does not offer home dialysis
Cleveland	1	
Catawba	2	
Gaston	9	
Total	**66**	

BMA Kings Mt. Census: 6/30/11	# In-Center Patients	# Home Patients
Gaston	18	NA, BMA Kings Mt. does not offer home dialysis
Cleveland	23	
Total	**41**	

As shown in the tables above, the applicant states that the four dialysis centers proposing to relocate stations to the new facility are currently serving 26 in-center patients from Cleveland County and no home patients from Cleveland County.
In Section III.7, page 57, BMA states:

> *"As of December 31, 2011, there were 238 dialysis patients residing within Cleveland County. Of these, 22 were home dialysis patients (Source: July 2011 SDR, Table B). Of the 22 home dialysis patients, six were home hemo-dialysis patients (Source: SEKC Zip Code reports). Of the six home hemo-dialysis patients, BMA assumes that all were being followed by the BMA Gastonia facility; BMA Gastonia is providing treatment for six Cleveland County home hemo-dialysis patients (Source: BMA records)."*

The following table reflects the number of home hemodialysis patients and home peritoneal dialysis patients dialyzing in the counties served by the four facilities from which BMA is proposing to transfer patients, plus Gaston County.

Home Patients Dialyzing by County

County	# Home Hemodialysis Patients	# Home Peritoneal Dialysis Patients
Alexander	0	7
Burke	0	13
Caldwell	0	12
Catawba	3	26
Cleveland	6	16
Gaston	20	14
Iredell	1	42
Lincoln	5	12
McDowell	2	4

Source: Southeastern Kidney Council's (SKC) June 30, 2011 ESRD Prevalence Report.

In Section III.7, pages 55-60, the applicant provides the following assumptions and methodology used to project utilization. Beginning on page 56, the applicant states:

> *"This project has significant patient support and nephrology physician support. BMA conservatively projects that 37 patients will transfer their care to the new FMC Cleveland County upon completion of this project. Of these 37 patients, BMA projects that 31 will be in-center patients and seven will* [be] *home hemo-dialysis patients.*

The next table identifies the expected county of origin for the patients expected to be dialyzing at FMC Cleveland County during Operating Years 1 and 2 of this project."

County	Operating YR 1 CY14			Operating YR 2 CY15			County Patients as % of Total	
	In-Center	Home Hemo	Home PD	In-Center	Home Hemo	Home PD	Year 1	Year 2
Cleveland	32.2	7.4	1.0	34	7.8	2.0	100 %	100 %
Total	**32.2**	**7.4**	**1.0**	**34**	**7.8**	**2.0**	**100%**	**100%**

As illustrated in the chart above, from page 56, the applicant projects to have an in-center total of 32 patients (32 patients / 10 stations = 3.2 patients per station) by the end of Year 1 and 34 patients (34 patients / 10 stations = 3.4 patients per station) by the end of Year 2 for the 10 proposed stations. However, the applicant does not adequately demonstrate the reasonableness of patients who live in Cleveland County and currently choose to receive treatment in Hickory, Morganton, Lincolnton and Kings Mountain choosing to travel to Shelby, in Cleveland County when they currently have that option, but choose not to use it. In addition, the applicant does not adequately demonstrate that BMA's current Cleveland County patients, particularly those who reside near and receive dialysis at BMA Kings Mountain, actually live closer to the proposed facility than to the facility where they are currently receiving treatment. Further, the applicant provides letters from only 19 in-center patients who have indicated an interest in transferring because the proposed facility would be closer to their home. Therefore, the applicant does not adequately identify the population proposed to be served.

Need for the Proposed Relocation of Stations and Development of a New Facility

The applicant proposes to establish a 10-station dialysis facility by relocating two stations from BMA Burke County, an existing 25-station dialysis facility in Burke County; six stations from BMA Hickory, an existing 33-station dialysis facility in Catawba County; one station from BMA Lincolnton, an existing 25-station dialysis facility in Lincoln County; and one station from BMA Kings Mountain, an existing 14-station facility in Gaston County.

In Section III.7, pages 56-58, the applicant provides the following assumptions:

"***Assumptions:***

1. *BMA assumes that the patient population of FMC Cleveland will be comprised of patients from Cleveland County. BMA is serving a significant number of Cleveland County dialysis patients at its facilities in Burke, Catawba, Lincoln and Gaston Counties.*

2. *BMA assumes that the patient population of Cleveland County will grow at a rate exceeding the current published Five Year Average Annual Change Rate of 4.1%.*

   a. *The Cleveland County Five Year Average Annual Change Rate published within the July 2011 SDR is a function of the growth of the ESRD patient population over the most recent five years.*

   b. *The change rate is not compatible with the significant increase in the ESRD patient population of Cleveland County since December 31, 2009.*

   c. *BMA has evaluated the change in the ESRD patient population of Cleveland County on a quarterly basis since December 31, 2009.*

   ...

12/31/2009	3/31/2010	6/30/2010	9/30/2010	12/31/2010	3/31/2011	6/30/2011
210	210	221	231	238	239	247

Source: SEKC Zip Code Reports for periods indicated

   d. *The above table demonstrates that the ESRD patient population of Cleveland county* [sic] *has increased from 210 total patients as of December 31, 2009 to 247 patients as of June 30, 2011. This is a raw change of 37 patients or 17.62% in a period of 18 months. This calculates to and* [sic] *average annual change of 11.75%.*

Step 1: *247-210 = 37*
Step 2: *37/210 = .17619048, rounded to 17.62%*
Step 3: *17.62% / 6 quarters = 2.937%*
Step 4: *Multiply 2.937 X 4 quarters to obtain annual change: 11.75%*

   e. *... As the table above demonstrates, the population has increased by 9 patients in the first six months of this year. If that rate were annualized it is equivalent to 18 new patients in 2011, or a rate of 7.56% for this year.*

   f. *The published change rate of 4.1% is not consistent with the realities of Cleveland County for 2010 and 2011.*

   g. *Based upon the foregoing information, BMA suggests that a more appropriate growth rate to be used for Cleveland County patient projections is* ***5.5202%.*** *This is* ***one half*** *of the calculated recent*

annual growth rate for Cleveland County (see d. above). [Emphasis in original.]

3. *BMA also assumes that as the home peritoneal dialysis patient population increases, some home PD patients will begin their care with the new BMA facility. BMA is conservatively projecting few PD patients. ... Rather, BMA assumes that only one new home PD patient will utilize FMC Cleveland County in the first year of operations, and that only two PD patients will utilize the facility in the second year of operations. ...*

4. *BMA assumes that the four DCI dialysis facilities currently operating in Cleveland County will continue to see an increase in their patient populations at a rate as described above, 5.5202%. BMA is not proposing that patients served by those facilities would transfer to the new FMC Cleveland County dialysis facility. Rather, BMA is proposing that any increases in the ESRD patient population of Cleveland County will be a function of existing provider patient populations increasing at a similar rate.*

5. *As of December 31, 2011* [2010] *there were 238 dialysis patients residing within Cleveland County. Of these, 22 were home dialysis patients (Source: July 2011 SDR, Table B). Of the 22 home dialysis patients, six were home hemo-dialysis patients (Source: SEKC Zip Code Reports). Of the six home hemo-dialysis patients, BMA assumes that all were being followed by the BMA Gastonia facility; BMA Gastonia is providing treatment for six Cleveland County home hemo-dialysis patients (Source: BMA records).*

6. *BMA is also providing treatment for 26 in-center dialysis patients at its dialysis facilities in Burke County, Catawba County, Lincoln County and Cleveland County."*

As shown above, the applicant projects a 5.5202% annual growth rate for Cleveland County based on *"**one half** of the calculated recent annual growth rate for Cleveland County (see d. above)"*; not on the Semiannual Dialysis Report (SDR) currently published Five Year Annual Change Rate of 4.1%. [Emphasis in original.] Project analyst calculated one-half of the "calculated rate" referenced in *d* above (11.75%) which equals 5.875%, not 5.5202% [11.75% x .5 = 5.875]. In addition, the "calculated rate" is basically the annual growth rate for the last year (6/30/10 – 6/30/11) [(247 – 221)/221 = 26 / 221 = .117647 or 11.76%], since there was no growth over the first 3 months of the 18-month period the applicant used in its "calculated rate". The methodology used in determining County Need in the SDR includes a Five Year Annual Change Rate in order to smooth out the ups and downs of any one year, including changes in the number of facilities, stations or patients throughout a county and thus provides a more stable, predictive growth rate than using a shorter time period. The 11 station deficit is based on the County Need

Methodology, so the 10 stations proposed to be relocated under ESRD-2: Relocation of Dialysis Stations are the result of the Five Year Annual Change Rate of 4.1% applied to Cleveland County's dialysis population, and not recent growth. The applicant is proposing to develop a new facility and thus does not have a facility growth rate to use in projections. In addition, it did not provide a growth rate for the Cleveland County patients it currently serves in the transferring facilities. Therefore, the most reasonable growth rate to use is the Five Year Annual Change Rate published in the SDR, which is 4.1%: not 11.76% or 5.5202%.

