

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 5, 2015

Findings Date: November 5, 2015

Project Analyst: Celia C. Inman

Team Leader: Lisa Pittman

Project ID #: G-11100-15

Facility: Carolina Dialysis of Mebane

FID #: 100545

County: Alamance

Applicant: Carolina Dialysis of Mebane, LLC

Project: Add eight dialysis stations for a total of 20 dialysis stations upon project completion

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 (“the applicant”) proposes to add eight dialysis stations for a total of 20 dialysis stations at the existing Carolina Dialysis-Mebane facility (CDM) at 1410 South Third Street in Mebane, Alamance County.

Need Determination

The 2015 State Medical Facilities Plan (2015 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 18 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 in the July 2015 SDR is 3.75 patients per station. This utilization rate was calculated based on 45 in-center dialysis patients and 12 certified dialysis stations. (45 patients / 12 stations = 3.75 patients per station).

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

October 1 REVIEW-July 2015 SDR

Required SDR Utilization	80.00%	
Center Utilization Rate as of 12/31/14	93.75%	
Certified Stations	12	
Pending Stations	0	
Total Existing and Pending Stations	12	
In-Center Patients as of 12/31/14 (SDR2)	45	
In-Center Patients as of 6/30/14 (SDR1)	37	
Step	Description	
	Difference (SDR2 - SDR1)	8
(i)	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/14	0.4324
(ii)	Divide the result of Step (i) by 12	0.0360
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	0.4324
(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	64.4595
(v)	Divide the result of Step (iv) by 3.2 patients per station	20.1436
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations] to determine the number of stations needed	8

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 8 stations. 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 eight new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2015 SMFP which is applicable to this review. *POLICY GEN-3: BASIC PRINCIPLES* on page 38 of the 2015 SMFP is applicable to this review because the facility need methodology 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

The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 13-17 and Section O, pages 63-68. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), pages 14-17, Section C.3, pages 23-24, Section I, pages 45-48, Section L, pages 56-60 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B, pages 16-17, Section N, page 62, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need methodology in the July 2015 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add eight dialysis stations for a total of 20 dialysis stations at the existing Carolina Dialysis-Mebane facility upon completion of the project.

Population to be Served

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Alamance County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 26, the applicant provides a table showing the historical patient origin for in-center (IC), home hemodialysis (HH) and peritoneal dialysis (PD) patients served by Carolina Dialysis-Mebane.

**Historical Patient Origin
Carolina Dialysis-Mebane
As of September 1, 2015**

County	IC	HH	PD
Alamance	43	0	5
Guilford	1	0	1
Orange	10	1	2
Total	54	1	8

In Section C.1, page 20, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion on December 31, 2016, as summarized in the table below.

**Projected Carolina Dialysis-Mebane Patient Origin
 By County of Residence**

County	Operating Year 1			Operating Year 2			County Patients as % of Total	
	IC	HH	PD	IC	HH	PD	OY 1	OY2
Alamance	51.5	0.0	6.0	56.0	0.0	6.5	77.2%	77.6%
Guilford	1.0	0.0	1.0	1.0	0.0	1.0	2.7%	2.5%
Orange	12.0	1.0	2.0	13.0	1.0	2.0	20.1%	19.9%
Total	64.5	1.0	9.0	69.5[70.0]	1.0	9.5	100.0%	100.0%

Totals may not sum due to rounding

The applicant provides the assumptions and methodology for the above projections on pages 20-22. In Section G.2, page 40, the applicant states:

“... CDM is the only facility in Mebane and proposes to serve a patient population residing primarily in the eastern side of Alamance County and western Orange County.”

Exhibit C-1 includes a letter signed by 26 patients currently dialyzing at Carolina Dialysis-Mebane, pledging their support for the proposed project.

The applicant adequately identifies the population to be served.

Analysis of Need

The applicant proposes to add eight dialysis stations to the existing Carolina Dialysis-Mebane facility for a total of 20 certified dialysis stations upon project completion. In Section C.2, page 23, the applicant states the need for the proposed project is based on the following factors:

- ESRD patients require dialysis treatment on a regular and consistent basis in order to maintain life.
- Failure to add the proposed stations will lead to higher utilization rates at the existing facility.
- Carolina Dialysis-Mebane census has been increasing at a rate greater than the Five-Year Average Annual Change Rate for Alamance County of 3.3%. The applicant’s facility need methodology calculates CDM’s net in-center growth rate for one year at 43.24%.

Projected Utilization

The applicant projects serving 64 in-center dialysis patients on 20 dialysis stations at the end of the first operating year. This is 3.2 patients per station or an 80.0% utilization rate.

