

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 22, 2016

Findings Date: April 22, 2016

Project Analyst: Celia C. Inman

Assistant Chief: Martha J. Frisone

Project ID #: J-11133-16

Facility: Fresenius Medical Care Morrisville

FID #: 160069

County: Wake

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

Project: Develop a new 10-station dialysis facility by relocating four stations from Cary Kidney Center and six stations from Southwest Wake County Dialysis

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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) and Carolina Dialysis, LLC (the "applicants") propose to develop a new 10-station dialysis facility, Fresenius Medical Care Morrisville (FMC Morrisville), by relocating four existing certified dialysis stations from Cary Kidney Center and six existing certified dialysis stations from Southwest Wake County Dialysis. All three facilities are located in Wake County. The applicants do not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

Need Determination

The applicants propose to relocate existing dialysis stations within Wake County; therefore, there are no need methodologies in the 2016 State Medical Facilities Plan (2016 SMFP) applicable to this review.

Policies

POLICY GEN-3: BASIC PRINCIPLES on page 39 of the 2016 SMFP is not applicable to this review because neither the county nor facility need methodology is applicable to this review.

POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES on page 39 of the 2016 SMFP is not applicable to this review because the applicant does not propose a capital expenditure greater than \$2 million.

However, *POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS* on page 33 of the 2016 SMFP is applicable to this review.

POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS 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 [sic] county is currently serving residents of that contiguous [sic] 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 applicants propose to develop a new 10-station dialysis facility, FMC Morrisville, in Wake County, by relocating 10 existing Wake County dialysis stations: four from Cary Kidney Center and six from Southwest Wake County Dialysis. Because all three facilities are located in Wake County, there is no change in the total dialysis station inventory in Wake County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicants adequately demonstrate that the application is consistent with Policy ESRD-2 in the 2016 SMFP. 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 applicants, BMA and Carolina Dialysis, propose to develop FMC Morrisville, a new 10-station Wake County dialysis facility, by relocating four existing certified dialysis stations from Cary Kidney Center and six existing certified dialysis stations from Southwest Wake County Dialysis. The applicants refer to Cary Kidney Center as BMA Cary and Southwest Wake County Dialysis as BMA Southwest Wake throughout the application. Except where the applicants are quoted, the Findings refer to the facilities as Cary Kidney Center and Southwest Wake County Dialysis, in accordance with the January 2016 North Carolina Semiannual Dialysis Report (SDR).

Population to be Served

On page 369, the 2016 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 Wake County. Facilities may serve residents of counties not included in their service area.

In Section C.1, page 20, the applicants state they propose to develop a new 10-station dialysis facility by relocating four dialysis stations from Cary Kidney Center and six dialysis stations from Southwest Wake County Dialysis. The applicants provide the projected patient origin for FMC Morrisville for in-center (IC), home hemodialysis (HH) and peritoneal (PD) patients for the first two years of operation following completion of the project, CY2018 and CY2019, as follows:

County	Operating Year (OY) 1			Operating Year (OY) 2			Percent of Total	
	IC	HH	PD	IC	HH	PD	OY1	OY2
Wake	30.5	3.1	7.4	31.0	4.3	7.7	91.1%	91.5%
Durham	1.0		1.0	1.0		1.0	4.4%	4.3%
Orange			1.0			1.0	2.2%	2.1%
Chatham	1.0			1.0			2.2%	2.1%
Total*	32.5	3.1	9.4	33.0	4.3	9.7	100.0%	100.0%

*Rounded down to the whole patient

The applicants have identified 37 in-center patients and 11 home patients who are interested in transferring their care to the proposed facility. The applicants state that each patient resides in close proximity to the proposed facility and is currently receiving dialysis care and treatment at another BMA dialysis facility in Wake County. Exhibit C-1 contains copies of signed letters of support from these patients indicating that they would consider transferring their care to the new facility upon certification. The letters state the patients' county of residence, zip code and the facility in which they currently dialyze.

The applicants adequately identify the population to be served.

Analysis of Need

In Section C.2, page 24, the applicants discuss the necessity to relocate stations to the proposed Morrisville facility in western Wake County, stating:

"The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment, and the stated desires of the patients to have dialysis at the Morrisville location."

