

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: May 5, 2014

PROJECT ANALYST: Celia C. Inman

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: G-10255-14 / Carolina Dialysis of Mebane / Add two dialysis stations for a total of 12 certified stations upon completion of this project / Alamance 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

Carolina Dialysis of Mebane, LLC d/b/a Carolina Dialysis - Mebane proposes to add two dialysis stations for a total of 12 certified dialysis stations upon completion of this project. The facility is located at 1410 South 3<sup>rd</sup> Street, Mebane, Alamance County. The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 13 dialysis stations in Alamance County; therefore, it does not indicate additional stations are needed based on the county need methodology. However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for Carolina Dialysis - Mebane (FMC Mebane<sup>1</sup>) in the January 2014 SDR is 3.40 patients per station. This utilization rate was calculated based on 34 in-center dialysis patients and 10 certified dialysis stations. (34 patients / 10 stations = 3.4 patients per station).

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<sup>1</sup> Carolina Dialysis of Mebane, LLC acquired FMC Mebane in August 2012. The January SDR still refers to the center as FMC Mebane.

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

**APRIL 1 REVIEW-JANUARY 2014 SDR**

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/13		85%
Certified Stations		10
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>10</b>
In-Center Patients as of 6/30/13 (SDR2)		34
In-Center Patients as of 12/31/12 (SDR1)		31
Step	Description	
(i)	Difference (SDR2 - SDR1)	3
	Multiply the difference by 2 for the projected net in-center change	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/12	0.1935
(ii)	Divide the result of Step (i) by 12	0.0161
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 12/31/12 until 6/30/13)	0.0968
(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	37.2903
(v)	Divide the result of Step (iv) by 3.2 patients per station	11.6532
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations] to determine the number of stations needed	2

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 2 stations, up to a maximum of 10. Step (C) of the facility need methodology states *“The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.”* The applicant proposes to add two new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3: BASIC PRINCIPLES, page 38, of the 2014 SMFP is applicable to this review. Policy GEN-3 states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant*

*shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

### Promote Safety and Quality

In Section II.3, pages 33-35, the applicant discusses insuring and maintaining quality care. On page 33, the applicant states:

*“The Quality Team monitors quality improvement, regulatory compliance, systems education and technical proficiency for FMC facilities. They are under the direct supervision of the Business Unit Vice President of Quality who leads the implementation of all quality initiatives which may be generated by corporate or at the business unit level.”*

The applicant further states that other quality monitoring activities used include: periodic unannounced technical audits, Quality Improvement committee minutes, ongoing clinical review program, certification compliance surveys, and Core Indicator measurements. The applicant also states it has eliminated the re-use concept in its facilities and provides every patient a new dialyzer at each treatment, thereby enhancing quality. See Exhibit 13 for copies of the Quality Assessment and Performance Improvement for FMS Inpatient Services Programs.

In Section 1.13, page 5-9, the applicant discusses the quality of services provided at Carolina Dialysis - Mebane, attributing much of its success in providing quality services to the expertise of its healthcare leaders: UNC Hospitals and Fresenius Medical Care (FMC), parent company to National Medical Care, Inc, parent to Bio-Medical Applications of North Carolina. On page 5, the applicant states, *“The excellence in patient care and patient outcomes facilitated by Carolina Dialysis, LLC is a direct result of the culture Carolina Dialysis, LLC, fosters among its staff and physicians.”* The applicant states that Carolina Dialysis, LLC and UNC Hospitals have chosen Renal Research Institute (RRI) as the contracted manager for the facility. The applicant further states that FMC offers a strong corporate structure and extensive management background to the Carolina Dialysis - Mebane facility, specifically its Clinical Services Department, Technical Services Department, Regulatory Affairs and Law Departments, and other management resources as discussed, in part, below.

- Clinical Services Department
  - Serves as a central resource for the entire FMC network
  - Provides facilities with the best procedures and equipment available
  - Assists facility managers and medical personnel with questions and concerns on clinical operations
  - Provides ongoing Clinical Review Program, guidelines for comprehensive staff training, and Quality Assurance Program

- Technical Services Department
  - Oversees the technical and mechanical aspects of dialysis
  - Supported by a research and quality control team that leads the industry in dealing with technically complex issues facing dialysis providers
  
- Regulatory Affairs and Law Departments
  - Deals with legal and regulatory issues
  - Provides interpretation of legislation and government policy to ensure compliance
  
- Other Management Resources, including but not limited to
  - Revenue Operations – draws experience through interaction with more than 13 Medicare intermediaries and numerous third-party carriers
  - Accounting and Budget – tailored to ensure effective financial management of dialysis treatment centers
  - Facility Design and Maintenance – experienced architectural staff promotes development of efficiently designed facilities
  - Human Resources – develops productivity standards, job descriptions, staff performance reviews, personnel policies and procedures and employee relations.
  - Information Systems – develops comprehensive facility automation including enhanced software for clinical management to support delivery of high quality care
  - Operations Department – ensures effective transition of acquired programs in the division, the training of all field staff on systems applications, and the efficiency of facility administrative support
  - Health, Safety, and Risk Management – provides regulatory information used to ensure compliance in the dialysis setting and provides risk management services.
  - Renal Research Institute – a wholly-owned subsidiary of FMCNA, initiates a wide range of research activities including the development and evaluation of the latest technology with the goal of creating innovative clinical protocols for improved renal care.
  - Business Units and Regional Vice Presidents – provide operational direction and monitoring of daily operations.