In Section C.1, pages 20-22, the applicant provides the assumptions and methodology it uses to determine the need for additional dialysis stations at Carolina Dialysis-Mebane. The applicant's assumptions and methodology are summarized below:

- CDM assumes a growth rate of 8% (20% of the annualized growth between June and September 2015) through the end of the second year of operation.
 - The in-center dialysis patient population of CDM has been increasing at a rate far greater than the Alamance County five-year average annual change rate of 3.3%, published in the July 2015 SDR. The facility need methodology calculates a 12-month increase of over 43% for CDM's in-center patient population.
 - The applicant expects the CDM census to continue to increase. On June 30, 2015, the facility census was 46 in-center patients, on September 15, 2015, the census was 54, an increase of eight patients or 17.4% in three months. The applicant states that this would represent a growth of 32 patients, if annualized.
- CDM is located in Mebane. The applicant states that the city of Mebane "*actually includes area within both Alamance and Orange Counties.*" The applicant states that due to the proximity of the center to Orange County and the number of Orange County patients dialyzing with CDM, it will project a growth of the Orange County population of CDM patients at the same 8% discussed above.
- The applicant assumes the Guilford County patients (one in-center and one PD) will continue to dialyze at CDM, but the applicant does not project any growth in this segment of the patient population.
- The project is scheduled for completion on December 31, 2016. Operating Year 1 is January 1 – December 31, 2017. Operating Year 2 is January 1 – December 31, 2018.

In Section C.1, page 22, the applicant provides the calculations used to arrive at the projected in-center patient census for Operating Year 1, ending December 31, 2017 and Operating Year 2, ending December 31, 2018, as shown below.

Carolina Dialysis-Mebane	In-Center Dialysis
CDM begins with the Alamance and Orange County patients dialyzing at Carolina Dialysis-Mebane on September 1, 2015.	53
CDM projects this patient population forward for four months to December 31, 2015, using the 8% growth rate.	$[53 \times (.08 / 12 \times 4)] + 53 = 54.4$
CDM projects the Alamance and Orange County patient population forward for one year to December 31, 2016.	$(54.4 \times .08) + 54.4 = 58.8$
CDM adds the 1 patient from Guilford County. This is the projected starting census.	$58.8 + 1 = 59.8$
CDM projects the Alamance and Orange County patient population forward for one year to December 31, 2017.	$(59.8 \times .08) + 59.8 = 63.5$
CDM adds the 1 patient from Guilford County. This is the project census for the end of Operating Year 1.	$63.5 + 1 = 64.5$
CDM projects the Alamance and Orange County patient population forward for one year to December 31, 2018.	$(64.5 \times .08) + 64.5 = 68.5$
CDM adds the 1 patient from Guilford County. This is the project census for the end of Operating Year 2.	$68.5 + 1 = 69.5$

As shown in the previous table, at the end of Operating Year 1, the applicant is projecting an in-center patient census at CDM of 64.5 patients, which the applicant rounds down to 64, for a utilization rate of 80.0% or 3.2 patients per station ($64 \text{ patients} / 20 \text{ stations} = 3.2 / 4 = .800$). At the end of Operating Year 2, the applicant is projecting an in-center patient census of 69.5, rounded down to 69, for a utilization rate of 86.25%. The projected utilization of 3.2 patients per station per week for Operating Year 1 satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

The following table illustrates peritoneal dialysis projections of nine patients at the end of Operating Years 1 and 2, based on the applicant's calculations on page 22.

Carolina Dialysis-Mebane	Peritoneal Dialysis
CDM begins with the Alamance and Orange County patients dialyzing at Carolina Dialysis-Mebane on September 1, 2015.	7
CDM projects this patient population forward for four months to December 31, 2015, using the 8% growth rate.	$[7 \times (.08 / 12 \times 4)] + 7 = 7.1$
CDM projects the Alamance and Orange County patient population forward for one year to December 31, 2016.	$(7.1 \times .08) + 7.1 = 7.5$
CDM adds the 1 patient from Guilford County. This is the projected starting census.	$7.5 + 1 = 8.5$
CDM projects the Alamance and Orange County patient population forward for one year to December 31, 2017.	$(7.5 \times .08) + 7.5 = 8.0$
CDM adds the 1 patient from Guilford County. This is the project census for the end of Operating Year 1.	$8 + 1 = 9.0$
CDM projects the Alamance and Orange County patient population forward for one year to December 31, 2018.	$(8.0 \times .08) + 8.0 = 8.5$
CDM adds the 1 patient from Guilford County. This is the project census for the end of Operating Year 2.	$8.5 + 1 = 9.5$

Note: The Project Analyst calculates a census a bit higher in Operating Years 1 and 2, 9.2 and 9.9, respectively, both still less than a census of 10.

