ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

Decision Date: December 19, 2017
Findings Date: December 19, 2017

Project Analyst: Julie Halatek
Team Leader: Fatimah Wilson

Project ID #: G-11403-17
Facility: Carolina Dialysis – Mebane
FID #: 100545
County: Alamance
Applicant: Carolina Dialysis of Mebane, LLC
Project: Add 7 dialysis stations for a total of 27 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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.

NC

Carolina Dialysis of Mebane, LLC (CDM-LLC), the applicant, proposes to add 7 dialysis stations to the existing facility, Carolina Dialysis – Mebane (Carolina Dialysis) for a total of 27 stations upon project completion. The parent companies of CDM-LLC are Fresenius Medical Care Holdings, Inc. (Fresenius) and Carolina Dialysis, LLC. According to information in Exhibit F-1, Fresenius owns approximately 51 percent of Carolina Dialysis and Carolina Dialysis, LLC owns approximately 49 percent of Carolina Dialysis. Carolina Dialysis offers both peritoneal dialysis (PD) and home hemodialysis (HH) training programs.

Need Determination

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2017 Semiannual Dialysis Report (SDR), Table D, the county need methodology shows there is a surplus of 27 dialysis stations in Alamance County; thus, the applicant cannot

apply to add any additional stations based on the county need methodology. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80 percent. The applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Carolina Dialysis in the July 2017 SDR, Table B, is 3.25 patients per station per week, or 81.25 percent (3.25 / 4 patients per station = 0.8125 or 81.25%). This utilization rate was calculated based on 65 in-center dialysis patients and 20 certified dialysis stations (65 patients / 20 stations = 3.25 patients per station per week) as of December 31, 2016.

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

JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/16		81.25%
Certified Stations		20
Pending Stations		0
Total Existing and Pending Stations		**20**
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR2)		65
In-Center Patients as of 6/30/16 (January 2017 SDR) (SDR1)		56
Step	**Description**	**Result**
(i)	Difference (SDR2 - SDR1)	9
	Multiply the difference by 2 for the projected net in-center change	18
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.3214
(ii)	Divide the result of Step (i) by 12	0.0268
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/16 until 12/31/17)	0.3214
(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	85.8929
(v)	Divide the result of Step (iv) by 3.2 patients per station	26.8415
	and subtract the number of certified and pending stations to determine the number of stations needed	**7**

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

Policies

There is one policy in the 2017 SMFP which is applicable to this review. POLICY GEN-3: BASIC PRINCIPLES on page 33 of the 2017 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.4(a), pages 8-9; Section K.1(g), page 54; Section N.1, page 64; Section O, pages 65-68, and referenced exhibits. The information provided by the applicant is reasonable and 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), page 9; Section C.3, page 19; Section L, pages 58-62; Section N.1, page 64, and referenced exhibits. The information provided by the applicant is reasonable and 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.4(c), page 10; Section C, pages 14-18; Section F, pages 33-41; Section K, pages 52-54; Section N.1, page 64, and referenced exhibits. However, the applicant does not adequately demonstrate that the proposed project is the least costly or most effective alternative or that the project will not result in the unnecessary duplication of existing health service capabilities or facilities. See the discussions regarding alternatives and duplication found in Criteria (4) and (6), respectively, which are incorporated herein by reference. Based on these facts, the applicant does not adequately demonstrate that the proposal will maximize healthcare value.

The applicant adequately demonstrates how its proposal incorporates the concepts of quality in meeting the facility need as identified by the applicant. However, the applicant does not adequately demonstrate how its proposal maximizes healthcare value for resources spent in meeting the facility need as identified by the applicant. Therefore, the application is not consistent with Policy GEN-3.

Conclusion

The information in the application, including any exhibits, with regard to the facility need determination in the July 2017 SDR is reasonable and adequately supported because application

of the facility need methodology shows a need for up to seven additional stations at Carolina Dialysis.

The information in the application regarding conformity with Policy GEN-3 is not reasonable and adequately supported for the following reasons:

- The applicant does not adequately demonstrate that the project as proposed is the least costly or most effective alternative to meet the need identified. The discussion regarding alternatives found in Criterion (4) is incorporated herein by reference.
- The applicant does not adequately demonstrate that the project as proposed will not result in the unnecessary duplication of existing or approved health care service capabilities or facilities. The discussion regarding duplication found in Criterion (6) is incorporated herein by reference.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant does not adequately demonstrate that 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.

NC

The applicant proposes to add 7 dialysis stations to the existing facility for a total of 27 stations upon project completion. The applicant currently provides both PD and HH training programs and plans to continue to provide these services.

Patient Origin

On page 373, the 2017 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 North Carolina counties is a separate dialysis station planning area."* Thus, the service area for this facility is Alamance County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 28, the applicant provides a table showing the historical patient origin for in-center (IC), home peritoneal dialysis (PD), and home hemodialysis (HH) patients served by Carolina Dialysis, as shown below.

