

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 1, 2017

Findings Date: June 1, 2017

Project Analyst: Gloria C. Hale

Team Leader: Fatimah Wilson

Project ID #: F-11323-17

Facility: South Charlotte Dialysis

FID #: 955814

County: Mecklenburg

Applicant: DVA Healthcare Renal Care, Inc.

Project: Relocate facility to a new location and add four dialysis stations for a total of 27 stations upon completion of the project. Add a home dialysis training program.

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

DVA Healthcare Renal Care, Inc. d/b/a South Charlotte Dialysis proposes to relocate South Charlotte Dialysis to a new location and add four dialysis stations for a total of 27 dialysis stations upon completion of the project. In addition, a home dialysis training program will be developed.

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 January 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for Mecklenburg County. However, 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 South Charlotte Dialysis in the January 2017 SDR is 3.55 patients per station per week. This utilization rate was calculated based on 78 in-center dialysis patients and 22 certified dialysis stations as of June 30, 2016 (78 patients/ 22 stations = 3.55 patients per station per week). Application of the facility need methodology indicates that four additional stations are needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/16		88.64%
Certified Stations		22
Pending Stations		1
Total Existing and Pending Stations		23
In-Center Patients as of 6/30/16 (SDR2)		78
In-Center Patients as of 12/31/15 (SDR1)		71
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	7
	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/15	.1972
(ii)	Divide the result of step (i) by 12	.0164
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/16 until 12/31/16)	.0984
(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	85.6752
(v)	Divide the result of step (iv) by 3.2 patients per station	26.7735
	and subtract the number of certified and pending stations to determine the number of stations needed	3.77

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is four stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the January 2017 SDR. 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 four new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There are three policies in the 2017 SMFP which are applicable to this review: *Policy GEN-3: Basic Principles*, *Policy ESRD-2: Relocation of Dialysis Stations*, and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy GEN-3, on page 33 of the 2017 SMFP, states:

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

The applicant addresses *Policy GEN-3* as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 9-10, Section N.1, page 54, and Exhibit K-1(g). The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 10, Section C.3, pages 16-17, Section L.1, pages 48-50, Section N.1, page 54, 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.4(c), page 11, Section C.1, pages 14-16, and N.1, page 54. 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. The application is consistent with *Policy GEN-3*.

Policy ESRD-2, on page 27 of the 2017 SMFP, states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate all 22 certified dialysis stations and one pending dialysis station (Project ID #F-11247-16) at South Charlotte Dialysis to a new location within Mecklenburg County. Because the facility is currently located in Mecklenburg County and will be relocated within Mecklenburg County, there is no change in the total dialysis station inventory in Mecklenburg County. Therefore, the application is consistent with *Policy ESRD-2*.

Policy GEN-4, on page 33 of the 2017 SMFP, states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards

implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

The proposed capital expenditure for this project is greater than \$2 million, but less than \$5 million. In Section C.5, pages 12-13, the applicant describes several strategies that will be implemented to address energy efficiency and water conservation, including new facility alignment with Village Green 2020 Environmental Goals which include:

- *"Energy Conservation – Reduce energy use and carbon emissions by 10% per treatment*
- *Water Conservation – Reduce water use by 30% per treatment*
- *Paper Conservation – Reduce paper use by 15% per treatment*
- *Waste Reduction – Increase solid waste recycling to 45% of locations"*

In addition, on pages 12-13, the applicant states that new dialysis centers will include energy efficient lighting methods, water optimization protocols to reduce water usage, the use of interior finishes/materials based on sustainable design and indoor environmental quality, high performance mechanical systems, the use of Energy Star appliances, and facility design/exteriors that optimize solar daylighting.

The applicant adequately demonstrates conformity with the requirements of *Policy GEN-4*.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the January 2017 SDR, and the following policies in the 2017 SMFP: *Policy GEN-3*, *Policy ESRD-2*, and *Policy GEN-4*. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to relocate South Charlotte Dialysis and add four dialysis stations for a total of 27 dialysis stations upon completion of the project. In addition, a home dialysis training program will be developed.