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

Promote Equitable Access

In Section II, page 26, the applicant states:

*“CDM has removed the economic barriers with regard to access to treatment. The overwhelming majority of dialysis treatments are covered by Medicare / Medicaid; in fact, within this application, CDM is projecting that 71.2% of the In-Center dialysis treatments will be covered by Medicare or Medicaid. Thus, the overwhelming majority of the In-Center revenue is derived from government payors.”*

The applicant states on page 27 that Carolina Dialysis - Mebane is also keenly sensitive to the second element of “equitable access” – time and distance barriers. The applicant states that at this time, Alamance County has four operational dialysis facilities. The applicant further states that as the patient population continues to increase, the need for dialysis stations will continue to increase and it will apply to develop new dialysis facilities when needed.

In Section VI.1, page 50, the applicant states:

*“CDM and parent organizations, Fresenius Medical Care and Carolina Dialysis, LLC., has [sic] a long history of providing dialysis services to the underserved populations of North Carolina. Fresenius Medical Care Holding, Inc. parent company to Bio-Medical Applications of North Carolina, Inc. and Renal Research Institute, currently operates 100 facilities in 42 North Carolina Counties; in addition, Fresenius through BMA, has seven facilities under development or pending CON approval; Carolina Dialysis, LLC has one other facility under development in Lee County. Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.”*

The applicant further states, *“It is CDM policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”*

The applicant states that the patient population of the Carolina Dialysis – Mebane facility is comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
Carolina Dialysis-Mebane	7.7%	35.9%	66.7%	41.0%	66.7%

Note: The Medicare percentage represents the percentage of patients receiving some type of Medicare benefit, not the percentage of facility treatment reimbursement.

The applicant adequately demonstrates that the proposal will promote equitable access.

### Maximize Healthcare Value

In Section II, page 27, the applicant states it is projecting a capital expenditure of \$6,000 for this project and is not seeking State or Federal monies or charitable contributions to develop the project. Rather, Carolina Dialysis – Mebane, through its parent company (FMC and Carolina Dialysis, LLC) is taking on the financial burden to complete this addition of stations in an effort to bring dialysis treatment close to the patient homes. The applicant goes on to state:

*“As an additional consideration, CDM notes that the overwhelming majority of dialysis treatments are reimbursed through Medicare, Medicaid, or other government payor sources. ... The point here is that government payors are working from a fixed payment schedule, often at significantly lower reimbursement rates than the posted charges. As a consequence, CDM must work diligently to control costs of delivery for dialysis. CDM does.”*

In Section V, page 49, the applicant states that its facilities have done an excellent job of containing costs while providing outstanding care and treatment to patients.

The applicant adequately demonstrates that the proposal will maximize healthcare value. Consequently, the applicant demonstrates that the projected volumes for the proposed service incorporate the basic principles in meeting the needs of the patients to be served. The application is consistent with the facility need determination in the January 2014 SDR and Policy GEN-3.

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES is not applicable to this review because the applicant is not proposing a capital expenditure greater than \$2 million.

Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

### C

The applicant, Carolina Dialysis - Mebane proposes to add two dialysis stations to the existing Carolina Dialysis - Mebane ESRD facility for a total of 12 dialysis stations upon completion of the project.

Population to be Served and Demonstration of Need

In Section IV.1, page 43, the applicant states the number of patients served at Carolina Dialysis - Mebane as of December 31, 2013 as follows:

County	# Patients Dialyzing at Home	# Patients Dialyzing In-Center
Alamance	6	27
Orange	1	4
Guilford	0	1
Total	7	32

The applicant proposes to add two dialysis stations to the existing Carolina Dialysis - Mebane facility for a total of 12 certified dialysis stations. In Section II, page 22 and Section 111.7, page 40, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as summarized in the table below:

**Projected Dialysis Patient Origin**

COUNTY	OPERATING YEAR 1 CY2016		OPERATING YEAR 2 CY2017		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	In-Center Patients	Home Patients	In-Center Patients	Home Patients	Year 1	Year 2
Alamance	35.6	7.9	39.1	8.7	87.89%	88.84%
Orange	4.0	1.0	4.0	1.0	10.09%	9.30%
Guilford	1.0	0.0	1.0	0.0	2.02%	1.86%
Total	40.6	8.9	44.1	9.7	100.00%	100.00%

In Section II, pages 13-16, and Section III. 7, pages 37-41, the applicant provides the assumptions and methodology it uses to project the proposed Carolina Dialysis - Mebane facility patient utilization.

The assumptions and methodology are summarized below:

- The January 2014 SDR reports FMC Mebane was operating at 85% utilization with a census of 34 in-center patients dialyzing on 10 certified dialysis stations as of June 30, 2013.
- On pages 13 and 38, Carolina Dialysis - Mebane projects the project will be complete December 31, 2015. The applicant further states, “*Operating Year 1 is the period from January 1, 2015 - December 31, 2016. Operating Year 2 is the period from January 1, 2016 - December 31, 2017.*” Obviously, the dates provided for Operating Years 1 and 2 are two-year periods, not one year

periods. The financials provided in Section X document that Operating Year 1 is Calendar Year 2016 and Operating Year 2 is Calendar Year 2017.

- Carolina Dialysis - Mebane assumes that the patient population of Alamance County will grow at 9.68%, the past 6-month growth or one half of the calculated annual rate of 19.4% produced by the applicant's Facility Need Methodology on page 36 of the application. The projected rate is more than the Alamance County five-year average annual change rate of 5.1% as published in the January 2014 SDR.
- Carolina Dialysis – Mebane is serving four in-center patients from Orange County and one patient from Guilford County. The applicant will reflect those patients in the facility census in the future, but will not demonstrate any increase in this segment of the patient population.
- Carolina Dialysis – Mebane assumes that Alamance County home patients served by the facility will similarly increase at a rate of 9.68%.