The applicants state that there is not another dialysis facility in the immediate area of Morrisville and that the proposed facility will include a home therapies program, because the existing home therapy programs at Wake Dialysis and BMA Raleigh are not convenient to the patients in the Morrisville and western Wake County area.

On pages 21-23, the applicants provide the methodology and assumptions used to project utilization, as follows:

1. A significant number of BMA dialysis patients reside in Morrisville and western areas of Wake County, in the general area of Morrisville. Exhibit C-1 includes letters from 37 in-center and 11 home patients who the applicants state reside in close proximity to Morrisville and/or could be better served by a facility at the proposed location. The letters confirm a willingness to transfer care to the proposed facility.
2. The applicants project only 30 of the 37 in-center patients who signed letters will transfer their care to the new facility. Two of the 30 patients are from outside Wake County, one from Durham County and one from Chatham County, but are dialyzing at a BMA Wake County facility. Both will transfer their care to the proposed facility.

3. The applicants assume that one Wake County in-center dialysis patient will change to the home hemodialysis modality each year.
4. The applicants assume that each of the 11 home training patients who signed letters will transfer their care to the proposed facility. One of the 11 home patients is from Durham County and one is from Orange County.
5. The project is scheduled for completion December 31, 2017.

Operating Year 1 is Calendar Year 2018, January 1 through December 31, 2018.
 Operating Year 2 is Calendar Year 2019, January 1 through December 31, 2019.

6. The applicants assume the Wake County dialysis patients transferring to the new FMC Morrisville facility are a part of the Wake County ESRD patient population as a whole, and that this population will increase at the Wake County Five Year Average Annual Change Rate (AACR) of 5.0%, as published in the January 2016 SDR. Non-Wake County patients are not projected to increase and are added to the census in a separate step.

Projected Utilization

The applicants' methodology is illustrated in the following tables.

FMC Morrisville	In-Center
Begin the facility census with the in-center patients projected to transfer care to the proposed facility upon certification on December 31, 2017.	30
Project growth of the census by the Wake County Five Year Average Annual Change Rate for one year to December 31, 2018.	$(30 \times 0.05) + 30 = 31.5$
Subtract one patient projected to change to home hemodialysis.	$31.5 - 1 = 30.5$
Add the Durham and Chatham County patients. This is the census at the end of OY1, December 31, 2018.	$30.5 + 2 = 32.5$
Project growth of the census by the Wake County Five Year Average Annual Change Rate for one year to December 31, 2019.	$(30.5 \times 0.05) + 30.5 = 32.0$
Subtract one patient projected to change to home hemodialysis.	$32 - 1 = 31$
Add the Durham and Chatham County patients. This is the census at the end of OY2, December 31, 2019.	$31 + 2 = 33.0$

FMC Morrisville	Home Hemodialysis
Begin the facility census with two hemodialysis patients projected to transfer care to the proposed facility upon certification on December 31, 2017.	2
Project growth of the census by the Wake County Five Year Average Annual Change Rate for one year to December 31, 2018.	$(2 \times 0.05) + 2 = 2.1$
Add one patient projected to change to home hemodialysis. This is the census at the end of OY1, December 31, 2018.	$2.1 + 1 = 3.1$
Project growth of the census by the Wake County Five Year Average Annual Change Rate for one year to December 31, 2019.	$(3.1 \times 0.05) + 3.1 = 3.3$
Add one patient projected to change to home hemodialysis. This is the census at the end of OY2, December 31, 2019.	$3.3 + 1 = 4.3$

FMC Morrisville	Peritoneal
Begin the facility census with seven Wake County home PD patients projected to transfer care to the proposed facility upon certification on December 31, 2017.	7
Project growth of the census by the Wake County Five Year Average Annual Change Rate for one year to December 31, 2018.	$(7 \times 0.05) + 7 = 7.4$
Add the two Durham and Orange County patients. This is the census at the end of OY1, December 31, 2018.	$7.4 + 2 = 9.4$
Project growth of the census by the Wake County Five Year Average Annual Change Rate for one year to December 31, 2019.	$(9.4 \times 0.05) + 9.4 = 9.7$
Add the two Durham and Orange County patients. This is the census at the end of OY2, December 31, 2019.	$9.7 + 2 = 11.7$

