TOPCATS Division
2321 West Morehead Street
Charlotte, NC 28208

September 3, 2019

Ms. Tanya Saporito, Project Analyst
Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, NC 27603

RE: Total Renal Care of North Carolina, LLC'S Public Written Comments on Bio-Medical Applications of North Carolina Inc.'s CON Application

Project ID#:	G-11737-19
Facility:	BMA of South Greensboro
Project Description:	Relocate 12 dialysis stations from BMA Burlington (Alamance County) to BMA of South Greensboro (Guilford County). Upon completion, BMA of South Greensboro will have 56 dialysis stations
County:	Guilford
FID#:	980838

Dear Ms. Saporito:

The July 2019 Semiannual Dialysis Report (SDR) indicates that there is a projected 20 station deficit in Guilford County. Total Renal Care of North Carolina, LLC (TRC or DaVita) and Bio-Medical Applications of North Carolina Inc. (BMA) submitted applications pursuant to Policy ESRD-2 for the August 1, 2019 review period, seeking a total of 22 dialysis stations. TRC submits these comments in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) to address the representations in the application submitted by BMA to relocate 12 dialysis stations from BMA Burlington in Alamance County to BMA of South Greensboro in Guilford County (Project ID# G-11737-19).

The Agency has deemed these applications competitive, because the approval of one may result in the denial of the other. In a comparative analysis, TRC's application is superior to BMA's. However, it is possible for the Agency to conditionally approve both applications in a manner it has done in the recent past.

The Agency could approve TRC's application to develop Central Greensboro Dialysis, a new 10 station facility (Project ID# G-11744-19) and also approve BMA's application in whole or in part by one of the following methods:

1. **Treat BMA Application as part Facility Need and part Policy ESRD-2**

Pursuant to the July 2019 SDR, BMA of South Greensboro is eligible to add stations via the Facility Need methodology:

October 1 Review Table (July SDR)

Required SDR utilization		**80%**
Name of Facility Identified in Section A, Question 5 - **BMA South Greensboro**		
July 2019 SDR		
Facility utilization rate (as of 12/31 of the previous year)		99.49%
# of certified stations (as of 12/31/2018)		49
# of pending stations *		0
Total certified and pending stations *		**49**
In-center patients (as of 12/31 of the previous year) – SDR2 (current SDR)		195
In-center patients (as of 6/30 of the previous year) – SDR1 (previous SDR)		188
Step	**Description**	
(i)	Difference (SDR2 - SDR1)	7
	Multiply the difference by 2 to project the net in-center change for 1 year	14
	Divide the projected net in-center change for 1 year by the number of in-center patients from SDR1	0.074468
(ii)	Divide the result of Step (i) by 12	0.006206
(iii)	Multiply the result of Step (ii) by 12	0.074468
(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	209.5213
(v)	Divide the result of Step (iv) by 3.2 patients per station	65.4754
	Subtract the number of certified and pending stations to determine the number of stations needed	16

* Include all additional stations approved and previously proposed. Do not subtract stations approved or previously proposed to be relocated to another facility.

BMA could have applied for 10 of its proposed 12 stations under the Facility Need methodology.[1] That review cycle would start October 1, 2019. Because these competitive applications were filed for the August 1, 2019 review cycle, the Agency decision is due in late December. Late December would also fall within the 5-month review cycle of a September-filed application.

If the Agency treats BMA's application partly as an early-filed Facility Need Methodology Application (for 10 stations) and partly as a Policy ESRD-2 Application (for 2 stations), BMA's Application would only take 2 of the 10 deficit stations remaining after approving TRC for the 10 stations it applied for under Policy ESRD-2, since Facility Need Applications do not require a deficit of stations. Both applications could be approved with eight (8) Policy ESRD-2 stations to spare.

2. Downsize BMA to 10-station expansion

If the Agency deems that BMA's application must be entirely reviewed as a Policy ESRD-2 Application, both applications could still be approved if the Agency downsizes BMA's Application by two (2) stations.

[1] In fact, BMA fails to conform to Criterion 4 for not demonstrating how its current application is a more effective alternative than filing a Facility Need application.

There is substantial, recent Agency precedent for downsizing one or more competing applications so that all applicants in a competitive review receive something.[2]

3. Let BMA choose Option 1 or 2

The Agency could approve BMA under the following alternative conditions:

a. BMA is approved for all 12 stations for which it applied if BMA accepts a condition stating that 10 of the 12 stations are approved as Facility Need Methodology stations. Two (2) stations could be approved as Policy ESRD-2 stations.

b. Alternatively, BMA is approved for only 10 stations if BMA does not accept the former alternative condition, all of which would be treated as Policy ESRD-2 stations.

In its Conditional Approval response letter, BMA would inform the Agency which condition it wanted to accept.

Comparative Analysis

If the Agency, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, decides not to pursue one of the three options allowing both applications to be approved, TRC's application is comparatively superior to BMA's application.

1. Access to Alternative Providers

This is the most important comparative factor in this competitive review. BMA concedes that the 20-station deficit of stations presents an opportunity for an additional, alternative provider to enter Guilford County.

On page 60 of its application:

"BMA also notes that with a 20 station deficit as published in the July 2019 SDR it is possible that another provider may apply to transfer stations into Guilford County. The only provider with a sufficient number of surplus stations in a contiguous county would be DaVita Dialysis.

Approval of this application to relocate 12 stations into BMA of South Greensboro will necessarily result in the denial of an application by DaVita Dialysis. The station deficit is 20 stations. If BMA is approved to relocate 12 stations into BMA of South Greensboro then the deficit is reduced to eight stations.

[2] Attachment 1 contains the 2014 Agency Findings for the Nash County competitive dialysis applications submitted by BMA and TRC, along with the Court of Appeals opinion upholding the Agency's decision in those findings. Moreover, Attachment 2 contains the April 5, 2019 Agency Findings for Mecklenburg County Bed and Operating Room Applications, where the Agency downsized applicants for acute care beds and operating rooms.

The NC State Medical Facilities Plan has determined that the minimum dialysis facility size is 10 stations. Approval of BMA for all 12 stations will remove the possibility of approval of an application by DaVita because the deficit would be reduced to less than 10 stations."

Approval of Central Greensboro Dialysis would introduce an additional alternative provider in Guilford County, creating greater patient choice. Therefore, with regard to providing Guilford County dialysis patients access to an alternative provider, the proposal submitted by TRC is the more effective alternative.

2. SMFP Principles - Home Training

While BMA of South Greensboro will refer home patients to BMA of Greensboro, Central Greensboro Dialysis will offer home training and support to patients on site making TRC's proposal the more effective alternative with respect to this comparative factor.

3. Access by Underserved Groups

BMA provided the following in response to Section L question 3(b)

Projected Payor Mix during the Second Full Operating Year

Payor Source	In-center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self Pay		1.19%				
Insurance **		58.55%				
Medicare **		5.73%				
Medicaid **		5.35%				
Other: Medicare / Commercial		25.13%				
Other: Misc. (includes VA)		4.04%				
Total		100%				

* Including any managed care plans.

BMA does not include its policy on Charity Care or reduced cost care in response to Section L question 4(b). However, on its Form F.2 Income Statement on page 86, BMA states:

"The applicant does not collect data on patients receiving charity care. Therefore, the applicant cannot quantify the number of patients receiving charity care each year. The applicant generally assumes that all patients desire and plan to attend 1o legitimate medical bills. However, in some cases, patients do not have sufficient financial resources to attend to all medical bills; this results in unpaid or un-collectable accounts. The applicant allocates these un-collectables to a "Bad Debt" account."

It goes on to say in its Form F.2 Income Statement Assumptions:

"The Charity Care line is actually facility contributions to the American Kidney Fund."

An additional inconsistency is the addition of a separate line item for "Other: Medicare/ Commercial" when the CON application requests that the Medicare line include any managed care plans. It is unclear what the 25.13% accounts for, but it certainly appears to include commercial insurance. These inconsistent statements make it unclear what then is represented in its payor mix.

If a comparison is made of the information as presented in each application:

(a) Medicare: TRC is the more effective alternative with 75.6% vs BMA's 5.73%[3]

(b) Medicaid: TRC is the more effective alternative with 6.1% vs BMA's 5.35%

(c) Self Pay: The proposals are equally effective or not possible to compare given the inconsistencies noted above regarding BMA's responses regarding charity care.

With regard to access by underserved groups, the proposal submitted by TRC is the more effective alternative.

4. Staffing

a. Direct Care Staff Salaries

The following table outlines the projected annual salaries and benefits for direct care staff in BMA and TRC's applications:

	TRC Salary during OY2	BMA Salary during OY2
RN	$67650 $27060 (taxes & benefits at 40%) =>$94710	$75005 $27002 (taxes & benefits at 36%) =>$102007
Home RN	$32800 $13120 (taxes & benefits at 40%) =>$45920	-
PCT	$32800 $13120 (taxes & benefits at 40%) =>$45920	$31820 $11455 (taxes & benefits at 36%) =>$43275

Central Greensboro Dialysis projects the higher annual salary for Home Training Nurse and PCTs. TRC's proposal is the more effective alternative with regard to this comparative factor.

[3] Looking at BMA's revenue projections, it appears that they may have transposed the values for Insurance and Medicare in the table on page 57 of their application. Even if that is the case, TRC still proposes a higher Medicare percentage (75.6%) compared to BMA (58.55%).

b. Availability of Staff and Medical Director

While both applications demonstrate the availability of a Medical Director, BMA's application indicates that its present staffing for 49 stations (for 171 patients at the end of the last full operating year) will remain unchanged for the proposed 56 stations and an additional 40 patients (projected 211 patients at the end of OY2).

BMA's direct care staff projections are insufficient. Therefore, TRC's proposal is the more effective alternative with regard to this comparative factor.

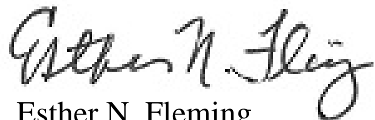
5. Other Factors

Relative to the other factors that the Agency historically uses in comparative analyses for ESRD, TRC and BMA are equally effective or the responses are not conducive to comparison.

Upon further review, TRC may determine that some non-conformities, inconsistencies or errors exist in the BMA application.

You can contact me at 704-323-8384 if you have any questions or need more information.

Sincerely,



Esther N. Fleming
Director, Healthcare Planning

Attachment 1:

- March 6, 2014 Agency Findings for Nash County applications Project ID# L-10182-13 and Project ID# L-10211-13

- June 7, 2016 Court of Appeals of North Carolina Opinion re: BMA v NC DHSR & TRC

Attachment 2:

- April 5, 2019 Agency Findings for Mecklenburg County Bed and Operating Room Applications

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE:	February 27, 2014
FINDINGS DATE:	March 6, 2014
PROJECT ANALYST:	Julie Halatek
INTERIM CHIEF:	Martha J. Frisone
PROJECT I.D. NUMBER:	L-10182-13 / Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Rocky Mount / Add 11 dialysis stations for a total of 41 dialysis stations upon completion of this project and Project I.D. #L-10177-13 / Nash County
	L-10211-13 / Total Renal Care, Inc. d/b/a Nash County Dialysis / Develop a new 12-station kidney disease treatment center in Nash County / Nash County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C - BMA Rocky Mount
C - Nash County Dialysis

The 2013 State Medical Facilities Plan (2013 SMFP) and the July 2013 Semiannual Dialysis Report (July 2013 SDR) provide a county need methodology for determining the need for new dialysis stations. According to Section 2(E) of the dialysis station county need methodology, found on page 380 of the 2013 SMFP:

"*If a county's December 31, 2013 projected station deficit is 10 or greater and the July SDR shows that utilization of each dialysis facility in the county is 80 percent or greater, the December 31, 2013 county station need determination is the same as the December 31, 2013 projected station deficit. If a county's December 31, 2013 projected station deficit is less than 10 or if the utilization of any dialysis facility in*

> *the county is less than 80 percent, the county's December 31, 2013 station need determination is zero."*

The county need methodology results in a need determination for 19 dialysis stations in Nash County.

Two applications were received by the Certificate of Need Section (CON Section) for development of the 19 dialysis stations. The two applicants applied for a total of 23 dialysis stations. Pursuant to the need determination in the July 2013 SDR, 19 dialysis stations is the maximum number of dialysis stations that may be approved in this review.

BMA Rocky Mount – Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Rocky Mount (BMA Rocky Mount) proposes to add 11 stations to its existing facility for a total of 41 stations upon completion of this project and Project I.D. #L-10177-13 (relocate 12 stations to a new facility in Nash County). The July 2013 SDR identifies a need determination for no more than 19 dialysis stations in Nash County. The applicant proposes to develop no more than 11 new dialysis stations in Nash County. Therefore, the application is conforming to the need determination in the July 2013 SDR.

Nash County Dialysis – Total Renal Care, Inc. d/b/a Nash County Dialysis (Nash County Dialysis) proposes to develop a new 12-station dialysis facility in Rocky Mount, Nash County. The July 2013 SDR identifies a need determination for no more than 19 dialysis stations in Nash County. The applicant proposes to develop no more than 12 new dialysis stations in Nash County. Therefore, the application is conforming to the need determination in the July 2013 SDR.

There is one policy in the 2013 SMFP applicable to both applications. Policy GEN-3: Basic Principles 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."*

BMA Rocky Mount

<u>Promote Safety and Quality</u>

In Section II.1, page 25, the applicant states:

> *"…BMA's parent company, Fresenius Medical Care, encourages all BMA facilities to attain the FMC UltraCare certification. This is not a one time test, but rather is an ongoing process aimed at encouraging all staff, vendors, physicians, and even patients to be a part of the quality care program. Facilities are evaluated annually for UltraCare certification. …"*

In Section II.3, pages 34-36, the applicant describes the methods used to ensure and maintain quality of care, which include the following:

- Facility Programs
  - Quality Improvement Program
  - Staff Orientation and Training
  - In-Service Education

- Corporate programs
  - Technical Audits
  - Continuous Quality Improvement

- External Surveys - DFS Certification Surveys
- Core Indicators of Quality
- Single Use Dialyzers

BMA Rocky Mount adequately demonstrates that the proposal will promote safety and quality.

<u>Promote Equitable Access</u>

In Section II.1, pages 26-27, the applicant states:

> *"BMA has removed the economic barriers with regard to access to treatment. The overwhelming majority of dialysis treatments are covered by Medicare/Medicaid; in fact, within this application, BMA is projecting that 84.2% of the In-center dialysis treatments will be covered by Medicare or Medicaid; an additional 3.7% are expected to be covered by VA. Thus, 87.9% of the In-center revenue is derived from government payors. …*
>
> *10A NCAC 2202 (b)(8) requires a commitment by BMA 'to admit and provide services to patients who nave* [sic] *no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.' BMA provides such assurances within Section VI of this application.*
>
> *…*
>
> *BMA is also keenly sensitive to the second element of 'equitable access' - time and distance barriers. At this time, Nash County has two operational dialysis facilities and one proposal for a new facility under CON review (FMC South Rocky Mount,*

Project ID # L-10177-13). As the dialysis patient population of Nash County continues to increase, the need for dialysis stations will continue to increase. BMA will apply to develop new dialysis facilities when needed. …

Over the years, BMA has sought to develop new facilities and new dialysis stations in an effort to make dialysis convenient to the patient. This application to add 11 dialysis stations to BMA Rocky Mount is another example of BMA efforts to meet the needs of the ESRD patient population of Nash County."

In Section VI.1(a), page 54, 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. …

BMA of North Carolina has 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. …

The facility will conform to the North Carolina State Building Code, the National Fire Protection Association 101 Life Safety Code, the Americans with Disabilities Act, ANSI Standards for Handicapped Access, and any other applicable requirement of federal, state, and local bodies."

In Section VI.2, page 57, the applicant states:

"The design of the facility is such that handicapped persons will have easy access to the facility; the facility will comply with ADA requirements. It was constructed in compliance with applicable sections of North Carolina State Building Code, Vol. #1-General Construction, which lists minimum requirements for the handicapped applicable to institutional and residential structures. In addition, wheelchairs are always available for transporting patients who are unable to stand or walk."

In Section VI.7, page 58, the applicant states:

"The BMA admission policy states that 'patients shall be accepted for treatment at BMA when such treatment is deemed indicated and appropriate according to the clinical judgment of the patients' attending physician. No arbitrary criteria with respect to the patient's age or magnitude of complicating medical problems are established.'

BMA also has an AIDS policy that states 'a diagnosis of AIDS or HIV-positive status (absent other contraindications) is not acceptable reason to refuse referral of a patient. Established referral patterns should be followed without regard to AIDS status of patients.'

Please see Exhibit 9 for a copy of policy/procedure."

BMA Rocky Mount adequately demonstrates that medically underserved groups will have equitable access to the proposed services.

Maximize Healthcare Value

In Section II.1, page 27, the applicant states:

> *"BMA is not projecting a capital expenditure for this project. BMA is not seeking State or Federal monies to develop the CON application or the additional dialysis stations at the facility; BMA is not seeking charitable contributions. Rather, BMA, through its parent company, FMC is taking on the burden to complete this addition of stations in an effort to bring dialysis treatment close to the patient homes."*

BMA Rocky Mount adequately demonstrates that the proposed project will maximize healthcare value.

BMA Rocky Mount adequately demonstrates that projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served.

The application is consistent with Policy GEN-3 and is therefore conforming to this criterion.

Nash County Dialysis

Promote Safety and Quality

In Section II.3, pages 25-27, the applicant states:

> *"DaVita HealthCare Partners Inc., operating at* [sic] *Total Renal Care, Inc. d/b/a Nash County Dialysis is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita's Quality Management Program is facilitated by a dedicated clinical team of Registered Nurses who make up our Clinical Support Services and Biomedical Quality Management Coordinators working under the direction of our Director of Clinical Support Services and Area Biomedical Administrator. These efforts receive the full support and guidance of the clinical executive leadership team of DaVita. Combined, this group brings hundreds of years of ESRD experience to the program. The program exemplifies DaVita's total commitment to enhancing the quality of patient care through its willingness to devote the necessary resources to achieve our clinical goals.*
>
> *Our Quality Management Program includes the following Quality Programs:*
>
> - *Quality Improvement Methodology - utilizing outcome-driven, patient centered management programs to measure, monitor and manage outcomes.*

- *Computerized Information System - integrating clinical and laboratory information for comprehensive outcomes tracking and reporting.*
- *Teammate and Patient Education Program - ensuring continuous updates and training to ensure high quality patient care.*
- *Quality Assessment Audit Program - systematically utilizing a comprehensive detailed assessment tool to assure the highest quality standards in every facility.*
- *Quality Management Team - experienced clinical facilitators for implementing and maintaining ongoing quality improvement programs.*
- *Quality Biomedical Team - experienced specialists in all aspects of Biomedical requirements (i.e., water treatment, disinfection and machine maintenance).*

DaVita's Quality Management Team works closely with each facility's Quality Improvement team to:

- *Improve patient outcomes*
- *Provide patient and teammate training*
- *Develop Quality Improvement Programs*
- *Facilitate the Quality Improvement Process*
- *Continuously improve care delivered*
- *Assure facilities meet high quality standards*

DaVita has a quality improvement Program, IMPACT (Incident Management of Patients Actions Centered on Treatment), with focus care in the first 90 days to improve key indicators and to address the elevated risk of mortality for patients new to dialysis. …

Our goal is to have each facility serve as a quality improvement laboratory, where successful outcomes can be disseminated throughout DaVita.

…

Nash County Dialysis will be attended by Dr. Will Bynum and other admitting Nephrologists who directly oversee the quality of care of the dialysis facility. In addition, Dr. Bynum will serve as Medical Director and will provide the overall medical supervision of the dialysis unit. The facility administrator is the day to day manager of the facility and maintains the company's Quality Management Program that monitors the overall care of the patients. The Quality Management Program is reviewed by the Quality Assurance Committee consisting of the Nephrologists, Unit Administrator, clinical teammates, social worker and the dietitian. This Quality Assurance Program will address Nash County Dialysis as a whole, then compares each sister unit to the whole and to industry standards. The Committee then makes recommendations to improve quality. Continuous Quality Improvement teams address facility issues with the goal of improving patient care and patient outcomes."

Nash County Dialysis adequately demonstrates that the proposed project will promote safety and quality.

Promote Equitable Access

In Section VI.1(a), page 45, the applicant states:

> *"Nash County Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. We will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.*
>
> *Nash County Dialysis will make every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. The facility will provide dialysis six days per week with two patient shifts per day to accommodate patient need.*
>
> *Nash County Dialysis will not require payment upon admission to its services; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons."*

In Section VI.2, page 48, the applicant states:

> *"Nash County Dialysis will satisfy all state requirements and local building codes to allow equal access for handicapped patients. Many of our patients will be severely physically handicapped. The facility will ensure access by these individuals by providing wheelchair ramps, handicapped bathrooms, wheelchair scales and ADA compliant doors at the facility. Additionally, our teammates will be trained to assist handicapped persons into and out of their dialysis treatment stations."*

In Section VI.7, page 49, the applicant states:

> *"Nash County Dialysis will have an open policy and accept all patients including those with hepatitis and/or AIDS. This facility will have an established isolation area for the treatment of any patient with hepatitis and will accept patients with AIDS. See* ***Exhibit 25*** *for a copy of the Interpretive Guidelines, Tag Number V266 and the DaVita Hemodialysis Policies, Procedures and Guidelines referencing Hepatitis Surveillance, Vaccination and Infection Control Measures. Total Renal Care, Inc. complies with all federal and state requirements pertaining to isolation of patients with communicable diseases."* (emphasis in original)

In Section VI.1(c), page 46, the applicant projects that that 91.9 percent of its patients will have some or all of their services paid for by Medicare or Medicaid. On pages 45-46, the applicant also provides the basis for these projections as follows:

> *"TRC currently does not have any facilities in Nash County from which to draw this information. Therefore we have based our payor mix on the average percentages of patients who are currently dialyzing at Wilson Dialysis Center. Wilson Dialysis Center is a DaVita owned facility in Wilson County, which is contiguous to Nash*

County. The pertinent demographics of Wilson County, while not identical to Nash County, are similar. …"

Nash County Dialysis adequately demonstrates that the proposed project will promote equitable access to the proposed services.

Maximize Healthcare Value

In Section III.9, pages 35-36, the applicant states:

"Nash County Dialysis will promote cost-effective approaches in the facility in the following ways:

- *This application calls for the development of a new, state of the art facility that will require the purchase of hundreds of items that will include dialysis machines, chairs and TVs. The parent corporation, DaVita HealthCare Partners, operates over 1,900 dialysis facilities nationwide. The corporation has a centralized purchasing department that negotiates national contracts with numerous vendors in order to secure the best product available at the best price. We will be purchasing the equipment for this project under this procedure.*

- *Nash County Dialysis will purchase all of the products utilized in the facility, from office supplies to drugs to clinical supplies, under a national contract in order to secure the best products at the best price.*

- *Nash County Dialysis will be a facility that utilizes single-use dialyzers. The dialyzers will be purchased under a national contract in order to get the best quality dialyzer for the best price.*

- *Nash County Dialysis will install an electronic patient charting system that reduces the need for paper in the facility. Much of the other documentation in the facility will also be done on computer which reduces the need for paper.*

- *Nash County Dialysis Bio-medical Technician assigned to the facility will conduct preventative maintenance on the dialysis machines on a monthly, quarterly and semi-annual schedule that reduces the need for repair maintenance and parts. This will extend the life of the dialysis machines.*

- *Nash County Dialysis will have an inventory control plan that ensures enough supplies are available without having an inordinate amount of supplies on hand. Supply orders will be done in a timely manner to ensure that the facility does not run out of supplies, thus avoiding emergency ordering, which is costly."*

Nash County Dialysis adequately demonstrates that the proposed project will maximize healthcare value.

Nash County Dialysis adequately demonstrates that projected volumes for the proposed services incorporate basic principles in meeting the needs of patients to be served.

The application is consistent with Policy GEN-3 and is therefore conforming to this criterion.

Summary

Both applications are conforming to the need determination in the July 2013 SDR for 19 dialysis stations in Nash County. However, the limit on the number of dialysis stations that may be approved in this review is 19. Collectively, the two applicants propose a total of 23 dialysis stations. Therefore, even if both applications are conforming or conditionally conforming to all statutory and regulatory review criteria, both applications cannot be approved as proposed. See the Conclusion following the Comparative Analysis for the decision.

(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 Rocky Mount
C - Nash County Dialysis

There are currently two dialysis facilities located in Nash County. FMC of Spring Hope is currently certified for 10 stations and is approved to add 3 stations (Project I.D. #L-8796-12). BMA Rocky Mount is currently certified for 42 stations. There is a third facility approved—FMC South Rocky Mount—which will be certified for 12 stations (Project I.D. #L-10177-13). Those 12 stations are being relocated from BMA Rocky Mount, which will leave BMA Rocky Mount with 30 certified stations when Project I.D. #L-10177-13 is complete, if no further stations are approved. See the following table:

Nash County Dialysis Facilities			
Dialysis Facility	**Certified Stations 12/31/12**	**% Utilization**	**Patients Per Station**
FMC Spring Hope*	10	82.50%	3.3
BMA Rocky Mount**	42	91.07%	3.6

Source: July 2013 SDR, Table A.
*FMC Spring Hope is approved to develop three additional stations (Project I.D. #L-8796-12) for a total of 13 stations upon project completion.
**BMA is approved to relocate 12 stations to a new facility (FMC South Rocky Mount) (Project I.D. #L-10177-13).

Table B: ESRD Dialysis Station Need Determinations by Planning Area in the July 2013 SDR indicates that, as of December 31, 2012, there were 259 total patients from Nash County. Pursuant to the need determination in the 2013 SMFP and the July 2013 SDR, there is a need for 19 additional dialysis stations in Nash County.

BMA Rocky Mount proposes to add 11 stations at its existing facility in response to the need determination. The applicant was previously approved in Project I.D. #L-10177-13 to relocate 12 stations and the home training program to a new facility in south Rocky Mount. In Section II, page 13, the applicant states that it plans to maintain a small home training presence at the existing BMA Rocky Mount facility.

Population to be Served

In Section III.7, page 42, the applicant provides projected patient origin for the first two years of operation following completion of the proposed project, as illustrated in the following table:

BMA Rocky Mount - Projected Patient Origin						
County	Year One: 2015		Year Two: 2016		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis Patients	In-Center Patients	Home Dialysis Patients	Year 1	Year 2
Nash	73.5	0.0	73.1	2.0	55.5%	56.0%
Edgecombe	32.0	0.0	32.0	0.0	24.1%	23.9%
Halifax	25.0	0.0	25.0	0.0	18.9%	18.6%
Wilson	1.0	0.0	1.0	0.0	0.8%	0.7%
Warren	1.0	0.0	1.0	0.0	0.8%	0.7%
TOTAL	**132.5**	**0.0**	**132.1**	**2.0**	**100.0%**	**100.0%**

The applicant adequately identifies the population it proposes to serve.

Need Analysis

The assumptions and methodology used to project in-center utilization are provided in Section II.1, pages 14-16 and pages 19-22, and Section III.7, pages 40-43. The applicant states on pages 14-16:

> *"**Assumptions:***
>
> 1. *This project is scheduled for completion December 31, 2014.*
>   *Operating Year 1: January 1, 2015 through December 31, 2015.*
>   *Operating Year 2: January 1, 2016 through December 31, 2016.*
>
> 2. *The July 2013 SDR reports that BMA Rocky Mount was operating at 91.07% utilization with a census of 153 patients dialyzing on 42 certified dialysis stations as of December 31, 2012.*
>
> 3. *BMA does **not** assume that the patient population of Nash County will grow at the Nash County Five Year Average Annual Change Rate as published in the July 2013 SDR (9.6%). Rather, BMA will use a much more conservative growth rate of 2.1%.*

The growth rate as published within the SDR is suspect. The DHSR Medical Facilities Planning Section has developed this SDR using provider self reported information. This was the first time the SDR was prepared in such a manner.

BMA, like all other providers in North Carolina has participated in the Self Reporting process. Unfortunately, the BMA Rocky Mount and BMA East Rocky Mount facilities erred in preparation of the self reported data. Rather than provide the county of residence for all patients, the facilities actually reported all patients as residing in the County of the dialysis facility. Consequently, while the information in Table A of the SDR is correct, the information in Table B contains errors.

BMA has brought the errors to the attention of the Division of Health Service Regulation and all other dialysis providers currently operating in North Carolina. A copy of the information provided to DHSR is included in Exhibit 32 of this application.

4. *In CON Project ID # L-10177-13, BMA projected that 26 dialysis patients from BMA Rocky Mount, who reside in Nash County would transfer their care to the new FMC South Rocky Mount. Within this application, BMA will maintain those projected transfers.*

5. *As of June 30, 3013* [sic], *BMA Rocky Mount was serving a total of 59 in-center dialysis patients, and 18 home patients, from counties other than Nash. The next table identifies the county of residence for the patient population of BMA Rocky Mount as of June 30, 2013.*

BMA Rocky Mount	*June 30, 2013*		
	In-Center	*PD*	*HH*
Nash	*95*	*12*	*5*
Edgecombe	*32*	*10*	*0*
Halifax	*25*	*8*	*0*
Wilson	*1*	*0*	*0*
Warren	*1*	*0*	*0*
TOTAL	*154*	*30*	*5*

6. *BMA assumes that the patient population of BMA Rocky Mount but residing in other Counties is dialyzing at BMA Rocky Mount as a function of patient choice. BMA will not project any increase within this segment of the BMA Rocky Mount patient population. Each of the other Counties identified has at least one existing dialysis facility. In the interest of providing a most conservative approach to projections of future patient populations to e* [sic] *served, BMA does not project additional growth of the patient population from other Counties. BMA does assume that these patients will continue to dialyze at BMA Rocky Mount as a function of patient choice.*

7. *As noted above, BMA will utilize a growth factor of 2.1%. The basis for this growth factor is included within the information provided at Exhibit 32, Tab F.*

BMA has calculated a Five Year Average Annual Change Rate for Nash County using the more correct data from the BMA Rocky Mount and BMA East Rocky Mount facilities. The corrected information is included in Exhibit 32, Tab B. BMA incorporated this information into the Patient Origin Report as provided by DHSR Medical Facilities Planning Section and included at Exhibit 32, Tab C. The resultant corrected information is included at Exhibit 32, Tab D.

8. *BMA assumes that in Operating Year 2 of this project, two of the Nash County in-center patients will change modality to home peritoneal dialysis."* (emphasis in original)

The applicant states on pages 41-43:

*"**Methodology:***

The next table represents BMA calculations of future patient population at BMA Rocky Mount.

BMA begins with the 95 Nash County in-center dialysis patients served as of June 30, 2013.	*95 In-center patients*
BMA projects this patient population forward for 6 months to December 31, 2013 using a growth rate of one half of 2.1%.	*[95 X (.021 / 12 X 6)] + 95 = 96.0*
BMA projects this in-center patient population forward for 12 months to December 31, 2014. This is the projected certification date of this project.	*(96 X .021) + 96 = 98.0*
BMA subtracts the 26 Nash County residents projected to transfer to the new FMC South Rocky Mount.	*98.0 – 26 = 72*
BMA adds the 59 in-center patients from other counties. This is the projected beginning census for this project.	*72.0 + 59 = 131*
BMA projects the Nash County in-center patient population forward for 12 months to December 31, 2015.	*(72.0 X .021) + 72.0 = 73.5*
BMA adds the 59 in-center patients from other counties. This is the projected ending census for Operating Year 1.	*73.5 + 59 = 132.5*
*BMA projects the Nash County in-center patient population forward for 12 months to December 31, 2016.**	*(73.5 X .021) + 73.5 = 75.1*
BMA subtracts two patients projected to change to modality to home peritoneal dialysis.	*75.1 – 2 = 73.1*
BMA adds the 59 in-center patients from other counties. This is the projected ending census for Operating Year 2.	*73.1 + 59 = 132.1*

*The applicant made a rounding error which does not alter the projected utilization. In projecting the Nash County in-center population forward for 12 months to December 31, 2016, the applicant shows an in-center patient population calculation of 75.1. The calculation, done out with more than one decimal place, is (73.5 X .021) + 73.5 = 75.0435. While the calculation methods are correct, rounding is incorrect; the projected number of Nash County in-center patients for the end of Operating Year Two is still 73 patients.

Summary:

Based on the above, BMA projects to serve the following number of patients by modality and county of residence for Operating Years One and Two:

BMA Rocky Mount	*Operating Year 1*		*Operating Year 2*		*County patients as a percent of TOTAL*	
	In-Center	*PD*	*In-Center*	*PD*	*Year 1*	*Year 2*
Nash	*73.5*		*73.1*	*2*	*55.5%*	*56.0%*
Edgecombe	*32.*		*32*		*24.1%*	*23.9%*
Halifax	*25*		*25*		*18.9%*	*18.6%*
Wilson	*1*		*1*		*0.8%*	*0.7%*
Warren	*1*		*1*		*0.8%*	*0.7%*
TOTAL	*132.5*	*0.0*	*132.1*	*2.0*	*100.0%*	*100.0%*

> *BMA also recognizes that Craig Smith, CON Section Chief, has previously indicated that patients are not partial patients, but rather are whole. In the following utilization calculations BMA has rounded down to the whole number. Utilization at BMA Nations Ford* [sic] *is expected to be:*
>
> *Operating Year 1*
> *132 patients dialyzing on 41 stations = 3.22 patients per station*
> *132 (4 X 41) = .805, or 80.5%*
>
> *Operating Year 2*
> *132 patients dialyzing on 41 stations = 3.22 patients per station*
> *132 (4 X 41) = .805, or 80.5%"* (emphasis in original)

Projected utilization is based on reasonable, credible, and supported assumptions. Specifically, continued growth at the facility is adequately supported by the historic growth. Furthermore, the applicant makes adjustments for the patients expected to transfer to the new facility in south Rocky Mount. Therefore, the applicant adequately demonstrates the need for the proposed stations.

In summary, the applicant adequately identified the population to be served and demonstrated the need this population has for the addition of 11 dialysis stations to the existing BMA Rocky Mount facility. Therefore, the application is conforming to this criterion.

Nash County Dialysis proposes to develop a new 12-station facility offering in-center dialysis and training for home hemodialysis and home peritoneal dialysis. An unrelated developer will purchase the property and build a shell building. Nash County Dialysis will lease the building. Nash County Dialysis will then up-fit the shell building, hire and train employees, purchase dialysis machines, and purchase the equipment needed to operate the facility.

Population to be Served

In Section III.7, page 29, the applicant provides projected patient origin for the first two years of operation following completion of the proposed project, as illustrated in the following table:

Nash County Dialysis - Projected Patient Origin						
County	Year One: 2015/2016		Year Two: 2016/2017		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis Patients	In-Center Patients	Home Dialysis Patients	Year 1	Year 2
Nash	33	8	37	9	87.2%	88.5%
Wilson	6	0	6	0	12.8%	11.5%
TOTAL	**39**	**8**	**43**	**9**	**100.0%**	**100.0%**

The applicant adequately identified the population proposed to be served.

<u>Need Analysis</u>

The assumptions and methodology used to project in-center utilization are provided in Section II.1, pages 13-17, and Section III.7, pages 30-34. The applicant states on pages 13-14:

> *"The July 2013 SDR Table B indicates that there were 259 patients living in Nash County as of December 31, 2012 including 43 home patients. Of the 216 in-center patients, 186 were receiving dialysis from a Nash County facility and the other 30 were receiving dialysis from a facility outside Nash County. See the table below excerpted from the 12/31/2012 Patient Origin Data chart (**Exhibit 11**).*

Provider Number	*Facility Name*	*Facility County*	*Home Patients*	*In-Center*	*County Total*
34-2517	*Rocky Mount Kidney Center (BMA)*	*Nash*	*33*	*153*	*186*
34-2644	*FMC of Spring Hope*	*Nash*	*0*	*33*	*33*
34-2589	*Zebulon Kidney Center (BMA)*	*Wake*	*0*	*14*	*14*
34-2507	*Wilson Dialysis (DaVita)*	*Wilson*	*6*	*5*	*11*
34-2637	*Forest Hills Dialysis (DaVita)*	*Wilson*	*0*	*5*	*5*
34-2577	*Dialysis Care of Edgecombe County (DaVita)*	*Edgecombe*	*0*	*3*	*3*
34-2512	*BMA of Raleigh Dialysis*	*Wake*	*2*	*0*	*2*
34-2596	*FMC Dialysis Services East Carolina University*	*Pitt*	*1*	*1*	*2*
34-2571	*Dialysis Care Franklin County (DaVita)*	*Franklin*	*0*	*2*	*2*
34-2502	*Greensville Dialysis Center (FMC)*	*Pitt*	*1*	*0*	*1*
	Nash Totals		*43*	*216*	*259*

> *Total Renal Care, Inc. uses the following assumptions in projecting a future census for the Nash County ESRD dialysis patient population.*
>
> - *TRC assumes that a significant number of Nash County in-center ESRD dialysis patients are leaving Nash County three times a week to receive their dialysis treatments at facilities outside Nash County.*
>
> - *TRC assumes that all ESRD patients prefer to dialyze at a facility that is convenient and close to their place of residence. Specifically, ESRD patients residing in Nash County will want to dialyze at a dialysis facility in Nash County. Since a significant number of ESRD patients who live in Nash County are apparently leaving the county to obtain their dialysis treatments elsewhere, if those patients have a choice of a facility that is closer and has*

greater flexibility and availability of shift times such as the new facility would provide, many of them will find it more convenient to transfer to a facility within Nash County. Additionally some patients residing in contiguous counties such as Wilson and Edgecombe may find a facility in Rocky Mount more convenient than a facility in their own county and may desire to transfer to the new facility.

- *The patient population in Nash County will be projected forward using the current Five Year Average Annual Change Rate of 9.6% as published in the July 2013 SDR.*
- *TRC assumes that the percentage of patients dialyzing on home therapies on June 30, 2015 will be the same as the percentage published in the July 2013 SDR. The July 2013* [SDR] *indicates that as of December 31, 2012, 16.6% of the dialysis patients in Nash County were home dialysis patients.*
- *A new facility should project its growth by taking into account patient proximity to its location, and also allowing for the continued growth of existing dialysis facilities in the County by focusing its projections on patients served by sister facilities of the proponent of the application in other nearby counties. This approach builds the new facility's growth projections upon the existing referral patterns that have brought patients to its sister facilities.*
- *Letters of support from patients indicating a willingness to consider transferring to a new facility are strong evidence of patient support and commitment."* (emphasis in original)

The applicant states, regarding the methodology used to determine utilization, on pages 31-32:

*"**<u>Calculating the Future Number of In-Center Patients</u>***

*The excerpt from the Patient Origin Data chart above shows that as of 12/31/2012, TRC provided in-center dialysis to 15 residents of Nash County at facilities outside of the County. As demonstrated by the patient support letters in **Exhibit 12**, as of September 1, 2013, that number had grown to at least 25 patients.*

Facility	*Nash County in-center patients as of 12/31/2012 based on Patient Origin Data*	*Nash County in-center patients as of 09/1/2013 based on Support Letters*
Wilson Dialysis in Wilson County	*5*	*8*
Forest Hills Dialysis in Wilson County	*5*	*7*
Dialysis Care of Edgecombe County	*3*	*10*
Dialysis Care Franklin County	*2*	
TOTAL	*15*	*25*

In addition to these patients, as of September 1, 2013 Dr. Bynum, a nephrologist, also provided in-center dialysis to 1 Nash County dialysis patient who did not identify where she was currently receiving her dialysis, but indicated that she would consider transferring to the new Nash County Dialysis when it is open. There are

*also 6 dialysis patients who reside in Wilson County who indicated their willingness to consider transferring to the new facility since it would be more convenient for them than their current facility. See patient letters in **Exhibit 12**.*

*Thus, based on the patient support letters included in **Exhibit 12**, TRC begins its projections with 26 Nash County patients (25 from DaVita facilities and 1 whose current facility is unknown) and 6 Wilson County patients as of September 1, 2013.*

First, TRC projects the Nash County patient census forward for four months (to December 31, 2013), using the Five Year Average Annual Change Rate of 9.6% as published in the July 2013 SDR. This is the projected patient census as of December 31, 2013.

- *26 X 1.032 = 26.8*

TRC then projects that Nash County patient census forward for one full year, using the Five Year Average Annual Change Rate of 9.6% to derive the projected patient census as of December 31, 2014.

- *26.8 X 1.096 = 29.4*

<u>In-Center Patients at Certification</u>

TRC again projects the Nash County patient census forward, this time for 6 months, using the Five Year Average Annual Change Rate of 9.6% as published in the July 2013 SDR. This is the projected Nash County patient census for June 30, 2015, the day before the projected certification date for the project.

- *29.4 X 1.048 = 30.8*

In addition there are 6 Wilson County patients who have indicated by support letters that they would consider transferring to the new facility. We have not applied the Nash County Five Year Average Annual Change Rate to these patients since Wilson County's change rate would be different from Nash County's. We have simply added those patients to the Nash County census.

- *30.8 + 6 = 36.8*

Based on these calculations, on July 1, 2015, the projected certification date for the project, TRC is projecting that it will have 30 Nash County in-center patients and 6 Wilson County in-center patients for a total of 36 in-center patients.

<u>In-Center Patients at the End of Operating Years One and Two</u>

To calculate the in-center patients at the end of operating years one and two, TRC again applies the Nash County Five Year Average Annual Change Rate of 9.6% to the starting census of Nash County patients and then adds the 6 Wilson County in-

center patients to that total. This results in an in-center census of 39 patients at the end of Operating Year 1 and 43 patients at the end of Operating Year 2.

- *30.8 X 1.096 = 33.8 Nash County in-center patients plus 6 Wilson County in-center patients for a total of 39.8 or 39 in-center patients as of June 30, 2016, the end of Operating Year 1.*

- *33.8 X 1.096 = 37.0 Nash County in-center patients plus 6 Wilson County in-center patients for a total of 43.0 or 43 in-center patients as of June 30, 2017, the end of Operating Year 2."* (emphasis in original)

Projected utilization is based on reasonable, credible, and supported assumptions. Specifically, the applicant documents that as many as 32 in-center patients would be interested in transferring to the proposed facility. Continued growth of this population is also adequately supported by the five year average annual change rate as published by the Agency in the July 2013 SDR. Therefore, the applicant adequately demonstrates the need for the proposed 12-station facility.

In summary, the applicant adequately identified the population to be served and demonstrated the need this population has for the development of a new 12-station dialysis facility. 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.

NA - Both Applications

(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.

C - BMA Rocky Mount
C - Nash County Dialysis

BMA Rocky Mount – In Section III.9, pages 44-45, the applicant describes the alternatives it considered prior to the submission of its application:

"BMA of North Carolina has considered several alternatives to this project. …

(a) BMA considered not applying to develop these 11 stations. However, as noted within the application BMA is serving a significant number of dialysis patients who reside in Rocky Mount, Nash and other counties in the area. BMA expects this patient population to continue to increase based upon the patient relationship with BMA facilities and the participation of nephrology

physicians from Boice-Willis. BMA projections of patient population to be served certainly warrant 11 additional stations at the facility.

(b) *BMA could have chosen to develop a new facility pursuant to the County Need Determination, and could have applied for up to 19 dialysis stations. In fact, BMA has applied in August 2013 to develop the new FMC South Rocky Mount.*

…

BMA does not believe that another part of the county would be suitable for development of a new facility or 10 or more stations.

…

Development of new stations at BMA Rocky Mount was the most suitable alternative.

(c) *BMA could have applied by way of the County Need Determination to add some stations to its proposed FMC South Rocky Mount. However, within the application to develop FMC South Rocky Mount, BMA proved the need for 12 stations at that location. It is not likely that the proposed FMC South Rocky Mount facility could support additional stations and remain compliant with 10A NCAC 14C. 2203(a). Thus, BMA has made the decision to site stations at the BMA Rocky Mount facility. Development of new stations at BMA Rocky Mount was the most suitable alternative.*

(d) *BMA could have used the Nash County Five Year Average Annual Change Rate as published in the July 2013 SDR. BMA has noted its disagreement with the SDR as published. … BMA has offered an application which is based on credible information and offers a conservative approach to projections of need."*

Furthermore, the application is conforming with all other applicable statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative.

The applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion.

Nash County Dialysis – In Section III.9, pages 34-35, the applicant describes the alternatives it considered prior to the submission of its application:

"One alternative considered was to do nothing on our part. We determined that while this may be the least costly; however, it is not the most effective alternative for the large number [of] *dialysis patients we are serving who live in Scotland* [sic] *County who travel outside their county for dialysis treatments.*

The other alternative is to do the right thing and bring additional dialysis services and a new provider to the patients who live in Nash County. It was determined that the facility would be located in Rocky Mount. Most of the patient [sic] *who signed letters indicated that they live in or near Rocky Mount. The proposed site for the dialysis facility is near major highways that run north and south and east and west, providing easy access for patients.*

…

Total Renal Care will up-fit the shell building and turn it into a modern, state-of-the-art dialysis facility that will serve the needs of the ESRD dialysis patients living in Nash County, but dialyzing outside of the county. It will also be available to new dialysis patients who are diagnosed with End Stage Renal Disease and find themselves in need for dialysis treatments. Having a second provider in the county offers the Nephrologists and patients an alternative."

Furthermore, the application is conforming with all other applicable statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative.

The applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion.

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C - BMA Rocky Mount
C - Nash County Dialysis

BMA Rocky Mount – In Section VIII.1, page 62, the applicant states that this is an existing facility and no renovations are necessary to accommodate the 11 stations. All equipment is to be leased, not purchased. As a result, the applicant projects no capital costs. In Section IX, page 66, the applicant states that because this is an existing facility, there will be no start-up costs or initial operating expenses as a result of this project.

In Section X.1, page 67, the applicant provides the following information regarding the facility's allowable charge per treatment by payor source:

BMA Rocky Mount Allowable Charge per Treatment by Payment Source		
	In-Center	**Home PD**
Commercial Insurance*	$1,375.00	$1,375.00
Medicare	$234.00	$234.00
Medicaid	$137.29	$137.29
VA	$146.79	$147.85
Private Pay	$1,375.00	$1,375.00

*The applicant notes that commercial charges listed do not reflect actual reimbursement rates. The applicant states that it is industry standard for providers to have contractual relationships with various providers that results in less reimbursement than the stated charge.

In Section X, pages 68 and 74, the applicant projects revenues and operating costs for the first two operating years of the proposed project, as shown in the table below.

BMA Rocky Mount			
	Current Operating Year	Year 1	Year 2
Gross Revenue	$12,355,720	$8,256,342	$8,506,168
Contractual Adjustments	$2,962,347	$1,776,899	$1,844,268
Net Revenue	$9,393,372	$6,479,443	$6,661,899
Total Operating Costs	$7,009,864	$5,372,268	$5,511,318
Net Profit	$2,383,508	$1,107,175	$1,150,581

As shown in the table above, the applicant projects that revenues will exceed operating costs in each of the first two years of operation following completion of this project. Revenues and operating costs are based on reasonable, credible and supported assumptions, including the projected number of treatments, charges, reimbursement rates, contractual adjustments and salaries.

According to the Centers for Medicare & Medicaid Services (CMS), the End-Stage Renal Disease Prospective Payment System (ESRD PPS) base rate for CY 2012 was $234.81.[1] The applicant appears to use the CY 2012 ESRD PPS reimbursement rates in its pro formas. In Section X.1, pages 67-68, the applicant does not reduce the Medicare reimbursement rate by 20 percent. While Medicare will routinely pay for 80 percent of Medicare-approved dialysis treatments, the patient is responsible for the remaining 20 percent. Thus, the total revenue for each Medicare patient would be 100 percent of the maximum allowable charge: Medicare would pay 80 percent and the patient would pay 20 percent. Moreover, in Section X.2, page 68, the applicant provides a table with a line item labeled *"Other Deductions from Revenue (Total Contractual Allowances)"* and deducts more than 20 percent of the gross patient service revenue as contractual allowances. In Section X.4, pages 73-74, the applicant provides a table showing actual and estimated annual operating expenses. The applicant includes a line item for bad debt and charity expenses in its annual operating expenses. Between contractual adjustments and bad debt/charity items, the applicant reduces its gross revenue for the current operating year, Operating Year One, and Operating Year Two by 28.5 percent, 26.2 percent, and 26.4 percent, respectively.

In Section X.4, page 76, the applicant discusses the impact of a potential cut in Medicare reimbursement rates due to the implementation of the American Taxpayer Relief Act of 2012. The applicant states that Medicare reimbursement rates may be cut as much as 9 percent. The applicant states that if the Medicare reimbursement rate were cut 9 percent, the facility would have less profit but would also have less tax liability. A proposed rule was published in the Federal Register on July 8, 2013 proposing a Medicare ESRD PPS base rate of $216.95 (which would have been a cut of 12 percent from the CY 2013 Medicare ESRD PPS base rate). However, the final rule, published in the Federal Register and effective on December 10, 2013, fixed the CY 2014 Medicare ESRD PPS base rate at $239.02. The applicant, in its alternate pro formas, demonstrates that even if the Medicare reimbursement rate were as low as $213, the

[1] "End-Stage Renal Disease Prospective Payment System," Payment System Fact Sheet Series, ICN 905143, December 2012.

facility will still generate revenues exceeding expenses during the first two operating years of the project.

The applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming with this criterion.

Nash County Dialysis – In Section VIII.1, page 55, the applicant states the capital cost is projected to be $1,589,227. In Section IX.3, page 59, the applicant states that the total working capital needed will be $979,174 ($150,088 in start-up expenses and $829,086 in initial operating expenses.)

In Section VIII.2-3, pages 56-57, and Section IX.4, pages 59-60, and Exhibit 29, the applicant states it will fund the capital and working capital needs of the proposed project from the cash reserves of DaVita HealthCare Partners, Inc., the parent company of Total Renal Care, Inc. Exhibit 29 contains a letter, dated September 12, 2013, from the Chief Accounting Officer of DaVita HealthCare Partners, Inc., which states:

> *"I am the Chief Accounting Officer of DaVita HealthCare Partners, Inc. ("DaVita"), which is the parent company and 100% owner of Total Renal Care, Inc. ("Total Renal Care"). I also serve as the Chief Accounting Officer of Total Renal Care, which will be applying for a certificate of need to develop a new End Stage Renal Disease hemodialysis facility in Rocky Mount in Nash County, which is projected to open in the third quarter of 2015.*
> *DaVita, through Total Renal Care has committed cash reserves in the total amount of $2,668,401 for the capital costs, start up costs and the working capital needed for this new facility. Our company is absolutely committed to the development and operation of this new facility, and we will ensure that these funds are made available."*

In Exhibit 30, page F-6, the applicant provides audited financial statements for DaVita HealthCare Partners, Inc. (DaVita) which document that DaVita had $533,748,000 in cash and cash equivalents as of December 31, 2012. The applicant adequately demonstrated the availability of sufficient funds for the capital and working capital needs of the project.

In Section X.1, page 61, the applicant provides the following information regarding the facility's allowable charge per treatment by payor source:

Nash County Dialysis Allowable Charge per Treatment by Payment Source	
	In-Center
Commercial	$1,442.00
Medicare	$192.28
Medicaid	$143.00
Medicare/Medicaid	$240.36
Medicare/Commercial	$240.36
VA	$193.00

*The applicant notes that for the Medicare only charges, it applied the Medicare ESRD PPS base rate for CY 2013—$240.36—minus 20 percent when there is no secondary payor—to get the charge of $192.28.

According to the Centers for Medicare & Medicaid Services (CMS), the End-Stage Renal Disease Prospective Payment System (ESRD PPS) base rate for CY 2013 was $240.36.[2] As noted above, the applicant reduces its ESRD PPS base rate by 20 percent to account for patient responsibility. In Section X.2, page 61, and Section X.4, page 64, the applicant documents that bad debt and charity expenses were deducted from revenues.

In Section X, pages 61 and 64, the applicant projects the revenues and operating costs for the first two operating years of the proposed project, as shown in the table below.

Nash County Dialysis		
	Year 1	**Year 2**
Net Revenue	$1,928,798	$2,121,721
Total Operating Costs	$1,797,870	$1,923,139
Net Profit	$130,928	$198,582

As shown in the table above, the applicant projects that revenues will exceed operating costs in each of the first two years of operation following completion of this project. Revenues and operating costs are based on reasonable, credible and supported assumptions, including the projected number of treatments, charges, reimbursement rates and salaries.

The applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming with 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 Rocky Mount
C - Nash County Dialysis

There are currently two dialysis facilities located in Nash County. FMC of Spring Hope is currently certified for 10 stations and is approved to add 3 stations (Project I.D. #L-8796-12). BMA Rocky Mount is currently certified for 42 stations. There is a third facility approved—FMC South Rocky Mount—which will be certified for 12 stations (Project I.D. #L-10177-13). Those 12 stations are being relocated from BMA Rocky Mount, which will leave BMA Rocky Mount with 30 certified stations when Project I.D. #L-10177-13 is complete, if no further stations are approved. See the following table:

[2] "End-Stage Renal Disease Prospective Payment System," Payment System Fact Sheet Series, ICN 905143, December 2012.

Nash County Dialysis Facilities			
Dialysis Facility	**Certified Stations 12/31/12**	**% Utilization**	**Patients Per Station**
FMC Spring Hope*	10	82.50%	3.3
BMA Rocky Mount**	42	91.07%	3.6

Source: July 2013 SDR, Table A.
*FMC Spring Hope is approved to develop three additional stations (Project I.D. #L-8796-12) for a total of 13 stations upon project completion.
**BMA is approved to relocate 12 stations to a new facility (FMC South Rocky Mount) (Project I.D. #L-10177-13).

BMA Rocky Mount – The 2013 SMFP and the July 2013 SDR indicate a need for 19 additional dialysis stations in Nash County. BMA Rocky Mount proposes to add 11 certified stations to its existing facility in Rocky Mount, in Nash County. The applicant adequately demonstrates the need to add 11 stations to the existing facility. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. Therefore, the applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

Nash County Dialysis – The 2013 SMFP and the July 2013 SDR indicate a need for 19 additional dialysis stations in Nash County. Nash County Dialysis proposes to develop a new 12-station dialysis facility in Rocky Mount, in Nash County. The applicant adequately demonstrates the need to develop a new 12-station dialysis facility. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. Therefore, the applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, 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 - BMA Rocky Mount
C - Nash County Dialysis

BMA Rocky Mount – In Section VII.1, page 59, the applicant projects the following staffing during the first two operating years:

Position	Total FTEs Years 1 and 2
RN	7.00
Technician	15.00
Clinical Manager	1.00
Admin. (Dir. of Ops.)	0.20
Dietician	1.30
Social Worker	1.30
Home Training Nurse	1.00
Chief Tech	0.40
Equipment Tech	1.70
In-Service	0.33
Clerical	2.00
Total	**31.23**

As shown in the above table, the applicant proposes a total of 31.23 FTE positions, which is also the current staffing level. BMA Rocky Mount is currently certified for 42 certified dialysis stations. The applicant has been approved to relocate 12 stations to a new facility in south Rocky Mount. In this application, the applicant proposes to add 11 stations for a total of 41 certified dialysis stations upon project completion. The applicant reasonably projects the same staffing levels for the proposed 41 certified dialysis stations as the current staffing for the 42 existing certified dialysis stations.