Carolina Dialysis Patients by County – 6/30/2017			
County	**# of IC Patients**	**# of HH Patients**	**# of PD Patients**
Alamance	42	0	6
Orange	26	0	2
Caswell	2	0	0
Guilford	1	0	2
Total	**71**	**0**	**10**

In Section C.7, page 26, the applicant states that *"…the facility did not have an active home hemodialysis patient as of June 30, 2017. The facility has had home hemodialysis patients, and will maintain that modality as an option for dialysis patients."*

In Section C.1, page 13, the applicant provides the projected patient origin for Carolina Dialysis for in-center (IC), home peritoneal dialysis (PD), and home hemodialysis (HH) patients for the first two operating years (OY) following completion of the project, as shown in the table below.

Carolina Dialysis Patients by County – Operating Years 1 & 2								
County	**Operating Year 1 CY 2020**			**Operating Year 2 CY 2021**			**County Patients as % of Total**	
	IC	**HH**	**PD**	**IC**	**HH**	**PD**	**OY 1**	**OY 2**
Alamance	52.0	4.3	6.9	56.0	5.4	7.2	60.9%	61.8%
Orange	32.0	0.0	2.0	34.0	0.0	2.0	33.3%	32.8%
Caswell	3.0	0.0	0.0	3.0	0.0	0.0	2.9%	2.7%
Guilford	1.0	0.0	2.0	1.0	0.0	2.0	2.9%	2.7%
Total*	**88.0**	**4.3**	**10.9**	**94.0**	**5.4**	**11.2**	**100.0%**	**100.0%**

*In-center totals have been rounded down to the whole patient.

The applicant provides the assumptions and methodology for the projections above on pages 14-18. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section C.2, page 18, the applicant states the need for the proposed project is based on the need for regular and consistent dialysis treatment for patients with end stage renal disease. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference. See also Section B.2, page 6.

Projected Utilization

In Section C.1, page 13, the applicant provides projected utilization during the first two years of operation following project completion, as illustrated in the table below:

Carolina Dialysis Patients by County – Operating Years 1 & 2								
County	**Operating Year 1 CY 2020**			**Operating Year 2 CY 2021**			**County Patients as % of Total**	
	IC	**HH**	**PD**	**IC**	**HH**	**PD**	**OY 1**	**OY 2**
Alamance	52.0	4.3	6.9	56.0	5.4	7.2	60.9%	61.8%
Orange	32.0	0.0	2.0	34.0	0.0	2.0	33.3%	32.8%
Caswell	3.0	0.0	0.0	3.0	0.0	0.0	2.9%	2.7%
Guilford	1.0	0.0	2.0	1.0	0.0	2.0	2.9%	2.7%
Total*	**88.0**	**4.3**	**10.9**	**94.0**	**5.4**	**11.2**	**100.0%**	**100.0%**

*In-center totals have been rounded down to the whole patient.

In Section C.1, pages 14-16, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below:

- On page 14, the applicant assumes that the in-center patient population currently receiving treatment at Carolina Dialysis will increase at a rate of 8.0 percent. The applicant states that this is higher than the Alamance County Five Year Average Annual Change Rate (AACR) of 4.1 percent published in the July 2017 SDR because the recent historical facility growth rate has been as high as 32 percent. The applicant states that it does not believe that a 32 percent growth rate is reasonable or sustainable, but that a future growth rate which is one-fourth of the recent historical growth rate is more conservative and reasonable to use for future projections.

  Carolina Dialysis serves a number of patients from both Alamance and Orange counties. In the January 2015 SDR, the Five Year AACR for Alamance County was 2.8 percent; in the July 2017 SDR, the Five Year AACR for Alamance County is 4.1 percent. In the January 2015 SDR, the Five Year AACR for Orange County was -3.2 percent; in the July 2017 SDR, the Five Year AACR for Orange County is 6.3 percent. The consistent increase in the Five Year AACRs for each county found in the respective SDRs provide adequate support to demonstrate growth in the ESRD patient population for each county as a whole as well as the applicant's facility growth rate.

- The applicant projects one Alamance County patient per year will transfer from the in-center setting to the HH setting. The applicant will also project growth of the HH patient population at a rate of 4.1 percent, which is the Five Year AACR for Alamance County as published in the July 2017 SDR.

- The applicant will project growth of the Alamance County PD patient population at a rate of 4.1 percent, which is the Five Year AACR for Alamance County as published in the July 2017 SDR. The applicant will include patients from other counties dialyzing at Carolina Dialysis, assuming they are there by patient choice, but will not project any increase in the PD patient population from outside of Alamance County.

- The applicant states that it serves a number of patients from Alamance and Orange counties, and that the facility is located on the east side of Alamance County (close to Orange County). The applicant states that it assumes patients from Caswell and Guilford counties are dialyzing at Carolina Dialysis by patient choice.

- The project is scheduled for completion on December 31, 2019. OY1 is CY 2020. OY2 is CY 2021.

