

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 22, 2017

Findings Date: December 22, 2017

Project Analyst: Gregory F. Yakaboski

Team Leader: Fatimah Wilson

Project ID #: F-11406-17

Facility: Metrolina Kidney Center

FID #: 955949

County: Union

Applicant(s): Bio-Medical Applications of North Carolina, Inc.

Project: Add six dialysis stations for a total of 22 stations upon completion of this project, Project ID# F-11208-16 (relocate 10 stations to FKC Indian Trail), Project ID# F-11242-16 (add 5 stations and develop a home hemodialysis and a peritoneal dialysis program) and Project ID# F-11383-17 (cost overrun for Project ID# F-11242-16).

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

Bio-Medical Applications of North Carolina, Inc. (BMA) proposes to add six dialysis stations to the Metrolina Kidney Center (also known as BMA Monroe) facility for a total of 22 certified dialysis stations upon completion of this project, Project ID# F-11208-16 (relocate 10 stations to FKC Indian Trail), Project ID# F-11242-16 (add 5 stations and a home hemodialysis and a peritoneal dialysis program) and Project ID# F-11383-17 (cost overrun for Project ID# F-11242-16). Fresenius Medical Care Holdings, Inc. (Fresenius) is the parent company of BMA.

Metrolina Kidney Center is also referred to as BMA Monroe throughout these findings and in the application.

BMA Monroe does not currently offer either home hemodialysis or a peritoneal program. BMA Monroe proposed to add home therapies (both home hemodialysis and a peritoneal program) as part of Project ID# F-11242-16 (add 5 stations).

Need Determination

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2017 Semiannual Dialysis Report (SDR), Table D, the county need methodology shows there is a deficit of five dialysis stations in Union County. In order for there to be a county station need determination in the SDR the county's projected station deficit must be 10 stations or greater, 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 BMA Monroe in the July 2017 SDR, Table B, is 4.0 patients per station per week, or 100.0% ($4.0 / 4 \text{ patients per station} = 1.0$ or 100.0%). This utilization rate was calculated based on 84 in-center dialysis patients and 21 certified dialysis stations ($84 \text{ patients} / 21 \text{ stations} = 4.0 \text{ patients per station per week}$).

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 12/31/16		100.0%
Certified Stations		21
Pending Stations		5
Total Existing and Pending Stations		26
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR2)		84
In-Center Patients as of 6/30/16 (Jan 2017 SDR) (SDR1)		76
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	8
	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.2105
(ii)	Divide the result of Step (i) by 12	0.0175
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.2105
(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	101.6842
(v)	Divide the result of Step (iv) by 3.2 patients per station	31.7763
	and subtract the number of certified and pending stations to determine the number of stations needed	5.7763

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is six 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, page 9, Section K.1(g), page 46, Section N.1, page 56 and Section O, pages 58-62, and referenced exhibits. 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, page 10, Section I, pages 39-42, Section L, pages 50-54, and referenced exhibits and Section N.1, page 56. 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, Section K and Section N, page 56, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

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

Conclusion

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

- The applicant's use of the facility need methodology in accordance with the July 2017 SDR.
- The applicant's use of 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

BMA proposes to add six dialysis stations to the BMA Monroe facility for a total of 22 certified dialysis stations upon completion of this project, Project ID# F-11208-16 (relocate 10 stations to FKC Indian Trail), Project ID# F-11242-16 (add 5 stations) and Project ID# F-11383-17 (cost overrun for Project ID# F-11242-16).

BMA Monroe does not currently offer either home hemodialysis or a peritoneal program. BMA Monroe proposed to add home therapies (both home hemodialysis and a peritoneal program) as part of Project ID# F-11242-16 (add 5 stations).