The following table shows hours of operation as proposed by the applicant in Section VII.10, on page 61:

Weekly Hours of Operation				
Day	**Morning**	**Afternoon**	**Evening**	**Total**
Monday	6	5	0	11
Tuesday	6	5	0	11
Wednesday	6	5	0	11
Thursday	6	5	0	11
Friday	6	5	0	11
Saturday	6	5	0	11
Sunday	0	0	0	0
Total	36	30	0	66
Total Hours Operation per Year (weekly hours x 52):				**3,432**

The following table shows the number of FTE direct care staff positions the applicant proposes based on the number of hours the facility will operate, as reported by the applicant in Section VII.1, page 59, and VII.10, page 61:

	# FTEs	Hrs/Yr/FTE	Total FTE Hours (annual)	Total Hrs of Operation (annual)	FTE Hrs/Hrs of Operation
RN	7.0	2,080	14,560	3,432	4.2
Techs	15.0	2,080	31,200	3,432	9.1
Total	22.0	2,080	45,760	3,432	13.3

Based on the proposed operating hours for the facility, it will be open 3,432 hours a year. In Section VII.1, page 59, the applicant projects 22.0 total Patient Care Technician and

Registered Nurse FTEs. Assuming one FTE works 2,080 hours annually, 22.0 FTEs would work a total of 45,760 hours annually, which is sufficient to cover the 3,432 hours of operation. The applicant proposes more than sufficient direct care staff to provide the proposed services.

In addition, the proposed facility projects to serve 132 in-center patients in Operating Year One on 41 stations in 2 shifts, per day, Monday through Saturday. The following table illustrates the maximum number of in-center patients per shift.

Time/Shift	M/W/F Patients	T/TH/SA Patients
Morning (41 stations)	41	41
Afternoon (41 stations)	41	41

As shown in the table above, the 41-station facility would be able to dialyze up to a maximum of 164 in-center patients on 41 dialysis stations, assuming one patient per station per shift and two shifts per day, Monday through Saturday. The applicant states it projects to serve 132 in-center patients in Operating Year Two on 41 stations.

In Section V.4(c), page 51, the applicant states that Michael Holland, MD has agreed to serve as Medical Director for the facility. Exhibit 21 contains a letter from Michael Holland, MD, which states: "*I am writing to wholeheartedly endorse the Certificate of Need application by Bio-Medical Applications of North Carolina, Inc., to add 11dialysis* [sic] *stations at the BMA Rocky Mounty* [sic] *dialysis. I am pleased to continue serving as Medical Director for BMA Rocky Mount."*

The information regarding staffing provided in Section VII is reasonable and credible and supports a finding of conformity with this criterion.

Nash County Dialysis – In Section VII.1, page 51, the applicant projects the following staffing during the first two operating years:

Position	Total FTEs Years 1 and 2
RN	1.5
RN HT	0.7
Patient Care Technician	4.5
Bio-Med Tech	0.3
Admin	1.0
Dietician	0.4
Social Worker	0.4
Unit Secretary	1.0
Total	**9.8**

As shown in the above table, the applicant proposes a total of 9.8 full-time equivalent (FTE) positions. In Section VII.4, page 53, the applicant states that it does not anticipate having any difficulty staffing the proposed facility.

The following table shows hours of operation as proposed by the applicant in Section VII.10, on page 54:

Weekly Hours of Operation				
Day	**Morning**	**Afternoon**	**Evening**	**Total**
Monday	4	6	0	10
Tuesday	4	6	0	10
Wednesday	4	6	0	10
Thursday	4	6	0	10
Friday	4	6	0	10
Saturday	4	6	0	10
Sunday	0	0	0	0
Total	24	36	0	60
Total Hours Operation per Year (weekly hours x 52):				**3,120**

The following table shows the number of FTE direct care staff positions the applicant proposes based on the number of hours the facility will operate, as reported by the applicant in Section VII.10, page 54:

	# FTEs	**Hrs/Yr/FTE**	**Total FTE Hours (annual)**	**Total Hrs of Operation (annual)**	**FTE Hrs/Hrs of Operation**
RN	1.5	2,080	3,120	3,120	1.0
Techs	4.5	2,080	9,360	3,120	3.0
Total	6.0	2,080	12,480	3,120	4.0

Based on the proposed operating hours for the facility, it will be open 3,120 hours a year. In Section VII, page 51, the applicant projects 6.0 total Patient Care Technician and Registered Nurse FTEs. Assuming one FTE works 2,080 hours annually, 6.0 FTEs would work a total of 12,480 hours annually, which is sufficient to cover the 3,120 hours of operation. The applicant proposes more than sufficient direct care staff to provide the proposed services.

In addition, the proposed facility projects to serve 39 in-center patients in Operating Year One on 12 stations in 2 shifts, per day, Monday through Saturday. The following table illustrates the maximum number of in-center patients per shift.

Time/Shift	**M/W/F Patients**	**T/TH/SA Patients**
Morning (12 stations)	12	12
Afternoon (12 stations)	12	12

As shown in the table above, the proposed 12-station facility would be able to dialyze up to a maximum of 48 in-center patients on 12 dialysis stations, assuming one patient per station per shift and two shifts per day, Monday through Saturday. The applicant states it projects to serve 43 in-center patients in Operating Year Two on 12 stations.

In Section V.4(c), page 41, the applicant states that Will Bynum, MD has agreed to serve as Medical Director of the facility. Exhibit 21 contains a letter from Will Bynum, MD stating that has agreed to serve as Medical Director of the proposed facility and that he has a nephrology practice in Nash County. The letter in Exhibit 21 states:

> *"As a practicing Nephrologist in Nash County, I support the efforts of Total Renal Care to expand their service into Nash County. I have agreed to serve as Medical Director for the facility. I will refer End State Renal Disease patients to Nash County Dialysis."*

The information regarding staffing provided in Section VII is reasonable and credible and supports a finding of conformity with 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 - BMA Rocky Mount
C - Nash County Dialysis

BMA Rocky Mount – In Section II.1, pages 23-24, and Sections V.1-2, pages 48-50, the applicant lists the providers of the necessary ancillary and support services, and provides documentation in Exhibits 16, 17, 18, 20, and 21. Exhibit 16 contains a copy of the existing Hospital Affiliation Agreement between BMA Rocky Mount and Nash General Hospital. Exhibit 17 contains a copy of the existing Transplant Agreement between BMA Rocky Mount and East Carolina University School of Medicine/Pitt County Memorial Hospital. The information provided in Section V and the referenced exhibits is reasonable and credible and supports a finding of conformity with this criterion.

Nash County Dialysis – In Section II.1, pages 22-24, and Sections V.1-2, pages 39-40, the applicant lists the providers of the necessary ancillary and support services. In Exhibits 7, 8, 15, 16, 17, 19, 20, and 21, the applicant documents how the project will be coordinated with the existing health care system. Exhibit 7 contains a copy of a letter dated September 10, 2013, from the Chief Operating Officer of Nash Hospitals, Inc., which states: "*This letter is to inform CON that Nash Hospitals, Inc. will enter into a Patient Transfer Agreement with Total Renal Care, Inc. when they are issued the Certificate of Need."* Exhibit 7 also contains a copy of a letter dated August 26, 2013, from the President and Chief Executive Officer of Wilson Medical Center, which states: *"Our hospital will enter into a Patient Transfer Agreement with Total Renal Care, Inc. when they are issued the Certificate of Need."* Exhibit 8 contains a copy of a letter dated September 13, 2013, from the President of Vidant Medical Center, which states: *"Our hospital will enter into a Transplant Agreement with Total Renal Care, Inc. when the Certificate of Need is awarded."* Exhibit 8 also contains a copy of a letter dated September 3, 2013, from the Assistant Vice President of Carolinas Medical Center, which states: *"Our hospital will enter into a Transplant Agreement with Total Renal Care, Inc. when the Certificate of Need is awarded."* The information provided in Section V and the referenced exhibits is reasonable and credible and supports a finding of conformity with 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 - Both Applications

(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 - Both Applications

(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 - BMA Rocky Mount
C - Nash County Dialysis

Nash County Dialysis proposes to have an unrelated developer construct a 7,400 square foot building on Lot #8 of Winstead Park, on Winstead Avenue and English Road, in Rocky Mount. In Section XI.5(d), page 70, the applicant states, "*The facility will be constructed with energy-efficient glass, mechanically operated patient access doors and energy-efficient cooling and heating.*" In Section XI.6(g), pages 71-72, the applicant states the facility will be constructed in compliance with all laws and regulations pertaining to fire and safety equipment, and other health and safety requirements. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction costs will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges, which is incorporated hereby as if set forth fully herein. 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 - BMA Rocky Mount
NA - Nash County Dialysis

BMA Rocky Mount – In Section VI.1(a), page 54, 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.

BMA of North Carolina has 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 represented 84.8% of North Carolina dialysis treatments in BMA facilities in FY 2012. Medicaid treatments represented an additional 4.5% of treatments in BMA facilities in FY 2012, [sic] *Low income and medically underinsured persons will continue to have access to all services provided by BMA."*

The following table illustrates the current payor mix for BMA Rocky Mount, as provided by the applicant in Section VI.1(b), pages 54-55:

BMA Rocky Mount Payor Mix as of June 30, 2013			
Payor Source	**In-Center**	**HH**	**PD**
Private Pay	0.0%	0.00%	0.00%
Commercial Insurance	12.2%	29.05%	29.05%
Medicare	81.4%	65.34%	65.34%
Medicaid	2.8%	2.59%	2.59%
Medicare/Medicaid	0.0%	0.00%	0.00%
Medicare/Commercial	0.0%	0.00%	0.00%
State Kidney Program	0.0%	0.00%	0.00%
VA	3.7%	3.02%	3.02%
Other: Self/Indigent	0.0%	0.00%	0.00%
Total	**100.0%**	**100.00%**	**100.00%**

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Nash County and statewide.

	Total # of Medicaid Eligibles as % of Total Population* as of June 2010	**Total # of Medicaid Eligibles Age 21 and older as % of Total Population* as of June 2010**	**% Uninsured 2008-2009 (Estimate by Cecil G. Sheps Center)***
Nash County	20%	8.7%	19.7%
Statewide	17%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by BMA Rocky Mount. In fact, in 2011 only 5.8 percent of all newly-diagnosed ESRD patients (incident ESRD patients) in North Carolina's Network 6 were under the age of 35.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 45.9 percent for those age 20 and younger and 30.6 percent for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' 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 or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The Centers for Medicare & Medicaid Services (CMS) website states:

> *"Although the ESRD population in less than 1% of the entire U.S. population it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings. ...*
>
> *Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the*

> *total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9) populations."*[3]

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report (page 225), provides these national statistics for FY 2010: *"On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy."* Of the 376,000 ESRD patients, 38.23 percent were African American, 55.38 percent were white, 55.65 percent were male, and 44.65 percent were 65 and older. The report further states:

> *"Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid....Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively."*

The report provides 2010 ESRD spending, by payor, as follows:

ESRD Spending by Payor

Payor	Spending in Billions	% of Total Spending
Medicare Paid	$29.6	62.32%
Medicare Patient Obligation	$4.7	9.89%
Medicare HMO	$3.4	7.16%
Non-Medicare	$9.8	20.63%

Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 340.

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender demonstrating the following:

[3] www.cms.gov/medicare/end-stage-renaldisease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf

Number and Percent of Dialysis Patients by Age, Race and Gender		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%
Other	219	2.3%

Source: Southeastern Kidney Council (SKC) Network 6.
Includes North Carolina, South Carolina and Georgia

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

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

C - BMA Rocky Mount
C - Nash County Dialysis

BMA Rocky Mount – Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.1(f), page 56, 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 VI.6(a), page 58, the applicant states: "*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.* Therefore, the application is conforming to this criterion.

Nash County Dialysis – Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.1(f), page 47, the applicant states: "*Nash County Dialysis will have no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993."* In Section VI.6(a), page 49, the applicant states: "*There have been no civil*

rights equal access complaints filed within the last five years against any facility operated by Total Renal Care, Inc. or by any facility in North Carolina owned by DaVita HealthCare Partners, Inc." 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 - BMA Rocky Mount
C - Nash County Dialysis

BMA Rocky Mount – In Section VI.1(c), page 55, the applicant provides the following projected payor mix during the second year of operation:

Payor	In-Center	HH	PD
Private Pay	0.0%	0.00%	0.00%
Commercial Insurance	12.2%	29.05%	29.05%
Medicare	81.4%	65.34%	65.34%
Medicaid	2.8%	2.59%	2.59%
Medicare/Medicaid	0.0%	0.00%	0.00%
Medicare/Commercial	0.0%	0.00%	0.00%
State Kidney Program	0.0%	0.00%	0.00%
VA	3.7%	3.02%	3.02%
Other: Self/Indigent	0.0%	0.00%	0.00%
Total	**100.0%**	**100.00%**	**100.00%**

The applicant projects 84.2 percent of its in-center patients will have some or all of their care paid for by Medicare or Medicaid (81.4 percent Medicare plus 2.8 percent Medicaid). The applicant projects 67.93 percent of its home hemodialysis and peritoneal dialysis patients will have some or all of their care paid for by Medicare or Medicaid (65.34 percent Medicare plus 2.59 percent Medicaid). In Section VI.1(a), page 54, 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.*
>
> *BMA of North Carolina has 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 represented 84.8% of North Carolina dialysis treatments in BMA facilities in FY 2012. Medicaid treatments represented an additional 4.5% of treatments in BMA facilities in FY 2012,* [sic] *Low income and medically underinsured persons will continue to have access to all services provided by BMA."*

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

Nash County Dialysis – In Section VI.1(c), page 46, the applicant projects the following payor mix during the second year of operation:

Payor Source	Percent Utilization by Payor Source
Private Pay	0.0%
Medicare	19.7%
Medicaid	5.4%
Medicare/Medicaid	35.5%
Commercial Insurance	5.4%
VA	2.7%
Indigent	0.0%
Medicare/Commercial	31.3%
TOTAL	**100.0%**

In Section VI.1(a), page 45, the applicant states:

> *"Nash County Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. We will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.*
>
> …
>
> *Nash County Dialysis will not require payment upon admission to its services; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons."*

In Section VI.1(c), pages 45-46, the applicant states:

> *"TRC currently does not have any facilities in Nash County from which to draw this information. Therefore we have based our payor mix on the average percentages of patients who are currently dialyzing at Wilson Dialysis Center. Wilson Dialysis Center is a DaVita owned facility in Wilson County, which is contiguous to Nash County. The pertinent demographics of Wilson County, while not identical to Nash County, are similar. Moreover, there are several dialysis patients in Wilson County who dialyze in Wilson County at a TRC facility, who are expected to transfer to the new TRC facility in Nash County, so it is reasonable to use the payor mix from Wilson Dialysis Center as a basis for the payor mix for the Nash County facilty."*

Wilson County is contiguous to Nash County. U.S. Census Bureau data show substantial similarities in the economic status of the two counties. The poverty level

in Wilson County is similar to that of Nash County. The families living below the poverty level is 22.8 percent in Wilson County and 17.6 percent in Nash County. The per capita income is $20,671 in Wilson County and $23,364 in Nash County. Further, as of July 2009, the population of Wilson County was 81,234 and the population of Nash County was 95,840. As of June 2010, the total Medicaid eligible population was 17,804 in Wilson County and 18,756 in Nash County. Thus it is reasonable to assume that these two contiguous counties are comparable in economic status. Furthermore, Wilson County is where almost all of the patients projected to transfer to the proposed facility currently receive their dialysis treatments.

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. 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 - BMA Rocky Mount
C - Nash County Dialysis

BMA Rocky Mount – In Section VI.5, pages 57-58, the applicant describes the range of means by which patients will have access to the proposed services. The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity with this criterion.

Nash County Dialysis – In Section VI.5, pages 48-49, the applicant describes the range of means by which patients will have access to the proposed services. The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity with 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 - BMA Rocky Mount
C - Nash County Dialysis

BMA Rocky Mount – In Section V.3, pages 50-51, the applicant provides information about how its proposed health services will accommodate the needs of health professional training programs in the area. On page 50, the applicant states: *"Exhibit 19 contains a letter from Anita Harris, FMC Director of Operations, to Wilson Community College inviting the school to include BMA Rocky Mount Center as a clinical rotation site for the Health Occupations students. This type of agreement is typical for all BMA facilities."* The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion.

Nash County Dialysis – In Section V.3, page 41, the applicant provides information about how its proposed health services will accommodate the needs of health professional training programs in the area. The applicant states: *"See **Exhibit 19** for a copy of the letters sent by Dodie Robinson, Regional Operations Director, to the President of Nash Community College and the Career Technical Coordinator at Nash Central High School."* The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with 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 Rocky Mount
C - Nash County Dialysis

There are currently two dialysis facilities located in Nash County. FMC of Spring Hope is currently certified for 10 stations and is approved to add 3 stations (Project I.D. #L-8796-12). BMA Rocky Mount is currently certified for 42 stations. There is a third facility approved—FMC South Rocky Mount—which will be certified for 12 stations (Project I.D. #L-10177-13). Those 12 stations are being relocated from BMA Rocky Mount, which will leave BMA Rocky Mount with 30 certified stations when Project I.D. #L-10177-13 is complete, if no further stations are approved. See the following table:

Nash County Dialysis Facilities			
Dialysis Facility	**Certified Stations 12/31/12**	**% Utilization**	**Patients Per Station**
FMC Spring Hope*	10	82.50%	3.3
BMA Rocky Mount**	42	91.07%	3.6

Source: July 2013 SDR, Table A.
*FMC Spring Hope is approved to develop three additional stations (Project I.D. #L-8796-12) for a total of 13 stations upon project completion.
**BMA is approved to relocate 12 stations to a new facility (FMC South Rocky Mount) (Project I.D. #L-10177-13).

BMA Rocky Mount – In Section V.7, pages 52-53, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

> *"BMA has been providing dialysis treatment to the overwhelming majority of the Nash County ESRD patient population as is noted within this application. Further, the*

physicians of Boice-Willis are likewise providing medical coverage for patients from Nash County. This facility will have added value stemming from the strength of our relationship with the nephrology physicians at Boice-Willis. The practice brings together a team of highly qualified nephrologists to serve the ESRD patient needs of the area."

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area will have 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 to add 11 dialysis stations to BMA Rocky Mount and that it is a cost-effective alternative;
- The applicant adequately demonstrates that it will continue to provide quality services; and
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations.

The application is conforming to this criterion.

Nash County Dialysis – In Section V.7, pages 42-44, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

"DaVita HealthCare Partners Inc. and Total Renal Care, Inc. do not expect that this proposal will have any adverse effect on competition within Nash County. In fact, because at this time there is only one provider of dialysis services in Nash County, the addition of a second provider should enhance competition."

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area will have 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 to develop a new 12-station facility in Nash County and that it is a cost-effective alternative;
- The applicant adequately demonstrates that it will provide quality services; and
- The applicant demonstrates that it will provide adequate access to medically underserved populations.

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 - BMA Rocky Mount
NA - Nash County Dialysis

BMA Rocky Mount – According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, BMA Rocky Mount operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

Nash County Dialysis does not have an existing facility in Nash County.

(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 - BMA Rocky Mount
C - Nash County Dialysis

BMA Rocky Mount's application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as promulgated in 10A NCAC 14C .2200. See discussion below.

Nash County Dialysis's application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as promulgated in 10A NCAC 14C .2200. See discussion below.

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

.2202 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:

(1) Utilization rates;

-C- **BMA Rocky Mount –** See Section II, page 11, which indicates the facility had a 91.07 percent utilization rate as of December 31, 2012.

-NA- **Nash County Dialysis –** The applicant proposes a new facility.

(2) Mortality rates;

-C- **BMA Rocky Mount –** See Section IV.2, page 46, where the applicant reports 2010, 2011 and 2012 facility mortality rates of 18.7 percent, 19.4 percent and 23.0 percent, respectively.

-NA- **Nash County Dialysis –** The applicant proposes a new facility.

(3) The number of patients that are home trained and the number of patients on home dialysis;

-C- **BMA Rocky Mount –** In Section IV.3, page 46, the applicant states that BMA Rocky Mount had 35 patients that were home trained in 2013.

-NA- **Nash County Dialysis –** The applicant proposes a new facility.

(4) The number of transplants performed or referred;

-C- **BMA Rocky Mount –** In Section IV.4, page 46, the applicant states BMA Rocky Mount referred 18 patients for transplant evaluation in 2012. BMA Rocky Mount had seven patients receive a transplant in 2012.

-NA- **Nash County Dialysis –** The applicant proposes a new facility.

(5) The number of patients currently on the transplant waiting list;

-C- **BMA Rocky Mount** – In Section VI.5, page 46, the applicant states that BMA Rocky Mount has 22 patients on the transplant waiting list.

-NA- **Nash County Dialysis –** The applicant proposes a new facility.

(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;

-C- **BMA Rocky Mount** – In Section IV.6, pages 46-47, the applicant reports a total of 289 hospital admissions in 2012; 201 were non-dialysis related and 88 were dialysis-related.

-NA- **Nash County Dialysis –** The applicant proposes a new facility.

(7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.

-C- **BMA Rocky Mount –** In Section IV.7, page 47, the applicant reports that in 2012 there was one patient with an infectious disease, and no patients converted to infectious status in 2012.

-NA- **Nash County Dialysis –** The applicant proposes a new facility.

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

(1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.

-NA- **BMA Rocky Mount** – The applicant does not propose a new facility.

-C- **Nash County Dialysis –** Exhibit 7 contains a letter dated September 10, 2013, signed by the Chief Operating Officer, Nash Hospitals, Inc., stating that the hospital will enter into a Patient Transfer Agreement with the applicant when a certificate of need is issued. The letter describes the services that the hospital will provide to patients of the dialysis facility. Exhibit 7 also contains a letter dated August 26, 2013, signed by the President & CEO, Wilson Medical Center, stating that the hospital will enter into a Patient Transfer Agreement with the applicant when a certificate of need is issued. This letter also describes the services that the hospital will provide to patients of the dialysis facility. In Section II.1, page 11, the applicant also states, *"Nash County Dialysis will seek out other area hospitals to establish patient transfer agreements once the Certificate of Need has been awarded."*

(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:

(A) timeframe for initial assessment and evaluation of patients for transplantation,
(B) composition of the assessment/evaluation team at the transplant center,
(C) method for periodic re-evaluation,
(D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and
(E) signatures of the duly authorized persons representing the facilities and the agency providing the services.

-NA- **BMA Rocky Mount –** The applicant does not propose a new facility.

-C- **Nash County Dialysis –** Exhibit 8 contains a letter dated September 13, 2013, signed by the President of Vidant Medical Center, stating that the hospital will enter into a Transplant Agreement with the applicant when a certificate of need is issued. The letter includes the requirements listed in subsection 2(a)-(e) of this rule. Exhibit 8 also contains a letter dated September 3, 2013, signed by the Assistant Vice President of Carolinas Medical Center, stating that the hospital will enter into a Transplant Agreement with the applicant when a certificate of need is issued. This letter also includes the requirements listed in subsection 2(a)-(e) of this rule. In Section II.1, page 11, the applicant also states, *"Nash County Dialysis will seek out other area transplant centers to establish transplant agreements once the Certificate of Need has been awarded."*

(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.

-NA- **BMA Rocky Mount –** The applicant does not propose a new or replacement facility.

-C- **Nash County Dialysis –** Exhibit 9 contains a copy of an email response, sent September 5, 2013, from the Utilities Communication Coordinator for the Town of Rocky Mount, stating that electric and natural gas services are available at the primary site. In Section XI.5(e), page 71, the applicant states, "*The facility will be located in an area that is supplied by potable city water.* ***Exhibit 10*** *of the application describes the procedures that will be in place so that the facility will comply with 42 C.F.R. Section 405.2100. The facility will modify the existing water by providing for dechlorinization, softening, reverse osmosis water systems combined with pyrogen filters for bacteria removal."* (emphasis in original) Exhibit 10 also contains a copy of an email response sent September 5, 2013, from an Engineering Technician for the Town of Rocky Mount, documenting the availability of water and sewer at the primary site.

(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.

-C- **BMA Rocky Mount –** Exhibit 12 contains copies of written policies and procedures for back-up electrical services in the event of a power outage.

-C- **Nash County Dialysis –** In Section XI.5(f), page 71, the applicant states, *"The site will be served by standing power service. The facility will provide in its procedures for temporary power outages that sometimes occur during a treatment shift. This is done by resetting the machines, all which have a provision contained in their construction for hand rotation. This is considered adequate for temporary power outages.* ***Exhibit 9*** *contains a copy of the policies and procedures for temporary power outages."* (emphasis in original) Exhibit 9 also documents a written request, dated September 9, 2013, from Nash

County Dialysis to the Regional Operations Director for DaVita, Inc., requesting to add Nash County Dialysis to the network of facilities that provide back-up to other facilities when there are emergencies. The letter requests Dialysis Care of Edgecombe County as the primary back-up and Wilson Dialysis Center and Forest Hills Dialysis Center as secondary back-ups.

(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-NA- **BMA Rocky Mount** – The applicant does not propose a new facility.

-C- **Nash County Dialysis –** In Sections XI.2 and XI.3, pages 67-39, the applicant describes the location of both the primary and secondary sites located at Winstead Park, at Winstead Avenue and English Road, Rocky Mount (different lots of the same business park). The applicant states in Section XI.1, page 67, *"Attached as* ***Exhibit 32*** [sic] *is a copy of a letter from R. Gregg Hill, Manager of Hill/Gray Seven, LLC, indicating his intent to negotiate the purchase of property and construct a shell building. Once the shell building is constructed, Total Renal Care, Inc. will up-fit the shell building. This exhibit also has a copy of the DaVita Minimum Base Building Improvements and the DaVita Inc. Standard Lease Agreement."* Exhibit 33 (the correct exhibit) also contains a written commitment from the applicant to pursue acquiring the sites and documentation that the primary and secondary sites are available for acquisition.

(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- **BMA Rocky Mount –** In Section XI.6(g), page 80, the applicant states, "*BMA of North Carolina provides and will continue to provide services in conformity with applicable laws and regulations pertaining to staffing, fire safety and equipment, physical environment and other relevant health and safety requirements."* In Sections VII.1 & VII.2, pages 59-60, the applicant indicates staffing will meet or exceed minimum requirements. See Exhibit 11 for documentation regarding the water supply. Exhibit 9 contains a copy of the HIV/HBV Policy and Procedure. Exhibits 14 and 15 contain copies of FMC's Training Program and Continuing Education Outline.

-C- **Nash County Dialysis –** In Sections XI.5(e) and XI.5(g), pages 71-72, the applicant states the dialysis center will operate in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, and other relevant health and safety requirements. In Sections

VII.1 & VII.2, pages 51-52, the applicant indicates staffing will meet or exceed minimum requirements. See Exhibit 10 for documentation regarding the water supply. Exhibit 25 contains a copy of the Isolation Policies and Procedures. Exhibit 36 contains a copy of the Safety Training Outline and Exhibit 37 contains a copy of a sample of an in-service training calendar like the one that will be used at the facility.

(7) The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.

-C- **BMA Rocky Mount –** In Section III.7, pages 38-43, BMA Rocky Mount provided projected patient origin based on historical experience for the first two years of operation following completion of the project.

-C- **Nash County Dialysis** – The information regarding patient origin and all of the assumptions and methodology is found in Section III.7, pages 29-34.

(8) For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.

-NA- **BMA Rocky Mount** – The applicant does not propose a new facility.

-C- **Nash County Dialysis –** In Section III.8, page 30, the applicant states that all patients are projected to live within a 30-mile radius of the proposed sites for Nash County Dialysis.

(9) A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.

-C- **BMA Rocky Mount –** In Section II.1, page 17, the applicant states, *"BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services."*

-C- **Nash County Dialysis** – In Section II.1, pages 17-18, the applicant states, *"Total Renal Care, Inc. d/b/a Nash County Dialysis will admit and provide dialysis services to patients who have no insurance or other source of payment if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services."*

.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- **BMA Rocky Mount** – The applicant does not propose a new facility.

-C- **Nash County Dialysis** – The applicant projects to serve 39 in-center patients on 12 dialysis stations at the end of Operating Year 1, which is 3.25 patients per station per week (39 / 12 = 3.25). The applicant provides the assumptions and methodology used to project utilization in Section II, pages 13-15, and Section III.7, pages 29-32. The applicant provides letters from 32 patients who would consider transferring their care to the proposed facility in Exhibit 12. See Criterion (3) for additional discussion which is incorporated hereby as if set forth fully herein.

(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- **BMA Rocky Mount** – In Sections II.1, page 18 and III.7, page 43, the applicant projects to serve 132 in-center patients by the end of Operating Year 1, which is 3.22 patients per station (132 / 41 = 3.22). See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

-NA- **Nash County Dialysis –** The applicant proposes a new facility.

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

-C- **BMA Rocky Mount** – In Section II, pages 18-22, and Section III.7, pages 38-43, the applicant provides the assumptions and methodology used to project utilization of the facility. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

-C- **Nash County Dialysis –** In Section II, pages 18-22, and in Section III.7, pages 29-34, the applicant provides the assumptions and methodology used to project utilization of the facility. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

.2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

(1) diagnostic and evaluation services;

-C- **BMA Rocky Mount –** These services are provided by Nash General Hospital. See Section V.1, page 48.

-C- **Nash County Dialysis –** These services will be provided by Nash Health Care Systems and Wilson Medical Center. See Section V.1, page 39.

(2) maintenance dialysis;

-C- **BMA Rocky Mount –** This service is provided by BMA Rocky Mount. See Section V.1, page 48.

-C- **Nash County Dialysis –** This service will be provided by Nash County Dialysis. See Section V.1, page 39.

(3) accessible self-care training;

-C- **BMA Rocky Mount –** These services are provided by BMA Rocky Mount. See Section V.1, page 48.

-C- **Nash County Dialysis –** These services will be provided by Nash County Dialysis. See Section V.1, page 39.

(4) accessible follow-up program for support of patients dialyzing at home;

-C- **BMA Rocky Mount –** This service is provided by BMA Rocky Mount. See Section V.1, page 48, and Section V.2(d), pages 49-50.

-C- **Nash County Dialysis –** This service will be provided by Nash County Dialysis. See Section V.1, page 39, and Section V.2(d), page 40.

(5) x-ray services;

-C- **BMA Rocky Mount –** These services are provided by Nash General Hospital or Boice-Willis Clinic. See Section V.1, page 48.

-C- **Nash County Dialysis –** These services will be provided by Nash Health Care Systems and Wilson Medical Center. See Section V.1, page 39.

(6) laboratory services;

-C- **BMA Rocky Mount –** These services are provided by SPECTRA. See Section V.1, page 48.

-C- **Nash County Dialysis –** These services will be provided by Dialysis Laboratories. See Section V.1, page 39.

(7) blood bank services;

-C- **BMA Rocky Mount –** These services are provided by Nash General Hospital. See Section V.1, page 48.

-C- **Nash County Dialysis –** These services will be provided by Nash Health Care Systems and Wilson Medical Center. See Section V.1, page 39.

(8) emergency care;

-C- **BMA Rocky Mount –** These services are provided by BMA Rocky Mount and Nash General Hospital. See Section V.1, page 48.

-C- **Nash County Dialysis –** These services will be provided by Nash Health Care Systems and Wilson Medical Center. See Section V.1, page 39.

(9) acute dialysis in an acute care setting;

-C- **BMA Rocky Mount –** This service is provided by Nash General Hospital. See Section V.1, page 48.

-C- **Nash County Dialysis –** These services will be provided by Nash Health Care Systems and Wilson Medical Center. See Section V.1, page 39.

(10) vascular surgery for dialysis treatment patients;

-C- **BMA Rocky Mount –** This service is provided by Raleigh Access Center, Hardee's Heart Center, or Triangle Interventional Center. See Section V.1, page 48.

-C- **Nash County Dialysis –** These services will be provided by Nash Health Care Systems and Wilson Medical Center. See Section V.1, page 39.

(11) transplantation services;

-C- **BMA Rocky Mount –** These services are provided by Duke University Medical Center. See Section V.1, page 48.

-C- **Nash County Dialysis –** These services will be provided by Carolinas Medical Center. See Section V.1, page 39.

(12) vocational rehabilitation counseling and services; and

-C- **BMA Rocky Mount –** These services are provided by Nash County Vocational Rehabilitation. See Section V.1, page 48.

-C- **Nash County Dialysis –** These services will be provided by the N.C. Department of Vocational Rehabilitation. See Section V.1, page 39.

(13) transportation.

-C- **BMA Rocky Mount –** This service is provided by Tar River Transit. See Section V.1, page 48.

-C- **Nash County Dialysis –** This service will be provided by Tar River Transit. See Section V.1, page 39.

.2205 STAFFING AND STAFF TRAINING

(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.

-C- **BMA Rocky Mount –** In Section VII.1, page 59, the applicant provides the proposed staffing. In Section VII.2, page 60, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion which is incorporated hereby as if set forth fully herein.

-C- **Nash County Dialysis –** In Section VII.1, page 51, the applicant provides the proposed staffing. In Section VII.2, page 52, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion which is incorporated hereby as if set forth fully herein.

(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.

-C- **BMA Rocky Mount –** See Section VII.5, page 60, and Exhibits 14 and 15.

-C- **Nash County Dialysis –** See Section VII.5, page 53, and Exhibits 27 and 37.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the need determination in the 2013 SMFP and the July 2013 SDR, no more than 19 dialysis stations may be approved in this review for Nash County. Because BMA Rocky Mount proposes an additional 11 stations and Nash County Dialysis proposes an additional 12 stations, for a total of 23 stations, both of the applications cannot be approved as proposed. The analyst considered all of the information in each application and reviewed each application individually against all applicable review criteria and the analyst conducted a comparative analysis of the proposals. Based on that review and for the reasons set forth below and in the rest of the findings, the application submitted by BMA Rocky Mount, Project I.D. #L-10182-13, is approved for 7 dialysis stations and the application submitted by Nash County Dialysis, Project I.D. #L-10211-13, is approved for 12 dialysis stations.

<u>SMFP Principles</u>

Basic Principle 12 regarding the Availability of Dialysis Care as contained in Chapter 14, page 361 of the 2013 SMFP states:

> "*Availability of Dialysis Care: The North Carolina State Health Coordinating Council encourages applicants for dialysis stations to provide or arrange for:*
> *a. Home training and backup for patients suitable for home dialysis in the ESRD dialysis facility or in a facility that is a reasonable distance from the patient's residence;*
> *b. ESRD dialysis service availability at times that do not interfere with ESRD patients' work schedule;*
> *c. Services in rural, remote areas."*

Home Training

BMA Rocky Mount – In Section II, page 13, the applicant states:

> *"BMA has proposed to relocate the home training program from BMA Rocky Mount to the new FMC South Rocky Mount Dialysis facility. The new facility will have more space dedicated to the home training program. The current BMA Rocky Mount facility can not be physically expanded. Consequently, the growing home dialysis program is operated in limited space. Additional space in the new location will enhance home training and support for home dialysis patients.*
>
> *In subsequent deliberations regarding the home program, BMA has determined to maintain a small home training presence at the BMA Rocky Mount facility. This does not change the projections within CON Project ID # L-10177-13, the BMA proposal to develop FMC South Rocky Mount. …"*

Nash County Dialysis – In Section V.2(d), page 40, the applicant states, *"Nash County Dialysis will provide home training in peritoneal dialysis and follow-up and home training in*

home hemodialysis and fillow-up [sic].*"* The applicant goes on to describe the program available for the support of patients dialyzing at home.

With regard to home training, both applications are equally effective since both propose to make it available in their Nash County facilities.

Hours of Availability

BMA Rocky Mount – In Section VII.10, page 61, the applicant states dialysis services will be available from 6:00 AM to 5:00 PM, Monday through Saturday. BMA Rocky Mount does not propose a third shift.

Nash County Dialysis – In Section VII.10, page 54, the applicant states dialysis services will be available from 6:00 AM to 4:00 PM, Monday through Saturday. Nash County Dialysis does not propose a third shift.

With regard to hours of operation, the applications are equally effective because they both propose two shifts per day, six days per week.

Services in rural, remote areas

Nash County is not a remote area. Regardless of whether Nash County is considered rural or not, both applications are equally effective since BMA Rocky Mount is located in Rocky Mount and Nash County Dialysis would be located in Rocky Mount.

Facility Location

Both applicants propose locations in Rocky Mount, Nash County. According to Google Maps, the proposed locations of the competing applications are only 0.1 of a mile apart. With regard to location, both applications are equally effective alternatives.

Access by Underserved Groups

BMA Rocky Mount – In Sections VI.1(b) & (c), pages 54-55, the applicant states that 84.2 percent of its in-center patients will have some or all of their services covered by Medicare or Medicaid. BMA Rocky Mount based its projected payor mix on the current payor mix at BMA Rocky Mount.

Nash County Dialysis – In Section VI.1(c), pages 45-46, the applicant states that 86.5 percent of its in-center patients will have some or all of their services covered by Medicare or Medicaid. In Section VI.1(c), pages 45-46, the applicant states:

> *"TRC currently does not have any facilities in Nash County from which to draw this information. Therefore we have based our payor mix on the average percentages of patients who are currently dialyzing at Wilson Dialysis Center. Wilson Dialysis Center is a DaVita owned facility in Wilson County, which is contiguous to Nash County. The pertinent demographics of Wilson County, while not identical to Nash*

> *County, are similar. Moreover, there are several dialysis patients in Wilson County who dialyze in Wilson County at a TRC facility, who are expected to transfer to the new TRC facility in Nash County, so it is reasonable to use the payor mix from Wilson Dialysis Center as a basis for the payor mix for the Nash County facility. …"*

Nash County Dialysis based its projected payor mix on the payor mix for patients currently dialyzing at Wilson Dialysis Center, some of who are projected to transfer to the proposed Nash County Dialysis facility. Wilson County is contiguous to Nash County and the demographics are similar.

Generally, the application proposing the highest Medicare/Medicaid percentage is the most effective alternative with regard to this comparative factor. Nash County Dialysis proposes the highest percentage of patients to have some or all of their services paid for by Medicare or Medicaid. Therefore, the Nash County Dialysis application is the more effective alternative with regard to this comparative factor.

Access to Ancillary and Support Services

BMA Rocky Mount – In Sections V.1 and V.2, pages 48-49, the applicant lists the providers of the necessary ancillary and support services. In Exhibits 16, 17, 18 and 19, the applicant documents how the project will be coordinated with the existing health care system. BMA Rocky Mount has an existing transfer agreement with Nash General Hospital. Nash General Hospital is located in Rocky Mount. According to Google Maps, Nash General Hospital is approximately 0.6 of a mile from BMA Rocky Mount.

Nash County Dialysis – In Section V.1 and V.2, pages 39-40, the applicant lists the providers of the necessary ancillary and support services. In Exhibits 7, 8, 17, 19 and 22, the applicant documents how the project will be coordinated with the existing health care system. Exhibit 7 contains a copy of a letter of intent from Nash General Hospital, as well as one from Wilson Medical Center, to enter into a Patient Transfer Agreement with the facility. Nash General Hospital is located in Rocky Mount. According to Google Maps, Nash General Hospital is approximately 0.4 of a mile from the proposed primary site.

Both applications are equally effective with regard to access to ancillary and support services.

Service to Nash County Residents

Currently 186 of the 216 in-center dialysis patients who reside in Nash County receive treatment at facilities controlled by the parent company of BMA Rocky Mount, Fresenius Medicare Care Holdings, Inc. (FMC). There are two existing FMC-owned facilities in Rocky Mount—BMA Rocky Mount and FMC of Spring Hope. The Medical Director for BMA Rocky Mount, Dr. Michael Holland of Boice-Willis Clinic, states that his group *"…has been providing nephrology services to area residents for many years. I have ongoing relationships with physicians in the region and have an active role in the care of dialysis patients admitted to area hospitals."*

DaVita, Inc. (DaVita), the ultimate parent company of Total Renal Care, Inc. d/b/a Nash County Dialysis, identifies 15 of the 216 in-center dialysis patients who reside in Nash County as receiving treatment in one of its facilities; however, none of these facilities are located within Nash County. Additionally, while the December 31, 2012 data included in the July 2013 SDR indicates that 15 of the 216 in-center patients from Nash County receive treatment in DaVita-owned facilities, the applicant indicates that 25 Nash County residents are currently receiving treatment at DaVita-owned facilities. Of the 43 in-center patients projected to utilize the facility at the end of Operating Year Two, the applicant projects that 37, or 86 percent, will be residents of Nash County.

With regard to service to Nash County patients, both applications are equally effective.

Access to Alternative Providers

Currently, there are two existing dialysis facilities and one approved dialysis facility in Nash County. All three of these facilities are owned and operated by FMC. Currently, 186 of the 216 in-center dialysis patients who reside in Nash County receive treatment at FMC-operated facilities.

DaVita does not currently operate any dialysis facilities in Nash County. However, DaVita does operate two facilities in Wilson County; one facility in Edgecombe County; and one facility in Franklin County. Wilson, Edgecombe, and Franklin counties are contiguous to Nash County. The applicant reports that it currently serves 25 Nash County residents in one of its facilities.

Therefore, with regard to providing dialysis patients access to an alternative provider in Nash County, the proposal submitted by Nash County Dialysis is the most effective alternative.

Revenues and Operating Costs

In Section X of the application, each applicant projects the revenues and operating costs for the first two operating years of the proposed project, as shown in the tables below. Generally, the application proposing the lower average net revenue per treatment and the lower average operating cost per treatment is the more effective alternative.

Average Net Revenue Per Treatment

BMA Rocky Mount	Year One	Year Two
Projected Net Revenue	$7,011,022	$7,091,714
# Dialysis Treatments*	19,108	19,252
Average Net Revenue per Treatment	$366.92	$368.36

*Includes home dialysis treatments.

Nash County Dialysis	Year One	Year Two
Projected Net Revenue	$1,928,798	$2,121,721
# Dialysis Treatments*	6,669	7,336
Average Net Revenue per Treatment	$289.22	$289.22

*Includes home dialysis treatments.

With respect to the projected average net revenue per treatment, the proposal submitted by Nash County Dialysis is the more effective alternative.

Average Operating Cost Per Treatment

BMA Rocky Mount	Year One	Year Two
Projected Operating Costs	$5,372,268	$5,511,318
# Dialysis Treatments*	19,108	19,252
Average Operating Cost per Treatment	$281.15	$286.27

*Includes home dialysis treatments.

Nash County Dialysis	Year One	Year Two
Projected Operating Costs	$1,797,870	$1,923,139
# Dialysis Treatments*	6,669	7,336
Average Operating Cost per Treatment	$269.59	$262.15

*Includes home dialysis treatments.

Nash County Dialysis projects the lowest average operating cost per treatment. With respect to the projected average operating costs per treatment, the proposal submitted by Nash County Dialysis is the more effective alternative.

Staffing

Direct Care Staff Salaries

The following table illustrates projected annual salaries during Year One for direct care staff (registered nurses and technicians) as reported in Section VII.1 of the respective applications. Generally, the application proposing the higher annual salary for direct care staff is the more effective alternative.

Position	BMA Rocky Mount	Nash County Dialysis
Registered Nurse	$49,275	$67,980
Technician	$23,909	$25,750

Nash County Dialysis projects the higher annual salary for both registered nurses and technicians. Therefore, the proposal submitted by Nash County Dialysis is the more effective alternative with respect to direct care staff salaries.

Availability of Staff and Medical Director

Both applicants projected sufficient shifts and a sufficient number of direct care staff for the projected number of patients to be served in Year Two. Both have budgeted sufficient staff salaries. Both have identified a Medical Director. See discussion in Criterion (7). With regard to the availability of staff and a Medical Director, both applications are equally effective.

SUMMARY

Both applications were determined to be conforming with all applicable statutory and regulatory review criteria.

For each of the comparative analysis factors listed below, the applications were determined to be equally effective:

- Home Training
- Hours of Availability
- Services in Rural, Remote Areas
- Facility Location
- Access to Ancillary and Support Services
- Service to Nash County Residents
- Availability of Staff and Medical Director

For each of the comparative analysis factors listed below, the application submitted by Nash County Dialysis was determined to be the more effective alternative than the application submitted by BMA Rocky Mount:

- Access by Underserved Groups
- Access to Alternative Providers
- Average Net Revenue per Treatment
- Average Operating Cost per Treatment
- Direct Care Staff Salaries

CONCLUSION

G.S.131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of dialysis stations that can be approved by the CON Section. The CON Section determined that the application submitted by Nash County Dialysis is the most effective alternative proposed in this review for 19 dialysis stations in Nash County and that application is approved as conditioned below. The approval of the BMA Rocky Mount application in its entirety would result in the approval of dialysis stations in Nash County in excess of the county need determination in the 2013 SMFP and July 2013 SDR and therefore, the BMA Rocky Mount application can only be approved for seven additional stations.

The application submitted by Nash County Dialysis is approved subject to the following conditions.

1. **Total Renal Care, Inc. d/b/a Nash County Dialysis shall materially comply with all representations made in its certificate of need application.**

2. **Total Renal Care, Inc. d/b/a Nash County Dialysis shall develop and be certified for no more than 12 dialysis stations upon completion of this project, which shall include any home hemodialysis training or isolation stations.**

3. **Total Renal Care, Inc. d/b/a Nash County Dialysis shall install plumbing and electrical wiring through the walls for no more than 12 dialysis stations, which shall include any home hemodialysis training or isolation stations.**

4. **Total Renal Care, Inc. d/b/a Nash County Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**

The application submitted by BMA Rocky Mount is approved subject to the following conditions.

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Rocky Mount shall materially comply with all representations made in its certificate of need application.**

2. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Rocky Mount shall develop and be certified for no more than 7 dialysis stations upon completion of this project, which shall include any home hemodialysis training or isolation stations.**

3. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Rocky Mount shall install plumbing and electrical wiring through the walls for no more than 7 dialysis stations, which shall include any home hemodialysis training or isolation stations.**

4. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Rocky Mount shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**

788 S.E.2d 684 (Table)
Unpublished Disposition
NOTE: THIS OPINION WILL NOT APPEAR IN A PRINTED VOLUME. THE DISPOSITION WILL APPEAR IN THE REPORTER.
Court of Appeals of North Carolina.

BIO–MEDICAL APPLICATIONS OF NORTH CAROLINA, INC. d/b/a BMA Rocky Mount, Petitioner,
v.
NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, Certificate of Need Section, Respondent,
and
Total Renal Care, Inc. d/b/a Nash County Dialysis, Respondent–Intervenor.

No. COA15–815.
|
June 7, 2016.

***1** Appeal by Petitioner from Final Decision entered 26 March 2015 by Administrative Law Judge Augustus B. Elkins II in the Office of Administrative Hearings. Heard in the Court of Appeals 2 December 2015.

Attorneys and Law Firms

Smith Moore Leatherwood LLP, by Marcus C. Hewitt and Elizabeth Sims Hedrick, for Petitioner–Appellant.

Attorney General Roy Cooper, by Assistant Attorney General Bethany A. Burgon, for Respondent–Appellee.

Wyrick Robbins Yates & Ponton LLP, by Lee M. Whitman, Tobias S. Hampson, and Elizabeth Frock Runyon, for Respondent–Intervenor–Appellee.

Opinion

INMAN, Judge.

In this case, we affirm an administrative agency determination that Petitioner argues was based upon erroneous data because Petitioner has failed to demonstrate that it suffered substantial prejudice as a result of the error.

Petitioner–Appellant Bio–Medical Applications (“BMA”) appeals the Final Decision of the Office of Administrative Hearings (“OAH”) which affirmed the 27 February 2014 decision of the North Carolina Department of Health and Human Services, Certificate of Need Section, (“CON Section” or the “Agency”) to award Respondent–Intervenor–Appellee Total Renal Care, Inc. (“TRC”) a Certificate of Need (“CON”) to develop a new 12–station dialysis facility in Nash County and limited the CON awarded to BMA to seven stations at its existing facility in Nash County. The CON Section’s decision was part of a competitive CON review in which TRC and BMA submitted applications in response to a county need determination in the July 2013 Semiannual Dialysis Report (“SDR”) issued by the Medical Facilities Planning Branch (the “Planning Branch”) of the State Health Coordinating Council.

On appeal, BMA first contends that the Final Decision erroneously concluded that the Agency properly evaluated the need for TRC’s proposal. BMA’s argument as to this issue is two-fold. First, BMA argues that the Agency erroneously accepted TRC’s representation that 26 Nash County patients were interested in transferring to its new proposed dialysis facility. Second, BMA argues that the Agency’s Final Decision was arbitrary and capricious because it approved TRC’s use of a projected growth rate of 9.6% which both the Agency and TRC knew was wrong. Instead, BMA contends that the Agency should have used a 2.1% projected growth rate.

Next, BMA argues that the Final Decision’s conclusion that BMA did not suffer substantial prejudice was erroneous. BMA contends that the denial of BMA’s competitive application to develop four of the eleven dialysis stations for which it had demonstrated need constitutes substantial prejudice.

Finally, BMA argues that Administrative Law Judge Augustus Elkins II (“ALJ Elkins”) abused his discretion by excluding evidence offered by BMA to rebut the presumption that the data published in the SDR is always deemed credible and reasonable.

After careful review, because BMA is unable to demonstrate that it suffered substantial prejudice based on the Agency’s reliance on the erroneous projected growth rate, we affirm the Final Decision.

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Factual and Procedural Background

***2** Each year, the State Coordinating Council prepares and publishes a "State Medical Facilities Plan" (the "State Plan") which inventories the services, facilities, and equipment subject to CON regulation. Dialysis facilities are subject to CON regulation. The State Plan uses historical data to project future need for CON-regulated services and equipment. The Governor signs and approves the State Plan.

The need for new dialysis stations is projected twice a year, in January and July, and is published in the Semiannual Dialysis Report ("SDR"). The Planning Branch collects historical patient information directly from providers and uses it to create an inventory of dialysis facilities, including information regarding the number of patients who receive dialysis services and how each existing dialysis facility is utilized. The SDR calculates an average annual change rate of the dialysis population living in each county over the previous five years ("the AACR") and then, using the AACR, projects the future need for additional dialysis stations for each county based on the county's projected patient population ("the county need determination").[1]

The July 2013 SDR projected a county need determination of 19 new dialysis stations in Nash County. At the time, BMA was the only in-center dialysis provider in Nash County. It is undisputed that the AACR stated in that report, a 9.6% increase in patients needing dialysis services in Nash County, was incorrect. As a result, the number of stations identified as being needed in Nash County in the July 2013 SDR was significantly larger than what was actually needed had the correct AACR—2.1%—been used. Had the correct data been reported, it would have reflected a deficit of only two stations in Nash County. It appears that this error in determining the projected growth rate was based, in part, on BMA's self-reported data to the Planning Branch.

Regardless of how the error occurred, after the July 2013 SDR was released, BMA formally notified the Planning Branch and the Agency of its errors and requested the Planning Branch reissue the SDR using an AACR of 2.1%. Although the Director of the Division of Health Services Regulation refused to reissue the SDR, BMA filed a petition with the Planning Branch requesting that an adjustment be made to correct the data reflecting the number of patients receiving dialysis services, which was incorporated by the Agency into the AACR and the need analysis showing a deficit of 19 stations. The Agency claimed that it could not amend the SDR and that it was bound by the figures published in the SDR when reviewing CON applications. According to officials at the Agency, only the Governor had the power to amend the published SDR, and BMA should petition the Governor to change it. BMA did not petition the Governor to amend the need determination for Nash County.

On 16 September 2013, both BMA and TRC submitted CON applications; TRC applied to build a new 12–bed facility, and BMA applied to expand its existing dialysis facility by 11 stations. In order to establish a new dialysis facility, TRC had to comply with 10A NCAC 14C.2203(a), which provides that "[a]n 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 [.]" Consequently, in order to establish a need for its proposed new dialysis facility with 12 stations, TRC had to be able to reasonably predict to serve 39 patients.

***3** TRC alleged in its CON application that its starting patient population was based on 32 letters of support, 26 Nash County patients and six Wilson County patients. However, only one of the letters identified the patient's county of residence. At the OAH hearing, TRC admitted that it had "incorrectly represented the county of residence of the patients who signed support letters." William Hyland, Director of CON for TRC, testified that the actual breakdown was as follows: 21 patient letters from Nash County residents, nine from Wilson County residents, one from an Edgecombe County resident, and one from an unknown residence. Thus, while there was still a total of 32 patient letters, the actual county breakdown was different than what was stated in TRC's CON application. The breakdown of patient letters by county is important because the 9.6% AACR would only be applied to the number of Nash County patients receiving services. Accordingly, TRC's ability to project that it would be serving 39 patients at the end of its first year of operation is based in large part on where each patient resides.

With regard to the population growth projection for Nash County, TRC used the erroneous 9.6% AACR published in the SDR. BMA used the actual historical AACR of 2.1% in its application. The Agency began reviewing applications on 1 October 2013. Accepting TRC's projection of a 9.6% AACR and the 32 patient letters (even though the letters did not state the patient's county of residence), the Agency approved TRC's application to build a new 12–station facility. Accepting BMA's use of the 2.1% AACR and patient projections, the Agency approved BMA to develop seven dialysis stations instead of the 11 it requested.

BMA appealed the Agency's decision to OAH. The matter was heard on 8 to 17 October 2014 before ALJ Elkins. On 26 March 2015, ALJ Elkins issued his Final Decision affirming the Agency's Decision. Pertinent findings and conclusions are discussed below.

Analysis

On appeal, BMA challenges various decisions the Agency made in the CON application review process including its use of the incorrect AACR of 9.6% and its acceptance of the patient letters TRC provided to support its application for a new dialysis facility. This Court finds it troubling that the need for dialysis services was so substantially overstated given the purpose of the CON laws. *See* *AH N.C. Owner LLC v. N.C. Dep't of Health & Human Servs.,* ––– N.C.App. ––––, ––––, 771 S.E.2d 537, 549 (2015) ("In addition to controlling health care costs and avoiding the costly and unnecessary duplication of health service facilities, a primary reason for the existence of the CON laws is to protect the health and well-being of the citizens of North Carolina."). However, in addition to this Court's conclusion that the only remedy to amend a flawed SDR is to petition the Governor, *see* *Bio–Med. Applications of N.C., Inc. v. N.C. Dep't of Health & Human Servs.,* 179 N.C.App. 483, 490, 634 S.E.2d 572, 577 (2006), BMA's inability to establish substantial prejudice as a result of the CON section's decisions to use the erroneous AACR and the patient letters leaves us no other choice but to affirm the Final Decision.