The applicant states that CDM was serving a single home hemodialysis patient as of September 1, 2015 and does not expect a change in that patient population; therefore the applicant projects one home hemodialysis patient each year.

The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

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

“Each facility has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.”

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

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
Carolina Dialysis-Mebane	16.4%	40.0%	81.8%	38.2%	60.0%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 81.8% of the facility treatment reimbursement is from Medicare.

The applicant states that the above projections are based on the current demographics of the Carolina Dialysis-Mebane facility.

The applicant further states that Medicare and Medicaid represents 82.54% and 4.63%, respectively, of dialysis treatments in Fresenius related facilities in fiscal year 2014. The applicant confirms that low income and medically underinsured persons will continue to have access to all services provided by CDM and that the facility will conform with all codes and standards for handicapped access.

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

Conclusion

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

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

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.

CA

In Section E.1, page 30, the applicant discusses the alternatives considered prior to submitting this application, which include:

- 1) Maintain the Status Quo - the applicant states that failure to develop additional capacity at the facility would result in higher utilization rates and potentially restrict patient admissions.
- 2) Submit an application for fewer dialysis stations – the applicant states that with projections to realize utilization rates of 80% at the end of the first year of operations with the proposed eight stations, the addition of fewer station would result in higher utilization rates.

After considering the above alternatives, the applicant states that CDM believes it is most appropriate to apply for the proposed eight stations.

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

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

- 1. Carolina Dialysis Mebane, LLC d/b/a Carolina Dialysis-Mebane shall materially comply with all representations made in the certificate of need application.**
 - 2. Carolina Dialysis Mebane, LLC d/b/a Carolina Dialysis-Mebane shall develop and operate no more than eight additional dialysis stations for a total of 20 certified stations which shall include any home hemodialysis training or isolation stations.**
 - 3. Carolina Dialysis Mebane, LLC d/b/a Carolina Dialysis-Mebane shall install plumbing and electrical wiring through the walls for no more than 8 additional dialysis stations for a total of 20 dialysis stations which shall include any home hemodialysis training or isolation stations.**
 - 4. Carolina Dialysis Mebane, LLC d/b/a Carolina Dialysis-Mebane shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add eight dialysis stations to the existing Carolina Dialysis-Mebane facility for a total of 20 certified dialysis stations upon project completion.

Capital Costs

In the table in Section F.1, page 32, the applicant shows the capital cost of the project as summarized in the following table:

Project Capital Costs

Water Treatment Equipment	\$ 4,400
Equipment/Furniture	\$ 25,500
Total Capital Cost	\$ 29,900

Carolina Dialysis-Mebane is an existing dialysis facility with an ongoing operation; therefore the applicant does not project any working capital needs.

Availability of Funds

In Section F.5, page 33, the applicant states, “*CDM is utilizing accumulated reserves to finance this project.*” Exhibit F-1 contains a letter dated September 15, 2014 from Carolina Dialysis CFO, Ronald Falk, MD, acknowledging the proposed project and committing sufficient cash reserves for development of the project.

In Section F.7, page 34, the applicant refers to Exhibit F-2 for a copy of the most recent Carolina Dialysis-Mebane balance sheet. As of June 30, 2015, Carolina Dialysis-Mebane had \$5,570 cash, \$162,978 temporary investments and \$493,498 accounts receivable with \$1,793,160 in total assets and \$321,695 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.

Financial Feasibility

In Section R, Form C, pages 84-91, the applicant provides its allowable charge per treatment for each payment source for in-center, home hemodialysis and peritoneal dialysis patients, along with its revenue assumptions.

The applicant provides the following assumptions for patient treatments:

- Treatments = Patients (rounded down) x 3 treatments per week x 52 weeks (156 treatments per patient)
- Missed Treatments for In-center patients = 5%
- CY2015 is considered an interim year with the June 30, 2015 in-patient census of 46 (8 for peritoneal patients) considered to be average census for the year.

The applicant projects revenues and summarizes operating expenses in Section R, Form B, page 82, as presented in the table below.