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 Union 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 (IC) patients served by BMA Monroe, as shown below:

Dialysis Patients as of 6/30/17

COUNTY	IC	HH	PD
Union	87	0	0
South Carolina	2	0	
Totals	89	0	0

BMA Monroe does not currently provide service for home hemodialysis (HH) patients and peritoneal (PD) patients. BMA Monroe proposed to add home therapies (both home hemodialysis and a peritoneal program) as part of Project ID# F-11242-16 (add 5 stations) which project was issued a certificate of need on January 6, 2017.

In Section C, page 14, the applicant identifies the patient population it proposes to serve during operating year one (OY1) and operating year two (OY2) following project completion, as illustrated in the table below:

COUNTY	OPERATING YEAR 1 CY2019			OPERATING YEAR 2 CY2020			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Union	69.10	3.00	5.00	75.00	4.35	6.58	97.5%	97.7%
South Carolina	2.00	0.00	0.00	2.00	0.00	0.00	2.50%	2.30%
Totals	71.09 [71.10]	3.00	5.00	77.00	4.30	6.60	100.0%	100.0%

The applicant provides the assumptions and methodology for the projections above on pages 14-19. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section B-2, page 7, the applicant states the need for the proposed project is based on the facility need methodology. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference. See also Section C-2, page 17 and Section E.1, page 23.

In Section C, pages 14-19, the applicant provides the assumptions used to project utilization as follows:

- OY1 is Calendar Year 2019 (CY2019)
- OY2 is Calendar Year 2020 (CY2020)
- BMA Monroe had 87 in-center patients who are residents of Union County as of June 30, 2017
- BMA applies an annual growth rate of 11.5% in projecting patient growth of Union County residents. The five year average annual change rate (AACR) for Union County is 8.9%. (See July 2017 SDR). However, the applicant utilizes an 11.5% patient growth rate based on two factors: 1) the facility need methodology calculates a growth rate in excess of 21.0%; and 2) BMA Monroe’s average annual growth rate over the last five years is 11.91% (See table on page 14 of the application). The 11.5% patient growth rate utilized by BMA is less than both the facility need methodology’s (21.0%) or the facility’s (11.9%) growth rate. [Note: BMA Monroe’s average annual growth rate over the last five years is 11.66%, as opposed to 11.91% (49 patients / 84 patients = 0.58333 / 5 years = 11.66%)]
- BMA Monroe had two in-center patients who were not residents of Union County as of June 30, 2017. The two non-Union County residents were residents of South Carolina. BMA assumes that the two residents of South Carolina will continue to dialyze at BMA Monroe and are utilizing the facility by choice. The two South Carolina residents are factored into projected utilization however, in projected population BMA does not project any increase from South Carolina.
- BMA subtracts a total of 37 in-center patients from BMA Monroe as of June 30, 2018: BMA was approved to develop two new facilities, FKC Indian Trail and FKC

Southeast Mecklenburg County. In both applications BMA projected patients transferring their care from BMA Monroe, for a combined total of 37 patients transferring from BMA Monroe. BMA projects both projects to be completed by June 30, 2018.

- BMA assumes that each year two in-center patients currently dialyzing at BMA Monroe will change to home dialysis, one each to HH and PD: BMA made this assumption in Project ID #F-11241-17 and continues this assumption in this application.
- BMA assumes that six home patients who are residents of Union County but dialyze with FMC Charlotte, would transfer their care to BMA Monroe.

Projected Utilization

In Section C, page 16, the applicant provides the methodology used to project utilization summarized as follows:

