

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

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

Decision Date: February 12, 2018
Findings Date: February 12, 2018

Team Leader: Gloria C. Hale
Assistant Chief: Lisa Pittman

Project ID #: F-11417-17
Facility: Mint Hill Dialysis
FID #: 070389
County: Mecklenburg
Applicant(s): DVA Healthcare Renal Care, Inc.
Project: Add six dialysis stations to for a total of 22 stations

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.

C

DVA Healthcare Renal Care, Inc. (DVA) d/b/a Mint Hill Dialysis proposes to add six dialysis stations to the existing facility for a total of 22 stations upon completion of the project.

Need Determination

The 2017 State Medical Facilities Plan (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), the county need methodology shows there is a surplus of 14 dialysis stations in Mecklenburg 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%. 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 Mint Hill Dialysis in the July 2017 SDR is 3.88 patients per station per week, or 97% (3.88 / 4 patients per station = 0.97 or 97%). This utilization rate was calculated based on 62 in-center dialysis patients and 16 certified dialysis stations (62 patients / 16 stations = 3.88 patients per station per week).

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

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/17		97%
Certified Stations		16
Pending Stations		0
Total Existing and Pending Stations		16
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR2)		62
In-Center Patients as of 6/30/16 (Jan. 2017 SDR) (SDR1)		46
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	16
	Multiply the difference by 2 for the projected net in-center change	32
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.6957
(ii)	Divide the result of step (i) by 12	0.0580
(iii)	Multiply the result of step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.6960
(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 SDR1	105.1520
(v)	Divide the result of step (iv) by 3.2 patients per station	32.8600
	and subtract the number of certified and pending stations to determine the number of stations needed	17

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 17 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 six 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, pages 9-11, Section K.1, pages 40-41, Section N.1-2, page 51, Section O, page 52, and Exhibits B-4, K-1(d), K-1(f), K-1(g), O-2. 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, pages 10-11, Section L, pages 45-49, Section N.1, page 51, and Exhibit L-3. 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, page 11, Section F, pages 24-27, Section K, pages 40-41, Section N, page 51, and Exhibits F-5, F-7, and F-8. 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.

Conclusion

The information in the application is reasonable and adequately supported because the applicant relies on existing policies, historical data, and verifiable sources to provide future projections and demonstrate conformity with *Policy GEN-3*.

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.

- (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

DVA proposes to add six dialysis stations to the existing facility for a total of 22 stations upon completion of the project.

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 consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 19, the applicant provides a table showing the historical patient origin for in-center patients served by Mint Hill Dialysis, as shown below:

**Mint Hill Dialysis
 Historical Patient Origin
 December 31, 2016**

County	In-Center Patients
Mecklenburg	42
Alamance	1
Cabarrus	3
Union	10
Georgia	1
Other States	5
Total	62

In Section C, page 14, the applicant provides the projected patient origin for Mint Hill Dialysis for in-center patients for operating year one (OY1) and operating year 2 (OY2) following completion of the proposed project, as shown below:

**Mint Hill Dialysis
 Projected Patient Origin**

COUNTY	OPERATING YEAR 1 CY2019	OPERATING YEAR 2 CY2020	COUNTY PATIENTS AS % OF TOTAL*	
			OY 1	OY 2
Mecklenburg	65	76	76.5%	79.2%
Alamance	1	1	1.2%	1.0%
Cabarrus	3	3	3.5%	3.1%
Union	10	10	11.8%	10.4%
Georgia	1	1	1.2%	1.0%
Other States	5	5	5.9%	5.2%
Totals	85	96	100.0%	100.0%

*Totals may not foot due to rounding.

The applicant provides the assumptions and methodology used to project patient origin on pages 14-16. The applicant adequately identifies the population to be served.

Analysis of Need

The applicant proposes to add six dialysis stations to the existing facility for a total of 22 stations upon completion of the project. In Section B.2, pages 6-7, the applicant states the need for the proposed project is based on the facility need methodology and demonstrates how the facility qualifies for six additional stations. In Section N.1, page 51, the applicant states, *“The expansion of Mint Hill Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and other [sic] involved in the dialysis process to receive services.”*

In Section C.1, page 14, the applicant provides the assumptions used to project utilization at Mint Hill Dialysis, summarized as follows:

- OY1 is calendar year 2019 (CY2019), January 1, 2019 – December 31, 2019
- OY2 is calendar year 2020 (CY2020), January 1, 2020 – December 31, 2020
- In-center patient population is projected to grow at 16.0%, a conservative growth rate given the facility’s average annual growth rate of 38.7% over the past five years.
- The 16% growth rate is applied to the Mecklenburg County in-center patient population only which was 42 patients on July 1, 2016. The remaining 20 patients residing outside Mecklenburg County are added with no growth expected.