Carolina Dialysis-Mebane	Operating Year 1 1/1/17-12/31/17	Operating Year 2 1/1/18-12/31/18
Total Net Revenue	\$ 3,285,047	\$ 3,556,920
Total Operating Expenses	3,218,119	\$ 3,316,429
Net Profit	\$ 66,927	\$ 240,490

Totals may not sum due to rounding

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

Section R, Form A-Operating Expense Statement, pages 78-79, appears to have the correct figures in the table; however the formatting of the form is off, therefore the expense figures and subtotals do not line up and the Subtotal Property, Ownership and Use and the Total Operating Expense figures do not appear on Form A. A calculation by the Project Analyst confirms the total Operating Expense figures incorporated in Form B are the correct totals, based on an individual tally of expense figures in Form A. Because of the formatting, it is not possible for the Project Analyst to confirm all individual expenses as they appear on Form A. Based on the assumptions provided, the Analyst is able to confirm the line items of Salary-RN, Salary-patient care tech, Salary-administrative and Payroll taxes and benefits on Form A.

In Section H.1, page 41, the applicant provides projected staffing and salaries. The applicant appears to have erroneously entered the total annual salaries per position, rather than the annual salary per FTE, as the table is labeled. A careful analysis of the number of FTE positions, the increase in the number of FTE positions and the dollar amounts provided for salary confirms that premise. Further analysis shows that Form A includes total salary in Operating Year 2 to cover 3.0 RN FTE positions and 6.0 patient care tech FTE positions, not 4.0 and 8.0, respectively, as shown in the staffing chart in Section H.1. A comparison of identified salaries and payroll tax and benefits provided on the Section H.1 staffing chart and Form A indicate the budgeted operating costs on Form A are inadequate by \$205,347 in Operating Year 2.

	Staffing H.1	Form A	Difference
	4.0 RN, 8.0 PCT	3.0 RN, 6.0 PCT	1.0 RN, 2.0 PCT
Salary-RN (includes home training nurse)	\$ 363,659	\$ 293,201	\$ (70,459)
Salary-Pt Care Tech	\$ 318,202	\$ 238,652	\$ (79,550)
Shortfall on Form A for identified staffing			\$ (150,009)
Payroll tax and benefits	\$ 330,621	\$ 275,283	\$ (55,338)
Shortfall on Form A for payroll tax and benefits			\$ (55,338)
Total shortfall on Form A for identified staffing and benefits			\$ (205,347)

Therefore, Form A in Section R, page 78, does not show budgeted operating costs adequate to cover the projected staffing. However, as discussed above the applicant projects that revenues will exceed operating expenses in Operating Year 2 by \$240,490, which is an adequate net revenue to cover the additional staffing and benefit costs. Furthermore, 3.0 RN FTE positions and 6.0 patient care tech FTE positions could be sufficient to provide adequate direct care staffing for the number of proposed hours of operation. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

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

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Alamance County. Facilities may also serve residents of counties not included in their service area.

The applicant proposes to add eight dialysis stations to the existing Carolina Dialysis-Mebane facility in Alamance County. The July 2015 SDR indicates there are five dialysis facilities in Alamance County, as follows:

Alamance County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/14	Percent Utilization	Patients Per Station
BMA Burlington (Fresenius)	45	63.33%	2.53
Burlington Dialysis (DaVita)	26	86.54%	3.46
Carolina Dialysis-Mebane (Fresenius)	12	93.75%	3.75
Graham Dialysis*(DaVita)	0	0.00%	0.00
North Burlington Dialysis (DaVita)	13	117.31%	4.69

Source: July 2015 SDR, Table A.

*Certificate issued 6/30/14 (G-10265-14) to develop a new 10-station dialysis center by relocating eight stations from Burlington Dialysis Center and two stations from North Burlington Dialysis Center.

As illustrated above, the applicant’s parent company, Fresenius, operates two of the five dialysis facilities in Alamance County. DaVita operates the other three Alamance County dialysis facilities (Graham Dialysis is not yet operational). All of the Alamance County dialysis facilities are operating at or above 63% utilization. Carolina Dialysis-Mebane is operating at 93.75% utilization. In Section G, page 40, the applicant states:

“This application does not create a new dialysis facility in Alamance County. Approval of this application will result in eight additional stations in the Service Area. However, CDM is the only facility in Mebane and proposes to serve a patient population residing primarily on the eastern side of Alamance County and western

Orange County. Based upon the geographic location of the other facilities in the county, CDM does not believe these stations will result in unnecessary duplication of existing or approved facilities.”

In Section C.1, page 20, the applicant demonstrates that Carolina Dialysis-Mebane will serve a total of 64 in-center patients on 20 stations at the end of the first operating year, which is 3.2 patients per station per week, or a utilization rate of 80.0% ($64/20 = 3.2$; $3.2/4 = 0.800$). CDM also has a home training and support program for both peritoneal and home hemodialysis.

The applicant adequately demonstrates the need for additional stations at CDM based on the number of in-center patients it proposes to serve. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on competition found in Criterion (18a) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Alamance County. Consequently, the application is conforming to this criterion.