Begin with the in-center patients from Union County utilizing BMA Monroe as of June 30, 2017.	87
Project the in-center patient population from Union County forward six months to December 31, 2017.	$1.0575 \times 87 = 92$
Project the Union County patient population forward for six months to June 30, 2018 using the projected 11.5% annual growth rate.	$1.0575 \times 92 = 97.29$
Subtract the 37 in-center patients projected to transfer to FKC Indian Trail and FKC Southeast Mecklenburg County.	$97.29 - 37 = 60.29$
Project the Union County patient population forward for six months to December 31, 2018 using the projected 11.5% annual growth rate.	$1.0575 \times 60.29 = 63.76$
Add in the 2 patients who reside in South Carolina. This is the projected census for the proposed project as of January 1, 2019.	$63.76 + 2 = 65.76$
Project the Union County patient population forward for one year to December 31, 2019 using the projected 11.5% annual growth rate.	$1.115 \times 63.76 = 71.09$
Subtract two Union County in-center patients projected to change modality to home dialysis.	$71.09 - 2 = 69.09$
Add in the 2 patients who reside in South Carolina. This is the projected ending census for Operating Year 1 (CY 2019). *	$69.09 + 2 = 71.09$
Project the Union County patient population forward for one year to December 31, 2020 using the projected 11.5% annual growth rate.	$1.115 \times 69.09 = 77.04$
Subtract two Union County in-center patients projected to change modality to home dialysis.	$77.04 - 2 = 75.04$
Add in the 2 patients who reside in South Carolina. This is the projected ending census for Operating Year 2 (CY 2020). *	$75.04 + 2 = 77.04$

*Note: The application mentions Anson County here which is a typo based on the entirety of the application.

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2019) the facility is projected to serve 71 in-center patients and at the end of OY2 (CY2020) the facility is projected to serve 77 in-center patients.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.23 patients per station per week or 80.75% ($71 \text{ patients} / 22 \text{ stations} = 3.23 / 4 = 0.8075$ or 80.75%).
- OY2: 3.5 patients per station per week or 87.5% ($77 \text{ patients} / 22 \text{ stations} = 3.5 / 4 = 0.875$ or 87.5%).

The projected utilization of 3.23 patients per station per week at the end of OY1 meets the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected in-center patient utilization is based on reasonable and adequately supported assumptions regarding continued growth at BMA Monroe.

Projected Utilization- HH and PD Patients

- BMA assumes that 6 home patients (2 HH patients and 4 PD patients) who are residents of Union County but dialyze with FMC Charlotte, would transfer their care to BMA Monroe.
- BMA assumes that each year two in-center patients currently dialyzing at BMA Monroe will change to home dialysis, one each to HH and PD: BMA made this assumption in Project ID #F-11241-17 and continues this assumption in this application.

	OY1 (CY2019)	OY2 (CY2020)
HH Patients	3	5
PD Patients	4	6

In the July 2017 SDR, Table A: *Dialysis Data by County of Patient Origin-December 2016* documents that nine home training patients who were residents of Union County utilized the FMC Charlotte facility. Projected HH and PD utilization is based on reasonable and adequately supported assumptions regarding continued growth at BMA Monroe.

Access

In Section L.1, page 50, the applicant states that Fresenius operates 109 facilities in 48 North Carolina counties (includes its affiliations with RRI facilities). The applicant states *“Fresenius related facilities have a long history of providing dialysis services to the underserved populations of North Carolina. ... Each of the Fresenius related facilities has a patient population which includes low-income, racial and ethnic minorities, women, handicapped persons, elderly, or other underserved persons.”* Furthermore, the applicant states: *“It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”* (See application page 50)

In Section L, page 54, the applicant reports that 81.31% of the patients who received treatments at BMA Monroe had some or all of their services paid for by Medicare or Medicaid in CY2016, as illustrated in the table below:

BMA Monroe Historical Payor Mix CY2016

Payment Source	Percent of Total Patients
Medicare	67.42%
Medicaid	7.32%
Medicare/ Commercial	6.57%
Commercial Insurance	9.68%
Self Pay/Indigent/Charity	3.45%
Misc. (incl. VA)	5.55%
Total	100.00%

In Section L, page 51, the applicant projects 77.0% of its patients will be Medicare or Medicaid recipients in OY2 (CY2020). The projected payor mix is based on recent experience of BMA Monroe's in-center program and FMC Charlotte's home therapies program. 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 applicant uses historical data that is clearly cited and is reasonable to use to make the assumptions used by the applicant with regard to identifying the population to be served and with regard to demonstrating the need the population projected to be served has for the proposed services.
- The applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need the population projected to be served has for the proposed services.
- The applicant uses historical data to project future access to the services it provides for all residents, including underserved groups.