The following table demonstrates the calculations used to arrive at the projected In-Center patient census for Operating Years One and Two.

<b>Carolina Dialysis - Mebane</b>	<b>In-Center Patients</b>
Carolina Dialysis-Mebane begins with Alamance County patients utilizing Carolina Dialysis-Mebane as of December 31, 2013	27
The census is increased by the applicant's calculated average annual change rate for one year to December 31, 2014.	$(27 \times .0968) + 27 = 29.6$
The census is increased by the applicant's calculated average annual change rate for one year to December 31, 2015.	$(29.6 \times .0968) + 29.6 = 32.5$
Carolina Dialysis-Mebane adds five patients from Orange and Guilford County. This is the projected beginning census for this for the project (January 1, 2016).	$32.5 + 5 = 37.5$
The census of Alamance County residents is increased by the applicant's calculated average annual change rate for one year to December 31, 2016.	$(32.5 \times .0968) + 32.5 = 35.6$
Carolina Dialysis-Mebane adds five patients from Orange and Guilford County. This is the projected ending census for Operating Year 1 (December 31, 2016).	$35.6 + 5 = 40.6$
The census of Alamance County residents is increased by the applicant's calculated average annual change rate for one year to December 31, 2017.	$(35.6 \times .0968) + 35.6 = 39.1$
Carolina Dialysis-Mebane adds five patients from Orange and Guilford County. This is the projected ending census for Operating Year 2 (December 31, 2017).	$39.1 + 5 = 44.1$

At the end of operating year one, Carolina Dialysis - Mebane is projecting an in-center patient census of 40 patients for a utilization rate of 83.3% or 3.3 (40 patients / 12

stations = 3.33) patients per station. At the end of operating year two, Carolina Dialysis - Mebane is projected to have an in-center patient census of 44 patients for a utilization rate of 91.6% or 3.66 (44 patients / 12 stations = 3.66) patients per station.

The following table demonstrates the calculations used to project the home patient population at Carolina Dialysis – Mebane, using the same 9.68% annual growth rate.

<b>Carolina Dialysis - Mebane</b>	<b>Home Patients</b>
Carolina Dialysis-Mebane begins with Alamance County home patients utilizing Carolina Dialysis-Mebane as of December 31, 2013	6
The census is increased by the applicant’s calculated average annual change rate for one year to December 31, 2014.	$(6 \times .0968) + 6 = 6.6$
The census is increased by the applicant’s calculated average annual change rate for one year to December 31, 2015.	$(6.6 \times .0968) + 6.6 = 7.2$
Carolina Dialysis-Mebane adds one patient from Orange County. This is the projected beginning census for this for the project.	$7.2 + 1 = 8.2$
The census of Alamance County residents is increased by the applicant’s calculated average annual change rate for one year to December 31, 2016.	$(7.2 \times .0968) + 7.2 = 7.9$
Carolina Dialysis-Mebane adds one patient from Orange County. This is the projected ending census for Operating Year 1.	$7.9 + 1 = 8.9$
The census of Alamance County residents is increased by the applicant’s calculated average annual change rate for one year to December 31, 2017.	$(8.9 \times .0968) + 8.9 = 9.7$
Carolina Dialysis-Mebane adds one patient from Orange County. This is the projected ending census for Operating Year 2.	$9.7 + 1 = 10.7$

As shown above and in Section II, page 22 and Section III.7, page 40, the applicant provides its projection of patient population to be served by modality and county of residence.

COUNTY	OPERATING YEAR 1 CY2016		OPERATING YEAR 2 CY2017		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Alamance	35.6	7.9	39.1	8.7	87.89%	88.84%
Orange	4.0	1.0	4.0	1.0	10.09%	9.30%
Guilford	1.0	0.0	1.0	0.0	2.02%	1.86%
Total	40.6	8.9	44.1	9.7	100.00%	100.00%

Projected patient in-center utilization at the end of Year One is 3.3 in-center patients per station per week which satisfies the 3.2 in-center patients per station required by 10A NCAC 14C .2203(b).

Carolina Dialysis - Mebane assumes that the patient population of Alamance County will grow at 9.68%, which is one half of the calculated annual rate of 19.4% produced by the applicant's Facility Need Methodology on page 36 of the application. On page 38, the applicant states:

*"CDM does **not** assume that the patient population of Carolina Dialysis – Mebane will increase at a rate commensurate with the Alamance Five year Average Annual Change Rate as published in the January 2014 SDR. The Alamance growth rate is 5.1%.*

*CDM was only certified for operation on July 20, 2012. In the time since then the facility census has increased quickly. In fact, the Facility Need Methodology (see III.2) indicates the growth of the facility was calculated to be 19.4% in the six months ended June 30, 2013; this was less than a year after opening. CDM is not going to project the population to increase at this rate going forward. However, CDM does believe a rate of 5.1% is not appropriate to project future population of the facility."*

As stated by the applicant above, the growth rate of 19.4% was calculated based on the annualized difference in the number of patients five months after opening and 11 months after opening. The applicant does not propose to go forward at a growth rate of 19.4%, but rather states:

*"CDM assumes the facility census of Alamance County residents will increase at a rate of 9.68%. This is one half of the calculated rate produced by the Facility Need Methodology."*

The applicant assumes that the patient population of the Mebane facility will continue to increase at a rate faster than that of the county patient population. This assumption is supported by an analysis of the growth in the Mebane population as compared to the total Alamance County population. Statistics provided as North Carolina QuickFacts<sup>2</sup> from the US Census Bureau show Mebane's population has grown at a far higher rate than the county as a whole. Mebane's growth from 2010 to 2012 was 11.6%, more than six times that of Alamance County's growth at only 1.6%. Projected utilization is based on reasonable and supported assumptions regarding continued growth.