Continuing in Section III.7, page 59, the applicant states *"BMA begins projections of future patient population to be served with the patients it is currently treating."*

The following table illustrates the applicant's projected number of patients based on the assumptions quoted above and a growth rate of 5.5202%.

	In-Center Patients	Home Hemodialysis Patients
Proposed facility begins with Cleveland County patients currently served by BMA as of 12/31/10	26	6
1/1/10 – 12/31/11	26.0000 x 1.055202 = 27.4353	6.0000 x 1.055202 = 6.3312
1/1/12 – 12/31/12	27.4353 x 1.055202 = 28.9497	6.3312 x 1.055202 = 6.6807
1/1/13 – 12/31/13	28.9497 x 1.055202 = 30.5478	6.6807 x 1.055202 = 7.0495
1/1/14 – 12/31/14 **(PY1)**	30.5478 x 1.055202 = **32.2341**	7.0495 x 1.055202 = 7.4386
1/1/15 – 12/31/15 **(PY2)**	32.2341 x 1.055202 = **34.0135**	7.4386 x 1.055202 = 7.8493

If the applicant used the Five Year Annual Change Rate of 4.1%, as shown in the table below, the applicant would not meet the performance standard of at least 3.2 patients per week, per station by the end of the first operating year. See 10A NCAC 14C .2203.

	In-Center Patients	Home Hemodialysis Patients
Proposed facility begins with Cleveland County patients currently served by BMA as of 12/31/10	26	6
1/1/10 – 12/31/11	26.0000 x 1.041 = 27.0660	6.0000 x 1.041 = 6.2460
1/1/12 – 12/31/12	27.0660 x 1.041 = 28.1757	6.2460 x 1.041 = 6.5021
1/1/13 – 12/31/13	28.1757 x 1.041 = 29.3309	6.5021 x 1.041 = 6.7687
1/1/14 – 12/31/14 **(PY1)**	29.3309 x 1.041 = **30.5335**	6.7687 x 1.041 = 7.0462
1/1/15 – 12/31/15 **(PY2)**	30.5335 x 1.041 = **31.7853**	7.0462 x 1.041 = 7.3351

In Section III.3, page 43, the applicant states *"This proposal is designed to make more effective use of existing certified dialysis stations."* Further, in Section III.9, page 61, the applicant states:

"a) BMA considered not applying to develop this facility. However, as noted within the application BMA is serving a significant number of Cleveland County dialysis patients. BMA expects this patient population to continue to increase based upon the patient relationship with BMA facilities and the presence of Metrolina Nephrology Associates.

b) BMA could have chosen another part of the county for development of the facility. However, as described within this application, development in Shelby is the most logical of choices."

Cleveland County already has four dialysis facilities; two of which are in Shelby. Further, in Exhibit 22, Patient Letters of Support, the applicant includes 26 letters from BMA patients who live in Cleveland County: 19 letters from in-center patients and 7 from home hemodialysis patients. Of the in-center letters, 79% (15 / 19 = .79) have a Kings Mountain ZIP Code, 3 have ZIP Codes from the northern part of the county, and 1 has a Shelby ZIP Code. If only 19 patients transfer, the new facility would serve 22 patients per week, or 2.2 patients per station, by the end of the first operating year

In summary, the applicant does not adequately identify the population to be served by the proposed relocation of stations, transfer of patients and development of a new dialysis facility; and does not adequately demonstrate the need this population has for the proposed project, in the proposed location. Therefore, the application is non-conforming with this criterion.

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

NA
DCI Shelby
DCI Boiling Springs

NC
BMA

In Section III.6, page 54, the **FMC Cleveland** states:

"Not applicable. This is an application to transfer existing certified stations from the four BMA facilities to develop FMC Cleveland County in Cleveland County. To the extent that this could be considered a reduction in service at BMA Burke County, BMA Lincolnton, BMA Hickory or BMA Kings Mountain, BMA notes that the projected

utilization at these facilities is not negatively impacted and no patients will be denied treatment as a result of this transfer (See discussion at III.3 (c). BMA Burke County, BMA Hickory, BMA Lincolnton, BMA Kings Mountain will continue to have capacity to accept dialysis patients. BMA will apply for additional stations at these facilities using the Facility Need Methodology as each demonstrates need for additional stations. BMA has specifically discussed the future potential need for additional stations at BMA Hickory."

This Criterion is applicable to the proposed reduction in service at BMA Burke County, BMA Lincolnton, BMA Hickory and BMA Kings Mountain.

According to the applicant, 56% (23/41 = .561) of the patients dialyzing at BMA Kings Mountain are from Cleveland County, which is reasonable since the BMA Kings Mountain facility is less than 750 feet from the Cleveland County line, and the majority of Kings Mountain is in Cleveland County. In addition, BMA Kings Mountain is 15.4 miles from to DCI Shelby South, 17.3 miles from DCI Shelby and 15 miles from the proposed location.

Distance Between Facilities

	DCI Shelby	DCI Shelby South	Proposed Location Kennedy St., Shelby	DCI Boiling Springs
BMA Kings Mountain	17.3 miles, 25 minutes	15.4 miles, 21 minutes	15 miles, 22 minutes	23.8 miles, 35 minutes
Kennedy Street, Shelby	2.2 miles, 5 minutes	2.9 miles, 8 minutes		12.5 miles, 21 minutes

The following table shows the current utilization of the four BMA facilities as well as the expected utilization after the proposed station relocations.

Existing BMA Dialysis Facilities 12/31/10				Proposed Utilization Subtracting Relocations*
	Beginning	Current Utilization	Remaining	
BMA Burke County				
Stations	25	2.92	23	3.13
Patients	73	73%	72	78%
BMA Hickory				
Stations	33	3.39	27	4.11
Patients	112	85%	111	103%
BMA Lincolnton				
Stations	25	2.92	24	3.00
Patients	73	73%	72	75%
BMA Kings Mountain				
Stations	14	3.21	13	1.69
Patients	45	80%	22	42%

* Assuming total # of patients stays constant.

Assuming that the number of patients the applicant contends will transfer from each existing facility actually transfer, this proposal would leave BMA Hickory operating at 103% of capacity and would unable to serve all of its remaining patients without either

offering a third shift or developing additional stations. Further, updated data shows that by June 30, 2011, the number of in-center patients dialyzing at BMA Hickory had increased to 115, which would increase utilization of the facility to 106% of capacity, exacerbating the issue.

The applicant's projected patient transfer from BMA Kings Mountain would leave that facility seriously underutilized at 42% of capacity. Further, updated data shows that by June 30, 2011, the number of in-center patients at BMA Kings Mountain had decreased to 41, further lowering its utilization after project completion to only 35% of capacity.

In summary, the applicant does not adequately demonstrate that the needs of the population presently served will be met by the proposed relocation or that the effect of the 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 will not be negative. Therefore, the application is non-conforming with this criterion.