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

C

The following table illustrates the projected staffing for Carolina Dialysis-Mebane, as provided by the applicant in Section H.1, page 41. The table provided by the applicant and reproduced below, erroneously shows the total salary for a position category, not the average annual salary for each FTE position.

	Current FTE Positions [a]	FTE Positions to be added [b]	Total FTE Positions [a+b]	Current Annual Salary [per FTE]	Projected Annual Salary Yr 2 [per FTE]
Medical Director*					
RN	2.00	2.00	4.00	\$ 128,960	\$ 281,836
Pt Care Tech	4.00	4.00	8.00	\$ 145,600	\$ 318,202
Home Training Nurse	1.00		1.00	\$ 74,880	\$ 81,823
Dietary	0.60	0.25	0.85	\$ 33,696	\$ 52,162
Social Services	0.60	0.25	0.85	\$ 38,688	\$ 59,890
Salary - Admin and Other			0.00		
Clinical Manager	1.00		1.00	\$ 83,200	\$ 90,915
Director of Operations	0.20		0.20	\$ 23,920	\$ 26,138
In-Service	0.15		0.15	\$ 10,296	\$ 11,251
Clerical	1.00		1.00	\$ 33,280	\$ 36,366
Chief Tach	0.15		0.15	\$ 8,736	\$ 9,546
Equip Tech	0.50	0.25	0.75	\$ 20,592	\$ 33,752
Total FTEs	11.20	6.75	17.95	\$ 601,848	\$ 1,001,882
Benefits				\$ 198,610	\$ 330,621
Total				\$ 800,458	\$ 1,332,503

*The Medical Director is a contract position, not an employee of the facility.

The following table reflects the applicant's projected number of direct care staff FTE positions at Carolina Dialysis-Mebane for Operating Year 2, per page 44.

Projected Direct Care Staff Hours – Operating Year 2

Direct Care Positions	# FTEs* [a]	Hours / Year / FTE [b]	Total Annual FTE Hours [c] = [a] x [b]	Total Annual Hours of Operation ** [d]	FTE Hours / Hours of Operation [e] = [c] ÷ [d]
RN	4.0	2,080	8,320	3,120	2.67
Patient Care Tech	8.0	2,080	16,640	3,120	5.33
Total	12.0	2,080	24,960	3,120	8.00

* FTEs should match the direct care Total FTE Positions [a+c] listed in the Facility Staffing table in Section H, Question 1.

** Total annual hours of operation from the Proposed Hours of Operation table in Section H, Question 6.

The tables above project 4.0 RN FTE positions and 8.0 patient care tech FTE positions. Form A budgets only 3.0 RN FTE positions and 6.0 patient care tech FTE positions. The facility currently employs 2.0 RN FTE positions and 4.0 patient care tech positions. Form A budgets to increase the RN and patient care tech FTE positions by 50%, while the applicant proposes to increase the number of stations by 66.7%. The following table reflects the projected direct care staff hours for the RN and patient care tech FTE positions as budgeted in Form A.

Projected Direct Care Staff Hours – Operating Year 2 Per Form A

Direct Care Positions	# FTEs* [a]	Hours / Year / FTE [b]	Total Annual FTE Hours [c] = [a] x [b]	Total Annual Hours of Operation [d]	FTE Hours / Hours of Operation [e] = [c] ÷ [d]
RN	3.0	2,080	6,240	3,120	2.00
Patient Care Tech	6.0	2,080	12,480	3,120	4.00
Total	9.0	2,080	18,720	3,120	6.00

As the above table shows, Form A budgets 6.0 FTE hours of direct care staffing per hour of facility operation. Budgeted staffing appears adequate for Operating Year 2’s projected 3,120 annual hours of operation and projected 86% utilization on 20 stations.

In Section H.3, page 42, the applicant describes its experience and process for recruiting and retaining staff and states, “*CDM anticipates no difficulties in filling staff positions.*” In Section I.3, page 46, the applicant states that Amy Mottl, M.D. will serve as the Medical Director for the facility. In Exhibit I-6, the applicant provides a letter dated September 8, 2015, signed by Dr. Mottl of UNC Health Care Kidney Center confirming her commitment to serve as Medical Director. Exhibit I-7 contains Dr. Mottl’s curriculum vitae. In Section I.3, page 47, the applicant lists 16 nephrologists who will provide medical coverage at the proposed facility.