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<sup>2</sup> <http://quickfacts.census.gov>

Thus the applicant adequately identifies the population to be served and adequately demonstrates the need that population has for the proposed services.

Access to Services

In Section VI.1(a), page 50, the applicant states:

*“It is clear that Carolina Dialysis - Mebane provides service to historically underserved populations. It is CDM policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”*

On page 50, the applicant states that the patient population of the Carolina Dialysis – Mebane facility is comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
Carolina Dialysis-Mebane	7.7%	35.9%	66.7%	41.0%	66.7%

Note: The Medicare percentage represents the percentage of patients receiving some type of Medicare benefit, not the percentage of facility treatment reimbursement.

On pages 51 and 70, the applicant projects that 71% of its patients will be covered by Medicare or Medicaid. The applicant adequately demonstrates 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.

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed project based on reasonable and supported utilization projections and assumptions and demonstrates that all residents of the area will have adequate access to the services. Therefore, the application is conforming to this criterion.

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

NA

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

C

In Section III.9, page 42, the applicant discusses the alternatives considered prior to the submission of its application, which include:

- 1) Maintain the Status Quo – the applicant states, *“Failure to expand potentially denies patients a choice of dialysis at Carolina Dialysis – Mebane.”*
- 2) Apply for fewer expansion stations – the applicant states, *“This option seems to ignore the growing patient census at CDM. The Facility Need Calculations demonstrate that the facility is growing at 19.4% annually, significantly more than the Alamance County Five Year Average Annual Change Rate.”*
- 3) Chosen alternative – applying to expand the existing Carolina Dialysis – Mebane facility by adding two stations for a total of 12 certified dialysis stations.

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative based on the following:

- Carolina Dialysis – Mebane projected its patient population using an annual growth rate of 9.68%, one half its calculated annual growth rate of 19.4%.
- The Mebane community population is increasing at a far greater rate than Alamance County as a whole.
- The projected utilization is conforming with Criteria and Standards For End-Stage Renal Disease Services 10A NCAC 14C .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.”*

On page 19, the applicant projects it will serve 40 patients on 12 stations at the end of the first operating year.  $40 / 12 \text{ stations} = 3.33$ .

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Carolina Dialysis, LLC d/b/a Carolina Dialysis - Mebane shall materially comply with all representations made in the certificate of need application.**
  - 2. Carolina Dialysis, LLC d/b/a Carolina Dialysis - Mebane shall develop and operate no more than two additional dialysis stations for a total of no more than twelve (12) certified dialysis stations which shall include any home hemodialysis training stations or isolation stations.**
  - 3. Carolina Dialysis, LLC d/b/a Carolina Dialysis - Mebane shall install plumbing and electrical wiring through the walls for no more than twelve (12) dialysis stations which shall include any home training or isolation stations.**
  - 4. Carolina Dialysis, LLC d/b/a Carolina Dialysis - Mebane shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

## C

In the table in Section VIII, page 59, the applicant shows the capital cost of the project is \$6,000, which includes other equipment and furniture totaling \$4,000 and \$2,000 for water treatment equipment. In Section IX, page 63, the applicant states that because the project is for additional stations at an existing facility, there are no associated startup or initial operating expenses.

On page 61, the applicant states, *“This project will be financed through accumulated reserves.”* The applicant further states:

*“Please refer to Exhibit 24 for letter of commitment from Dr. Ronald Falk, Member Manager of Carolina Dialysis of Mebane. This letter will verify the availability of the CDM funds necessary for the project.”*

*In addition, the exhibit contains a letter from Mark Fawcett, Vice President and Assistant Treasurer, Fresenius Medical Care Holdings, Inc. This letter will verify the availability of the FMC funds necessary for the project; FMC is serving in a back-up position to the LLC. ”*

In Section VIII.8(b), page 62, the applicant states:

*“Carolina Dialysis of Mebane does not have any other CON projects at this time”.*

In Section VIII.7(a), page 61, the applicant states:

*“Exhibit 10 includes a copy of the Carolina Dialysis of Mebane Balance sheet demonstrating sufficient capital funds for this project. In addition, please refer to Exhibit [sic] for a copy of the most recent audited FMC Holdings, Inc., Consolidated Balance Sheet for 2011 and 2012.”*

Exhibit 10 contains Carolina Dialysis – Mebane’s Balance Sheet demonstrating cash in the amount of \$550,243 as of December 31, 2013 and a copy of the most recent audited Fresenius Medical Care Holdings, Inc. and Subsidiaries Consolidated Financial Statements. Thus, the applicant adequately demonstrates the availability of adequate funds to develop the project.

Based on information provided by the applicant in Section X.1, page 64, the dialysis facility’s projected allowable charges per treatment for each payment source are as follows:

<b>SOURCE OF PAYMENT</b>	<b>ALLOWABLE CHARGE PER TREATMENT</b>
Private Pay	\$1,425.00
Commercial Insurance	\$1,425.00
Medicare	\$234.00
Medicaid	\$137.29
VA	\$146.79
Medicare/Medicaid	\$234.00
Medicare/Commercial	\$234.00
State Kidney Program	\$100.00
Other: Self/Indigent	\$1,425.00

Based on the calculations presented in Section X.3, page 68, the facility reimbursement is the same as presented above as allowable charges.