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

CA
DCI Shelby
DCI Boiling Springs

NC
FMC Cleveland

DCI Shelby - In Section III.9, pages 54-58, **DCI Shelby** discusses the alternatives it considered to meet the need for the proposed services. The application is conforming to the facility need methodology for additional stations. See Criterion (1) for discussion. Furthermore, the applicant adequately demonstrates the need for four additional stations based on the number of in-center patients it proposes to serve. See Criterion (3) for discussion. The application is conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a), (20) and 10A NCAC 14C .2200 for discussion. The applicant adequately demonstrates that the proposal to add four dialysis stations is its least costly or most effective alternative. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

1. **Dialysis Clinic, Inc. d/b/a DCI Shelby shall materially comply with all representations made in its certificate of need application.**

2. **Dialysis Clinic, Inc. d/b/a DCI Shelby shall be certified for no more than 29 dialysis stations, which shall include any home hemodialysis and isolation stations, upon completion of this project.**

3. **Dialysis Clinic, Inc. d/b/a DCI Shelby shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations for a total of 29 stations, which shall include any home hemodialysis and isolation stations, upon completion of this project.**

4. **Dialysis Clinic, Inc. d/b/a DCI Shelby 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.**

DCI Boiling Springs - In Section III.9, pages 54-57, **DCI Boiling Springs** discusses the alternatives it considered to meet the need for the proposed services. The application is conforming to the facility need methodology for additional stations. See Criterion (1) for discussion. Furthermore, as conditioned, the applicant adequately demonstrates the need for one additional station based on the number of in-center patients it proposes to serve. See Criterion (3) for discussion. The application is conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a), (20) and 10A NCAC 14C .2200 for discussion. As conditioned, the applicant adequately demonstrates that the proposal to add one dialysis stations is a least costly or most effective alternative. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

1. **Dialysis Clinic, Inc. d/b/a DCI Boiling Springs shall materially comply with all representations made in its certificate of need application.**

2. **Dialysis Clinic, Inc. d/b/a DCI Boiling Springs shall be certified for no more than 11 dialysis stations, which shall include any home hemodialysis and isolation stations, upon completion of this project.**

3. **Dialysis Clinic, Inc. d/b/a DCI Boiling Springs shall install plumbing and electrical wiring through the walls for no more than one additional dialysis station for a total of 11 stations, which shall include any home hemodialysis and isolation stations, upon completion of this project.**

4. **Dialysis Clinic, Inc. d/b/a DCI Boiling Springs 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.**

FMC Cleveland - In Section III.9, page 61, BMA discusses the alternatives it considered to meet the need for the proposed services, including not applying to develop the facility and choosing another part of Cleveland County to locate the proposed facility. The application is consistent with Policy ESRD-2: Relocation of Dialysis Stations. See Criterion (1) for discussion. However, the applicant does not adequately demonstrate that this proposal is the least costly or most effective alternative. The applicant does not adequately demonstrate the need to relocate 10 stations and develop a new dialysis facility in Cleveland County, based on the current number of in-center patients it reasonably proposes to serve and on the current treatment location of the in-center patients it proposes to transfer to serve. The applicant fails to adequately demonstrate that Shelby is the best location for developing a new facility to serve Cleveland County patients currently served by BMA in other counties. In Section III.3, pages 53-54, the applicant uses total Cleveland County ESRD patient origin by ZIP code, to justify Shelby as the appropriate location. However, the ZIP code data provided in support letters from 19 in-center patients and 7 home-hemodialysis patients indicates the majority of BMA's Cleveland County patients live in the Kings Mountain ZIP Code 28086. See Criterion (3) for discussion. In addition, on the map provided by BMA, the locations of BMA's Cleveland County patients do not indicate a need for a facility in Cleveland County, in Shelby. Furthermore, the application is an unnecessary duplication of services. See discussion in Criterion (6). The application is non-conforming to the following applicable statutory and regulatory criteria: (3), (5), (6), (12) (18a), (20) and 10A NCAC 14C .2200. See each Criterion for discussion. The applicant does not adequately demonstrate that the proposal to relocate ten dialysis stations and develop a new facility in Cleveland County is its least costly or most effective alternative. Consequently, the application is non- conforming to this criterion and is disapproved.

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C
DCI Shelby
DCI Boiling Springs

NC
FMC Cleveland

DCI Shelby - In Section VIII.1, page 83, **DCI Shelby** states the capital cost of the proposed project is projected to be $66,000. In Section IX, page 90, the applicant states that there will be no start-up costs or initial operating expenses.

In Section VIII.2, page 86, DCI Shelby states it will fund the capital costs of the project from the accumulated reserves of DCI Shelby. Exhibit 20 contains a letter, dated August 31, 2011, from the Secretary and Treasurer which states in part:

"As the Secretary and Treasurer for Dialysis Clinic, Inc., I am responsible for the financial operations of the corporation. As such, I am very familiar with the financial position of DCI Shelby. DCI Shelby reserve funds totaling $66,000 will be used for the purchase of new dialysis machines, chairs and televisions for the four additional stations to be restored at the DCI Shelby clinic. No new services are proposed; therefore there are no start-up or initial operating costs for the project.

For verification of reserve funds available for this project, please see the June 2011 [sic] *balance sheet for DCI Shelby indicating an available cash amount of $6,772,800, which is more than sufficient to fund this project."*

In Exhibit 21, the applicant provides FFY09 and FFY10 financial statements for DCI Shelby which document that DCI Shelby had $6,183,859 in cash and cash equivalents as of September 30, 2010. The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

In pages 105-110, the applicant projects revenues will exceed expenses in the first two years of operation after completion of the project.

In Section X, pages 92-93, and in the financials in pages 105-110, the applicant projects revenues and operating costs. The following table illustrates the allowable charge per patient treatment in 2010, as reported by the applicant on page 92.

Source of Payment	Charge per Treatment
Private Pay	NA
Medicare	$152.00
Medicaid	$145.00
Blue Cross/Blue Shield	$980.00
Commercial Insurance	$547.00
VA	$319.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. The applicant states in the notes to the financials, page 108 *"Hemodialysis treatments per year are based on the assumption of 3 treatments per week, 52 weeks per year, less 7% missed treatments, based on DCI's historical experience."*

The applicant projects 96 in-center patients and 13,926 treatments in Year One. At 100% attendance, 96 patients would have 14,976 treatments in Year One [96 x 3 = 288; 288 x 52 = 14,976]. After deducting 7% of the treatments as missed treatments, the applicant projects 13,926 treatments for Year One [14,976 x 7% = 1,048.3; 14,976 – 1,048 = 13,928]. The applicant projects 98 in-center patients and 14,216 treatments in Year Two. At 100% attendance, 98 patients would have 15,288 treatments in Year One [98 x 3 = 294; 294 x 52 = 15,288]. After deducting 7% of the treatments as missed treatments, the

applicant projects 14,216 treatments for Year One [15,288 x 7% = 1,070.2; 15,288 – 1,070 = 14,218]. Therefore, the applicant has under-projected its revenue.

The applicant 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.

DCI Boiling Springs - In Section VIII.1, page 83, **DCI Boiling Springs** states the capital cost is projected to be $70,000. In Section IX, page 90, the applicant states that there will be no start-up costs or initial operating expenses.

In Section VIII.2, page 86, DCI Boiling Springs states it will fund the capital costs of the project from the accumulated reserves of DCI Shelby. Exhibit 18 contains a letter, dated August 31, 2011, from the Secretary and Treasurer which states in part:

> *"As the Secretary and Treasurer for Dialysis Clinic, Inc., I am responsible for the financial operations of the corporation. As such, I am very familiar with the financial position of DCI Shelby, the funding source for the DCI Boiling Springs project. DCI Shelby reserve funds totaling $70,000 will be used to purchase new dialysis machines, chairs, televisions and plumbing connectors for the four additional stations to be developed at the DCI Boiling Springs clinic. No new services are proposed; therefore there are no start-up or initial operating costs for the project.*
>
> *For verification of reserve funds available for this project, please see the June 2011* [sic] *balance sheet for DCI Shelby indicating an available cash amount of $6,772,800, which is more than sufficient to fund this project."*

In Exhibit 19, the applicant provides FFY09 and FFY10 financial statements for DCI Shelby which document that DCI Shelby had $6,183,859 in cash and cash equivalents as of September 30, 2010. The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

In pages 105-109, the applicant projects revenues will exceed expenses in the first two years of operation after completion of the project.

In Section X, pages 92-93, and in the financials in pages 105-109, the applicant projects revenues and operating costs. The following table illustrates the allowable charge per patient treatment in 2010, as reported by the applicant on page 92.