In Section C.1, page 15, the applicant provides the calculations used to arrive at the projected in-center patient census for OY1 and OY2 as summarized in the table below.

Carolina Dialysis	In-Center Dialysis
Starting point of calculations is in-center patients dialyzing at Carolina Dialysis on June 30, 2017.	71
In-center patient population is projected forward by six months to December 31, 2017. Projection is based on one-half of the projected growth rate (8.0%).	71 X 1.04 = 73.8
One in-center patient, assumed to be from Alamance County, is subtracted as projected to transfer to the HH modality.	73.8 – 1 = 72.8
In-center patient population is projected forward by one year to December 31, 2018, using the projected growth rate (8.0%).	72.8 X 1.08 = 78.7
One in-center patient, assumed to be from Alamance County, is subtracted as projected to transfer to the HH modality.	78.7 – 1 = 77.7
In-center patient population is projected forward by one year to December 31, 2019, using the projected growth rate (8.0%).	77.7 X 1.08 = 83.9
One in-center patient, assumed to be from Alamance County, is subtracted as projected to transfer to the HH modality. This is the starting in-center census for the project.	83.9 – 1 = 82.9
In-center patient population is projected forward by one year to December 31, 2020, using the projected growth rate (8.0%).	82.9 X 1.08 = 89.5
One in-center patient, assumed to be from Alamance County, is subtracted as projected to transfer to the HH modality. This is the projected census on December 31, 2020 (OY1).	89.5 – 1 = 88.5
In-center patient population is projected forward by one year to December 31, 2020, using the projected growth rate (8.0%).	88.5 X 1.08 = 95.6
One in-center patient, assumed to be from Alamance County, is subtracted as projected to transfer to the HH modality. This is the projected census on December 31, 2021 (OY2).	95.6 – 1 = 94.6

The applicant projects to serve 88 in-center patients on 27 stations, which is 3.26 patients per station per week (88 patients / 27 stations = 3.26), by the end of OY1 and 94 in-center patients on 27 stations, which is 3.48 patients per station per week (94 patients / 27 stations = 3.48), by the end of OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). The July 2017 SDR states that Carolina Dialysis's utilization rate was 81.25 percent (3.25 patients per station per week) as of December 31, 2016.

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. The applicant uses a more conservative growth rate than the facility's historical growth rate to project future utilization and applies that projected growth rate to the appropriate patient population. Therefore, the applicant adequately demonstrates the need to add 7 dialysis stations to its existing facility for a total of 27 dialysis stations upon project completion.

Home Hemodialysis and Peritoneal Dialysis

In Section C.1, pages 16-17, the applicant states that it expects its Alamance County home hemodialysis patient census will increase as one in-center patient per year will transfer to the HH modality, as well as grown annually at a rate of 4.1 percent, which is the Alamance County AACR published in the July 2017 SDR. The applicant states that while it does not currently have any home hemodialysis patients utilizing that modality at Carolina Dialysis, it has had home hemodialysis patients in the past, and discusses the reasons it believes its projections with regard to growth of the home hemodialysis population are reasonable on page 17.

On page 17, the applicant provides the calculations used to arrive at the projected home hemodialysis patient census for OY1 and OY2 as summarized in the table below.

Carolina Dialysis	Home Hemodialysis
Starting point of calculations is home hemodialysis patients dialyzing at Carolina Dialysis on June 30, 2017.	0
One in-center patient, assumed to be from Alamance County, is added as projected to transfer to the HH modality by the end of 2017.	1
HH patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (4.1%).	1 X 1.041 = 1.041
One in-center patient, assumed to be from Alamance County, is added as projected to transfer to the HH modality.	1.041 + 1 = 2.041
HH patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (4.1%).	2.041 X 1.041 = 2.12
One in-center patient, assumed to be from Alamance County, is added as projected to transfer to the HH modality.	2.12 + 1 = 3.12
HH patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (4.1%).	3.12 X 1.041 = 3.25
One in-center patient, assumed to be from Alamance County, is added as projected to transfer to the HH modality. This is the projected census on December 31, 2020 (OY1).	3.25 + 1 = 4.25
HH patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (4.1%).	4.25 X 1.041 = 4.43
One in-center patient, assumed to be from Alamance County, is added as projected to transfer to the HH modality. This is the projected census on December 31, 2021 (OY2).	4.43 + 1 = 5.43

In Section C.1, pages 16-18, the applicant states that it expects its Alamance County home peritoneal dialysis (PD) patient census will continue to increase annually at a rate of 4.1 percent, which is the Alamance County Five Year AACR published in the July 2017 SDR. The applicant states that it projects the PD patients from other counties will continue to dialyze at Carolina Dialysis by patient choice but does not project any growth in patients from other counties.

On page 18, the applicant provides the calculations used to arrive at the projected home peritoneal dialysis patient census for OY1 and OY2 as summarized in the table below.