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.<sup>3</sup> In Sections X.2-X.4, pages 66-73, the applicant reported projected revenues and expenses as follows:

	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$ 2,015,374	\$ 2,204,756
Total Operating Costs	\$1,982,741	\$2,118,661
Net Profit	\$32,632	\$86,095

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. See Section X.3, pages 67-69 of the application for the applicant's assumptions on number of treatments (3 treatments/week, 52 weeks/year, and 6.5% missed treatments) for in-center patients and 144 annual treatments for home program patients. The applicant's projections of treatments and revenues are reasonable based on the number of in-center and home patients projected for the first two operating years. See Criterion (3) for further discussion on the applicant's assumptions for projections which are hereby incorporated as if set forth fully herein.

In Section VII.1, page 56 and Section X.5, page 74, the applicant provides projected staffing and salaries. The applicant states compliance with all staffing requirements in 42 C.F.R. Section 494 (formerly 405.2100) on page 57. Staffing by shift is provided on page 58. The applicant provides adequate staffing to provide dialysis treatments for the number of patients projected.

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

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add two dialysis stations to its existing facility for a total of 12 certified dialysis stations upon completion of the proposed project. According to the January 2014 SDR, the county need methodology shows there is a surplus of 13 dialysis stations in Alamance County. There is no county need determination for additional dialysis stations or facilities in Alamance County. However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for Carolina Dialysis - Mebane (FMC Mebane) in the

<sup>3</sup> [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/End-Stage\\_Renal\\_Disease\\_Propective\\_Payment\\_System\\_ICN905143.pdf](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/End-Stage_Renal_Disease_Propective_Payment_System_ICN905143.pdf) and <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-Sheets/2013-Fact-Sheets-Items/2013-07-012.html>

January 2014 SDR is 3.4 patients per station. This utilization rate was calculated based on 34 in-center dialysis patients and 10 certified dialysis stations. (34 patients / 10 stations = 3.4 patients per station). The applicant is applying for additional stations based on the facility need methodology. According to the January 2014 SDR, Carolina Dialysis -Mebane was operating at 85% capacity ( $34 / 10 = 3.4$ ;  $3.4 / 4 = 0.85$  or 85%). The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility. Based on the calculations above, the applicant is eligible to expand its facility and may apply for two additional stations. See Criterion (1) for the discussion on facility need which is hereby incorporated as if set forth fully herein.

Based on the applicant's projections on page 19, upon completion of the proposed project, the facility will have 12 stations serving a proposed 40 in-center patients in Operating Year 1, which is a utilization rate of 83.3% ( $40 / 12 = 3.33$ ;  $3.33 / 4 = .833$  or 83.3%). The applicant based its utilization projections on reasonable and supported assumptions. See the discussion of methodology and assumptions in Criterion (3) which is incorporated hereby as if set forth fully herein. Therefore, the applicant is conforming with the required performance standard in 10A NCAC 14C .2203.

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 to this criterion.

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

C

The following table illustrates the projected staffing for Carolina Dialysis - Mebane, as provided by the applicant in Section VII.1, page 56.

<b>Position</b>	<b>Total FTE Positions</b>
RN	2.00
Pt Care Tech	4.00
Clinical Mgr (DON)	1.00
Chief Tech	0.10
MD	
Admin	0.15
Dietician	0.33
Social Worker	0.33
Home Training Nurse	0.66
Clerical/Medical Records	0.80
In-Service Tech	0.20
Equipment Tech	0.50
<b>Total</b>	<b>10.07</b>

As shown in the above table, the applicant proposes to employ a total of 10.07 full-time equivalent (FTE) positions to staff the Carolina Dialysis - Mebane facility upon completion of the proposed project. In Section VII.1, page 57, the applicant states,

*“CDM anticipates no difficulties in filling staff positions.”*

The following table shows the projected number of direct care staff for each shift offered at Carolina Dialysis - Mebane after the addition of the two dialysis stations.

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	7:00 am to 12:00 pm	4	4	4	4	4	4
Afternoon	12:00 pm to 5:00 pm	4	4	4	4	4	4
Evening	N/A	0	0	0	0	0	0

In Section V.4, page 47, the applicant states that Amy Mottl, M.D., of UNC Kidney Center will serve as Medical Director of the proposed facility. Exhibit 21 contains a letter signed by Dr. Mottl, expressing support for the addition of two stations and agreeing to continue her relationship with the facility. In Section VII, page 58, the applicant states there are 14 nephrologists providing coverage at the facility, with each one maintaining privileges at one or more of the following hospitals: UNC Hospital, Central Carolina Hospitals, and Alamance Regional Medical Center. The 14 nephrologists expressing support for the project and a willingness to provide coverage are listed on page 48 of the application.