The Project Analyst notes that the applicant’s calculation of its facility’s average annual growth rate is based on four years of growth and not five. The applicant provides a table showing historical utilization and growth rates in Section C.1, page 15 which is summarized below. The Project Analyst’s additions to the table are provided in brackets.

Mint Hill Dialysis Historical Utilization and Growth

Year Ending	# of Patients	Growth Rate	[# of Years of Growth]
12/31/2012	18	n/a	
12/31/2013	33	83.3%	[1]
12/31/2014	40	21.2%	[2]
12/31/2015	45	12.5%	[3]
12/31/2016	62	37.8%	[4]
[4-year average annual growth rate]		38.7%	

Since Mint Hill Dialysis had no patients on December 31, 2011, as reported in the July 2012 SDR, it was not possible for the Project Analyst to calculate a five year annual growth rate for the facility. However, given the facility’s average annual growth rate of 38.7%, which is much higher than the Five Year Average Annual Change Rate (AACR) for Mecklenburg County of 5.1% as reported in the July 2017 SDR, the applicant’s application of a 16% annual average growth rate to only the in-center patients from Mecklenburg County is conservative, reasonable and adequately supported.

In addition, the applicant erred in stating in its assumption, in Section C.1, page 15, that it applies the 16% annual average growth rate to 42 patients from Mecklenburg County beginning on July 1, 2016. In the methodology on page 15, the applicant applies the 16% average annual growth rate to 42 patients from Mecklenburg County on January 1, 2017. The applicant states, on page 14, that Mint Hill Dialysis had 62 in-center patients as of December 31, 2016, and that 42 of them reside in Mecklenburg County. Data reported on

the End Stage Renal Disease Data Collection Form for Mint Hill Dialysis confirms that there were 42 patients from Mecklenburg County as of December 31, 2016.

In Section C.1, page 15, the applicant provides the methodology used to project utilization for operating years one and two, summarized as follows:

Begin with the Mecklenburg County patients dialyzing at Mint Hill Dialysis as of January 1, 2017.	42
Project the Mecklenburg County patient population forward one year to December 31, 2017 using an average annual growth rate of 16%.	$42 \times 1.16 = 48.72$
Add 20 in-center patients from outside Mecklenburg County. This is the ending census for December 31, 2017.	$48.72 + 20 = 68.72$
Project the Mecklenburg County patient population forward one year to December 31, 2018 using an average annual growth rate of 16%.	$48.72 \times 1.16 = 56.5152$
Add 20 in-center patients from outside Mecklenburg County. This is the ending census for December 31, 2018.	$56.5152 + 20 = 76.5152$
Project the Mecklenburg County patient population forward one year to December 31, 2019 using an average annual growth rate of 16%.	$56.5152 \times 1.16 = 65.5576$
Add 20 in-center patients from outside Mecklenburg County. This is the ending census for December 31, 2019, OY1.	$65.5576 + 20 = 85.5576$
Project the Mecklenburg County patient population forward one year to December 31, 2020 using an average annual growth rate of 16%.	$65.5576 \times 1.16 = 76.0469$
Add 20 in-center patients from outside Mecklenburg County. This is the ending census for December 31, 2020, OY2.	$76.0469 + 20 = 96.0469$

The applicant states, on page 15, that the numbers of projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 the facility is projected to serve 85 in-center patients and at the end of OY2 the facility is projected to serve 96 in-center patients. Therefore, the facility's projected utilization at the end of OY1 will be 3.86 patients per station per week ($85 \text{ patients} / 22 \text{ dialysis stations} = 3.86$) which exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

In summary, the applicant adequately identifies the patient origin and adequately demonstrates the need for six additional dialysis stations at Mint Hill Dialysis.

Access

In Section L, page 45, the applicant states that Mint Hill Dialysis makes services available to all patients in the service area without regard to race, color, national origin, gender, sexual orientation, age, religion or disability.