***4** To be entitled to appellate relief, a petitioner must show not only that the Agency's findings or conclusions were erroneous based on the enumerated grounds in N.C. Gen.Stat. § 150B–51(b) (2015), but the petitioner also must show that the Agency substantially prejudiced its rights. *CaroMont Health, Inc. v. N.C. Dep't of Health & Human Servs.,* 231 N.C.App. 1, 3–5, 751 S.E.2d 244, 247–48 (2013). Substantial prejudice in this context requires more than a showing that a petitioner is an "affected person," as provided in N.C. Gen.Stat. § 131E–188(a). *Parkway Urology, P.A. v. N.C. Dep't of Health & Human Servs.,* 205 N.C.App. 529, 535–36, 696 S.E.2d 187, 192–93 (2010). While there is no bright-line rule as to what constitutes substantial prejudice, our appellate courts have held that to obtain relief, a petitioner must show more than increased competition. *Id.* at 539, 696 S.E.2d at 195. Moreover, any claim of substantial prejudice must be based on more than conjecture or allegations. *See generally* *CaroMont Health,* 231 N.C.App. at 6, 751 S.E.2d at 249 ("CaroMont's alleged loss of volume and revenue, even if considered to show other than the normal effects of competition, was speculative and not supported by a preponderance of the evidence because there was no evidence that such alleged loss of volume and revenue was reasonably certain to result from the Agency's decision to approve the GGC Application rather than other factors."); *Ridge Care, Inc. v. N.C. Dep't of Health & Human Servs.,* 214 N.C.App. 498, 506, 716 S.E.2d 390, 396 (2011) (rejecting the petitioners' claim that they were substantially prejudiced because the Agency's decision would lead to increased costs and a loss of staff and patients when there was no evidence provided in support of those claims).

BMA challenges several of the Agency's findings including its use of an erroneous AACR of 9.6% and its reliance on TRC's patient letters supporting its application to open a new dialysis facility. However, as Judge Elkins found,

> The 9.6% growth rate is what led to the need determination and is the growth rate on which the 19 stations depend. Of great importance in this case, without the 9.6% growth rate, there would not have been a 19–station deficit in Nash County nor would there have been a need determination in Nash County. If the July 2013 SDR had been changed by the Governor, then neither BMA's nor TRC's applications would have been before the CON Section.

In fact, Elizabeth Brown ("Ms.Brown"), who has worked for the Planning Branch since 2006, testified that using an AACR of 2.1% would result in only a two-station deficit in Nash County. The county need methodology—the only methodology used in the SDR and in BMA's application for a certificate of need—treats a deficit of fewer than ten stations as a *zero* deficit. Thus, if the corrected underlying data had been considered by the CON Section, BMA would not have been allowed to develop any new dialysis stations, instead of the seven stations it was awarded using the erroneous AACR. Furthermore, the fact that TRC may not have been able to open any facility in Nash County to compete with BMA is not enough to establish substantial prejudice. *See* *CaroMont Health,* 231

N.C.App. at 3–6, 751 S.E.2d at 24749. Consequently, BMA is unable to show that the Agency's decision resulted in substantial prejudice, and we affirm the Final Decision.

Conclusion

***5** Based on BMA's failure to establish that it suffered substantial prejudice, we affirm the Final Decision.

AFFIRMED.

Judges STEPHENS and HUNTER, JR. concur.

Report per Rule 30(e).

All Citations

788 S.E.2d 684 (Table), 2016 WL 3166601

Footnotes

1 Applicants seeking to add dialysis stations can seek either a "county need determination" as set out in the SDR or seek a "facility need determination," a methodology which is used to permit existing facilities to expand. However, an existing facility may only apply for a "facility need determination" if there is no "county need determination." Since there was a "county need determination" set out in the July 2013 SDR, BMA could only apply for new dialysis stations using the "county need determination."

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ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

Decision Date: March 29, 2019
Findings Date: April 5, 2019

Project Analyst: Julie M. Faenza
Primary Co-Signer: Fatimah Wilson, Team Leader
Secondary Co-Signer: Martha J. Frisone, Chief

COMPETITIVE REVIEW

Project ID #:	F-11612-18
Facility:	Metrolina Vascular Access Care
FID #:	180517
County:	Mecklenburg
Applicants:	Fresenius Vascular Care Charlotte MSO, LLC Metrolina Vascular Access Care, LLC
Project:	Develop a new ambulatory surgical facility in Charlotte with one operating room and one procedure room focused on vascular access procedures for patients with end stage renal disease

Project ID #:	F-11619-18
Facility:	Carolina Center for Specialty Surgery
FID #:	050268
County:	Mecklenburg
Applicant:	Waveco, LLC
Project:	Develop one additional operating room pursuant to the 2018 SMFP need determination for a total of three operating rooms

Project ID #:	F-11620-18
Facility:	Carolinas Medical Center
FID #:	943070
County:	Mecklenburg
Applicant:	The Charlotte-Mecklenburg Hospital Authority
Project:	Develop four additional operating rooms pursuant to the 2018 SMFP need determination

Project ID #:	F-11621-18
Facility:	Atrium Health Pineville
FID #:	010778
County:	Mecklenburg
Applicant:	Mercy Hospital, Inc. Mercy Health Services, Inc. The Charlotte-Mecklenburg Hospital Authority
Project:	Develop one additional operating room pursuant to the 2018 SMFP need determination for a total of 11 operating rooms

Project ID #:	F-11622-18
Facility:	Atrium Health Pineville
FID #:	010778
County:	Mecklenburg
Applicant:	Mercy Hospital, Inc. Mercy Health Services, Inc. The Charlotte-Mecklenburg Hospital Authority
Project:	Develop 50 additional acute care beds pursuant to the 2018 SMFP need determination for a total of 271 acute care beds

Project ID #:	F-11624-18
Facility:	Novant Health Huntersville Medical Center
FID #:	990440
County:	Mecklenburg
Applicants:	Novant Health, Inc. The Presbyterian Hospital
Project:	Add 12 acute care beds and one operating room pursuant to need determinations in the 2018 SMFP

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 – All Applications

Need Determinations

Acute Care Beds – The 2018 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional acute care beds in North Carolina by

service area. Application of the need methodology in the 2018 SMFP identified a need for 50 additional acute care beds in the Mecklenburg County service area. Two applications were submitted to the Healthcare Planning and Certificate of Need Section (CON Section), proposing to develop a total of 62 new acute care beds in Mecklenburg County. However, pursuant to the need determination, only 50 acute care beds may be approved in this review for Mecklenburg County. See the Conclusion following the Comparative Analysis for the decision.

Only qualified applicants can be approved to develop new acute care beds. On page 40, the 2018 SMFP states:

> *"A person is a qualified applicant if he or she proposes to operate the additional acute care beds in a hospital that will provide:*
>
> *(1) a 24-hour emergency services department,*
> *(2) inpatient medical services to both surgical and non-surgical patients, and*
> *(3) if proposing a new licensed hospital, medical and surgical services on a daily basis within at least five of the major diagnostic categories as recognized by the Centers for Medicare and Medicaid services (CMS), as …* [listed on pages 40-41 of the 2018 SFMP]*."*

<u>*Operating Rooms (ORs)*</u> – Chapter 6 of the 2018 SMFP includes a methodology for determining the need for additional ORs in North Carolina by service area. Application of the need methodology in the 2018 SMFP identifies a need for six additional ORs in the Mecklenburg County service area. Five applications were submitted to the CON Section, proposing to develop a total of eight ORs. However, pursuant to the need determination, only six ORs may be approved in this review for Mecklenburg County. See the Conclusion following the Comparative Analysis for the decision.

<u>Policies</u>

There are two policies applicable to the review of the six applications submitted in response to the two need determinations in the 2018 SMFP for the Mecklenburg County service area.

Policy GEN-3: Basic Principles, on page 33 of the 2018 SMFP, states:

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

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 33 of the 2018 SMFP, states:

> *"Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.*
>
> *In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*
>
> *Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

F-11612-18/Metrolina Vascular Access Care/Develop one OR

The applicants, Fresenius Vascular Care Charlotte MSO, LLC and Metrolina Vascular Access Care, LLC (FVCC and MVAC, respectively) propose to develop Metrolina Vascular Access Care (Metrolina VAC), a new ambulatory surgical facility (ASF) in Charlotte with one OR and one procedure room (PR) focused on vascular access procedures for patients with end stage renal disease (ESRD).

Need Determination. The applicants do not propose to develop more ORs than are determined to be needed in the Mecklenburg County service area.

Policy GEN-3. In Section B, pages 12-14, the applicants explain why they believe their application is conforming to Policy GEN-3. The applicants state:

- They will have experienced support staff and physicians who will be able to fully support the needs of patients, and they will provide extensive training, educational opportunities, and patient safety programs. The applicants provide examples of training programs they plan to offer in Exhibit H-3.
- By providing vascular access procedures in an ASF instead of in a hospital, patients will receive high quality care at lower costs. The applicants plan to offer full and partial waivers to patients on a sliding income scale and state they are committed to providing access for all patients regardless of payor source. The applicants provide their proposed financial policies in Exhibits L-4.1, L-4.2, and L-4.3.

- Patients will receive coordinated care for their vascular access needs without needing to seek care in a hospital setting, which exposes vulnerable ESRD patients with weakened immune systems to more health risks.
- The applicants state that they plan to coordinate care for patients by also offering ESRD patients access to doctors in the same medical office building as the proposed ASF.
- The applicants state that their projections are based on historical utilization data combined with projections from physicians who will participate in providing care at the ASF. The applicants state that people from lower socioeconomic classes are disproportionately affected by ESRD and thus they are even more prepared to offer financial options to the medically underserved. The applicants state that they further plan to maximize value for resources expended by developing the proposed facility with energy saving and water conservation features that will provide greater cost savings.

Policy GEN-4. In Section B, page 15, the applicants explain why they believe their application is conforming to Policy GEN-4. The applicants provide a written statement which says they will develop and implement their facility by designing it to conform to or exceed the energy efficiency and water conservation standards found in the most recent edition of relevant building codes. The applicants list a number of energy efficient features that they will implement in the development of the proposed facility, including use of recycled content materials and high efficiency LED lighting with sensors. The applicants adequately demonstrate that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants do not propose to develop more ORs than are determined to be needed in Mecklenburg County.
- The applicants adequately demonstrate that the proposal is consistent with Policy GEN-3.
- The applicants adequately demonstrate that the proposal is consistent with Policy GEN-4.

F-11619-18/Carolina Center for Specialty Surgery/Develop one OR

The applicant, Waveco, LLC (Waveco) operates Carolina Center for Specialty Surgery (CCSS), a multispecialty ASF with two ORs. The applicant proposes to develop an additional OR pursuant to the 2018 SMFP need determination for a total of three ORs upon project completion.

Need Determination. The applicant does not propose to develop more ORs than are determined to be needed in Mecklenburg County.

Policy GEN-3. In Section B, pages 15-19, the applicant explains why it believes its application is conforming to Policy GEN-3. The applicant states:

- It uses a conservative approach to determine which cases are performed at CCSS to ensure quality and safety. It has policies and procedures in place to enhance quality and examples of these policies are provided in Exhibit B-3.1. CCSS and its surgeons also participate in nationwide quality organizations that result in enhanced patient safety and improved outcomes.
- The applicant states it provides the best care possible to every patient. The applicant states that it offers a 30 percent discount off of gross charges for any uninsured patient, and while it has not been historically successful at promoting access to charity care patients, it is currently revising its charity care policies to provide more access to charity care patients. The applicant provides a copy of its charity care policy in Exhibit L-4.
- The applicant states patients receiving services at an ASF can realize cost savings of 100 percent compared with similar services provided in a hospital setting. The applicant states it has steadily increased the number of cases it performs, which shifts appropriate cases to a lower cost outpatient setting.
- The applicant states the proposed project will allow CCSS to serve more patients and thus shift more patients to a lower cost outpatient setting. The applicant states serving more patients will result in more quality results to report to national organizations it is affiliated with, which will also benefit patients everywhere by providing more data.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more ORs than are determined to be needed in Mecklenburg County.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4.

F-11620-18/Carolinas Medical Center/Develop four ORs

The applicant, The Charlotte-Mecklenburg Hospital Authority (CMHA) operates Carolinas Medical Center (CMC), an acute care hospital licensed for 62 ORs. The applicant proposes to develop four additional ORs pursuant to the 2018 SMFP need determination for a total of 64 ORs upon completion of this project and Project I.D. #F-11106-15 (relocate two ORs as part of developing Randolph Surgery Center).

Need Determination. The applicant does not propose to develop more ORs than are determined to be needed in Mecklenburg County.

Policy GEN-3. In Section B, pages 14-17, the applicant explains why it believes its application is conforming to Policy GEN-3. The applicant states:

- It is nationally recognized as a hospital that provides high quality care, receives numerous awards for the quality care it provides, and is often listed as a top hospital in the United States for certain programs.
- The applicant states it has historically provided care to everyone in need, regardless of demographic characteristics. The applicant states that in 2017, 44 percent of Mecklenburg patients on Medicaid or who were uninsured were treated at CMC, and states that in 2016, CMC served more Medicaid and uninsured patients than any other provider in the state.
- The applicant states it is containing costs by developing the ORs in existing space, only requiring renovations rather than building new space, which it states maximizes healthcare value.
- The applicant states the proposed project will allow CMC to continue to demonstrate the concepts of safety, quality, access, and value because it will allow more access to patients, including the medically underserved, and will be able to provide safe, high quality surgical services to those patients.

Policy GEN-4. In Section B, pages 18-19, the applicant explains why it believes its application is conforming to Policy GEN-4. The applicant provides a written statement which says it will work with professionals who have experience in developing energy efficient projects and that it will meet or exceed standards listed in current building codes. The applicant states it was named a 2018 Energy Star Partner of the Year by the Environmental Protection Agency, and in order to be awarded that designation, the applicant states that it has to prove organization-wide energy savings and actively participate in Energy Star benefits. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more ORs than are determined to be needed in Mecklenburg County.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4.

F-11621-18/Atrium Health Pineville (AH Pineville)/Develop one OR

The applicants, Mercy Hospital, Inc., Mercy Health Services, Inc. and the Charlotte-Mecklenburg Hospital Authority (collectively CMHA) operate Atrium Health Pineville (AH Pineville), a general acute care hospital licensed for10 ORs. The applicants propose to develop an additional OR pursuant to the 2018 SMFP need determination for a total of 11 ORs upon project completion.

Need Determination. The applicants do not propose to develop more ORs than are determined to be needed in the Mecklenburg County service area.

Policy GEN-3. In Section B, pages 17-22, the applicants explain why it believes its application is conforming to Policy GEN-3. The applicants state:

- AH Pineville has a five star rating from CMS on a summary of quality measures on Hospital Compare, receives numerous awards for the quality care it provides, and the applicants have provided documentation of its Performance Improvement, Utilization, and Risk Management Plans in Exhibit B-3.
- The applicants state AH Pineville has historically provided care to everyone in need, regardless of demographic characteristics. The applicants state AH Pineville provided more than $29 million in charity care in CY 2017 and has made the recruitment and retention of bilingual employees a priority.
- The applicants state they are containing costs by developing the additional OR in existing space without requiring new construction or extensive and cost-prohibitive renovations. The applicants state that while the project will require some renovations, they will be significantly less than what would be required to build new space, which they state maximizes healthcare value.
- The applicants state the proposed project will allow AH Pineville to continue to demonstrate the concepts of safety, quality, access, and value because it will allow more access to patients, including the medically underserved, and it will be able to provide safe, high quality acute care services to those patients.

Policy GEN-4. In Section B, pages 20-22, the applicants explain why they believe their application is conforming to Policy GEN-4. The applicants provide a written statement saying they will work with professionals to develop the proposed project to ensure energy efficient systems are being used to the degree appropriate with the proposed renovations. The applicants adequately demonstrate that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

<u>Conclusion</u> - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more ORs than are determined to be needed in the Mecklenburg County service area.
- The applicants adequately demonstrate that the proposal is consistent with Policy GEN-3.
- The applicants adequately demonstrate that the proposal is consistent with Policy GEN-4.

F-11622-18/Atrium Health Pineville/Develop 50 acute care beds

The applicants, Mercy Hospital, Inc.; Mercy Health Services, Inc.; and The Charlotte-Mecklenburg Hospital Authority (collectively CMHA) operate Atrium Health Pineville (AH Pineville), a 221 acute care bed hospital in Mecklenburg County. The applicants propose to

develop 50 additional acute care beds pursuant to the 2018 SMFP need determination for a total of 271 acute care beds upon project completion.

Need Determination. The applicants do not propose to develop more acute care beds than are determined to be needed in the Mecklenburg County service area. In Section B, page 21, the applicants adequately demonstrate that they meet the requirements of a "qualified applicant" as defined in Chapter 5, pages 40-41, of the 2018 SMFP.

Policy GEN-3. In Section B, pages 32-35, the applicants explain why they believe their application is conforming to Policy GEN-3. The applicants state:

- AH Pineville has a five star rating from CMS on a summary of quality measures on Hospital Compare, receives numerous awards for the quality care it provides, and the applicants have provided documentation of its Performance Improvement, Utilization, and Risk Management Plans in Exhibit B-10.
- The applicants state AH Pineville has historically provided care to everyone in need, regardless of demographic characteristics. The applicants state AH Pineville provided $141 million in charity care in CY 2017 and has made the recruitment and retention of bilingual employees a priority.
- The applicants state they are containing costs by developing the acute care beds as part of a building already being developed, which they state maximizes healthcare value.
- The applicants state the proposed project will allow AH Pineville to continue to demonstrate the concepts of safety, quality, access, and value because it will allow more access to patients, including the medically underserved, and it will be able to provide safe, high quality acute care services to those patients.

Policy GEN-4. In Section B, pages 35-37, the applicants explain why they believe their application is conforming to Policy GEN-4. The applicants provide a written statement saying they will work with professionals who have experience in developing energy efficient projects and they will meet or exceed standards listed in current building codes. The applicants adequately demonstrate that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

<u>Conclusion</u> - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants do not propose to develop more acute care beds than are determined to be needed in Mecklenburg County and meet the requirements in Chapter 5 of the 2018 SMFP to develop the proposed beds.
- The applicants adequately demonstrate that the proposal is consistent with Policy GEN-3.
- The applicants adequately demonstrate that the proposal is consistent with Policy GEN-4.

F-11624-18/Novant Health Huntersville Medical Center/Develop 12 acute care beds and 1 OR

The applicants, Novant Health, Inc. and The Presbyterian Hospital **(Novant)** propose to add 12 acute care beds and one OR to Novant Health Huntersville Medical Center (**NHHMC**), an existing acute care hospital in Mecklenburg County. NHHMC currently is licensed for 91 acute care beds and five ORs. At the completion of this project and Project I.D. #F-11110-15 (add 48 acute care beds and one OR), NHHMC will be licensed for 151 acute care beds and seven ORs.

Need Determination. The applicants do not propose to develop more acute care beds or ORs than are determined to be needed in Mecklenburg County.

Policy GEN-3. In Section B, pages 18-21, the applicants explain why they believe their application is conforming to Policy GEN-3. The applicants state:

- They will be better able to manage surgical volumes due to operational efficiency which will result in a reduction of costs and increased safety and quality.
- Adding additional labor, delivery, recovery, and post-partum (LDRP) acute care beds allow for greater flexibility to respond to the needs of individual mothers as well as reduce risks associated by having to transfer patients to different rooms.
- By adding more acute care beds and ORs, NHHMC will have an increased capacity to care for patients that currently face access challenges due to limited capacity at NHHMC.
- They will serve all people, including all medically underserved people, without discrimination. The applicants provide copies of their policies related to equitable access to care in Exhibits B-10.13-23.
- NHHMC's existing LDRP beds operated at 93 percent capacity in 2017 and at 97 percent of capacity in the first six months of 2018; the applicants state adding more LDRP beds is the most cost-effective way to increase capacity since the beds will be created by converting unlicensed observation beds to licensed beds and will not involve construction.
- The applicants state that additional OR capacity will prevent delays that extend inpatient hospital stays and can increase costs while also allowing better scheduling and fewer overtime hours required from staff. The applicants also state that it is cost-effective because the OR will be created by remodeling existing space.
- They can achieve greater cost savings and have higher productivity at their new expanded facility by utilizing their existing resources that already exist and which can easily be moved to the new expanded facility.

Policy GEN-4. In Section B, pages 22-23, the applicants explain why they believe their application is conforming to Policy GEN-4. The applicants provide a written statement which says they will develop and implement their facility by designing it to conform to or exceed the energy efficiency and water conservation standards found in the most recent edition of relevant building codes. The applicants also list a number of methods they are currently using to provide greater energy efficiency and water conservation and provide a copy of their Sustainable Energy Management Plan in Exhibit B-11.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants do not propose to develop more acute care beds than are determined to be needed in Mecklenburg County and meets the requirements in Chapter 5 of the 2018 SMFP to develop the proposed beds.
- The applicants do not propose to develop more ORs than are determined to be needed in Mecklenburg County.
- The applicants adequately demonstrate that the proposal is consistent with Policy GEN-3.
- The applicants adequately demonstrate that the proposal is consistent with Policy GEN-4.

(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 – All Applications

F-11612-18/Metrolina Vascular Access Care/Develop one OR

The applicants propose to develop a new ASF with one OR and one PR dedicated to providing vascular access services for ESRD patients.

In Section A.10, page 9, the applicants state Metrolina Vascular Access Care, LLC is a new entity whose sole member is Metrolina Nephrology Associates (MNA). MNA is an independent nephrology practice with offices in multiple cities and with existing vascular access centers in Charlotte and Concord. Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care (AVC) is an affiliate of Fresenius Medical Care (FMC). On page 10, the applicants state:

> "*MNA has come together with Azura Vascular Care to provide office-based vascular access services in Mecklenburg, through a Management Services Organization ('MSO') arrangement creating Fresenius Vascular Care Charlotte MSO, LLC.*"

Patient Origin - On page 57, the 2018 SMFP defines the service area for ORs as *"…the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* Figure 6.1, on page 62, shows Mecklenburg County as its own OR planning area. Thus, the service area for this facility is Mecklenburg County. Facilities may also serve residents of counties not included in their service area. The following table illustrates projected patient origin.

Metrolina VAC Projected Patient Origin		
County	Operating Room	Procedure Room
	% Patients	% Patients
Mecklenburg	71.32%	71.32%
Union	10.49%	10.49%
Gaston	7.22%	7.22%
Anson	1.83%	1.83%
Cabarrus	0.96%	0.96%
Chesterfield (SC)	0.77%	0.77%
Stanly	0.48%	0.48%
Other NC Counties*	4.81%	4.81%
Unknown/Other States	0.67%	0.67%
TOTAL	**100.00%**	**100.00%**

Source: Section C, page 19
*Other NC Counties include Cleveland, Lincoln, Buncombe, Iredell, Alexander, Catawba, Montgomery, Moore, Robeson, and Rowan counties.

In Section C, page 20, the applicants provide the assumptions and methodology used to project their patient origin. The applicants' assumptions are reasonable and adequately supported.

Analysis of Need - In Section C, pages 21-31, the applicants provide clinical background information on ESRD and its effects, then explain the factors they believe support the need the population projected to utilize the proposed services has for the proposed services:

- *Clinical background on ESRD and vascular access:* The applicants state that approximately eight to ten percent of adults have some level of chronic kidney disease, and ESRD, or kidney failure, affects approximately 660,000 Americans, including almost 18,000 North Carolinians. The applicants state that there are only two options for ESRD patients to survive – they must receive a kidney transplant, or they must receive chronic dialysis treatment (typically three times per week in a dialysis center, with some patients dialyzing at home). The applicants state that ESRD is usually caused by high blood pressure and/or diabetes, and state that it disproportionately affects minorities and lower socioeconomic classes. The applicants state that surgically created vein and artery blood shunts, or vascular accesses, are necessary in order for an ESRD patient to receive hemodialysis. The dialysis machines remove the blood from the patient, filter the blood, and return the blood to the patient. The removal and return of the blood is done via vascular accesses. These vascular accesses are critical to an ESRD patient's care, and blocked or non-functioning vascular accesses disrupt dialysis, which in turn can cause hospitalization, complications, and even death. The applicants state that while these vascular accesses are critical for patients receiving hemodialysis treatments, they are prone to becoming blocked from clots, infected, or causing injury to the patient's artery and veins. The applicants state industry data shows that the average ESRD patient experiences 1.6 to 2.7 interventions to vascular access per year (this average includes all ESRD patients, including those who have not needed interventions). The applicants state that the North Carolina treatment centers and providers affiliated with the applicants performed 2.18 vascular accesses per patient in 2017.

The applicants state that historically, vascular accesses required inpatient surgery, but those surgeries have become more routine and office-based. The applicants state that their experience shows that up to 50 percent of existing vascular access patients present with complications requiring same-day procedures to continue dialysis, and they state that same-day treatment is the standard of care. The applicants state that the proposed facility is necessary because existing ASFs have not and will not provide same-day care to patients with vascular access issues since most procedures at an ASF are elective and scheduled in advance. The applicants state that the current alternative, without these types of proposed facilities, is for the ESRD patient to go to the emergency room, get stabilized, and get sent home until they can be fit into a surgical schedule. The applicants state that providing vascular access interventions at a dedicated ASF will result in cost savings, as it is more cost-effective to provide same day outpatient care than it is to present at an emergency room, receive inpatient treatment, and later obtain surgery. (pages 21-22)

- *Improved outcomes for patients:* The applicants cite three studies which each show that patients who receive vascular access services at a dedicated vascular access center achieve better clinical outcomes, such as fewer hospital days per patient, fewer missed treatments, and lower mortality rates. The applicants state that providing vascular access care in dedicated ASFs will allow for increased levels of expertise for patients. The applicants state that in addition to receiving more specialized care at a dedicated vascular access ASF, avoiding the hospital reduces the risk to patients of additional infection or other complications. The applicants also state that a dedicated vascular access ASF will allow for more coordination of care for patients who have multiple co-morbidities. (pages 22-24)
- *Maintaining access to care for patients:*
  - <u>Drawbacks to inpatient hospitals:</u> The applicants state that ESRD patients needing vascular access interventions often don't present to a hospital as an emergent case, which can lead to long delays with the inability to dialyze, and which results in patient deterioration. The applicants state that ESRD patients are often scheduled at the end of the day, after emergency and scheduled cases; often require bloodwork before a procedure can be performed; and the facility typically only puts a catheter in place until the patient can be scheduled for a longer period of time in an OR for the appropriate procedure. (page 24)
  - <u>Drawbacks to existing ASFs</u>: The applicants state that non-dedicated ASFs have many of the same difficulties as hospitals do for ESRD patients. The applicants state that the typical payor mix at a freestanding ASF relies on more commercial reimbursement than exists among the ESRD patient population. The applicants also state that ASFs often have treatment requirements which exclude ESRD patients, such as clinically ill status levels or no missed dialysis treatments. (pages 24-25)
- *Reducing costs of ESRD care:* The applicants state that due to the nature of ESRD and other complicated health needs of patients, the average ESRD patient costs the health care system approximately 10 times more than the average Medicare patient. The applicants state that the studies they previously cited show reduced costs of treatment in addition to better outcomes, including costs reduced by several hundred dollars per year, for those who receive vascular access services in dedicated vascular access centers. (pages 25-26)
- *Increases in population:* The applicants state that their primary area of patient origin will be Mecklenburg County and that their secondary area of patient origin will be Gaston and Union counties. The applicants cite data from the North Carolina Office of State Budget and Management (NC OSBM) which projects that all three counties will experience

population growth by 2023, with Mecklenburg County experiencing the most growth, and all three counties will see the population age 65+ grow at a higher rate than any other age group. The applicants state that the elderly population uses ESRD services at a higher rate than other populations. The applicants also state that minorities are disproportionately affected by ESRD. The applicants cite data from the 2016 United States Renal Data System which shows that ESRD prevalence is 3.7 times greater in Black people, 1.4 times greater in American Indians, and 1.5 times greater in Asian people as compared with White people. The applicants provide data from Claritas showing projected population growth by different racial and ethnic groups and state that the data shows that, for every county in their projected area of patient origin, every racial and ethnic group is growing at a faster rate than White people. Finally, the applicants provide the number of ESRD patients by county for December 31 of years 2013-2017 and state that the rate of increase in ESRD patients in all three counties of the area of patient origin is higher than the increase in the overall population. (pages 26-30)

- *Historical utilization:* The applicants state that MNA became affiliated with Azura Vascular Care (AVC), an affiliate of Fresenius Medical Care (FMC), in 2016. The applicants provide their historical data from MNA/AVC physicians who utilized MNA's Charlotte Vascular Access Center from annualized 2016 through 2018 annualized, as shown in the table below.

Charlotte Vascular Access Center Historical Utilization					
Case Type	**Service**	**2016***	**2017**	**2018****	**CAGR**
OR	Angioplasty	720	818	923	13.8%
OR	Stents	69	85	123	33.5%
OR	Thrombectomy	139	169	150	3.9%
OR Appropriate Volume Totals		928	1,072	1,196	13.5%
PR	Catheter Change	22	19	34	24.3%
PR	Catheter Insertion	156	123	134	-7.3%
PR	Catheter Other***	9	9	182	349.7%
PR	Catheter Removal***	139	143	14	-68.2%
PR	Fistulagram	286	299	273	-2.3%
PR	Other	19	7	11	-23.9
PR Appropriate Volume Totals		631	600	648	1.3%
All OR & PR Volume Totals		1,559	1,672	1,844	8.8%

*2016 annualized data = June 2016 – December 2016 actual data annualized on a straight line basis.
**2018 annualized data = January 2018 – July 2018 actual data by procedure, plus actual total center volume August 2018 – September 2018 annualized using the Excel trending function.
***The Project Analyst believes that the numbers for "Catheter Other" and "Catheter Removal" were inadvertently reversed in the application. However, this does not have any effect on the review of the application.

The applicants state that in addition to the growth of the number of vascular access procedures (including both OR-appropriate and PR-appropriate procedures), the total number of patients seen by MNA has been growing over the last three years as well. On page 31, the applicants provide the historical number of patients seen at MNA from 2016 to 2018, as shown in the table below.

MNA Historical Utilization				
	2016	**2017**	**2018**	**CAGR**
In-Center Patients	1,388	1,441	1,506	4.2%
Home Patients	163	163	162	-0.3%
Total Patients	**1,551**	**1,604**	**1,668**	**3.7%**

Source: pages 30-31 of the application

The information is reasonable and adequately supported for the following reasons:

- There is a need determination for six ORs in Mecklenburg County in the 2018 SMFP. The applicants are applying to develop one OR in Mecklenburg County in accordance with the OR need determination in the 2018 SMFP.
- The applicants use reasonable and clearly identified historical and demographic data to make assumptions with regard to identifying the population to be served.
- The applicants provide reliable data, make reasonable statements about the data, and use reasonable assumptions about the data to demonstrate the need the population to be served has for the proposed services.

Projected Utilization - In Section Q, the applicants provide projected utilization, as illustrated in the following table.

In Table 4 in Section C, Question 4, page 30, and Section Q, the applicants provide historical utilization for the office-based vascular access center for three years (2016 – 2018). For 2018, the number of OR appropriate cases reported in Section C are slightly lower than the numbers reported in Section Q but the differences are minor. Projected utilization was calculated in the table below using the applicants' assumptions and methodology but starting with the lower baseline numbers as reported in Section C. The projected number of surgical cases in brackets in the following table show what the applicants projected as compared to projections starting with the lower baseline numbers. All subsequent tables in these findings use the lower numbers from Section C as the baseline.

Metrolina VAC Projected OR Utilization			
	1st Full FY 5/20-4/21	**2nd Full FY 5/21-4/22**	**3rd Full FY 5/22-4/23**
Projected # of Surgical Cases	1,442 [1,455]	1,521 [1,533]	1,633 [1,647]
Annual Minutes [# of Cases X 68.6 minutes (1)]	98,921.2	104,340.6	112,023.8
Total Hours (2)	1,648.7	1,739.0	1,867.1
Average Annual Operating Hours – Group 6 (3)	1,312.5	1,312.5	1,312.5
Number of ORs Needed (4)	1.3	1.3	1.4
# of PRs	1	1	1
# of Procedures	725	754	783

(1) The Final Case Time in minutes for Group 6 facilities in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

In Section C, pages 30-32, and Section Q, the applicants provide the assumptions and methodology used to project utilization, which are summarized below.

On page 31, the applicants state that their projected utilization is based on the following:

- Historical cases performed in the office-based vascular access center in Charlotte
- Growth in the overall service area population
- Growth of the minority population in the service area
- Growth in the number of ESRD patients seen by the applicants
- Growth in the overall number of ESRD patients in the service area
- Growth in the number of vascular access procedures performed in the office-based vascular access center in Charlotte
- Increased marketing by the applicants

On pages 31-32, the applicants state that 2018 annualized utilization data for MNA was used as the baseline. Two different time periods were used to annualize the 2018 actual utilization data: January to July for procedure types and August to September for total volume using the "Trend" function in Microsoft Excel. On page 32, the applicants provide the following growth rates which were used to project the 2018 annualized utilization data forward through the third full operating year of the project.

- CY 2018 to CY 2019: 5.5 percent
- CY 2019 to CY 2020: 4.25 percent
- CY 2020 to CY 2021: 4.0 percent
- CY 2021 to CY 2022: 4.0 percent
- CY 2022 to CY 2023: 3.5 percent

On page 32, the applicants state that the historical growth rate for OR-appropriate cases from 2017 to 2018 annualized was 12 percent.

On page 32, the applicants provide the following assumptions regarding projected utilization for fistula creation cases:

- Assume an average of nine fistula creation cases per month during the first operating year, which starts May 1, 2020.
- For 2021, new patient fistula creation cases are increased by 60 percent over the 2020 projections.
- For 2022, new patient fistula creation cases are increased by 50 percent over the 2021 projections.
- For 2023, new patient fistula creation cases are increased by 33.3 percent over the 2022 projections.

On page 32, the applicants state that the final step in their methodology was to convert the projected utilization from calendar years to operating years. The applicants do not explain how they converted the CY data to OY data. However, the Project Analyst notes that when the data for CYs 2020 and 2021 are each divided by 12 months, and when eight months of data for CY

2020 is combined with four months of data for CY 2021, the calculations match the applicants' projections.

The following table illustrates how projected surgical cases were converted to surgical hours using the OR Need Methodology in Chapter 6 of the 2018 SMFP.

Metrolina VAC Projected OR Utilization			
	1st Full FY 5/20-4/21	2nd Full FY 5/21-4/22	3rd Full FY 5/22-4/23
Projected # of Surgical Cases	1,442 [1,455]	1,521 [1,533]	1,633 [1,647]
Final Case Time (1)	99,058.4	104,409.2	112,023.8
Total Surgical Hours (2)	1,651.0	1,740.2	1,867.1
Average Annual Operating Hours – Group 6 (3)	1,312.5	1,312.5	1,312.5
Number of ORs Needed (4)	1.3	1.3	1.4

(1) The Average Case Time for Group 6 in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

As shown in the table above, using the OR Need Methodology in Chapter 6 of the 2018 SMFP, the applicants show a need for 1.4 ORs in the third OY, which would be rounded down to 1. This is consistent with 10A NCAC 14C .2103, which requires the applicants to demonstrate the need for the number of ORs they propose to develop, using the OR Need Methodology in the applicable SMFP, for the third OY following project completion.

Furthermore, the applicants state that physician letters of support provided with the application support their projections. In Exhibit C-4.1, the applicants provide letters of support with projections for the number of OR surgery cases, PR cases, and fistula creation cases (when applicable) the physicians project to perform during OY3, along with the basis for their projections. The physicians who have written letters of support and their projections are shown in the table below.

Name	OR Cases		PR Cases		Fistula Creation Cases
	2017	OY 3	2017	OY 3	OY 3
Interventional Nephrologists					
Donald Berling	288	519	103	181	--
Verachai Lohavichan	192	346	118	207	--
Thomas Smarz, Jr.	170	306	149	261	--
Totals	**650**	**1,171**	**370**	**649**	**--**
Vascular Surgeons					
Jason Burgess	80	100	42	74	100
Paul Orland	73	100	34	60	100
Totals	**153**	**200**	**76**	**134**	**200**
Combined Totals	**803**	**1,371**	**446**	**783**	**200**

Note: the information in this table was compiled by the Project Analyst directly from the letters of support from the physicians themselves found in Exhibit C-4.1.

Physicians who will be performing the procedures were historically affiliated with MNA, which became affiliated with AVC in 2016.

Projected utilization is reasonable and adequately supported for the following reasons:

- There is a need determination in the 2018 SMFP for six ORs in the Mecklenburg County OR planning area.
- The applicants adequately demonstrate which surgical services will be performed in the OR and which ones will be performed in the PR.
- The applicants rely on their historical utilization in projecting future utilization.
- The applicants' historical utilization already meets the performance standard promulgated in 10A NCAC 14C .2103(a).
- Projections from physicians planning to utilize Metrolina VAC are reasonable and adequately supported.
- The applicants' projected utilization meets the performance standard promulgated in 10A NCAC 14C .2013(a).

<u>Access</u> - In Section C, page 36, the applicants state:

> *"MVAC will expand access to healthcare services for the medically underserved by providing vascular access procedures to patients who are indigent, self pay/charity patients, or who are otherwise medically underserved. MVAC is committed to provide services to all patients regardless of their ability to pay. MVAC will not discriminate against anyone due to age, race, color, ethnicity, religion, gender, sexual orientation, or disability status. The facility will obtain Medicare and Medicaid certification and proposes to serve a significant portion of Medicare, Medicaid, and uninsured patients."*

In Section L, page 70, the applicants project the following payor mix during the second year of operation following completion of the project, as illustrated in the following table.

Metrolina VAC Projected Payor Mix 2nd Full FY 5/21-4/22)	
Payor Source	**% of Patients (OR & PR)**
Charity Care	1.0%
Medicare*	65.6%
Medicaid*	5.1%
Insurance*	28.3%
TOTAL	**100.0%**

*Including any managed care plans

The projected payor mix is reasonable and adequately supported.

<u>Conclusion</u> - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants adequately identify the population to be served.
- The applicants adequately explain why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicants project the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately support their assumptions.

F-11619-18/Carolina Center for Specialty Surgery/Develop one OR

The applicant proposes to develop one additional OR at its existing ASF for a total of three ORs upon project completion. The applicant, Waveco, LLC, is a joint venture between NeuroSpine, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Atrium Health (**Atrium**). Each entity owns 50 percent of Waveco, LLC.

This application is one of four applications filed in the same review cycle for acute care beds and ORs by applicants who are owned by and/or affiliated with Atrium. On February 7, 2018, The Charlotte-Mecklenburg Hospital Authority, which owns and operates the facilities involved in these four applications, announced that it was changing its name and would do business as Atrium Health. There are six facilities relevant to this review that are part of the Atrium health system in Mecklenburg County. The following table identifies these facilities, the current name, and effective date of the change.

ATRIUM HEALTH FACILITIES MECKLENBURG COUNTY		
Previous Name	**Current Name**	**Effective Date of Change**
Carolinas Medical Center	Carolinas Medical Center	NA (will not change)
Carolinas Medical Center – Mercy	Carolinas Medical Center – Mercy	NA (will not change)
Carolinas HealthCare System Union	Atrium Health Union	January 1, 2019
Carolinas HealthCare System Pineville	Atrium Health Pineville	January 1, 2019
Carolinas HealthCare System University	Atrium Health University City	December 1, 2018
Carolinas HealthCare System Huntersville	Atrium Health Huntersville Surgery	December 1, 2018

<u>Patient Origin</u> - On page 57, the 2018 SMFP defines the service area for ORs as *"…the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* Figure 6.1, on page 62, shows Mecklenburg County as its own OR planning area. Thus, the service area for this facility is Mecklenburg County. Facilities may also serve residents of counties not included in their service area. The following table illustrates historical and projected patient origin.

CCSS Historical & Projected Patient Origin				
County	**CY 2017 (Last Full FY)**		**CY 2022 (3rd Full FY)**	
	# Patients	**% Patients**	**# Patients**	**% Patients**
Mecklenburg	727	37.1%	871	37.1%
York (SC)	204	10.4%	244	10.4%
Union	151	7.7%	181	7.7%
Gaston	150	7.7%	180	7.7%
Cabarrus	92	4.7%	110	4.7%
Other*	637	32.3%	758	32.3%
TOTAL	**1,961**	**100.0%**	**2,344**	**100.0%**

Source: Section C, pages 21-22
*Other includes Alexander, Alleghany, Anson, Ashe, Avery, Brunswick, Buncombe, Burke, Caldwell, Catawba, Chatham, Cleveland, Craven, Cumberland, Davidson, Davie, Forsyth, Franklin, Guilford, Harnett, Haywood, Henderson, Iredell, Lincoln, Montgomery, New Hanover, Polk, Randolph, Richmond, Robeson, Rutherford, Stanly, Stokes, Surry, Transylvania, Tyrrell, Vance, Wake, Watauga, Wilkes, and Yadkin counties, and other states.

In Section C, page 22, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

<u>*Analysis of Need*</u> - Atrium submitted three separate applications in response to the OR Need Determination in the 2018 SMFP. Atrium proposes to add one OR to CCSS; one OR to Atrium Health Pineville (AH Pineville); and four ORs to Carolinas Medical Center (CMC). In Section C, pages 23-40, the applicant discusses the need for all of Atrium's OR proposals. In a competitive review, every application is evaluated independently, as if there are no other applications in the review, to determine whether the application is conforming to all statutory and regulatory review criteria. Therefore, the discussion in this section focuses only on the need as it relates to CCSS.

In Section C, pages 23-25, Atrium states the need for six ORs in Mecklenburg County was generated by Atrium facilities. However, anyone may apply to meet the need, not just Atrium. Atrium has the burden of demonstrating the need for the proposed ORs in its applications as submitted.

With regard to CCSS, the applicant states the following that it believes supports the need the population projected to utilize the proposed services has for the proposed services:

- *Trends in outpatient surgery:* The applicant states that, due to advances in technological development as well as in the care provided to patients, outpatient surgery volume is expected to continue increasing. The applicant also states reduced costs for services performed on an outpatient basis, along with insurance reimbursement pressures, will feed the projected increase. The applicant states with payment trends moving toward more innovative payment models, high quality services at ASFs with lower costs will be more and more attractive to patients. The applicant further states Medicare is increasing the number of procedures it permits to be performed in an outpatient setting. The applicant states that according to research done by Press Ganey Associates, patients receiving

services in an ASF later report a 92 percent satisfaction rate. The applicant states that in addition to patient satisfaction, physicians have increased satisfaction as a result of more flexible scheduling, more consistent staffing, and lower turnaround time, which corresponds to better patient outcomes. (pages 25-26)

- *Trends in North Carolina and Mecklenburg County:* The applicant states that, from FFY 2014 through FFY 2017, SMFP data showed outpatient surgeries statewide had a three year CAGR of 1.3 percent, and the ratio of outpatient surgeries to total surgeries was consistently around 72 percent. The applicant states that, for the same time period (FFY 2014-2017), Mecklenburg County outpatient surgeries had a three year CAGR of 3.9 percent, and were also consistently at a ratio of 72 percent compared with total surgeries. The applicant states that, according to the 2018 and proposed 2019 SMFPs, Mecklenburg County ASFs had utilization rates of 112 percent and 99 percent in 2016 and 2017, respectively, compared with the SMFP's Operating Room Need Methodology standard hours. (pages 27-29)
- *Historical utilization at CCSS:* The applicant states that, even when adjusted for OR shifts that are pending as the result of approved but not yet fully developed projects, CCSS is above 100 percent utilization based on the total surgical hours it performed compared with the standard OR hours in the Operating Room Need Methodology in the 2018 SMFP. The table below shows the utilization of each ASF in Mecklenburg County as shown in the 2018 SMFP, with adjustments made by the applicant to account for pending OR shifts:

Mecklenburg County 2018 SMFP ASF Utilization Adjusted for Pending OR Shifts				
Facility	**Total Cases**	**Total Hours**	**Adjusted Hours**	**Adjusted Utilization**
Charlotte Surgery Center	7,908	9,226	7,872	117%
SouthPark Surgery Center	10,788	8,810	7,872	112%
Carolina Center for Specialty Surgery	1,880	2,663	2,624	101%
Novant Health Matthews Surgery Center	1,907	2,479	2,624	101%
Novant Health Huntersville Outpatient Surgery	2,385	2,147	2,624	82%
Novant Health Ballantyne Outpatient Surgery	923	1,231	2,624	47%
Randolph Surgery Center	0	0	7,872	0%
CHS Huntersville Surgery Center	0	0	1,313	0%

Source: Section C, page 34

The applicant does not explain how it arrived at its adjustments, but the information provided by the applicant shows that CCSS was at 101 percent of capacity in FY 2017. (page 34)

- *Need for additional capacity at CCSS:* The applicant states CCSS has met a unique need by providing neurosurgery services at an ASF, along with orthopedic surgery and pain management. The applicant states CCSS has exceeded its capacity for its two ORs, and in order to be able to continue shifting ASF-appropriate cases away from the hospital setting, it needs to be able to expand. (page 35)
- *Population growth and aging in Mecklenburg County:* The applicant states the population of Mecklenburg County is growing rapidly. The applicant cites data from NC OSBM which states Mecklenburg County is projected to have the highest statewide numerical increase in population and the fifth highest statewide percentage increase in population in 2020 when compared to 2010. The applicant further states Mecklenburg County's population age 65 and older will grow 17.5 percent between 2018 and 2025, and Mecklenburg County

will have the second highest total of residents age 65 and older out of all the counties in North Carolina. The applicant states this is significant because older residents use healthcare services at a higher rate than younger residents. The Project Analyst verified that Mecklenburg County's population age 65 and older will grow at one of the fastest rates of any county in North Carolina between 2018 and 2025, and the numerical increase in the population of residents age 65 and older between 2018 and 2025 is the highest of any county in the state. (pages 39-40)

The information is reasonable and adequately supported for the following reasons:

- There is a need determination for six ORs in Mecklenburg County in the 2018 SMFP. The applicant is applying to develop one OR in Mecklenburg County in accordance with the OR need determination in the 2018 SMFP.
- The applicant uses reasonable and clearly identified historical and demographic data to make assumptions with regard to identifying the population to be served.
- The applicant provides reliable data, makes reasonable statements about the data, and uses reasonable assumptions about the data to demonstrate the need the population to be served has for the proposed services.

Projected Utilization - In Section Q, the applicant provides projected utilization, as illustrated in the following table.

CCSS Projected OR Utilization			
	1st Full FY CY 2020	**2nd Full FY CY 2021**	**3rd Full FY CY 2022**
Projected # of Surgical Cases	2,158	2,251	2,344
Final Case Time (1)	85.0	85.0	85.0
Total Surgical Hours (2)	3,058	3,189	3,321
Average Annual Operating Hours – Group 6 (3)	1,312.5	1,312.5	1,312.5
Number of ORs Needed (4)	2.3	2.4	2.5

(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

In Section Q, Form C Method, pages 1-46, the applicant provides the assumptions and methodology used to project utilization for all of the facilities which are part of the Atrium health system in Mecklenburg County, which are briefly summarized below.

Carolina Center for Specialty Surgery – The assumptions and methodology used to project utilization at CCSS are found on pages 3-6. The applicant starts with historical utilization and projects utilization forward using a 1.8% compound annual growth rate (CAGR), which is based on growth from CY 2015 to CY 2018 (annualized). The CAGR used is one half of the historical CAGR of 3.5%. Then the applicant makes assumptions about shifts of patients to other Atrium facilities in Mecklenburg County, Union County, and South Carolina. The following table illustrates projected OR utilization at CCSS.

CCSS Projected OR Utilization					
	CY 2018*	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**
Baseline CCSS Cases	1,975	2,010	2,046	2,082	2,119
Cases to Shift (65% of 346)**	225	225	225	225	225
Ramp-Up of Cases to Shift	--	--	50%	75%	100%
Cases Shifted	--	--	112	169	225
Total Cases after Shift	**1,975**	**2,010**	**2,158**	**2,251**	**2,344**
Final Case Time in Minutes (1)	85.0	85.0	85.0	85.0	85.0
Total Hours (2)	2,798	2,848	3,058	3,189	3,321
Average Annual Operating Hours – Group 6 (3)	1,312.5	1,312.5	1,312.5	1,312.5	1,312.5
Number of ORs Needed (4)	2.1	2.2	2.3	2.4	2.5
Number of Existing ORs	2.0	2.0	2.0	2.0	2.0
Surplus (-) / Deficit	**0.1**	**0.2**	**0.3**	**0.4**	**0.5**

*The applicant states CY 2018 data is annualized based on actual data for January 2018 – July 2018.

**The applicant identified 346 cases that would have been appropriate to shift from CMC to CCSS in 2018 but the applicant assumes that only 65% would actually shift.

(1) The Final Case Time in minutes for the facility in the 2018 SMFP.

(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.

(3) From Table 6B in the 2018 SMFP.

(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

As shown in the table above, using the OR Need Methodology in Chapter 6 of the 2018 SMFP, the applicant shows a need for 0.5 of an additional OR in the third OY, which would be rounded to one. Atrium proposes to add one additional OR at CCSS. The proposal is consistent with 10A NCAC 14C .2103(a), which requires an applicant to demonstrate the need for the number of ORs it proposes to develop, using the OR Need Methodology in the applicable SMFP, for the third OY following project completion.

Atrium Health Pineville - The assumptions and methodology used to project utilization at AH Pineville are found on pages 7-12. The applicant starts with historical utilization and projects utilization forward using two different CAGRs: one for inpatient cases (7.1%) and one for outpatient cases (3.2%). The CAGRs are based on growth from CY 2015 to CY 2018 (annualized). The CAGR used for inpatient cases is equal to the actual CAGR. The CAGR used for outpatient cases is equal to the lowest growth rate during the time period analyzed. Then the applicant makes assumptions about shifts of patients to other Atrium facilities in Mecklenburg County, Union County, and South Carolina. The following table illustrates projected OR utilization at AH Pineville.

AH Pineville Projected OR Utilization						
	CY 2018	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**
Baseline Inpatient Cases	3,635	3,893	4,169	4,464	4,780	5,118
Baseline Outpatient Cases	5,039	5,203	5,372	5,546	5,726	5,912
Inpatient Cases to CHS Fort Mill	--	--	--	-433	-445	-457
Outpatient Cases to CHS Fort Mill	--	--	--	-649	-667	-686
Inpatient Cases to AH Union	--	-14	-29	-45	-91	-124
Outpatient Cases to AH Union	--	-18	-36	-55	-111	-151
Total Inpatient Cases	3,635	3,879	4,140	3,986	4,244	4,537
Total Outpatient Cases	5,039	5,185	5,336	4,842	4,948	5,075
Final Inpatient Case Time (1)	170.5	170.5	170.5	170.5	170.5	170.5
Final Outpatient Case Time (1)	92.4	92.4	92.4	92.4	92.4	92.4
Total Surgical Hours (2)	**18,089**	**19,008**	**19,982**	**18,784**	**19,680**	**20,709**
Average Annual Operating Hours – Group 3 (3)	1,755.0	1,755.0	1,755.0	1,755.0	1,755.0	1,755.0
Number of ORs Needed (4)	10.3	10.8	11.4	10.7	11.2	11.8
Number of Existing ORs	10.0	10.0	10.0	10.0	10.0	10.0
Surplus (-) / Deficit	**0.3**	**0.8**	**1.4**	**0.7**	**1.2**	**1.8**

(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

As shown in the table above, using the OR Need Methodology in Chapter 6 of the 2018 SMFP, the applicant shows a need for 1.8 additional ORs at AH Pineville in the third OY, which would be rounded to 2. Atrium proposes to add one additional OR at AH Pineville. The proposal is consistent with 10A NCAC 14C .2103(a), which requires an applicant to demonstrate the need for the number of ORs it proposes to develop, using the OR Need Methodology in the applicable SMFP, for the third OY following project completion.

Carolinas Medical Center - The assumptions and methodology used to project utilization at CMC are found on pages 13-24. The applicant starts with historical utilization and projects utilization forward using two different CAGRs: one for inpatient cases (1.3%) and one for outpatient cases (0.4%). These CAGRs are not based on the historical CAGRs at CMC. The applicant states that growth at CMC has been constrained *"by a lack of sufficient capacity."* The applicant states that projected growth in surgical cases is expected to be consistent with projected growth in acute care bed utilization. Then the applicant makes assumptions about shifts of patients to other Atrium facilities in Mecklenburg County, Union County, and South Carolina. The following table illustrates projected utilization at CMC.

CMC Projected OR Utilization						
	CY 2018*	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**
CMC Baseline Inpatient Cases	20,956	21,210	21,467	21,727	21,991	22,257
CMC Baseline Outpatient Cases	22,733	22,886	23,042	23,199	23,357	23,517
Outpatient Cases to CCSS	--	--	-112	-169	-225	-225
Outpatient Cases to RSC	--	-2,541	-2,858	-3,176	-3,237	-3,300
Outpatient Cases to CSC	--	-443	-499	-554	-565	-576
Inpatient Cases to CHS Fort Mill	--	--	--	-369	-379	-389
Outpatient Cases to CHS Fort Mill	--	--	--	-553	-569	-584
Inpatient Cases to AH Union	--	-64	-131	-200	-407	-553
Outpatient Cases to AH Union	--	-78	-160	-244	-497	-674
Total Inpatient Cases	20,956	21,146	21,336	21,158	21,205	21,315
Total Outpatient Cases	22,733	19,824	19,413	18,503	18,264	18,158
Inpatient Final Case Time (1)	221.5	221.5	221.5	221.5	221.5	221.5
Outpatient Final Case Time (1)	133.1	133.1	133.1	133.1	133.1	133.1
Total Surgical Hours (2)	**127,791.6**	**122,040.2**	**121,829.9**	**119,154.1**	**118,797.4**	**118,968.4**
Average Annual Operating Hours – Group 2 (3)	1,950.0	1,950.0	1,950.0	1,950.0	1,950.0	1,950.0
Number of ORs Needed (4)	65.5	62.6	62.5	61.1	60.9	61.0
Number of Existing ORs	55.0	55.0	55.0	55.0	55.0	55.0
Surplus (-) / Deficit	**10.5**	**7.6**	**7.5**	**6.1**	**5.9**	**6.0**

Source: Tables on page 22 of the application.
*The applicant states that CY 2018 data is annualized based on actual data for January 2018 – July 2018.
(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

As shown in the table above, using the OR Need Methodology in Chapter 6 of the 2018 SMFP, the applicant shows a need for 6 additional ORs at CMC in the third OY. The CMHA proposes to add four ORs at CMC. The proposal is consistent with 10A NCAC 14C .2103(a), which requires an applicant to demonstrate the need for the number of ORs it proposes to develop, using the OR Need Methodology in the applicable SMFP, for the third OY following project completion.

Atrium Health University City - AH University City is an acute care hospital with 11 ORs (excluding a dedicated C-Section OR). There are two projects which were previously approved but which are not yet developed as of the date of these findings which will impact the future total of ORs at AH University City:

- Project I.D. #F-11106-15/Randolph Surgery Center/Relocate three ORs from AH University City to RSC
- Project I.D. #F-11349-17/Atrium Health Huntersville Surgery/Separately license one OR currently on the hospital license

Atrium projects utilization separately for the hospital and the approved ASF. This section discusses projected OR utilization at the hospital. After the approved projects are operational, AH University City will have seven ORs.