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis stations as “the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 20, the applicant provides the historical patient origin for South Charlotte Dialysis as of June 30, 2016, which is summarized in the following table:

**South Charlotte Dialysis
 Historical Patient Origin
 6/30/16**

County	In-Center Patients	Peritoneal Dialysis (PD) Patients
Mecklenburg	74	0
Union	2	0
Other states	2	0
TOTAL	78	0

In supplemental information, the applicant provides the projected patient origin for South Charlotte Dialysis for operating year one (OY1), January 1, 2019 – December 31, 2019, and OY2, January 1, 2020 – December 31, 2020, following completion of the project as follows:

**South Charlotte Dialysis
 Projected Patient Origin**

County	OY1 (CY2019)		OY2 (CY2020)		County Patients as Percent of Total	
	In-Center Patients	PD Patients	In-Center Patients	PD Patients	OY1 (CY2019)	OY2 (CY2020)
Mecklenburg	87	2	92	3	95.7%	96.0%
Union	2	0	2	0	2.2%	2.0%
Other states	2	0	2	0	2.2%	2.0%
Total*	91	2	96	3	100.0%	100.0%

*Totals may not foot due to rounding.

The applicant provides the assumptions and methodology used to project in-center and PD patient origin in Section C.1, pages 14-16. The applicant adequately identifies the projected patient origin.

Analysis of Need

The applicant states, in Section C.2, page 16, that the relocation of the entire South Charlotte Dialysis facility is needed since it “*maxed out its capacity for growth*” after a major renovation was completed in 2012. The applicant further states, on page 16, that the facility relocation is necessary to accommodate further growth. In Section C.5, page 17, the applicant states that it selected a site that would be convenient for South Charlotte Dialysis’ patients, thereby selecting a primary site that is .09 miles from the facility’s existing site. In addition, the applicant states that a home training program was needed that was closer to patients’ homes to make dialysis services and support more convenient.

In addition, the applicant proposes to add four dialysis stations to South Charlotte Dialysis for a total of 27 certified dialysis stations upon completion of the project pursuant to the 2017 SMFP Facility Need Methodology. In Section C.1, pages 14-15, the applicant provides the following assumptions to project utilization of in-center patients:

1. As reported in Table A of the January 2017 SDR, South Charlotte Dialysis had 78 in-center dialysis patients as of June 30, 2016. Of these 78 in-center patients, 74 were residents of Mecklenburg County and 4 were residents of Union County and other states.
2. The number of in-center dialysis patients from Mecklenburg County only are projected forward from July 1, 2016 to December 31, 2020 by applying the Average Annual Change Rate (AACR) for Mecklenburg County of 5% each year.
3. No growth calculations are performed on the four patients residing outside Mecklenburg County.
4. OY1 is projected to be January 1, 2019 through December 31, 2019, calendar year 2019 (CY2019), and OY2 is projected to be January 1, 2020 through December 31, 2020 (CY2020).

Projected Utilization for In-Center Patients

	In-Center
The applicant begins with the Mecklenburg County in-patient census at the facility on July 1, 2016.	74
The Mecklenburg County in-center patient census is projected forward to December 31, 2016, increased by the Five Year AACR for Mecklenburg County of 5%.	$(74 \times 0.025) + 74 = 75.85$
The applicant adds four patients from outside Mecklenburg County. This is the ending census for December 31, 2016.	$75.85 + 4 = 79.85$
The Mecklenburg County in-center patient census is projected forward one year to December 31, 2017 and is increased by the Five Year AACR for Mecklenburg County of 5%.	$(75.85 \times 0.05) + 75.85 = 79.64$
The applicant adds four patients from outside Mecklenburg County. This is the ending census for December 31, 2017.	$79.64 + 4 = 83.64$
The Mecklenburg County in-center patient census is projected forward one year to December 31, 2018 and is increased by the Five Year AACR for Mecklenburg County of 5%.	$(79.64 \times 0.05) + 79.64 = 83.62$
The applicant adds four patients from outside Mecklenburg County for the ending census for December 31, 2018.	$83.62 + 4 = 87.62$
The census of Mecklenburg County in-center patients is projected forward one year to December 31, 2019 and is increased by the Five Year AACR for Mecklenburg County of 5%.	$(83.62 \times 0.05) + 83.62 = 87.80$
The applicant adds four patients from outside Mecklenburg County for the ending census of OY1.	$87.80 + 4 = 91.80$
The census of Mecklenburg County in-center patients is projected forward one year to December 31, 2020 and is increased by the Five Year AACR for Mecklenburg County of 5%.	$(87.80 \times 0.05) + 87.80 = 92.19$
The applicant adds four patients from outside Mecklenburg County for the ending census of OY2.	$92.19 + 4 = 96.19$