In Section L, page 49, the applicant reports that 87.3% of the in-center patients who received treatments at Mint Hill Dialysis had some or all of their services paid for by Medicare or Medicaid in CY 2016, as illustrated in the table below.

**Mint Hill Dialysis
Historical Payor Mix CY 2016**

Payment Source	Percent of Total Patients
Medicare	16.4%
Medicaid	7.3%
Commercial Insurance	7.3%
Medicare/Commercial	49.1%
Medicare/Medicaid	14.5%
VA	5.4%
Total	100.0%

In Section L.1, page 46, the applicant projects that the same percentage of the facility's in-center patients, 87.3%, will be Medicare or Medicaid recipients. The applicant adequately demonstrates 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 population to be served by the proposed project will be from the same counties as they have been historically.
- The applicant uses reasonable assumptions and methodology to project the number of in-center patients to be served at the facility.
- The applicant projects that the facility will serve a similar percentage of Medicaid and Medicare recipients as it has historically.

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.

- (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 proposes to add six dialysis stations to an existing facility, therefore there will be no reduction or elimination of a service, including the relocation of a facility.

- (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 23, the applicant discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo – based on the growth rate at Mint Hill Dialysis the applicant dismissed this option as not effective.
2. Relocate existing stations from another DaVita facility in Mecklenburg County- The applicant states that of the six operational DaVita facilities in Mecklenburg County, only one was operating at less than 80% utilization – North Charlotte Dialysis. The applicant states that this facility has experienced significant growth in the recent past, therefore relocating any of the stations at that facility would be detrimental to the patients being served there. Therefore, this is not the most effective alternative.

In Section E.2, page 23, the applicant states that it has demonstrated that there is a need for additional stations at Mint Hill Dialysis and that doing so will address growth and access. Therefore, the proposed alternative represented in the application is the most effective alternative to meet the identified need.

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 the proposal is its most effective alternative to meet the identified need.

This determination is based on a review of the:

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

Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. DVA Healthcare Renal Care, Inc. d/b/a Mint Hill Dialysis shall materially comply with all representations made in the certificate of need application.**
 - 2. DVA Healthcare Renal Care, Inc. d/b/a Mint Hill Dialysis shall develop and operate no more than six additional dialysis stations for a total of 22 certified stations upon completion of the project which shall include any home hemodialysis training or isolation stations.**
 - 3. DVA Healthcare Renal Care, Inc. d/b/a Mint Hill Dialysis shall install plumbing and electrical wiring through the walls for six additional dialysis stations for a total of 22 dialysis stations which shall include any home hemodialysis training or isolation stations.**
 - 4. DVA Healthcare Renal Care, Inc. d/b/a Mint Hill Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to the 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

DVA proposes to add six dialysis stations to the existing facility for a total of 22 stations upon completion of the project.

Capital and Working Capital Costs

In Section F.1, page 24, the applicant projects the capital cost for the proposed project, as summarized in the table below:

**Mint Hill Dialysis
Projected Capital Costs**

Construction Contract	\$559,890
Dialysis Machines	\$137,800
Equipment/furniture not included above	\$201,189
Architect/engineering fees	\$50,500
Interest during Construction	\$14,241
Total	\$963,620

In Section F.10, pages 26-27, the applicant states that there are no working capital needs for the proposed project since Mint Hill Dialysis is an existing, operational facility.

Availability of Funds

In Section F.2, page 25, the applicant states it will finance the capital costs with accumulated reserves/owner's equity of DVA.

Exhibit F contains a letter dated September 12, 2017, from the Chief Accounting Officer of DaVita Inc., the parent company and 100% owner of DVA Healthcare Renal Care, Inc., which authorizes and commits cash reserves for the project capital costs of \$963,620. Exhibit F-7 contains DaVita Inc.'s Form 10-K for the fiscal year ended December 31, 2016. As of December 31, 2016, DaVita Inc. had \$913,187,000 in cash and cash equivalents, \$18,741,257,000 in total assets and \$5,822,999,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

In Section R, Form B of the pro forma financial statements, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

MINT HILL DIALYSIS Revenue and Expenses		
	OY1	OY2
Total Treatments	11,930	13,412
Total Gross Revenues (Charges)	\$3,554,612	\$3,996,208
Deductions form Gross Revenues	\$89,990	\$101,141
Total Net Revenue	\$3,464,622	\$3,895,067
Average Net Revenue per Treatment	\$290	\$290
Total Operating Expenses (Costs)	\$3,078,785	\$3,389,033
Average Operating Expense per Treatment	\$258	\$253
Net Income	\$385,837	\$506,034

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.