The applicant adequately demonstrates the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed 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 I, pages 45-48, the applicant describes the necessary ancillary and support services and explains how they will be provided. Exhibit I contains copies of letters from providers of specified services expressing an interest in providing them to Carolina Dialysis-Mebane. The applicant discusses coordination with the existing health care system on pages 46-48. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information in Section I and referenced Exhibits is reasonable 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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

C

In Section L.1, pages 56-57, the applicant states that Fresenius Medical Care Holdings, Inc., parent company to Carolina Dialysis Mebane, LLC, currently operates 100¹ dialysis facilities in 42 North Carolina counties (including affiliations with Renal Research Institute facilities). 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 applicant states that CDM and Fresenius related facilities have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. The applicant further states in Section C.3, page 24, that Medicare and Medicaid represents 82.54% and 4.63%, respectively, of North Carolina dialysis treatments in Fresenius related facilities in FY 2014.

In Section L.7, page 60, the applicant reports that as of December 31, 2014, 83.5% of the patients who were receiving treatments at Carolina Dialysis-Mebane 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 CDM.

HISTORICAL PAYOR MIX

SOURCE OF PAYMENT	CDM % of Total Patients
Self Pay/Indigent/Charity	5.1%
Medicare	48.1%
Medicaid	3.8%
Commercial Insurance	11.4%
Medicare/Commercial	31.6%
Total	100.00%

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Alamance, Guilford and Orange counties and statewide.

¹Section C.3, page 23, states that Fresenius currently operates 102 dialysis facilities in North Carolina counties.

County	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Alamance	16.4%	6.2%	21.0%
Guilford	15.3%	5.9%	19.5%
Orange	8.6%	3.5%	18.9%
Statewide	16.5%	6.7%	19.7%

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

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).²

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. But it does not include information on the number of elderly, handicapped, minorities or women utilizing health services.

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report* provides prevalence data on North Carolina dialysis patients by age, race and gender on page 59, summarized as follows:

²<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

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

Source: Southeastern Kidney Council Network 6 Inc. 2014 Annual Report.³

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

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

C

In Section L.3(e) page 59, 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,

³<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

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 L.6, page 59, the applicant states, *“There have been no Civil Rights complaints lodged against any CDM North Carolina facilities in the past five years.”*

The application is conforming to this criterion.

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

C

In Section C.3, page 23, the applicant states that the patient population of the CDM facility is expected to be comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
Carolina Dialysis-Mebane	16.4%	40.0%	81.8%	38.2%	60.0%

Note: The Medicare percentage represents patients receiving some type of Medicare benefit. This is not to say that 81.8% of the facility treatment reimbursement is from Medicare.

In Section L.3(b), page 58, 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.”

On page 57, the applicant reports that it expects over 83.5% of the in-center patients who receive treatments at Carolina Dialysis-Mebane to have all or part of their services paid for by Medicare or Medicaid, as indicated below.

**Carolina Dialysis-Mebane
 Projected Payor Mix Project Year 2
 Percent of Patients**

Payor Source	In-Center	Home-Hemo	Home PD
Self Pay/Indigent/Charity	4.35%	0.00%	11.11%
Medicare	47.83%	0.00%	44.44%
Medicaid	4.35%	0.00%	0.00%
Commercial Insurance	11.59%	100.00%	11.11%
Medicare/Commercial	31.88%	0.00%	33.33%
TOTAL	100.00%	100.00%	100.00%

Totals may not sum due to rounding.

On page 57, the applicant states:

“CDM payor mix has historically been calculated based upon treatment volumes. In this application, revenues will be projected using a payor mix based upon treatment volumes. The above table has requested the percent of patients by category. Assigning a projected payor mix classification to categories with small numbers, and resultant efforts to project “whole” patients does not allow for an accurate projection of the payor mix, by percentage of patients expected by the facility. For purposes of this table, the Applicant has rounded to the nearest whole number.”

Form C – Revenue Assumptions, pages 84-91, show the payor mix as a percent of treatments, as shown below.

**Carolina Dialysis-Mebane
 Projected Payor Mix Project Year 2
 Percent of Treatments**

Payor Source	In-Center	Home-Hemo	Home PD
Self Pay/Indigent/Charity	4.82%	0.00%	4.82%
Medicare	48.06%	0.00%	48.06%
Medicaid	3.90%	0.00%	3.90%
Commercial Insurance	11.29%	0.00%	11.29%
Medicare/Commercial	31.93%	100.00%	31.93%
TOTAL	100.00%	100.00%	100.00%

Page 57 identifies Commercial Insurance as the only payor source for home-hemo patients, while page 91 identifies Medicare/Commercial as the only payor source for home-hemo. It appears, the applicant made a typographical error in one of the tables; however the differentiation between Commercial Insurance and Medicare/Commercial does not appear relevant to this discussion. 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 L.4, page 59, the applicant states:

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. Carolina Dialysis-Mebane has 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.