The applicants project to serve 32 in-center patients or 3.2 patients per station ($32/10 = 3.2$) by the end of Operating Year 1 and 33 in-center patients or 3.3 patients per station ($33/10 = 3.3$) by the end of Operating Year 2 for the proposed 10-station facility. This satisfies the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). The applicants project four home hemodialysis patients and 10 peritoneal patients in the second year of operation. In this application, the applicants assume a projected annual rate of growth of 5.0% for the Wake County dialysis patient census, which is consistent with the Wake County Five Year Average Annual Change Rate (2010-2014). The applicants state they round calculations of patients down to the whole

patient. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section L.1(a), pages 76-77, the applicants state that each of BMA's 102 facilities in 42 North Carolina Counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons. Form C, page 101, shows the applicants project over 86% of the projected in-center patients will have some or all of their services paid for by Medicare or Medicaid. The applicants adequately demonstrate the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicants adequately identify the population to be served, adequately demonstrate the need that this population has for the proposed project, and adequately demonstrate the extent to which all residents, including underserved groups, will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

The applicants propose to relocate four existing dialysis stations from the Cary Kidney Center facility and six existing dialysis stations from the Southwest Wake County Dialysis facility, both in Wake County, to develop a new 10-station dialysis facility, FMC Morrisville, also in Wake County. As stated in the assumptions on page 21 of the application, the applicants assume that the Wake County dialysis patients transferring to the new FMC Morrisville facility are a part of the Wake County ESRD patient population as a whole, rather than all being transfers from the facilities that are relocating stations.

In Section D.1, on pages 38-41, the applicants discuss how the needs of dialysis patients at Southwest Wake County Dialysis and Cary Kidney Center will continue to be met after the relocation of stations to the proposed FMC Morrisville dialysis facility. The applicants state that the development of the proposed facility results in the following changes to the existing facilities named above.

	Current Stations	Stations to be Relocated	Stations Remaining	Transferring Patients
Southwest Wake County Dialysis	30	6	24	1
Cary Kidney Center	28	4	24	20

The applicants state the relocation of stations and transfer of patients is projected to occur on December 31, 2017.

Southwest Wake County Dialysis

On pages 38-39 of the application, the applicants provide the assumptions used to project Southwest Wake County Dialysis' utilization on December 31, 2017. The assumptions are summarized below:

- Southwest Wake County Dialysis is a 30-station dialysis facility and cannot be expanded, though the facility has been certified for as many as 31 stations in the past (Section C-12, page 34).
- The January 2016 SDR reports the Southwest Wake County Dialysis' census was 115 patients on June 30, 2015.
- On December 31, 2015, per the applicants, Southwest Wake County Dialysis' census was comprised of 117 Wake County patients and 1 Johnston County patient for a total of 118 patients.
- Growth of the Wake County patient population is projected using the 5.0% Wake County Five Year Average Annual Change Rate as published in the January 2016 SDR.
- The applicants assume the 1 Johnston County patient is dialyzing at Southwest Wake County Dialysis as a function of patient choice and does not project an increase in that patient population.
- The applicants state that Southwest Wake County Dialysis qualifies for additional stations by way of the Facility Need Methodology and BMA will file a CON application on March 15, 2016 seeking to add six dialysis stations at Southwest Wake County Dialysis.

Based on the above assumptions, the applicants project utilization at Southwest Wake County Dialysis as follows:

BMA begins with the Wake County ESRD patient population of Southwest Wake as of December 31, 2015. (30 stations)	117
BMA projects this population forward for 12 months to December 31, 2016, using the 5.0% Wake County change rate.	$(117 \times 0.05) + 117 = 122$
BMA projects this population forward for 12 months to December 31, 2017, the projected date of certification of this project.	$(122 \times 0.05) + 122 = 128$
BMA adds the Johnson County patient.	$128 + 1 = 129$
BMA subtracts 1 patient expected to transfer as of December 31, 2017. (24 stations)	$129 - 1 = 128$

Note: the applicants round down to the nearest whole number in each calculation.

Thus, as of December 31, 2017, following the relocation of stations and transfer of patients, Southwest Wake County Dialysis is projected to have 128 patients and 24 stations, which is a utilization rate of 133% ($128 \text{ patients} / 24 \text{ stations} = 5.3 / 4 = 1.33$).