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 does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, this Criterion is not applicable to this review

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

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 facility need methodology BMA qualifies for six additional dialysis stations and additional dialysis stations are needed at BMA Monroe. Therefore, maintaining the status quo is not the most effective alternative.
2. Apply for Less Than Six Stations- based on the facility need methodology BMA Monroe has demonstrated the need for six additional dialysis stations. Therefore, applying for less than six dialysis stations is not the most effective alternative.

After considering these alternatives to its proposal, the applicant believes the most effective and least costly alternative is to add six additional stations to ensure adequate access for the patients dialyzing at BMA Monroe.

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.

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

- The applicant uses reasonable and adequately supported assumptions to project utilization.
- The data cited is reasonable to use to support the assumptions of the applicant with regard to the least costly or most effective alternative for development of the proposed project.

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 and is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to the facility need determination in the July 2017 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than 6 additional dialysis stations for a total of no more than 22 certified stations at Metrolina Kidney Center upon completion of this project, Project ID# F-11208-16 (relocate 10 stations to FKC Indian Trail), Project ID# F-11242-16 (add 5 stations and develop a home hemodialysis and a peritoneal dialysis program) and Project ID# F-11383-17 (cost overrun for Project ID# F-11242-16), which shall include any home hemodialysis training or isolation stations.**

3. Bio-Medical Applications of North Carolina, Inc. 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

BMA proposes to add six dialysis stations to the BMA Monroe facility for a total of 22 certified dialysis stations upon completion of this project, Project ID# F-11208-16 (relocate 10 stations to FKC Indian Trail), Project ID# F-11242-16 (add 5 stations) and Project ID# F-11383-17 (cost overrun for Project ID# F-11242-16).

BMA Monroe does not currently offer either home hemodialysis or a peritoneal program. BMA Monroe proposed to add home therapies (both home hemodialysis and a peritoneal program) as part of Project ID# F-11242-16 (add 5 stations).

Capital and Working Capital Costs

In Section F, page 25, the applicant states that there will be no capital costs associated with the proposed project. In Section F, page 29, the applicant states that there will be no working capital costs for the proposed project since BMA Monroe is an existing facility.

Financial Feasibility

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

	Operating Year 1 (CY2019)	Operating Year 2 (CY2020)
Total Treatments	10,670	12,253
Total Gross Revenues (Charges)	\$34,272,872	\$38,707,528
Total Net Revenue	\$2,555,633	\$3,022,483
Average Revenue per Treatment	\$239.52	\$246.67
Total Operating Expenses (Costs)	\$2,484,086	\$2,775,084
Average Expense per Treatment	\$232.81	\$226.48
Net Income	\$71,547	\$247,399

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately

demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

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

- The applicant uses reasonable and adequately supported assumptions to project utilization.
- Historical data is used to provide future projections of costs and charges and demonstrate financial feasibility of the project.

This determination is based on a review of the:

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

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

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

C

BMA proposes to add six dialysis stations to the BMA Monroe facility for a total of 22 certified dialysis stations upon completion of this project, Project ID# F-11208-16 (relocate 10 stations to FKC Indian Trail), Project ID# F-11242-16 (add 5 stations) and Project ID# F-11383-17 (cost overrun for Project ID# F-11242-16).

BMA Monroe does not currently offer either home hemodialysis or a peritoneal program. BMA Monroe proposed to add home therapies (both home hemodialysis and a peritoneal program) as part of Project ID# F-11242-16 (add 5 stations).