The assumptions and methodology used to project utilization at AH University City are found on pages 25-29. The applicant starts with historical utilization and projects utilization forward using two different CAGRs: one for inpatient cases (1.5%) and one for outpatient cases (1.6%). The CAGRs are based on growth from CY 2015 to CY 2018 (annualized). The CAGRs used are less the historical CAGRs (3.5% and 3.1%, respectively). Then the applicant makes assumptions about shifts of patients to other Atrium facilities in Mecklenburg County, Union County, and South Carolina. The following table illustrates projected utilization at AH University City.

AH University City Projected OR Utilization						
	CY 2018*	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**
Baseline Inpatient Cases	1,158	1,176	1,194	1,212	1,231	1,249
Baseline Outpatient Cases	4,967	5,045	5,124	5,205	5,286	5,369
Outpatient Cases to RSC	--	-96	-108	-120	-122	-125
Outpatient Cases to CSC	--	-448	-504	-560	-571	-582
Inpatient Cases to CHS Fort Mill	--	--	--	-5	-5	-5
Outpatient Cases to CHS Fort Mill	--	--	--	-8	-8	-8
Inpatient Cases to AH Union	--	-1	-2	-3	-6	-8
Outpatient Cases to AH Union	--	-1	-2	-3	-7	9
Total Inpatient Cases	1,158	1,175	1,192	1,204	1,220	1,236
Total Outpatient Cases	4,967	4,500	4,510	4,514	4,578	4,645
Inpatient Final Case Time (1)	135.4	135.4	135.4	135.4	135.4	135.4
Outpatient Final Case Time (1)	84.3	84.3	84.3	84.3	84.3	84.3
Total Surgical Hours (2)	**9,591.8**	**8,974.1**	**9,026.5**	**9,059.2**	**9,185.2**	**9,315.4**
Average Annual Operating Hours – Group 4 (3)	1,500.0	1,500.0	1,500.0	1,500.0	1,500.0	1,500.0
Number of ORs Needed (4)	6.4	6.0	6.0	6.0	6.1	6.2
Number of Existing ORs	7.0	7.0	7.0	7.0	7.0	7.0
Surplus (-) / Deficit	**-0.6**	**-1.0**	**-1.0**	**-1.0**	**-0.9**	**-0.8**

*The applicant states that CY 2018 data is annualized based on actual data for January 2018 – July 2018.
(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

As shown in the table above, using the OR Need Methodology in Chapter 6 of the 2018 SMFP, the applicant shows a need for 0.8 of an additional OR at AH University City in the third OY. However, Atrium does not propose to add any additional ORs at AH University City as part of this review.

Atrium Health Huntersville Surgery – Currently, the ORs located at AH Huntersville are on the license of AH University City. In Project I.D. #F-11349-17, AH Huntersville was approved to become a separately licensed ASF with one OR. The development of the ASF is projected to be complete in May 2019.

The applicant starts with historical utilization and projects utilization forward using a 1.4% compound annual growth rate (CAGR), which is based on growth from CY 2015 to CY 2018 (annualized). The CAGR used is less than the historical CAGR of 2.9%. Then the applicant makes assumptions about shifts of patients to other Atrium facilities in Mecklenburg County, Union County, and South Carolina. The following table illustrates projected at CCSS.

AH Huntersville Projected OR Utilization						
	CY 2018*	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**
Baseline Cases	2,011	2,040	2,070	2,100	2,130	2,161
Cases to RSC	--	-40	-45	-50	-51	-52
Cases to CSC	--	-538	-605	-672	-685	-698
Total Cases	2,011	1,462	1,420	1,378	1,394	1,411
Final Case Time (1)	45.0	45.0	45.0	45.0	45.0	45.0
Total Surgical Hours (2)	**1,508.3**	**1,096.5**	**1,065.0**	**1,033.5**	**1,045.5**	**1,058.3**
Average Annual Operating Hours – Group 5 (3)	1,312.5	1,312.5	1,312.5	1,312.5	1,312.5	1,312.5
Number of ORs Needed (4)	1.1	0.8	0.8	0.8	0.8%	0.8
Number of Existing ORs	1.0	1.0	1.0	1.0	1.0	1.0
Surplus (-) / Deficit	**0.1**	**-0.2**	**-0.2**	**-0.2**	**-0.2**	**-0.2**

*The applicant states that CY 2018 data is annualized based on actual data for January 2018 – August 2018.
(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

As shown in the table above, using the OR Need Methodology in Chapter 6 of the 2018 SMFP, the applicant shows a need for zero additional ORs in the third OY. Atrium does not propose to add any additional ORs at AH Huntersville as part of this review.

Atrium Health System Combined - To meet the performance standard promulgated in 10A NCAC 14C .2103(b) in effect at the time of the submission of this application, an applicant proposing to add new ORs to a facility in its service area must demonstrate the need its entire health system has for all of the ORs proposed by the end of the third operating year. Altogether, Atrium proposes to add six ORs to its system:

- Project I.D. #F-11619-18/Carolina Center for Specialty Surgery/Add one OR
- Project I.D. #F-11620-18/Carolina Medical Center/Add four ORs
- Project I.D. #F-11621-18/Atrium Health Pineville/Add one OR

The following table illustrates the need for additional ORs for the entire health system.

Atrium Health OR Need			
	Deficits / Surpluses (-)		
	1st Full FY CY 2020	**2nd Full FY CY 2021**	**3rd Full FY CY 2022**
CCSS	0.3	0.4	0.5
AH Pineville	1.4	0.7	1.2
CMC	7.5	6.1	5.9
AH University City	-1.0	-1.0	-1.0
AH Huntersville Surgery Center	-0.2	-0.2	-0.2
Total Deficit/Surplus (-)	**8.0**	**6.0**	**6.4**

As shown in the table above, the Atrium health system has a projected deficit of 6.4 ORs. The CMHA proposes to add a total of six ORs in the three applications submitted in this review.

The three proposals meet the standard promulgated in 10A NCAC 14C .2103(b), requiring an applicant proposing to add new ORs to a service area to project sufficient surgical cases and hours to demonstrate the need for all of the existing, approved, and proposed ORs in the applicant's health system in the third operating year of the project based on the Operating Room Need Methodology in the 2018 SMFP.

Analysis of Support for Atrium's Assumptions - There are two issues which potentially call into question whether Atrium's assumptions and methodology are adequately supported. Each is discussed individually below.

- *CHS Fort Mill Litigation* - Just prior to filing this application, on October 1, 2018, Atrium petitioned the Supreme Court of South Carolina for a writ of certiorari, asking the Supreme Court to review the most recent outcome of the CHS Fort Mill litigation, which would award the certificate of need to develop a hospital in Fort Mill to a different applicant. Publicly available information obtained by the Agency shows that the Supreme Court of South Carolina denied Atrium's petition for a writ of certiorari on February 20, 2019. Thus, any projections involving a shift of patients to CHS Fort Mill are questionable. However, the outcome of that decision would result in more patients remaining at existing Atrium facilities, which would increase utilization.
- *Projected Inpatient Surgical Cases at CMC-Main* - CMC uses a projected growth rate for inpatient surgical cases at CMC-Main that is not supported by its historical inpatient surgical case volumes over time. CMC-Main does not adequately demonstrate in the application as submitted that the growth rate used to project inpatient surgical cases is reasonable and adequately supported given that that growth rate is based not on inpatient surgical cases but on acute care days of care and the acute care days of care growth rate was increased by an inadequately explained shift of patients back to CMC-Main apparently just for the purpose of calculating a higher growth rate.

Nevertheless, according to information provided by Atrium to the Agency in its 2019 Hospital and ASF LRAs, which are public records and were received by the Agency during the review, the Atrium health system already has a significant deficit of ORs. The table below shows the number of inpatient and outpatient surgical cases reported by each Atrium facility on its 2019 LRA. The reporting period is October 1, 2017 to September 30, 2018. Even when using the Final Case Times for each type of case as reported in the 2019 SMFP (the LRAs all have at least some increase in the average case times, with one exception), the facilities in the system show the following deficits and surpluses:

Atrium Health OR Deficits/Surpluses Based on 2019 LRA Cases					
Facility	**FY 2018 Cases***	**Final Case Time****	**Average Annual Op. Hours****	**# ORs Needed**	**Surplus (-) / Deficit**
CCSS	1,983	85.0	1,312	2.1	0.1
AH Pineville Inpatient	3,477	174.0	1,755	10.5	0.5
AH Pineville Outpatient	4,930	101.6			
CMC Inpatient***	20,877	224.7	1,950	65.8	10.8
CMC Outpatient***	22,464	134.0			
AH University City Inpatient	1,084	112.6	1,500	6.9	-0.1
AH University City Outpatient****	6,745	74.1			
System Total	**61,560**			**85.3**	**11.3**

*Does not include C-Sections performed in dedicated C-Section ORs
**From 2019 SMFP
***Includes CMC-Mercy
****Includes the OR that will become part of AH Huntersville Surgery Center

When using the calculations shown in the table above, CMC has a deficit of 10.8 ORs. This is a conservative number because it uses a final case times for outpatient surgical cases that is lower than what CMC reported on its 2019 LRA. The 2018 SMFP showed CMC had a deficit of 16.65 ORs, and the 2019 SMFP shows CMC has a deficit of 12.47 ORs. CMC could hold its current utilization steady through OY3 and it would not only show the need for the four additional ORs it proposes to add to its facility, but it would also by itself meet the standard promulgated in 10A NCAC 14C .2103(b). In other words, CMC-Main shows a need for all six ORs that are proposed in the three Atrium applications using the OR Need Methodology in the 2018 SMFP.

Projected utilization is reasonable and adequately supported for the following reasons:

- There is a need determination in the 2018 SMFP for six ORs in the Mecklenburg County OR planning area.
- The applicant relies on its historical utilization in projecting future utilization.
- The applicant's projected utilization meets the performance standard promulgated in 10A NCAC 14C .2103(a).
- The health system's historical utilization already meets the performance standard promulgated in 10A NCAC 14C .2103(b).

<u>Access</u> - In Section C, page 44, the applicant states *"CCSS provides services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay in full."*

In Section L, page 81, the applicant projects the following payor mix during the second year of operation following completion of the project, as illustrated in the following table.

CCSS Projected Payor Mix – 2nd Full FY (CY 2021)			
Payor Source	**Total Facility**	**ORs**	**PRs**
Self-Pay	0.6%	0.6%	0.4%
Medicare*	29.4%	22.8%	56.2%
Medicaid*	0.9%	0.6%	2.0%
Insurance*	64.3%	71.6%	34.6%
Other	4.8%	4.3%	6.8%
TOTAL	**100.0%**	**100.0%**	**100.0%**

*Including any managed care plans

The projected payor mix is reasonable and adequately supported.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately support their assumptions.

F-11620-18/Carolinas Medical Center/Develop four ORs

The applicant proposes to develop four additional ORs at its existing hospital for a total of 64 ORs upon completion of this project and Project I.D. #F-11106-15 (relocate two ORs as part of developing Randolph Surgery Center). This application is one of four applications filed in the same review cycle for acute care beds and ORs by applicants who are owned by and/or affiliated with Atrium.

On February 7, 2018, The Charlotte-Mecklenburg Hospital Authority, which owns and operates the facilities involved in these four applications, announced that it was changing its name and would do business as Atrium Health. There are six facilities relevant to this review that are part of the Atrium health system in Mecklenburg County. The following table identifies these facilities, the current name, and effective date of the change.

ATRIUM HEALTH FACILITIES MECKLENBURG COUNTY		
Previous Name	**Current Name**	**Effective Date of Change**
Carolinas Medical Center	Carolinas Medical Center	NA (will not change)
Carolinas Medical Center – Mercy	Carolinas Medical Center – Mercy	NA (will not change)
Carolinas HealthCare System Union	Atrium Health Union	January 1, 2019
Carolinas HealthCare System Pineville	Atrium Health Pineville	January 1, 2019
Carolinas HealthCare System University	Atrium Health University City	December 1, 2018
Carolinas HealthCare System Huntersville	Atrium Health Huntersville Surgery	December 1, 2018

<u>Patient Origin</u> - On page 57, the 2018 SMFP defines the service area for ORs as *"…the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* Figure 6.1, on page 62, shows Mecklenburg County as its own OR planning area. Thus, the service area for this facility is Mecklenburg County. Facilities may also serve residents of counties not included in their service area. The following table illustrates historical and projected patient origin.

CMC Operating Rooms Historical & Projected Patient Origin				
County	**CY 2017 (Last Full FY)**		**CY 2023 (FY 3)**	
	# Patients	**% Patients**	**# Patients**	**% Patients**
Mecklenburg	14,494	43.8%	13,616	46.2%
York (SC)	2,548	7.7%	1,559	5.3%
Union	2,449	7.4%	1,548	5.2%
Gaston	2,250	6.8%	2,101	7.1%
Cabarrus	1,324	4.0%	1,239	4.2%
Other*	10,027	30.3%	9,440	32.0%
TOTAL	**33,091**	**100.0%**	**29,503**	**100.0%**

Source: Section C, pages 22-23
*Other includes Alamance, Alexander, Alleghany, Anson, Ashe, Avery, Beauford, Bladen, Brunswick, Buncombe, Burke, Caldwell, Carteret, Caswell, Catawba, Chatham, Cherokee, Clay, Cleveland, Columbus, Craven, Cumberland, Davidson, Davie, Duplin, Durham, Edgecombe, Forsyth, Franklin, Guilford, Halifax, Harnett, Haywood, Henderson, Hoke, Iredell, Johnston, Lee, Lenoir, Lincoln, Macon, Madison, Martin, McDowell, Mitchell, Montgomery, Moore, Nash, New Hanover, Onslow, Orange, Pamlico, Pasquotank, Pender, Person, Pitt, Polk, Randolph, Richmond, Robeson, Rockingham, Rowan, Rutherford, Scotland, Stanly, Stokes, Surry, Swain, Transylvania, Wake, Washington, Watauga, Wayne, Wilkes, Wilson, Yadkin, and Yancey counties, and other states.

In Section C, page 23, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

<u>Analysis of Need</u> - Atrium submitted three separate applications in response to the OR Need Determination in the 2018 SMFP. Atrium proposes to add one OR to CCSS; one OR to Atrium Health Pineville (AH Pineville); and four ORs to Carolinas Medical Center (CMC). In Section C, pages 24-45, the applicant discusses the need for all of Atrium's OR proposals. In a competitive review, every application is evaluated independently, as if there are no other applications in the review, to determine whether the application is conforming to all statutory and regulatory review criteria. Therefore, the discussion in this section focuses only on the need as it relates to CMC.

In Section C, pages 24-26, Atrium states the need for six ORs in Mecklenburg County was generated by Atrium facilities. However, anyone may apply to meet the need, not just Atrium. Atrium has the burden of demonstrating the need for the proposed ORs in its applications as submitted.

With regard to CMC, the applicant states the following that it believes supports the need the population projected to utilize the proposed services has for the proposed services:

- *Trends in inpatient surgery:* The applicant states technology and its advances are creating integration between advanced imaging techniques and surgical procedures in the OR. The applicant states that CMC has several ORs it has developed with specific types of imaging equipment, such as equipment for endovascular imaging or an intraoperative MRI, to perform more advanced and complex surgeries using those pieces of imaging equipment. (pages 26-27)
- *Trends in outpatient surgery:* The applicant states that, due to advances in technological development as well as in the care provided to patients, outpatient surgery volume is expected to continue increasing. The applicant also states reduced costs for services performed on an outpatient basis, along with insurance reimbursement pressures, will feed the projected increase. The applicant states that despite movement toward sending low-acuity patients to freestanding ASFs for treatment, some patients will continue to require hospital-based outpatient surgery due to risk factors or comorbidities. (page 27)
- *Trends in North Carolina and Mecklenburg County:* The applicant states that, from FFY 2014 through FFY 2017, SMFP data showed inpatient surgeries statewide had a three year CAGR of 1.5 percent, outpatient surgeries statewide had a three year CAGR of 1.3 percent, and the ratio of outpatient surgeries to total surgeries was consistently around 72 percent. The applicant states that, for the same time period (FFY 2014-2017), Mecklenburg County inpatient surgeries had a three year CAGR of 3.5 percent, outpatient surgeries had a three year CAGR of 3.9 percent, and were also consistently at a ratio of 72 percent compared with total surgeries. The applicant states that, according to the 2016 – proposed 2019 SMFPs, Mecklenburg hospital outpatient and ASF outpatient surgeries have grown at a 3.9 percent CAGR, but the increase in the number of outpatient surgeries performed at hospitals is double the increase in the number of outpatient surgeries performed at ASFs. The applicant states that, according to the 2018 and proposed 2019 SMFPs, Mecklenburg County hospital ORs had utilization rates of 97 percent and 96 percent in 2016 and 2017, respectively, compared with the SMFP's Operating Room Need Methodology standard hours. The applicant states that, because of ASF projects under development which will increase the availability of ASF-based outpatient surgical services, it believes that inpatient settings have the greatest need for additional OR capacity at this point. The applicant states ASFs cannot be used for stays longer than 24 hours and typically have lower capacity than ORs at a hospital, which can stay open far longer than those at an ASF. (pages 28-31)
- *Historical utilization at CMC:* The applicant states that, even when adjusted for OR shifts that are pending as the result of approved but not yet fully developed projects, CMC is above 100 percent utilization based on the total surgical hours it performed compared with the standard OR hours in the Operating Room Need Methodology in the 2018 SMFP. The table below shows the utilization of each hospital in Mecklenburg County as shown in the 2018 SMFP, with adjustments made by the applicant to account for pending OR shifts:

Mecklenburg County 2018 SMFP Hospital OR Utilization Adjusted for Pending OR Shifts				
Facility	**Total Cases**	**Total Hours**	**Adjusted Hours**	**Adjusted Utilization**
CMC	43,543	129,027	107,250	120%
Novant Health Matthews Medical Center	5,597	9,317	9,000	104%
Novant Health Huntersville Medical Center	4,980	9,385	9,000	104%
AH Pineville	8,133	17,738	17,550	101%
AH University City	7,383	9,731	10,500	93%
Novant Health Presbyterian Medical Center	29,898	57,606	70,200	82%

Source: Section C, page 36

The applicant does not explain how it arrived at its adjustments, but the information provided by the applicant shows that CMC was at 120 percent of capacity in FY 2017. (page 36)

- *Need for additional capacity at CMC:* The applicant states CMC provides multiple types of services unique to Mecklenburg County hospitals, such as being a Level I Trauma Center, providing solid organ transplantation, and having Levine Children's Hospital (on page 16, the applicant states that Levine Children's Hospital is the largest children's hospital between Atlanta and Washington, D.C.). The applicant states that its ORs operate longer (more hours) than any other facility in Mecklenburg County, due in part to its longer than average inpatient case times. (pages 37-38)
- *Population growth and aging in Mecklenburg County:* The applicant states the population of Mecklenburg County is growing rapidly. The applicant cites data from NC OSBM which states Mecklenburg County is projected to have the highest statewide numerical increase in population and the fifth highest statewide percentage increase in population in 2020 when compared to 2010. The applicant further states Mecklenburg County's population age 65 and older will grow 17.5 percent between 2018 and 2025, and Mecklenburg County will have the second highest total of residents age 65 and older out of all the counties in North Carolina. The applicant states this is significant because older residents use healthcare services at a higher rate than younger residents. The Project Analyst verified that Mecklenburg County's population age 65 and older will grow at one of the fastest rates of any county in North Carolina between 2018 and 2025, and the numerical increase in the population of residents age 65 and older between 2018 and 2025 is the highest of any county in the state. (pages 43-44)

The information is reasonable and adequately supported for the following reasons:

- There is a need determination for six ORs in Mecklenburg County in the 2018 SMFP. The applicant is applying to develop four ORs in Mecklenburg County in accordance with the OR need determination in the 2018 SMFP.
- The applicant uses reasonable and clearly identified historical and demographic data to make assumptions with regard to identifying the population to be served.
- The applicant provides reliable data, makes reasonable statements about the data, and uses reasonable assumptions about the data to demonstrate the need the population to be served has for the proposed services.

<u>*Projected Utilization*</u> - In Section Q, the applicant provides projected utilization, as illustrated in the following table.

CMC Projected OR Utilization			
	1st Full FY CY 2021	2nd Full FY CY 2022	3rd Full FY CY 2023
Projected # of Inpatient Surgical Cases	21,158	21,204	21,315
Projected # of Outpatient Surgical Cases	18,503	18,265	18,158
Projected # of Total Surgical Cases	39,660	39,468	39,473
Final Inpatient Case Time (minutes) (1)	221.5	221.5	221.5
Final Outpatient Case Time (minutes) (1)	133.1	133.1	133.1
Total Hours (Total Minutes / 60 minutes per hour) (2)	119,152	118,794	118,967
Average Annual Operating Hours – Group 2 (3)	1,950	1,950	1,950
Number of ORs Needed (Annual Hours / Average Operating Hours) (4)	61.1	60.9	61.0

(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

In Section Q, Form C Method, pages 1-46, the applicant provides the assumptions and methodology used to project utilization for all of the facilities which are part of the Atrium health system in Mecklenburg County, which are briefly summarized below.

Carolina Center for Specialty Surgery – The assumptions and methodology used to project utilization at CCSS are found on pages 3-6. The applicant starts with historical utilization and projects utilization forward using a 1.8% compound annual growth rate (CAGR), which is based on growth from CY 2015 to CY 2018 (annualized). The CAGR used is one half of the historical CAGR of 3.5%. Then the applicant makes assumptions about shifts of patients to other Atrium facilities in Mecklenburg County, Union County, and South Carolina. The following table illustrates projected OR utilization at CCSS.

CCSS Projected OR Utilization					
	CY 2018*	CY 2019	CY 2020	CY 2021	CY 2022
Baseline CCSS Cases	1,975	2,010	2,046	2,082	2,119
Cases to Shift (65% of 346)**	225	225	225	225	225
Ramp-Up of Cases to Shift	--	--	50%	75%	100%
Cases Shifted	--	--	112	169	225
Total Cases after Shift	**1,975**	**2,010**	**2,158**	**2,251**	**2,344**
Final Case Time in Minutes (1)	85.0	85.0	85.0	85.0	85.0
Total Hours (2)	2,798	2,848	3,058	3,189	3,321
Average Annual Operating Hours – Group 6 (3)	1,312.5	1,312.5	1,312.5	1,312.5	1,312.5
Number of ORs Needed (4)	2.1	2.2	2.3	2.4	2.5
Number of Existing ORs	2.0	2.0	2.0	2.0	2.0
Surplus (-) / Deficit	**0.1**	**0.2**	**0.3**	**0.4**	**0.5**

*The applicant states CY 2018 data is annualized based on actual data for January 2018 – July 2018.
**The applicant identified 346 cases that would have been appropriate to shift from CMC to CCSS in 2018 but the applicant assumes that only 65% would actually shift.
(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

As shown in the table above, using the OR Need Methodology in Chapter 6 of the 2018 SMFP, the applicant shows a need for 0.5 of an additional OR in the third OY, which would be rounded to one. Atrium proposes to add one additional OR at CCSS. The proposal is consistent with 10A NCAC 14C .2103(a), which requires an applicant to demonstrate the need for the number of ORs it proposes to develop, using the OR Need Methodology in the applicable SMFP, for the third OY following project completion.

Atrium Health Pineville - The assumptions and methodology used to project utilization at AH Pineville are found on pages 7-12. The applicant starts with historical utilization and projects utilization forward using two different CAGRs: one for inpatient cases (7.1%) and one for outpatient cases (3.2%). The CAGRs are based on growth from CY 2015 to CY 2018 (annualized). The CAGR used for inpatient cases is equal to the actual CAGR. The CAGR used for outpatient cases is equal to the lowest growth rate during the time period analyzed. Then the applicant makes assumptions about shifts of patients to other Atrium facilities in Mecklenburg County, Union County, and South Carolina. The following table illustrates projected OR utilization at AH Pineville.

AH Pineville Projected OR Utilization						
	CY 2018	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**
Baseline Inpatient Cases	3,635	3,893	4,169	4,464	4,780	5,118
Baseline Outpatient Cases	5,039	5,203	5,372	5,546	5,726	5,912
Inpatient Cases to CHS Fort Mill	--	--	--	-433	-445	-457
Outpatient Cases to CHS Fort Mill	--	--	--	-649	-667	-686
Inpatient Cases to AH Union	--	-14	-29	-45	-91	-124
Outpatient Cases to AH Union	--	-18	-36	-55	-111	-151
Total Inpatient Cases	3,635	3,879	4,140	3,986	4,244	4,537
Total Outpatient Cases	5,039	5,185	5,336	4,842	4,948	5,075
Final Inpatient Case Time (1)	170.5	170.5	170.5	170.5	170.5	170.5
Final Outpatient Case Time (1)	92.4	92.4	92.4	92.4	92.4	92.4
Total Surgical Hours (2)	**18,089**	**19,008**	**19,982**	**18,784**	**19,680**	**20,709**
Average Annual Operating Hours – Group 3 (3)	1,755.0	1,755.0	1,755.0	1,755.0	1,755.0	1,755.0
Number of ORs Needed (4)	10.3	10.8	11.4	10.7	11.2	11.8
Number of Existing ORs	10.0	10.0	10.0	10.0	10.0	10.0
Surplus (-) / Deficit	**0.3**	**0.8**	**1.4**	**0.7**	**1.2**	**1.8**

(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

As shown in the table above, using the OR Need Methodology in Chapter 6 of the 2018 SMFP, the applicant shows a need for 1.8 additional ORs at AH Pineville in the third OY, which would be rounded to 2. Atrium proposes to add one additional OR at AH Pineville. The proposal is consistent with 10A NCAC 14C .2103(a), which requires an applicant to demonstrate the need for the number of ORs it proposes to develop, using the OR Need Methodology in the applicable SMFP, for the third OY following project completion.

Carolinas Medical Center - The assumptions and methodology used to project utilization at CMC are found on pages 13-24. The applicant starts with historical utilization and projects

utilization forward using two different CAGRs: one for inpatient cases (1.3%) and one for outpatient cases (0.4%). These CAGRs are not based on the historical CAGRs at CMC. The applicant states that growth at CMC has been constrained *"by a lack of sufficient capacity."* The applicant states that projected growth in surgical cases is expected to be consistent with projected growth in acute care bed utilization. Then the applicant makes assumptions about shifts of patients to other Atrium facilities in Mecklenburg County, Union County, and South Carolina. The following table illustrates projected utilization at CMC.

CMC Projected OR Utilization						
	CY 2018*	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**
CMC Baseline Inpatient Cases	20,956	21,210	21,467	21,727	21,991	22,257
CMC Baseline Outpatient Cases	22,733	22,886	23,042	23,199	23,357	23,517
Outpatient Cases to CCSS	--	--	-112	-169	-225	-225
Outpatient Cases to RSC	--	-2,541	-2,858	-3,176	-3,237	-3,300
Outpatient Cases to CSC	--	-443	-499	-554	-565	-576
Inpatient Cases to CHS Fort Mill	--	--	--	-369	-379	-389
Outpatient Cases to CHS Fort Mill	--	--	--	-553	-569	-584
Inpatient Cases to AH Union	--	-64	-131	-200	-407	-553
Outpatient Cases to AH Union	--	-78	-160	-244	-497	-674
Total Inpatient Cases	20,956	21,146	21,336	21,158	21,205	21,315
Total Outpatient Cases	22,733	19,824	19,413	18,503	18,264	18,158
Inpatient Final Case Time (1)	221.5	221.5	221.5	221.5	221.5	221.5
Outpatient Final Case Time (1)	133.1	133.1	133.1	133.1	133.1	133.1
Total Surgical Hours (2)	**127,791.6**	**122,040.2**	**121,829.9**	**119,154.1**	**118,797.4**	**118,968.4**
Average Annual Operating Hours – Group 2 (3)	1,950.0	1,950.0	1,950.0	1,950.0	1,950.0	1,950.0
Number of ORs Needed (4)	65.5	62.6	62.5	61.1	60.9	61.0
Number of Existing ORs	55.0	55.0	55.0	55.0	55.0	55.0
Surplus (-) / Deficit	**10.5**	**7.6**	**7.5**	**6.1**	**5.9**	**6.0**

Source: Tables on page 22 of the application.
*The applicant states that CY 2018 data is annualized based on actual data for January 2018 – July 2018.
(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

As shown in the table above, using the OR Need Methodology in Chapter 6 of the 2018 SMFP, the applicant shows a need for 6 additional ORs at CMC in the third OY. Atrium proposes to add four ORs at CMC. The proposal is consistent with 10A NCAC 14C .2103(a), which requires an applicant to demonstrate the need for the number of ORs it proposes to develop, using the OR Need Methodology in the applicable SMFP, for the third OY following project completion.

Atrium Health University City - AH University City is an acute care hospital with 11 ORs (excluding a dedicated C-Section OR). There are two projects which were previously approved but which are not yet developed as of the date of these findings which will impact the future total of ORs at AH University City:

- Project I.D. #F-11106-15/Randolph Surgery Center/Relocate three ORs from AH University City to RSC

- Project I.D. #F-11349-17/Atrium Health Huntersville Surgery/Separately license one OR currently on the hospital license

Atrium projects utilization separately for the hospital and the approved ASF. This section discusses projected OR utilization at the hospital. After the approved projects are operational, AH University City will have seven ORs.

The assumptions and methodology used to project utilization at AH University City are found on pages 25-29. The applicant starts with historical utilization and projects utilization forward using two different CAGRs: one for inpatient cases (1.5%) and one for outpatient cases (1.6%). The CAGRs are based on growth from CY 2015 to CY 2018 (annualized). The CAGRs used are less the historical CAGRs (3.5% and 3.1%, respectively). Then the applicant makes assumptions about shifts of patients to other Atrium facilities in Mecklenburg County, Union County, and South Carolina. The following table illustrates projected utilization at AH University City.

AH University City Projected OR Utilization						
	CY 2018*	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**
Baseline Inpatient Cases	1,158	1,176	1,194	1,212	1,231	1,249
Baseline Outpatient Cases	4,967	5,045	5,124	5,205	5,286	5,369
Outpatient Cases to RSC	--	-96	-108	-120	-122	-125
Outpatient Cases to CSC	--	-448	-504	-560	-571	-582
Inpatient Cases to CHS Fort Mill	--	--	--	-5	-5	-5
Outpatient Cases to CHS Fort Mill	--	--	--	-8	-8	-8
Inpatient Cases to AH Union	--	-1	-2	-3	-6	-8
Outpatient Cases to AH Union	--	-1	-2	-3	-7	9
Total Inpatient Cases	1,158	1,175	1,192	1,204	1,220	1,236
Total Outpatient Cases	4,967	4,500	4,510	4,514	4,578	4,645
Inpatient Final Case Time (1)	135.4	135.4	135.4	135.4	135.4	135.4
Outpatient Final Case Time (1)	84.3	84.3	84.3	84.3	84.3	84.3
Total Surgical Hours (2)	**9,591.8**	**8,974.1**	**9,026.5**	**9,059.2**	**9,185.2**	**9,315.4**
Average Annual Operating Hours – Group 4 (3)	1,500.0	1,500.0	1,500.0	1,500.0	1,500.0	1,500.0
Number of ORs Needed (4)	6.4	6.0	6.0	6.0	6.1	6.2
Number of Existing ORs	7.0	7.0	7.0	7.0	7.0	7.0
Surplus (-) / Deficit	**-0.6**	**-1.0**	**-1.0**	**-1.0**	**-0.9**	**-0.8**

*The applicant states that CY 2018 data is annualized based on actual data for January 2018 – July 2018.
(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

As shown in the table above, using the OR Need Methodology in Chapter 6 of the 2018 SMFP, the applicant shows a need for 0.8 of an additional OR at AH University City in the third OY. However, Atrium does not propose to add any additional ORs at AH University City as part of this review.

Atrium Health Huntersville Surgery – Currently, the ORs located at AH Huntersville are on the license of AH University City. In Project I.D. #F-11349-17, AH Huntersville was approved

to become a separately licensed ASF with one OR. The development of the ASF is projected to be complete in May 2019.

The applicant starts with historical utilization and projects utilization forward using a 1.4% compound annual growth rate (CAGR), which is based on growth from CY 2015 to CY 2018 (annualized). The CAGR used is less than the historical CAGR of 2.9%. Then the applicant makes assumptions about shifts of patients to other Atrium facilities in Mecklenburg County, Union County, and South Carolina. The following table illustrates projected at CCSS.

AH Huntersville Projected OR Utilization						
	CY 2018*	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**
Baseline Cases	2,011	2,040	2,070	2,100	2,130	2,161
Cases to RSC	--	-40	-45	-50	-51	-52
Cases to CSC	--	-538	-605	-672	-685	-698
Total Cases	2,011	1,462	1,420	1,378	1,394	1,411
Final Case Time (1)	45.0	45.0	45.0	45.0	45.0	45.0
Total Surgical Hours (2)	**1,508.3**	**1,096.5**	**1,065.0**	**1,033.5**	**1,045.5**	**1,058.3**
Average Annual Operating Hours – Group 5 (3)	1,312.5	1,312.5	1,312.5	1,312.5	1,312.5	1,312.5
Number of ORs Needed (4)	1.1	0.8	0.8	0.8	0.8%	0.8
Number of Existing ORs	1.0	1.0	1.0	1.0	1.0	1.0
Surplus (-) / Deficit	**0.1**	**-0.2**	**-0.2**	**-0.2**	**-0.2**	**-0.2**

*The applicant states that CY 2018 data is annualized based on actual data for January 2018 – August 2018.
(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

As shown in the table above, using the OR Need Methodology in Chapter 6 of the 2018 SMFP, the applicant shows a need for zero additional ORs in the third OY. The CMHA does not propose to add any additional ORs at AH Huntersville as part of this review.

Atrium Health System Combined - To meet the performance standard promulgated in 10A NCAC 14C .2103(b) in effect at the time of the submission of this application, an applicant proposing to add new ORs to a facility in its service area must demonstrate the need its entire health system has for all of the ORs proposed by the end of the third operating year. Altogether, Atrium proposes to add six ORs to its system:

- Project I.D. #F-11619-18/Carolina Center for Specialty Surgery/Add one OR
- Project I.D. #F-11620-18/Carolina Medical Center/Add four ORs
- Project I.D. #F-11621-18/Atrium Health Pineville/Add one OR

The following table illustrates the need for additional ORs for the entire health system.

Atrium Health OR Need			
	Deficits / Surpluses (-)		
	1st Full FY CY 2020	2nd Full FY CY 2021	3rd Full FY CY 2022
CCSS	0.3	0.4	0.5
AH Pineville	1.4	0.7	1.2
CMC	7.5	6.1	5.9
AH University City	-1.0	-1.0	-1.0
AH Huntersville Surgery Center	-0.2	-0.2	-0.2
Total Deficit/Surplus (-)	**8.0**	**6.0**	**6.4**

As shown in the table above, the Atrium health system has a projected deficit of 6.4 ORs. Atrium proposes to add a total of six ORs in the three applications submitted in this review. The three proposals meet the standard promulgated in 10A NCAC 14C .2103(b), requiring an applicant proposing to add new ORs to a service area to project sufficient surgical cases and hours to demonstrate the need for all of the existing, approved, and proposed ORs in Atrium's health system in the third operating year of the project based on the Operating Room Need Methodology in the 2018 SMFP.

Analysis of Support for Atrium's Assumptions - There are two issues which potentially call into question whether Atrium's assumptions and methodology are adequately supported. Each is discussed individually below.

- *CHS Fort Mill Litigation* - Just prior to filing this application, on October 1, 2018, Atrium petitioned the Supreme Court of South Carolina for a writ of certiorari, asking the Supreme Court to review the most recent outcome of the CHS Fort Mill litigation, which would award the certificate of need to develop a hospital in Fort Mill to a different applicant. Publicly available information obtained by the Agency shows that the Supreme Court of South Carolina denied Atrium's petition for a writ of certiorari on February 20, 2019. Thus, any projections involving a shift of patients to CHS Fort Mill are questionable. However, the outcome of that decision would result in more patients remaining at existing Atrium facilities, which would increase utilization.
- *Projected Inpatient Surgical Cases at CMC-Main* - CMC uses a projected growth rate for inpatient surgical cases at CMC-Main that is not supported by its historical inpatient surgical case volumes over time. CMC-Main does not adequately demonstrate in the application as submitted that the growth rate used to project inpatient surgical cases is reasonable and adequately supported given that that growth rate is based not on inpatient surgical cases but on acute care days of care and the acute care days of care growth rate was increased by an inadequately explained shift of patients back to CMC-Main apparently just for the purpose of calculating a higher growth rate.

Nevertheless, according to information provided by Atrium to the Agency in its 2019 Hospital and ASF LRAs, which are public records and were received by the Agency during the review, the Atrium health system already has a significant deficit of ORs. The table below shows the number of inpatient and outpatient surgical cases reported by each Atrium facility on its 2019 LRA. The reporting period is October 1, 2017 to September 30, 2018. Even when using the

Final Case Times for each type of case as reported in the 2019 SMFP (the LRAs all have at least some increase in the average case times, with one exception), the facilities in the system show the following deficits and surpluses:

Atrium Health Mecklenburg County OR Deficits/Surpluses Based on 2019 LRA Cases					
Facility	**FY 2018 Cases***	**Final Case Time****	**Average Annual Op. Hours****	**# ORs Needed**	**Surplus (-) / Deficit**
CCSS	1,983	85.0	1,312	2.1	0.1
AH Pineville Inpatient	3,477	174.0	1,755	10.5	0.5
AH Pineville Outpatient	4,930	101.6			
CMC Inpatient***	20,877	224.7	1,950	65.8	10.8
CMC Outpatient***	22,464	134.0			
AH University City Inpatient	1,084	112.6	1,500	6.9	-0.1
AH University City Outpatient****	6,745	74.1			
System Total	**61,560**			**85.3**	**11.3**

*Does not include C-Sections performed in dedicated C-Section ORs
**From 2019 SMFP
***Includes CMC-Mercy
****Includes the OR that will become part of AH Huntersville Surgery Center

When using the calculations shown in the table above, CMC has a deficit of 10.8 ORs. This is a conservative number because it uses a final case times for outpatient surgical cases that is lower than what CMC reported on its 2019 LRA. The 2018 SMFP showed CMC had a deficit of 16.65 ORs, and the 2019 SMFP shows CMC has a deficit of 12.47 ORs. CMC could hold its current utilization steady through OY3 and it would not only show the need for the four additional ORs it proposes to add to its facility, but it would also by itself meet the standard promulgated in 10A NCAC 14C .2103(b). In other words, CMC-Main shows a need for all six ORs that are proposed in the three Atrium applications using the OR Need Methodology in the 2018 SMFP.

Projected utilization is reasonable and adequately supported for the following reasons:

- There is a need determination in the 2018 SMFP for six ORs in the Mecklenburg County OR planning area.
- The applicant relies on its historical utilization in projecting future utilization.
- The applicant's historical utilization already meets the performance standard promulgated in 10A NCAC 14C .2103(a).

Access - In Section C, page 48, the applicant states *"CMC provides services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment."*

In Section L, page 85, the applicant projects the following payor mix during the second full fiscal year following completion of the project, as illustrated in the following table.

CMC Projected Payor Mix 2nd Full FY (CY 2022)		
Payor Source	**Total Facility**	**ORs**
Self-Pay	13.0%	6.0%
Medicare*	26.0%	27.3%
Medicaid*	27.0%	19.9%
Insurance*	33.0%	43.4%
Other	1.0%	3.4%
TOTAL	**100.0%**	**100.0%**

*Including any managed care plans

The projected payor mix is reasonable and adequately supported.

<u>*Conclusion*</u> - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately support their assumptions.

F-11621-18/Atrium Health Pineville (AH Pineville)/Develop one OR

The applicants propose to develop an additional OR at AH Pineville for a total of 11 ORs upon project completion. The applicants, Mercy Hospital, Inc., Mercy Health Services, Inc. and the Charlotte-Mecklenburg Hospital Authority (collectively CMHA) operate Atrium Health Pineville (AH Pineville). On page 10, the applicants state: *"At present, Mercy Hospital, Inc. (Applicant 1) is wholly owned by Mercy Health, Services Inc. (Applicant 2), which is wholly owned by The Charlotte-Mecklenburg Hospital Authority (Applicant 3)."*

This application is one of four applications filed in the same review cycle for acute care beds and ORs by applicants who are owned by and/or affiliated with Atrium. On February 7, 2018, The Charlotte-Mecklenburg Hospital Authority, which owns and operates the facilities involved in these four applications, announced that it was changing its name and would do business as Atrium Health. There are six facilities relevant to this review that are part of the Atrium health system in Mecklenburg County. The following table identifies these facilities, the current name, and effective date of the change.

ATRIUM HEALTH FACILITIES MECKLENBURG COUNTY		
Previous Name	**Current Name**	**Effective Date of Change**
Carolinas Medical Center	Carolinas Medical Center	NA (will not change)
Carolinas Medical Center – Mercy	Carolinas Medical Center – Mercy	NA (will not change)
Carolinas HealthCare System Union	Atrium Health Union	January 1, 2019
Carolinas HealthCare System Pineville	Atrium Health Pineville	January 1, 2019
Carolinas HealthCare System University	Atrium Health University City	December 1, 2018
Carolinas HealthCare System Huntersville	Atrium Health Huntersville Surgery	December 1, 2018

Patient Origin - On page 57, the 2018 SMFP defines the service area for ORs as *"the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* Figure 6.1, on page 62, shows Mecklenburg County as its own OR planning area. Thus, the service area for this facility is Mecklenburg County. Facilities may also serve residents of counties not included in their service area. The following table illustrates historical and projected patient origin.

AH Pineville Historical & Projected Patient Origin				
County	**CY 2017 (Last Full FY)**		**CY 2022 (3rd Full FY)**	
	# Patients	**% Patients**	**# Patients**	**% Patients**
Mecklenburg	3,093	37.4%	4,129	43.0%
York (SC)	2,691	32.6%	2,448	25.5%
Lancaster (SC)	1,009	12.2%	1,347	14.0%
Union	651	7.9%	595	6.2%
Gaston	180	2.2%	241	2.5%
Other*	639	7.7%	852	8.9%
TOTAL	**8,262**	**100.0%**	**9,612**	**100.0%**

Source: Section C, pages 21-22

***Other** includes Alexander, Alleghany, Anson, Ashe, Avery, Brunswick, Buncombe, Burke, Caldwell, Catawba, Chatham, Cleveland, Craven, Cumberland, Davidson, Davie, Forsyth, Franklin, Guilford, Harnett, Haywood, Henderson, Iredell, Lincoln, Montgomery, New Hanover, Polk, Randolph, Richmond, Robeson, Rutherford, Stanly, Stokes, Surry, Transylvania, Tyrrell, Vance, Wake, Watauga, Wilkes, and Yadkin counties, and other states.

In Section C, page 26, the applicants provide the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need - - Atrium submitted three separate applications in response to the OR Need Determination in the 2018 SMFP. Atrium proposes to add one OR to CCSS; one OR to AH Pineville; and four ORs to CMC. In Section C, pages 27-45, the applicant discusses the need for all of Atrium's OR proposals. In a competitive review, every application is evaluated independently, as if there are no other applications in the review, to determine whether the application is conforming to all statutory and regulatory review criteria. Therefore, the discussion in this section focuses only on the need as it relates to AH Pineville.

In Section C, page 29, Atrium states the need for six ORs in Mecklenburg County was generated by Atrium facilities. However, anyone may apply to meet the need, not just Atrium. Atrium has the burden of demonstrating the need for the proposed ORs in its applications as submitted.

With regard to AH Pineville, the applicants state the following that it believes supports the need the population projected to utilize the proposed services has for the proposed services:

- *Trends in inpatient surgery:* The applicants state technology and its advances are creating integration between advanced imaging techniques and surgical procedures in the OR. The applicants state that CMC has several ORs it has developed with specific types of imaging equipment, such as equipment for endovascular imaging or an intraoperative MRI, to perform more advanced and complex surgeries using those pieces of imaging equipment. (pages 30-31)
- *Trends in outpatient surgery:* The applicants state that, due to advances in technological development as well as in the care provided to patients, outpatient surgery volume is expected to continue increasing. The applicants also state reduced costs for services performed on an outpatient basis, along with insurance reimbursement pressures, will feed the projected increase. The applicants state that despite movement toward sending low-acuity patients to freestanding ambulatory surgical facilities (**ASF**) for treatment, some patients will continue to require hospital-based outpatient surgery due to risk factors or comorbidities. (page 31)
- *Trends in North Carolina and Mecklenburg County:* The applicants state that, from FFY 2014 through FFY 2017, SMFP data showed inpatient surgeries statewide had a three year CAGR of 1.5 percent, outpatient surgeries statewide had a three year CAGR of 1.3 percent, and the ratio of outpatient surgeries to total surgeries was consistently around 72 percent. The applicants state that, for the same time period (FFY 2014-2017), Mecklenburg County inpatient surgeries had a three year CAGR of 3.5 percent, outpatient surgeries had a three year CAGR of 3.9 percent, and were also consistently at a ratio of 72 percent compared with total surgeries. The applicants state that, according to the 2016 – proposed 2019 SMFPs, Mecklenburg hospital outpatient and ASF outpatient surgeries have grown at a 3.9 percent CAGR, but the increase in the number of outpatient surgeries performed at hospitals is double the increase in the number of outpatient surgeries performed at ASFs. The applicants state that, according to the 2018 and proposed 2019 SMFPs, Mecklenburg County hospital ORs had utilization rates of 97 percent and 96 percent in 2016 and 2017, respectively, compared with the SMFP's Operating Room Need Methodology standard hours. The applicants state that, because of ASF projects under development which will increase the availability of ASF-based outpatient surgical services, it believes that inpatient settings have the greatest need for additional OR capacity at this point. The applicants state ASFs cannot be used for stays longer than 24 hours and typically have lower capacity than ORs at a hospital, which can stay open far longer than those at an ASF. (pages 32-36)
- *Historical utilization at AH Pineville:* The applicants state that, even when adjusted for OR shifts that are pending as the result of approved but not yet fully developed projects, AH Pineville is above 100 percent utilization based on the total surgical hours it performed compared with the standard OR hours in the Operating Room Need Methodology in the 2018 SMFP. The table below shows the utilization of each hospital in Mecklenburg County as shown in the 2018 SMFP, with adjustments made by the applicants to account for pending OR shifts:

Mecklenburg County 2018 SMFP Hospital OR Utilization Adjusted for Pending OR Shifts				
Facility	**Total Cases**	**Total Hours**	**Adjusted Hours**	**Adjusted Utilization**
CMC	43,543	129,027	107,250	120%
Novant Health Matthews Medical Center	5,597	9,317	9,000	104%
Novant Health Huntersville Medical Center	4,980	9,385	9,000	104%
AH Pineville	8,133	17,738	17,550	101%
AH University City	7,383	9,731	10,500	93%
Novant Health Presbyterian Medical Center	29,898	57,606	70,200	82%

Source: Section C, page 37

The applicants do not explain how they arrived at the adjustments, but the information provided by the applicants show that AH Pineville was at 101 percent of capacity in FY 2017. (page 37)

- *Need for additional capacity at AH Pineville:* The applicants state AH Pineville is a rapidly growing tertiary care provider as a result of population growth and development in southern Mecklenburg County, as well as Atrium Health's significant expansion efforts at the facility over the last 12 years. As a result, the applicants state that its surgical cases has also grown and is now operating above capacity. (pages 40-41)
- *Need for additional capacity at CMC:* The applicants state CMC provides multiple types of services unique to Mecklenburg County hospitals, such as being a Level I Trauma Center, providing solid organ transplantation, and having Levine Children's Hospital (on page 16 of the CMC application, the applicants state that Levine Children's Hospital is the largest children's hospital between Atlanta and Washington, D.C.). The applicants state that CMC's ORs operate longer (more hours) than any other facility in Mecklenburg County, due in part to CMC's longer than average inpatient case times. (pages 42-43)
- *Need for additional capacity at CCSS:* The applicants state CCSS has met a unique need by providing neurosurgery services at an ASF, along with orthopedic surgery and pain management. The applicants state CCSS has exceeded its capacity for its two ORs, and in order to be able to continue shifting ASF-appropriate cases away from the hospital setting, it needs to be able to expand. (page 43)
- *Population growth and aging in Mecklenburg County:* The applicants state the population of Mecklenburg County is growing rapidly. The applicants cite data from NC OSBM which states Mecklenburg County is projected to have the highest statewide numerical increase in population and the fifth highest statewide percentage increase in population in 2020 when compared to 2010. The applicants further state Mecklenburg County's population age 65 and older will grow 17.5 percent between 2018 and 2025, and Mecklenburg County will have the second highest total of residents age 65 and older out of all the counties in North Carolina. The applicant states this is significant because older residents use healthcare services at a higher rate than younger residents. The Project Analyst verified that Mecklenburg County's population age 65 and older will grow at one of the fastest rates of any county in North Carolina between 2018 and 2025, and the numerical increase in the population of residents age 65 and older between 2018 and 2025 is the highest of any county in the state. (pages 39-40)

The information is reasonable and adequately supported for the following reasons:

- There is a need determination for six ORs in Mecklenburg County in the 2018 SMFP. The applicants are applying to develop one OR in Mecklenburg County in accordance with the OR need determination in the 2018 SMFP.
- The applicants use reasonable and clearly identified historical and demographic data to make assumptions with regard to identifying the population to be served.
- The applicants provide reliable data, makes reasonable statements about the data, and uses reasonable assumptions about the data to demonstrate the need the population to be served has for the proposed services.

Projected Utilization - In Section Q, the applicants provide projected utilization, as illustrated in the following table.

AH Pineville Projected OR Utilization			
	1st Full FY CY 2021	**2nd Full FY CY 2022**	**3rd Full FY 2023**
Projected # of Inpatient Surgical Cases	3,986	4244	4537
Projected # of Outpatient Surgical Cases	4,842	4,947	5,075
Projected # of Total Surgical Cases	8,828	9,191	9,212
Final Inpatient Case Time (minutes) (1)	170.5	170.5	170.5
Final Outpatient Case Time (minutes) (1)	92.4	92.4	92.4
Total Hours (Total Minutes / 60 minutes per hour) (2)	18,784	19,678	20,708
Average Annual Operating Hours – Group 3	1,755	1,755	1,755
Number of ORs Needed (Annual Hours / Average Operating Hours) (4)	10.7	11.2	11.8

(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

In Section Q, Form C Method, pages 1-46, the applicants provide the assumptions and methodology used to project utilization for all of the facilities which are part of the Atrium health system in Mecklenburg County, which are briefly summarized below.

Carolina Center for Specialty Surgery – The assumptions and methodology used to project utilization at CCSS are found on pages 3-6. The applicants start with historical utilization and project utilization forward using a 1.8% compound annual growth rate (CAGR), which is based on growth from CY 2015 to CY 2018 (annualized). The CAGR used is one half of the historical CAGR of 3.5%. Then the applicants make assumptions about shifts of patients to other Atrium facilities in Mecklenburg County, Union County, and South Carolina. The following table illustrates projected OR utilization at CCSS.

CCSS Projected OR Utilization					
	CY 2018*	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**
Baseline CCSS Cases	1,975	2,010	2,046	2,082	2,119
Cases to Shift (65% of 346)**	225	225	225	225	225
Ramp-Up of Cases to Shift	--	--	50%	75%	100%
Cases Shifted	--	--	112	169	225
Total Cases after Shift	**1,975**	**2,010**	**2,158**	**2,251**	**2,344**
Final Case Time in Minutes (1)	85.0	85.0	85.0	85.0	85.0
Total Hours (2)	2,798	2,848	3,058	3,189	3,321
Average Annual Operating Hours – Group 6 (3)	1,312.5	1,312.5	1,312.5	1,312.5	1,312.5
Number of ORs Needed (4)	2.1	2.2	2.3	2.4	2.5
Number of Existing ORs	2.0	2.0	2.0	2.0	2.0
Surplus (-) / Deficit	**0.1**	**0.2**	**0.3**	**0.4**	**0.5**

*The applicants state CY 2018 data is annualized based on actual data for January 2018 – July 2018.
**The applicants identified 346 cases that would have been appropriate to shift from CMC to CCSS in 2018 but the applicants assume that only 65% would actually shift.
(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

As shown in the table above, using the OR Need Methodology in Chapter 6 of the 2018 SMFP, the applicants show a need for 0.5 of an additional OR in the third OY, which would be rounded to one. Atrium proposes to add one additional OR at CCSS. The proposal is consistent with 10A NCAC 14C .2103(a), which requires an applicant to demonstrate the need for the number of ORs it proposes to develop, using the OR Need Methodology in the applicable SMFP, for the third OY following project completion.

Atrium Health Pineville - The assumptions and methodology used to project utilization at AH Pineville are found on pages 7-12. The applicants start with historical utilization and project utilization forward using two different CAGRs: one for inpatient cases (7.1%) and one for outpatient cases (3.2%). The CAGRs are based on growth from CY 2015 to CY 2018 (annualized). The CAGR used for inpatient cases is equal to the actual CAGR. The CAGR used for outpatient cases is equal to the lowest growth rate during the time period analyzed. Then the applicants make assumptions about shifts of patients to other Atrium facilities in Mecklenburg County, Union County, and South Carolina. The following table illustrates projected OR utilization at AH Pineville.

AH Pineville Projected OR Utilization						
	CY 2018	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**
Baseline Inpatient Cases	3,635	3,893	4,169	4,464	4,780	5,118
Baseline Outpatient Cases	5,039	5,203	5,372	5,546	5,726	5,912
Inpatient Cases to CHS Fort Mill	--	--	--	-433	-445	-457
Outpatient Cases to CHS Fort Mill	--	--	--	-649	-667	-686
Inpatient Cases to AH Union	--	-14	-29	-45	-91	-124
Outpatient Cases to AH Union	--	-18	-36	-55	-111	-151
Total Inpatient Cases	3,635	3,879	4,140	3,986	4,244	4,537
Total Outpatient Cases	5,039	5,185	5,336	4,842	4,948	5,075
Final Inpatient Case Time (1)	170.5	170.5	170.5	170.5	170.5	170.5
Final Outpatient Case Time (1)	92.4	92.4	92.4	92.4	92.4	92.4
Total Surgical Hours (2)	**18,089**	**19,008**	**19,982**	**18,784**	**19,680**	**20,709**
Average Annual Operating Hours – Group 3 (3)	1,755.0	1,755.0	1,755.0	1,755.0	1,755.0	1,755.0
Number of ORs Needed (4)	10.3	10.8	11.4	10.7	11.2	11.8
Number of Existing ORs	10.0	10.0	10.0	10.0	10.0	10.0
Surplus (-) / Deficit	**0.3**	**0.8**	**1.4**	**0.7**	**1.2**	**1.8**

(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

As shown in the table above, using the OR Need Methodology in Chapter 6 of the 2018 SMFP, the applicants show a need for 1.8 additional ORs at AH Pineville in the third OY, which would be rounded to 2. Atrium proposes to add one additional OR at AH Pineville. The proposal is consistent with 10A NCAC 14C .2103(a), which requires an applicant to demonstrate the need for the number of ORs it proposes to develop, using the OR Need Methodology in the applicable SMFP, for the third OY following project completion.