Conclusion

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.

This determination is based on a review of the information in the application, including any exhibits.

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.

C

DVA proposes to add six dialysis stations to the existing facility for a total of 22 stations upon completion of the project.

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 consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

According to the July 2017 SDR, there are 23 dialysis facilities in Mecklenburg County, 17 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the July 2017 SDR, is provided below:

**Mecklenburg County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2016**

Dialysis Facility	Owner	Location	Number of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	98.44%
BMA Nations Ford	BMA	Charlotte	28	93.75%
BMA of East Charlotte	BMA	Charlotte	25	92.00%
BMA of North Charlotte	BMA	Charlotte	36	102.78%
BMA West Charlotte	BMA	Charlotte	29	86.21%
Brookshire Dialysis	DaVita	Charlotte	0	0.00%
Carolinas Medical Center	CMC	Charlotte	9	27.78%
Charlotte Dialysis	DaVita	Charlotte	36	84.72%
Charlotte East Dialysis	DaVita	Charlotte	34	88.24%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	69.79%
DSI Glenwater Dialysis	DSI	Charlotte	42	77.38%
FMC Charlotte	BMA	Charlotte	43	90.70%
FMC Matthews	BMA	Matthews	21	111.90%
FKC Southeast Mecklenburg County**	BMA	Charlotte	0	0.00%
FMC Regal Oaks*	BMA	Charlotte	0	0.00%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
Fresenius Medical Care Southwest Charlotte***	BMA	Charlotte	10	40.00%
Huntersville Dialysis	DaVita	Huntersville	10	92.50%
Mint Hill Dialysis	DaVita	Mint Hill	16	96.88%
North Charlotte Dialysis Center	DaVita	Charlotte	41	74.39%
South Charlotte Dialysis	DaVita	Charlotte	22	86.36%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis*	DaVita	Charlotte	0	0.00%

Source: July 2017 SDR, Table B.

* Facility under development.

** FKC Southeast Mecklenburg County is a new facility under development, however it is erroneously named FMC of Southwest Charlotte in the July 2017 SDR, Table B. In addition, the FID# should be 160337.

*** FMC Southwest Charlotte is an existing facility, however the FID# is erroneous as listed in the July 2017 SDR, Table B. The FID# should be 120485.

As illustrated above, DaVita owns six of the 17 operational dialysis facilities in Mecklenburg County. As shown in the table above, five of DaVita's six operational dialysis facilities are operating above 80% utilization and two of those are operating above 90% utilization. In Section G of the application, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis

facilities in Mecklenburg County. The applicant states, in Section E.1, page 23, that DaVita's one dialysis facility that is operating below 80% capacity, North Charlotte Dialysis Center, has experienced significant growth recently and therefore would be negatively impacted by a relocation of stations to Mint Hill Dialysis. Four other dialysis facilities are operating below 80% utilization, including one BMA facility, two DSI facilities, and a CMC facility.

The applicant adequately demonstrates its proposal would not result in an unnecessary duplication of existing or approved dialysis services in Mecklenburg County based on the following analysis:

- The applicant is not proposing to develop a new dialysis facility, rather it is proposing to add dialysis stations based on the facility need methodology.
- All but one other operational DaVita dialysis facility in Mecklenburg County, with the exception of North Charlotte Dialysis Center which has experienced significant growth recently, are operating at over 80% of capacity.
- The applicant projects to serve more than 3.2 patients per station per week at the end of the first operating year as required by 10A NCAC 14C .2203(b).

This determination is based on a review of the:

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

Consequently, the applicant adequately demonstrates 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, page 32, the applicant provides the current and projected staffing for the facility, in full-time equivalents (FTEs), as illustrated in the following table. The applicant states the Medical Director will not be employed by the facility, and thus is not reflected on the staffing chart.

MINT HILL DIALYSIS			
POSITION	CURRENT # FTES	# FTES TO BE ADDED	PROJECTED # FTES
Registered Nurse	2	1	3
Technician (Patient Care)	6	3	9
Administrator	1	0	1
Dietician	1	0	1
Social Worker	1	0	1
Administrative Assistant	1	0	1
Bio-med Technician	1	0	1
Total	13	4	17

As illustrated in the table above, the applicant projects an increase of four FTEs for a total of 17 FTEs at Mint Hill Dialysis upon project completion.