Source of Payment	Charge per Treatment
Private Pay	NA
Medicare	$153.00
Medicaid	$145.00
Commercial Insurance	$333.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. The applicant states in the notes to the financials, page 107 *"Hemodialysis treatments per year are based on the assumption of 3 treatments per week, 52 weeks per year, less 7.0% missed treatments, based on DCI's historical experience of missed treatments."*

The applicant projects 56 in-center patients and 8,125 treatments in Year One and in Year Two. At 100% attendance, 56 patients would have 8,736 treatments in Year One and in Year Two [56 x 3 = 168; 168 x 52 = 8,736]. After deducting 7% of the treatments as missed treatments, the applicant projects 8,124 treatments for Year One and for Year Two [8,736 x 7% = 611.52; 8,736 – 612 = 8,124]. Therefore, the applicant has under-projected its revenue.

The applicant 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. However, see Criterion (3) for a discussion of the number of stations needed.

FMC Cleveland - In Section VIII.1, page 80, BMA states the capital cost is projected to be $857,751. In Section IX, pages 85-86, the applicant states that total start-up costs and initial operating expenses will be $1,091,217. However, the projected start-up costs and initial operating expenses are based on unreasonable projections of patient volume; therefore the start-up costs and initial operating costs are also unreasonable.

In Section VIII.2, page 82, BMA states it will fund the capital costs of the project from corporate accumulated reserves. Exhibit 24 contains a letter, dated September 15, 2011, from the Vice President of Fresenius Medical Care Holdings, Inc. which states in part:

> *"This is to inform you that Fresenius Medical Care Holdings, Inc. is the parent company of National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc.*
>
> *BMA proposes to develop a new 10 station dialysis facility in Shelby, Cleveland County by transferring existing certified dialysis stations from contiguous counties into Cleveland County. The project calls* [for] *the following capital expenditures on behalf of BMA.*
>
> *Capital Expenditure* *$857,751*
>
> *As Vice President, I am authorized and do hereby authorize the development of this 10 station dialysis facility, Fresenius Medical Care of Cleveland County, for capital costs of $857,751. Further, I am authorized and do hereby authorize and commit all necessary cash and cash reserves for the start-up and working capital which may be needed for this project."*

In Exhibit 10, the applicant provides CY09 and CY10 financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries which document that Fresenius Medical Care Holdings, Inc. and Subsidiaries had $163,292,000 in cash and cash equivalents as of December 31, 2010. In addition, as of December 31, 2010, the applicant had Total Current Assets of $2,753,682,000, Total Assets of $12,017,618,000, and Total Net Assets of $6,561,629,000 [total assets – total liabilities]. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In Section X, pages 89 and 94, the applicant projects revenues will exceed expenses in the first two years of operation after completion of the project, as shown in the table below.

Projected Revenues and Operating Costs for Years One and Two

	Year 1	Year 2
Projected Net Revenue	$1,636,735	$1,761,822
Projected Total Operating Costs	$1,484,155	$1,585,969
Projected Surplus/deficit*	$152,580	$175,853

* Calculated by Project Analyst.

The following table illustrates the allowable charge per patient treatment, as reported by the applicant in Section X.1, page 88.

BMA's Allowable Charge per Treatment

Source of Payment	In-Center	Home PD	Home Hemo
Private Pay	$1,375.00	$550.20	$1,375.00
Medicare	$234.00	$234.00	$234.00
Medicaid	$137.29	$55.41	$137.29
Commercial Insurance	$1,375.00	$550.20	$1,375.00
VA	$146.79	$63.39	$147.85

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.

The applicant projects 31 in-center patients and 4,522 treatments in Year One. At 100% attendance, 31 patients would have 4,836 treatments in Year One [31 x 3 = 93; 93 x 52 = 4,836]. After deducting 6.5% of the treatments as missed treatments, the applicant projects 4,522 treatments for Year One [4,836 x 6.5% = 314; 4,836 – 314 = 4,522]. The applicant projects 33 in-center patients and 4,813 treatments in Year Two. At 100% attendance, 33 patients would have 5,148 treatments in Year Two [33 x 3 = 99; 99 x 52 = 5,148]. After deducting 6.5% of the treatments as missed treatments, the applicant projects 4,813 treatments for Year Two [5,148 x 6.5% = 335; 5,148 – 335 = 4,813]. Therefore, the applicant has under-projected its revenue. However the projected revenue is based on unreasonable projections of patient volume, therefore the projected revenue is also unreasonable.

The applicant does not adequately demonstrate that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Therefore, the application is non-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.

C
DCI Shelby

CA
DCI Boiling Springs

NC
FMC Cleveland

DCI Shelby proposes to add four dialysis stations to the existing DCI Shelby facility for a total of 29 dialysis stations upon completion of this project. The applicant adequately demonstrates the need to add four stations based on the number of in-center patients it currently serves and the number it proposes to serve. See Section III.7, pages 53-54, Section III.9, pages 54-58, and Section V.7, pages 71-72. See Criteria (1) and (3) for additional discussion. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming with this criterion.

DCI Boiling Springs proposes to add four dialysis stations to the existing DCI Boiling Springs facility for a total of 14 dialysis stations upon completion of this project. The applicant adequately demonstrates the need to add one, not four stations based on the number of in-center patients it currently serves and the number it proposes to serve. See Section III.7, page 53, Section III.9, pages 54-57, and Section V.7, pages 70-72. See Criteria (1) and (3) for additional discussion. The applicant adequately demonstrates that the proposal as conditioned will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming with this criterion, subject to the condition to add one station in Condition 2, Criterion (4).

FMC Cleveland proposes to relocate ten dialysis stations and transfer 26 in-center patients to develop a dialysis facility in Shelby, Cleveland County. The following table shows the current utilization of the transferring facilities as well as the expected utilization after the proposed transfers.

Existing BMA Dialysis Facilities 12/31/10				Proposed Utilization Subtracting Transfers*
	Beginning	Current Utilization	Remaining	
BMA Burke County				
Stations	25	2.92	23	3.13
Patients	73	73%	72	78%
BMA Hickory				
Stations	33	3.39	27	4.11
Patients	112	85%	111	103%
BMA Lincolnton				
Stations	25	2.92	24	3.00
Patients	73	73%	72	75%
BMA Kings Mountain				
Stations	14	3.21	13	1.69
Patients	45	80%	22	42%

* Assuming total # of patients stays constant.

The proposed relocation of only 1 station and 22 patients from BMA Kings Mountain would leave that facility severely underutilized, operating at only 42% of capacity. Further, updated data shows that by June 30, 2011, the number of in-center patients at BMA Kings Mountain had decreased to 41, further lowering its projected utilization to 35% of capacity.

According to the applicant, 56% (23/41 = .561) of the patients dialyzing at BMA Kings Mountain are from Cleveland County. The BMA Kings Mountain facility is less than 750 feet from the Cleveland County line, and the majority of Kings Mountain is in Cleveland County. Cleveland County has 4 ESRD facilities; 2 of which are in Shelby. In addition, BMA Kings Mountain is 15.4 miles from DCI Shelby South, 17.3 miles from DCI Shelby and 15 miles from the proposed location.

Distance Between Facilities

	DCI Shelby	DCI Shelby South	Proposed Location Kennedy St., Shelby	DCI Boiling Springs
BMA Kings Mountain	17.3 miles, 25 minutes	15.4 miles, 21 minutes	15 miles, 22 minutes	23.8 miles, 35 miles
Kennedy Street, Shelby	2.2 miles, 5 minutes	2.9 miles, 8 minutes		12.5 miles, 21 minutes

The applicant does not adequately demonstrate the need to relocate ten stations and develop a new facility in Shelby based on the location and number of in-center patients it currently serves from Cleveland County, the number of patients it proposes to serve, and the location where it proposes to serve the transferred patients. See Section III.3, pages 43-54, Section III.7, pages 55-60, Section III.9, page 61, and Section V.7, pages 70-71. See Criteria (3) and (3a) for additional discussion. The applicant's proposal will result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is non-conforming with 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
DCI Shelby
DCI Boiling Springs
FMC Cleveland

In Exhibit 19, page 266, **DCI Shelby** provides its current and proposed staffing table. The applicant states that three additional full-time equivalent (FTE) positions will be required as a result of this project. Exhibit 17 contains a letter from Aamir Iqbal, MD stating that he is the current Medical Director of DCI Shelby and supports the proposed expansion of the facility. The information regarding staffing provided in Exhibit 19 is reasonable and credible and supports a finding of conformity with this criterion.