The applicant states, on page 15, that South Charlotte Dialysis will have 91 in-center patients, rounded down, by the end of OY1 or 3.37 patients per station per week (91 patients/ 27 stations = 3.37). By the end of OY2, the applicant projects South Charlotte

Dialysis will have 96 in-center patients, rounded down, or 3.56 patients per station per week (96 patients/ 27 stations = 3.56). Therefore, the applicant's projected utilization 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). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Projected Utilization for Peritoneal Dialysis (PD) Patients

In Section C.1, pages 15-16, the applicant provides the following assumptions to project utilization of PD patients:

- One of the two PD patients who currently receive home PD dialysis support at East Charlotte Dialysis, both of whom live in the same zip code area as the proposed, relocated South Charlotte Dialysis facility, 28226, is assumed to transfer his or her care upon certification of South Charlotte Dialysis.
- The period of growth will be July 1, 2016 through December 31, 2020 and will consist of at least one PD patient per year.

The applicant's methodology for projecting utilization for PD patients, in Section C.1, page 16, consists of beginning with one PD patient on January 1, 2019, then adding one PD patient during OY1, thereby ending CY2019 with two PD patients. For OY2, one additional PD patient will be added for a total of three PD patients at the end of OY2 (CY2020).

Access

In Section C.3, page 16, the applicant states that its policy is to make dialysis services available to all residents in the service area, "...without regard to race, sex, age, or handicap....regardless of ethnic or socioeconomic situation." In Section L.7, page 52, the applicant reports that 84.5% of South Charlotte Dialysis's in-center patients were Medicare or Medicaid recipients in CY2016. There were no home dialysis patients in CY2016. In Section L.1, page 49, the applicant projects that 84.4% of in-center patients and 68.5% of home dialysis patients at South Charlotte Dialysis will be Medicare or Medicaid recipients. The applicant projects that 79.1% of all patients at South Charlotte Dialysis 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

In summary, the applicant adequately identifies the population to be served, demonstrates the need for the facility to be relocated, the need the population has for four additional stations at South Charlotte Dialysis, and demonstrates the extent to which all residents of

the area, including underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to relocate South Charlotte Dialysis and add four dialysis stations for a total of 27 dialysis stations upon completion of the project. In addition, a home dialysis training program will be developed. The applicant states, in Section C.2, page 16, that the facility relocation is necessary to accommodate further growth. In Section C.5, page 17, the applicant states that it selected a site that would be convenient for South Charlotte Dialysis' patients, thereby selecting a primary site that is .09 miles from the facility's existing site. Therefore, it is assumed that all of the current patients of South Charlotte Dialysis will transfer to the new site for the facility upon its completion and certification. Therefore, the applicant adequately demonstrates that the needs of the population presently served will be met adequately by the proposed relocation.

The application is conforming to this criterion.

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

CA

In Section E.1, page 26, the applicant discusses the alternatives considered for meeting the needs of the proposed project, summarized as follows:

- Maintain the Status Quo – The applicant states that this alternative was dismissed because of the growth rate of the facility.
- Relocate Stations from Another DaVita Facility – The applicant states that of its six operational facilities in Mecklenburg County, three are operating at less than 80% utilization. However, given the significant growth of the three facilities in the recent past, relocating stations from them would be detrimental to the patients being served at them. Therefore, this alternative would not be an effective alternative.

In Section E.2, page 26, the applicant states that the proposal to relocate South Charlotte Dialysis and add four dialysis stations will *“help meet the growing demand for dialysis services at South Charlotte Dialysis... Given that the current site is at capacity, the addition of stations necessitates relocating to a new site.”* 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 the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. DVA Healthcare Renal Care, Inc. d/b/a South Charlotte Dialysis shall materially comply with all representations made in the certificate of need application and supplemental information provided. In those instances where representations conflict, South Charlotte Dialysis shall materially comply with the last made representation.**
 - 2. DVA Healthcare Renal Care, Inc. d/b/a South Charlotte Dialysis shall develop and operate no more than four additional dialysis stations for a total of no more than 27 certified dialysis stations upon completion of Project I.D. #F-11247-16 (add one dialysis station) and the completion of this project.**
 - 3. DVA Healthcare Renal Care, Inc. d/b/a South Charlotte Dialysis shall install plumbing and electrical wiring through the walls for four additional dialysis stations for a total of 27 dialysis stations which shall include any home hemodialysis training or isolation stations.**
 - 4. DVA Healthcare Renal Care, Inc. d/b/a South Charlotte 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 issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to relocate South Charlotte Dialysis and add four dialysis stations for a total of 27 dialysis stations upon completion of the project. In addition, a home dialysis training program will be developed.