The applicant documents the availability of adequate health manpower and management personnel, including the medical director, for the provision of dialysis services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section V.1, page 45, the applicant provides a list of providers of the necessary ancillary and support services. Acute dialysis in an acute care setting will be provided at Alamance Regional Medical Center or UNC Hospital, by patient choice. Alamance Regional Medical Center will provide diagnostic evaluation, X-ray, and blood bank services. Transplantation (Exhibit 17), psychological counseling, and pediatric nephrology will be referred to UNC Hospital. Vascular surgery will be provided by UNC Hospital, Alamance Vein and Vascular and Carolina Vascular Associates. All Carolina Dialysis – Mebane staff are trained to respond to emergencies and there is a fully stocked crash cart available on-site. If needed, patients will be transported by ambulance for further acute care. Spectra will provide laboratory services (Exhibit 18). Self care training, including hemodialysis, peritoneal dialysis, CAPD and CCPD will be provided on-site by Carolina Dialysis – Mebane. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:

- (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and

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

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

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

C

In Section VI.1(a), page 50, the applicant states that Fresenius Medical Care Holdings, inc. parent company to Bio-Medical Applications of North Carolina, inc. and Renal Research Institute, currently operates 100 dialysis facilities in 42 North Carolina counties. The applicant further states, *“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.”* The patient population of the Carolina Dialysis – Mebane facility is comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
Carolina Dialysis-Mebane	7.7%	35.9%	66.7%	41.0%	66.7%

Note: The Medicare percentage represents patients receiving some type of Medicare benefit: this is not to say 66.7% of the treatment reimbursement is from Medicare.

On page 50, the applicant further states:

*“CDM notes that the historical performance as reported here is a function of the payor mix for Carolina Dialysis – Mebane as of December 31, 2013. The historical performance does change as new patients are admitted. Commercial insurance for patients generally covers the patient for a period of 30 months from the beginning of treatment; thereafter, Medicare provides coverage for the patient. The commercial insurance population is therefore constantly changing. In addition, not every patient beginning dialysis has commercial insurance. Thus, the payor mix should be considered dynamic and not fixed.”*

In Section VI.1(b), page 51, the applicant reports that 71% of the patients who were receiving treatments at Carolina Dialysis – Mebane as of December 31, 2013, had some or all of their services paid for by Medicare or Medicaid in the past year. The following table illustrates the historical payment source for the facility.

<b>CAROLINA DIALYSIS - MEBANE PAYOR MIX</b>		
<b>SOURCE OF PAYMENT</b>	<b>IN-CENTER %</b>	<b>HOME %</b>
Commercial Insurance	4.8%	0.0%
Medicare	62.6%	70.8%
Medicaid	8.6%	0.0%
Medicare/Commercial*	22.9%	29.2%
Other: Self/Indigent	1.2%	0.0%
Total	100.0%	100.0%

\*Typographical error shows this as State Kidney Program on page 51.  
 Totals may not sum due to rounding.

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Alamance County and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Alamance County	16%	6.2%	21.0%
Statewide	17%	6.7%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2012 only 6.5% of all newly-diagnosed ESRD patients in North Carolina’s Network 6 were under the age of 35 (*ESRD Network 6 2012 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2012 – 12/31/2012, page 74*).

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data are available by age, race or gender. However, a direct comparison to the applicant’s current payor mix would be of little value. The population data by age, race or gender do not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM’s website does not include information on the number of handicapped persons.

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

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ....”*<sup>4</sup> (p. 216)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were white, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p.218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 216). The report further states:

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

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<sup>4</sup> [www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

The report states that the overall Medicare expenditures for chronic kidney disease for 2011 were \$49.2 billion, including Medicare Part D (p. 118). The *2013 USRDS Annual Data Report* provides 2011 ESRD spending by payor, as follows:

<b>ESRD Spending by Payor</b>		
<b>Payor</b>	<b>Spending in Billions</b>	<b>% of Total Spending</b>
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
<b>Total</b>	<b>\$49.2</b>	<b>100.0%</b>

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

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2012</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
0-19	73	0.5%
20-34	751	5.0%
35-44	1,442	9.7%
45-54	2,644	17.7%
55-64	4,013	26.9%
65+	5,995	40.2%
<b>Gender</b>		
Female	6,692	44.9%
Male	8,226	55.1%
<b>Race</b>		
African-American	9,346	62.7%
White/Caucasian	5,191	34.8%
Other	380	2.5%

Source: SKC Network 6, which includes North Carolina, South Carolina and Georgia.<sup>5</sup>

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

<sup>5</sup>[www.esrdnetwork6.org/publications/reports.html](http://www.esrdnetwork6.org/publications/reports.html)

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

C

In Section VI.1(f), page 53, the applicant states,

*“CDM 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 patients 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 CDM North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”*

In Section VI.6 (a), page 54, the applicant states, *“There have been no Civil Rights complaints lodged against any CDM in the past five years.”*

The application is conforming to this criterion.

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

C

In Section VI.1(d), page 52, the applicant states:

*“CDM will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”* [emphasis in original]

On page 51, Carolina Dialysis - Mebane reports that it expects over 71% of the in-center patients who received treatments at Carolina Dialysis - Mebane to have all their services paid for by Medicare or Medicaid as indicated below. Another 23% have a portion of their services paid for by Medicare.

<b>CAROLINA DIALYSIS - MEBANE IN-CENTER PAYOR MIX</b>	
<b>SOURCE OF PAYMENT</b>	<b>PERCENTAGE</b>
Commercial Insurance	4.8%
Medicare	62.6%
Medicaid	8.6%
Medicare/Commercial	22.9%
Other: Self/Indigent	1.2%
<b>Total</b>	<b>100.0%</b>

Totals may not sum due to rounding.