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

The July 2017 SDR, Table D, indicates there are four dialysis facilities (three existing and one approved) in Union County, as follows:

**Union County Dialysis Facilities
 December 31, 2016**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Marshville Dialysis	DVA	37	Marshville	12	0	77.08%
Union County Dialysis	DVA	93	Monroe	28	2	83.04%
Metrolina Kidney Center	BMA	84	Monroe	21	-5*	100.0%
Fresenius Kidney Care Indian Trail	BMA	0	Indian Trail	0	10*	0.00%

*Note: Two projects have been approved that impact Metrolina Kidney Center; Project ID# F-11208-16 (relocate 10 stations to FKC Indian Trail), Project ID# F-11242-16 (add 5 stations and a home PD program). Taken together they result in a decrease of 5 dialysis stations at Metrolina Kidney Center.

As shown in the table above two of the three existing facilities in Union County are operated by DVA. Based on the most recent SDR, two of the three facilities operated in Union County operated at 80.0% utilization or above. As shown in the table above, BMA’s only operational dialysis facility is operating at 100.0% utilization as of December 31, 2016. Therefore, the facility is well utilized.

In Section C, pages 14-16, the applicant demonstrates that BMA Monroe will service a total of 71 in-center patients at the end of OY1 (CY2019) for a utilization rate of 80.75% or 3.23 patients per station per week (71 patients / 22 stations = 3.23 / 4 = .8075 or 80.75%). The projected utilization of 3.23 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b). The applicant states that the projected utilization rates are based on patients currently dialyzing at Metrolina Kidney Center.

The applicant proposes to add six dialysis stations to the existing BMA Monroe facility in Monroe, in Union County. The applicant adequately demonstrates the need to add six additional stations at BMA Monroe based on the number of in-center patients it proposes to serve. The discussion on projected utilization found in Criterion (3) is incorporated herein by reference.

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

- The applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need for the proposed services.
- The applicant provides adequate documentation that the proposed services will not result in the unnecessary duplication of existing or approved health service capabilities or facilities.

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.

- (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 35, the applicant provides the following table to illustrate current and projected staffing in full time equivalents (FTEs) for BMA Monroe. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart.

POSITION	CURRENT # FTEs	# FTEs TO BE ADDED	PROJECTED # FTEs
Registered Nurse	3.50		3.50
Home Training Nurse	0.00	1.00	1.00
Technician (PCT))	8.00		8.00
Clinical Manager	1.00		1.00
Administrator	0.20		0.20
Dietician	0.65		0.65
Social Worker	0.65		0.65
Chief Tech	0.15		0.15
Equipment Tech	0.75		0.75
In-Service	0.20		0.20
Clerical	1.00		1.00
Total	16.10	1.00	17.10

As illustrated in the table above, the applicant projects to add 1.00 FTEs at BMA Monroe.

In Section H, page 37, the applicant provides the projected direct care staff for BMA Monroe in OY2 (CY2020).

DIRECT CARE POSITIONS	# FTEs	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	3.50	2,080	7,280	3,432	2.12
Technician (PCT)	8.00	2,080	16,640	3,432	4.85
Home Training RN	1.00	2,080	2,080	3,432	0.61
Total	12.5	4,160	26,000	3,432	7.58

In Section H.6, page 37, the applicant states dialysis services will be available from 6:00 AM to 5:00 PM, Monday through Saturday for a total of 11 hours per day/ 66 hours per week.

In Section I.3, page 40, the applicant identifies Dr. Andrew S. O’Conner as the Medical Director of the facility. In Exhibit I-5, the applicant provides a copy of a letter signed by Dr. O’Conner of Metrolina Nephrology supporting the project and confirming his commitment to continue to serve as Medical Director. In Section H.3, pages 35-36, the applicant describes the methods used to recruit and fill vacant or new positions.

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.
- 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 39, the applicant identifies the necessary ancillary and support services and indicates how they will be made available. The applicant discusses coordination with the existing health care system on pages 40-42. Exhibits I-2 through I-4, respectively, contain copies of agreements with BMA-Charlotte for home training, for Spectra laboratories services, Mercy Hospital, Inc. for transfer agreement, and Duke University Medical Center for transplant services. Exhibit I-5 contains a letter from Dr. Andrew Connor, MD of Metrolina Nephrology, medical director of the facility expressing his support for the proposed project and agreement to continue as Medical Director.