Capital and Working Capital Costs

In Section F.1, page 27, the applicant projects the total capital cost of the proposed project will be \$3,506,203, including:

**South Charlotte Dialysis
Projected Capital Costs**

Costs	Total Costs
Site	\$ 57,000
Construction	\$ 2,257,810
Equipment and furniture	\$ 1,049,193
Architect & Engineering Fees	\$ 142,200
Total Capital Costs	\$ 3,506,203

In Sections F.10 and F.11, page 30, the applicant states there will be no start-up expenses or initial operating expenses since South Charlotte Dialysis is an existing, operational facility.

Availability of Funds

In Section F.2, page 28, the applicant states it will finance the capital costs with accumulated reserves/owner's equity. Exhibit F-5 contains a letter dated March 14, 2017 signed by the Director of Healthcare Planning on behalf of the Chief Accounting Officer for DaVita HealthCare Partners, Inc. (DaVita), the parent company of the applicant, which states that DaVita has committed cash reserves in the amount of \$3,506,203 for the proposed project. In Exhibit F-7, the applicant provides the Securities and Exchange Commission Form 10-K for DaVita which indicates that as of December 31, 2015, it had \$1,499,116,000 in cash and cash equivalents, \$18,514,875,000 in total assets and \$5,948,238,000 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

In Section R, Form C of the pro formas, the applicant provides the allowable charges per treatment for each payment source, as illustrated in the table below:

Allowable Charges

Payor	In-Center Charge
Self Pay/Indigent/ Charity	*
Commercial Insurance	\$1,275.00
Medicare	\$230.39
Medicaid	\$143.00
Medicare/Commercial	\$230.39
Medicare/Medicaid	\$230.39
VA	\$193.00

*The applicant does not provide an allowable charge for self-pay/indigent/charity.

In Section R, Form C, the applicant states in its assumptions that it uses the average number of patients to calculate its revenues for the first and second years of the project. The applicant uses 89 in-center patients in OY1 and 93.5 in-center patients in OY2. The applicant uses 1.5 PD patients in OY1 and 2.5 PD patients in OY2. The applicant provides its beginning and ending census for in-center patients and PD patients for interim operating years, CY2016 through CY2018, and first and second operating years of the project, CY2019 and CY2020, in the following two tables:

In-center Patients

Year	Beginning census	Ending census	Average number of patients
CY2016	71	79	75.0
CY2017	79	83	81.0
CY2018	83	87	85.0
CY2019	87	91	89.0
CY2020	91	96	93.5

PD Patients

Year	Beginning census	Ending census	Average number of patients
CY2016	0	0	0.0
CY2017	0	0	0.0
CY2018	0	0	0.0
CY2019	1	2	1.5
CY2020	2	3	2.5

The applicant provides pro forma financial statements for the first two operating years of the project following completion of the project. In Form B, the applicant projects that revenues will exceed operating costs in the first and second operating years of the project, as shown in the table below.

	OY1 (CY2019)	OY2 (CY2020)
Total Treatments	13,193	13,860
Total Gross Revenues (Charges)	\$4,602,884	\$4,907,944
Deductions from Gross Revenues	\$96,487	\$102,339
Total Net Revenue	\$4,506,397	\$4,805,604
Total Operating Expenses (Costs)	\$3,798,241	\$3,997,795
Net Income	\$708,155	\$807,809

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section 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

In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to relocate South Charlotte Dialysis and add four dialysis stations for a total of 27 dialysis stations upon completion of the project. In addition, a home dialysis training program will be developed.

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

According to the January 2017 SDR, there are 22 dialysis facilities in Mecklenburg County. Of these, 16 are operational and six are under development. The applicant or its parent company owns and operates eight dialysis facilities, Bio-Medical Applications (BMA) of North Carolina, Inc. operates 11 facilities, DSI Renal, Inc. (DSI) operates two facilities, and Carolinas Medical Center (CMC) operates one facility, as shown in the table below.