Carolina Dialysis	Home PD Dialysis
Starting point of calculations is Alamance County home PD patients dialyzing at Carolina Dialysis on June 30, 2017.	6
Alamance County PD patient population is projected forward by six months to December 31, 2017. Projection is based on one-half of the AACR for Alamance County (4.1%).	6 X 1.0205 = 6.12
Alamance County PD patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (4.1%).	6.12 X 1.041 = 6.37
Alamance County PD patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (4.1%).	6.37 X 1.041 = 6.64
Alamance County PD patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (4.1%).	6.64 X 1.041 = 6.91
The patients from other counties are added. This is the projected census on December 31, 2020 (OY1).	6.91 + 4 = 10.91
Alamance County PD patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (4.1%).	6.91 X 1.041 = 7.2
The patients from other counties are added. This is the projected census on December 31, 2021 (OY2).	7.2 + 4 = 11.2

Projected utilization of the home peritoneal dialysis and hemodialysis programs is based on reasonable and adequately supported assumptions regarding continued growth. The applicant lists reasonable assumptions to support the methodology it uses and uses the Five Year AACR of 4.1 percent for Alamance County applied to the appropriate patient population.

Access

In Section L.1, page 58, the applicant states that each of Fresenius's 109 facilities in 48 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons.

The applicant projects that 81.8 percent of the dialysis patients at Carolina Dialysis will have some or all of their services paid for by Medicare and/or Medicaid in CY 2021. However, the applicant does not provide adequate information to determine its projected payor mix is reasonable and adequately supported. The discussion regarding access found in Criterion (13c) is incorporated herein by reference. The applicant does not adequately demonstrate the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses historical data that is clearly cited and is reasonable to use to make the assumptions used by the applicant with regard to identifying the population to be served and with regard to demonstrating the need the population projected to be served has for the proposed services.

- The applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need the population projected to be served has for the proposed services.

However, the information in the application regarding access to the proposed services for medically underserved groups is not reasonable and adequately supported because the applicant does not provide adequate documentation of how it projected its future payor mix.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant does not adequately demonstrate that 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

The applicant does not propose to reduce or eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

NC

In Section E, page 32, the applicant describes the alternatives it considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo – The applicant states that maintaining the status quo is not an effective alternative because utilization at Carolina Dialysis will increase and potentially restrict patient admissions.

- Apply for Fewer Stations - The applicant states this is not an effective alternative because the applicant projects that utilization will exceed 80 percent at the end of the first operating year even with adding seven stations. The applicant states that adding fewer stations will result in higher utilization rates.

After considering the above alternatives, the applicant states the proposed project represented in the application is the most effective alternative to meet the identified need for seven additional stations at Carolina Dialysis.

However, the applicant fails to consider relocating stations from another Alamance County facility as an alternative to this proposal. The applicant owns and operates one other facility in Alamance County. The ownership of facilities in Alamance County, along with the most recent information regarding utilization of those facilities, is shown in the table below:

Existing/Approved Dialysis Facilities in Alamance County – Table B July 2017 SDR						
Facility	**Owner**	**# Patients**	**Location**	**# Certified Stations – 6/9/17**	**# Approved Stations – 6/9/17**	**% Utilization**
Alamance County Dialysis	DaVita	22	Graham	10	0	55.0%
BMA Burlington	Fresenius	94	Burlington	45	0	52.2%
Burlington Dialysis	DaVita	96	Burlington	24	-12	100.0%
Carolina Dialysis – Mebane	Carolina Dialysis/ Fresenius	65	Mebane	20	0	81.3%
Elon Dialysis	DaVita	0	Burlington	0	10	0.0%
Mebane Dialysis	DaVita	0	Mebane	0	10	0.0%
North Burlington Dialysis	DaVita	68	Burlington	22	-8	106.3%

BMA Burlington, owned by Fresenius, has 45 in-center stations, with a current utilization rate of 52.2 percent (94 / 45 = 2.09; 2.09 / 4 = 0.522). In fact, the utilization of the 45 existing stations at BMA Burlington has been consistently decreasing since 2013, when the January 2014 SDR reported a patient population of 116 patients and a utilization rate of 64.5 percent. The applicant could relocate 7 stations from BMA Burlington, leaving that facility with 38 in-center stations, and still have room for additional patient growth. The applicant does not provide sufficient information to adequately document that the chosen alternative is the least costly or most effective alternative to meet the need for seven additional stations at Carolina Dialysis.

Furthermore, the application is not conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (6), (13c), and (18a), which are incorporated herein by reference. An application that cannot be approved is not an effective alternative.

The information in the application regarding which alternative is the least costly or most effective is not reasonable and adequately supported for the following reasons:

- The applicant fails to consider other alternatives that exist to the project as proposed.
- The applicant fails to provide reasonable and adequately supported information to support its determination that the project as proposed is the least costly or most effective alternative.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant does not adequately demonstrate that the application is conforming to this criterion.