In Exhibit 6, page 158, **DCI Boiling Springs** provides its current and proposed staffing table. The applicant states that three additional full-time equivalent (FTE) positions will be required as a result of this project. Exhibit 16 contains a letter from Syed Ahmed, MD stating that he is the current Medical Director of DCI Boiling Springs and supports the proposed expansion of the facility. The information regarding staffing provided in Exhibit 6 is reasonable and credible and supports a finding of conformity with this criterion, subject to the limitation on additional stations to one. See Criterion (4) Condition 2.

In Section VII.1, page 76, **FMC Cleveland** provides its proposed staffing table. The applicant states that 7.93 full-time equivalent (FTE) positions will be required to staff the proposed 10 station facility. Exhibit 21 contains a letter from M. Gene Radford, Jr., MD stating that he has agreed to serve as the Medical Director of the proposed FMC Cleveland 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
DCI Shelby
DCI Boiling Springs
FMC Cleveland

DCI Shelby - In Section V.1, page 62, **DCI Shelby** lists the providers of the necessary ancillary and support services, and in Sections V.2, pages 64-66, V.4, pages 67-68, and

V.5, pages 68-69, illustrates how the project will be coordinated with the existing health care system. The information provided in Section V is reasonable and credible and supports a finding of conformity with this criterion.

DCI Boiling Springs - In Section V.1, pages 61-62, **DCI Boiling Springs** lists the providers of the necessary ancillary and support services, and in Sections V.2, pages 63-65, V.4, pages 67-68, and V.5, pages 68-69, illustrates how the project will be coordinated with the existing health care system. The information provided in Section V is reasonable and credible and supports a finding of conformity with this criterion.

FMC Cleveland - In Section V.1, pages 66-67, BMA lists the providers of the necessary ancillary and support services, and in Sections V.2, pages 67-68, V.4, pages 68-69, and V.5, pages 69-70, illustrates how the project will be coordinated with the existing health care system. Although neither BMA nor Metrolina Nephrology Associates currently have a relationship or privileges at Cleveland Regional Medical Center, each state they will establish a relationship/privileges with the hospital if the proposal is approved. The information provided in Section V 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
DCI Shelby
DCI Boiling Springs
FMC Cleveland

(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

NA

(b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;

(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;

(iii) would cost no more than if the services were provided by the HMO; and

(iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA
DCI Shelby
DCI Boiling Springs

C
FMC Cleveland

FMC Cleveland – In Section XI, pages 96-99, the applicant discusses the primary and secondary sites for the proposed dialysis facility. The applicant plans to upfit leased space. The primary site has not been developed yet. The applicant states that the primary site will provide easy access from a major highway, Business-74 (north-south), through Shelby and the secondary site is easily accessible from local area thoroughfares. The applicant also proposes that both sites are close to many current BMA dialysis patients and close to the local hospital. Both sites are currently zoned for a dialysis center. On page 101, the applicant states the facility will be 4,666 square feet with energy saving features as described on pages 99-100. Therefore, the applicant adequately demonstrates that for the project as proposed, the cost, design and means of construction represent the most reasonable alternative and that the construction project would not unduly increase the costs of or charges for providing health services if the project were approvable. See Criterion (5) for discussion of costs and charges. 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
DCI Selby
DCI Boiling Springs
FMC Cleveland

DCI Shelby - In Section VI.1(b), page 73, **DCI Shelby** reports that 86.5% of the patients who received treatment at DCI Shelby had some or all of their services paid for by Medicare or Medicaid. The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

DCI Boiling Springs - In Section VI.1(b), page 73, **DCI Boiling Springs** reports that 85.3% of the patients who received treatment at DCI Boiling Springs had some or all of their services paid for by Medicare or Medicaid. The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

FMC Cleveland - In Section VI.1(c), pages 72-73, **FMC Cleveland** states that 82.6% of the patients who are projected to receive treatment at the proposed facility will have some or all of their services paid for by Medicare or Medicaid. The applicant further states:

> *"Projections of future reimbursement are a function of historical performance of the facilities contributing stations to this project. The facilities contributing stations to the project are operating in contiguous counties. BMA believes that the economic complexion of these counties is similar to Cleveland County and that it is therefore appropriate to use a blended payor mix from these facilities to develop the projected payor mix."*

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

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

C
DCI Shelby
DCI Boiling Springs
FMC Cleveland

DCI Shelby - In Section VI.1(f), page 75, **DCI Shelby** states:

"None of the DCI clinics have any obligation under any federal regulations to provide uncompensated care, community service or access by minorities and handicapped persons. However, during fiscal year 2010, DCI provided more than $635,000 in bad debt and charity care or approximately 10 percent of its gross revenue."

In Section VI.6(a), page 77, the applicant states:

"There have been no civil rights equal access complaints filed against DCI Shelby, DCI Kings Mountain, DCI Boiling Springs, DCI South or Dialysis Clinic, Inc., the parent company, during the past five years."

The application is conforming to this criterion.

DCI Boiling Springs - In Section VI.1(f), page 75, **DCI Boiling Springs** states:

"None of the DCI clinics have any obligation under any federal regulations to provide uncompensated care, community service or access by minorities and handicapped persons. However, during fiscal year 2010, DCI Boiling Springs provided more than $49,486 in bad debt and charity care."

In Section VI.6(a), page 77, the applicant states:

"There have been no civil rights equal access complaints filed against DCI Shelby, DCI Kings Mountain, DCI Boiling Springs, DCI South or Dialysis Clinic, Inc., the parent company, during the past five years."

The application is conforming to this criterion.

FMC Cleveland – In Section VI.1(f), page 74, BMA states:

> *"BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all people the same regardless of race or handicap status. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act."*

The application is conforming to this criterion.

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

C
DCI Shelby
DCI Boiling Springs
FMC Cleveland

DCI Shelby - In Section VI.1(a), page 73, **DCI Shelby** states:

> *"Because of this commitment, DCI willingly serves **any and all population groups** without regard to income, race or ethnic minority, sex, ability, age, or any perceived underserved status. ... DCI's commitment to its patients is exemplified in its admission policy and its equal treatment policy. Please see Exhibit 6 for copies of these policies."* [Emphasis in original.]

In Section VI.1(c), page 74, DCI Shelby projects that that 86.5% of in-center patients will have some or all of their services paid for by Medicare or Medicaid, as illustrated in the following table.

DCI Shelby – Projected Utilization by Payor Source

Payor	Percent Utilization by Payor	
	% In-Center Patients	% Home Patients
Medicare	81.3%	33.3%
Medicaid	5.2%	4.8%
Commercial Insurance	5.2%	23.8%
VA	5.2%	14.3%
Blue Cross/Blue Shield	3.1%	23.8%
TOTAL	100.0%	100.0%

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

DCI Boiling Springs - In Section VI.1(a), page 73, **DCI Boiling Springs** states:

> *"Because of this commitment, DCI willingly serves **any and all population groups** without regard to income, race or ethnic minority, sex, ability, age, or any perceived underserved status. ... DCI's commitment to its patients is exemplified in its admission policy and its equal treatment policy. Please see Exhibit 5 for copies of these policies."* [Emphasis in original.]

In Section VI.1(c), page 74, DCI Boiling Springs projects that that 85.3% of in-center patients will have some or all of their services paid for by Medicare or Medicaid, as illustrated in the following table.

DCI Boiling Springs – Projected Utilization by Payor Source

Payor	% In-Center Patients
Medicare	82.4%
Medicaid	2.9%
Commercial Insurance	14.7%
TOTAL	**100.0%**

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

FMC Cleveland – In Section VI.1(a), page 72, BMA states:

> *"BMA has a long history of providing dialysis services to the underserved populations of North Carolina. ...Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. The patient population of the FMC Cleveland County facility is expected to be similar to the facilities contributing stations to the project, and will likely be comprised of the following:*

Facility	*Medicaid/ Low Income*	*Elderly (65+)*	*Medicare*	*Women*	*Racial Minorities*
FMC Cleveland County	*3.60%*	*40.14%*	*75.86%*	*41.64%*	*37.58%*

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 75.86% of the facility treatment reimbursement is from Medicare.

In Section VI.1(c), page 73, BMA projects that that 82.6% of in-center patients will have some or all of their services paid for by Medicare or Medicaid, as illustrated in the following table.