Patients cannot self-refer for dialysis and dialysis treatment does require orders from an attending physician with staff privileges at the facility. Transient patients are accepted upon proper coordination of care with the patient’s regular nephrologist and a physician with staff privileges at the facility.”

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to 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 M, page 61, 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.”

Exhibit M-1 contains a copy of a letter from Fresenius Medical Care to the Department Head of the Nursing Program at Alamance Community College inviting the college to include Carolina Dialysis-Mebane in the clinical rotation for its nursing students. The

information provided in Section M is reasonable 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

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Alamance County. Facilities may also serve residents of counties not included in their service area.

The applicant proposes to add eight dialysis stations to the existing Carolina Dialysis-Mebane facility in Alamance County. The July 2015 SDR indicates there are five dialysis facilities in Alamance County, as follows:

Alamance County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/14	Percent Utilization	Patients Per Station
BMA Burlington (Fresenius)	45	63.33%	2.53
Burlington Dialysis (DaVita)	26	86.54%	3.46
Carolina Dialysis-Mebane (Fresenius)	12	93.75%	3.75
Graham Dialysis*(DaVita)	0	0.00%	0.00
North Burlington Dialysis (DaVita)	13	117.31%	4.69

Source: July 2015 SDR, Table A.

*Certificate issued 6/30/14 (G-10265-14) to develop a new 10-station dialysis center by relocating eight stations from Burlington Dialysis Center and two stations from North Burlington Dialysis Center.

As illustrated above, the applicant or a related entity operates two of the five dialysis facilities in Alamance County. DaVita operates the other three Alamance County dialysis

facilities. All of the Alamance County dialysis facilities are operating above 63% utilization. Carolina Dialysis-Mebane is operating at 93.75% utilization.

In Section N.1, page 62, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states,

“CDM does not expect this proposal to have effect on the competitive climate in Alamance County. At the present time, there are three other dialysis facilities in the county, each serving patients of Alamance and surrounding counties. CDM does not project to serve dialysis patients currently being served by another provider.

...

Carolina Dialysis-Mebane 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 greater than 83% of the In-center patients will be relying upon government payors (Medicare / Medicaid). The facility must capitalize upon every opportunity for efficiency.

CDM has done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives by offering another convenient venue for dialysis care and treatment.”

See also Sections C, F, G, H, L and P where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the sections above and referenced exhibits is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicant adequately demonstrates BMA will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates BMA will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (6) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

In Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company.

In Section O, beginning on page 63, the applicant discusses the methods it uses to insure and maintain quality. In Section O.3, pages 67-68, the applicant states:

“Fresenius related facilities have incurred two Immediate Jeopardy citations within the recent 18 month period.

- a. BMA Lumberton dialysis facility on May 6, 2015*
- b. BMA East Charlotte dialysis facility on August 11, 2015.”*

The applicant further states:

*“BMA Lumberton is back in full compliance with all CMS Guidelines.
BMA East Charlotte is back in full compliance with all CMS Guidelines.”*

Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

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

Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) Utilization rates;

- C- In Section P, page 70, and Exhibit G-1 (copy of the July 2015 SDR, Tables A and B), the applicant provides the utilization rates for Carolina Dialysis-Mebane. The December 31, 2014 utilization is 3.75 patients per station or 93.75% with 45 patients dialyzing on 12 stations.

.2202(a)(2) Mortality rates;

- C- In Section P, page 70, the applicant provides the mortality rates for Carolina Dialysis-Mebane from 2012 through 2014.

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

- C- In Section P, page 70, the applicant states that Carolina Dialysis-Mebane currently has nine dialysis patients who are home trained and dialyzing at home.

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

- C- In Section P, page 71, the applicant reports that Carolina Dialysis-Mebane referred nine patients for transplant evaluation in 2014.

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

- C- In Section P, page 71, the applicant states that Carolina Dialysis-Mebane has nine patients on the transplant waiting list.

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

-C- In Section P, page 71, the applicant reports a total of 63 hospital admissions in 2014 for Carolina Dialysis-Mebane with 11 (17.5%) being dialysis related.

.2202(a)(7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.

-C- In Section P, page 71, the applicant reports that Carolina Dialysis-Mebane does not have any patients with infectious disease, e.g. hepatitis and there were no conversions to infectious status during the last calendar year.

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

.2202(b)(1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100 (Replaced with 42 CFR Part 494).

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

.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- Carolina Dialysis-Mebane is an existing facility.

.2202(b)(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.