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of

the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add 7 dialysis stations to the existing facility for a total of 27 stations upon project completion.

Capital and Working Capital Costs

In Section F.1, pages 33-34, the applicant projects the capital cost for the proposed project will be $1,162,719, as shown in the table below.

Capital Cost by Line Item – Carolina Dialysis	
Item	**Cost**
Construction Contract	$786,710
Dialysis Machines	$120,000
Equipment/Furniture	$90,800
Architect/Engineering Fees	$78,671
Contingency	$86,538
Total	**$1,162,719**

In Sections F.10 and F.11, page 37, the applicant states that there are no projected start-up expenses or initial operating expenses because it is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 35, the applicant states it will finance the capital costs and working capital costs with accumulated reserves. Exhibit F-1 contains a letter dated September 15, 2017 from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., authorizing and committing $596,047 – approximately 51 percent of the total capital costs – for the project. Exhibit F-1 also contains a second letter dated September 15, 2017, from Ronald Falk, M.D., a member of the Board of Managers of Carolina Dialysis, LLC, authorizing and committing $572,672 – approximately 49 percent of the total capital costs – for the project. Each of the letters states that the capital expenditure is $1,168,719, and the amounts pledged are consistent with the higher capital expenditures cited in the letters. Regardless of whether the capital expenditure is correct in the application, at $1,162,719, or correct in the letters at $1,168,719, the applicant provides adequate documentation of the commitment of sufficient accumulated reserves for the capital cost of the proposed project.

Exhibit F-2 contains a copy of Fresenius Medical Care Holdings, Inc. and Subsidiaries (FMC) Consolidated Financial Statements for the years ending December 31, 2016 and 2015. These statements indicate that as of December 31, 2016, FMC had $357,899,000 in cash and cash equivalents, $20,135,661,000 in total assets, and $10,533,297,000 in net assets (total assets less total liabilities). Exhibit F-2 also contains a copy of the balance sheet for Carolina Dialysis Center as of June 30, 2017. The balance sheet indicates that as of June 30, 2017, Carolina

Dialysis Center had $77,100 in cash, $39,127,598 in total assets, and $32,848,461 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years, as shown in the table below.

Projected Revenues and Operating Expenses		
Carolina Dialysis	**Operating Year 1 CY 2020**	**Operating Year 2 CY 2021**
Total Treatments	14,523	15,708
Total Gross Revenues (Charges)	$57,482,876	$62,165,229
Total Net Revenue	$5,342,205	$5,821,978
Total Operating Expenses (Costs)	$4,976,788	$5,268,093
Net Income/Profit	**$365,417**	**$553,885**

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses reasonable and adequately supported assumptions to project utilization.
- Historical data is used to provide future projections of costs and charges and demonstrate financial feasibility of the project.
- Documentation of sufficient funding for the capital needs of the project is provided and is credible.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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.

NC

The applicant proposes to add 7 dialysis stations to the existing facility for a total of 27 stations upon project completion.

On page 373, the 2017 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 North Carolina counties is a separate dialysis station planning area."* Thus, the service area for this facility is Alamance County. Facilities may also serve residents of counties not included in their service area.

According to Table B of the July 2017 SDR, there are five existing dialysis facilities and two approved but not yet operational dialysis facilities in Alamance County, as shown in the table below.

Existing/Approved Dialysis Facilities in Alamance County – Table B July 2017 SDR

Facility	Owner	# Patients	Location	# Certified Stations – 6/9/17	# Approved Stations – 6/9/17	% Utilization
Alamance County Dialysis	DaVita	22	Graham	10	0	55.0%
BMA Burlington	Fresenius	94	Burlington	45	0	52.2%
Burlington Dialysis	DaVita	96	Burlington	24	-12	100.0%
Carolina Dialysis – Mebane	Carolina Dialysis/ Fresenius	65	Mebane	20	0	81.3%
Elon Dialysis	DaVita	0	Burlington	0	10	0.0%
Mebane Dialysis	DaVita	0	Mebane	0	10	0.0%
North Burlington Dialysis	DaVita	68	Burlington	22	-8	106.3%

In Section G, page 42, the applicant states:

> *"Based solely on the growth of the census with the* [sic] *Carolina Dialysis – Mebane, the applicant suggests that adding seven stations is not duplicating existing capacity. Moreover, CDM is actually taking a proactive step to ensure adequate access to care by the patients of the area who choose to dialyze at the facility."*

The applicant operates a second facility in Alamance County. BMA Burlington, owned by Fresenius, has 45 in-center stations, with a current utilization rate of 52.2 percent (94 / 45 = 2.09; 2.09 / 4 = 0.522). In fact, the utilization of the 45 existing stations at BMA Burlington has been consistently decreasing since 2013, when the January 2014 SDR reported a patient population of 116 patients and a utilization rate of 64.5 percent.

The applicant could relocate 7 stations from BMA Burlington, leaving that facility with 38 in-center stations, and still have room for additional patient growth.