On page 39, the applicants utilize the Facility Need Methodology to show Southwest Wake County Dialysis should qualify to apply for up to six additional stations in the April 1, 2016 Review Cycle.

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/15		92.74%
Certified Stations		31
Pending Stations	Project ID #J-10180-13 (Add 2 for a total of 30 at completion this project and Project ID # J-10152-13 / relocate 3 stations to FMC Northern Wake for a total of 28 at Southwest Wake County Dialysis)	2
Total Existing and Pending Stations		33
In-Center Patients as of 6/30/15 (SDR2)		115
In-Center Patients as of 12/31/14 (SDR1)		106
Step	Description	Result
	Difference (SDR2 - SDR1)	9
(i)	Multiply the difference by 2 for the projected net in-center change	18
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/14	0.1698
(ii)	Divide the result of step (i) by 12	0.0142
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/15 until 12/31/15)	0.0849
(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	124.7642
(v)	Divide the result of step (iv) by 3.2 patients per station	38.9888
	and subtract the number of certified and pending stations to determine the number of stations needed	5.9888

On page 40 of the application, the applicants state that BMA will be filing a CON application on March 15, 2016 seeking to add six dialysis stations at Southwest Wake County Dialysis, upon completion of the proposed project under review. BMA filed the CON application on March 15, 2016. The applicants further state:

“Assuming approval of the application to add six dialysis stations at BMA Southwest Wake, the facility would have a census of 128 patients dialyzing on 30 stations the day following relocation of the six stations to FMC Morrisville. This would equate to a utilization rate of 4.27 patients per station [sic]. BMA would operate a third, or evening dialysis shift at BMA Southwest Wake when the facility census reaches and exceeds 100% capacity, or in this case 120 patients.”

The applicants demonstrate that the needs of the population presently served at Southwest Wake County Dialysis will continue to be adequately met following the proposed relocation of six dialysis stations from Southwest Wake County Dialysis to FMC Morrisville.

Cary Kidney Center

On pages 40-41 of the application, the applicants provide the assumptions used to project Cary Kidney Center’s utilization on December 31, 2017. The assumptions are summarized below:

- Cary Kidney Center is a 28-station facility and cannot be expanded. Cary Kidney Center is the closest facility to the proposed Morrisville facility. The applicants propose to relocate four of Cary Kidney Center’s stations to the proposed facility (Section C-12, page 34).
- The January 2016 SDR reports the Cary Kidney Center’s census was 80 patients on June 30, 2015.
- On December 31, 2015, per the applicants, Cary Kidney Center’s census was 85 patients (83 Wake County patients, one from Durham County and one from out of state).
- The applicants project growth of the Wake County patient population using the 5.0% Wake County Five Year Average Annual Change Rate as published in the January 2016 SDR.
- The applicants assume the patient from out of state was a transient patient visiting the area and will not carry that patient forward in the projections. The applicants further assume the Durham County patient will be transferring care to the proposed facility for convenience of access.

Based on the above assumptions, the applicant provides the following table on page 41 of the application and states that as of December 31, 2017, 70 in-center patients will be dialyzing at Cary Kidney Center for a utilization of 2.92 patients per station or 73%. ($70 / 24 = 2.92 / 4 = 0.73$).

<i>“BMA begins with the Wake County ESRD patient population of BMA Cary as of December 31, 2015. (28 stations)</i>	83
<i>BMA projects this population forward for 12 months to December 31, 2016, using the Wake County Five Year Average Annual Change Rate.</i>	$(83 \times 0.05) + 83 = 86.2$
<i>BMA projects this population forward for 12 months to December 31, 2017.</i>	$(86.2 \times 0.05) + 86.2 = 89.5$
<i>BMA subtracts 20 patients currently dialyzing with BMA Cary, each of whom has signed letters of support for this project, and who are projected to transfer to FMC Morrisville.</i>	$89.5 - 20 = 69.5$ ”

Note: in the above calculations, the applicants did not round down to the nearest whole number as they did in the same projected utilization calculations above for Southwest Wake County Dialysis.

However, the Project Analyst does not agree with the applicants' calculations as presented above. The Project Analyst's calculations based on the same set of assumptions above results in the following projected utilization.