Carolinas Medical Center - The assumptions and methodology used to project utilization at CMC are found on pages 13-24. The applicants start with historical utilization and project utilization forward using two different CAGRs: one for inpatient cases (1.3%) and one for outpatient cases (0.4%). These CAGRs are not based on the historical CAGRs at CMC. The applicants state that growth at CMC has been constrained *"by a lack of sufficient capacity."* The applicants state that projected growth in surgical cases is expected to be consistent with projected growth in acute care bed utilization. Then the applicants make assumptions about shifts of patients to other Atrium facilities in Mecklenburg County, Union County, and South Carolina. The following table illustrates projected utilization at CMC.

CMC Projected OR Utilization						
	CY 2018*	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**
CMC Baseline Inpatient Cases	20,956	21,210	21,467	21,727	21,991	22,257
CMC Baseline Outpatient Cases	22,733	22,886	23,042	23,199	23,357	23,517
Outpatient Cases to CCSS	--	--	-112	-169	-225	-225
Outpatient Cases to RSC	--	-2,541	-2,858	-3,176	-3,237	-3,300
Outpatient Cases to CSC	--	-443	-499	-554	-565	-576
Inpatient Cases to CHS Fort Mill	--	--	--	-369	-379	-389
Outpatient Cases to CHS Fort Mill	--	--	--	-553	-569	-584
Inpatient Cases to AH Union	--	-64	-131	-200	-407	-553
Outpatient Cases to AH Union	--	-78	-160	-244	-497	-674
Total Inpatient Cases	20,956	21,146	21,336	21,158	21,205	21,315
Total Outpatient Cases	22,733	19,824	19,413	18,503	18,264	18,158
Inpatient Final Case Time (1)	221.5	221.5	221.5	221.5	221.5	221.5
Outpatient Final Case Time (1)	133.1	133.1	133.1	133.1	133.1	133.1
Total Surgical Hours (2)	**127,791.6**	**122,040.2**	**121,829.9**	**119,154.1**	**118,797.4**	**118,968.4**
Average Annual Operating Hours – Group 2 (3)	1,950.0	1,950.0	1,950.0	1,950.0	1,950.0	1,950.0
Number of ORs Needed (4)	65.5	62.6	62.5	61.1	60.9	61.0
Number of Existing ORs	55.0	55.0	55.0	55.0	55.0	55.0
Surplus (-) / Deficit	**10.5**	**7.6**	**7.5**	**6.1**	**5.9**	**6.0**

Source: Tables on page 22 of the application.
*The applicants state that CY 2018 data is annualized based on actual data for January 2018 – July 2018.
(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

As shown in the table above, using the OR Need Methodology in Chapter 6 of the 2018 SMFP, the applicants show a need for 6 additional ORs at CMC in the third OY. Atrium proposes to add four ORs at CMC. The proposal is consistent with 10A NCAC 14C .2103(a), which requires an applicant to demonstrate the need for the number of ORs it proposes to develop, using the OR Need Methodology in the applicable SMFP, for the third OY following project completion.

Atrium Health University City - AH University City is an acute care hospital with 11 ORs (excluding a dedicated C-Section OR). There are two projects which were previously approved but which are not yet developed as of the date of these findings which will impact the future total of ORs at AH University City:

- Project I.D. #F-11106-15/Randolph Surgery Center/Relocate three ORs from AH University City to RSC
- Project I.D. #F-11349-17/Atrium Health Huntersville Surgery/Separately license one OR currently on the hospital license

Atrium projects utilization separately for the hospital and the approved ASF. This section discusses projected OR utilization at the hospital. After the approved projects are operational, AH University City will have seven ORs.

The assumptions and methodology used to project utilization at AH University City are found on pages 25-29. The applicants start with historical utilization and projects utilization forward using two different CAGRs: one for inpatient cases (1.5%) and one for outpatient cases (1.6%). The CAGRs are based on growth from CY 2015 to CY 2018 (annualized). The CAGRs used are less the historical CAGRs (3.5% and 3.1%, respectively). Then the applicants make assumptions about shifts of patients to other Atrium facilities in Mecklenburg County, Union County, and South Carolina. The following table illustrates projected utilization at AH University City.

AH University City Projected OR Utilization						
	CY 2018*	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**
Baseline Inpatient Cases	1,158	1,176	1,194	1,212	1,231	1,249
Baseline Outpatient Cases	4,967	5,045	5,124	5,205	5,286	5,369
Outpatient Cases to RSC	--	-96	-108	-120	-122	-125
Outpatient Cases to CSC	--	-448	-504	-560	-571	-582
Inpatient Cases to CHS Fort Mill	--	--	--	-5	-5	-5
Outpatient Cases to CHS Fort Mill	--	--	--	-8	-8	-8
Inpatient Cases to AH Union	--	-1	-2	-3	-6	-8
Outpatient Cases to AH Union	--	-1	-2	-3	-7	9
Total Inpatient Cases	1,158	1,175	1,192	1,204	1,220	1,236
Total Outpatient Cases	4,967	4,500	4,510	4,514	4,578	4,645
Inpatient Final Case Time (1)	135.4	135.4	135.4	135.4	135.4	135.4
Outpatient Final Case Time (1)	84.3	84.3	84.3	84.3	84.3	84.3
Total Surgical Hours (2)	**9,591.8**	**8,974.1**	**9,026.5**	**9,059.2**	**9,185.2**	**9,315.4**
Average Annual Operating Hours – Group 4 (3)	1,500.0	1,500.0	1,500.0	1,500.0	1,500.0	1,500.0
Number of ORs Needed (4)	6.4	6.0	6.0	6.0	6.1	6.2
Number of Existing ORs	7.0	7.0	7.0	7.0	7.0	7.0
Surplus (-) / Deficit	**-0.6**	**-1.0**	**-1.0**	**-1.0**	**-0.9**	**-0.8**

*The applicants state that CY 2018 data is annualized based on actual data for January 2018 – July 2018.
(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

As shown in the table above, using the OR Need Methodology in Chapter 6 of the 2018 SMFP, the applicants show a need for 0.8 of an additional OR at AH University City in the third OY. However, Atrium does not propose to add any additional ORs at AH University City as part of this review.

Atrium Health Huntersville Surgery – Currently, the ORs located at AH Huntersville are on the license of AH University City. In Project I.D. #F-11349-17, AH Huntersville was approved to become a separately licensed ASF with one OR. The development of the ASF is projected to be complete in May 2019.

The applicants start with historical utilization and projects utilization forward using a 1.4% CAGR, which is based on growth from CY 2015 to CY 2018 (annualized). The CAGR used is less than the historical CAGR of 2.9%. Then the applicants make assumptions about shifts of patients to other Atrium facilities in Mecklenburg County, Union County, and South Carolina. The following table illustrates projected at CCSS.

AH Huntersville Projected OR Utilization						
	CY 2018*	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**
Baseline Cases	2,011	2,040	2,070	2,100	2,130	2,161
Cases to RSC	--	-40	-45	-50	-51	-52
Cases to CSC	--	-538	-605	-672	-685	-698
Total Cases	2,011	1,462	1,420	1,378	1,394	1,411
Final Case Time (1)	45.0	45.0	45.0	45.0	45.0	45.0
Total Surgical Hours (2)	**1,508.3**	**1,096.5**	**1,065.0**	**1,033.5**	**1,045.5**	**1,058.3**
Average Annual Operating Hours – Group 5 (3)	1,312.5	1,312.5	1,312.5	1,312.5	1,312.5	1,312.5
Number of ORs Needed (4)	1.1	0.8	0.8	0.8	0.8%	0.8
Number of Existing ORs	1.0	1.0	1.0	1.0	1.0	1.0
Surplus (-) / Deficit	**0.1**	**-0.2**	**-0.2**	**-0.2**	**-0.2**	**-0.2**

*The applicants state that CY 2018 data is annualized based on actual data for January 2018 – August 2018.
(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

As shown in the table above, using the OR Need Methodology in Chapter 6 of the 2018 SMFP, the applicants show a need for zero additional ORs in the third OY. The CMHA does not propose to add any additional ORs at AH Huntersville as part of this review.

Atrium Health System Combined - To meet the performance standard promulgated in 10A NCAC 14C .2103(b) in effect at the time of the submission of this application, an applicant proposing to add new ORs to a facility in its service area must demonstrate the need its entire health system has for all of the ORs proposed by the end of the third operating year. Altogether, Atrium proposes to add six ORs to its system:

- Project I.D. #F-11619-18/Carolina Center for Specialty Surgery/Add one OR
- Project I.D. #F-11620-18/Carolina Medical Center/Add four ORs
- Project I.D. #F-11621-18/Atrium Health Pineville/Add one OR

The following table illustrates the need for additional ORs for the entire health system.

Atrium Health OR Need			
	Deficits / Surpluses (-)		
	1st Full FY CY 2020	**2nd Full FY CY 2021**	**3rd Full FY CY 2022**
CCSS	0.3	0.4	0.5
AH Pineville	1.4	0.7	1.2
CMC	7.5	6.1	5.9
AH University City	-1.0	-1.0	-1.0
AH Huntersville Surgery Center	-0.2	-0.2	-0.2
Total Deficit/Surplus (-)	**8.0**	**6.0**	**6.4**

As shown in the table above, the Atrium health system has a projected deficit of 6.4 ORs. Atrium proposes to add a total of six ORs in the three applications submitted in this review.

The three proposals meet the standard promulgated in 10A NCAC 14C .2103(b), requiring an applicant proposing to add new ORs to a service area to project sufficient surgical cases and hours to demonstrate the need for all of the existing, approved, and proposed ORs in Atrium's health system in the third operating year of the project based on the Operating Room Need Methodology in the 2018 SMFP.

<u>*Analysis of Support for Atrium's Assumptions*</u> - There are two issues which potentially call into question whether Atrium's assumptions and methodology are adequately supported. Each is discussed individually below.

- *CHS Fort Mill Litigation* - Just prior to filing this application, on October 1, 2018, Atrium petitioned the Supreme Court of South Carolina for a writ of certiorari, asking the Supreme Court to review the most recent outcome of the CHS Fort Mill litigation, which would award the certificate of need to develop a hospital in Fort Mill to a different applicant. Publicly available information obtained by the Agency shows that the Supreme Court of South Carolina denied Atrium's petition for a writ of certiorari on February 20, 2019. Thus, any projections involving a shift of patients to CHS Fort Mill are questionable. However, the outcome of that decision would result in more patients remaining at existing Atrium facilities, which would <u>increase</u> utilization.
- *Projected Inpatient Surgical Cases at CMC-Main* - CMC uses a projected growth rate for inpatient surgical cases at CMC-Main that is not supported by its historical inpatient surgical case volumes over time. CMC-Main does not adequately demonstrate in the application as submitted that the growth rate used to project inpatient surgical cases is reasonable and adequately supported given that that growth rate is based not on inpatient surgical cases but on acute care days of care and the acute care days of care growth rate was increased by an inadequately explained shift of patients back to CMC-Main apparently just for the purpose of calculating a higher growth rate.

Nevertheless, according to information provided by Atrium to the Agency in its 2019 Hospital and ASF LRAs, which are public records and were received by the Agency during the review, the Atrium health system already has a significant deficit of ORs. The table below shows the number of inpatient and outpatient surgical cases reported by each Atrium facility on its 2019 LRA. The reporting period is October 1, 2017 to September 30, 2018. Even when using the Final Case Times for each type of case as reported in the 2019 SMFP (the LRAs all have at least some increase in the average case times, with one exception), the facilities in the system show the following deficits and surpluses:

Atrium Health Mecklenburg County OR Deficits/Surpluses Based on 2019 LRA Cases					
Facility	**FY 2018 Cases***	**Final Case Time****	**Average Annual Op. Hours****	**# ORs Needed**	**Surplus (-) / Deficit**
CCSS	1,983	85.0	1,312	2.1	0.1
AH Pineville Inpatient	3,477	174.0	1,755	10.5	0.5
AH Pineville Outpatient	4,930	101.6			
CMC Inpatient***	20,877	224.7	1,950	65.8	10.8
CMC Outpatient***	22,464	134.0			
AH University City Inpatient	1,084	112.6	1,500	6.9	-0.1
AH University City Outpatient****	6,745	74.1			
System Total	**61,560**			**85.3**	**11.3**

*Does not include C-Sections performed in dedicated C-Section ORs
**From 2019 SMFP
***Includes CMC-Mercy
****Includes the OR that will become part of AH Huntersville Surgery Center

When using the calculations shown in the table above, CMC has a deficit of 10.8 ORs. This is a conservative number because it uses a final case times for outpatient surgical cases that is lower than what CMC reported on its 2019 LRA. The 2018 SMFP showed CMC had a deficit of 16.65 ORs, and the 2019 SMFP shows CMC has a deficit of 12.47 ORs. CMC could hold its current utilization steady through OY3 and it would not only show the need for the four additional ORs it proposes to add to its facility, but it would also by itself meet the standard promulgated in 10A NCAC 14C .2103(b). In other words, CMC-Main shows a need for all six ORs that are proposed in the three Atrium applications using the OR Need Methodology in the 2018 SMFP.

Projected utilization is reasonable and adequately supported for the following reasons:

- There is a need determination in the 2018 SMFP for six ORs in the Mecklenburg County OR planning area.
- The applicants rely on their historical utilization in projecting future utilization.
- The applicants' historical utilization already meets the performance standard promulgated in 10A NCAC 14C .2103(a).

<u>Access</u> - In Section C, page 49, the applicants state they *"…provides services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment."* In Section L, page 85, the applicants project the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

AH Pineville Projected Payor Mix 3rd Full FY (CY 2022)		
Payor Source	**Total Facility**	**ORs**
Self-Pay	12.0%	3.4%
Medicare*	31.0%	40.0%
Medicaid*	16.0%	5.1%
Insurance*	39.0%	49.6%
Other	2.0%	1.9%
TOTAL	**100.0%**	**100.0%**

*Including any managed care plans

The projected payor mix is reasonable and adequately supported.

<u>Conclusion</u> - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants adequately identify the population to be served.
- The applicants adequately explain why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicants project the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately support their assumptions.

F-11622-18/Atrium Health Pineville/Develop 50 acute care beds

The applicants propose to develop 50 additional acute care beds at the existing hospital for a total of 271 acute care beds upon project completion.

On June 7, 2018, AH Pineville received a certificate of need for Project I.D. #F-11361-17, authorizing development of 15 additional acute care beds pursuant to the 2017 SMFP need determination. Prior to that, AH Pineville was licensed for 206 acute care beds. The project is not technically complete due to a requirement to submit annual reports for the first three operating years as required by a condition on the certificate. However, according to Agency records, the 15 additional acute care beds were licensed and serving patients as of October 23, 2018.

This application is one of four applications filed in the same review cycle for acute care beds and ORs by applicants who are owned by and/or affiliated with Atrium. On February 7, 2018, The Charlotte-Mecklenburg Hospital Authority, which owns and operates the facilities

involved in these four applications, announced that it was changing its name and would do business as Atrium Health. There are six facilities relevant to this review that are part of the Atrium health system in Mecklenburg County. The following table identifies these facilities, the current name, and effective date of the change.

ATRIUM HEALTH FACILITIES MECKLENBURG COUNTY		
Previous Name	**Current Name**	**Effective Date of Change**
Carolinas Medical Center	Carolinas Medical Center	NA (will not change)
Carolinas Medical Center – Mercy	Carolinas Medical Center – Mercy	NA (will not change)
Carolinas HealthCare System Union	Atrium Health Union	January 1, 2019
Carolinas HealthCare System Pineville	Atrium Health Pineville	January 1, 2019
Carolinas HealthCare System University	Atrium Health University City	December 1, 2018
Carolinas HealthCare System Huntersville	Atrium Health Huntersville Surgery	December 1, 2018

Patient Origin - On page 38, the 2018 SMFP defines the service area for acute care beds as *"the acute care bed planning area in which the bed is located. The acute care bed planning areas are the single and multicounty groupings shown in Figure 5.1."* Figure 5.1, on page 42, shows Mecklenburg County as its own acute care bed planning area. Thus, the service area for this facility is Mecklenburg County. Facilities may also serve residents of counties not included in their service area. The following table illustrates historical and projected patient origin.

AH Pineville Acute Care Beds Historical & Projected Patient Origin				
County	**CY 2017 (Last Full FY)**		**CY 2024 (3rd Full FY)**	
	# Discharges	**% Discharges**	**# Discharges**	**% Discharges**
Mecklenburg	5,680	42.9%	7,726	48.2%
York (SC)	3,967	30.0%	4,002	25.0%
Lancaster (SC)	1,468	11.1%	1,996	12.5%
Union	815	6.2%	535	3.3%
Gaston	248	1.9%	338	2.1%
Other*	1,047	7.9%	1,424	8.9%
TOTAL	**13,226**	**100.0%**	**16,021**	**100.0%**

Source: Section C, pages 41-42
*Other includes Alamance, Alexander, Anson, Ashe, Avery, Brunswick, Buncombe, Burke, Cabarrus, Caldwell, Catawba, Chatham, Cherokee, Clay, Cleveland, Columbus, Cumberland, Davidson, Durham, Edgecombe, Forsyth, Guilford, Haywood, Henderson, Hoke, Iredell, Jackson, Johnston, Lee, Lincoln, Macon, McDowell, Mitchell, Montgomery, Moore, Nash, New Hanover, Pitt, Polk, Randolph, Richmond, Robeson, Rockingham, Rowan, Rutherford, Scotland, Stanly, Stokes, Surry, Transylvania, Wake, Watauga, Wayne, and Wilkes counties, and other states.

In Section C, pages 42-43, the applicants provide the assumptions and methodology used to project their patient origin. The applicants' assumptions are reasonable and adequately supported.

Analysis of Need - In Section C, pages 43-56, the applicants state Atrium facilities were responsible for generating the need for 50 acute care beds in Mecklenburg County in the 2018 SMFP. On page 48, they state there is therefore a need for more acute care beds *"specifically at Atrium facilities."* However, anyone may apply to meet the need, not just Atrium. Atrium has the burden of demonstrating the need for the proposed beds in its applications as submitted.

In Section C, pages 43-44, the applicants summarize development of services at AH Pineville, and on pages 44-48, the applicants restate the methodology found in the 2018 SMFP which led to the need determination for Mecklenburg County. Beginning on page 48, the applicants describe the need they believe the population proposed to be served has for the proposed services:

- *Growth of AH Pineville and the surrounding area:* The applicants state that, at the time AH Pineville was originally opened in 1987, the area around it had not experienced much population growth; however, the applicants state that, from 1990 – 2007, the area's population increased by more than 250,000 people. The applicants describe projects developed related to master facility planning, and state as a result of the population growth and these projects, AH Pineville's inpatient days have grown at a 5.8 percent CAGR between 2013 and 2018. (pages 48-49)
- *Growth in utilization of AH Pineville:* The applicants state AH Pineville has the second highest bed deficit of all Atrium facilities, behind only CMC, and state it has grown more in two years than the 2018 SMFP projected it would grow in four years. The applicants state that from January through June 2018, AH Pineville's midnight average daily census (ADC) was 187, or 90.8 percent of capacity, with many days exceeding the average. The applicants state AH Pineville's 132 medical/surgical (M/S) acute care beds have an even higher capacity, often exceeding full capacity, and thus AH Pineville has had to transfer patients to other facilities when it has been at capacity. The applicants state these transfers are in excess of transfers to other facilities for specialized services not offered at AH Pineville, and state patients are often housed overnight in its emergency department until a bed is available for a patient. The applicants state that, starting on April 5, 2018, AH Pineville has been on constant temporary expansion overflow, receiving permission from the Agency for the addition of 20 temporary overflow acute care beds. The applicants state that the addition of the 50 beds will provide a permanent solution to the problem of capacity versus the current temporary fixes. (pages 49-54)
- *Population growth and aging in Mecklenburg County:* The applicants state the population of Mecklenburg County is growing rapidly. The applicants cite data from NC OSBM which states Mecklenburg County is projected to have the highest statewide numerical increase in population and the fifth highest statewide percentage increase in population in 2020 when compared to 2010. The applicants further state Mecklenburg County's population age 65 and older will grow 17.5 percent between 2018 and 2025, and Mecklenburg County will have the second highest total of residents age 65 and older out of all the counties in North Carolina. The applicants state this is significant because older residents use healthcare services at a higher rate than younger residents. The Project Analyst verified that Mecklenburg County's population age 65 and older will grow at one of the fastest rates of any county in North Carolina between 2018 and 2025, and the numerical increase in the population of residents age 65 and older between 2018 and 2025 is the highest of any county in the state. The applicants state that, in particular, population growth in the southern Charlotte region has exceeded previous population projections. (pages 54-56)

The information is reasonable and adequately supported for the following reasons:

- There is a need determination for 50 acute care beds in Mecklenburg County in the 2018 SMFP. The applicants are applying to develop 50 acute care beds in Mecklenburg County in accordance with the acute care bed need determination in the 2018 SMFP.
- The applicants use reasonable and clearly identified historical and demographic data to make assumptions with regard to identifying the population to be served.
- The applicants provide reliable data, make reasonable statements about the data, and use reasonable assumptions about the data to demonstrate the need the population to be served has for the proposed services.

Projected Utilization - In Section Q, the applicants provide utilization projections for the first three OYs, as shown in the table below.

AH Pineville Projected Utilization M/S Acute Care Beds			
	1st Full FY CY 2022	2nd Full FY CY 2023	3rd Full FY CY 2024
Projected # of Discharges	14,750	15,369	16,021
Projected # Patient Days	56,796	59,182	61,689
Projected # M/S Beds	197	197	197
Projected ADC*	156	162	169
Projected Utilization %**	79.2%	82.2%	85.8%

*ADC = # Patient Days / 365 days per year
**Utilization % = ADC / # M/S Beds

In Section Q, the applicants provide the assumptions and methodology used to project utilization, which are summarized below.

In Section Q, page 3, the applicants provide historical utilization for all acute care beds and M/S acute care beds, as shown in the table below.

AH Pineville Historical Acute Care Utilization					
	CY 2015	CY 2016	CY 2017	CY 2018*	CAGR
Total Acute Care Bed Days	57,815	61,095	65,193	68,295	5.7%
% Growth	--	5.7%	6.7%	4.8%	--
M/S Acute Care Bed Days	42,453	46,327	49,781	52,408	7.3%
% Growth	--	9.1%	7.5%	5.3%	--

Source: Atrium Health internal data.
*The applicants state CY 2018 data is annualized based on actual data for January 2018 – June 2018.

In Section Q, page 4, the applicants state they that M/S acute care bed days and total acute care bed days are projected to increase 4.8 percent annually, which is the lowest historical growth rate during the time period analyzed. The following table illustrates the results of this step of the applicants' methodology.

AH Pineville Projected Utilization Prior to Shifts to Other Facilities							
	CY 2018*	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**	**CY 2024**
Total Acute Care Bed Days	68,295	71,544	74,949	78,515	82,251	86,164	90,264
% Growth	--	4.8%	4.8%	4.8%	4.8%	4.8%	4.8%
M/S Acute Care Bed Days	52,408	54,902	57,514	60,250	63,117	66,120	69,266
% Growth	--	4.8%	4.8%	4.8%	4.8%	4.8%	4.8%

Source: Section Q, page 5
*The applicants state CY 2018 data is annualized based on actual data for January 2018 – June 2018.

Next, the applicants account for acute care bed days they project will shift from AH Pineville to other facilities.

CHS Fort Mill - The applicants do not explain how they calculated the number of patients that would shift from AH Pineville to CHS Fort Mill other than to say it was consistent with previous applications.

AH Union - In Section Q, pages 5-6, Atrium states that, as part of its plan to better utilize resources, it has worked to shift services to provide more medical care to Union County residents at AH Union. In Section Q, page 6, the applicants state that 78.1 percent of the total acute care bed days projected to shift to AH Union will be M/S acute care bed days, and state it is consistent with the patient population projected to shift to Union County from Mecklenburg County, but do not provide support for that statement.

The following tables illustrate utilization at AH Pineville after the projected shifts of patients to other facilities as reported in Section Q, page 6.

AH Pineville Projected Total Acute Care Bed Utilization						
	CY 2019	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**	**CY 2024**
Total Acute Care Bed Days	71,544	74,949	78,515	82,251	86,164	90,264
Shift to CHS Fort Mill	--	--	-7,276	-7,482	-7,693	-7,910
Shift to AH Union	-259	-528	-806	-1,639	-2,224	-2,829
Projected Total Acute Care Bed Days	71,285	74,421	70,433	73,130	76,247	79,525
ADC	195	204	193	200	209	218
Beds	221	221	221	271	271	271
Occupancy %	88.2%	92.3%	87.3%	73.8%	77.1%	80.4%

AH Pineville Projected M/S Acute Care Bed Utilization						
	CY 2019	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**	**CY 2024**
M/S Acute Care Bed Days	54,902	57,514	60,250	63,117	66,120	69,266
Shift to CHS Fort Mill	--	--	-4,883	-5,040	-5,201	-5,366
Shift to AH Union	-203	-412	-630	-1,281	-1,738	-2,211
Projected M/S Acute Care Bed Days	54,699	57,102	54,737	56,796	59,181	61,689
ADC	150	156	150	156	162	169
Beds	147	147	147	197	197	197
Occupancy %	102.0%	106.1%	102.0%	79.2%	82.2%	85.8%

Next, the applicants project the number of acute care discharges. The average length of stay (ALOS) is projected to be 4 days for total acute care beds and 3.85 days for M/S acute care beds based on 2018 experience.

AH Pineville Projected Total Acute Care Bed Discharges						
	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Projected Total Acute Care Bed Days	71,285	74,421	70,433	73,130	76,247	79,525
ALOS	4.00	4.00	4.00	4.00	4.00	4.00
Total Discharges	17,811	18,595	17,598	18,272	19,051	19,870

AH Pineville Projected M/S Acute Care Bed Discharges						
	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Projected M/S Acute Care Bed Days	54,699	57,102	54,737	56,796	59,181	61,689
ALOS	3.85	3.85	3.85	3.85	3.85	3.85
M/S Discharges	14,205	14,829	14,215	14,750	15,369	16,021

Projected Utilization – Other Atrium Facilities in Mecklenburg County - In Section Q, pages 8-25, projected utilization of all acute care beds under common ownership in Mecklenburg County is provided in response to the Criteria and Standards for Acute Care Beds promulgated in 10A NCAC 14C .3803(a). Each facility and its projections are discussed below.

CMC - In Section Q, pages 8 and 16, Atrium provides the historical utilization of CMC-Main and CMC-Mercy, as shown in the table below.

CMC Historical Acute Care Utilization					
	CY 2015	CY 2016	CY 2017	CY 2018*	CAGR
CMC-Main Acute Care Bed Days	265,408	264,900	267,955	273,479	1.0%
% Growth	--	-0.2%	1.2%	2.1%	--
CMC-Mercy Acute Care Bed Days	34,789	38,935	41,664	45,327	9.2%
% Growth	--	11.9%	7.0%	8.8%	--
Combined Total Acute Care Bed Days	300,197	303,835	309,619	318,806	2.0%
% Growth	--	1.2%	1.9%	3.0%	--

Source: Atrium Health internal data.
*The applicants state CY 2018 data is annualized based on actual data for January 2018 – June 2018.

In Section Q, page 9, Atrium states that there have been capacity constraints at CMC-Main resulting in shifting acute care patients to other Atrium facilities. However, to calculate an acute care bed growth rate for CMC-Main, Atrium adds back patient days "shifted" to other facilities. On page 9, Atrium states:

> *"In order to accurately reflect the growth historically generated by services at CMC, Atrium Health quantified the impact of the historical shifts of patient days to CMC-Mercy,* [AH University City]*, and Carolinas ContinueCare Hospital at University, as detailed below. In other words, Atrium Health added days shifted to other facilities to CMC's actual acute care days to determine what the historical growth rate at CMC would have been without shifts to other Atrium Health facilities."*

Adjustments to CMC-Mercy Historical Utilization - In Section Q, pages 9-10, Atrium states that, consistent with projections made in Project I.D. #F-10217-13, some patient days "shifted" from CMC-Mercy to Carolinas ContinueCare Hospital at University (**CCCHU**). In Section Q, page 10, Atrium also states that, as part of Project I.D. #F-10215-13 (add 34 acute care beds to the CMC-Mercy campus), it projected CMC-Mercy's historical utilization would grow at an annual rate of 1.7 percent. Atrium states it assumes that any growth above the 1.7 percent growth projected in an application submitted five years ago was attributable to "shifts" in patient days from CMC-Main, subtracts that growth from CMC-Mercy's historical utilization, and adds it to CMC-Main's historical utilization.

Adjustments to AH University City Historical Utilization - In Section Q, pages 10-11, Atrium states it adjusts AH University City's historical utilization to reflect what it believes is growth that should be attributed to CMC-Main. Atrium states that, as part of Project I.D. #F-10221-13, it projected a number of patient days per year would "shift" from CMC-Main to AH University City. Atrium also states AH University City's historical utilization was impacted by two other factors – a shift of patients from AH University City to CCCHU, and initiatives at AH University City resulting in increases in utilization.

Final Adjusted Historical Utilization for CMC-Main - In Section Q, page 12, Atrium states that in addition to the "shifts" in patients to CMC-Mercy and AH University City, CMC-Main also historically "shifted" patients to CCCHU.

The table below illustrates the impact of the shifts "back" to CMC-Main on the "historical" growth rate.

CMC-Main Adjusted Historical Acute Care Utilization Growth Rate					
	CY 2015	**CY 2016**	**CY 2017**	**CY 2018***	**CAGR**
Actual Patient Days	265,408	264,900	267,955	273,479	1.0%
Add Back Days Shifted to CMC-Mercy	3,577	7,318	9,582	12,709	--
Add Back Days Shifted to AH University City	--	--	2,000	2,709	--
Add Back Days Shifted to CCCHU	--	1,208	1,927	2,056	--
Adjusted Historical Utilization	268,985	273,426	281,465	290,952	2.7%

*The applicants state CY 2018 data is annualized based on actual data for January 2018 – June 2018.

As shown in the table above, without the "shifts back" to CMC-Main, the CAGR is one percent. With the "shifts back" to CMC-Main, the CAGR would be 2.7 percent.

Projected Utilization Prior to Shifts - In Section Q, pages 12-13, Atrium states it projects growth of patient days at CMC-Main at 1.3 percent, which is one-half of its adjusted historical utilization growth rate of 2.7 percent. In Section Q, page 17, Atrium states it projects growth of patient days at CMC-Mercy at 0.9 percent, which is one-half of the growth rate it used in Project I.D. #F-10215-13.

Projected Utilization After Shifts to CHS Fort Mill in South Carolina and AH Union – The following table illustrates projected acute care bed utilization at CMC.

CMC Projected Total Acute Care Bed Utilization						
	CY 2019	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**	**CY 2024**
Total Acute Care Bed Days	322,816	326,878	330,991	335,159	339,378	343,652
Shift to CHS Fort Mill	--	--	-6,203	-6,376	-6,553	-6,735
Shift to AH Union	-763	-1,553	-2,371	-4,824	-6,545	-8,325
Projected Total Acute Care Bed Days	322,053	325,325	322,417	323,959	326,280	328,592
ADC	882	891	883	888	894	900
Beds	1,055	1,055	1,055	1,055	1,055	1,055
Occupancy %	83.6%	84.5%	83.7%	84.2%	84.7%	85.3%

AH University City - In Section Q, page 20, Atrium provides the historical patient days at AH University City, as shown in the table below.

AH University City Historical Acute Care Utilization Growth Rates					
	CY 2015	**CY 2016**	**CY 2017**	**CY 2018***	**CAGR**
Patient Days	22,173	22,511	24,788	28,583	8.8%
Growth %	--	1.5%	10.1%	15.3%	--

Source: Atrium Health internal data.
*The applicants state CY 2018 data is annualized based on actual data for January 2018 – June 2018.

In Section Q, page 21, Atrium states it assumes patient days will increase 1.5 percent annually, which is the lowest growth rate during the time period analyzed. The following table illustrates the results of this step of the applicants' methodology.

AH University Projected Patient Days						
	CY 2019	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**	**CY 2024**
Projected Patient Days	29,018	29,461	29,910	30,366	30,829	31,299
Growth %	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%

Projected Utilization After Shifts to CHS Fort Mill in South Carolina and AH Union – The following table illustrates projected acute care bed utilization at AH University City.

AH University City Projected Total Acute Care Bed Utilization						
	CY 2019	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**	**CY 2024**
Total Acute Care Bed Days	29,018	29,461	29,910	30,366	30,829	31,299
Shift to CHS Fort Mill	--	--	-85	-88	-90	-93
Shift to AH Union	-12	-25	-39	-79	-107	-136
Projected Total Acute Care Bed Days	29,006	29,436	29,786	30,199	30,632	31,070
ADC	79	81	82	83	84	85
Beds	100	100	100	100	100	100
Occupancy %	79.0%	81.0%	82.0%	83.0%	84.0%	85.0%

Mecklenburg County Atrium Health System Summary – The following table illustrates projected utilization for all Atrium facilities in Mecklenburg County.

Atrium Projected Total Acute Care Bed Utilization			
	CY 2022	CY 2023	CY 2024
AH Pineville	73,130	76,247	79,525
CMC	323,959	326,280	328,592
AH University City	30,199	30,632	31,070
Projected Total Acute Care Bed Days	427,288	433,159	439,187
Average Daily Census (ADC)	1,171	1,187	1,203
Beds	1,426	1,426	1,426
Occupancy %	82.1%	83.2%	84.4%

As shown in the table above, in the third operating year following completion of the project, Atrium projects that the average occupancy rate for all acute care beds owned by Atrium in Mecklenburg County will be 84.4 percent. This exceeds the standard promulgated in 10A NCAC 14C .3803(a), which requires an applicant proposing to add new acute care beds to project an occupancy rate of at least 75.2 percent for facilities with a combined ADC of greater than 200.

Analysis of Support for Atrium's Assumptions

There are two issues which potentially call into question whether Atrium's assumptions are adequately supported. Each is discussed individually below.

- *CHS Fort Mill Litigation* - Just prior to filing this application, on October 1, 2018, Atrium petitioned the Supreme Court of South Carolina for a writ of certiorari, asking the Supreme Court to review the most recent outcome of the CHS Fort Mill litigation, which would award the certificate of need to develop a hospital in Fort Mill to a different applicant. Publicly available information obtained by the Agency shows that the Supreme Court of South Carolina denied Atrium's petition for a writ of certiorari on February 20, 2019. Thus, any projections involving a shift of patients to CHS Fort Mill are questionable. However, the outcome of that decision would result in more patients remaining at existing Atrium facilities, which would increase utilization.
- *Projected Acute Care Bed Utilization at CMC-Main* - Atrium does not adequately support its method of calculating the growth rate of acute care bed patient days. Atrium states that CMC-Main's historical growth rate for patient days was one percent, but then calculates a growth rate of 2.7 percent by "shifting" patients who were served at other facilities to CMC-Main for calculation of an "adjusted" growth rate. Atrium also calculates historical utilization at other facilities by assuming historical utilization grew at rates projected in applications submitted five years ago, and not based on actual historical data. Atrium states that the growth rate it calculated is conservative, but the growth rate it projects is higher than its historical growth rate for patient days, and the applicant does not provide sufficient information in the application as submitted to support the projected "adjusted" growth rate.

  In Section Q, page 1, the applicants state their assumptions and methodology are consistent with what the Agency has accepted in past applications, including in Project I.D. #s F-11361-17 and F-11362-17, which had a similar method of calculating historical growth rates as the current application. Since no two applications received by the Agency are

identical, assumptions and methodology accepted by the Agency in a previous application may not be appropriate for the Agency to accept in a subsequent application. The Project Analyst notes in both Project I.D. #s F-11361-17 and F-11362-17, despite using the same methodology of "shifting" patients served at other facilities to CMC-Main's historical utilization calculations, the growth rate used by the applicants in those applications was still lower than the actual historical growth rate. That is not the case in the current application.

Nevertheless, Atrium's actual historical utilization is more than sufficient to meet the performance standard promulgated in 10A NCAC 14C .3803(a). Even if Atrium had not annualized its CY 2018 patient days, and held its CY 2017 actual patient days constant through the end of the third operating year, it would still have a utilization rate of at least 75.2 percent, as shown in the table below:

Atrium Health Acute Care Bed Utilization	
	CY 2017
AH Pineville	65,193
CMC	309,619
AH University City	24,788
Projected Total Acute Care Bed Days	399,600
ADC	1,095
Beds	1,426
Occupancy %	76.8%

Projected utilization is reasonable and adequately supported for the following reasons:

- There is a need determination in the 2018 SMFP for 50 acute care beds in the Mecklenburg County acute care bed planning area.
- The applicants rely on their historical utilization in projecting future utilization.
- The applicants' historical utilization already meets the performance standard promulgated in 10A NCAC 14C .3803(a).

<u>*Access*</u> - In Section C, page 60, the applicants state AH Pineville *"provides services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment."*

In Section L, page 98, the applicants project the following payor mix during the third full fiscal year following completion of the project, as illustrated in the following table.

AH Pineville Projected Payor Mix 3rd Full FY (CY 2024)		
Payor Source	**Total Facility**	**M/S Beds**
Self-Pay	12.0%	6.0%
Medicare*	31.0%	60.3%
Medicaid*	16.0%	6.1%
Insurance*	39.0%	26.3%
Other	2.0%	1.3%
TOTAL	**100.0%**	**100.0%**

*Including any managed care plans

The projected payor mix is reasonable and adequately supported.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants adequately identify the population to be served.
- The applicants adequately explain why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicants project the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately support their assumptions.

F-11624-18/Novant Health Huntersville Medical Center/Develop 12 acute care beds and 1 OR

The applicants propose to add 12 acute care beds and one OR to NHHMC, which is currently licensed for 91 acute care beds and five ORs. At the completion of this project and Project I.D. #F-11110-15 (add 48 acute care beds and one OR), NHHMC will be licensed for 151 acute care beds and seven ORs.

Patient Origin - On page 38, the 2018 SMFP defines an acute care bed's service area as *"the acute care bed planning area in which the bed is located. The acute care bed planning areas are the single and multicounty groupings shown in Figure 5.1."* Figure 5.1, on page 42, shows Mecklenburg County as its own acute care bed service area. On page 57, the 2018 SMFP defines the service area for ORs as *"the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* Figure 6.1, on page 62, shows Mecklenburg County as its own OR planning area. Thus, the service area for this facility is Mecklenburg County. Facilities may

also serve residents of counties not included in their service area. The following table illustrates current and projected patient origin.

NHHMC Historical & Projected Patient Origin Acute Care Beds and ORs						
County	**Percentage of Total Patients**					
	Historical Last Full FY (CY 2017)			**Projected 3rd Full FY (CY 2023)**		
	Acute Care	**Inpatient OR**	**Outpatient OR**	**Acute Care**	**Inpatient OR**	**Outpatient OR**
Mecklenburg	64.8%	63.1%	54.1%	64.8%	63.1%	54.1%
Iredell	10.0%	11.2%	15.8%	10.0%	11.2%	15.8%
Lincoln	8.8%	9.0%	9.2%	8.8%	9.0%	9.2%
Gaston	5.1%	4.7%	5.6%	5.1%	4.7%	5.6%
Cabarrus	4.9%	6.3%	6.0%	4.9%	6.3%	6.0%
All Others	6.3%	5.6%	9.3%	6.3%	5.6%	9.3%
TOTAL	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**

Source: Section C, pages 27-30

In Section C, page 30, the applicants provide the assumptions and methodology used to project their patient origin. The applicants' assumptions are reasonable and adequately supported.

Analysis of Need - In Section C, pages 31-38, the applicants summarize the factors which led to this application, then explain the factors they believe support the need the population projected to utilize the proposed services has for the proposed services:

- NHHMC is currently licensed for 91 acute care beds and five ORs (excluding one dedicated C-Section OR). In Project I.D. #F-11110-15, the applicants were approved to relocate 48 acute care beds from Novant Health Presbyterian Medical Center (NHPMC) to NHHMC. The applicants state that the project will be complete in July 2019. The applicants state that NHHMC has experienced rapid growth since its opening in 2004, and approval of this project will allow NHHMC to take unlicensed existing labor, delivery, and recovery (LDR) rooms and convert them to licensed labor, delivery, recovery, and post-partum (LDRP) rooms. The applicants state that the additional OR will be created by renovation of existing space in the NHHMC surgical suite. (page 31)
- *Area population growth:* The applicants state that the northern part of the Greater Charlotte Market will increase by 9.1 percent over the next five years. The applicants state that much of that growth will be driven by the Huntersville area, with a projected growth of 10.4 percent over the next five years, and provide ZIP code population projections from Sg2, a healthcare intelligence, analytics, and consulting company. The applicants state that according to the North Carolina Office of State Budget and Management (NC OSBM), Mecklenburg County will grow at a rate of 1.9 overall between 2020 and 2025, and it remains the most populated county in North Carolina. The applicants state that Huntersville has the fastest growing population within Mecklenburg County, and states that it was ranked high on Nerd Wallet's list of best places for young families in North Carolina. (pages 32-33)

- *Factors specific to the need for acute care beds (pages 33-36):*
  - *Need for additional LDRP beds:* The applicants state that, in addition to the increasing population discussed above, total births at all facilities increased 7.2 percent between 2014 and 2017. At NHHMC, the applicants state that the patient population of women of child bearing age increased by 0.6 percent, but that the number of births increased by 33.3 percent, which demonstrates that more women were choosing to have their babies at NHHMC. The applicants also state that according to NHHMC License Renewal Applications (LRAs), total births at NHHMC increased at a Compound Annual Growth Rate (CAGR) of 10.2 percent when considering annualized 2018 data. The applicants state that as part of Project I.D. #F-11110-15, they projected future obstetrical cases at a growth rate of 1.28 percent, which would result in a projected 1,444 cases in CY 2022. However, the applicants' internal data shows that in CY 2016, they had 1,527 obstetric cases, and between 2016 and 2018 (annualized), the average growth rate was nine percent annually. The applicants also state that 2018 annualized data shows that the occupancy rate of the obstetric postpartum beds will be 97 percent. The applicants further state that by licensing the existing unlicensed LDR beds and converting them to licensed LDRP beds, they can gain the equivalent capacity of four additional postpartum rooms almost immediately and with very little capital cost. Finally, the applicants state that they have been increasing recruitment of OB/GYN staff at NHHMC, and in 2018, they started a Nocturnist Program at NHHMC. The applicants state that the Nocturnist Program partners Obstetric Hospitalists/Nocturnists with OB/GYN physicians to provide better continuity of care for patients who go into labor after traditional doctor office hours. The applicants state that this program provides high quality patient care and has improved the patient experience.
  - *Increase in utilization of all acute care beds:* The applicants state that since they opened in 2004, they have grown from 50 beds to 91 beds as of 2016. The applicants state that since the 91 beds became operational in 2016, the number of acute care cases grew at an average rate of 9.4 percent through 2018 annualized. The applicants state that in Project I.D. #F-11110-15, they had projected growth in the utilization of the acute care beds at a rate of 5.1 percent through the third operating year, and they state that the actual growth rate has been higher. The applicants state that they believe capacity constraints limited growth prior to the full complement of 91 beds being available in 2016, and they believe that capacity constraints, due to the growth of the obstetrics services, are again limiting growth.
- *Factors specific to the need for an OR (pages 36-38):*
  - *High historical utilization of existing ORs:* The applicants state that according to the OR Need Methodology in the 2018 SMFP, an OR at a hospital like NHHMC will be staffed an average of 2,000 hours per year, and standard OR case hours for purposes of calculating OR need are 75 percent of staffed hours, or 1,500 hours. Thus, with five shared ORs, NHHMC is expected to have an average of 10,000 staffed hours and 7,500 actual OR case hours. The applicants state that in FFY 2017, NHHMC had 11,806 staffed hours and 9,554 OR case hours, which means ORs were operating at a utilization rate of 81 percent. The applicants further state that 2018 annualized data show that the five shared ORs have a utilization rate of 84 percent. The applicants state that according to the 2018 SMFP OR Need Methodology, in FFY 2017, it actually needed six ORs to manage utilization without having staff work overtime and perform surgeries late in the day (9,554 OR case hours / 1,500 standard OR case hours = 6.4

ORs). The applicants state that according to SMFP principles, when the sixth OR is operational as of July 2019, it will be fully utilized from the first day it opens.

- *Projected utilization of existing and projected ORs:* The applicants state that if its adjusted surgical case hours grow at the surgical services average growth for all Novant facilities in Mecklenburg County (2.7 percent), and its actual case times remain constant, NHHMC will have 11,296 OR case hours in 2023 (the third operating year of the proposed project). The applicants state that if the 2018 SMFP OR Need Methodology is followed, NHHMC will have a need for eight ORs in 2023 (11,296 OR case hours / 1,500 standard OR case hours = 7.5 ORs).
- *Conformity with 10A NCAC 14C .2103(a):* The applicants state that they will demonstrate the need for seven ORs by the end of the third operating year of the proposed project, and will do by using a growth factor of 2.7 percent (the Project Analyst notes that the growth factor for Mecklenburg County in the 2018 SMFP is 8.2 percent).

The information is reasonable and adequately supported for the following reasons:

- There is a need determination for 50 acute care beds in Mecklenburg County in the 2018 SMFP. The applicants are applying to develop 12 acute care beds in Mecklenburg County in accordance with the acute care bed need determination in the 2018 SMFP.
- There is a need determination for six ORs in Mecklenburg County in the 2018 SMFP. The applicants are applying to develop one OR in Mecklenburg County in accordance with the OR need determination in the 2018 SMFP.
- The applicants' historical demographic data used for their assumptions with respect to identifying the population to be served are reasonable.
- The applicants' statements and assumptions are reasonable and adequately demonstrate the need the population to be served has for the proposed services.

Projected Utilization

Acute Care Beds
The Novant health system in Mecklenburg County consists of NHHMC, NHPMC, Novant Health Matthews Medical Center (NHMMC), Novant Health Mint Hill Medical Center (NHMHMC), and the proposed Novant Health Ballantyne Medical Center (NHBMC). Pursuant to 10A NCAC 14C .3803(a), the applicants must demonstrate that combined acute care bed utilization for the entire health system is at least 75.2 percent when a health system has an ADC of greater than 200 patients.

NHHMC **-** In Section Q, the applicants provide historical and projected acute care bed utilization, as illustrated in the following table.

NHHMC Historical and Projected Acute Care Bed Utilization							
	Prior Full FY CY 2017	Prior Full FY CY 2018*	Interim FY CY 2019	Interim FY CY 2020	1st Full FY CY 2021	2nd Full FY CY 2022	3rd Full FY CY 2023
# of General Acute Care Beds	85	85	131	131	143	143	143
# of Patient Days	21,640	23,926	25,577	27,623	29,833	32,220	34,797
# of ICU Beds	6	6	8	8	8	8	8
# of ICU Bed Patient Days	1,672	1,707	1,925	2,079	2,246	2,425	2,619
# of All Acute Care Beds	91	91	139	139	151	151	151
# of All Patient Days	23,312	25,634	27,502	29,702	32,079	34,645	37,416

*Annualized

In Section Q, the applicants provide the assumptions and methodology used to project utilization, which are summarized below.

Service Area - The applicants defined their service area as Mecklenburg County – the service area for acute care beds as defined in the 2018 SMFP. The applicants state that the first three operating years for the proposed project are CYs 2021, 2022, and 2023.

Projected Growth Rate - The projected growth rate was calculated by analyzing historical utilization of acute care beds beginning with CY 2016, which is when all 91 existing beds were licensed. Utilization for CY 2018 was annualized from actual utilization data for January 2018 to July 2018, a period of seven months. They divided the total for the period by 7 and then multiplied by 12. The results are illustrated in the following table.

NHHMC Calculation of Growth Rate				
	CY 2016	CY 2017	CY 2018 (annualized)	AAGR & ALOS
Admissions or Discharges*	6,262	6,867	7,490	
Annual Growth		9.7%	9.1%	9.4%
Patient Days*	21,165	23,312	25,634	
ALOS	3.4	3.4	3.4	3.4
Days in Period	366	365	365	
ADC	57.8	63.9	70.2	
# of Beds	91	91	91	
Occupancy Rate	63.5%	70.2%	77.2%	

***Source:** Trendstar Internal Data. CY 2018 Annualized – [(Jan to July) / 7] X 12 Months

The applicants assume an annual growth rate of eight percent, which is lower than the AAGR for CYs 2016-2018 (annualized) and an ALOS of 3.4 days, which is consistent with the historical ALOS.

Projected utilization is shown in the table below.

NHHMC Projected Acute Care Bed Utilization					
	Interim		1st Three Full FYs following Project Completion		
	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023
Admissions*	8,089	8,736	9,435	10,190	11,005
ALOS*	3.4	3.4	3.4	3.4	3.4
Patient Days	27,502	29,702	32,079	34,645	37,416
Days in Period	365	366	365	365	365
ADC	75.3	81.2	87.9	94.9	102.5
Beds	139	139	151	151	151
Occupancy Rate	54.2%	58.4%	58.2%	62.9%	67.9%

*The applicants state they used a growth rate of 8.0 percent and an ALOS of 3.4 based on the previous step.

NHBMC – In Project I.D. #F-11625-18, filed on the same date as this application, Novant proposes to establish NHBMC, a new general acute care hospital in Mecklenburg County, by relocating 36 acute care beds from NHPMC and two ORs and a gastrointestinal endoscopy (GI endo) room from Novant Health Ballantyne Outpatient Surgery (NHBOS). NHBMC is projected to be operational on January 1, 2023. The applicants provide the assumptions and methodology used to project utilization at the proposed NHBMC as part of this application.

Service Area - The service area is defined as six ZIP code areas. Ninety percent of the patients are expected to be residents of those six ZIP code areas. The remaining 10 percent will come from other ZIP codes in North Carolina, South Carolina, and other areas of in-migration. NHBMC will be located in ZIP code are 28277. The other five ZIP code areas are 28134, 28173, 28226, 29707, and 29720. All of these five ZIP code areas are adjacent to ZIP code 28277, with the exception of 29720, which is just south of the area with direct access via a major road.

Population of the Service Area - Population estimates and projections for each ZIP code area in the service area was obtained from the US Census Bureau and Claritas for the following age groups: 0-14 years; 15-44 years; 45-65 years; and 65+ years. In addition, the population of women age 15-44 years was obtained in order to project obstetric patient volumes. The applicants assume that the population in each ZIP code area will increase at the same rate it increased from CYs 2018-2023.

Average Discharge Use Rates - Discharge rates by age group and by ZIP code area were obtained from IBM Watson (f/k/a Truven) (for NC data) and from the South Carolina Revenue and Fiscal Affairs Office (for SC data). The most recent data available for both states was for CYs 2015-2017. The applicants then calculated the average discharge use rates per 1,000 population by age group and by ZIP code area, averaged the rates, and held the average of the rates at a constant level to project utilization. The data was limited to patients with a Diagnosis Related Group (DRG) weight less than 2.0, which the applicants state is appropriate for a community hospital.

Projected Acute Care Discharges (All Facilities) - The average discharge use rates were used to project total discharges at all facilities.

Market Shares and Projected Shifts - The applicants reviewed three years of market share data. The following factors were used to determine market shares for NHBMC:

- Novant's 2017 market share for each ZIP code
- The relative location of Novant hospitals and other hospitals
- Road networks
- The existing portion of Novant's market share that is expected to transfer to NHBMC
- Market share that NHBMC will pull away from other non-Novant hospitals
- Ramp-up period for patient shift to NHBMC

The following factors were considered in determining potential shifts from existing Novant facilities:

- NHBMC will not offer all of the same services currently offered by NHPMC.
- Some patients will choose to be treated by providers who are not located at NHBMC.
- The number of acute care beds and ORs will limit the number of patients and physicians that can shift to NHBMC.
- The applicants state that they believe location is more important for obstetric patients than for medical/surgical patients, and state that medical/surgical patients are projected to shift at a lower rate than obstetric patients.

The applicants state they assume 60 percent of Novant patients residing in ZIP code 28277, where NHBMC will be located, will shift to NHBMC, and assume that NHBMC will increase the existing market share in that ZIP code by 10 percent. The applicants assume patients residing in other ZIP codes will shift from Novant facilities to NHBMC at lower rates, and project an increase in market share of five percent. Finally, the applicants state that the shift in patients from other facilities and an increase in market share will happen over the course of three years, with 70 percent shifting to NHBMC in OY 1 (CY 2023), 85 percent shifting in OY 2 (CY 2024), and all remaining patients shifting in OY 3 (CY 2025). See Section Q for the market share and patient shift percentages.

Projected utilization during the first three full fiscal years following project completion are shown in the table below. Note: the first full year of operation for NHBMC, CY 2023, is the third full year of operation for the NHHMC project.

NHBMC Projected Acute Care Bed Utilization									
	Med/Surg Beds			**OB Beds**			**Total Acute Care Beds**		
	2023	**2024**	**2025**	**2023**	**2024**	**2025**	**2023**	**2024**	**2025**
Service Area Discharges	1,102	1,389	1,697	508	624	742	1,611	2,013	2,439
In-migration	122	154	189	56	69	82	179	224	271
Total Discharges	1,225	1,544	1,885	565	693	825	1,790	2,237	2,710
Average Length of Stay	3.9	3.9	3.9	2.5	2.5	2.5	3.5	3.5	3.5
Total Patient Days	4,777	6,020	7,353	1,412	1,733	2,061	6,189	7,753	9,414
Days in Year	365	366	365	365	366	365	365	366	365
Average Daily Census	13	16	20	4	5	6	17	21	26
Licensed Beds	28	28	28	8	8	8	36	36	36
Occupancy %	**46.7%**	**58.7%**	**71.9%**	**48.4%**	**59.2%**	**70.6%**	**47.1%**	**58.8%**	**71.6%**

NHMHMC was licensed as of October 1, 2018 for 36 acute care beds. An additional 14 acute care beds are approved and expected to be operational by June 1, 2023. The applicants updated the projected utilization from Project I.D. #F-7648-06 (the approved application) for the third full operating year, as shown in the table below.

NHMHMC Adjusted Projected Acute Care Bed Utilization			
	Days in F-7648-06	**Percent Decrease**	**Adjusted Days**
NHMHMC	13,753	28.3%	9,861
Volume Shifts			
NHPMC/NHCOH	7,565	28.3%	5,424
NHMMC	1,675	28.3%	1,201
NHHMC	97	28.3%	70

Growth Rate – A growth rate for the combined total patient days for all Novant facilities in Mecklenburg County was calculated, as shown in the table below.

Novant Health Mecklenburg County System Acute Care Bed Patient Days				
	CY 2016	**CY 2017**	**CY 2018***	**CAGR**
Patient Days	194,171	196,639	213,667	4.9%

*Annualized
Table NHMHMC.2, p.172

Projected Utilization - The applicants state that they relied on the following assumptions in projecting future growth at NHMHMC:

- The number of patient days in CY 2021 is the number of patient days projected in the third year of operation in Project I.D. #F-7648-06, reduced by 28.3 percent.
- Patient days are expected to increase 4.9 percent annually, consistent with the growth rate for patient days for the total Novant system in Mecklenburg County.
- No changes are anticipated regarding a shift of patients from the shift of patients projected in Project I.D. #F-7648-06.