Page 51 identifies 22.9% of the source of payment as State Kidney Program and 0% Medicare/Commercial; however, this is a typographical error, as confirmed by the applicant. Other locations in the application, including the financials in Section X list the 22.9% as Medicare/Commercial with 0% State Kidney Program. The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5, page 54, the applicant states that:

*“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. Carolina Dialysis - Mebane 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 applicant adequately demonstrates that it provides a range of means by which a person can access the proposed services. Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.3, page 47, the applicant states,

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

The applicant further states that Exhibit 19 contains a letter to Alamance Community College encouraging the school to include the Carolina Dialysis – Mebane facility in their clinical rotations for nursing students. 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

The applicant proposes to add two dialysis stations for a total of 12 certified dialysis stations upon completion of this project. According to the January 2014 SDR, Alamance County has four dialysis centers, as shown below:

ALAMANCE COUNTY DIALYSIS CENTERS		
FACILITY	LOCATION	UTILIZATION
BMA Burlington	Burlington	64.44%
Burlington Dialysis	Burlington	96.25%
FMC Mebane (Carolina Dialysis - Mebane)	Mebane	85.00%
North Burlington Dialysis	Burlington	115.00%

In Section V.7, pages 49, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states it does not expect this proposal to have an effect on the competitive climate in Alamance County. The applicant further states:

*“CDM does not expect this small expansion to affect other providers and seeks the opportunity to continue providing dialysis care and treatment to the patients of the area.*

...

*CDM is compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, CDM projects that 71% of the In-center patients will be relying upon either Medicare or Medicaid.*

...

*Our facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients.*

...

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

The information provided above by the applicant is reasonable and credible and adequately demonstrates that the addition of two stations to the existing facility will have a positive impact on cost-effectiveness, quality and access to the proposed dialysis services because:

- The applicant adequately demonstrates the need to add two certified dialysis stations to the existing 10-station Mebane facility;
- The applicant adequately demonstrates that the proposed project is a cost-effective alternative to meet the need to provide better access to patients in Alamance County;
- The applicant adequately demonstrates it has provided and will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494. The information regarding ancillary and support services and coordination of services with the existing health care community in Sections V and VII, pages 45-49 and 56-58, respectively, and referenced exhibits is reasonable and credible and demonstrates the provision of quality care; and
- The applicant demonstrates it will provide adequate access to medically underserved populations (more than 70% are Medicare or Medicaid patients and

more than 22% are covered by a combination of Medicare and Commercial Insurance).

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

Carolina Dialysis - Mebane currently provides dialysis services. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the Carolina Dialysis - Mebane facility operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C Section .2200. The specific findings are discussed below.

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

**.2202 INFORMATION REQUIRED OF APPLICANT**

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

(1) *Utilization rates;*

- C- In Section II.1, page 11, the applicant states that the utilization rate is reported in the January 2014 SDR. The January 2014 SDR shows a utilization rate of 85% for FMC Mebane<sup>6</sup>. The rate was calculated based on 34 in-center dialysis patients and 10 certified dialysis stations as of June 30, 2013 (34 patients / 10 stations = 3.40 patients per station; 3.40 patients per station / 4.00 patients per station = 85%). In Section II, page 19, the applicant projects serving 40 dialysis patients on 12 stations for a utilization rate of 83.3% ( $40 / 12 = 3.33 / 4 = 83.33\%$ ) in year 1 and 44 dialysis patients on 12 stations for a utilization rate of 91.7% ( $44 / 12 = 3.66 / 4 = 91.66\%$ ) in year 2. The applicant adequately demonstrates that the projection of patient utilization is based on reasonable and supported assumptions. See further discussion of the assumptions and projected utilization in Criterion (3) which is hereby incorporated as if set forth fully herein.

(2) *Mortality rates;*

- C- In Section IV.2, page 43, the applicant reports the 2012 and 2013 facility mortality rates as 15.4%.

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

- C- In Section IV.3, page 43, the applicant states, “*CDM has seven home trained dialysis patients at this time. All seven are dialyzing at home. The facility has trained three patients YTD.*”

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

- C- In Section IV.4, page 43, the applicant provides information showing Carolina Dialysis - Mebane referred 0 and 3 patients for transplant in 2012 and 2013, respectively and had 1 transplant performed in 2013.

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

- C- In Section IV.5, page 43, the applicant states, “*Carolina Dialysis - Mebane has ten patients on the transplant waiting list.*”

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

- C- In Section IV.6, page 44, the applicant states that there were 44 hospital admissions in 2013, 3 (6.8%) of which were dialysis related and 41 (93.2%) non-dialysis related.

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<sup>6</sup> Carolina Dialysis - Mebane acquired FMC Mebane in August 2012. The SDR still refers to the facility as FMC Mebane.

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

-C- In Section IV.7, page 44, the applicant provides information that shows there were 0 patients dialyzing at Carolina Dialysis - Mebane with Hepatitis B Conversions during 2012 and 2013. The applicant further shows 0 current patients with Infectious Disease (Hepatitis B).

(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:*

(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- Carolina Dialysis – Mebane is an existing facility. CDM includes a hospital affiliation agreement in Exhibit 16.

(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- Carolina Dialysis – Mebane is an existing facility. CDM includes a transplant agreement in Exhibit 17 which includes the items listed above.

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

-NA- Carolina Dialysis – Mebane is an existing facility.

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

-C- See Exhibit 12, in which the applicant provides copies of written policies and procedures, including back up procedures in the event of a power outage.

(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- Carolina Dialysis – Mebane is an existing facility.