FMC Cleveland County – Projected Utilization by Payor Source

Payor	Percent Utilization by Payor	
	% In-Center Patients	% Home Patients
Medicare	80.0%	64.0%
Medicaid	2.6%	0.0%
Commercial Insurance	11.0%	33.0%
VA	6.4%	3.0%
Self/Indigent	0.1%	0.0%
TOTAL	**100.0%**	**100.0%**

The applicant further states:

> *"Projections of future reimbursement are a function of historical performance of the facilities contributing stations to this project. The facilities contributing stations to the project are operating in contiguous counties. BMA believes that the economic complexion of these counties is similar to Cleveland County and that it is therefore appropriate to use a blended payor mix from these facilities to develop the projected payor mix for this facility."*

The applicant demonstrated 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
DCI Shelby
DCI Boiling Springs
FMC Cleveland

DCI Shelby - In Section VI.5, page 76, **DCI Shelby** describes the range of means by which patients will have access to the proposed services:

"Any patient with a medical need for dialysis treatments may be admitted to DCI clinics by any nephrologist who has admitting privileges with the clinic. To facilitate patient access, DCI has an open-door policy regarding physician admitting privileges and any licensed nephrologist may apply to admit his or her patients to any of the DCI clinics, including the Shelby clinic."

The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity with this criterion.

DCI Boiling Springs - In Section VI.5, page 76, **DCI Boiling Springs** describes the range of means by which patients will have access to the proposed services:

"Any patient with a medical need for dialysis treatments may be admitted to DCI clinics by any nephrologist who has admitting privileges with the clinic. To facilitate patient access, DCI has an open-door policy regarding physician admitting privileges and any licensed nephrologist may apply to admit his or her patients to any of the DCI clinics, including the Boiling Springs clinic."

The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity with this criterion.

FMC Cleveland - In Section VI.5, page 74, **BMA** describes the range of means by which patients will have access to the proposed services:

"Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC Cleveland County will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms."

The information provided in Section VI.5 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
DCI Shelby
DCI Boiling Springs
FMC Cleveland

DCI Shelby - In Section V.3(a), page 66, **DCI Shelby** states:

"DCI Shelby has well established relationships with clinical programs in the area. For example, the Cleveland County Emergency Medical Services utilizes the DCI Shelby facility as a training site for advanced life support, critical care and paramedic training for students. DCI provides didactic education as well as clinical instruction on-site for these students. Additionally, DCI Shelby offers the dialysis facility as a clinical training internship site for Gardner-Webb University's senior nursing students who are under the direction of a registered nurse. Cleveland Community College allied health students as well as Crest High School's health occupation students have clinical access to DCI Shelby and will continue with these rotations following completion of this project. See Exhibit 16 for documentation of some of these well-established clinical relationships.

Winston Salem State University and Western Carolina University also use DCI as a clinical experience for BSN students in the management area as well as dietitians and social workers. This clinical training is provided on an as-needed basis.

All of these clinical training programs are supportive of the proposed project and some have submitted letters to document that support. See Exhibit 23."

In Section V.3(c), page 67, DCI Shelby states:

"At the present time, the only clinical programs that have indicated a need for clinical rotations for their students are the programs already established with DCI Shelby. Certainly, other programs that have a need for clinical training sites for their students would be welcome. ...

In addition to offering its facilities for clinical rotations, DCI has endowed two scholarships ($25,000 each) for nursing students to allow qualified students to enter the nursing program at Gardner Webb University"

The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion.

DCI Boiling Springs - In Section V.3(a), pages 65-66, **DCI Boiling Springs** states:

"As existing dialysis facilities that operate under the same management, DCI Shelby, DCI Boiling Springs, DCI Kings Mountain and DCI South have well established relationships with clinical programs in the Cleveland County area. Although DCI Boiling Springs has only been in operation for four years, the DCI clinic has taken advantage of its relationship with the other DCI clinics to establish its own clinical training relationships with area programs. For example, the Cleveland County Emergency Medical Services utilizes the DCI Boiling Springs facility as a training site for advanced life support, critical care and paramedic training for students. DCI

provides didactic education as well as clinical instruction on-site for these students. Additionally, DCI Boiling Springs offers the dialysis facility as a clinical training internship site for Gardner-Webb University's senior nursing students who are under the direction of a registered nurse. Cleveland Community College allied health students as well as Crest High School's health occupation students have clinical access to DCI Boiling Springs and will continue with this rotation following completion of this project. See Exhibit 15 for documentation of these well-established clinical relationships.

Winston Salem State University and Western Carolina University also use DCI as a clinical experience for BSN students in the management area as well as dietitians and social workers. This clinical training is provided on an as-needed basis.

All of these clinical training programs are supportive of the proposed project and some have submitted letters to document that support. See Exhibit 21."

In Section V.3(c), page 66, DCI Boiling Springs states:

"At the present time, the only clinical programs that have indicated a need for clinical rotations for their students are the programs already established with DCI Boiling Springs. Certainly, other programs that have a need for clinical training sites for their students would be welcome. ...

In addition to offering its facilities for clinical rotations, DCI has endowed two scholarships ($25,000 each) for nursing students to allow qualified students to enter the nursing program at Gardner Webb University"

The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion.

FMC Cleveland- In Section V.3(a), page 68, BMA states:

"Exhibit 19 contains an executed affiliation agreement between FMC Cleveland County and Gaston College. Students are provided tours through the facilities and discussions regarding the different aspects of dialysis and facility operations.

All health related education and training programs are welcomed [sic] *to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment. This experience enhances the clinical experience of the students enrolled in these programs enabling them to learn about the disease, prognosis and treatment for the patient with end stage renal disease."*

In Section V.3(b), page 68, BMA states:

"BMA facilities regularly receive requests for information from individual students or program directors. The Center Manager or In-Service Coordinator of the facility provide discussion of ESRD and dialysis for students, after which time the students may observe, tour the facility and talk with patients. It is expected that FMC Cleveland County will similarly support health professional programs in Cleveland, Wake and Johnston Counties. [sic]"

In Section V.3(c), page 68, BMA states:

"Terri Carlton, RN, FMC Director of Operations for this facility has executed a formal relationship with Gaston College."

Although Gaston College is not very close to the proposed site in Shelby, FMC Cleveland has shown general conformity with this criterion and said in the Public Hearing that they would be contacting Gardner-Webb University regarding health education and training. The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion.

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

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

C
DCI Shelby

CA
DCI Boiling Springs

NC
FMC Cleveland

Dialysis Clinic, Inc. d/b/a DCI Shelby See Sections II, III, V, VI, and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the addition of four dialysis stations at DCI Shelby would have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- The addition of four dialysis stations at DCI Shelby is needed and the proposal is a cost-effective alternative to meet the need for four dialysis stations [see Criteria (1), (3), (4) (5), and (12) for additional discussion];
- The applicant has and will continue to provide quality services [see Criteria (7), (8) and (20) for additional discussion];
- The applicant has and will continue to provide adequate access to medically underserved populations [see Criterion (13) for additional discussion].

Therefore, the application is conforming to this criterion.

Dialysis Clinic, Inc. d/b/a DCI Boiling Springs Dialysis See Sections II, III, V, VI, and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the addition of one dialysis station, not four, at DCI Boiling Springs would have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- The addition of one dialysis station at DCI Boiling Springs is needed and the proposal is a cost-effective alternative to meet the need for one dialysis station [see Criteria (1), (3), (4) (5), (6), and (12) for additional discussion];
- The applicant has and will continue to provide quality services [see Criteria (7), (8) and (20) for additional discussion];
- The applicant has and will continue to provide adequate access to medically underserved populations [see Criterion (13) for additional discussion].

Therefore, the application is conforming to this criterion, subject to the condition to add one station in Condition 2, Criterion (4).

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC Cleveland County In Sections II, III, V, VI, and VII, the applicant discussed its proposal and the impact it would have upon the quality and access to the proposed services; however the information provided by the applicant in those sections is not reasonable and credible and fails to adequately demonstrate that the proposal would have a positive impact upon the cost effectiveness of the project for the following reason: The relocation of ten dialysis stations from four existing facilities in counties contiguous to Cleveland County to develop a new facility in Cleveland County is not needed and the proposal is not a cost-effective alternative to meet the need of the current patients [see Criteria (1), (3), (4) (5) and (6) for additional discussion].