In Section H.7, page 35, the applicant provides the projected direct care staff for Mint Hill Dialysis in OY2 (CY2020). In Section H.6, page 35, the applicant states that dialysis services will be available from 6:00 a.m. to 4:00 p.m., Monday through Saturday.

In Section I.3, page 37, the applicant identifies Dr. Jack Lohavichan, as the Medical Director of the proposed facility. In Exhibit I-3, the applicant provides a copy of an August 15, 2017 letter signed by Dr. Lohavichan, supporting the project and confirming his commitment to continue to serve as Medical Director. In Section H.3, pages 33-34, the applicant states that it recruits staff by working with a DaVita Teammate Recruiter, by utilizing its Teammate Referral Program and its Student Internship Program, and by offering a range of teammate benefits and competitive salaries.

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 Mint Hill 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 36, the applicant provides a list of the necessary ancillary and support services and indicates how they will be made available. Exhibit I-1 contains a copy of a letter from the Facility Administrator of Mint Hill Dialysis listing existing ancillary and support services that will continue to be made available to the facility. In addition, Exhibit I-1 contains copies of agreements with Charlotte East Dialysis and DaVita Laboratory Services, Inc. to provide home hemodialysis training and laboratory services, respectively. Exhibit I-3 contains letters from Dr. Jack Lohavichan, Medical Director of the facility, and Dr. Matthew Elliott, another nephrologist, expressing their support for the proposed project. In Section I.3 and Section I.4, pages 37-38, the applicant discusses how the proposed service will be coordinated with the existing health care system by identifying support from local nephrologists and by stating it has established relationships with several other healthcare providers and social services agencies within the county.

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

- A list of current and projected necessary ancillary and support services, and by whom they will be made available, is documented.
- The applicant identifies nephrologists in the area who have agreed to provide medical coverage at the facility, and
- The facility's Medical Director has provided a letter of support.

This determination is based on a review of the information in the application, including any exhibits.

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.

- (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.

NA

The applicant does not propose to construct any new space nor renovate any existing space. Therefore, Criterion 12 is not applicable to this review.

- (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 of the application, the applicant provides the information required in this criterion. The following table illustrates the actual payor mix for Mint Hill Dialysis during CY2016.

**Mint Hill Dialysis
Historical Payor Mix CY 2016**

Payment Source	In-Center Patients
Medicare	16.4%
Medicaid	7.3%
Commercial Insurance	7.3%
Medicare/Commercial	49.1%
Medicare/Medicaid	14.5%
VA	5.4%
Total	100.0%

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28¹. 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). However, a direct comparison to the applicant's current payor mix would be of little value because the population data by age, race or gender does not include information on the number of elderly minorities, women or handicapped persons utilizing health services.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant's historical payor mix is adequate documentation of the extent to which medically underserved populations utilize the applicant's existing services.

The application is conforming to this criterion based on a review of the:

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

¹http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-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, page 48, the applicant states, “*Mint Hill Dialysis has no obligation under any federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed on all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993. The facility has no obligation under the Hill Burton Act.*” In Section L.6, page 48, the applicant states “*There have been no civil rights equal access complaints filed within the last five years.*”

The application is conforming to this criterion based on a review of:

- Information in the application, including any exhibits.
 - Information which was publicly available during the review and used by the Agency.
- (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 L of the application, the applicant provides the information requested by this criterion. The following table illustrates the projected payor mix during the second full fiscal year.

**Mint Hill Dialysis
Projected Payor Mix OY2 (CY2020)**

Payment Source	In-Center Patients
Medicare	16.4%
Medicaid	7.3%
Commercial Insurance	7.3%
Medicare/Commercial	49.1%
Medicare/Medicaid	14.5%
VA	5.4%
Total	100.0%

The applicant provides its assumptions for the projected payor mix, stating on page 46, that it is based on the facility's historical payor mix from the last full operating year, which is provided on page 49.

The application is conforming to this criterion 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.
- 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 48, the applicant states that patients have access to dialysis services upon referral by a nephrologist who has privileges at Mint Hill Dialysis. The applicant further states that patients, families and friends may obtain access by contacting a nephrologist with privileges at the facility.

Therefore, the application is conforming to this criterion.