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

-C- In Section II, page 13, the applicant states:

*“CDM will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations. CDM staffing consistently meets CMS and State guidelines for dialysis staffing. Fire safety equipment, the physical environment, water supply and other relevant health and safety equipment will be appropriately installed and maintained at CDM.”*

In Section XI.6(g), page 79, the applicant states, *“CDM of North Carolina provides and will continue to provide services in conformity with applicable laws and regulations pertaining to staffing, fire safety and equipment, physical environment and other relevant health and safety requirements. Information detailing conformity can be found in Sections II and VII and exhibits referenced therein. Additionally, this applicant has confirmed its commitment to provide services in conformity with the law on the Certification page provided in the front of the application.”*

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

-C- The applicant provides the following projected patient origin on pages 16 and 40 of the application, as shown below.

**Projected Dialysis Patient Origin**

COUNTY	OPERATING YEAR 1 CY2016		OPERATING YEAR 2 CY2017		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Alamance	35.6	7.9	39.1	8.7	87.89%	88.84%
Orange	4.0	1.0	4.0	1.0	10.09%	9.30%
Guilford	1.0	0.0	1.0	0.0	2.02%	1.86%
Total	40.6	8.9	44.1	9.7	100.00%	100.00%

See Section III.7, pages 37-41 of the application for the applicant’s discussion of assumptions and methodology. See further discussion in Criterion (3) with regard to the methodology and assumptions the applicant uses to project patient origin which is incorporated hereby as if set forth fully herein.

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

-NA- The applicant is not proposing a new facility.

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

-C- In Section II, page 17, the applicant states,

*“CDM will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”*

**.2203 PERFORMANCE STANDARDS**

(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- The applicant proposes to add stations to an existing facility.

(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- On page 19, the applicant projects it will serve 40 patients on 12 stations at the end of the first operating year, based on the methodology and assumptions found in Section II, page 19 and in Section III of the application.  $40 / 12 \text{ stations} = 3.33 \text{ patients per station per week}$ . See the discussion of population and projected utilization in Criterion (3) which is hereby incorporated as if set forth fully herein.

**.2204 SCOPE OF SERVICES**

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

(1) *diagnostic and evaluation services;*

- C- Section II, page 23 and the table in Section V.1, page 45, both state patients will be referred to Alamance Regional Medical Center for diagnostic and evaluation services.

(2) *maintenance dialysis;*

- C- Section II, page 23 and the table in Section V.1, page 45, both state the applicant will provide in-center maintenance dialysis.

(3) *accessible self-care training;*

- C- In Section II, page 23, the applicant states, *“Patients who are candidates for self-care will be referred to the facility home training department.”* The table in Section V.1, page 45, shows patients will receive in-center hemodialysis, intermittent peritoneal dialysis, CAPD and CCPD on-site.

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

- C- In Section II, page 23, the applicant states, *“Patients who are candidates for home dialysis will be referred to the facility home training department.”* The applicant addresses accessible follow-up program for support of patients dialyzing at home in Section V, Question 2(d), page 46, stating,

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

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

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

(5) *x-ray services;*

-C- Section II, page 23 and the table in Section V.1, page 45, both state patients will be referred to Alamance Regional Medical Center for x-ray services.

(6) *laboratory services;*

-C- Section II, page 23 and the table in Section V.1, page 45, both state the facility provides on-site laboratory services through contract with Spectra Labs. Exhibit 18 contains a laboratory services agreement.

(7) *blood bank services;*

-C- Section II, page 23 and the table in Section V.1, page 45, both state patients will be referred to Alamance Regional Medical Center for blood bank services.

(8) *emergency care;*

-C- Section II, page 23 and the table in Section V.1, page 45, both state patients will be transported by ambulance to a hospital for emergency care beyond that available from the trained staff and fully stocked crash cart on site.

(9) *acute dialysis in an acute care setting;*

-C- Section II, page 23 and the table in Section V.1, page 45, both state patients will be referred to Alamance Regional Medical Center or UNC Hospital for acute dialysis in an acute care setting.

(10) *vascular surgery for dialysis treatment patients;*

-C- Section II, page 24 and the table in Section V.1, page 45, both state dialysis patients will be referred to UNC Hospital, Carolina Vascular Associates or Alamance Vein and Vascular for vascular surgery.

(11) *transplantation services;*

-C- In Section II, page 24, the applicant states, “*Carolina Dialysis – Mebane has a transplant agreement with CMC. A copy of an executed transplant agreement is included in Exhibit 17.*” The table in Section V.1, page 45 indicates the applicant’s patients have access to transplant services at UNC. Exhibit 17 contains a 2010 transplant agreement between FMC of Mebane and UNC Hospitals and a 2010 transplant agreement between Mebane Kidney Center and Duke University Medical Center.

(12) *vocational rehabilitation counseling and services; and*

-C- Section II, page 24 and the table in Section V.1, page 45, both state patients will be referred to the Division of Vocational Rehabilitation in Burlington.

(13) *transportation.*

-C- Section II, page 24 and the table in Section V.1, page 45, both state transportation services for patients are provided by Alamance Regional Consolidated Services.

## **.2205 STAFFING AND STAFF TRAINING**

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

-C- In Section VII.1, page 56, the applicant provides the proposed staffing for Carolina Dialysis - Mebane. On page 57, the applicant states, “*Carolina Dialysis – Mebane does and will comply with all staffing requirements as stated in 42 C.F.R. Section 494 (formerly 405.2100).*” See additional staffing details in Section 1.13 (c), page 9 and Section II.2. A, pages 29-30.

(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- In Section VII.5, page 57, the applicant refers to Exhibit 14 for an outline of the training program and Exhibit 15 for an outline of continuing education programs. The applicant also states that each new employee will be required to successfully complete a 10-week training program,

including training in the clinical aspects of their job, facility and corporate policies and procedures, safety precautions, OSHA regulations, and CPR.