Projected utilization at NHMHMC is shown in the table below. Note: the applicants did not provide projected utilization of acute care beds at NHMHMC during CY 2023, the third full year of operation following completion of the project at NHHMC. In the table below, utilization for CY 2023 is held constant at the level projected for CY 2022.

NHMHMC Projected Acute Care Bed Utilization			
	CY 2021	CY 2022	CY 2023
NHMHMC Adjusted Patient Days	9,861	10,344	10,344
Volume Shifts			
NHPMC/NHCOH	5,424	5,689	5,689
NHMMC	1,203	1,262	1,262
NHHMC	69	72	72

Table NHMHMC.3, p.172

NHPMC/NHMMC - The applicants calculated the ALOS for patients at NHPMC and NHMMC and the CAGR for total acute care patient days at NHPMC and NHMMC, as shown in the following table.

NHPMC and NHMMC Historical Acute Care Bed Utilization				
	CY 2016	CY 2017	CY 2018*	Averages
NHPMC – Acute Care Cases	25,488	25,316	26,815	2.6%
NHPMC – Acute Care Patient Days	136,605	136,639	149,549	4.6%
NHPMC – ALOS	5.4	5.4	5.6	5.4
NHMMC – Acute Care Cases	9,455	9,941	10,646	6.1%
NHMMC – Acute Care Patient Days	36,401	36,688	38,484	2.8%
NHMMC – ALOS	3.8	3.7	3.6	3.7

*Annualized
Table System.1, p.173

The following table illustrates projected discharges. The applicants project a growth rate of 2.6 percent for NHPMC and 6.1 percent at NHMMC.

NHPMC and NHMMC Projected Acute Care Discharges						
Facility	2018	2019	2020	2021	2022	2023
NHPMC	26,815	27,512	28,227	28,961	29,714	30,487
NHMMC	10,646	11,295	11,984	12,715	13,491	14,314

Impact of NHBMC on Novant Facilities - The applicants assume that development of NHBMC would result in a shift of patients from existing facilities in Mecklenburg County to NHBMC. See Section Q, page 167, for the specific number of patients expected to shift by facility.

Projected Utilization for the Novant Health System in Mecklenburg County – The following table illustrates projected utilization for all of the facilities in the Novant Health System in Mecklenburg County.

Novant Health System Projected Acute Care Bed Utilization			
	CY 2021	CY 2022	CY 2023
NHHMC Total Patient Days	32,010	34,573	37,316
NHBMC Total Patient Days	--	--	6,189
NHMMC Total Patient Days	45,843	48,654	50,708
NHPMC Total Patient Days	156,391	160,457	157,403
NHMHMC Total Patient Days	9,861	10,344	10,344
Novant System Total Patient Days	244,105	254,028	261,960
Number of Days per Year	365	365	365
ADC	669	696	718
Number of Licensed Beds	874	874	874
Utilization Rate	76.5%	79.6%	82.1%

At the end of the third year of operation following completion of the project, the utilization rate for all hospitals owned and operated by Novant is projected to be 82.1 percent. This meets the standard promulgated in 10A NCAC 14C .3803(a), which requires an applicant proposing to add new acute care beds to a service area to reasonably project that all acute care beds in the service area under common ownership to have a utilization of at least 75.2 percent when the combined acute care beds will have a combined ADC of greater than 200.

Analysis of Support for Novant's Assumptions - There are several issues with the data, assumptions, and methodology used by the applicants in this review. Each issue is discussed individually below.

Overstatement of Patient Days at NHPMC - In comments received by the Agency during the public comment period, Atrium claimed Novant overstates the acute care bed days at NHPMC for CYs 2016 and 2017. In response, the applicants state that there was an error with the calculation of the number of patients and acute care patient days. On pages 10-11 of the response, the applicants state:

> *"Atrium alleges the Application overstates historical utilization for Novant Health hospitals as compared to the LRAs and Table 5 of the 2018 SMFP. The allegation is false regarding NHHMC and NHMMC. The data for calendar years in the Application for NHHMC and NHMMC are correct and differences from FFY LRA or SMFP data are due to different time periods or data element definitions.*
>
> *Novant Health acknowledges an error in the calculation of historical utilization for NHPMC on page 109 of the Application. Counts of NHPMC acute care days and discharges excluded counts for Novant Health Charlotte Orthopedic Hospital (NHCOH); part of the NHPMC license, and included behavioral health patient days and discharges should have been excluded."*

At the public hearing, the applicants submitted revised calculations along with their response. However, the revised calculations cannot be considered since they would amend the application. Instead, the Project Analyst reviewed data in NHPMC's LRAs for FYs 2016, 2017, and 2018 in order to determine what the projections would be using the correct baseline data.

The following table illustrates NHPMC acute care bed days and admissions and NHCOH patient days and admissions as reported in the LRAs. The time period is different since the LRA data is for the federal fiscal year and the data in the application is CY, but the differences are minor. The averages were calculated by using the calculator found at http://cagrcalculator.net. ALOS is calculated by dividing the number of acute care patient days by acute care patients and appropriately rounding, if necessary.

NHPMC Corrected Historical Acute Care Bed Utilization				
	FFY 2016	FFY 2017	FFY 2018	Averages
NHPMC – Acute Care Admissions	26,325	27,558	27,728	2.6%
NHPMC – Acute Care Patient Days	123,643	124,695	126,975	1.3%
NHPMC – ALOS	4.7	4.5	4.6	4.6

The calculations in the table above were then applied to NHPMC's FFY 2018 data and projected forward through FFY 2024.

NHPMC Corrected Growth Rate Calculations							
	FFY 2018	FFY 2019	FFY 2020	FFY 2021	FFY 2022	FFY 2023	FFY 2024
NHPMC	27,728	28,449	29,189	29,948	30,727	31,526	32,346
Growth Rate	--	2.6%	2.6%	2.6%	2.6%	2.6%	2.6%

The following formula was used to convert the data from FFYs to CYs: CY 2018 = [(FFY 2018 / 4) X 3] + (FFY 2019 / 4). The results are illustrated in the table below.

NHPMC Corrected Projected Acute Care Bed Utilization Before Shifts						
	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023
NHPMC	27,908	28,634	29,379	30,143	30,927	31,732
Days (ALOS 4.6)	128,377	131,716	135,143	138,658	142,264	145,967

The following table illustrates corrected projected acute care bed utilization at NHPMC following projected patient shifts to NHBMC and NHMHMC using the applicants' assumptions.

NHPMC Corrected Adjusted Projected Acute Care Bed Utilization after Shifts			
	CY 2021	CY 2022	CY 2023
NHPMC Unadjusted Cases	30,143	30,927	31,732
NHPMC Unadjusted Days	138,658	142,264	145,967
NHBMC Shift in Cases	--	--	(233)
NHBMC Shift in Days (4.6)	--	--	(1,072)
NHMHMC Shift in Days	(5,424)	(5,689)	(5,968)
NHPMC Adjusted Days	133,234	136,575	138,927

The following table illustrates corrected projected acute care bed utilization for all facilities in the Novant health system in Mecklenburg County.

Novant Health System Corrected Projected Acute Care Bed Utilization			
	CY 2021	**CY 2022**	**CY 2023**
NHHMC Total Patient Days	32,010	34,573	37,316
NHBMC Total Patient Days	--	--	6,189
NHMMC Total Patient Days	45,843	48,654	50,708
NHPMC Total Patient Days	133,234	136,575	138,927
NHMHMC Total Patient Days	9,861	10,344	10,344
Novant System Total Patient Days	220,948	230,146	243,484
Number of Days per Year	365	365	365
ADC	605	631	667
Number of Licensed Beds	874	874	874
Utilization Rate	69.2%	72.2%	76.3%

As shown in the table above, adjusting NHPMC's projected utilization based on the corrected baseline data results in a lower overall utilization rate (76.3 percent) but that lower rate still exceeds the minimum rate required by 10A NCAC 14C .3803(a) (75.2 percent).

Impact of NHBMC on Novant Facilities is Understated - In comments received by the Agency during the public comment period, Atrium claims that Novant overstates the impact of NHBMC on non-Novant facilities, and understates the impact of NHBMC on Novant facilities. Assuming for the sake of argument that Atrium's claim about understated shifts from other Novant health system facilities and overstatement from non-Novant facilities is correct, the utilization rate for the Novant health system in Mecklenburg County would be 76.3 percent, which still exceeds 75.2 percent required by 10A NCAC 14C .3803(a).

Projected utilization is reasonable and adequately supported for the following reasons:

- There is a need determination in the 2018 SMFP for 50 acute care beds in the Mecklenburg County acute care bed planning area.
- The applicants reasonably rely on historical utilization and market share to project future utilization.
- The applicants reasonably project to meet the performance standard promulgated in 10A NCAC 14C .3803(a).

Operating Rooms

The Novant health system in Mecklenburg County consists of NHHMC, NHPMC, NHMMC, NHMHMC, NHBMC, Novant Health Huntersville Outpatient Surgery (NHHOS), Novant Health Matthews Outpatient Surgery (NHMOS), Novant Health Ballantyne Outpatient Surgery (NHBOS), and SouthPark Surgery Center (SPSC). Pursuant to 10A NCAC 14C .2103(b), the applicants must demonstrate the need for all existing, approved, and proposed ORs in the health system at the end of the third operating year, using the OR Need Methodology in the 2018 SMFP.

NHHMC - As of the date of these findings, NHHMC is licensed for five ORs. Pursuant to the CON issued for Project I.D. #F-11110-15, NHHMC will be licensed for six ORs. The sixth

OR is being relocated from NHPMC. In this application, the applicants propose to add a seventh OR to NHHMC.

In Section Q, the applicants provide historical and projected utilization, as shown in the table below.

NHHMC OR Need			
	CY 2021	**CY 2022**	**CY 2023**
Projected # of Inpatient Surgical Cases	1,573	1,615	1,659
Projected # of Outpatient Surgical Cases	3,965	4,072	4,182
Final Inpatient Case Time (1)	131.3	131.3	131.3
Final Outpatient Case Time (1)	93.1	93.1	93.1
Total Hours (Minutes / 60 minutes per hour) (2)	9,593	9,853	10,119
Average Annual Operating Hours – Group 4 (3)	1,500	1,500	1,500
Number of ORs Needed (Annual Hours / Average Operating Hours) (4)	6.4	6.6	6.7

(1) The Final Inpatient and Outpatient Case Times in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Times, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

In Section Q, the applicants provide the assumptions and methodology used to project utilization, which are summarized below.

Projected Growth Rate - The applicants analyzed historical surgical utilization in order to calculate a combined CAGR for all facilities in the Novant health system in Mecklenburg County, as shown in the following table.

Novant Health System Historical OR Utilization				
Facility	**CY 2016**	**CY 2017**	**CY 2018***	**CAGR**
Inpatient Cases				
NHPMC	8,166	8,117	8,439	1.7%
NHMMC	1,392	1,542	1,503	3.9%
NHHMC	1,261	1,352	1,452	7.3%
NHMHMC	--	--	--	--
Total	10,819	11,011	11,394	2.6%
Outpatient Cases				
NHPMC	21,754	21,947	22,718	2.2%
NHMMC	4,204	4,078	4,047	-1.9%
NHHMC	3,494	3,748	3,660	2.4%
NHMHMC	--	--	--	--
SPSC	10,467	10,852	11,417	4.4%
NHBOS	856	937	897	2.2%
NHHOS	2,259	2,553	3,029	15.8%
NHMOS	2,034	1,906	1,786	-6.3%
Total	45,068	46,021	47,554	2.7%
Total Cases				
All	55,887	57,032	58,948	2.7%

Source: Trendstar internal data.
*The applicants state CY 2018 is annualized based on January 2018 to July 2018 data.

The applicants rely on two full years of data and one partial year of data (annualized) to calculate the CAGR they used. To determine whether the growth rate calculated by and used by the applicants is reasonable, the Project Analyst reviewed the LRAs for all facilities in the Novant health system in Mecklenburg County for the last five years (FFYs 2014 – 2018) and calculated CAGRs based on five full years of data, as shown in the table below.

Novant Health System Historical OR Utilization (LRA Data)						
Facility	**FFY 2014**	**FFY 2015**	**FFY 2016**	**FFY 2017**	**FFY 2018**	**CAGR**
Inpatient Cases						
NHPMC	7,044	7,911	7,718	7,863	7,897	2.9%
NHMMC	1,237	1,341	1,384	1,509	1,560	6.0%
NHHMC	1,215	1,291	1,338	1,291	1,478	5.0%
NHMHMC	--	--	--	--	--	--
Total	9,496	10,543	10,440	10,663	10,935	3.6%
Outpatient Cases						
NHPMC	17,346	20,138	21,274	22,035	23,132	7.5%
NHMMC	3,578	3,768	4,143	4,088	4,068	3.3%
NHHMC	3,270	3,258	3,424	3,689	3,784	3.7%
NHMHMC	--	--	--	--	--	--
SPSC	9,316	10,022	10,402	10,788	11,056	4.4%
NHBOS	1,159	946	902	923	901	-6.1%
NHHOS	1,797	1,903	2,213	2,385	2,968	13.4%
NHMOS	1,900	1,887	2,016	1,907	1,903	0.0%
Total	38,366	41,922	44,374	45,815	47,812	5.7%
Total Cases						
All	47,862	52,465	54,814	56,478	58,747	5.3%

As shown in the table above, the 5-year CAGR for all facilities is 5.3 percent. The applicants used of a 2.7 percent growth rate to project surgical cases is reasonable and adequately supported.

The applicants make the following assumptions about projected utilization at NHHMC:

- All surgical cases are assumed to increase 2.7 percent per year, which is the Novant health system CAGR from CY 2016 to CY 2018 (annualized).
- The impact of the opening of NHMHMC on surgical utilization at NHHMC is based on the projections originally made in Project I.D. #F-7648-06. The applicants assume CY 2019 is the first full year of operation for NHMHMC, and thus, the first year surgical cases are assumed to shift from NHHMC to NHMHMC. The applicants reduce that number by 28.3 percent to reflect that only 36 of the 50 beds are licensed and there is one OR still to be relocated to NHMHMC.

The following table illustrates projected utilization at NHHMC as reported in Section Q using the assumptions described above.

NHHMC Projected OR Utilization						
	CY 2018	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**
Baseline Inpatient Cases	1,452	1,491	1,531	1,573	1,615	1,659
Baseline Outpatient Cases	3,660	3,759	3,860	3,965	4,072	4,182
Inpatient Cases to NHMHMC	--	-3	-4	-5	-5	-5
Outpatient Cases to NHMHMC	--	-24	-29	-35	-36	-37
Total Inpatient Cases	1,452	1,488	1,527	1,568	1,610	1,654
Total Outpatient Cases	3,660	3,735	3,831	3,930	4,036	4,145
Final Inpatient Case Time (1)	131.3	131.3	131.3	131.3	131.3	131.3
Final Outpatient Case Time (1)	93.1	93.1	93.1	93.1	93.1	93.1
Total Surgical Hours (2)	**8,857**	**9,052**	**9,286**	**9,529**	**9,786**	**10,051**
Average Annual Operating Hours – Group 4 (3)	1,500	1,500	1,500	1,500	1,500	1,500
Number of ORs Needed (4)	5.9	6.0	6.2	6.4	6.5	6.7
Surplus (-) / Deficit (based on 6 ORs)	**-0.1**	**0.0**	**0.2**	**0.4**	**0.5**	**0.7**

(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

As shown in the table above, using the OR Need Methodology in Chapter 6 of the 2018 SMFP, the applicants show a need for 6.7 ORs in the third OY, which would be rounded to 7. This is consistent with 10A NCAC 14C .2103(a), which requires the applicants to demonstrate the need for the number of ORs they propose to develop, using the OR Need Methodology in the applicable SMFP, for the third OY following project completion.

NHBOS – The applicants state that the two ORs currently at NHBOS will be relocated to NHBMC and NHBOS will close. The applicants assume that outpatient cases previously performed at NHBOS will be performed at NHBMC. The applicants project surgical cases at NHBOS through CY 2022 using the 2.7 percent annual growth rate, as shown in the table below.

NHBOS Projected OR Utilization					
	CY 2018	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**
Outpatient Cases	897	921	946	971	997
Final Outpatient Case Time (1)	86.0	86.0	86.0	86.0	86.0
Total Surgical Hours (2)	**1,285**	**1,320**	**1,355**	**1,392**	**1,430**
Average Annual Operating Hours – Group 6 (3)	1,312.5	1,312.5	1,312.5	1,312.5	1,312.5
Number of ORs Needed (3)	1.0	1.0	1.0	1.1	1.1
Surplus (-) / Deficit (based on 2 ORs)	**-1.0**	**-1.0**	**-1.0**	**-0.9**	**-0.9**

(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

NHBMC - In Project I.D. #F-11625-18, filed on the same date as this application, Novant proposes to establish NHBMC, a new general acute care hospital in Mecklenburg County, by relocating 36 acute care beds from NHPMC and two ORs and a GI endo room from NHBOS.

NHBMC is projected to be operational on January 1, 2023. The applicants provide the assumptions and methodology used to project utilization at the proposed NHBMC as part of this application.

The applicants calculated ratios of inpatient and outpatient surgical cases to acute care discharges for NHHMC and NHMMC. The 3-year average combined ratios were used to project inpatient and outpatient surgical cases at NHBMC. The following tables illustrate the results.

NHHMC and NHMMC Calculation of Ratios						
	NHHMC			**NHMMC**		
	CY 2016	**CY 2017**	**CY 2018***	**CY 2016**	**CY 2017**	**CY 2018***
Total Acute Care Discharges	6,262	6,867	7,490	9,455	9,941	10,646
Inpatient Surgical Cases	1,261	1,352	1,452	1,392	1,542	1,503
Ratio of Inpatient Surgical Cases to Acute Care Discharges	0.20	0.20	0.19	0.15	0.16	0.14
Outpatient Surgical Cases	3,494	3,748	3,660	4,204	4,078	4,047
Ratio of Outpatient Surgical Cases to Acute Care Discharges	0.56	0.55	0.49	0.44	0.41	0.38

Source: Table NHBMC.7
*CY 2018 data annualized from January - July

NHHMC and NHMMC Combined				
	CY 2016	**CY 2017**	**CY 2018***	**3-Year Average**
Total Acute Care Discharges	15,717	16,808	18,135	--
Inpatient Surgical Cases	2,653	2,894	2,955	--
Inpatient Surgical Case Ratio	0.17	0.17	0.16	0.17
Outpatient Surgical Cases	7,698	7,826	7,707	--
Outpatient Surgical Case Ratio	0.49	0.47	0.42	0.46

Source: Table NHBMC.7
*CY 2018 data annualized from January - July

The following table illustrates surgical utilization at NHBMC before shifts of patients from other facilities.

NHBMC Projected OR Surgical Cases Before Shifts of Patients from Other Facilities			
	CY 2023	**CY 2024**	**CY 2025**
Projected # of Inpatient Acute Care Discharges	1,790	2,237	2,710
Ratio of Inpatient Surgical Cases to Inpatient Acute Care Cases	0.17	0.17	0.17
Projected # of Inpatient Surgical Cases	301	376	455
Ratio of Outpatient Surgical Cases to Inpatient Acute Care Cases	0.46	0.46	0.46
Projected # of Outpatient Surgical Cases	824	1,029	1,247

The applicants project utilization of the proposed ORs at NHBMC for its first three operating years. NHBMC's first operating year is the same as NHHMC's third operating year. The projections are shown in the table below.

NHBMC Projected OR Utilization			
	CY 2023	**CY 2024**	**CY 2025**
Inpatient Cases	301	376	455
Final Inpatient Case Time (1)	115.3	115.3	115.3
Outpatient Cases	824	1,029	1,247
Final Outpatient Case Time (1)	73.3	73.3	73.3
Total Surgical Hours (2)	**1,585**	**1,980**	**2,397**
Average Annual Operating Hours – Group 4 (3)	1,500	1,500	1,500
Number of ORs Needed	1.1	1.3	1.6
Surplus (-) / Deficit (based on 2 ORs)	**-0.9**	**-0.7**	**-0.4**

(1) The Final Case Time in minutes for Group 4 facilities in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

NHMHMC was licensed as of October 1, 2018 for one dedicated C-Section OR and three shared ORs. An additional shared OR is approved and expected to be operational by June 1, 2023. The applicants updated the projected utilization from Project I.D. #F-7648-06 (the approved application) for the third full operating year, as shown in the table below.

NHMHMC Adjusted Projected Surgical Case Utilization			
	Cases in F-7648-06	**Percent Decrease**	**Adjusted Cases**
Inpatient Cases			
NHMHMC	936	28.3%	671
Volume Shifts			
NHPMC/NHCOH	518	28.3%	371
NHMMC	81	28.3%	58
NHHMC	7	28.3%	5
Outpatient Cases			
NHMHMC	2,840	28.3%	2,036
Volume Shifts			
NHPMC/NHCOH	1,005	28.3%	721
NHMMC	304	28.3%	218
NHHMC	48	28.3%	35
SouthPark	182	28.3%	130

The applicants state that they relied on the following assumptions in projecting future growth at NHMHMC:

- The number of surgical cases in CY 2021 is the number of surgical cases projected in the third year of operation in Project I.D. #F-7648-06, reduced by 28.3 percent.
- Surgical cases are expected to increase 2.7 percent annually, consistent with the growth rate for surgical cases for the total Novant system in Mecklenburg County.
- No changes are anticipated regarding a shift of patients from the shift of patients projected in Project I.D. #F-7648-06.

Projected growth of surgical cases at NHMHMC, along with how cases will shift from other Novant facilities, is shown in the table below. Note: the applicants did not project surgical cases for SPSC and outpatient surgical cases for NMMHC for CY 2023, so the utilization is held constant from CY 2022.

NHMHMC Adjusted Projected Surgical Case Utilization			
	CY 2021	**CY 2022**	**CY 2023**
Inpatient Cases			
NHMHMC Adjusted Surgical Cases	671	689	708
Volume Shifts			
NHPMC/NHCOH	371	381	392
NHMMC	58	60	61
NHHMC	5	5	5
Outpatient Cases			
NHMHMC Adjusted Surgical Cases	2,036	2,917	2,917
Volume Shifts			
NHPMC/NHCOH	721	740	760
NHMMC	218	224	224
NHHMC	35	36	37
SPSC	130	133	133

Table NHMHMC.3, p.172

The projected OR utilization at NHMHMC is shown in the table below.

NHMHMC Projected OR Utilization					
	CY 2019	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**
Adjusted Inpatient Cases	447	557	671	689	708
Final Inpatient Case Time (1)	115.3	115.3	115.3	115.3	115.3
Adjusted Outpatient Cases	1,368	1,696	2,036	2,091	2,148
Final Outpatient Case Time (1)	73.3	73.3	73.3	73.3	73.3
Total Surgical Hours (2)	**2,530**	**3,142**	**3,776**	**3,879**	**3,985**
Average Annual Operating Hours – Group 4 (3)	1,500	1,500	1,500	1,500	1,500
Number of ORs Needed	1.7	2.1	2.5	2.6	2.7
Surplus (-) / Deficit (based on 4 ORs)	**-2.3**	**-1.9**	**-1.5**	**-1.4**	**-1.3**

(1) The Final Case Time in minutes for Group 4 facilities in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

NHPMC – The applicants project surgical cases at NHPMC through CY 2023 using the 2.7 percent annual growth rate, and accounting for shifts in cases to NHMHMC and NHBMC, as shown in the table below.

NHPMC Projected OR Utilization						
	CY 2018	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**
Inpatient Cases	8,439	8,667	8,901	9,142	9,388	9,642
Less Cases Shifting to NHMHMC	--	-248	-308	-371	-381	-392
Less Cases Shifting to NHBMC	--	--	--	--	--	-40
Adjusted Inpatient Cases	8,439	8,419	8,593	8,771	9,007	9,210
Final Inpatient Case Time (1)	181.8	181.8	181.8	181.8	181.8	181.8
Outpatient Cases	22,718	23,331	23,961	24,608	25,272	25,955
Less Cases Shifting to NHMHMC	--	-484	-600	-721	-740	-760
Adjusted Outpatient Cases	22,718	22,847	23,361	23,887	24,532	25,195
Final Outpatient Case Time (1)	108.4	108.4	108.4	108.4	108.4	108.4
Total Surgical Hours (2)	**66,614**	**66,787**	**68,243**	**69,732**	**71,612**	**73,425**
Average Annual Operating Hours – Group 2 (3)	1,950	1,950	1,950	1,950	1,950	1,950
Number of ORs Needed	34.1	34.2	35.0	35.8	36.7	37.6
Surplus (-) / Deficit (based on 36 ORs)	**-1.9**	**-1.8**	**-1.0**	**-0.2**	**0.7**	**1.6**

(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

NHMMC – The applicants project surgical cases at NHMMC through CY 2023 using the 2.7 percent annual growth rate, and accounting for shifts in cases to NHMHMC and NHBMC, as shown in the table below.

NHMMC Projected OR Utilization						
	CY 2018	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**
Inpatient Cases	1,503	1,544	1,586	1,629	1,672	1,718
Less Cases Shifting to NHMHMC	--	-39	-48	-58	-60	-61
Less Cases Shifting to NHBMC	--	--	--	--	--	-43
Adjusted Inpatient Cases	1,503	1,505	1,538	1,571	1,612	1,614
Final Inpatient Case Time (1)	107.2	107.2	107.2	107.2	107.2	107.2
Outpatient Cases	3,660	3,759	3,860	3,965	4,072	4,182
Less Cases Shifting to NHMHMC*	--	-146	-182	-218	-224	-224
Adjusted Outpatient Cases	3,660	3,613	3,678	3,747	3,848	3,958
Final Outpatient Case Time (1)	84.8	84.8	84.8	84.8	84.8	84.8
Total Surgical Hours (2)	**7,858**	**7,795**	**7,946**	**8,103**	**8,319**	**8,478**
Average Annual Operating Hours – Group 4 (3)	1,500	1,500	1,500	1,500	1,500	1,500
Number of ORs Needed	5.2	5.2	5.3	5.4	5.5	5.7
Surplus (-) / Deficit (based on 6 ORs)	-0.8	-0.8	-0.7	-0.6	-0.5	-0.3

(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.
*Table System.7, the source of this information, uses the incorrect number of outpatient cases to shift to NHMHMC. The Project Analyst used the information for NHMMC in Table NHMHMC.3, page 172, instead.

SPSC – The applicants project surgical cases at SPSC through CY 2023 using the 2.7 percent annual growth rate, and accounting for shifts in cases to NHMHMC, as shown in the table below.

SPSC Projected OR Utilization						
	CY 2018	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**
Outpatient Cases	11,417	11,725	12,042	12,367	12,701	13,044
Less Cases Shifting to NHMHMC*	--	-87	-108	-130	-133	-133
Adjusted Outpatient Cases	11,417	11,638	11,934	12,237	12,568	12,911
Final Outpatient Case Time (1)	62.7	62.7	62.7	62.7	62.7	62.7
Total Surgical Hours (2)	**11,931**	**12,162**	**12,471**	**12,788**	**13,134**	**13,492**
Average Annual Operating Hours – Group 5 (3)	1,312.5	1,312.5	1,312.5	1,312.5	1,312.5	1,312.5
Number of ORs Needed	9.1	9.3	9.5	9.7	10.0	10.3
Surplus (-) / Deficit (based on 6 ORs)	**3.1**	**3.3**	**3.5**	**3.7**	**4.0**	**4.3**

(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.
*Table System.7, the source of this information, did not include the shift in outpatient cases to NHMHMC. The Project Analyst used the information for SPSC in Table NHMHMC.3, page 172.

NHMOS – The applicants project surgical cases at NHMOS through CY 2023 using the 2.7 percent annual growth rate, as shown in the table below.

NHMOS Projected OR Utilization						
	CY 2018	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**
Outpatient Cases	1,786	1,835	1,884	1,935	1,987	2,041
Final Outpatient Case Time (1)	78.1	78.1	78.1	78.1	78.1	78.1
Total Surgical Hours (2)	**2,325**	**2,389**	**2,452**	**2,519**	**2,586**	**2,657**
Average Annual Operating Hours – Group 6 (3)	1,312.5	1,312.5	1,312.5	1,312.5	1,312.5	1,312.5
Number of ORs Needed	1.8	1.8	1.9	1.9	2.0	2.0
Surplus (-) / Deficit (based on 2 ORs)	**-0.2**	**-0.2**	**-0.1**	**-0.1**	**0.0**	**0.0**

(1) The Final Case Time in minutes for the facility in the 2018 SMFP.
(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
(3) From Table 6B in the 2018 SMFP.
(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

NHHOS – The applicants project surgical cases at NHHOS through CY 2023 using the 2.7 percent annual growth rate, as shown in the table below.

NHHOS Projected OR Utilization						
	CY 2018	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**
Outpatient Cases	3,029	3,111	3,195	3,281	3,370	3,461
Final Outpatient Case Time (1)	64.1	64.1	64.1	64.1	64.1	64.1
Total Surgical Hours (2)	**3,236**	**3,324**	**3,413**	**3,505**	**3,600**	**3,698**
Average Annual Operating Hours – Group 6 (3)	1,312.5	1,312.5	1,312.5	1,312.5	1,312.5	1,312.5
Number of ORs Needed	2.5	2.5	2.6	2.7	2.7	2.8
Surplus (-) / Deficit (based on 2 ORs)	0.5	0.5	0.6	0.7	0.7	0.8

(1) The Final Case Time in minutes for the facility in the 2018 SMFP.

(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.

(3) From Table 6B in the 2018 SMFP.

(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

Novant Health System Combined - To meet the performance standard promulgated in 10A NCAC 14C .2103(b) in effect at the time of the submission of this application, an applicant proposing to add new ORs to a facility in its service area must demonstrate the need its entire health system has for all of the ORs proposed by the end of the third operating year. Altogether, the applicants propose to add one OR to the Novant Health system.

The following table illustrates the need for additional ORs for the entire health system.

Novant Health System OR Need			
	Deficits / Surpluses (-)		
	1st Full FY CY 2021	**2nd Full FY CY 2022**	**3rd Full FY CY 2023**
NHHMC	0.4	0.5	0.7
NHBMC	--	--	-0.9
NHMHMC	-1.5	-1.4	-1.3
NHPMC	-0.2	0.7	1.6
NHMMC	-0.6	-0.5	-0.3
SPSC	3.7	4.0	4.3
NHMOS	-0.1	0.0	0.0
NHHOS	0.7	0.7	0.8
Total Deficit/Surplus (-)	**2.4**	**4.0**	**4.9**

As shown in the table above, the Novant health system has a projected deficit of 4.9 ORs. NHHMC proposes to add one OR to its health system. The proposal meets the standard promulgated in 10A NCAC 14C .2103(b), requiring an applicant proposing to add new ORs to a service area to project sufficient surgical cases and hours to demonstrate the need for all of the existing, approved, and proposed ORs in Novant's health system in the third operating year of the project based on the Operating Room Need Methodology in the 2018 SMFP.

Projected utilization is reasonable and adequately supported for the following reasons:

- There is a need determination in the 2018 SMFP for 6 ORs in the Mecklenburg County OR planning area.
- The applicants rely on historical utilization in projecting future utilization:
  - The applicants project a growth rate that is less than its historical average.
  - The applicants use projections made previously as part of other approved projects when appropriate.
- The applicants reasonably project to meet the performance standards promulgated in 10A NCAC 14C .2103(a) and (b).

<u>Access</u> - In Section C, page 43, the applicants state *"Novant Health makes services accessible to indigent patients without regard to ability to pay. Novant Health Huntersville Medical Center provides services to all persons regardless of race, sex, age, religion, creed, disability, national origin or ability to pay."*

In Section L, page 89, the applicants project the following payor mix during the second full fiscal years of operation following completion of the project, as illustrated in the following table.

NHHMC Projected Payor Mix 3rd Full FY (CY 2022)				
Payor Source	**Total Facility**	**Acute Care**	**IP Surgery**	**OP Surgery**
Self-Pay	1.48%	1.24%	0.61%	0.55%
Charity Care	4.43%	3.72%	1.83%	1.66%
Medicare*	39.19%	41.03%	57.25%	28.12%
Medicaid*	7.70%	10.17%	2.91%	4.61%
Insurance*	43.93%	39.71%	34.92%	61.97%
Other	3.27%	4.13%	2.48%	3.09%
TOTAL	**100.00%**	**100.00%**	**100.00%**	**100.00%**

*Including any managed care plans

The projected payor mix is reasonable and adequately supported.

<u>Conclusion</u> - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants adequately identify the population to be served.

- The applicants adequately explain why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicants project the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately support their assumptions.

(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 – All Applications

None of the applications involve a proposal to reduce, eliminate, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to any of the applications in 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.

C – All Applications

F-11612-18/Metrolina Vascular Access Care/Develop one OR

The applicants propose to develop a new ASF with one OR and one PR dedicated to providing vascular access services for ESRD patients.

In Section E, pages 44-45, the applicants describe the alternatives they considered and explain why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintaining the Status Quo:* The applicants state that this proposal is not effective because the number of OR-appropriate procedures is growing at a higher rate than procedures which can be performed in an unlicensed facility. The applicants further state that the ESRD population itself is growing, and state that patients being forced into hospital settings is detrimental to patient outcomes. Therefore, maintaining the status quo is not an effective alternative.
- *Expanding the Vascular Access Center:* The applicants state that expanding the existing vascular access center does not address the need ESRD patients have for OR-appropriate procedures which cannot be performed in a vascular access center. Therefore, this is not an effective alternative.
- *Serving ESRD Patients' Vascular Access Needs in General ASFs:* The applicants state that existing ASFs which are not ESRD-focused are not designed for the care of emergent ESRD patients who are chronically ill and often require surgery immediately, which existing ASFs are not set up to accommodate. The applicants also state that existing ASFs do not have the physicians and clinicians available for the complex needs of ESRD patients

and that data shows that the most optimal outcomes for ESRD patients occur when the patients are seen in ESRD-focused ASFs. Therefore, this is not an effective alternative.

On pages 45-46, the applicants state that their proposal is the most effective alternative because it maximizes patient access, supports increasing demand for ESRD services, and will support coordination of care for ESRD patients. The applicants state that their proposal will provide ESRD patients with experienced physicians and support staff specializing in their unique needs, and will provide these resources to patients in a setting unavailable in any existing hospital or ASF.

The applicants adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicants provide credible information to explain why they believe the proposed project is the most effective alternative.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicants demonstrate that this proposal is their least costly or most effective alternative to meet the identified need for an ESRD-focused ASF with one OR and one PR in Mecklenburg County. Therefore, the application is conforming to this criterion.

F-11619-18/Carolina Center for Specialty Surgery/Develop one OR

The applicant proposes to develop an additional OR at its existing ASF for a total of three ORs upon project completion.

In Section E, pages 54-55, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintaining the Status Quo*: The applicant states this proposal is not effective because CCSS is already operating above its capacity and utilization is growing. Therefore, maintaining the status quo is not an effective alternative.
- *Develop More ORs*: The applicant states developing more ORs at CCSS would take away from proposing development of more ORs at CMC and AH Pineville, where ORs are also needed. The applicant also states that while adding one OR can be done in existing space with minimal costs, adding more than one OR would require more extensive construction and higher costs. Therefore, this is not an effective alternative.

- *Develop the ORs in a Different Facility*: The applicant states it considered proposing the OR in a different location, but it believes the OR is needed at CCSS, and has proposed developing other ORs in other facilities in Mecklenburg County. Therefore, this is not an effective alternative.

On page 55, the applicant states *"Compared to these alternatives, CCSS believes that the proposed project to add one operating room at its facility is the least costly and most effective alternative to meet a portion of the need for additional operating rooms in Mecklenburg County."*

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

<u>Conclusion</u> - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant demonstrates that this proposal is their least costly or most effective alternative to meet the identified need for one additional OR at CCSS. Therefore, the application is conforming to this criterion.

F-11620-18/Carolinas Medical Center/Develop four ORs

The applicant proposes to develop four additional ORs at its existing hospital for a total of 64 ORs upon completion of this project and Project I.D. #F-11106-15 (relocate two ORs as part of developing Randolph Surgery Center).

In Section E, pages 58-59, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintaining the Status Quo*: The applicant states this proposal is not effective because there is already a tremendous need at CMC which will only be partially met even with the proposed project. Therefore, maintaining the status quo is not an effective alternative.
- *Develop a Different Number of ORs*: The applicant states it considered developing fewer ORs, but believes that doing so would not meet the need CMC has for ORs. The applicant states it also considered developing more ORs at CMC, but concluded that the most cost effective way to develop the proposed project was to develop it in existing space, which is limited as to how many new ORs can be accommodated. Therefore, this is not an effective alternative.

- *Develop the ORs in a Different Facility*: The applicant states it considered developing the ORs in a different facility, but states that there is a need for additional surgical capacity at CMC, and has also proposed developing other ORs in other facilities in Mecklenburg County. Therefore, this is not an effective alternative.

On page 59, the applicant states *"Compared to these alternatives, CMC believes that the proposed project to add four operating rooms at CMC is the least costly and most effective alternative to meet a portion of the need for additional operating rooms in Mecklenburg County."*

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

<u>Conclusion</u> - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant demonstrates that this proposal is their least costly or most effective alternative to meet the identified need for four additional ORs at CMC. Therefore, the application is conforming to this criterion.

F-11621-18/Atrium Health Pineville (AH Pineville)/Develop one OR

The applicants propose to develop one additional OR at the existing hospital for a total of 11 ORs upon project completion.

In Section E, pages 58-59, the applicants describe the alternatives considered and explain why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintaining the Status Quo*: The applicants state this proposal is not effective because AH Pineville is already operating at full capacity and utilization is expected to continue to increase. Therefore, maintaining the status quo is not an effective alternative.
- *Develop More ORs*: The applicants state developing more ORs at AH Pineville would take away from proposing development of more ORs at CMC and CCSS, where ORs are also needed. The applicants also state that while adding one OR can be done in existing space with minimal costs, adding more than one OR would require more extensive construction and higher costs. Therefore, this is not an effective alternative.
- *Develop the ORs in a Different Facility*: The applicants state they considered proposing the OR in a different location, but it believes the OR is needed at AH Pineville, and has

proposed developing other ORs in other facilities in Mecklenburg County. Therefore, this is not an effective alternative.

On page 59, the applicants state *"Compared to these alternatives,* [AH] *Pineville believes that the proposed project to add one operating room at its facility is the least costly and most effective alternative to meet a portion of the need for additional operating rooms in Mecklenburg County."*

The applicants adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicants provide credible information to explain why it believes the proposed project is the most effective alternative.

<u>*Conclusion*</u> - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant demonstrates that this proposal is their least costly or most effective alternative to meet the identified need for an additional OR at AH Pineville. Therefore, the application is conforming to this criterion.

F-11622-18/Atrium Health Pineville/Develop 50 acute care beds

The applicants propose to develop 50 additional acute care beds at the existing hospital for a total of 271 acute care beds upon project completion.

In Section E, pages 69-70, the applicants describe the alternatives they considered and explain why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintaining the Status Quo*: The applicants state this alternative is not effective because it would result in continued inefficiencies, long wait times for patients in the emergency department before being admitted, and needing to transfer patients to other facilities due to a lack of beds. Therefore, maintaining the status quo is not an effective alternative.
- *Develop the Acute Care Beds in a Different Facility*: The applicants state they considered developing the acute care beds in a different facility. The applicants state that the CMC-Mercy campus of CMC and AH University City have recently grown their number of beds due to completion of older approved projects, and have sufficient capacity. The applicants state CMC needs additional capacity, but is limited by space, and cannot add beds to the facility until planning can be undertaken to develop more space on the CMC main campus. Therefore, this is not an effective alternative.

The applicants adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicants provide credible information to explain why they believe the proposed project is the most effective alternative.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes the applicants demonstrate that this proposal is the least costly or most effective alternative to meet the identified need for 50 additional acute care beds at AH Pineville. Therefore, the application is conforming to this criterion.

F-11624-18/Novant Health Huntersville Medical Center/Develop 12 acute care beds and 1 OR

The applicants propose to add 12 acute care beds and one OR to NHHMC, which is currently licensed for 91 acute care beds and five ORs. At the completion of this project and Project I.D. #F-11110-15 (add 48 acute care beds and one OR), NHHMC will be licensed for 151 acute care beds and seven ORs.

In Section E, pages 57-58, the applicants describe the alternatives they considered and explain why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Extend Staffed Hours for Existing ORs at NHHMC or NHHOS:* The applicants state this proposal is not effective because it would be less desirable for physicians and patients, who do not typically want to schedule surgeries late at night or on weekends, and it would not reduce staffing costs. Therefore, extending staffed hours for existing ORs is not an effective alternative.
- *Add an Additional OR at NHHOS:* The applicants state adding an OR to NHHOS would cost more as new space would have to be constructed and would provide less flexibility to accommodate all patients – emergency, inpatient and outpatient. Therefore, this is not an effective alternative.
- *Construct Additional Postpartum Acute Care Beds on a Different Floor:* The applicants state developing additional postpartum beds on a different floor would cost more, result in disruption to services, and not expand capacity quickly enough to meet the need. Therefore, this is not an effective alternative.
- *Designate Some of the 48 Beds Under Development as Postpartum Beds:* As part of Project I.D. #F-11110-15, the applicants are developing 48 additional acute care beds. The applicants state designating some of those beds as postpartum beds would take away from

the areas those beds are planned to be utilized – medical/surgical patients, NICU patients, and ICU patients. Therefore, this is not an effective alternative.

On page 57, the applicants state the need for both the acute care beds and the OR was discussed elsewhere in the application. The Project Analyst notes in Section C, pages 31-38, the applicants discuss the need for the specific services to be developed in the manner they propose.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicants demonstrate that this proposal is their least costly or most effective alternative to meet the identified need for 12 additional acute care beds and one additional OR at NHHMC. Therefore, the application is conforming to this criterion.

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C – All Applications

F-11612-18/Metrolina Vascular Access Care/Develop one OR

The applicants propose to develop a new ASF with one OR and one PR dedicated to providing vascular access services for ESRD patients.

Capital and Working Capital Costs - In Section Q, on Form F.1a, the applicants project the total capital cost of the project as shown in the table below.

Construction/Site Costs	$1,925,000
Contingency/Fees	$495,000
Medical Equipment	$74,000
Non-Medical Equipment/Furniture	$126,000
Interest During Construction	$42,677
Miscellaneous Costs	$237,323
Total	**$2,900,000**

In Form F.1a, the applicants state that FVCC will incur all capital costs. Form F.1a also contains a statement saying that the contingency costs include the working capital costs.

In Section Q, the applicants provide the assumptions used to project the capital cost.

In Section F, page 49, the applicants project that start-up costs will be $56,094 and initial operating expenses will be $223,906 for a total working capital of $280,000. On page 50, the applicants provide the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds - In Section F, page 48, the applicants state that the entire capital cost of the proposed project will be funded through loans to FVCC. In Section F, page 50, the applicants state that their working capital expenses will also be funded entirely through loans to FVCC. On page 50, the applicants state that the working capital costs have been included in the total capital costs on Form F.1a.

Exhibit F-2.1 contains a letter dated October 3, 2018 from the Senior Vice President and Treasurer of National Medical Care, Inc., offering to provide a loan of $2,900,000 to FVCC. The letter also states that National Medical Care, Inc. is a wholly-owned affiliate of Fresenius Medical Care AG & Co. KGaA (FMC), which the letter states is a publicly traded organization listed on the Frankfurt stock exchange. The letter in Exhibit F-2.1 states:

> *"Fresenius Vascular Care Charlotte MSO, LLC, the co-applicant for the proposed project, will incur the capital cost for the new ASC. The total capital cost of the project is estimated at approximately $2,900,000. The Applicant will fund the capital cost of the project through a loan from National Medical Care, Inc., which is a wholly-owned affiliate of Fresenius Medical Care AG & Co. KGaA ("Fresenius"), a publicly traded corporation listed on the Frankfurt stock exchange. As demonstrated in its public filings* [included in Exhibit F-2.3]*, Fresenius has sufficient financial reserves to fund the project capital costs associated with the North Carolina certificate of need application to develop a new ASC in Mecklenburg County.*
>
> *As Senior Vice President and Treasurer of National Medical Care, Inc., I confirm that I am authorized to commit to enter into a loan agreement to provide funds necessary for the capital cost of this CON project, based on the proposed terms shown in the enclosed term sheet* [found in Exhibit F-2.2] *as well as other commercially reasonable terms to be negotiated and approved between lender and borrower…"*

Exhibit F-2.2 contains a list of terms for the proposed loan to FVCC, including the statement that the loan will be in the form of a revolving line of credit.

Exhibit F-2.3 contains the 2017 Annual Report for FMC, the parent company of both FVCC and National Medical Care, Inc., which includes its Consolidated Financial Statements for 2015-2017. The Consolidated Financial Statements indicate that as of December 31, 2017, FMC had adequate cash and assets to fund the capital and working capital costs of the proposed project.

Financial Feasibility - The applicants provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.3, the applicants project that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

Metrolina VAC Revenues and Operating Expenses			
	1st Full FY 5/20-4/21	2nd Full FY 5/21-4/22	3rd Full FY 5/22-4/23
Total # of Cases (ORs and PRs)	2,180	2,287	2,430
Total Gross Revenues (Charges)	$9,402,681	$10,025,727	$10,646,164
Total Net Revenue	$3,571,397	$3,808,047	$4,043,706
Average Net Revenue per Case	$1,638	$1,665	$1,664
Total Operating Expenses (Costs)	$3,267,819	$3,378,478	$3,445,152
Average Operating Expense per Case	$1,499	$1,477	$1,418
Net Income	$303,578	$429,569	$598,554

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

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants adequately demonstrate that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicants adequately demonstrate availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicants adequately demonstrate 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.

F-11619-18/Carolina Center for Specialty Surgery/Develop one OR

The applicant proposes to develop an additional OR at its existing ASF for a total of three ORs upon project completion.

Capital and Working Capital Costs - In Section Q, on Form F.1a, the applicant projects the total capital cost of the project, as shown in the table below.

Construction	$536,778
Contingency/Fees/Miscellaneous	$542,144
Medical Equipment	$711,790
Non-Medical Equipment/Furniture	$121,800
Total	**$1,912,512**

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 58-59, the applicant states there are no projected working capital costs because the facility is already operational.

Availability of Funds - In Section F, page 57, the applicant states the capital cost of the proposed project will be equally funded by NeuroSpine, LLC and Atrium Health, the parent companies of the applicant. The applicant states Atrium Health will provide half of the projected capital cost - $956,256 – through accumulated reserves, and states that NeuroSpine, LLC will fund the remaining $956,256 through a loan.

Exhibit F-2.1 contains a letter dated October 15, 2018 from the Executive Vice President and Chief Financial Officer of Atrium Health, agreeing to commit $956,256 in accumulated reserves to fund the proposed project. Exhibit F-2.1 also contains a letter dated October 15, 2018 from a member of NeuroSpine, LLC, stating that NeuroSpine, LLC will take out a loan to cover the remaining $956,256 of the capital cost, and states that an included bank letter verifies the availability of funding.

Exhibit F-2.1 further contains a letter dated September 19, 2018 from a Senior Vice President of SunTrust Bank, offering to provide a loan to NeuroSpine, LLC for its portion of the capital expenditure, and containing potential loan terms.

Exhibit F-2.2 contains the Basic Financial Statements of Atrium Health for the years ending December 31, 2017 and 2016. The Basic Financial Statements indicate that as of December 31, 2017, Atrium Health had adequate cash and assets to fund its portion of the capital cost of the proposed project.

Financial Feasibility - The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.3, the applicant projects revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

CCSS Revenues and Operating Expenses			
	1st Full FY CY 2020	**2nd Full FY CY 2021**	**3rd Full FY CY 2022**
Total # of Cases (ORs and PRs)	2,715	2,808	2,901
Total Gross Revenues (Charges)	$26,036,786	$27,815,029	$29,684,364
Total Net Revenue	$16,434,504	$17,428,268	$18,468,255
Average Net Revenue per Case	$6,053	$6,207	$6,366
Total Operating Expenses (Costs)	$6,180,138	$6,509,040	$6,853,143
Average Operating Expense per Case	$2,276	$2,318	$2,362
Net Income	$8,825,902	$9,456,774	$10,117,753

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

for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- 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.

F-11620-18/Carolinas Medical Center/Develop four ORs

The applicant proposes to develop four additional ORs at its existing hospital for a total of 62 ORs upon completion of this project and Project I.D. #F-11106-15 (relocate two ORs as part of developing Randolph Surgery Center).

Capital and Working Capital Costs - In Section Q, on Form F.1a, the applicant projects the total capital cost of the project, as shown in the table below.

Construction	$6,500,000
Medical Equipment	$3,100,000
Non-Medical Equipment/Furniture	$260,000
Fees	$1,100,000
Financing Costs/Interest	$600,099
Other (including Contingency)	$3,470,000
Total	**$15,030,099**

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 62-63, the applicant states there are no projected working capital costs because the facility is already operational.

Availability of Funds - In Section F, page 61, the applicant states the capital cost of the proposed project will be funded via accumulated reserves of Atrium Health. Exhibit F-2.1 contains a letter dated October 15, 2018 from the Executive Vice President and Chief Financial Officer of Atrium Health, agreeing to commit $15,030,099 in accumulated reserves to fund the proposed project.

Exhibit F-2.2 contains the Basic Financial Statements of Atrium Health for the years ending December 31, 2017 and 2016. The Basic Financial Statements indicate that as of December 31, 2017, Atrium Health had adequate cash and assets to fund its portion of the capital cost of the proposed project.

Financial Feasibility - The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.3, the applicant projects revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

CMC Revenues and Operating Expenses			
	1st Full FY CY 2021	**2nd Full FY CY 2022**	**3rd Full FY CY 2023**
Total # of Cases	29,580	29,469	29,503
Total Gross Revenues (Charges)	$1,325,031,972	$1,359,679,185	$1,402,070,910
Total Net Revenue	$417,061,017	$423,001,110	$431,030,094
Average Net Revenue per Case	$14,099	$14,354	$14,610
Total Operating Expenses (Costs)	$202,186,810	$207,424,275	$213,508,006
Average Operating Expense per Case	$6,835	$7,039	$7,237
Net Income	$214,874,207	$215,576,835	$217,522,088

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

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- 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.

F-11621-18/Atrium Health Pineville (AH Pineville)/Develop one OR

The applicants propose to develop an additional OR at its existing hospital for a total of three 11 upon project completion.

Capital and Working Capital Costs - In Section Q, on Form F.1a, the applicants project the total capital cost of the project, as shown in the table below.

Construction/Renovation	$1,240,000
Architect/Engineering Fees	$150,000
Medical Equipment	$1,000,000
Non-Medical Equipment	$15,000
Furniture	$15,000
Consultant Fees (Permits and Inspection)	$150,000
Other	$230,000
Total	**$2,800,000**

*Other includes (IS, Security, Internal Allocation, Contingency)

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 62-63, the applicants state there are no projected working capital costs because the proposed project does not involve a new service.

Availability of Funds - In Section F, page 61, the applicants state the capital cost of the proposed project will be funded by accumulated reserves of Atrium Health.
Exhibit F-2.1 contains a letter dated October 15, 2018 from the Executive Vice President and Chief Financial Officer of Atrium Health, agreeing to commit $2,800,000 in accumulated reserves to fund the proposed project.

Exhibit F-2.2 contains the Basic Financial Statements of Atrium Health for the years ending December 31, 2017 and 2016. The Basic Financial Statements indicate that as of December 31, 2017, Atrium Health had adequate cash and assets to fund the capital cost of the proposed project.

Financial Feasibility - The applicants provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.3, the applicants project revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

AH Pineville Revenues and Operating Expenses – Surgical Services			
	1st Full FY CY 2021	2nd Full FY CY 2022	3rd Full FY CY 2023
Total # of Cases (ORs)	8,828	9,191	9,612
Total Gross Revenues (Charges)	$384,289,179	$412,072,517	$443,861,857
Total Net Revenue	$65,993,857	$70,342,968	$75,361,862
Average Net Revenue per Case	$7,475	$7,653	$7,840
Total Operating Expenses (Costs)	$47,035,544	$49,591,736	$52,453,431
Average Operating Expense per Case	$5,327	$5,395	$5,457
Net Income	$65,993,857	$70,342,968	$75,361,862

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

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants adequately demonstrate the capital costs are based on reasonable and adequately supported assumptions.
- The applicants adequately demonstrate availability of sufficient funds for the capital needs of the proposal.
- The applicants adequately demonstrate 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.

F-11622-18/Atrium Health Pineville/Develop 50 acute care beds

The applicants propose to develop 50 additional acute care beds at the existing hospital for a total of 271 acute care beds upon project completion.

Capital and Working Capital Costs - In Section Q, on Form F.1a, the applicants project the total capital cost of the project, as shown in the table below.

Site Costs/Construction	$23,308,330
Medical Equipment	$2,894,245
Furniture	$127,680
Fees	$2,181,208
Financing Costs/Interest	$1,909,207
Other (including Contingency)	$1,461,395
Total	**$31,882,065**

In Section Q, the applicants provide the assumptions used to project the capital cost.

In Section F, pages 73-74, the applicants state there are no projected working capital costs because the facility is already operational.

Availability of Funds - In Section F, page 72, the applicants state the capital cost of the proposed project will be funded via accumulated reserves of Atrium Health. Exhibit F-2.1 contains a letter dated October 15, 2018 from the Executive Vice President and Chief Financial Officer of Atrium Health, agreeing to commit $31,882,065 in accumulated reserves to fund the proposed project.

Exhibit F-2.2 contains the Basic Financial Statements of Atrium Health for the years ending December 31, 2017 and 2016. The Basic Financial Statements indicate that as of December 31, 2017, Atrium Health had adequate cash and assets to fund the capital cost of the proposed project.

Financial Feasibility - The applicants provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.4, the applicants project revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

AH Pineville Revenues and Operating Expenses – M/S Beds			
	1st Full FY CY 2022	**2nd Full FY CY 2023**	**3rd Full FY CY 2024**
Total # of Discharges	14,750	15,369	16,021
Total Gross Revenues (Charges)	$183,968,960	$197,445,723	$211,986,287
Total Net Revenue	$46,941,277	$49,837,333	$52,921,876
Average Net Revenue per Discharge	$3,182	$3,243	$3,303
Total Operating Expenses (Costs)	$39,143,892	$41,731,457	$44,519,957
Average Operating Expense per Discharge	$2,654	$2,715	$2,779
Net Income	$7,797,385	$8,105,877	$8,401,919

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

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants adequately demonstrate the capital costs are based on reasonable and adequately supported assumptions.
- The applicants adequately demonstrate availability of sufficient funds for the capital needs of the proposal.
- The applicants adequately demonstrate 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.

F-11624-18/Novant Health Huntersville Medical Center/Develop 12 acute care beds and 1 OR

The applicants propose to add 12 acute care beds and one OR to NHHMC, which currently has 91 licensed acute care beds and five licensed ORs. At the completion of this project and Project I.D. #F-11110-15 (add 48 acute care beds and one OR), NHHMC will have 151 licensed acute care beds and seven ORs.