BMA begins with the Wake County ESRD patient population of Cary Kidney Center as of December 31, 2015. (28 stations)	83
BMA projects this population forward for 12 months to December 31, 2016, using the 5.0% Wake County change rate.	$(83 \times 0.05) + 83 = 87.15$
BMA projects this population forward for 12 months to December 31, 2017, the projected date of certification of this project.	$(87.15 \times 0.05) + 87.15 = 91.50$
BMA subtracts 20 patients expected to transfer their care to the new FMC Morrisville facility upon certification. (24 stations)	$91.50 - 20 = 71.50$

The Project Analyst's calculations in the above table assume the traditional rounding of 0.50 and above to the next whole number in the final calculation. This follows the same methodology the applicants used for projecting Cary Kidney Center above and simply corrects the erroneous numbers. Thus, as of December 31, 2017, following the relocation of stations and transfer of patients, Cary Kidney Center is projected to have 72 patients and 24 stations, which is a utilization rate of 75% ($71 / 24 = 3.0 / 4 = 0.75$).

If the Project Analyst assumes the same rounding methodology the applicants applied in the Southwest Wake County Dialysis' projected utilization (rounding down to the nearest whole number in each calculation), the result is a projected 71 patients for a utilization rate of 74% ($71 / 24 = 2.96 / 4 = 0.74$).

BMA begins with the Wake County ESRD patient population of Cary Kidney Center as of December 31, 2015. (28 stations)	83
BMA projects this population forward for 12 months to December 31, 2016, using the 5.0% Wake County change rate.	$(83 \times 0.05) + 83 = 87$
BMA projects this population forward for 12 months to December 31, 2017, the projected date of certification of this project.	$(87 \times 0.05) + 87 = 91$
BMA subtracts 20 patients expected to transfer their care to the new FMC Morrisville facility upon certification. (24 stations)	$91 - 20 = 71$

Note: the above calculations are rounded down to the whole number in each calculation to be consistent with the applicants' above projected utilization calculations for Southwest Wake County Dialysis.

In either case, the projected utilization for Cary Kidney Center, after the relocation of stations and transfer of patients is 74% to 75%, demonstrating that the needs of the population

presently served at Cary Kidney Center will continue to be adequately met following the proposed relocation of four dialysis stations from Cary Kidney Center to FMC Morrisville. On page 41, the applicants state that BMA will apply for additional stations at Cary Kidney Center when the facility qualifies for and can demonstrate the need for additional stations.

In Section D.2, page 41, the applicants state:

“The relocation of stations from BMA Southwest Wake and BMA Cary will not alter or affect the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care.”

Conclusion

The applicants adequately demonstrate that the needs of the population presently served will continue to be adequately met following the proposed relocation of four dialysis stations from Cary Kidney Center and six dialysis stations from Southwest Wake County Dialysis to FMC Morrisville and that access for medically underserved groups will not be negatively impacted.

Therefore, 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, pages 42-43, the applicants describe the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the status quo – The applicants state that maintaining the status quo is not an effective alternative due to the projected future ESRD patient population of Wake County within its existing BMA facilities. Eight of BMA’s 12 facilities are at physical plant capacity and cannot be further expanded in their current situations. Therefore, this alternative was rejected.
- Develop a facility in another area of Wake County - The applicants state that evaluation of the existing patient populations served by BMA, and projections of future patient populations, indicate that the patient population in the Morrisville area might be better served by a new facility. Therefore, this alternative was rejected.
- Develop a larger facility – The applicants state they considered applying for more stations but rejected the alternative because the 10-station facility will meet the needs of the projected patients who will transfer their care to the proposed facility upon certification, and will also meet the performance standards at 10A NCAC 14C .2203.

- Expand at existing facilities – The applicants state that eight of the existing Wake County BMA facilities cannot be expanded due to physical plant capacity; therefore this alternative was rejected.
- Move stations into an existing BMA facility with capacity for additional stations - The applicants state that this alternative was rejected because moving stations into another facility would not address the needs of the specific patient population to be served and would only shift the finite space issue to another facility.