In Section G, page 42, the applicant does not discuss why it chose not to relocate seven of the existing certified stations from BMA Burlington to address the facility need at Carolina Dialysis. The July 2017 SDR reports a surplus of 27 dialysis stations in Alamance County.

Approval of the application's proposal would increase the surplus of dialysis stations in Alamance County to 34.

The information in the application regarding unnecessary duplication of existing or approved health care service capabilities or facilities is not reasonable and adequately supported for the following reasons:

- The applicant did not address the surplus of dialysis stations in Alamance County.
- The applicant did not address why a facility with excess capacity and declining utilization could not relocate existing stations instead of developing new stations.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant does not adequately demonstrate that the application is conforming to this criterion.

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

C

In Section H.1, page 43, the applicant provides its current and projected staffing in full time equivalents (FTEs) for Carolina Dialysis in OY2. The applicant states the Medical Director is not directly employed by the facility, and thus is not reflected on the staffing chart. The applicant's current and projected staff are shown in the table below.

Carolina Dialysis – Current/Proposed Facility Staffing			
Position	**Current # of FTEs**	**Projected # of FTEs to be Added**	**Projected # of FTEs – OY2**
Registered Nurse	3.0	1.0	4.0
Home Training Nurse	0.5	1.0	1.5
LPN	1.0	0.0	1.0
Patient Care Technician	8.0	2.0	10.0
Clinical Manager	1.0	0.0	1.0
Administration	0.2	0.0	0.2
Dietician	0.6	0.3	0.9
Social Worker	0.6	0.3	0.9
In-Service	0.2	0.0	0.2
Clerical	0.8	0.0	0.8
Chief Tech	0.2	0.0	0.2
Equipment Tech	1.0	0.0	1.0
Total	**17.1**	**4.6**	**21.7**

In Section H.7, page 45, the applicant provides the projected direct care staff for the proposed facility in OY 2 (CY 2021), as shown in the table below:

Direct Care Positions	# FTEs	Hours per Year per FTE	Total Annual FTE Hours	Total Annual Hours of Operation	# FTE Hours per Hour of Operation
Registered Nurse	4.00	2,080	8,320	3,744	2.22
Home Training Nurse	1.50	2,080	3,120	3,744	0.83
LPN	1.0	2,080	2,080	3,744	0.56
Patient Care Technician	10.00	2,080	20,800	3,744	5.56
Total	**16.50**	**2,080**	**34,320**	**3,744**	**9.17**

In Section H.6, page 45, the applicant states dialysis services will be available from 4:30 AM to 4:30 PM, Monday through Saturday, for a total of 12 hours per day / 72 hours per week.

In Section I.3, page 48, the applicant identifies Dr. Amy Mottl as the current and continuing Medical Director of the facility. In Exhibit I-5, the applicant provides a copy of a letter signed by Dr. Mottl supporting the project and confirming her commitment to continue to serve as Medical Director. In Section H.3, page 44, the applicant describes the methods used to recruit and fill positions at the facility.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides appropriate documentation of the availability of adequate health manpower and management personnel for the provision of the proposed dialysis services.
- The applicant provides appropriate and credible documentation of support from the current and continuing Medical Director of Carolina Dialysis.
- The applicant provides appropriate and credible documentation of the availability of other resources, including methods of recruitment and documentation of staff training, necessary for the provision of the proposed dialysis services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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.1, page 47, the applicant identifies the necessary ancillary and support services that serve Carolina Dialysis. Exhibit I-5 contains a letter from the medical director of the

facility expressing her support for the proposed project. The applicant discusses coordination with the existing health care system on pages 48-50. Exhibits I-2 through I-4, respectively, contain copies of agreements for lab services, acute care services, and transplantation services.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides appropriate and credible documentation of the availability of necessary ancillary and support services for the provision of the proposed dialysis services.
- The applicant provides credible documentation of ongoing coordination with the existing health care system.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

(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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

(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.

C

In Section K.2, page 54, the applicant states that the existing facility has 4,027 square feet of treatment area, and the applicant proposes to construct an additional 2,152 square feet of treatment area, which includes isolation space. The applicant provides the facility's line drawings in Exhibit K-1. The drawing depicts a 12,631 square foot facility, with 24 main floor dialysis stations, two private treatment area dialysis stations, and one isolation dialysis station, for a total of 27 stations. The drawing also depicts space for both home PD and HH training. In Section K.1, pages 52-53, the applicant describes its plans for energy-efficiency, including water conservation. The applicant states its plans for implementing applicable energy saving features, including energy-efficient lighting fixtures, plumbing, and heating and cooling systems.