Capital and Working Capital Costs - In Section Q, on Form F.1a, the applicants project the total capital cost of the project as shown in the table below.

Construction Costs	$3,995,563
Fees	$377,000
Medical Equipment	$1,402,010
Furniture	$1,600
Interest During Construction	$433,228
Miscellaneous Costs	$901,414
Total	**$7,110,815**

In Section Q, the applicants provide the assumptions used to project the capital cost.

In Section F, page 61, the applicants project that there will be start-up costs of $625,000, but no initial operating expenses, since the services are an expansion of existing services.

Availability of Funds - In Section F, pages 59 and 61, the applicants state that the entire capital and working capital costs of the proposed project will be funded through accumulated reserves or owner's equity.

Exhibit F-2.1 contains a letter dated October 15, 2018 from the Senior Vice President of Operational Finance for Novant Health, Inc., the parent entity of Novant Health Huntersville Medical Center, committing sufficient accumulated reserves to cover the capital and working capital costs of the this project. Exhibit F.2-2 contains the Audited Financial Statements for

Novant Health, Inc., for the fiscal years ending December 31, 2017 and 2016. The statements show that as of December 31, 2017, Novant Health, Inc. had adequate cash and assets to fund the capital and working capital costs of the proposed project.

Financial Feasibility - The applicants provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.4, the applicants project that revenues will exceed operating expenses in the first three operating years of the project, for both acute care beds and ORs, as shown in the tables below.

NHHMC Revenues and Operating Expenses – Acute Care Beds			
	1st Full FY CY 2021	2nd Full FY CY 2022	3rd Full FY CY 2023
Total # of Admissions	9,435	10,190	11,005
Total Gross Revenues (Charges)	$168,842,000	$188,101,000	$206,959,000
Total Net Revenue	$69,342,000	$78,310,000	$87,344,000
Average Net Revenue per Admission	$7,349	$7,685	$7,937
Total Operating Expenses (Costs)	$46,300,000	$51,266,000	$56,079,000
Average Operating Expense per Admission	$4,907	$5,031	$5,096
Net Income	$23,042,000	$27,044,000	$31,265,000

NHHMC Revenues and Operating Expenses – ORs			
	1st Full FY CY 2021	2nd Full FY CY 2022	3rd Full FY CY 2023
Total # of Surgical Cases	5,537	5,687	5,840
Total Gross Revenues (Charges)	$206,490,000	$216,297,000	$232,693,000
Total Net Revenue	$78,405,000	$82,129,000	$87,967,000
Average Net Revenue per Case	$14,160	$14,442	$15,063
Total Operating Expenses (Costs)	$45,921,000	$47,860,000	$51,331,000
Average Operating Expense per Case	$8,293	$8,416	$8,790
Net Income	$32,484,000	$34,269,000	$36,636,000

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

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants adequately demonstrate that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicants adequately demonstrate availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicants adequately demonstrate 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.

(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 – All Applications

The 2018 SMFP includes need determinations for 50 acute care beds and six ORs in the Mecklenburg County service area.

Acute Care Beds. On page 38, the 2018 SMFP defines the service area for acute care beds as *"the acute care bed planning area in which the bed is located. The acute care bed planning areas are the single and multicounty groupings shown in Figure 5.1."* Figure 5.1, on page 42, shows Mecklenburg County as its own acute care bed planning area. Thus, the service area for this facility is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

As of the date of this decision, there are nine existing and approved acute care hospitals owned by two providers (Atrium and Novant) in the Mecklenburg County Service Area, as illustrated in the following table.

Mecklenburg County Acute Care Hospitals	
Facility	**Existing/Approved Beds**
AH Pineville	221
AH University City	100
CMC-Main	859
CMC-Mercy *	196
Atrium Total	**1,376**
NH Huntersville Medical Center	91 (+48)
NH Health Matthews Medical Center	154
NH Health Presbyterian Medical Center	503 (-16)
NH Charlotte Orthopedic Hospital **	28 (+4)
NH Mint Hill Medical Center	36 (+14)
Novant Total	**862**
Mecklenburg County Total	**2,238**

Source: Table 5A, 2018 SMFP; applications under review; 2019 LRAs; Agency records.
Note: Numbers in parentheses reflect approved changes in bed inventory.
* CMC-Mercy, while a separate location, is licensed as part of CMC.
** NHCOH, while a separate location, is licensed as part of NHPMC.

Operating Rooms. On page 57, the 2018 SMFP defines the service area for ORs as *"…the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* Figure 6.1, on page 62, shows Mecklenburg County as its own OR planning area. Thus, the service area for this facility is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

Not including dedicated C-Section ORs and trauma ORs, there are 155 existing ORs in Mecklenburg County, allocated between 17 facilities, as shown in the table below.

Mecklenburg County OR Inventory						
Facility	**IP ORs**	**OP ORs**	**Shared ORs**	**Excluded C-Section, and Trauma ORs**	**CON Adjustments**	**Total ORs**
AH Huntersville Surgery Center	0	0	0	0	1	1
AH Pineville	3	0	9	-2	0	10
AH University City	1	2	9	-1	-4	7
CCSS	0	2	0	0	0	2
CMC	10	11	41	-5	-2	55
Atrium Health System Total	**14**	**15**	**59**	**-8**	**-5**	**75**
Charlotte Surgery Center	0	7	0	0	-1	6
Randolph Surgery Center	0	0	0	0	6	6
Charlotte Surgery Center System Total	**0**	**7**	**0**	**0**	**5**	**12**
Matthews Surgery Center	0	2	0	0	0	2
NHBOS*	0	2	0	0	0	2
NHHMC	1	0	6	-2	1	6
NHHOS	0	2	0	0	0	2
NHMHMC	1	0	3	-1	1	4
NHMMC	2	0	6	-2	0	6
NHPMC	5	6	29	-2	-2	38
SouthPark Surgery Center	0	6	0	0	0	6
Novant Health System Total	**9**	**18**	**103**	**-7**	**0**	**65**
Carolinas Ctr for Ambulatory Dentistry**	0	0	0	0	2	2
Mallard Creek Surgery Center**	0	2	0	0	0	2
Total	**23**	**42**	**105**	**-15**	**0**	

Sources: Table 6A, 2018 SMFP; 2019 LRAs; Agency records

* Project I.D. #F-11625-18 was submitted in the same review cycle as these applications. Novant proposes to develop NHBMC, a new hospital by relocating existing beds and ORs. The ORs will be relocated from NHBOS, which close once the ORs are relocated to NHBMC.

** These facilities are part of demonstration projects and the ORs are not included in the SMFP need determination calculations.

F-11612-18/Metrolina Vascular Access Care/Develop one OR

The applicants propose to develop a new ASF with one OR and one PR dedicated to providing vascular access services for ESRD patients.

The applicants adequately demonstrate the need to develop the new ASF with one OR and one PR, dedicated to performing vascular access services for ESRD patients, based on the number of projected patients they propose to serve.

In Section G, pages 55-56, the applicants state that the proposed project will not result in unnecessary duplication of existing or approved services or facilities because their proposal fills an unmet need. On page 55, the applicants state:

> *"The proposed project will not result in unnecessary duplication because there are currently no ESRD-focused or vascular ASCs in North Carolina. Instead, existing vascular access centers are unlicensed physician office settings that are currently providing care to ESRD patients but whose ability to offer a full range of vascular access services is restricted. With the trend towards more complex cases, providing a full range of services to ESRD patients is currently limited in the office setting."*

The applicants adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2018 SMFP for six ORs in the Mecklenburg County service area and the applicants propose to develop one OR.
- The applicants adequately demonstrate that the proposed OR is needed in addition to the existing or approved ORs in Mecklenburg County.

<u>Conclusion</u> - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

F-11619-18/Carolina Center for Specialty Surgery/Develop one OR

The applicant proposes to develop an additional OR at its existing ASF for a total of three ORs upon project completion.

The applicant adequately demonstrates the need to develop an additional OR at its existing facility based on the number of projected patients it proposes to serve.

In Section G, page 64, the applicant states the proposed project will not result in unnecessary duplication of existing or approved services or facilities because its proposal fills an unmet need. On page 64, the applicant states:

> *"The 2018 SMFP includes a need determination for six additional operating rooms in Mecklenburg County. ... To meet a portion of the identified need, Atrium Health and its partners are submitting three concurrent and complementary applications, including the one proposed operating room CCSS* [sic]. *As described in Section C.4, CCSS's surgical utilization is projected to continue increasing and will necessitate the proposed additional operating room to meet the needs of its patients. As the only freestanding ASC focused on minimally-invasive neurosurgery and other specialty surgical care, no other provider can meet the needs of CCSS's patients."*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2018 SMFP for six ORs in the Mecklenburg County service area and the applicant proposes to develop one OR.
- The applicant adequately demonstrates that the proposed OR is needed in addition to the existing or approved ORs in Mecklenburg County.

<u>*Conclusion*</u> - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

F-11620-18/Carolinas Medical Center/Develop four ORs

The applicant proposes to develop four additional ORs at its existing hospital for a total of 64 ORs upon completion of this project and Project I.D. #F-11106-15 (relocate two ORs as part of developing Randolph Surgery Center).

The applicant adequately demonstrates the need to develop four additional ORs at its existing facility based on the number of projected patients it proposes to serve.

In Section G, page 68, the applicant states the proposed project will not result in unnecessary duplication of existing or approved services or facilities because its proposal fills an unmet need. On page 68, the applicant states:

> *"The 2018 SMFP includes a need determination for six additional operating rooms in Mecklenburg County. ... To meet a portion of the identified need, Atrium Health is submitting three concurrent and complementary applications, including the four*

> *proposed operating rooms at CMC. As described in Section C.4, CMC performs more surgical cases than any other facility in Mecklenburg County and has a need for additional operating room capacity to meet the need of its patient population. As the only Level I trauma center and quaternary academic medical center in the region, no other provider can meet the unique needs of CMC's patients."*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2018 SMFP for six ORs in the Mecklenburg County service area and the applicant proposes to develop four ORs.
- The applicant adequately demonstrates that the proposed four ORs are needed in addition to the existing or approved ORs in Mecklenburg County.

<u>Conclusion</u> - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

F-11621-18/Atrium Health Pineville (AH Pineville)/Develop one OR

The applicants proposes to develop an additional OR at its existing facility for a total of 11 ORs upon project completion.

The applicants adequately demonstrate the need to develop an additional OR at its existing facility based on the number of projected patients it proposes to serve.

In Section G, page 67, the applicants state the proposed project will not result in unnecessary duplication of existing or approved services or facilities because its proposal fills an unmet need. On page 64, the applicants state:

> *"The 2018 SMFP includes a need determination for six additional operating rooms in Mecklenburg County. ... To meet a portion of the identified need, Atrium Health is submitting three concurrent and complementary applications, including the one proposed operating room at CHS Pineville. As described in Section C.4, CHS Pineville's surgical utilization is projected to continue increasing and will necessitate the proposed additional operating room to meet the needs of its patients. As the only tertiary hospital in Mecklenburg County locate outside of the center city area, no other provider can meet the needs of CHS Pineville's patients."*

The applicants adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2018 SMFP for six ORs in the Mecklenburg County service area and the applicants propose to develop one OR.
- The applicants adequately demonstrate that the proposed OR is needed in addition to the existing or approved ORs in Mecklenburg County.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

F-11622-18/Atrium Health Pineville/Develop 50 acute care beds

The applicants propose to develop 50 additional acute care beds at the existing hospital for a total of 271 acute care beds upon project completion.

The applicants adequately demonstrate the need to develop 50 additional acute care beds at the existing facility based on the number of projected patients it proposes to serve.

In Section G, page 79, the applicants state the proposed project will not result in unnecessary duplication of existing or approved services or facilities because its proposal will solve the problem of extremely high utilization. On page 79, the applicants state:

> *"The 2018 SMFP includes a need determination for 50 additional acute care beds in Mecklenburg County. ...,* [AH Pineville] *regularly experiences extremely high utilization when it is difficult to accommodate any additional patients. Further,* [AH Pineville] *expects its utilization to grow in the future due to many of the same factors that contributed to its past growth."*

The applicants adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2018 SMFP for 50 acute care beds in the Mecklenburg County service area and the applicants propose to develop 50 acute care beds.
- The applicants adequately demonstrate that the proposed 50 acute care beds are needed in addition to the existing or approved acute care beds in Mecklenburg County.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

F-11624-18/Novant Health Huntersville Medical Center/Develop 12 acute care beds and 1 OR

The applicants propose to add 12 acute care beds and one OR to NHHMC, which currently has 91 licensed acute care beds and five licensed ORs. At the completion of this project and Project I.D. #F-11110-15 (add 48 acute care beds and one OR), NHHMC will have 151 licensed acute care beds and seven ORs.

The applicants adequately demonstrate the need to develop the 12 additional acute care beds and one additional OR at NHHMC based on the number of projected patients they propose to serve.

In Section G, pages 68-69, the applicants state that the proposed project will not result in unnecessary duplication of existing or approved services or facilities because the applicants are asking for less than the full need determination for both acute care beds and ORs. On page 68, the applicants state:

> *"For the service area, the 2018 SMFP shows a need for 50 more acute care beds in Mecklenburg County. As the proposed project requests fewer acute care beds than the 2018 SMFP show are needed there is no unnecessary duplication in the service area.*
>
> *…*
>
> *For the service area, the 2018 SMFP shows a need for six operating rooms in Mecklenburg County. As the proposed project requests fewer operating rooms than the 2018 SMFP shows are needed there is no unnecessary duplication in the service area."*

The applicants adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2018 SMFP for the proposed acute care beds and the proposed OR.
- The applicants adequately demonstrate the need the population proposed to be served has for the existing and approved acute care beds and existing and approved ORs.

<u>*Conclusion*</u> - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(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 – All Applications

F-11612-18/Metrolina Vascular Access Care/Develop one OR

In Section Q, Form H, the applicants provide projected staffing for the proposed services as illustrated in the following table.

Metrolina VAC Projected Staffing	
Position	**First 3 Full FYs**
Registered Nurses	4.8
Case Manager	0.6
Central Sterile Supply Techs	0.4
Administrator	1.5
Marketing	0.8
Radiology Tech	2.0
TOTAL	**10.1**

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicants are budgeted in Form F.3, which is found in Section Q. In Section H, pages 57-58, the applicants describe the methods used to recruit or fill new positions and their existing training and continuing education programs. In Exhibits H-3 and H-4.2, the applicants provide supporting documentation. In Section H, page 58, the applicants identify the proposed medical director. In Exhibit H-4.1, the applicants provide a letter from the proposed medical director, expressing his support for the proposed project and indicating an interest in serving as medical director for the proposed services.

The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

F-11619-18/Carolina Center for Specialty Surgery/Develop one OR

In Section Q, Form H, the applicant provides historical and projected staffing for the existing and proposed services, as illustrated in the following table.

CCSS Historical and Projected Staffing		
Position	**Last Full FY (CY 2017)**	**First 3 Full FYs (CYs 2020-2022)**
Director	1.00	1.00
Certified Nurse Aide	1.00	1.00
Imaging Technician I	1.43	2.43
Instrument Technician	3.00	3.00
Manager – Pre/Post Nursing	1.00	1.00
OR Assistant	1.00	1.00
OR Registered Nurse	3.00	4.00
PACU Registered Nurse	5.92	6.92
Patient Representative	1.65	1.65
Surgical Technician	3.00	4.00
TOTAL	**22.00**	**26.00**

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 66-67, the applicant describes the methods used to recruit or fill vacant or new positions and its existing training and continuing education programs, and provides supporting documentation in Exhibit H-3. In Section H, page 67, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the current medical director, which expresses his support for the proposed project and indicates an interest in continuing to serve as medical director for the existing and proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

F-11620-18/Carolinas Medical Center/Develop four ORs

In Section Q, Form H, the applicant provides historical and projected staffing for the existing and proposed services, as illustrated in the following table.

CMC Surgical Services Historical and Projected Staffing		
Position	**Last Full FY (CY 2017)**	**First 3 Full FYs (CYs 2021-2023)**
Registered Nurses	226.17	232.17
Licensed Practical Nurses	1.02	1.02
Aides & Attendants	72.32	72.32
Admin/Management	6.46	6.46
Supervisory	17.63	17.63
Professional	11.04	11.04
Registered Technologists	3.57	3.57
Technicians	174.67	177.17
Plant/Food Service	4.26	4.26
Temp Help	8.52	8.52
Clerical/Secretarial	31.48	31.48
TOTAL	**557.14**	**565.64**

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 70-71, the applicant describes the methods used to recruit or fill vacant or new positions and its existing training and continuing education programs. In Section H, page 71, the applicant identifies the current chief surgical officer. In Exhibit H-4, the applicant provides a letter from the chief surgical officer, which expresses his support for the proposed project and indicates an interest in continuing to serve as chief surgical officer for the existing and proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

F-11621-18/Atrium Health Pineville (AH Pineville)/Develop one OR

In Section Q, Form H, the applicants provide historical and projected staffing for the existing and proposed services, as illustrated in the following table.

AH Pineville Historical and Projected Staffing		
Position	**Last Full FY (CY 2017)**	**First 3 Full FYs (CYs 2021-2023)**
RNs	64.39	66.79
Aides & Attendants	11.04	11.64
Admin/management	2.52	2.52
Supervisory	1.85	1.85
Professional	2.68	2.68
Registered Tech	1.69	1.69
Technicians	42.79	44.39
Plant/Food Service	3.07	3.07
Temp Help	3.47	3.47
Unit Secretary	0.56	0.56
Clerical/Secretarial	7.31	7.31
TOTAL	**141.37**	**145.97**

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicants are budgeted in Form F.3, which is found in Section Q. In Section H, pages 69-70, the applicants describe the methods used to recruit or fill vacant or new positions and its existing training and continuing education programs, and provides supporting documentation in Exhibit M-2. In Section H, page 70, the applicants identify the current medical director. In Exhibit H-4, the applicants provide a letter from the current medical director, which expresses his support for the proposed project and indicates an interest in continuing to serve as medical director for the existing and proposed services.

The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

F-11622-18/Atrium Health Pineville/Develop 50 acute care beds

In Section Q, Form H, the applicants provide historical and projected staffing for the existing and proposed services, as illustrated in the following table.

AH Pineville M/S Acute Care Beds Historical and Projected Staffing				
Position	**Last Full FY (CY 2017)**	**1st Full FY (CY 2022)**	**2nd Full FY (CY 2023)**	**3rd Full FY (CY 2024)**
Registered Nurses	203.54	226.99	236.53	246.55
Aides and Attendants	12.01	13.39	13.96	14.55
Supervisory	4.02	4.48	4.67	4.87
Technicians	75.18	83.84	87.36	91.07
Clerical/Secretarial	0.36	0.40	0.42	0.44
Unit Secretary	7.48	8.34	8.69	9.06
Temporary Help	8.19	9.13	9.52	9.92
TOTAL	**310.78**	**346.59**	**361.15**	**376.45**

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicants are budgeted in Form F.4, which is found in Section Q. In Section H, pages 81-82, the applicants describe the methods used to recruit or fill vacant or new positions and the existing training and continuing education programs. In Section H, page 82, the applicants identify the current chief medical officer. In Exhibit H-4, the applicants provide a letter from the chief medical officer, which expresses his support for the proposed project and indicates an interest in continuing to serve as chief medical officer for the existing and proposed services.

The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

F-11624-18/Novant Health Huntersville Medical Center/Develop 12 acute care beds and 1 OR

In Section Q, Form H, the applicants provide current and projected staffing for the proposed services, as illustrated in the following tables.

NHHMC Acute Care Beds Current and Projected Staffing				
Position	Current	Projected		
		1st Full FY (CY 2021)	2nd Full FY (CY 2022)	3rd Full FY (CY 2023)
Medical Unit Receptionist	5.00	5.00	5.00	5.00
Certified Nurse Aide 1	5.41	4.00	4.39	4.81
Certified Nurse Aide 2	0.65	0.00	0.00	0.00
Surgical Tech	4.20	4.00	4.39	4.81
Registered Nurse	35.77	37.45	39.00	41.02
Assistant Nurse Manager	0.00	3.00	3.00	3.00
Nurse Manager	1.00	1.00	1.00	1.00
TOTAL	**52.03**	**54.45**	**56.78**	**59.64**

NHHMC Operating Rooms Current and Projected Staffing				
Position	Current	Projected		
		1st Full FY (CY 2021)	2nd Full FY (CY 2022)	3rd Full FY (CY 2023)
Surgical Unit Specialist	0.00	1.05	1.08	1.11
OR Assistant	2.02	2.73	2.81	2.88
Registered Nurse (OR)	13.67	13.34	13.69	14.06
Surgical Tech	9.20	13.27	13.63	14.00
Clinical Coordinator (RN)	0.90	0.95	0.97	1.00
Assistant Manager	0.90	0.95	0.97	1.00
CRNA Supervisor	1.00	1.05	1.08	1.11
CRNA	13.76	16.00	16.43	16.88
Registered Nurse (Anesthesia)	0.27	0.32	0.32	0.33
Anesthesia Tech	2.00	2.10	2.16	2.21
Nurse Manager (Administration)	1.00	1.00	1.00	1.00
Office Coordinator	1.00	1.00	1.00	1.00
Sterile Processing Tech	6.77	8.82	9.06	9.30
Sterile Processing Supervisor	1.00	1.55	2.10	2.15
Clinical Coordinator (RN)	1.00	1.05	1.08	1.11
Assistant Nurse Manager	1.00	1.05	1.08	1.11
Registered Nurse (Recovery)	6.11	6.99	7.18	7.38
TOTAL	**61.60**	**73.25**	**75.65**	**77.66**

The assumptions and methodology used to project staffing are provided in Section H, page 70, and Section Q. Adequate costs for the health manpower and management positions proposed by the applicants are budgeted in Form F.3, which is found in Section Q. In Section H, pages 70-72, the applicants describe the methods used to recruit or fill new positions and their existing training and continuing education programs. In Exhibits H-2.2, H-2.3, H-2.4, and H-

3, the applicants provide supporting documentation. In Section H, page 74, the applicants identify the current chief of medical staff and chief of surgery. In Exhibits H-4.1 and H-4.3, the applicants provide letters from the chief of medical staff and chief of surgery, respectively, expressing their support for the proposed project and indicating an interest in continuing to serve in their current roles for the proposed services. In Section H, page 74, the applicants describe their physician recruitment plans.

The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(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 – All Applications

F-11612-18/Metrolina Vascular Access Care/Develop one OR

In Section I, page 60, the applicants state that the following ancillary and support services are necessary for the proposed services:

- Sterile Processing
- X-Ray Services
- Anesthesiology
- Patient Registration/Billing
- Medical Records/Coding
- Administration
- Quality Assurance
- Maintenance/Janitorial Services
- Medical Director
- Nursing Director
- Medical Supplies
- Software/Database Services

On pages 60-61, the applicants adequately explain how each ancillary and support service will be made available and provide supporting documentation in Exhibits A-10.1, I-1, and H-4.1.

In Section I, page 61, the applicants describe their proposed relationships with other local health care and social service providers and provide supporting documentation in Exhibits C-

4.2 and I-2. The applicants adequately demonstrate that the proposed services will be coordinated with the existing health care system.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11619-18/Carolina Center for Specialty Surgery/Develop one OR

In Section I, page 69, the applicant states the following ancillary and support services are necessary for the proposed services:

- Laboratory
- Pathology
- Radiology
- Pharmacy Consulting
- Anesthesia
- Sterile Processing
- Patient Reception
- Medical Records
- Billing and Insurance
- Housekeeping
- Laundry and Linen
- Maintenance

On page 69, the applicant adequately explains how each ancillary and support service will be made available and provides supporting documentation in Exhibits I-1.1 and 1-1.2.

In Section I, page 70, the applicant describes its existing relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11620-18/Carolinas Medical Center/Develop four ORs

In Section I, page 73, the applicant states the following ancillary and support services are necessary for the proposed services:

- Laboratory
- Radiology
- Pharmacy
- Housekeeping
- Maintenance
- Administrative
- Other Ancillary and Support Services

On page 73, the applicant adequately explains how each ancillary and support service will be made available and provides supporting documentation in Exhibit I-1.

In Section I, page 73, the applicant describes its existing relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11621-18/Atrium Health Pineville (AH Pineville)/Develop one OR

In Section I, page 72, the applicants state the following ancillary and support services are necessary for the proposed services:

- Laboratory
- Radiology
- Pharmacy
- Housekeeping
- Maintenance
- Administrative
- Other Ancillary and Support Services

On page 72, the applicants adequately explains how each ancillary and support service will be made available and provides supporting documentation in Exhibits I-1.1.

In Section I, page 72, the applicants describe its existing relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-2. The applicants adequately demonstrate that the proposed services will be coordinated with the existing health care system.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11622-18/Atrium Health Pineville/Develop 50 acute care beds

In Section I, page 84, the applicants state the following ancillary and support services are necessary for the proposed services:

- Laboratory
- Radiology
- Pharmacy
- Housekeeping
- Maintenance
- Administrative
- Other Ancillary and Support Services

On page 84, the applicants adequately explain how each ancillary and support service will be made available and provide supporting documentation in Exhibit I-1.

In Section I, page 84, the applicants describe the existing relationships with other local health care and social service providers and provide supporting documentation in Exhibit I-2. The applicants adequately demonstrate that the proposed services will be coordinated with the existing health care system.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11624-18/Novant Health Huntersville Medical Center/Develop 12 acute care beds and 1 OR

In Section I, page 77, the applicants state that the following ancillary and support services are necessary for the proposed services:

Acute Care Beds

- Medical/Surgical Beds
- Hospitalist/Inpatient Care Specialist Physicians
- Medical Staff
- Physician Practices

- Physical, Speech, and Occupational Therapy Services
- Respiratory Therapy

<u>Operating Rooms</u>

- Pre-Operative Services
- Facility/Professional Component
- Post-Operative Area
- Anesthesia
- Chief of Surgical Services

<u>All Services</u>

- Food & Nutrition
- Housekeeping
- Laundry and Linen
- Materials Management/Purchasing
- Billing & Finance
- Sterile Processing
- Laboratory
- Pathology
- Radiology

On page 77, the applicants adequately explain how each ancillary and support service is or will be made available.

In Section I, pages 78-79, the applicants describe their existing and proposed relationships with other local health care and social service providers and provide supporting documentation in Exhibit I-2. The applicants adequately demonstrate that the proposed services will be coordinated with the existing health care system.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes 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 – All Applications

None of the applications include projections 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, none of the applications include projections 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 – All Applications

None of the applicants is an HMO. Therefore, Criterion (10) is not applicable to any of the applications in this review.

(11) Repealed effective July 1, 1987.

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

C – All Applications

F-11612-18/Metrolina Vascular Access Care/Develop one OR

In Section K, page 63, and Exhibit K-1, the applicants state that an unrelated developer will construct a medical office building, and the applicants will upfit 6,896 square feet of space in the medical office building to house the proposed ASF. Line drawings are provided in Exhibit K-1. On page 64, the applicants adequately explain how the cost, design, and means of construction represent the most reasonable alternative for the proposal. On page 64, the applicants adequately explain why the proposal will not unduly increase the costs to the applicants of providing the proposed services or the costs and charges to the public for the proposed services. On page 64, the applicants identify any applicable energy saving features that will be incorporated into the construction plans. On pages 65-66, the applicants identify the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer, and waste disposal and power at the site. Supporting documentation is provided in Exhibits K-5.1, K-5.2, K-5.4, K-5.5, and K-5.6.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11619-18/Carolina Center for Specialty Surgery/Develop one OR

In Section K, page 73, the applicant states the proposed project involves renovating 503 square feet of existing space. Line drawings are provided in Exhibit C-1. On page 74, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal. On page 74, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 74, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11620-18/Carolinas Medical Center/Develop four ORs

In Section K, page 77, the applicant states the proposed project involves renovating 11,917 square feet of existing space. Line drawings are provided in Exhibit C-1. On page 78, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal. On page 78, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services. On pages 78-79, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11621-18/Atrium Health Pineville (AH Pineville)/Develop one OR

In Section K, page 76, the applicants state the proposed project involves renovating 3,670 square feet of existing space. Line drawings are provided in Exhibit C-1. On page 77, the applicants adequately explain how the cost, design, and means of construction represent the most reasonable alternative for the proposal. On page 77, the applicants adequately explain

why the proposal will not unduly increase the costs to the applicants of providing the proposed services or the costs and charges to the public for the proposed services. On pages 77-78, the applicants identify any applicable energy saving features that will be incorporated into the construction plans.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11622-18/Atrium Health Pineville/Develop 50 acute care beds

In Section K, page 88, the applicants state the proposed project involves renovating 37,715 square feet of existing space. Line drawings are provided in Exhibit C-1.

On August 23, 2018, the Agency determined that a proposal from Atrium to construct a new patient tower on the campus of AH Pineville was exempt from review, pursuant to G.S. 131E-184(g). In that request, Atrium proposed to develop an eight-story tower, approximately 269,000 square feet in total, which would be adjacent to and connected to AH Pineville. As part of that proposal, Atrium stated it planned to relocate 36 existing acute care beds to the second level of the proposed patient tower, and it planned to relocate 22 existing acute care beds and 14 unlicensed observation beds to the third level of the proposed patient tower.

As part of this proposed project under review, the applicants plan to develop 14 new acute care beds on the third floor of the patient tower, instead of 14 unlicensed observation beds, and develop the remaining 36 acute care beds on the fourth level of the patient tower. In Section C, pages 38-40, the applicants state that they included in their capital expenditures the entire cost of the core and shell of levels three and four; the entire cost of developing the 50 acute care beds (not just the cost to develop 36 acute care beds and the costs to convert 14 unlicensed observation beds to acute care beds), and the portions of site, foundation, engineering, and other costs that are attributable to levels three and four. Thus, while the applicants state that the space will be renovated, it can also be considered new construction.

On page 89, the applicants adequately explain how the cost, design, and means of construction represent the most reasonable alternative for the proposal. On page 89, the applicants adequately explain why the proposal will not unduly increase the costs to the applicants of providing the proposed services or the costs and charges to the public for the proposed services. On pages 89-91, the applicants identify any applicable energy saving features that will be incorporated into the construction plans.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11624-18/Novant Health Huntersville Medical Center/Develop 12 acute care beds and 1 OR

In Section K, page 81, the applicants state that the project involves renovating 6,676 square feet of existing space. Line drawings are provided in Exhibit K-2. On pages 81-82, the applicants adequately explain how the cost, design, and means of construction represent the most reasonable alternative for the proposal and provide supporting documentation in Exhibit K-4. On page 82, the applicants adequately explain why the proposal will not unduly increase the costs to the applicants of providing the proposed services or the costs and charges to the public for the proposed services. On page 82, the applicants identify any applicable energy saving features that will be incorporated into the construction plans.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

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

NA – Metrolina Vascular Access Care
C – All Other Applications

F-11612-18/Metrolina Vascular Access Care/Develop one OR

Neither the applicants nor any related entities own, operate, or manage an existing health service facility located in the service area. Therefore, Criterion (13a) is not applicable to this review.

F-11619-18/Carolina Center for Specialty Surgery/Develop one OR

In Section L, page 79, the applicant provides the historical payor mix for patients utilizing CCSS during CY 2017, as shown in the table below.

CCSS Historical Payor Mix Last Full FY (CY 2017)			
Payor Source	**Total Facility**	**ORs**	**PRs**
Self-Pay	0.4%	0.4%	0.4%
Medicare*	28.2%	20.2%	56.2%
Medicaid*	0.6%	0.2%	2.0%
Insurance*	65.8%	74.7%	34.6%
Other	5.0%	4.5%	6.8%
TOTAL	**100.0%**	**100.0%**	**100.0%**

*Including any managed care plans

On pages 78-79, the applicant provides the following comparison.

	% of Total Patients Served at CCSS during CY 2017	% of the Population of Mecklenburg County
Female	48.0%	51.2%
Male	52.0%	48.8%
Unknown	0.0%	0.0%
64 and Younger	70.0%	86.4%
65 and Older	30.0%	13.6%
American Indian	0.0%	0.0%
Asian	1.0%	5.5%
Black or African-American	10.0%	33.3%
Native Hawaiian or Pacific Islander	0.0%	1.0%
White or Caucasian	88.0%	57.6%
Other Race	1.0%	2.6%
Declined / Unavailable	0.0%	0.0%

Source: CCSS internal data, NC OSBM population data

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently uses the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

F-11620-18/Carolinas Medical Center/Develop four ORs

In Section L, page 84, the applicant provides the historical payor mix for patients utilizing CMC during CY 2017, as shown in the table below.

CMC Historical Payor Mix Last Full FY (CY 2017)		
Payor Source	**Total Facility**	**PRs**
Self Pay	13.0%	6.0%
Medicare*	26.0%	27.3%
Medicaid*	27.0%	19.9%
Insurance*	33.0%	43.4%
Other	1.0%	3.4%
TOTAL	**100.0%**	**100.0%**

*Including any managed care plans

On pages 83-84, the applicant provides the following comparison.

	% of Total Patients Served at CMC during CY 2017	% of the Population of Mecklenburg County
Female	60.0%	51.2%
Male	40.0%	48.8%
Unknown	0.0%	0.0%
64 and Younger	78.1%	86.4%
65 and Older	21.9%	13.6%
American Indian	0.1%	0.0%
Asian	1.5%	5.5%
Black or African-American	35.2%	33.3%
Native Hawaiian or Pacific Islander	0.0%	1.0%
White or Caucasian	44.0%	57.6%
Other Race	16.2%	2.6%
Declined / Unavailable	2.4%	0.0%

Source: Atrium internal data, NC OSBM population data

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently uses the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

F-11621-18/Atrium Health Pineville (AH Pineville)/Develop one OR

In Section L, page 83, the applicants provide the historical payor mix for patients utilizing AH Pineville during CY 2017, as shown in the table below.

AH Pineville Historical Payor Mix Last Full FY (CY 2017)		
Payor Source	**Total Facility**	**ORs**
Self-Pay	12.0%	3.4%
Medicare*	31.0%	40.0%
Medicaid*	16.0%	5.1%
Insurance*	39.0%	49.6%
Other**	2.0%	1.9%
TOTAL	**100.0%**	**100.0%**

*Including any managed care plans
**Other government sources and worker's comp

On pages 82-83, the applicants provide the following comparison.

	% of Total Patients Served at AH Pineville during CY 2017	% of the Population of Mecklenburg County
Female	57.8%	51.2%
Male	42.2%	48.8%
Unknown	0.0%	0.0%
64 and Younger	71.0%	86.4%
65 and Older	29.0%	13.6%
American Indian	0.1%	0.0%
Asian	1.2%	5.5%
Black or African-American	24.9%	33.3%
Native Hawaiian or Pacific Islander	0.0%	1.0%
White or Caucasian	62.1%	57.6%
Other Race	9.5%	2.6%
Declined / Unavailable	2.0%	0.0%

Source: Atrium Health internal data, NC OSBM population data

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently uses the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

F-11622-18/Atrium Health Pineville/Develop 50 acute care beds

In Section L, page 96, the applicants provide the historical payor mix for patients utilizing AH Pineville during CY 2017, as shown in the table below.

AH Pineville Historical Payor Mix Last Full FY (CY 2017)		
Payor Source	**Total Facility**	**M/S Beds**
Self Pay	12.0%	6.0%
Medicare*	31.0%	60.3%
Medicaid*	16.0%	6.1%
Insurance*	39.0%	26.3%
Other	2.0%	1.3%
TOTAL	**100.0%**	**100.0%**

*Including any managed care plans

On pages 95-96, the applicants provide the following comparison.

	% of Total Patients Served at AH Pineville during CY 2017	% of the Population of Mecklenburg County
Female	57.8%	51.2%
Male	42.2%	48.8%
Unknown	0.0%	0.0%
64 and Younger	71.0%	86.4%
65 and Older	29.0%	13.6%
American Indian	0.1%	0.0%
Asian	1.2%	5.5%
Black or African-American	24.9%	33.3%
Native Hawaiian or Pacific Islander	0.0%	1.0%
White or Caucasian	62.1%	57.6%
Other Race	9.5%	2.6%
Declined / Unavailable	2.0%	0.0%

Source: Atrium internal data, NC OSBM population data

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicants adequately document the extent to which medically underserved populations currently uses the applicants' existing services in comparison to the percentage of the population in the applicants' service area which is medically underserved. Therefore, the application is conforming to this criterion.

F-11624-18/Novant Health Huntersville Medical Center/Develop 12 acute care beds and 1 OR

In Section L, page 87, the applicants provide the historical payor mix during the last full fiscal year prior to submission of the application for the proposed services as shown in the table below.

NHHMC Historical Payor Mix CY 2017				
Payor Source	**Total Facility**	**Acute Care**	**IP Surgery**	**OP Surgery**
Self-Pay	1.41%	1.25%	0.61%	0.55%
Charity Care	4.22%	3.74%	1.83%	1.66%
Medicare*	38.79%	38.64%	57.25%	28.12%
Medicaid*	7.43%	10.78%	2.91%	4.61%
Insurance*	44.90%	41.23%	34.92%	61.97%
Other	3.25%	4.36%	2.48%	3.09%
TOTAL	**100.00%**	**100.00%**	**100.00%**	**100.00%**

*Including any managed care plans

In Section L, page 87, the applicants provide the following comparison.

	% of Total Patients Served at NHHMC during CY 2017	% of the Population of Mecklenburg County
Female	61.0%	51.2%
Male	39.0%	48.8%
Unknown	0.0%	0.0%
64 and Younger	75.5%	89.1%
65 and Older	24.5%	10.9%
American Indian	0.2%	1.0%
Asian	1.9%	5.5%
Black or African-American	41.5%	33.3%
Native Hawaiian or Pacific Islander	0.0%	Not Reported
White or Caucasian	46.8%	57.6%
Other Race	6.9%	2.6%
Declined / Unavailable	0.0%	0.0%

Sources: NHHMC Internal Truven Data, NC OSBM

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicants adequately document the extent to which medically underserved populations currently use the applicants' existing services in comparison to the percentage of the population in the applicants' service area which is medically underserved. 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;

NA – Metrolina Vascular Access Care
C – All Other Applications

F-11612-18/Metrolina Vascular Access Care/Develop one OR

Neither the applicants nor any related entities own, operate, or manage an existing health service facility located in the service area. Therefore, Criterion (13b) is not applicable to this review.

F-11619-18/Carolina Center for Specialty Surgery/Develop one OR

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 80, the applicant states it has no such obligation. In Section L, page 80, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11620-18/Carolinas Medical Center/Develop four ORs

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 85, the applicant states it has no such obligation. In Section L, page 85, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11621-18/Atrium Health Pineville (AH Pineville)/Develop one OR

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 84, the applicants state it has no such obligation. In Section L, page 84, the applicants state that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicants or a related entity and located in North Carolina.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11622-18/Atrium Health Pineville/Develop 50 acute care beds

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 97, the applicants state they have no such obligation. In Section L, page 97, the applicants state that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicants or a related entity and located in North Carolina.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11624-18/Novant Health Huntersville Medical Center/Develop 12 acute care beds and 1 OR

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 88, the applicants state two facilities – Novant Health Forsyth Medical Center and NHPMC – were previously subject to Hill-Burton obligations. The applicants state that both facilities have exceeded the required amount of the obligation and both facilities have met all obligations under applicable regulations. In Section L, page 88, the applicants state that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicants or a related entity and located in North Carolina.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes 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 – All Applications

F-11612-18/Metrolina Vascular Access Care/Develop one OR

In Section L, page 70, the applicants project the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Metrolina VAC Projected Payor Mix 2nd Full FY (5/21-4/22)	
Payor Source	**% of Patients (OR & PR)**
Charity Care	1.0%
Medicare*	65.6%
Medicaid*	5.1%
Insurance*	28.3%
TOTAL	**100.0%**

*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicants project that 1.0 percent of total services will be provided to charity care patients, 65.6 percent to Medicare patients, and 5.1 percent to Medicaid patients.

On page 70, the applicants provide the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicants rely on their own historical data in projecting future utilization.
- The applicants explain any changes made to their historical payor mix.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11619-18/Carolina Center for Specialty Surgery/Develop one OR

In Section L, page 81, the applicant projects the following payor mix during the second year of operation following completion of the project, as illustrated in the following table.

CCSS Projected Payor Mix 2nd Full FY (CY 2021)			
Payor Source	**Total Facility**	**ORs**	**PRs**
Self Pay	0.6%	0.6%	0.4%
Medicare*	29.4%	22.8%	56.2%
Medicaid*	0.9%	0.6%	2.0%
Insurance*	64.3%	71.6%	34.6%
Other	4.8%	4.3%	6.8%
TOTAL	**100.0%**	**100.0%**	**100.0%**

*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.6 percent of total services will be provided to self-pay patients, 29.4 percent to Medicare patients, and 0.9 percent to Medicaid patients.

On pages 81-82, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicant relies on its own historical data in projecting future utilization.
- The applicant explains any changes made to its historical payor mix.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11620-18/Carolinas Medical Center/Develop four ORs

In Section L, page 85, the applicant projects the following payor mix during the second full fiscal year following completion of the project, as illustrated in the following table.

CMC Projected Payor Mix 2nd Full FY (CY 2022)		
Payor Source	**Total Facility**	**ORs**
Self Pay	13.0%	6.0%
Medicare*	26.0%	27.3%
Medicaid*	27.0%	19.9%
Insurance*	33.0%	43.4%
Other	1.0%	3.4%
TOTAL	**100.0%**	**100.0%**

*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 13 percent of total services will be provided to self-pay patients, 26 percent to Medicare patients, and 27 percent to Medicaid patients.

On page 86, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicant relies on its own historical data in projecting future utilization.
- The applicant explains why there are no changes to its historical payor mix.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11621-18/Atrium Health Pineville (AH Pineville)/Develop one OR

In Section L, page 85, the applicants project the following payor mix during the second year of operation following completion of the project, as illustrated in the following table.

AH Pineville Projected Payor Mix 2nd Full FY (CY 2022)		
Payor Source	**Total Facility**	**ORs**
Self-Pay	12.0%	3.4%
Medicare*	31.0%	40.0%
Medicaid*	16.0%	5.1%
Insurance*	39.0%	49.6%
Other**	2.0%	1.9%
TOTAL	**100.0%**	**100.0%**

*Including any managed care plans
**Other government sources and worker's comp

As shown in the table above, during the second full fiscal year of operation, the applicants project that 12.0 percent of total services will be provided to self-pay patients, 31.0 percent to Medicare patients, and 16.0 percent to Medicaid patients.

On pages 85-86, the applicants provide the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicants rely on their own historical data in projecting future utilization.
- The applicants explain why there are no changes to their historical payor mix.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11622-18/Atrium Health Pineville/Develop 50 acute care beds

In Section L, page 98, the applicants project the following payor mix during the second full fiscal year following completion of the project, as illustrated in the following table.

AH Pineville Projected Payor Mix 2nd Full FY (CY 2024)		
Payor Source	**Total Facility**	**M/S Beds**
Self-Pay	12.0%	6.0%
Medicare*	31.0%	60.3%
Medicaid*	16.0%	6.1%
Insurance*	39.0%	26.3%
Other	2.0%	1.3%
TOTAL	**100.0%**	**100.0%**

*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicants project that 12 percent of total services will be provided to self-pay patients, 31 percent to Medicare patients, and 16 percent to Medicaid patients.

On page 98, the applicants provide the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicants rely on their own historical data in projecting future utilization.
- The applicants explain why there are no changes to their historical payor mix.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11624-18/Novant Health Huntersville Medical Center/Develop 12 acute care beds and 1 OR

In Section L, page 89, the applicants project the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

NHHMC Projected Payor Mix 2nd Full FY (CY 2022)				
Payor Source	**Total Facility**	**Acute Care**	**IP Surgery**	**OP Surgery**
Self-Pay	1.48%	1.24%	0.61%	0.55%
Charity Care	4.43%	3.72%	1.83%	1.66%
Medicare*	39.19%	41.03%	57.25%	28.12%
Medicaid*	7.70%	10.17%	2.91%	4.61%
Insurance*	43.93%	39.71%	34.92%	61.97%
Other	3.27%	4.13%	2.48%	3.09%
TOTAL	**100.00%**	**100.00%**	**100.00%**	**100.00%**

*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicants project that 1.48 percent of total services will be provided to self-pay patients, 4.43 percent to charity care patients, 39.19 percent to Medicare patients, and 7.70 percent to Medicaid patients.

On page 89, the applicants provide the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the

project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicants rely on their own historical data in projecting future utilization.
- The applicants account for differences between the historical payor mix and projected payor mix.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes 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 – All Applications

F-11612-18/Metrolina Vascular Access Care/Develop one OR

In Section L, page 71, the applicants adequately describe the range of means by which patients will have access to the proposed services.

Conclusion -The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11619-18/Carolina Center for Specialty Surgery/Develop one OR

In Section L, page 84, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11620-18/Carolinas Medical Center/Develop four ORs

In Section L, page 87, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11621-18/Atrium Health Pineville (AH Pineville)/Develop one OR

In Section L, page 86, the applicants adequately describe the range of means by which patients will have access to the proposed services.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11622-18/Atrium Health Pineville/Develop 50 acute care beds

In Section L, page 99, the applicants adequately describe the range of means by which patients will have access to the proposed services.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

F-11624-18/Novant Health Huntersville Medical Center/Develop 12 acute care beds and 1 OR

In Section L, page 91, the applicants adequately describe the range of means by which patients will have access to the proposed services.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes 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 – All Applications

F-11612-18/Metrolina Vascular Access Care/Develop one OR

In Section M, page 72, the applicants describe the extent to which health professional training programs in the area will have access to the facility for training purposes, and provide a list of health professional training programs that MNA has existing agreements with, which will extend to the current project.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicants adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

F-11619-18/Carolina Center for Specialty Surgery/Develop one OR

In Section M, page 85, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes, and provides supporting documentation in Exhibit M-2.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

F-11620-18/Carolinas Medical Center/Develop four ORs

In Section M, pages 88-89, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes, and provides supporting documentation in Exhibit M-2.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

F-11621-18/Atrium Health Pineville (AH Pineville)/Develop one OR

In Section M, page 87, the applicants describe the extent to which health professional training programs in the area will have access to the facility for training purposes, and provides supporting documentation in Exhibit M-2.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

F-11622-18/Atrium Health Pineville/Develop 50 acute care beds

In Section M, pages 101-102, the applicants describe the extent to which health professional training programs in the area will have access to the facility for training purposes, and provide supporting documentation in Exhibit M-2.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicants adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

F-11624-18/Novant Health Huntersville Medical Center/Develop 12 acute care beds and 1 OR

In Section M, pages 93-94, the applicants describe the extent to which health professional training programs in the area will have access to the facility for training purposes and provide supporting documentation in Exhibit H-2.1.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicants adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

(15) Repealed effective July 1, 1987.

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

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

C – All Applications

The 2018 SMFP includes need determinations for 50 acute care beds and six ORs in the Mecklenburg County service area.

Acute Care Beds. On page 38, the 2018 SMFP defines the service area for acute care beds as *"the acute care bed planning area in which the bed is located. The acute care bed planning areas are the single and multicounty groupings shown in Figure 5.1."* Figure 5.1, on page 42, shows Mecklenburg County as its own acute care bed planning area. Thus, the service area for this facility is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

As of the date of this decision, there are nine existing and approved acute care hospitals owned by two providers (Atrium and Novant) in the Mecklenburg County Service Area, as illustrated in the following table.

Mecklenburg County Acute Care Hospitals	
Facility	**Existing/Approved Beds**
AH Pineville	221
AH University City	100
CMC-Main	859
CMC-Mercy *	196
Atrium Total	**1,376**
NH Huntersville Medical Center	91 (+48)
NH Health Matthews Medical Center	154
NH Health Presbyterian Medical Center	503 (-16)
NH Charlotte Orthopedic Hospital **	28 (+4)
NH Mint Hill Medical Center	36 (+14)
Novant Total	**862**
Mecklenburg County Total	**2,238**

Source: Table 5A, 2018 SMFP; applications under review; 2019 LRAs; Agency records.
Note: Numbers in parentheses reflect approved changes in bed inventory.
* CMC-Mercy, while a separate location, is licensed as part of CMC.
** NHCOH, while a separate location, is licensed as part of NHPMC.

Operating Rooms. On page 57, the 2018 SMFP defines the service area for ORs as *"…the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* Figure 6.1, on page 62, shows Mecklenburg County as its own OR planning area. Thus, the service area for this facility is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

Not including dedicated C-Section ORs and trauma ORs, there are 155 existing ORs in Mecklenburg County, allocated between 17 facilities, as shown in the table below.

Mecklenburg County OR Inventory						
Facility	**IP ORs**	**OP ORs**	**Shared ORs**	**Excluded C-Section, and Trauma ORs**	**CON Adjustments**	**Total ORs**
AH Huntersville Surgery Center	0	0	0	0	1	1
AH Pineville	3	0	9	-2	0	10
AH University City	1	2	9	-1	-4	7
CCSS	0	2	0	0	0	2
CMC	10	11	41	-5	-2	55
Atrium Health System Total	**14**	**15**	**59**	**-8**	**-5**	**75**
Charlotte Surgery Center	0	7	0	0	-1	6
Randolph Surgery Center	0	0	0	0	6	6
Charlotte Surgery Center System Total	**0**	**7**	**0**	**0**	**5**	**12**
Matthews Surgery Center	0	2	0	0	0	2
NHBOS*	0	2	0	0	0	2
NHHMC	1	0	6	-2	1	6
NHHOS	0	2	0	0	0	2
NHMHMC	1	0	3	-1	1	4
NHMMC	2	0	6	-2	0	6
NHPMC	5	6	29	-2	-2	38
SouthPark Surgery Center	0	6	0	0	0	6
Novant Health System Total	**9**	**18**	**103**	**-7**	**0**	**65**
Carolinas Ctr for Ambulatory Dentistry**	0	0	0	0	2	2
Mallard Creek Surgery Center**	0	2	0	0	0	2
Total	**23**	**42**	**105**	**-15**	**0**	

Sources: Table 6A, 2018 SMFP; 2019 LRAs; Agency records

* Project I.D. #F-11625-18 was submitted in the same review cycle as these applications. Novant proposes to develop NHBMC, a new hospital by relocating existing beds and ORs. The ORs will be relocated from NHBOS, which close once the ORs are relocated to NHBMC.

** These facilities are part of demonstration projects and the ORs are not included in the SMFP need determination calculations.

F-11612-18/Metrolina Vascular Access Care/Develop one OR

The applicants propose to develop a new ASF with one OR and one PR dedicated to providing vascular access services for ESRD patients.

In Section N, pages 74-75, the applicants describe the expected effects of the proposed services on competition in the service area and discuss how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. On page 74, the applicants state:

> *"MVAC will have a positive impact on competition in the service area. …*
>
> *MVAC is specifically focused on providing quality care and cost-effective vascular access services to ESRD patients in Mecklenburg County and surrounding counties. The proposed MVAC will build on the existing vascular access centers' track record of success in providing care for this vulnerable population. The proposed project is necessary in order to provide a full range of vascular access services to the ESRD population in the service area. … The proposed project will increase access to care without negatively impacting existing providers in the service area."*

The applicants adequately describe the expected effects of the proposed services on competition in the service area and adequately demonstrate:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

F-11619-18/Carolina Center for Specialty Surgery/Develop one OR

The applicant proposes to develop an additional OR at its existing ASF for a total of three ORs upon project completion.

In Section N, pages 86-89, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicant states that CCSS promotes cost-effectiveness by providing surgical services at up to half the cost of the same services in a hospital setting. The applicant states that CCSS promotes quality with its existing programs and policies designed to ensure safety and quality and by participating in national quality organizations. The applicant states that CCSS promotes access to underserved

groups by committing to serve all patients and describing its financial policies designed to assist patients who need financial help with services.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

F-11620-18/Carolinas Medical Center/Develop four ORs

The applicant proposes to develop four additional ORs at its existing hospital for a total of 62 ORs upon completion of this project and Project I.D. #F-11106-15 (relocate two ORs as part of developing Randolph Surgery Center).

In Section N, pages 90-93, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicant states that CMC promotes cost-effectiveness by minimizing costs associated with developing the proposed project. The applicant states that CMC promotes quality with its existing programs and policies designed to ensure safety and quality and by participating in national quality organizations. The applicant states that CMC promotes access to underserved groups by committing to serve all patients and describing its financial policies designed to assist patients who need financial help with services.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

F-11621-18/Atrium Health Pineville (AH Pineville)/Develop one OR

The applicants propose to develop an additional OR at its existing facility for a total of 11 ORs upon project completion.
In Section N, pages 89-91, the applicants describe the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicants state that AH Pineville promotes cost-effectiveness by providing surgical services in a resource-responsible manner as the facility has the existing space necessary to accommodate the additional operating room without requiring new construction or extensive and cost-prohibitive renovations. The applicants states that AH Pineville promotes quality with its existing programs and policies designed to ensure safety and quality and by participating in national quality organizations. The applicants state AH Pineville promotes quality with its existing programs and policies designed to ensure safety and quality and by participating in national quality organizations. The applicants state AH Pineville promotes access to underserved groups by committing to serve all patients and describing its financial policies designed to assist patients who need financial help with services.

The applicants adequately describe the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

F-11622-18/Atrium Health Pineville/Develop 50 acute care beds

The applicants propose to develop 50 additional acute care beds at the existing hospital for a total of 271 acute care beds upon project completion.

In Section N, pages 103-105, the applicants describe the expected effects of the proposed services on competition in the service area and discuss how any enhanced competition in the service area will promote cost-effectiveness, quality, and access to the proposed services. The applicants state AH Pineville promotes cost-effectiveness by constructing the new beds in a less expensive manner than by developing a new bed tower just for the new beds. The applicants state AH Pineville promotes quality with its existing programs and policies designed to ensure safety and quality and by participating in national quality organizations. The applicants state AH Pineville promotes access to underserved groups by committing to serve all patients and describing its financial policies designed to assist patients who need financial help with services.
The applicants adequately describe the expected effects of the proposed services on competition in the service area and adequately demonstrate:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

F-11624-18/Novant Health Huntersville Medical Center/Develop 12 acute care beds and 1 OR

The applicants propose to add 12 acute care beds and one OR to NHHMC, which currently has 91 licensed acute care beds and five licensed ORs. At the completion of this project and Project I.D. #F-11110-15 (add 48 acute care beds and one OR), NHHMC will have 151 licensed acute care beds and seven ORs.

In Section N, pages 95-97, the applicants describe the expected effects of the proposed services on competition in the service area and discuss how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicants state that the minimal costs to convert existing space for the proposed services promotes cost-effectiveness. The applicants state that more efficient care will reduce the risk of errors and enhance the quality of the care for the patients. The applicants state that by increasing capacity at the facility, they can continue to provide access to medically underserved patients, particularly Medicare and Medicaid patients.

The applicants adequately describe the expected effects of the proposed services on competition in the service area and adequately demonstrate:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(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.