After considering the above alternatives, the applicants state that given the residence location of the existing patients projected to be served and the physical plant capacity issues, the project 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. Bio-Medical Applications of North Carolina, Inc. and Carolina Dialysis, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Bio-Medical Applications of North Carolina, Inc. and Carolina Dialysis, LLC shall relocate no more than 4 dialysis stations from Cary Kidney Center and no more than 6 dialysis stations from Southwest Wake County Dialysis.**
- 3. Bio-Medical Applications of North Carolina, Inc. and Carolina Dialysis, LLC shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation or home hemodialysis stations.**
- 4. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 4 dialysis stations at Cary Kidney Center for a total of no more than 24 dialysis stations at Cary Kidney Center upon project completion.**
- 5. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 6 dialysis stations at Southwest Wake County Dialysis for a total of no more than 24 dialysis stations at Southwest Wake County Dialysis upon project completion.**
- 6. Bio-Medical Applications of North Carolina, Inc. and Carolina Dialysis, LLC 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 applicants, BMA and Carolina Dialysis, propose to develop a new 10-station Wake County dialysis facility by relocating four stations from Cary Kidney Center and six stations from Southwest Wake County Dialysis.

Capital and Working Capital Costs

In Section F.1, page 45, the applicants project \$1,607,166 in capital costs to develop the proposed project. In Sections F.10-F.12, pages 48-50, the applicants state that start-up expenses and initial operating expenses incurred for this project will be \$143,044 and \$1,243,444, respectively, for a total estimated working capital of \$1,386,488.

Availability of Funds

In Section F.2, page 46, and Section F.13, page 50, the applicants state they will finance the capital costs and working capital costs with accumulated reserves of both Bio-Medical Applications of North Carolina, Inc. and Carolina Dialysis, LLC, as shown below.

Accumulated Reserves / Owner's Equity

	BMA	Carolina Dialysis	Total
Capital Costs	\$1,285,733	\$321,433	\$1,607,166
Working Capital	\$1,386,488	-0-	\$1,386,488

Exhibit F-1 contains a letter dated February 15, 2016, from Carolina Dialysis, LLC Board Member, Terry Sullivan, authorizing and committing \$321,433 in capital costs for the project. The exhibit also contains a letter dated February 15, 2016 from the Senior Vice President & Treasurer for Fresenius Medical Care Holdings, Inc. (FMCH), as the parent company of BMA and also as the guarantor of the funds on behalf of Carolina Dialysis, LLC, which states authorization and commitment of the cash reserves for the full project capital costs of \$1,607,166, as well as, "any additional funds as may be necessary for start-up costs in the new location." Exhibit F-2 contains the Consolidated Financial Statements for FMCH which indicates that it had \$195 million in cash and cash equivalents as of December 31, 2014. The exhibit also contains Carolina Dialysis' December 31, 2015 Balance Sheet, showing cash of \$273,583 and temporary investments of \$17 million. The applicants adequately demonstrate that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

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

	CY2018	CY2019
Total Net Revenue	\$1,969,069	\$2,098,268
Total Operating Expenses	\$1,874,099	\$1,966,450
Net Income	\$94,971	\$131,818

Totals may not sum due to rounding.

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

Conclusion

In summary, the applicants adequately demonstrate that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. 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 applicants, BMA and Carolina Dialysis, propose to develop a new 10-station Wake County dialysis facility by relocating four stations from Cary Kidney Center and six stations from Southwest Wake County Dialysis.

On page 369, the 2016 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 Wake County. Facilities may serve residents of counties not included in their service area.

The applicants operate 12 dialysis centers in Wake County. DaVita is the only other provider of dialysis services in Wake County, and operates one dialysis center, Wake Forest Dialysis Center, as shown in the table below.

**Wake County Dialysis Facilities
 Certified Stations and Utilization as of June 30, 2015**

Dialysis Facility	Certified Stations 6/30/15	# In-center Patients	Percent Utilization	Patients/Station
BMA Owned/Operated Facilities				
BMA of Fuquay-Varina Kidney Center	20	77	96.25%	3.8500
BMA of Raleigh Dialysis	50	163	81.50%	3.2600
Cary Kidney Center (BMA Cary)	28	80	71.43%	2.8571
FMC Apex	20	49	61.25%	2.4500
FMC Central Raleigh	19	55	72.37%	2.8947
FMC Eastern Wake	14	61	108.93%	4.3571
FMC Millbrook	17	57	83.82%	3.3529
FMC New Hope Dialysis	36	110	76.39%	3.0556
FMC Northern Wake*	0	0	0.00%	0.0000
Southwest Wake County Dialysis	31	115	92.74%	3.7097
Wake Dialysis Clinic	50	198	99.00%	3.9600
Zebulon Kidney Center	30	99	82.50%	3.3000
Davita Owned/Operated Facilities				
Wake Forest Dialysis Center	20	73	91.25%	3.6500