Costs and charges are described by the applicant in Section F, pages 33-41, and in Section R pro forma financial statements. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides credible documentation that the cost, design, and means of construction represent the most reasonable alternative.
- The applicant provides appropriate and credible documentation of the inclusion of energy saving features into the construction plans.
- The applicant provides credible documentation of costs and charges which do not show undue increases related to construction costs.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

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

C

In Section L.7, page 62, the applicant reports that 87.79 percent of the patients who received treatments at Carolina Dialysis had some or all of their services paid for by Medicare or Medicaid in CY 2016. The historical payor mix for patients dialyzing at Carolina Dialysis is shown in the table below.

Carolina Dialysis Historical Payor Mix CY 2016

Payment Source	% Total Patients
Self-Pay/Indigent/Charity	0.43%
Medicare	57.95%
Medicaid	4.41%
Commercial Insurance	11.07%
Medicare/Commercial	25.43%
VA	0.72%
Total	**100.00%**

Note: Total may not foot due to rounding.

The applicant states that it is unable to separate the historical payor mix by treatment modality and so it provides the historical payor mix for the overall patient population.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant’s service area.

Percent of Population						
County	**% 65+**	**% Female**	**% Racial & Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
Alamance	17%	53%	35%	19%	10%	14%
Statewide	16%	51%	37%	16%	10%	13%

Source: http://www.census.gov/quickfacts/table; Latest Data 7/1/16 as of 8/22/17
*Excludes *"White alone"* who are *"not Hispanic or Latino"*
***"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable…The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."*

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina, and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*[1] percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28[2]. In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant's historical payor mix is adequate documentation that it currently provides services to medically underserved populations.
- The applicant's historical payor mix is adequate documentation of the extent to which medically underserved populations utilize the applicant's existing services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

[1]http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf
[2]http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

(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 L.3(d), page 61, the applicant states that it has no obligation to provide uncompensated care or community service under federal regulations. In Section L.6, page 61, the applicant states there have been no civil rights access complaints filed within the last five years.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides credible information about its lack of obligation to provide any uncompensated care or community service under any federal regulations.
- The applicant states it has not had any civil rights access complaints filed against it within the last five years.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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

NC

In Section L.1(a), page 59, the applicant 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."*

In Section L.1(b), page 59, the applicant projects that 81.8 percent of all patients in CY 2021 who will receive dialysis treatments at Carolina Dialysis will have all or part of their services paid for by Medicare and/or Medicaid, as shown in the table below.

Carolina Dialysis Projected Payor Mix CY 2021				
Payment Source	**% Total Patients**	**% IC Patients**	**% HH Patients**	**% PD Patients**
Self-Pay/Indigent/Charity	0.90%	1.14%	1.12%	1.12%
Medicare	55.50%	56.60%	47.77%	47.77%
Medicaid	4.50%	5.63%	0.00%	0.00%
Commercial Insurance	16.40%	10.30%	51.02%	51.02%
Medicare/Commercial	21.80%	25.04%	0.08%	0.08%
Misc. (including VA)	0.90%	1.29%	0.00%	0.00%
Total	**100.00%**	**100.00%**	**100.00%**	**100.00%**

Note: Totals may not foot due to rounding.

The applicant does not explain how it arrived at its projected payor mix for operating year two. In Section L.7, page 62, in providing its historical payor mix, the applicant provides the payor mix for the entire facility only – not broken down by modality, as it does in Section L.1(b) – and states the following:

> *"Carolina Dialysis is not able to separate prior years payor mix information by modality. Therefore, all of 2016 revenues are lumped into one 'bucket' of revenue. While the revenue can be sorted by payor classification, it is not possible to separate by modality."*

Despite saying that the payor mix cannot be separated by modality, the applicant then projects its future payor mix, broken down by modality, in Section L.7, but offers no assumptions or methodology to explain its projections. Furthermore, the projected overall facility payor mix is not similar enough to the historical payor mix to be able to logically conclude that the projected payor mix is based upon the historical payor mix based on information in the application as submitted. There are numerous changes to percentages and the application as submitted does not explain the reasons that may exist for those changes. See the table below.

Carolina Dialysis Payor Mix Changes			
Payment Source	**% Total Patients CY 2016**	**% Total Patients CY 2021**	**Difference**
Self-Pay/Indigent/Charity	0.43%	0.90%	0.47%
Medicare	57.95%	55.50%	-2.45%
Medicaid	4.41%	4.50%	0.09%
Commercial Insurance	11.07%	16.40%	5.33%
Medicare/Commercial	25.43%	21.80%	-3.63%
Misc. (including VA)	0.72%	0.90%	0.18%
Total	**100.00%**	**100.00%**	

Because the applicant's projected payor mix is questionable, the applicant does not adequately demonstrate that medically underserved groups will have adequate access to the proposed dialysis services.