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

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

.2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

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

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

-C- The applicant states, in Section P, page 72, that Carolina Dialysis-Mebane “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.” See also Section B.4 and B.5, pages 13-19; Section H.2, page 42; Section K.1 (g), page 53; and Exhibits K-2 and K-3.

.2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- In Section C.1, page 20, the applicant provides projected patient origin by county for Carolina Dialysis-Mebane, based on the facility’s existing patient origin. The applicant’s assumptions and methodology for its projections are provided on pages 20-22 of the application. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

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

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

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

-C- In Section P, page 73, 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.”

10 NCAC 14C .2203 PERFORMANCE STANDARDS

.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

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

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

-C- The applicant proposes to serve 64 patients at the end of Operating Year 1 on 20 dialysis stations, which equates to a utilization rate of 3.2 patients per station ($64 / 20 = 3.2$).

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

-C- In Section C.1, pages 20-22, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

.2204(1) Diagnostic and evaluation services;

-C- In Section P, page 73, and Section I.1, page 45, the applicant states that diagnostic and evaluation services will be referred to Alamance Regional Medical Center.

.2204(2) Maintenance dialysis;

-C- In Section P, page 73, and Section I.1, page 45, the applicant states CDM will provide in-center dialysis maintenance at the existing facility.

.2204(3) Accessible self-care training;

- C- In Section P, page 74, and Section I.1, page 45, the applicant states candidates for self-care are referred to the facility home training department and trained on-site.

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

- C- In Section P, page 74, and Section I.1, page 45, the applicant states the facility will provide follow-up services to its patients.

.2204(5) X-ray services;

- C- In Section P, page 74, and Section I.1, page 45, the applicant states that x-ray services will be referred to Alamance Regional Medical Center or other local providers.

.2204(6) Laboratory services;

- C- Laboratory services will be provided on-site by the applicant through a contract with Spectra Labs, as stated by the applicant in Section P, page 74, and Section I.1, page 45. Exhibit I-3 contains a letter from the Vice President at Spectra Laboratories and an agreement documenting their intention to provide the above services to the proposed facility.

.2204(7) Blood bank services;

- C- In Section P, page 74, and Section I.1, page 45, the applicant states that blood bank services will be referred to Alamance Regional Medical Center. Exhibit I-4 contains an affiliation agreement whereby The University of North Carolina Hospitals will provide services to the facility's dialysis patients.

.2204(8) Emergency care;

- C- The applicant states, in Section P, page 74, and Section I.1, page 45, that facility staff will provide emergency care on site until emergency responders arrive and that a fully stocked 'crash cart' will be available for use at the proposed facility. Patients in need of emergency care at a hospital are transported via emergency services.

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

- C- In Section P, page 74, and Section I.1, page 45, the applicant states that acute dialysis services will be referred to Alamance Regional Medical Center. Exhibit I-4 contains an affiliation agreement whereby The University of North Carolina Hospitals will provide services to the facility's dialysis patients.

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

- C- In Section P, page 74, and Section I.1, page 45, the applicant states that vascular surgery patients will be referred to UNC Hospitals, Alamance Vein and Vascular and Carolina Vascular Associates. Exhibit I-4 contains an affiliation agreement whereby The University of North Carolina Hospitals will provide services to the facility's dialysis patients.

.2204(11) Transplantation services;

- C- In Section P, page 74, and Section I.1, page 45, the applicant states that transplantation services will be referred to UNC Hospitals. Exhibit I-5 contains an agreement, documenting The University of North Carolina Hospitals will provide transplantation services for the facility's dialysis patients.

.2204(12) Vocational rehabilitation counseling and services; and

- C- In Section P, page 75, and Section I.1, page 45, the applicant states that patients will be referred to the North Carolina Division of Vocational Rehabilitation Services in Alamance County for vocational rehabilitation counseling and services.

.2204(13) Transportation

- C- In Section P, page 75, and Section I.1, page 45, the applicant states that transportation services will be provided by Alamance Regional Consolidated Services.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

.2205(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100 (Replaced with 42 CFR Part 494).

- C- In Section H.1, page 41, the applicant provides a current and proposed staffing chart. In Section H.2, page 42, the applicant states the facility will comply with all staffing requirements set forth in the Federal code. The discussion regarding proposed staffing found in Criterion (7) is incorporated herein by reference.

.2205(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.

- C- In Section P, page 75, the applicant discusses the required training for staff and states that training is continually updated, as needed, by the In-Service Instructor and Director of Nursing. In Section H.4, page 42, the applicant further discusses its ongoing training program. Exhibit H-1 contains an outline of the training program

and an example of one of the training modules. Exhibit H-2 contains a training checklist and a list annual training requirements.