Therefore, the application is non-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
DCI Shelby
DCI Boiling Springs
FMC Cleveland

DCI Shelby - The applicant currently provides dialysis services at **DCI Shelby**. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy within the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

DCI Boiling Springs - The applicant currently provides dialysis services at **DCI Boiling Springs**. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy within the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

FMC Cleveland - The applicant is proposing to relocate 10 stations from four other locations and develop a new facility. The four locations from which the applicant proposes to transfer stations include: BMA Burke County, BMA Hickory, BMA Lincolnton, and BMA Kings Mountain. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the transferring facilities operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy within the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C
DCI Shelby

CA
DCI Boiling Springs

NC
FMC Cleveland

The Criteria and Standards for End Stage Renal Disease Services, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review.

The proposal submitted by **DCI Shelby** is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C .2200.

The proposal submitted by **DCI Boiling Springs** is conditionally conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C .2200.

The proposal submitted by **FMC Cleveland** is not conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C .2200.

The specific findings are discussed below.

.2202 INFORMATION REQUIRED OF APPLICANTS

(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-	**DCI Shelby**	See Section III.7, page 53, Section IV.1-2, page 59, and the July 2011 SDR, Table A.
-C-	**DCI Boiling Springs**	See Section III.7, page 53, Section IV.1-2, page 58, and the July 2011 SDR, Table A.
-NC-	**FMC Cleveland**	For projected utilization rates see Section III.7, page 56. For utilization rates for the facilities proposing to transfer stations see Section IV.1-2, pages 62-63, and the July 2010 SDR, Table A. However the proposed utilization rates are not credible. See Criterion 3 for discussion.

If the applicant used the Five Year Annual Change

Rate of 4.1%, as shown in the table below, the applicant would not meet the performance standard of at least 3.2 patients per week, per station by the end of the first operating year. See 10A NCAC 14C .2203.

	In-Center Patients
Proposed facility begins with Cleveland County patients currently served by BMA as of 12/31/10	26
1/1/10 – 12/31/11	26.0000 x 1.041 = 27.0660
1/1/12 – 12/31/12	27.0660 x 1.041 = 28.1757
1/1/13 – 12/31/13	28.1757 x 1.041 = 29.3309
1/1/14 – 12/31/14 **(PY1)**	29.3309 x 1.041 = **30.5335**
1/1/15 – 12/31/15 **(PY2)**	30.5335 x 1.041 = **31.7853**

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

-C- **DCI Shelby** See Section IV.2, page 59.
-C- **DCI Boiling Springs** See Section IV.2, page 58.
-C- **FMC Cleveland** For the facilities proposed to transfer stations see Section IV.2, page 63

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

-C- **DCI Shelby** See Section IV.1 & 3, pages 59-60.
-C- **DCI Boiling Springs** See Section IV.1 & 3, pages 58-59.
-C- **FMC Cleveland** For the facilities proposed to transfer stations see Section IV.1 & 3, pages 62-63.

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

-C- **DCI Shelby** See Section IV.4, page 60.
-C- **DCI Boiling Springs** See Section IV.4, page 59.
-C- **FMC Cleveland** For the facilities proposed to transfer stations see Section IV.4, page 64.

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

-C- **DCI Shelby** See Section IV.5, page 60.
-C- **DCI Boiling Springs** See Section IV.5, page 59.
-C- **FMC Cleveland** For the facilities proposed to transfer stations see Section IV.5, page 64.

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

-C- **DCI Shelby** See Section IV.6, pages 60.
-C- **DCI Boiling Springs** See Section IV.6, pages 59.
-C- **FMC Cleveland** For the facilities proposed to transfer stations see Section IV.6, page 64.

.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-	**DCI Shelby**	See Section IV.7, page 61.
-C-	**DCI Boiling Springs**	See Section IV.7, page 60.
-C-	**FMC Cleveland**	For the facilities proposed to transfer stations see Section IV.7, pages 64-65.

(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.*

-NA-	**DCI Shelby**	DCI Shelby is an existing facility.
-NA-	**DCI Boiling Springs**	DCI Boiling Springs is an existing facility.
-C-	**FMC Cleveland**	See Exhibit 16 for an agreement with Gaston Hospital.

.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-	**DCI Shelby**	DCI Shelby is an existing facility.
-NA-	**DCI Boiling Springs**	DCI Boiling Springs is an existing facility.
-C-	**FMC Cleveland**	See Exhibit 17.

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

-NA-	**DCI Shelby**	DCI Shelby is an existing facility.
-NA-	**DCI Boiling Springs**	DCI Boiling Springs is an existing facility.
-C-	**FMC Cleveland**	See Exhibits 30 and 31.

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

-C-	**DCI Shelby**	See Section XI.6(f), page 99, and Exhibit 22.
-C-	**DCI Boiling Springs**	See Section XI.6(f), page 99, and Exhibit 20.
-C-	**FMC Cleveland**	See Section XI.6(f), page 100, and Exhibit 12.

.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-	**DCI Shelby**	DCI Shelby is an existing facility.
-NA-	**DCI Boiling Springs**	DCI Boiling Springs is an existing facility.
-C-	**FMC Cleveland**	See Section XI.1-2, pages 96-98, and Exhibits 29-31.

.2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, and other relevant health and safety requirements.*

-C-	**DCI Shelby**	See Section VII, pages 79-81, Section XI.5, page 97, and Section XI.6(g), pages 99-100.
-C-	**DCI Boiling Springs**	See Section VII, pages 79-82, Section XI.5, page 97, and Section XI.6(g), page 99.
-C-	**FMC Cleveland**	See Section VII, pages 77-78, Section XI.5, page 99, and Section XI.6(g), pages 100-101.

.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-	**DCI Shelby**	See Section III.7, pages 53-54. See Criterion (3) for discussion.
-C-	**DCI Boiling Springs**	See Section III.7, page 53. See Criterion (3) for discussion.
-NC-	**FMC Cleveland**	The applicant does not adequately demonstrate the reasonableness of projected patient origin. See Section III.7, pages 55-60. See Criterion (3) for discussion. Furthermore, the applicant does not adequately demonstrate the reasonableness of patients who live in Cleveland County and currently choose to receive treatment in Hickory, Morganton, Lincolnton and

Kings Mountain choosing to travel to Shelby, in Cleveland County when they currently have that option, but choose not to use it. In addition, the applicant does not adequately demonstrate that BMA's current Cleveland County patients actually live closer to the proposed facility than to the facility where they are currently receiving treatment. Therefore, the applicant does not adequately identify the population proposed to be served.

.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-	**DCI Shelby**	DCI Shelby is an existing facility.
-NA-	**DCI Boiling Springs**	DCI Boiling Springs is an existing facility.
-C-	**FMC Cleveland**	See Section II.1, pages 20-21 and Section III.9, page 60.

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

-C-	**DCI Shelby**	See Section II.1, page 20.
-C-	**DCI Boiling Springs**	See Section II.1, pages 20-21.
-C-	**FMC Cleveland**	See Section II.1, page 21.

.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-	**DCI Shelby**	DCI Shelby is an existing facility.
-NA-	**DCI Boiling Springs**	DCI Boiling Springs is an existing facility.
-NC-	**FMC Cleveland**	BMA does not adequately demonstrate the need to develop a 10-station facility in Cleveland County based on utilization of 3.2 patients per station per week. See Criterion 3 for discussion. If the applicant used the Five Year Annual Change Rate of 4.1%, as shown in the table below, the applicant would not meet the performance standard of at least 3.2 patients per week, per station by the end of the first operating

year. See 10A NCAC 14C .2203.

	In-Center Patients
Proposed facility begins with Cleveland County patients currently served by BMA as of 12/31/10	26
1/1/10 – 12/31/11	26.0000 x 1.041 = 27.0660
1/1/12 – 12/31/12	27.0660 x 1.041 = 28.1757
1/1/13 – 12/31/13	28.1757 x 1.041 = 29.3309
1/1/14 – 12/31/14 **(PY1)**	29.3309 x 1.041 = **30.5335**
1/1/15 – 12/31/15 **(PY2)**	30.5335 x 1.041 = **31.7853**

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

-C- **DCI Shelby** In Section III.7, pages 53-54, the applicant projects to serve 96 in-center patients or 3.3 patients per station [96 / 29 = 3.3] by the end of Year 1 for the proposed 29-station facility. See Criterion (3) for discussion.