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

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

This determination is based on a review of the:

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

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

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

NA

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

- (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, this Criterion 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 any construction or renovation. Therefore, this Criterion 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, page 51, the applicant reports that 81.31% of the patients who received treatments at BMA Monroe had some or all of their services paid for by Medicare or Medicaid in CY2016, as illustrated in the table below:

BMA Monroe Historical Payor Mix CY2016

Payment Source	Percent of Total Patients
Medicare	67.42%
Medicaid	7.32%
Medicare/ Commercial	6.57%
Commercial Insurance	9.68%
Self Pay/Indigent/Charity	3.45%
Misc. (incl. VA)	5.55%
Total	100.00%

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 and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Union	12%	51%	27%	10%	6%	11%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

*Excludes "White alone" who are "not Hispanic or Latino"

***"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

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

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

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

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

This determination is based on a review of the:

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

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

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

²http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

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

C

In Section L, page 53 the applicant states, “*BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations*”. In Section L.6, page 53, the applicant states, “*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.*”

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

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

This determination is based on a review of the:

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

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

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

C

In Section L, page 50, the applicant states: “*It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.*” In Section L, page 51, the applicant projects that 77.0% of all patients in OY2 (CY2020) will have all or part of their services paid for by Medicare and or Medicaid, as indicated in the table below:

BMA Monroe Projected Payor Mix CY2020

Payment Source	% of IC Patients	% of HH Patients	% of PD Patients	% of Total Patients
Medicare	63.91%	50.86%	50.86%	62.10%
Medicaid	8.56%	3.39%	3.39%	8.00%
Medicare/ Commercial	7.42%	4.49%	4.49%	6.90%
Commercial Insurance	8.64%	38.78%	38.78%	12.60%
Self Pay/Indigent/Charity	5.58%	2.48%	2.48%	4.60%
Misc. (Incl. VA)	5.89%	0.00%	0.00%	5.70%
Total	100.00%	100.00%	100.00%	100.00%

BMA Monroe does not currently offer either home hemodialysis or a peritoneal program. BMA Monroe proposed to add home therapies (both home hemodialysis and a peritoneal program) as part of Project ID# F-11242-16 (add 5 stations). The projected payor mix is based on recent experience of BMA Monroe’s in-center program and FMC Charlotte’s home therapies program. In CY2016, 81.31% of the patients who received treatments at BMA Monroe had some or all of their services paid for by Medicare or Medicaid in CY2016 while the applicant is projecting this percentage to decrease from 81.31% to 77.0% of all patients in OY2 (CY2020). The percentage decrease is based on the facility adding home therapy patients to the payor mix in CY2020 whereas in CY2016 the facility did not offer home therapies.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant’s projected payor mix adequately demonstrates that medically underserved populations will have adequate access to the proposed 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.

- (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 53, the applicant states *“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FKC Indian Trail [sic] will have an open policy, which means that any Nephrologist may apply to admit patients to the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms. ... Transient patients are accepted upon proper coordination of care with the patient’s regular nephrologist and a physician with staff privileges at the facility.”* Based on

the entirety of the application the project analyst believes the mention of “*FKC Indian Trail*” above is a typo and should read Metrolina Kidney Center.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant adequately demonstrates that the facility will provide a range of means by which a person can access the services.

This determination is based on a review of the:

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

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

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

C

In Section M.1, page 55, the applicant states that it has offered BMA Monroe as a clinical training site for nursing students from South Piedmont Community College. A copy of a letter sent by the applicant to the college, dated September 14, 2017, is included in Exhibit M-1. Based on the entirety of the application the project analyst believes the mention of “*FKC Indian Trail*” on page 55 of the application is a typo and should read Metrolina Kidney Center.