**Mecklenburg County Dialysis Facilities
 Certified Stations and Utilization as of June 30, 2016**

Facility	Owner	Location	Number of Certified Stations	Utilization as of June 30, 2016
BMA Beatties Ford	BMA	Charlotte	32	99.22%
BMA Nations Ford	BMA	Charlotte	28	100.00%
BMA of East Charlotte	BMA	Charlotte	25	90.00%
BMA of North Charlotte	BMA	Charlotte	36	92.36%
BMA West Charlotte	BMA	Charlotte	29	83.62%
Brookshire Dialysis	DaVita	Charlotte	0	0.00%
Carolinas Medical Center	CMC	Charlotte	9	25.00%
Charlotte Dialysis	DaVita	Charlotte	36	86.88%
Charlotte East Dialysis	DaVita	Charlotte	34	75.00%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	63.54%
DSI Glenwater Dialysis	DSI	Charlotte	42	76.19%
FMC Charlotte	BMA	Charlotte	43	87.21%
FMC Matthews	BMA	Matthews	21	108.33%
FMC of Southwest Charlotte*	BMA	Charlotte	0	0.00%
FMC Regal Oaks*	BMA	Charlotte	0	0.00%
FKC Southeast Mecklenburg County*	BMA	Charlotte	0	0.00%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
Huntersville Dialysis	DaVita	Huntersville	10	75.00%
Mint Hill Dialysis	DaVita	Mint Hill	16	71.88%
North Charlotte Dialysis Center	DaVita	Charlotte	41	82.93%
South Charlotte Dialysis	DaVita	Charlotte	22	88.64%
University City Dialysis*	DaVita	Charlotte	10	0.00%

*Facility under development.

As shown in the table above, three of DaVita’s six facilities that are operational are operating above 80% utilization (3.2 patients per station per week) and one is operating above 88% utilization. DaVita’s two remaining dialysis facilities are under development. Six of the 16 operational dialysis facilities in the county are operating below 80% utilization, including three DaVita facilities, two DSI facilities, and a CMC facility.

The applicant proposes to relocate South Charlotte Dialysis and add four in-center dialysis stations for a total of 27 dialysis stations upon completion of the project. As of June 30, 2016, South Charlotte Dialysis was serving 78 patients on 22 dialysis stations, which is 3.55 patients per station per week or 88.64% of capacity. The applicant does not propose to establish a new facility, rather the applicant proposes to relocate the entire facility to a new location which is .09 miles from the existing location, and to add four dialysis stations. The applicant provides reasonable projections for the in-center patient

population it proposes to serve in Section C.1, pages 14-15, of the application. At the end of OY1, the applicant projects utilization will be 3.37 in-center patients per station per week (91 patients /27 dialysis stations = 3.37), which is 84.3% of capacity. Therefore, the facility is expected 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). The applicant adequately demonstrates the need to develop four additional dialysis stations at the existing facility based on the number of in-center patients it proposes to serve.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities. Therefore, 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 35, the applicant provides the current staffing for the facility, which includes 15.5 full-time equivalent (FTE) employees, and the proposed staffing for the facility following completion of the project, which includes 20.0 FTE employees. Therefore, the applicant projects to add 4.5 FTEs at South Charlotte Dialysis. Projected direct care staff in OY2, from Section H.7, page 38, is shown in the following table:

**South Charlotte Dialysis
 Direct Care Staff
 OY2**

Direct Care Positions	# of FTEs	Hours per Year per FTE	Total Annual FTE Hours	Total Annual Hours of Operation	#FTE Hours per Hour of Operation
RN	4	2,080	8,320	3,120	2.7
Technician (PCT)	11	2,080	22,880	3,120	7.3
Total	15	2,080	31,200	3,120	10.0

In Section H.6, page 38, the applicant states that dialysis services will be available from 6:00 AM to 4:00 PM, Monday through Saturday, for a total of 10 hours per day/ 60 hours per week.

In Section H.3, pages 36-37, the applicant describes its experience and process for recruiting and retaining staff. Exhibit I-3 contains a copy of a letter from Christopher Buehrig, M.D., stating his willingness to continue serving as the Medical Director for the facility. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section I.1, page 39, the applicant includes a list of providers of the necessary ancillary and support services it will make available. In Exhibit I-1, the applicant provides a list of the providers and services it has agreements with, including blood bank services, x-ray services, and surgical services. In addition, Exhibit I-1 lists two additional agencies it will partner with to provide services if necessary, namely, North Carolina Division of Vocational Rehabilitation Services and the Mecklenburg Transportation System. In addition, the applicant provides a copy of an agreement with Total Renal Laboratories, Inc. for laboratory services in Exhibit I-1. In Section I.4, page 41, the applicant states that it has established relationships with healthcare providers and social service agencies in Mecklenburg County over the years. In addition, Exhibit I-3 contains letters from the medical director of the facility and an additional Nephrologist that express support for the proposed project. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

C

The applicant proposes to relocate South Charlotte Dialysis and add four dialysis stations for a total of 27 dialysis stations upon completion of the project. In addition, a home dialysis training program will be developed.