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

C

In Section V.1, page 50, the applicant states that Mint Hill Dialysis has been offered as a clinical training site for nursing students from Winthrop University. Exhibit M-2 contains a copy of the student training agreement with Winthrop University.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant has demonstrated its intent to offer the facility as a clinical training site.

Therefore, 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.

C

DVA proposes to add six dialysis stations to the existing facility for a total of 22 stations upon completion of the project.

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 consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

According to the July 2017 SDR, there are 23 dialysis facilities in Mecklenburg County, 17 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the July 2017 SDR, is provided below:

**Mecklenburg County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2016**

Dialysis Facility	Owner	Location	Number of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	98.44%
BMA Nations Ford	BMA	Charlotte	28	93.75%
BMA of East Charlotte	BMA	Charlotte	25	92.00%
BMA of North Charlotte	BMA	Charlotte	36	102.78%
BMA West Charlotte	BMA	Charlotte	29	86.21%
Brookshire Dialysis	DaVita	Charlotte	0	0.00%
Carolinas Medical Center	CMC	Charlotte	9	27.78%
Charlotte Dialysis	DaVita	Charlotte	36	84.72%
Charlotte East Dialysis	DaVita	Charlotte	34	88.24%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	69.79%
DSI Glenwater Dialysis	DSI	Charlotte	42	77.38%
FMC Charlotte	BMA	Charlotte	43	90.70%
FMC Matthews	BMA	Matthews	21	111.90%
FKC Southeast Mecklenburg County**	BMA	Charlotte	0	0.00%
FMC Regal Oaks*	BMA	Charlotte	0	0.00%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
Fresenius Medical Care Southwest Charlotte***	BMA	Charlotte	10	40.00%
Huntersville Dialysis	DaVita	Huntersville	10	92.50%
Mint Hill Dialysis	DaVita	Mint Hill	16	96.88%
North Charlotte Dialysis Center	DaVita	Charlotte	41	74.39%
South Charlotte Dialysis	DaVita	Charlotte	22	86.36%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis*	DaVita	Charlotte	0	0.00%

Source: July 2017 SDR, Table B.

* Facility under development.

** FKC Southeast Mecklenburg County is a new facility under development, however it is erroneously named FMC of Southwest Charlotte in the July 2017 SDR, Table B. In addition, the FID# should be 160337.

*** FMC Southwest Charlotte is an existing facility, however the FID# is erroneous as listed in the July 2017 SDR, Table B. The FID# should be 120485.

As illustrated above, DaVita owns six of the 17 operational dialysis facilities in Mecklenburg County. As shown in the table above, five of DaVita's six operational dialysis facilities are operating above 80% utilization and two of those are operating above 90% utilization. Five dialysis facilities are operating below 80% utilization, including one BMA facility, two DSI facilities, one DaVita facility and a CMC facility.

In Section N, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition will have a

positive impact on the cost-effectiveness, quality and access to the proposed services. In Section N, page 51, the applicant states,

“The expansion of Mint Hill Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and other [sic] involved in the dialysis process to receive services.”

Conclusion

The application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the proposed project will be cost-effective,
- The applicant adequately demonstrates it will provide quality services, and
- The applicant adequately demonstrates that it will provide access to medically underserved populations.

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.

(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 9-10, and Section O, page 52, the applicant discusses the methods it uses to ensure and maintain quality. In Section O.2, page 52, and Exhibit O-2, the applicant states that the most recent recertification survey for Mint Hill Dialysis was completed on January 12, 2017 and that no condition-level deficiencies were cited.

In Exhibit O-3, the applicant lists two dialysis facilities in the state owned by DaVita, Southeastern Dialysis Center – Kenansville and Durham Dialysis, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant provides documentation regarding the deficiencies and subsequent compliance with CMS Conditions for Coverage in Exhibit O-3. The applicant states, on page 52, that both facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. 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 applicant provides sufficient evidence that quality of care has been provided in the past.

- (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 with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

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

10A 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- The applicant is proposing to add dialysis stations to an existing facility, Mint Hill Dialysis. Therefore, this performance standard is not applicable.
- .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- In Section C.1, pages 14-16, the applicant demonstrates that Mint Hill Dialysis will serve a total of 85 in-center patients at the end of OY1 (CY2019), which is 3.86 patients per station per week ($85 \text{ patients} / 22 \text{ stations} = 3.86$). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

- C- In Section C.1, pages 14-16, 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.