Source: 2016 SMFP

*Project ID #J-10152-13 / Relocate 10 dialysis stations from BMA Wake (BMA of Raleigh Dialysis) and 3 stations from BMA Southwest Wake (Southwest Wake County Dialysis) to develop a new 13-station facility in North Raleigh

As shown in the table above, seven of the 12 BMA Wake County dialysis facilities are operating above 80% utilization (3.2 patients per station), and 10 of the 12 facilities are operating at or above 70% utilization (2.8 patients per station). Furthermore, FMC Northern Wake is a new facility and was not certified until January 11, 2016.

The applicants provide reasonable projections for the patient population they propose to serve on pages 20-23 of the application. The growth projections are based on a projected 5.0% average annual growth rate in the number of Wake County dialysis patients transferring their care to the proposed facility. At the end of the first operating year following project completion, FMC Morrisville projects the in-center utilization will be 3.2 in-center patients per station (32 patients / 10 dialysis stations = 3.2), which is 80% of capacity. The applicants do not propose to increase the number of certified stations in the service area. The applicants adequately demonstrate the need to develop a new 10-station dialysis center by relocating existing Wake County BMA dialysis stations.

The applicants adequately demonstrate 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 59, the applicants provide the proposed staffing for the new facility, which includes 10.11 full-time equivalent (FTE) employee positions, as shown below.

Position	Projected # of FTE Positions
Medical Director*	
RN	1.50
Technician	4.00
Clinical Manager	1.00
Administration – FMC Director of Operations	0.15
Dietitian	0.33
Social Worker	0.33
Home Training RN	1.00
Chief Technician	0.15
Equipment Technician	0.50
In-Service	0.15
Clerical	1.00
Total FTE Positions	10.11

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

In Section H.3, page 60, the applicants describe their experience and process for recruiting and retaining staff. Exhibit I-6 contains a copy of a letter from Adam Stern, M.D., expressing his interest in serving as the Medical Director for the facility. The applicants adequately demonstrate 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 63, the applicants include a list of providers of the necessary ancillary and support services. Exhibits I-3, 4 and 5 contain documentation for laboratory, hospital and transplant services, respectively. Exhibit I-6 contains a letter from the proposed medical director of the facility expressing his support for the proposed project. The applicants discuss coordination with the existing health care system on pages 64-66. The applicants adequately demonstrate 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 applicants propose to develop the new facility in a 10,554 square foot building to be located in Morrisville in western Wake County. In Section F.1, page 45, the applicants list

the project costs, including \$1,026,014 for construction, \$581,152 in miscellaneous costs including water treatment equipment, furniture, architect/engineering fees, and a contingency for a total project cost of \$1,607,166. In Section K.1, pages 68-70, the applicants describe their plans for energy-efficiency and water conservation. Costs and charges are described by the applicant in Section R of the application, beginning on page 97. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicants adequately demonstrate 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.1, page 76, the applicants state that BMA and Carolina Dialysis have a long history of providing dialysis services to the underserved populations of North Carolina. FMC, BMA's parent company, currently operates 102 facilities in 42 North Carolina Counties, including affiliations with RRI facilities. The applicants further state it is 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 which would classify a patient as underserved. On page 77, the applicants state:

"BMA of north Carolina and Carolina Dialysis have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. For example, Medicare (includes Medicare Advantage treatments) represented 81.38% of North Carolina dialysis treatments in BMA facilities in FY 2015; Medicaid treatments represented an additional 4.87% of treatments in BMA facilities for FY 2015."

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 applicants' 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**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Wake	10%	51%	39%	12%	5%	14%
Statewide	15%	51%	36%	17%	10%	15%

<http://www.census.gov/quickfacts/table> Latest Data as of 12/22/15

*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."

However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The *Southeastern Kidney Council Network 6 Inc. Annual Report*¹ provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

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

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

The applicants demonstrate that they currently provide 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 80, the applicants state:

“BMA of North Carolina and Carolina Dialysis facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. ... The applicant will treat all patients the same regardless of race or handicap status.”