The information in the application regarding access to the proposed services for medically underserved groups is not reasonable and adequately supported because the applicant does not provide adequate documentation of how it projected its future payor mix.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant does not adequately demonstrate that 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 61, 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.*
>
> *…. 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 information in the application, including any exhibits, is reasonable and adequately supported because the applicant adequately demonstrates that the facility will provide a range of means by which a person can access the services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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.1, page 63, the applicant states, *"CDM has communicated with the local student nursing programs encouraging those programs to utilize the resources of the Carolina Dialysis-Mebane facility to enhance the educational opportunities for the nursing student."* In Exhibit M-1, the applicant provides a copy of a letter to Vance Granville Community College inviting the nursing students to include Carolina Dialysis in their clinical rotations.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant adequately documents that the proposed health services will accommodate the clinical needs of health professional training programs in the area.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

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

NC

The applicant proposes to add 7 dialysis stations to the existing facility for a total of 27 stations upon project completion.

On page 373, the 2017 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 North Carolina counties is a separate dialysis station planning area."* Thus, the service area for this facility is Alamance County. Facilities may also serve residents of counties not included in their service area.

The applicant is eligible to apply for additional stations at Carolina Dialysis based on application of the facility need methodology because the utilization rate reported in the July 2017 SDR was 81.25 percent, or 3.25 patients per station per week.

In Section N, page 64, the applicant states that it does not expect this project to have an effect on competition in Alamance County. See also Sections B, C, E, F, G, H, and L where the applicant discusses the impact of the project on cost-effectiveness, quality, and access.

According to Table B of the July 2017 SDR, there are five existing dialysis facilities and two approved but not yet operational dialysis facilities in Alamance County, as shown in the table below.

Existing/Approved Dialysis Facilities in Alamance County – Table B July 2017 SDR						
Facility	**Owner**	**# Patients**	**Location**	**# Certified Stations – 6/9/17**	**# Approved Stations – 6/9/17**	**% Utilization**
Alamance County Dialysis	DaVita	22	Graham	10	0	55.0%
BMA Burlington	Fresenius	94	Burlington	45	0	52.2%
Burlington Dialysis	DaVita	96	Burlington	24	-12	100.0%
Carolina Dialysis – Mebane	Carolina Dialysis/ Fresenius	65	Mebane	20	0	81.3%
Elon Dialysis	DaVita	0	Burlington	0	10	0.0%
Mebane Dialysis	DaVita	0	Mebane	0	10	0.0%
North Burlington Dialysis	DaVita	68	Burlington	22	-8	106.3%

The applicant operates a second facility in Alamance County. BMA Burlington, owned by Fresenius, has 45 in-center stations, with a current utilization rate of 52.2 percent (94 / 45 = 2.09; 2.09 / 4 = 0.522). In fact, the utilization of the 45 existing stations at BMA Burlington has been consistently decreasing since 2013, when the January 2014 SDR reported a patient population of 116 patients and a utilization rate of 64.5 percent.

The applicant could relocate 7 stations from BMA Burlington, leaving that facility with 38 in-center stations, and still have room for additional patient growth.

In Section G, page 42, the applicant does not discuss why it chose not to relocate seven of the existing certified stations from BMA Burlington to address the facility need at Carolina Dialysis. The July 2017 SDR reports a surplus of 27 dialysis stations in Alamance County. Approval of the application's proposal would increase the surplus of dialysis stations in Alamance County to 34.

The information in the application regarding how any enhanced competition will have a positive impact upon the cost effectiveness and access to the services proposed is not reasonable and adequately supported for the following reasons:

- The applicant fails to adequately demonstrate that the proposed project is the least costly or most effective alternative and that it would not lead to unnecessary duplication. See the discussions on alternatives and duplication found in Criteria (4) and (6), respectively, which are incorporated herein by reference.

- The applicant fails to adequately demonstrate that underserved populations will have adequate access to the proposed services. See the discussions regarding access found in Criteria (3) and (13c), which are incorporated herein by reference.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant does not adequately demonstrate that 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 Section B.4, pages 8-9, Section O, pages 65-68, and referenced exhibits, the applicant discusses the methods it uses to ensure and maintain quality in its dialysis facilities.

Fresenius Medical Care, the parent company of Carolina Dialysis, owns, operates, and/or is affiliated with 109 facilities in North Carolina as of September 15, 2017. In Section O and referenced exhibits, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation during the 18 month look-back period. The applicant states that two facilities, RAI West College and BMA East Rocky Mount, received Immediate Jeopardy citations within the 18 month look-back period, but states that both facilities are back in compliance and provides corresponding documentation in Exhibits O-3 and O-4. 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 information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides adequate and credible documentation of its current policies with regard to providing quality care.
- The applicant provides accurate information regarding past deficiencies and how those deficiencies were addressed.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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 application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific criteria are discussed below.

10A NCAC 14C .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- Carolina Dialysis is 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- In Section C.1, pages 14-18, the applicant documents the need for the project and demonstrates that it will serve a total of 88 in-center patients on 27 stations at the end of the first operating year, which is 3.26 patients per station per week or a utilization rate of 81.5 percent. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 14-18, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides adequate and credible documentation that it meets the performance standard required by this Rule.
- The applicant provides all documentation of its assumptions and methodology required by this Rule.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.