-CA- **DCI Boiling Springs** In Section III.2, page 50, the applicant projects to serve 56 in-center patients by the end of Year 1 for the proposed 14-station facility. However, the number of stations was conditioned and lowered to 1. See Criterion 4, Condition 2.

Using Cleveland County's Five Year Average Annual Change Rate of 4.1% to project growth, the facility would project to serve 37 in-center patients or 3.36 patients per station [37 / 11 = 3.36] by the end of Year 1 for the conditioned 11-station project. See Criterion (3) for discussion.

-NA- **FMC Cleveland** BMA is not proposing to add stations to an existing or previously CON-approved facility. BMA is proposing to develop a new facility.

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

-C- **DCI Shelby** In Section III.2, pages 47-51, the applicant provides the assumptions and methodology used to project patient utilization. See Criterion (3) for discussion.

-CA- **DCI Boiling Springs** In Section III.2, pages 45-51, the applicant provides the assumptions and methodology used

to project patient utilization. The methodology includes using a growth rate that is lower than the Facility Change Method, but unsubstantiated and still too high. As conditioned, using the Five Year Average Annual Change Rate of 4.1% to project utilization, the facility needs 1 additional station. See Criterion (3) for discussion.

-NC- **FMC Cleveland**

In Section III.3, pages 43-54, and Section III.7, pages 55-60, the applicant provides the assumptions and methodology used to project patient utilization. See Criterion 3 for discussion of reasonableness of projections.

The applicant projects a 5.5202% annual growth rate for Cleveland County based on *"**one half** of the calculated recent annual growth rate for Cleveland County (see d. above)"*; not on the Semiannual Dialysis Report (SDR) currently published Five Year Annual Change Rate of 4.1%. [Emphasis in original.] Project analyst calculated one-half of the "calculated rate" referenced in *d* above (11.75%) which equals 5.875%, not 5.5202% [11.75% x .5 = 5.875]. In addition, the "calculated rate" is basically the annual growth rate for the last year (6/30/10 – 6/30/11) [(247 – 221)/221 = 26 / 221 = .117647 or 11.76%], since there was no growth over the first 3 months of the 18-month period the applicant used in its "calculated rate". The methodology used in determining County Need in the SDR includes a Five Year Annual Change Rate in order to smooth out the ups and downs of any one year, including changes in the number of facilities, stations or patients throughout a county and thus provides a more stable, predictive growth rate. The methodology used in determining Facility Need in the SDR includes a one year growth rate based on the most recent 6 months' growth because a facility's own experience is being used to predict its future growth and need. The applicant is proposing to develop a new facility and thus does not have a facility growth rate to use in projections and it did not provide a growth rate for the Cleveland

County patients it currently serves in the transferring facilities. Therefore, the most reasonable growth rate to use is the Five Year Annual Change Rate published in the SDR, which is 4.1%: not 11.76% or 5.5202%.

.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- **DCI Shelby** See Section V.1, page 62.
-C- **DCI Boiling Springs** See Section V.1, page 61.
-C- **FMC Cleveland** See Section V.1, page 66.

.2204(2) Maintenance dialysis;

-C- **DCI Shelby** See Section V.1, page 62.
-C- **DCI Boiling Springs** See Section V.1, page 61.
-C- **FMC Cleveland** See Section V.1, page 66.

.2204(3) Accessible self-care training;

-C- **DCI Shelby** See Section V.1, page 62.
-C- **DCI Boiling Springs** See Section V.1, page 61.
-C- **FMC Cleveland** See Section V.1, page 66

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

-C- **DCI Shelby** See Section V.1, page 62.
-C- **DCI Boiling Springs** See Section V.1, page 61.
-C- **FMC Cleveland** See Section V.1, page 66.

.2204(5) X-ray services;

-C- **DCI Shelby** See Section V.1, page 62.
-C- **DCI Boiling Springs** See Section V.1, page 61.
-C- **FMC Cleveland** See Section V.1, page 66.

.2204(6) Laboratory services;

-C- **DCI Shelby** See Section V.1, page 63.
-C- **DCI Boiling Springs** See Section V.1, pages 61-62.
-C- **FMC Cleveland** See Section V.1, page 66.

.2204(7) Blood bank services;

-C- **DCI Shelby** See Section V.1, page 63.
-C- **DCI Boiling Springs** See Section V.1, page 62.
-C- **FMC Cleveland** See Section V.1, page 66.

.2204(8) Emergency care;

-C- **DCI Shelby** See Section V.1, page 62.
-C- **DCI Boiling Springs** See Section V.1, page 61.
-C- **FMC Cleveland** See Section V.1, page 66.

.2204(9) Acute dialysis in an acute care setting;

-C- **DCI Shelby** See Section V.1, page 62.
-C- **DCI Boiling Springs** See Section V.1, page 61.
-C- **FMC Cleveland** See Section V.1, page 66.

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

-C- **DCI Shelby** See Section V.1, page 63.
-C- **DCI Boiling Springs** See Section V.1, page 62.
-C- **FMC Cleveland** See Section V.1, page 66.

.2204(11) Transplantation services;

-C- **DCI Shelby** See Section V.1, page 62.
-C- **DCI Boiling Springs** See Section V.1, page 62.
-C- **FMC Cleveland** See Section V.1, page 66.

.2204(12) Vocational rehabilitation counseling and services;

-C- **DCI Shelby** See Section V.1, page 63.
-C- **DCI Boiling Springs** See Section V.1, page 62.
-C- **FMC Cleveland** See Section V.1, page 66.

.2204(13) Transportation

-C- **DCI Shelby** See Section V.1, page 63.
-C- **DCI Boiling Springs** See Section V.1, page 62.
-C- **FMC Cleveland** See Section V.1, page 66.

.2205 STAFFING AND STAFF TRAINING

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

-C- **DCI Shelby** See Section VII, pages 79-82.
-C- **DCI Boiling Springs** See Section VII, pages 79-82.
-C- **FMC Cleveland** See Section VII, pages 76-79.

.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- **DCI Shelby** See Section VII.5, page 80, and Exhibit 7.
-C- **DCI Boiling Springs** See Section VII.5, page 80, and Exhibit 7.
-C- **FMC Cleveland** See Section VII.5, page 77, and Exhibit 15.

DISCUSSION OF COMPARATIVE ANALYSIS

DCI, Inc. d/b/a **DCI Shelby**, DCI, Inc. d/b/a **DCI Boiling Springs** and BMA d/b/a **FMC Cleveland** each filed an application for review beginning October 1, 2011. DCI Shelby proposes to add four stations to its existing ESRD facility in Shelby and DCI Boiling Springs proposes to add four stations to its existing ESRD facility in Boiling Springs; each pursuant to the ESRD Facility Need Methodology. FMC Cleveland proposes to relocate ten stations from four existing facilities outside of Cleveland County to develop a 10-station ESRD facility in Shelby, Cleveland County, pursuant to Policy ESRD 2: Relocation of Dialysis Stations. Thus, the proposals are for the same or similar services. Further, the proposed FMC Cleveland site is within two and one-half miles and five minutes of the current DCI Shelby site, and 11 miles and 21 minutes from the current DCI Boiling Springs site. Although FMC Cleveland states that it is only going to serve its own patients and is not going to take patients from the existing providers, geographically FMC Cleveland proposes to serve essentially the same patient population as the DCI facilities. The following table illustrates the proposed service areas for each proposal.

PATIENT ORIGIN	DCI SHELBY	DCI BOILING SPRINGS	FMC CLEVELAND
Facility ZIP Code	28150	28152	28150 (Proposed)
Cleveland County	83.7%	70.8%	100.0%
Gaston County	12.0%		
Lincoln County	2.6%	3% [2.1%]	
Rutherford County		26% [27.1%]	
Cherokee, SC County	1.7%		

Pursuant to 10A NCAC 14C .0202(f), *"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 determined that the approval of the DCI Shelby application (Project I.D. #C-8732-11) and/or the DCI Boiling Springs application (Project I.D. #C-8733-11) filed in this review period did not result in the disapproval of the FMC Cleveland application (Project I.D. #C-8756-11) also filed in this review period. Rather, the FMC Cleveland application was disapproved for other reasons.

In summary, the Agency determined that the three applications submitted for review beginning October 1, 2011 are not competitive, and therefore, a comparative analysis was not prepared.