In Section L.6, page 81, the applicants state there have been no civil rights access complaints filed against any BMA North Carolina facilities within the past 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 R, page 101, the applicants report that 86% of the in-center patients who will receive treatments at FMC Morrisville will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected (CY2019) payment source for the facility for in-center patients:

Payment Source	In-Center Patients
Self Pay/Indigent/Charity	8.58%
Medicare	73.44%
Medicaid	2.73%
Commercial Insurance	4.74%
Medicare/Commercial Insurance	10.31%
VA	0.20%
Total	100.00%

In Section L, pages 77-79, the applicants provide the assumptions used to project payor mix. The applicants' projected payment sources in Section L are consistent with the facility's projected (CY2019) payment sources as reported by the applicants in Section R, page 101. The applicants demonstrate that medically underserved groups

will have adequate access to the services offered at FMC Morrisville. 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 81, the applicants describe the range of means by which a person will have access to the dialysis services at FMC Morrisville, including referrals from nephrologists, other physicians, or hospital emergency rooms. The applicants adequately demonstrate 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 83, the applicants state that BMA facilities routinely work with local community training programs and students, and that the proposed facility will also offer the same opportunities to local health professional training programs. Exhibit M-1 contains a copy of correspondence to an area health professional training program expressing an interest on the part of the applicants to offer the facility as a clinical training site. 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 applicants propose to develop a new 10-station Wake County dialysis facility by relocating four stations from Cary Kidney Center and six stations from Southwest Wake County Dialysis.

On page 369, the 2016 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 Wake County. Facilities may serve residents of counties not included in their service area.

The applicants operate 12 dialysis centers in Wake County. DaVita is the only other provider of dialysis services in Wake County, and operates one dialysis center, Wake Forest Dialysis Center, as shown in the table below.

**Wake County Dialysis Facilities
 Certified Stations and Utilization as of June 30, 2015**

Dialysis Facility	Certified Stations 6/30/15	# In-center Patients	Percent Utilization	Patients/Station
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Zebulon Kidney Center	30	99	82.50%	3.3000
Davita Owned/Operated Facilities				
Wake Forest Dialysis Center	20	73	91.25%	3.6500

Source: January 2016 SDR, Table A.

*Project ID #J-10152-13 / Relocate 10 dialysis stations from BMA Wake (BMA of Raleigh Dialysis) and 3 stations from BMA Southwest Wake (Southwest Wake County Dialysis) to develop a new 13-station facility in North Raleigh

As shown in the table above, seven of the twelve BMA Wake County dialysis facilities are operating above 80% utilization (3.2 patients per station), and ten of the twelve BMA facilities are operating at or above 70% utilization (2.8 patients per station). The FMC Northern Wake facility is a new facility and was not certified until January 11, 2016.

In Section N.1, pages 84-85, the applicants discuss how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicants state,

“BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 86% of the In-center treatments will be reimbursed at government payors (Medicare / Medicaid / VA) rates. The facility must capitalize upon every opportunity for efficiency.

BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. ... This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives by offering another convenient venue for dialysis care and treatment.”

See also Sections A, B, C, D, E, F, G, H, I, K, L, N, and O where the applicants discuss 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 applicants adequately demonstrate the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need, including projected utilization, and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicants adequately demonstrate they will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicants demonstrate that they will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) 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 A-4, the applicants identify the kidney disease treatment centers located in North Carolina owned and operated by the applicants or an affiliated company. In Section O.3, pages 89-91, the applicants identify two of its 102 Fresenius affiliated North Carolina facilities, BMA Lumberton and BMA East Charlotte, as having been 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 applicants state that both facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicants adequately demonstrate that they have 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 with 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.

-C- In Section C, the applicants adequately demonstrate the need to establish the proposed 10-station FMC Morrisville dialysis facility by relocating 10 existing Wake County dialysis stations to the proposed facility. At the end of the first operating year, the applicants project FMC Morrisville will serve 32 patients for a utilization of 3.2 patients per station per week. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

.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.

- NA- The applicants are not 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. The applicants are seeking to develop a new 10-station dialysis facility.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 21-23, the applicants provide the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