In Section K.2, page 44, the applicant states that the treatment area of the proposed relocated South Charlotte Dialysis facility will be 7,705 square feet which will include home training and isolation room space. The applicant provides the facility's line drawing in supplemental information. The drawing depicts a 13,581 square foot facility, including office space, 26 dialysis stations located in open space and one isolation dialysis station in an enclosed room, for a total of 27 dialysis stations. In addition, two home training rooms are located in enclosed spaces. In Section F.1, page 27, the applicant lists its project costs, including \$57,000 in site costs, \$2,257,810 for construction, and \$1,191,393 in miscellaneous costs including dialysis machines, water treatment equipment, furniture, and architect/engineering fees for a total project cost of \$3,506,203. In Section B.5, pages 12-13, the applicant describes its plans to assure improved energy-efficiency and water conservation, including the following:

- The use of full LED lighting packages with occupancy and vacancy sensors, dimmers, and a full lighting control system that will provide 28% energy reduction.
- Interior finishes and materials will be used based on sustainable design and *"Indoor Environmental Quality criteria...defined in the US Green Building Council's LEED Rating system."*
- The HVAC system will be selected for its high performance and energy efficiency.
- All appliances, when possible, and most information technology equipment will be Energy Star rated.
- Water optimization protocols will be utilized to reduce the volume of water required to provide patient care, including adjusting the recovery rate for reverse osmosis devices and utilizing water-conserving plumbing fixtures.

Costs and charges are described by the applicant in Section F, pages 27-32, and in Section R pro forma financial statements. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans and that the construction cost will not unduly increase costs and charges for health services. Therefore, 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 52, the applicant reports that 84.5% of the in-center patients who received treatments at South Charlotte Dialysis in CY2016 had some or all of their services paid for by Medicare or Medicaid. The table below shows the historical (CY2016) payment source for the facility for in-center patients:

**South Charlotte Dialysis
Historical Utilization, CY2016**

Payment Source	In-Center
Private Pay	0.0%
Medicare	15.6%
Medicaid	13.0%
Commercial Insurance	11.7%
Medicare/Commercial Insurance	27.3%
Medicare/Medicaid	28.6%
VA	3.9%
Total	100.0%

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**
Mecklenburg	10%	52%	51%	15%	6%	19%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

*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., V2015) refers to the final year of the series (2010 thru 2015). 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 27-28², summarized as follows:

¹<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

²http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

2015 Patients and Percentages*		
	Total Network 6 Patients	Total Network 6 Percentage
Age		
0-19	137	0.3%
20-34	2,142	4.7%
35-44	4,493	9.8%
45-54	8,422	18.3%
55-64	12,024	26.1%
65+	18,817	40.9%
Gender		
Female	20,805	45.2%
Male	25,230	54.8%
Race		
African-American	30,092	65.4%
White	15,049	32.7%
Other	894	1.9%

*2015 Calendar Year data from the IPRO ESRD Network of the South Atlantic at http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older and over 67% were non-Caucasian. (IPRO SA Network 6).

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

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

C

In Section L.3, page 51, the applicant states:

“South Charlotte Dialysis has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are

placed upon 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 46, the applicant states it has had no civil rights equal access complaints filed within the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section L.1(b), page 49, the applicant projects that 79.1% of all patients at South Charlotte Dialysis, 84.4% of the in-center patients and 68.5% of PD patients, who will receive care at South Charlotte Dialysis in OY2, CY2020, will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected OY2 payment source for the facility:

**South Charlotte Dialysis
 Projected Payor Source, OY2 (CY2020)**

Payor Source	In-Center Patients	PD Patients	Total Patients
Private Pay	0.0%	0.0%	0.0%
Medicare	15.6%	15.8%	15.7%
Medicaid	12.9%	5.3%	10.4%
Commercial Insurance	11.7%	28.9%	17.4%
Medicare/Commercial Insurance	27.3%	39.5%	31.3%
Medicare/Medicaid	28.6%	7.9%	21.7%
VA	3.9%	2.6%	3.5%
Total	100.0%	100.0%	100.0%