This determination is based on a review of the:

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

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

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

BMA proposes to add six dialysis stations to the BMA Monroe facility for a total of 22 certified dialysis stations upon completion of this project, Project ID# F-11208-16 (relocate 10 stations to FKC Indian Trail), Project ID# F-11242-16 (add 5 stations) and Project ID# F-11383-17 (cost overrun for Project ID# F-11242-16).

BMA Monroe does not currently offer either home hemodialysis or a peritoneal program. BMA Monroe proposed to add home therapies (both home hemodialysis and a peritoneal program) as part of Project ID# F-11242-16 (add 5 stations).

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

The July 2017 SDR, Table D, indicates there are four dialysis facilities (three existing and one approved) in Union County, as follows:

**Union County Dialysis Facilities
 December 31, 2016**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Marshville Dialysis	DVA	37	Marshville	12	0	77.08%
Union County Dialysis	DVA	93	Monroe	28	2	83.04%
Metrolina Kidney Center	BMA	84	Monroe	21	-5*	100.0%
Fresenius Kidney Care Indian Trail	BMA	0	Indian Trail	0	10*	0.00%

*Note: Two projects have been approved that impact Metrolina Kidney Center; Project ID# F-11208-16 (relocate 10 stations to FKC Indian Trail), Project ID# F-11242-16 (add 5 stations and a home PD program). Taken together they result in a decrease of 5 dialysis stations at Metrolina Kidney Center.

As shown in the table above two of the three existing facilities in Union County are operated by DVA. Based on the most recent SDR, two of the three facilities operated in Union County operated at 80.0% utilization or above. As shown in the table above, BMA's only operational dialysis facility is operating at 100.0% utilization as of December 31, 2016. Therefore, the facility is well utilized.

In Section C, pages 14-16, the applicant demonstrates that BMA Monroe will service a total of 71 in-center patients at the end of OY1 (CY2019) for a utilization rate of 80.75% or 3.23 patients per station per week (71 patients / 22 stations = 3.23 / 4 = .8075 or 80.75%). The projected utilization of 3.23 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b).

In Section N, pages 56-57, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services and states:

“The applicant does not expect this proposal to have effect on the competitive climate in Union County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the BMA Monroe facility begins with patients currently served by the facility, growth of that patient population, and a projection of 37 patients to transfer their care to FKC Indian Trail or FKC Southeast Mecklenburg County. BMA projects growth of the Union County ESRD patient population at a rate of 9.0% based upon the recent growth trends of the facility.”

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

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

This determination is based on a review of the:

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

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

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

Fresenius Medical Care Holdings, Inc. owns and operates over 100 facilities in North Carolina as of September 15, 2017. In Section O and referenced Exhibits, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation during the 18 month look-back period.

In Section B, page 9, Section O, pages 58-62 and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality. In Exhibit O-2, the applicant provides a document indicating that a survey of Metrolina Kidney Center was completed on October 13, 2016 and no condition level deficiencies were cited. On page 60, that applicant states “*The Metrolina Kidney Center meets the Conditions for Coverage for ESRD facilities. See Exhibit O-2.*”

In Section O, pages 61-62, the applicant states that out of more than 100 facilities located in North Carolina operated by the applicant or a related entity, only the two listed below were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application.

BMA QUALITY CARE			
FACILITY	SURVEY DATE	BACK IN COMPLIANCE	
RAI West College-Warsaw	3/15/2016	Yes	4/11/2016
BMA East Rocky Mount	1/25/2017	Yes	3/2/2017

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

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

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

This determination is based on a review of the:

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

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

(21) Repealed effective July 1, 1987.

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

C

The application is conforming 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

- (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 not proposing to establish a new End Stage Renal Disease facility
- (b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.
- C- In Section C, pages 14-17, the applicant demonstrates that BMA Monroe will service a total of 71 in-center patients at the end of OY1 (CY2019) for a utilization rate of 80.75% or 3.23 patients per station per week ($71 \text{ patients} / 22 \text{ stations} = 3.23 / 4 = .8075$ or 80.75%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.
- C- In Section C, pages 14-19, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

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

This determination is based on a review of the:

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

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