In Section L.1, page 49, the applicant provides the assumptions used to project payor mix. The applicant states that its projected payor source for in-center patients is based on the facility's historical payor sources and that its projected payor source for PD patients is based on the historical payor source percentages from DaVita operated facilities in Mecklenburg County in the last full operating year. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at South Charlotte Dialysis. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, page 51, the applicant describes the range of means by which a person will have access to the dialysis services at South Charlotte Dialysis. Access to dialysis services will be granted upon referral by a nephrologist with privileges at the facility. Patients who contact the facility for access will be referred to a qualified nephrologist for evaluation and admission. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section M.1, page 53, the applicant states that it has offered South Charlotte Dialysis as a training site for nursing students at Brookstone College. Exhibit M-2 contains a copy of a Student Training Agreement with Brookstone College of Business which offers numerous DaVita dialysis facilities, including South Charlotte Dialysis, as training sites for the college's students. The information provided is reasonable and adequately supports a determination 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.

C

The applicant proposes to relocate South Charlotte Dialysis and add four dialysis stations for a total of 27 dialysis stations upon completion of the project. In addition, a home dialysis training program will be developed.

On page 373, the 2017 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty*

Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

According to the January 2017 SDR, there are 22 dialysis facilities in Mecklenburg County. Of these, 16 are operational and six are under development. The applicant or its parent company owns and operates eight dialysis facilities, Bio-Medical Applications (BMA) of North Carolina, Inc. operates 11 facilities, DSI Renal, Inc. (DSI) operates two facilities, and Carolinas Medical Center (CMC) operates one facility, as shown in the table below.

**Mecklenburg County Dialysis Facilities
Certified Stations and Utilization as of June 30, 2016**

Facility	Owner	Location	Number of Certified Stations	Utilization as of June 30, 2016
BMA Beatties Ford	BMA	Charlotte	32	99.22%
BMA Nations Ford	BMA	Charlotte	28	100.00%
BMA of East Charlotte	BMA	Charlotte	25	90.00%
BMA of North Charlotte	BMA	Charlotte	36	92.36%
BMA West Charlotte	BMA	Charlotte	29	83.62%
Brookshire Dialysis	DaVita	Charlotte	0	0.00%
Carolinas Medical Center	CMC	Charlotte	9	25.00%
Charlotte Dialysis	DaVita	Charlotte	36	86.88%
Charlotte East Dialysis	DaVita	Charlotte	34	75.00%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	63.54%
DSI Glenwater Dialysis	DSI	Charlotte	42	76.19%
FMC Charlotte	BMA	Charlotte	43	87.21%
FMC Matthews	BMA	Matthews	21	108.33%
FMC of Southwest Charlotte*	BMA	Charlotte	0	0.00%
FMC Regal Oaks*	BMA	Charlotte	0	0.00%
FKC Southeast Mecklenburg County*	BMA	Charlotte	0	0.00%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
Huntersville Dialysis	DaVita	Huntersville	10	75.00%
Mint Hill Dialysis	DaVita	Mint Hill	16	71.88%
North Charlotte Dialysis Center	DaVita	Charlotte	41	82.93%
South Charlotte Dialysis	DaVita	Charlotte	22	88.64%
University City Dialysis*	DaVita	Charlotte	10	0.00%

*Facility under development.

As shown in the table above, three of DaVita’s six operational facilities are operating above 80% utilization (3.2 patients per station per week).

In Section N.1, page 54, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

“The relocation and expansion of South Charlotte Dialysis will have no effect on competition in Mecklenburg County. ...this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DVA Healthcare Renal Care, Inc. The relocation and expansion of South Charlotte Dialysis will address the physical inadequacy of the existing facility, ensuring accessibility to dialysis for our patients.”

See also Sections B, C, D, E, K, L, and N and where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3), (3a) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

In Exhibit O-3 the applicant identifies five of its facilities, South Charlotte Dialysis, Southeastern Dialysis Center - Kenansville, Durham Dialysis, Marshville Dialysis, and Durham West 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 states, in Section O.3, page 55, and Exhibit O-3, and in supplemental information, that all five 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 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 promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- South Charlotte Dialysis is an existing facility that will be relocated.

.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 projects to serve 91 in-center patients by the end of OY1, which is 3.37 patients per station per week ($91 / 27 = 3.37$). 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.