NA – Metrolina Vascular Access Care
C – All Other Applications

F-11612-18/Metrolina Vascular Access Care/Develop one OR

Neither the applicants nor any related entities own, operate, or manage an existing health service facility located in North Carolina. Therefore, Criterion (20) is not applicable to this review.

F-11619-18/Carolina Center for Specialty Surgery/Develop one OR

In Exhibit O.3, the applicant provides a list of all healthcare facilities with ORs located in North Carolina which are owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 23 hospitals and ASFs located in North Carolina.

In Section O, page 92, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care that occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in two of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 23 facilities, the applicant provided sufficient evidence that

quality care has been provided in the past. Therefore, the application is conforming to this criterion.

F-11620-18/Carolinas Medical Center/Develop four ORs

In Exhibit O.3, the applicant provides a list of all healthcare facilities with ORs located in North Carolina which are owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 23 hospitals and ASFs located in North Carolina.

In Section O, page 92, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care that occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in two of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 23 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

F-11621-18/Atrium Health Pineville (AH Pineville)/Develop one OR

In Exhibit O.3, the applicants provide a list of all healthcare facilities with ORs located in North Carolina which are owned, operated, or managed by the applicants or a related entity. The applicants identify a total of 21 hospitals and ASFs located in North Carolina.

In Section O, page 94, the applicants state that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care that occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in two of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 23 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

F-11622-18/Atrium Health Pineville/Develop 50 acute care beds

In Exhibit O.3, the applicants provide a list of all healthcare facilities with acute care beds located in North Carolina which are owned, operated, or managed by the applicants or a related entity. The applicants identify a total of 18 hospitals located in North Carolina.

In Section O, page 92, the applicants state that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care that occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in two of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the

quality of care provided at all 18 facilities, the applicants provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

F-11624-18/Novant Health Huntersville Medical Center/Develop 12 acute care beds and 1 OR

In Section O, page 100, the applicants identify the hospitals located in North Carolina owned, operated, or managed by the applicants or a related entity. The applicants identify a total of 16 hospitals located in North Carolina.

In Section O, page 100, the applicants state that, during the 18 months immediately preceding the submittal of the application, none of these facilities operated out of compliance with any Medicare Conditions of Participation. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in one of these facilities. After reviewing and considering information provided by the applicants and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 16 facilities, the applicants provided sufficient evidence that quality care has been provided in the past. Therefore, 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 – All Applications

SECTION .3800 – CRITERIA AND STANDARDS FOR ACUTE CARE BEDS are applicable to:

- Project I.D. #F-11622-18/Atrium Health Pineville/Develop 50 acute care beds and
- Project I.D. #F-11624-18/Novant Health Huntersville Medical Center/Develop 12 acute care beds.

10A NCAC 14C .3803 PERFORMANCE STANDARDS

(a) An applicant proposing to develop new acute care beds shall demonstrate that the projected average daily census (ADC) of the total number of licensed acute care beds proposed to be licensed within the service area, under common ownership with the applicant, divided by the total number of those licensed acute care beds is reasonably

projected to be at least 66.7 percent when the projected ADC is less than 100 patients, 71.4 percent when the projected ADC is 100 to 200 patients, and 75.2 percent when the projected ADC is greater than 200 patients, in the third operating year following completion of the proposed project or in the year for which the need determination is identified in the State Medical Facilities Plan, whichever is later.

-C- **Atrium Health Pineville.** The applicants propose to develop 50 additional acute care beds for a total of 271 acute care beds upon project completion. The projected ADC of the total number of licensed acute care beds proposed to be licensed within the service area and owned by Atrium is greater than 200. The applicants adequately demonstrate that the projected utilization of the total number of licensed acute care beds proposed to be licensed within the service area and which are owned by Atrium is reasonably projected to be at least 75.2 percent by the end of the third operating year following completion of the proposed project. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

-C- **Novant Health Huntersville Medical Center.** The applicants propose to develop 12 additional acute care beds for a total of 151 acute care beds upon completion of this project and Project I.D. #F-11110-15. The projected ADC of the total number of licensed acute care beds proposed to be licensed within the service area and owned by Novant is greater than 200. The applicants adequately demonstrate that the projected utilization of the total number of licensed acute care beds proposed to be licensed within the service area and which are owned by Novant is reasonably projected to be at least 75.2 percent by the end of the third operating year following completion of the proposed project. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

(b) An applicant proposing to develop new acute care beds shall provide all assumptions and data used to develop the projections required in this rule and demonstrate that they support the projected inpatient utilization and average daily census.

-C- **Atrium Health Pineville.** See Section C, pages 43-56, for the applicants' discussion of need, and Section Q, for the applicants' data, assumptions, and methodology used to project utilization. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

-C- **Novant Health Huntersville Medical Center.** See Section Q for the applicants' data, assumptions, and methodology used to project utilization. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS are applicable to:

- Project I.D. #F-11612-18/Metrolina Vascular Access Care/Develop one OR
- Project I.D. #F-11619-18/Carolina Center for Specialty Surgery/Develop one OR
- Project I.D. #F-11620-18/Carolinas Medical Center/Develop four ORs
- Project I.D. #F-11621-18/Atrium Health Pineville/Develop one OR
- Project I.D. #F-11624-18/Novant Health Huntersville Medical Center/Develop one OR

10A NCAC 14C .2103 PERFORMANCE STANDARDS

(a) A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program, or to add a specialty to a specialty ambulatory surgical program shall demonstrate the need for the number of proposed operating rooms in the facility that is proposed to be developed or expanded in the third operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.

-C- **Metrolina Vascular Access Care.** The applicants propose to establish a new ASF with one OR and one PR, which will be dedicated to providing vascular access services for ESRD patients. In Section Q, the applicants adequately demonstrate the need for the proposed OR in the third operating year. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

-C- **Carolina Center for Specialty Surgery.** The applicant proposes to develop one additional OR at its existing ASF for a total of three ORs upon project completion. In Section Q, the applicant adequately demonstrates the need for the proposed OR in the third operating year. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

-C- **Carolinas Medical Center.** The applicant proposes to develop four additional ORs at its existing hospital for a total of 64 ORs upon completion of this project and Project I.D. #F-11106-15 (relocate two ORs as part of developing Randolph Surgery Center). In Section Q, the applicant adequately demonstrates the need for the four proposed ORs in the third operating year. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

-C- **Atrium Health Pineville.** The applicants propose to develop an additional OR at its existing facility for a total of 11 ORs upon project completion. In Section Q, the applicants adequately demonstrate the need for the proposed OR in the third operating year. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

-C- **Novant Health Huntersville Medical Center.** The applicants propose to add one OR to NHHMC for a total of seven ORs upon completion of this project and Project I.D. #F-11110-15. In Section Q, the applicants adequately demonstrate the need for the proposed OR in the third operating year. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

(b) A proposal to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the third operating year of the proposed project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.

-NA- **Metrolina Vascular Access Care.** The applicants are not part of an existing health system in Mecklenburg County. Therefore, this Rule is not applicable to this review.

-C- **Carolina Center for Specialty Surgery.** This proposal would add one new OR to CCSS for a total of three ORs upon project completion. The applicant projects sufficient surgical cases and hours to demonstrate the need for an additional OR in the applicant's health system in the third operating year based on the Operating Room Need Methodology in the 2018 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

-C- **Carolinas Medical Center.** This proposal would add four new ORs to CMC for a total of 64 ORs upon completion of this project and Project I.D. #F-11106-15 (relocate two ORs as part of developing Randolph Surgery Center). The applicant projects sufficient surgical cases and hours to demonstrate the need for four additional ORs in the applicant's health system in the third operating year based on the Operating Room Need Methodology in the 2018 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

-C- **Atrium Health Pineville.** This proposal would add one new OR to AH Pineville for a total of 11 ORs upon project completion. The applicants project sufficient surgical cases and hours to demonstrate the need for an additional OR in the applicant's health system in the third operating year based on the Operating Room Need Methodology in the 2018 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

-C- **Novant Health Huntersville Medical Center.** This proposal would add one new OR to NHHMC for a total of seven ORs upon completion of this project and Project I.D. #F-11110-15. The applicants project sufficient surgical cases and hours to demonstrate the need for an additional OR in the applicants' health system in the third operating year based on the Operating Room Need Methodology in the 2018 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(c) An applicant that has one or more existing or approved dedicated C-section operating rooms and is proposing to develop an additional dedicated C-section operating room

in the same facility shall demonstrate that an average of at least 365 C-sections per room were performed in the facility's existing dedicated C-section operating rooms in the previous 12 months and are projected to be performed in the facility's existing, approved, and proposed dedicated C-section rooms during the third year of operation following completion of the project.

-NA- None of the applications involves a proposal to develop a dedicated C-section OR. Therefore, this Rule is not applicable to any of the applications in this review.

(d) An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty area to a specialty ambulatory surgical program shall:

(1) provide documentation to show that each existing ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently utilized an average of at least 1,312.5 hours per operating room per year; and

(2) demonstrate the need in the third operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.

-NA- None of the applications involves a proposal to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty area to an existing specialty ambulatory surgical program. Therefore, this Rule is not applicable to any of the applications in this review.

(e) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.

-C- **Metrolina Vascular Access Care.** In Section C, pages 31-32, and Section Q, the applicants provide the assumptions and data supporting the methodology for their utilization projections. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

-C- **Carolina Center for Specialty Surgery.** In Section Q, the applicant provides the assumptions and data supporting the methodology for its utilization projections. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

-C- **Carolinas Medical Center.** In Section Q, the applicant provides the assumptions and data supporting the methodology for its utilization projections. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

-C- **Atrium Health Pineville.** In Section Q, the applicants provide the assumptions and data supporting the methodology for its utilization projections. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

-C- **Novant Health Huntersville Medical Center.** In Section Q, the applicants provide the assumptions and data supporting the methodology for their utilization projections. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

COMPARATIVE ANALYSIS FOR OPERATING ROOMS

Pursuant to G.S. 131E-183(a)(1) and the 2018 State Medical Facilities Plan, no more than six ORs may be approved for Mecklenburg County in this review. Because the five applications in this review collectively propose to develop eight additional ORs to be located in Mecklenburg County, all of the applications cannot be approved for the total number of ORs proposed. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposals should be approved.

Below is a brief description of each project included in the Operating Room Comparative Analysis:

- Project I.D. #F-11612-18/**Metrolina Vascular Access Care**/Develop a new ambulatory surgical facility in Charlotte with one OR and one procedure room focused on vascular access procedures for patients with end stage renal disease
- Project I.D. #F-11619-18/**Carolina Center for Specialty Surgery**/Develop one additional OR pursuant to the 2018 SMFP need determination
- Project I.D. #F-11620-18/**Carolinas Medical Center**/Develop four additional ORs pursuant to the 2018 SMFP need determination
- Project I.D. #F-11621-18/**Atrium Health Pineville**/Develop one additional OR pursuant to the 2018 SMFP need determination
- Project I.D. #F-11624-18/**Novant Health Huntersville Medical Center**/Add 12 acute care beds and one OR pursuant to need determinations in the 2018 SMFP

Conformity with Review Criteria

All the applications are conforming to all applicable statutory and regulatory review criteria. Therefore, with regard to conformity with review criteria, all the applications are equally effective alternatives.

Physician Support

Each application documents physician support of the proposed project. Therefore, with regard to physician support, all the applications are equally effective alternatives.

Geographic Accessibility

Not including dedicated C-Section ORs and trauma ORs, there are 155 existing ORs in Mecklenburg County, allocated between 17 facilities, as shown in the table below.

Mecklenburg County OR Inventory						
Facility	IP ORs	OP ORs	Shared ORs	Excluded C-Section, and Trauma ORs	CON Adjustments	Total ORs
AH Huntersville Surgery Center	0	0	0	0	1	1
AH Pineville	3	0	9	-2	0	10
AH University City	1	2	9	-1	-4	7
CCSS	0	2	0	0	0	2
CMC	10	11	41	-5	-2	55
Atrium Health System Total	**14**	**15**	**59**	**-8**	**-5**	**75**
Charlotte Surgery Center	0	7	0	0	-1	6
Randolph Surgery Center	0	0	0	0	6	6
Charlotte Surgery Center System Total	**0**	**7**	**0**	**0**	**5**	**12**
Matthews Surgery Center	0	2	0	0	0	2
NHBOS*	0	2	0	0	0	2
NHHMC	1	0	6	-2	1	6
NHHOS	0	2	0	0	0	2
NHMHMC	1	0	3	-1	1	4
NHMMC	2	0	6	-2	0	6
NHPMC	5	6	29	-2	-2	38
SouthPark Surgery Center	0	6	0	0	0	6
Novant Health System Total	**9**	**18**	**103**	**-7**	**0**	**65**
Carolinas Ctr for Ambulatory Dentistry**	0	0	0	0	2	2
Mallard Creek Surgery Center**	0	2	0	0	0	2
Total	**23**	**42**	**105**	**-15**	**0**	**155**

Sources: Table 6A, 2018 SMFP; 2019 LRAs; Agency records

* Project I.D. #F-11625-18 was submitted in the same review cycle as these applications. Novant proposes to develop NHBMC, a new hospital by relocating existing beds and ORs. The ORs will be relocated from NHBOS, which close once the ORs are relocated to NHBMC.

** These facilities are part of demonstration projects and the ORs are not included in the SMFP need determination calculations.

The following table illustrates where the ORs are located in Mecklenburg County.

City	System	Total # of ORs (excluding dedicated C-section and trauma ORs)	Population as of July 1, 2017	# of ORs per 10,000 Population
Charlotte	CMHA	64		
	Charlotte Surgery Center	12		
	Novant	44		
	Mallard Creek Surgery Center	2		
	Carolinas Center for Ambulatory Dentistry	2		
	Charlotte Total	**124**	**845,235**	**1.5**
Pineville	CMHA	**10**	**9,200**	**10.9**
Huntersville	CMHA	1		
	Novant	8		
	Huntersville Total	**9**	**59,494**	**1.5**
Matthews	Novant	**8**	**31,028**	**2.6**
Mint Hill	Novant	**4**	**27,177**	**1.5**
Total		**155**	**1,074,596**	**1.4**

As shown in the table above, the existing ORs are located in Charlotte, Pineville, Huntersville, Matthews and Mint Hill. **MVAC** proposes to develop a new ASF with one OR in Charlotte. **CCSS** and **CMC** propose to add ORs to existing facilities in Charlotte. **AH Pineville** proposes to add one OR to an existing facility in Pineville. **NHHMC** proposes to add one OR to an existing facility in Huntersville. Six of the eight proposed ORs would be located in Charlotte, which already has 124 ORs or 1.5 ORs per 10,000. One proposed OR would be located in Huntersville, which already has 9 ORs or 1.5 ORs per 10,000. The remaining OR would be located in Pineville, which already has 10 ORs or 10.9 ORs per 10,000. However, Pineville is located very close to the NC/SC border, and thus, AH Pineville serves a number of SC residents.

Furthermore, the analysis of geographic accessibility is also impacted by differences in the type of:

- facilities (single specialty ASF versus Hospital);
- surgical services proposed (ASF limited to vascular access versus Hospital); and
- patients served (dialysis patients only versus Hospital).

Thus, no conclusion was made as to whether one proposal is more effective than the other proposals with regard to geographic accessibility.

<u>Patient Access to a New Provider</u>

Generally, the application proposing to increase patient access to a new provider in the service area is the more effective alternative with regard to this comparative factor.

MVAC. The applicants do not currently own or operate any existing surgical facilities anywhere in North Carolina. Therefore, this proposed facility would be a new provider of surgical services in Mecklenburg County.

CCSS, CMC, and **AH Pineville.** Each of these proposals is from an applicant affiliated with Atrium Health. The Atrium Health system provides surgical services at the following existing and approved facilities in Mecklenburg County:

- CMC
- AH Pineville
- AH University City
- CCSS
- AH Huntersville Outpatient Surgery

NHHMC. This proposal is from an applicant affiliated with Novant Health. The Novant Health system serves provides surgical services at the following existing and approved facilities in Mecklenburg County:

- NHPMC
- NHHMC
- NHMMC
- NHMHMC
- NHBOS
- NHHOS
- Matthews Surgery Center
- SouthPark Surgery Center

Therefore, with regard to introducing a new provider of surgical services in Mecklenburg County, the application submitted by **MVAC** is the more effective alternative.

Patient Access to Lower Cost Surgical Services

There are two types of licensed health service facilities that have ORs: hospitals and ASFs. Many surgical services can be appropriately offered on an outpatient basis in either a hospital or an ASF. However, the cost to the patient for the same service is likely to be higher if that service is provided on an outpatient basis in a hospital rather than in an ASF. But for some patients, an ASF may not be the appropriate setting in order to safely have surgery as an outpatient. Inpatients that need surgical services during their inpatient stay and patients in the emergency room that need immediate surgery require access to ORs in the hospital.

The following table identifies the existing and approved ORs in Mecklenburg County by inpatient, shared and dedicated outpatient.

	Total ORs*	IP ORs	% IP of Total ORs	OP ORs**	% OP of Total ORs	Shared ORs ***	Shared as a % of Total ORs
Mecklenburg County ORs	155	9	5.8%	44	28.4%	101	65.2%

Source: 2019 SMFP, Agency files.
* Total ORs includes existing and approved ORs and excludes dedicated C-Section and excluded trauma ORs.
** Includes a total of four single-specialty demonstration project ORs at Carolinas Center for Ambulatory Dentistry and Mallard Creek Surgery Center.
*** Shared ORs serve both inpatients and outpatients and are only found in hospitals.

The table below shows the percentage of total Mecklenburg County surgical cases that were outpatient surgeries in FY 2017, based on data reported in the 2019 SMFP.

Ambulatory Surgical Cases as Percent of Total Mecklenburg County Surgical Cases					
Facility	**Type of ORs**	**IP Cases**	**Outpatient Cases**	**Total Cases**	**Percent Ambulatory**
AH Pineville	Shared	3,284	4,849	8,133	60%
AH University City	Shared	960	6,423	7,383	87%
Charlotte Surgery Center	ASF	-	7,908	7,908	100%
CCSS	ASF	-	1,880	1,880	100%
CMC	Shared	18,968	22,519	41,487	54%
Mallard Creek Surgery Center	ASF	-	2,227	2,227	100%
Matthews Surgery Center	ASF	-	1,907	1,907	100%
NHBOS	ASF	-	923	923	100%
NHHMC	Shared	1,291	3,689	4,980	74%
NHHOS	ASF	-	2,385	2,385	100%
NHMMC	Shared	1,509	4,088	5,597	73%
NHPMC	Shared	7,863	22,035	29,898	74%
SouthPark Surgery Center	ASF	-	10,788	10,788	100%
Totals		**33,875**	**91,621**	**125,496**	**73%**

Source: Table 6B of the 2019 SMFP, 2018 LRAs

Note: This table excludes AH Huntersville Surgery Center, Carolinas Center for Ambulatory Surgery, NHMHMC, and Randolph Surgery Center, since they did not serve patients during FY 2017.

As the table above shows, in FFY 2017, 73 percent of all Mecklenburg County surgical cases were performed on an outpatient basis. There are 10 existing or approved ASFs located in Mecklenburg County.

The following table compares FFY 2017 Mecklenburg County ASF surgical cases by specialty with the state as a whole.

FFY 2017 Surgical Cases by Specialty		
Surgical Specialty	**% of Total ASF Surgeries**	
	North Carolina	**Mecklenburg County**
Ophthalmology	38.0%	33.0%
Orthopedics	29.1%	37.6%
Otolaryngology	16.4%	18.0%
General Surgery	5.3%	0.0%
Urology	2.4%	0.6%
Podiatry	2.2%	3.1%
Obstetrics and Gynecology	2.0%	0.7%
Neurosurgery	1.7%	5.5%
Plastic Surgery	1.5%	1.4%
Oral Surgery	0.8%	0.0%
Vascular	0.2%	0.0%
Other	0.1%	0.1%
Total Cases	**100.0%**	**100.0%**

Totals may not sum due to rounding.

Source: 2018 LRAs

As shown in the comparison above, Mecklenburg County ASFs perform a higher percentage of orthopedic surgery and a lower percentage of ophthalmology surgery than ASFs in North Carolina on average.

Based on the fact that 73 percent of Mecklenburg County's FY 2017 surgical cases were performed on an outpatient basis and ORs in ASFs represent 28 percent of all ORs located in Mecklenburg County, projects proposing the development of ASF ORs would be the more effective alternative.

Therefore, the applications submitted by **MVAC** and **CCSS** are the more effective proposals with respect to this comparative factor. The applications submitted by **CMC**, **AH Pineville**, and **NHHMC** are less effective with respect to this comparative factor.

Patient Access to Multiple Services

The following table illustrates the surgical specialties (as defined in the annual LRAs) proposed by each facility in this review.

Services Proposed to be Offered					
Specialty and Related Sub-specialties	**MVAC (OP only)**	**CCSS (OP only)**	**CMC (IP and OP)**	**AH Pineville (IP and OP)**	**NHHMC (IP and OP)**
Cardiothoracic, excluding Open Heart			X	X	X
Open Heart			X	X	X
General Surgery			X	X	X
Neurosurgery, including Spine Surgery		X	X	X	X
Obstetrics and Gynecology, excluding C-Section			X	X	X
Ophthalmology			X	X	X
Oral Surgery /Dental			X	X	X
Orthopedic, including Spine Surgery		X	X	X	X
Otolaryngology (ENT)			X	X	X
Plastic Surgery			X	X	X
Podiatry		X			X
Urology		X	X	X	X
Vascular	X		X	X	X
Other					
Pain Management		X	X		
GI			X		
Breast				X	

As the above table illustrates, the three existing hospitals in this review (**CMC**, **AH Pineville** and **NHHMC**), offer a full continuum of emergency, medical and surgical services and they propose access to a broader range of specialties. **MVAC** and **CCSS** each propose to provide fewer surgical services but they are both ASFs, not hospitals, and **MVAC** only proposes to serve ESRD patients.

The following table provides the number of cases by surgical specialty, as reported in the 2018 LRA by existing licensed facilities in Mecklenburg County that offer surgical services.

FFY 2017 Surgical Cases by Specialty (Excluding C-Sections)					
	Hospital IP	**Hospital OP**	**ASF**	**Total**	**% of Total**
Orthopedic	12,684	13,268	10,527	36,479	28.60%
General Surgery	9,617	15,611	7	25,235	19.78%
Ophthalmology	44	7,870	9,243	17,157	13.45%
Obstetrics and GYN, excluding C-Section	1,640	9,858	188	11,686	9.16%
Otolaryngology (ENT)	568	3,413	5,053	9,034	7.08%
Neurosurgery	4,092	1,315	1,533	6,940	5.44%
Urology	1,395	4,087	170	5,652	4.43%
Plastic Surgery	583	2,149	396	3,128	2.45%
Podiatry	9	2,023	871	2,903	2.28%
Vascular	1,829	820	0	2,649	2.08%
Other	312	1,765	29	2,106	1.65%
Open Heart	1,761	0	0	1,761	1.38%
Oral Surgery /Dental	229	1,342	1	1,572	1.23%
Cardiothoracic, excluding Open Heart	1,168	82	0	1,250	0.98%
Totals, excluding C-Sections	**35,931**	**63,603**	**28,018**	**127,552**	**100.00%**

Totals may not sum due to rounding.
Source: Mecklenburg County providers' 2018 LRAs

As the table above shows, orthopedic surgery makes up 28.60 percent of cases performed in FFY 2017 followed by 19.78 percent general surgery, 13.45 percent ophthalmology, 9.16 percent obstetrics and gynecology, 7.08 percent otolaryngology (ENT), 5.44 percent neurosurgery, 4.43 percent urology, and 2.45 percent plastic surgery.

As a newly proposed ASF, proposing to provide vascular access services to ESRD patients, **MVAC** does not project to offer any of the top eight surgical specialties performed in Mecklenburg County. As an existing multispecialty ASF, **CCSS** has historically provided three of the top eight surgical specialties performed in Mecklenburg County, and nothing in the application as submitted suggests an increase in the type of surgical specialties **CCSS** proposes to perform. **CMC**, **AH Pineville**, and **NHHMC** have historically provided all of the top eight surgical specialties performed in Mecklenburg County, and nothing in the applications as submitted suggests a change in the type of surgical specialties the facilities project to offer.

Because each facility is expected to continue to offer all of the top eight surgical specialties performed in Mecklenburg County, **CMC**, **AH Pineville**, and **NHHMC** offer access to a broader range of specialties and are therefore more effective alternatives.

Competition

There are 155 existing and approved ORs (excluding dedicated C-Section ORs and trauma ORs) located in Mecklenburg County. The table below shows the number and percentage of ORs controlled by each applicant or health system.

ORs in Mecklenburg County by Applicant/Health System		
Applicant/Health System	**Number of ORs**	**Percent of ORs**
Atrium (CCSS, CMC, AH Pineville)	75	48.4%
Novant (NHHMC)	65	41.9%
MVAC	0	0.0%
Others	15	9.7%
Total	155	100.0%

There is a need determination in the 2018 SMFP for 6 ORs, which increases the total number of existing and approved ORs (excluding dedicated C-Section ORs and trauma ORs) located in Mecklenburg County to 161 ORs. The table below shows the number of ORs and percentage of the total each applicant or health system would control if all applications were approved as submitted.

ORs in Mecklenburg County by Applicant/Health System – Assuming Approval		
Applicant/Health System	**Number of ORs**	**Percent of ORs**
Atrium (CCSS, CMC, AH Pineville)	81	50.3%
Novant (NHHMC)	66	41.0%
MVAC	1	0.6%
Others	15	9.3%
Total	161	100.0%

If all Atrium Health applications (**CCSS, CMC,** and **AH Pineville**) are approved as submitted, Atrium would control 81 of the 161 existing and approved ORs located in Mecklenburg County or 50.3 percent. If **NHHMC's** application is approved, Novant Health would control 66 of the 161 existing and approved ORs located in Mecklenburg County or 41.0 percent. If **MVAC's** application is approved, **MVAC** would control 1 of the 161 existing and approved ORs located in Mecklenburg County or 0.6 percent.

Therefore, with regard to competition, the application submitted by **MVAC** is the most effective alternative and the application submitted by **NHHMC** is a more effective alternative than the applications submitted by **CCSS, CMC,** and **AH Pineville**.

Service to Residents of the Service Area

On page 57, the 2018 SMFP defines the service area for ORs as *"…the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* Figure 6.1, on page 62, shows Mecklenburg County as its own OR planning area. Thus, the service area for this facility is Mecklenburg County. Facilities may also serve residents of counties not included in their service area. Generally, the application projecting to serve the highest percentage of Mecklenburg County residents is the more effective alternative with regard to this comparative factor since the need determination is for six additional ORs to be located in Mecklenburg County.

3rd Full FY		
Applicant	**% of Mecklenburg County Residents**	
MVAC	71.32%	
CCSS	37.1%	
CMC	46.2%	
AH Pineville	43.0%	
NHHMC	63.1% inpatient	54.1% outpatient

Source: Section C.3 (all applications)

As shown in the table above, **MVAC** projects to serve the highest percentage of Mecklenburg County residents during the third full fiscal year of operation following project completion. Therefore, with regard to projected service to Mecklenburg County residents, **MVAC** is the most effective alternative. **NHHMC**, as shown in the table above, projects to serve the second highest percentage of Mecklenburg County residents during the third full FY. Therefore, **NHHMC** is a more effective alternative with regard to projected service to Mecklenburg County residents. With regard to projected service to Mecklenburg County residents, **CCSS**, **CMC**, and **AH Pineville** are less effective alternatives.

Access by Underserved Groups

Underserved groups is defined in G.S. 131E-183(a)(13) as follows:

> *"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."*

Projected Charity Care

The following table shows projected charity care during the third full fiscal year following project completion for each facility. Generally, the application proposing to provide more charity care is the most effective alternative with regard to this comparative factor.

Projected Charity Care 3rd Full FY			
Applicant	**Projected Total Charity Care**	**Charity Care per Surgical Case**	**% of Net Surgical Revenue**
MVAC	$106,462	$65	2.6%
CCSS*	$85,667	$30	0.5%
CMC	$83,810,211	$2,123	19.4%
AH Pineville	$15,002,180	$1,561	11.7%
NHHMC	$4,052,000	$694	4.6%

Source: Forms F.3, F.4 and F.5 for each applicant.

* With regard to charity care, in its pro formas, CCSS provides information for all cases performed in the OR and the PR and there is no way to determine charity care for just the cases performed in the OR. Thus, the charity care per surgical case and charity care percentage of net surgical revenue includes cases performed in the OR and in the PR.

As shown in the table above, **CMC** projects the most charity care in dollars, the highest charity care per surgical case, and the highest charity care as a percent of net revenue. Therefore, the application submitted by **CMC** is the most effective alternative with regard to access to charity care. However,

the differences in the types of facilities and the number and types of surgical services proposed by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

Projected Medicare

The following table shows total projected surgical cases and projected Medicare cases during the third full fiscal year following project completion for each facility. Generally, the application proposing to serve more Medicare patients is the most effective alternative with regard to this comparative factor.

Projected Medicare Cases 3rd Full FY			
	Total Cases	**Medicare Cases**	**% of Total Cases**
MVAC	1,633	1,080	66.1%
CCSS	2,344	552	23.5%
CMC	39,473	8,054	20.4%
AH Pineville	9,612	3,840	40.0%
NHHMC	5,840	1,719	29.4%

Source: Section Q, Form F.4 for each applicant

As shown in the table above, **MVAC** projects to serve the highest percentage of Medicare patients in the third full fiscal year following project completion. Therefore, the application submitted by **MVAC** is the most effective application with respect to service to Medicare patients. However, differences in the types of facilities and the number and types of surgical services proposed by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

Projected Medicaid

The following table shows total projected surgical cases and projected Medicaid cases during the third full fiscal year following project completion for each facility. Generally, the application proposing to serve more Medicaid patients is the most effective alternative with regard to this comparative factor.

Projected Medicaid Cases 3rd Full FY			
	Total Cases	**Medicaid Cases**	**% of Total Cases**
MVAC	1,633	84	5.1%
CCSS	2,344	18	0.8%
CMC	39,473	5,872	14.9%
AH Pineville	9,612	492	5.1%
NHHMC	5,840	255	4.4%

Source: Section Q, Form F.4 for each applicant.

As shown in the table above, **CMC** projects to serve the highest percentage of Medicaid patients in the third full fiscal year following project completion. Therefore, the application submitted by **CMC** is the most effective application with respect to service to Medicaid patients. However, differences in the types of facilities and the number and types of surgical services proposed by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

Projected Average Net Revenue per Case

The following table shows the projected average net surgical revenue per surgical case in the third full fiscal year following project completion for each facility. Generally, the application proposing the lowest average net revenue per case is the more effective alternative with regard to this comparative factor to the extent the average reflects a lower cost to the patient or third party payor.

Average Net Revenue per Case 3rd Full FY			
Applicant	Total # of Cases	Net Revenue	Average Net Revenue per Case
MVAC	1,633	$4,043,706	$2,476
CCSS	2,344	$18,468,255	$7,879
CMC	39,473	$431,010,506	$10,919
AH Pineville	9,612	$127,815,293	$13,297
NHHMC	5,840	$87,967,000	$15,063

Source: Section Q, Forms F.3, F.4 and F.5 in each application

As shown in the table above, **MVAC** projects the lowest net revenue per surgical case in the third full fiscal year following project completion. Therefore, the application submitted by **MVAC** is the most effective application with respect to net revenue per surgical case. However, differences in the types of facilities and the number and types of surgical services proposed by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

Projected Average Operating Expense per Case

The following table shows the projected average operating expense per case in the third full fiscal year following project completion for each facility. Generally, the application proposing the lowest average operating expense per case is the more effective alternative with regard to this comparative factor to the extent it reflects a more cost effective service which could also result in lower costs to the patient or third party payor.

Average Operating Expense per Case 3rd Full FY			
Applicant	Total # of Cases	Operating Expenses	Average Operating Expense per Case
MVAC	1,633	$3,445,152	$2,110
CCSS	2,344	$8,350,502	$3,563
CMC	39,473	$213,508,006	$5,409
AH Pineville	9,612	$52,453,431	$5,457
NHHMC	5,840	$51,331,000	$8,790

Source: Forms F.3, F.4 and F.5 for OR revenue in each application

As shown in the table above, **MVAC** projects the lowest operating expense per surgical case in the third full fiscal year following project completion. Therefore, the application submitted by **MVAC** is the most effective application with respect to operating expense per surgical case. However, differences in the types of facilities and the number and types of surgical services proposed by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

SUMMARY

Due to significant differences in the types of surgical facilities, types of surgical services to be offered, number of total operating rooms, total revenues and expenses, and the differences in presentation of pro forma financial statements, the comparatives may be of less value and result in less than definitive outcomes than if all applications were for like facilities of like size, proposing like services and reporting in like formats.

The following table lists the comparative factors and states which applicant is the most effective or more effective alternative with regard to that particular comparative factor. Note: the comparative factors are listed in the same order they are discussed in the Comparative Analysis, which should not be construed to indicate an order of importance.

Comparative Factor	MVAC	CCSS	CMC	AH Pineville	NHHMC
Conformity with Review Criteria	Yes	Yes	Yes	Yes	Yes
Physician Support	Equally Effective	Equally Effective	Equally Effective	Equally Effective	Equally Effective
Geographic Accessibility	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Patient Access to New Provider	**Most Effective**	Less Effective	Less Effective	Less Effective	Less Effective
Patient Access to Lower Cost Surgical Services	**Most Effective**	**Most Effective**	Less Effective	Less Effective	Less Effective
Patient Access to Multiple Surgical Specialties	Less Effective	Less Effective	**Most Effective**	**Most Effective**	**Most Effective**
Competition	**Most Effective**	Less Effective	Less Effective	Less Effective	**More Effective**
Service to Residents of the Service Area	**Most Effective**	Less Effective	Less Effective	Less Effective	**More Effective**
Access by Underserved Groups					
Projected Charity Care	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Medicare	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Medicaid	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Average Net Revenue per Case	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Average Operating Expense per Case	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive

All applications are conforming to all review criteria, and thus all applications are approvable. However, since collectively they propose a total of eight ORs and the need determination is only six ORs , only six ORs can be approved. As shown in the table above:

- **MVAC** is the most effective alternative with regard to
  - Patient Access to New Provider
  - Patient Access to Lower Cost Surgical Services
  - Competition
  - Service to Residents of the Service Area
- **NHHMC** is the most effective alternative with regard to:
  - Patient Access to Multiple Surgical Specialties
  - Competition
  - Service to Residents of the Service Area
- **CCSS** is the most effective alternative with regard to:
  - Patient Access to Lower Cost Surgical Services
- **AH Pineville** is the most effective alternative with regard to:
  - Patient Access to Multiple Surgical Specialties
- **CMC** is the most effective alternative with regard to:
  - Patient Access to Multiple Surgical Specialties

CONCLUSION

Each application is individually conforming to the need determination in the 2018 SMFP for six additional ORs Mecklenburg County as well as individually conforming to all review criteria. However, G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of acute care beds that can be approved by the Healthcare Planning and Certificate of Need Section.

Based upon the independent review of each application and the Comparative Analysis, the following applications are approved as submitted:

- **Project I.D. #F-11612-18/Metrolina Vascular Access Care/Develop one OR**
- **Project I.D. #F-11624-18/Novant Health Huntersville Medical Center/Develop one OR**
- **Project I.D. #F-11619-18/Carolina Center for Specialty Surgery/Develop one OR**
- **Project I.D. #F-11621-18/Atrium Health Pineville/Develop one OR**

As there are only two ORs not approved, **Project I.D. #F-11620-18/Carolinas Medical Center/Develop four ORs** is approved to develop only two of the four ORs it proposed. The AH Pineville application was selected over the CMC application because AH Pineville requested only one OR and CMC requested four ORs. Approving AH Pineville still leaves two ORs that can be approved for CMC.

Project I.D. #F-11612-18 is approved subject to the following conditions.

1. Metrolina Vascular Access Care, LLC and Fresenius Vascular Care Charlotte MSO, LLC shall materially comply with all representations made in the certificate of need application.
2. Metrolina Vascular Access Care, LLC and Fresenius Vascular Care Charlotte MSO, LLC shall develop Metrolina Vascular Access Care, a new ambulatory surgical facility, with one operating room and one procedure room, to be focused on vascular access procedures for patients with end stage renal disease.
3. Upon completion of the project, Metrolina Vascular Access Care shall be licensed for no more than one operating room.
4. Metrolina Vascular Access Care, LLC and Fresenius Vascular Care Charlotte MSO, LLC shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
5. Metrolina Vascular Access Care, LLC and Fresenius Vascular Care Charlotte MSO, LLC shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care, or a comparable accreditation authority within two years following licensure of the facility.
6. For the first three years of operation following completion of the project, Metrolina Vascular Access Care, LLC and Fresenius Vascular Care Charlotte MSO, LLC shall not increase charges more than 5 percent of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.
7. The procedure room shall not be used for procedures that should be performed only in an operating room based on current standards of practice.

8. Procedures performed in the procedure room shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.
9. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Metrolina Vascular Access Care, LLC and Fresenius Vascular Care Charlotte MSO, LLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
    a. Payor mix for the services authorized in this certificate of need.
    b. Utilization of the services authorized in this certificate of need.
    c. Revenues and operating costs for the services authorized in this certificate of need.
    d. Average gross revenue per unit of service.
    e. Average net revenue per unit of service.
    f. Average operating cost per unit of service.
10. Metrolina Vascular Access Care, LLC and Fresenius Vascular Care Charlotte MSO, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

Project I.D. #F-11624-18 is approved subject to the following conditions.

1. Novant Health, Inc. and The Presbyterian Hospital shall materially comply with all representations made in the certificate of need application.
2. Novant Health, Inc. and The Presbyterian Hospital shall develop 12 additional acute care beds and one additional operating room at Novant Health Huntersville Medical Center for a total of 151 acute care beds and seven operating rooms upon completion of this project and Project I.D. #F-11110-15 (relocate 48 acute care beds and one operating room from Novant Health Presbyterian Medical Center).
3. Upon completion of this project and Project I.D. #F-11110-15, Novant Health Huntersville Medical Center shall be licensed for no more than 151 acute care beds and seven operating rooms.
4. Novant Health, Inc. and The Presbyterian Hospital shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
5. Novant Health, Inc. and The Presbyterian Hospital shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.
6. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Novant Health, Inc. and The Presbyterian Hospital shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
    a. Payor mix for the services authorized in this certificate of need.
    b. Utilization of the services authorized in this certificate of need.
    c. Revenues and operating costs for the services authorized in this certificate of need.
    d. Average gross revenue per unit of service.
    e. Average net revenue per unit of service.
    f. Average operating cost per unit of service.

7. Novant Health, Inc. and The Presbyterian Hospital shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

Project I.D. #F-11619-18 is approved subject to the following conditions.

1. Waveco, LLC shall materially comply with all representations made in the certificate of need application.
2. Waveco, LLC shall develop one additional operating room at Carolina Center for Specialty Surgery for a total of three operating rooms upon project completion.
3. Upon completion of the project, Carolina Center for Specialty Surgery shall be licensed for no more than three operating rooms.
4. Waveco, LLC shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
5. For the first three years of operation following completion of the project, Waveco, LLC shall not increase charges more than 5 percent of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.
6. The procedure room shall not be used for procedures that should be performed only in an operating room based on current standards of practice.
7. Procedures performed in the procedure room shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.
8. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Waveco, LLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
    a. Payor mix for the services authorized in this certificate of need.
    b. Utilization of the services authorized in this certificate of need.
    c. Revenues and operating costs for the services authorized in this certificate of need.
    d. Average gross revenue per unit of service.
    e. Average net revenue per unit of service.
    f. Average operating cost per unit of service.
9. Waveco, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

Project I.D. #F-11621-18 is approved subject to the following conditions.

1. Mercy Hospital, Inc., Mercy Health Services, Inc., and The Charlotte-Mecklenburg Hospital Authority shall materially comply with all representations made in the certificate of need application.
2. Mercy Hospital, Inc., Mercy Health Services, Inc., and The Charlotte-Mecklenburg Hospital Authority shall develop one additional operating room at Atrium Health Pineville for a total of 13 operating rooms upon project completion.
3. Upon completion of the project, Atrium Health Pineville shall be licensed for no more than 13 operating rooms.
4. Mercy Hospital, Inc., Mercy Health Services, Inc., and The Charlotte-Mecklenburg Hospital Authority shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
5. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Mercy Hospital, Inc., Mercy Health Services, Inc., and The Charlotte-Mecklenburg Hospital Authority shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
    a. Payor mix for the services authorized in this certificate of need.
    b. Utilization of the services authorized in this certificate of need.
    c. Revenues and operating costs for the services authorized in this certificate of need.
    d. Average gross revenue per unit of service.
    e. Average net revenue per unit of service.
    f. Average operating cost per unit of service.
6. Mercy Hospital, Inc., Mercy Health Services, Inc., and The Charlotte-Mecklenburg Hospital Authority shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

Project I.D. #F-11620-18 is approved subject to the following conditions.

1. The Charlotte-Mecklenburg Hospital Authority shall materially comply with all representations made in the certificate of need application.
2. The Charlotte-Mecklenburg Hospital Authority shall develop no more than two additional operating rooms at Carolinas Medical Center for a total of no more than 62 operating rooms upon completion of this project and Project I.D. #F-11106-15 (relocate 2 ORs).
3. Upon completion of the project, Carolinas Medical Center shall be licensed for no more than 62 operating rooms.
4. The Charlotte-Mecklenburg Hospital Authority shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
5. The Charlotte-Mecklenburg Hospital Authority shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.
6. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, The Charlotte-

Mecklenburg Hospital Authority shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:

a. Payor mix for the services authorized in this certificate of need.
b. Utilization of the services authorized in this certificate of need.
c. Revenues and operating costs for the services authorized in this certificate of need.
d. Average gross revenue per unit of service.
e. Average net revenue per unit of service.
f. Average operating cost per unit of service.

7. The Charlotte-Mecklenburg Hospital Authority shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

COMPARATIVE ANALYSIS FOR ACUTE CARE BEDS

Pursuant to G.S. 131E-183(a)(1) and the 2018 State Medical Facilities Plan, no more than 50 acute care beds may be approved for Mecklenburg County in this review. Because the two applications in this review collectively propose to develop 62 additional acute care beds to be located in Mecklenburg County, both applications cannot be approved for the total number of beds proposed. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

Below is a brief description of each project included in the Acute Care Bed Comparative Analysis.

- Project I.D. #F-11622-18/**Atrium Health Pineville**/Develop 50 additional acute care beds pursuant to the need determination in the 2018 SMFP for a total of 271 acute care beds
- Project I.D. #F-11624-18/**Novant Health Huntersville Medical Center**/Add 12 acute care beds and one OR pursuant to the need determinations in the 2018 SMFP

Conformity with Review Criteria

Both applications are conforming to all applicable statutory and regulatory review criteria. Therefore, both applications are equally effective alternatives with respect to this comparative factor.

Geographic Accessibility

There are 2,238 acute care beds in Mecklenburg County, allocated between seven hospitals, as shown in the table below.

Mecklenburg County Acute Care Hospitals		
Facility	**Location**	**Existing/Approved Beds**
AH Pineville	10628 Park Road, Charlotte	221
AH University City	8800 North Tryon Street, Charlotte	100
CMC-Main (including CMC-Mercy)	1000 Blythe Boulevard, Charlotte 2001 Vail Avenue, Charlotte (CMC-Mercy campus)	1,055
Atrium Health Total		**1,376**
NH Huntersville Medical Center	10030 Gilead Road, Huntersville	91 (+48)
NH Health Matthews Medical Center	1500 Matthews Township Parkway, Matthews	154
NH Health Presbyterian Medical Center	200 Hawthorne Lane, Charlotte	531 (-12)
NH Mint Hill Medical Center	8201 Healthcare Loop, Mint Hill	36 (+14)
Novant Total		**862**
Mecklenburg County Total		**2,238**

Source: Table 5A, 2018 SMFP; applications under review; 2019 LRAs; Agency records.
Note: Numbers in parentheses reflect approved changes in bed inventory.

Four of the seven hospitals are located in Charlotte, one is located in Matthews, one is located in Mint Hill and one is located in Huntersville. Neither **AH Pineville** nor **NHHMC** proposes to expand geographic access to acute care services in Mecklenburg County by developing acute care beds in a new location within the service area. Therefore, because both applicants propose to locate additional

acute care beds at their existing hospitals, the two applications are comparable with regard to geographic access.

Competition

There are 2,238 existing and approved acute care beds located in Mecklenburg County. **AH Pineville** is affiliated with Atrium Health, which currently controls 1,376 of the 2,238 acute care beds in Mecklenburg County or 61.5 percent. **NHHMC** is affiliated with Novant Health, which currently controls 862 of the 2,238 acute care beds in Mecklenburg County or 38.5 percent.

If **AH Pineville's** application is approved, Atrium would control 1,426 of the 2,288 existing or approved acute care beds in Mecklenburg County or 62.3 percent. If **NHHMC's** application is approved, Novant Health would control 874 of the 2,288 existing and approved acute care beds in Mecklenburg County or 38.2 percent.

Therefore, with regard to competition, the application submitted by **NHHMC** is the most effective alternative.

Service to Residents of the Service Area

On page 38, the 2018 SMFP defines the service area for acute care beds as *"…the acute care bed planning area in which the bed is located. The acute care bed planning areas are the single and multicounty groupings shown in Figure 5.1."* Figure 5.1, on page 42, shows Mecklenburg County as its own acute care bed planning area. Thus, the service area for this facility is Mecklenburg County. Facilities may also serve residents of counties not included in their service area. Generally, the application projecting to serve the highest percentage of Mecklenburg County residents is the more effective alternative with regard to this comparative factor since the need determination is for 50 additional acute care beds for Mecklenburg County.

Percent of Mecklenburg County Residents 3rd Full FY	
Applicant	**% of Mecklenburg County Residents**
AH Pineville	48.2%
NHHMC	64.8%

Source: Section C.3 of each applications

As shown in the table above, **NHHMC** projects to serve the highest percentage of Mecklenburg County residents during the third full fiscal year following project completion. Therefore, with regard to projected service to Mecklenburg County residents, **NHHMC** is the most effective alternative.

Access by Underserved Groups

Underserved groups is defined in G.S. 131E-183(a)(13) as follows:

> *"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."*

The following table compares the percentage of services provided by each facility during CY 2017 to women, patients 65 and older and racial minorities.

CY 2017			
Applicant	**Women**	**Age 65+**	**Racial Minorities**
AH Pineville	57.8%	29.0%	37.9%
NHHMC	61.0%	24.5%	53.2%

Source: Section L.1 of each application

As shown in the table above, **AH Pineville** served a higher percentage of persons 65 and older, while **NHHMC** served a higher percentage of women and a higher percentage of racial minorities.

Projected Charity Care

The following table compares projected charity care in the third full fiscal year following project completion for each facility. Generally, the application proposing to provide the most charity care is the most effective alternative with regard to this comparative factor.

Charity Care Projections 3rd Full FY				
Applicant	**Projected Total Charity Care**	**Projected Total Patient Days**	**Charity Care per Patient Day**	**% of Net Revenue**
AH Pineville	$63,541,000	79,525	$799	11.7%
NHHMC	$44,302,000	37,416	$1,184	12.2%

Source: Forms F.3, F.4 and F.5 of each application

As shown in the table above, **AH Pineville** projects the most charity care in dollars. However, **NHHMC** projects the most charity care per patient day and the highest charity care as a percent of net revenue. If approved, AH Pineville would be licensed for 271 beds while NHHMC would be licensed for only 151 beds. The more beds, the more patients and the more patients the more revenues. It would be expected that AH Pineville's charity care dollars would be greater than NHHMC's charity care dollars. Therefore, the application submitted by **NHHMC** is the most effective alternative with regard to access to charity care.

Projected Medicare

The following table compares projected Medicare patients as a percentage of total patients during the third full fiscal year following project completion. Generally, the application proposing the highest percentage of Medicare patients is the more effective alternative with regard to this comparative factor. Due to differences in the pro formas submitted by each applicant, it is not possible to compare them except at the total facility level.

Medicare Projections Entire Facility 3rd Full FY	
	Medicare Patients as a % of Total Patients
AH Pineville	31.0%
NHHMC	39.19%

Source: Section L.3 of each application

As shown in the table above, **NHHMC** projects to serve the highest percentage of Medicare patients in the third full fiscal year following project completion. Therefore, the application submitted by **NHHMC** is the most effective application with respect to service to Medicare patients.

Projected Medicaid

The following table compares projected Medicaid patients as a percentage of total patients during the third full fiscal year following project completion. Generally, the application proposing the highest percentage of Medicaid patients is the more effective alternative with regard to this comparative factor. Due to differences in the pro formas submitted by each applicant, it is not possible to compare them except at the total facility level.

Medicaid Projections Entire Facility 3rd Full FY	
	Medicaid Patients as a % of Total Patients
AH Pineville	16.0%
NHHMC	7.7%

Source: Section L.3 of each application

As shown in the table above, **AH Pineville** projects to serve the highest percentage of Medicaid patients in the third full fiscal year following project completion. Therefore, the application submitted by **AH Pineville** is the most effective application with respect to service to Medicaid patients.

Projected Average Net Revenue per Patient Day

The following table compares projected average net revenue per patient day in the third full fiscal year following project completion for each facility. Generally, the application proposing the lowest average net revenue per patient day is the more effective alternative with regard to this comparative factor to the extent the average reflects a lower cost to the patient or third party payor.

Average Net Revenue per Patient Day 3rd Full FY			
Applicant	**Total # of Patient Days**	**Net Revenue**	**Average Net Revenue per Patient Day**
AH Pineville	79,525	$545,143,000	$6,855
NHHMC	37,416	$363,118,000	$9,705

Source: Section C and Section Q, Forms F.3, F.4, and F.5 of each application

As shown in the table above, **AH Pineville** projects the lowest net revenue per patient day in the third full fiscal year following project completion. Therefore, the application submitted by **AH Pineville** is the most effective application with respect to net revenue per patient day.

Projected Average Operating Expense per Patient Day

The following table compares the projected average operating expense per patient day in the third full fiscal year following project completion for each of the facilities, based on the information provided in the applicants' pro forma financial statements. Generally, the application proposing the lowest average operating expense per patient day is the more effective alternative with regard to this comparative factor to the extent it reflects a more cost effective service which could also result in lower costs to the patient or third party payor.

Average Operating Expense per Patient Day 3rd Full FY			
Applicant	**Total # of Patient Days**	**Operating Expenses**	**Average Operating Expense per Patient Day**
AH Pineville	79,525	$388,013,000	$4,879
NHHMC	37,416	$200,511,000	$5,359

Source: Section C and Section Q, Forms F.3, F.4, and F.5 in each application

As shown in the table above, **AH Pineville** projects the lowest operating expense per patient day in the third full fiscal year following project completion. Therefore, the application submitted by **AH Pineville** is the most effective application with respect to operating expense per patient day.

SUMMARY

The following table lists the comparative factors and states which applicant is the most effective alternative with regard to that particular comparative factor. Note: the comparative factors are listed in the same order they are discussed in the Comparative Analysis, which should not be construed to indicate an order of importance.

Comparative Factor	AH Pineville	NHHMC
Conformity with Review Criteria	Yes	Yes
Geographic Accessibility	Equally Effective	Equally Effective
Competition	Less Effective	**Most Effective**
Service to Residents of the Service Area	Less Effective	**Most Effective**
Access by Underserved Groups		
Women	Less Effective	**Most Effective**
Population Aged 65 and Older	**Most Effective**	Less Effective
Racial Minorities	Less Effective	**Most Effective**
Projected Charity Care	Less Effective	**Most Effective**
Projected Medicare	Less Effective	**Most Effective**
Projected Medicaid	**Most Effective**	Less Effective
Projected Average Net Revenue per Patient Day	**Most Effective**	Less Effective
Projected Average Operating Expense per Patient Day	**Most Effective**	Less Effective

Both applications are conforming to all review criteria, and thus both applications are approvable. However, since collectively they propose a total of 62 acute care beds and the need determination is only 50 beds, only 50 beds can be approved.

As shown in the table above, **NHHMC** was determined to be the more effective alternative for the following six factors:

- Competition
- Service to Residents of the Service Area
- Access by Women
- Access by Racial Minorities
- Projected Charity Care
- Access by Medicare Patients

As shown in the table above, **AH Pineville** was determined to be the more effective alternative for the following four factors:

- Access by the Population Aged 65 and Older
- Access by Medicaid Patients
- Projected Average Net Revenue per Patient Day
- Projected Average Operating Expense per Patient Day

CONCLUSION

Each application is individually conforming to the need determination in the 2018 SMFP for 50 additional acute care beds Mecklenburg County as well as individually conforming to all review criteria. However, G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of acute care beds that can be approved by the Healthcare Planning and Certificate of Need Section.

Based on the independent review of both applications and the Comparative Analysis, Project I.D. #F-11624-18/Novant Health Huntersville Medical Center/Add 12 acute care beds and one OR is approved to develop 12 additional acute care beds. As there are 38 acute care beds not approved, Project I.D. #F-11622-18/Atrium Health Pineville/Add 50 acute care beds is approved to develop only 38 additional acute care beds.

Project I.D. #F-11624-18 is approved subject to the following conditions.

1. Novant Health, Inc. and The Presbyterian Hospital shall materially comply with all representations made in the certificate of need application.
2. Novant Health, Inc. and The Presbyterian Hospital shall develop 12 additional acute care beds and one additional operating room at Novant Health Huntersville Medical Center for a total of 151 acute care beds and seven operating rooms upon completion of this project and Project I.D. #F-11110-15 (relocate 48 acute care beds and one operating room from Novant Health Presbyterian Medical Center).
3. Upon completion of this project and Project I.D. #F-11110-15, Novant Health Huntersville Medical Center shall be licensed for no more than 151 acute care beds and seven operating rooms.

4. Novant Health, Inc. and The Presbyterian Hospital shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
5. Novant Health, Inc. and The Presbyterian Hospital shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.
6. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Novant Health, Inc. and The Presbyterian Hospital shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
    a. Payor mix for the services authorized in this certificate of need.
    b. Utilization of the services authorized in this certificate of need.
    c. Revenues and operating costs for the services authorized in this certificate of need.
    d. Average gross revenue per unit of service.
    e. Average net revenue per unit of service.
    f. Average operating cost per unit of service.
7. Novant Health, Inc. and The Presbyterian Hospital shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

Project I.D. #F-11622-18 is approved subject to the following conditions.

1. Mercy Hospital, Inc., Mercy Health Services, Inc., and The Charlotte-Mecklenburg Hospital Authority shall materially comply with all representations made in the certificate of need application.
2. Mercy Hospital, Inc., Mercy Health Services, Inc., and The Charlotte-Mecklenburg Hospital Authority shall develop 38 additional acute care beds at Atrium Health Pineville for a total of 259 acute care beds upon completion of this project and Project I.D. #F-11361-17 (add 15 acute care beds).
3. Upon completion of the project, Atrium Health Pineville shall be licensed for no more than 259 acute care beds.
4. Mercy Hospital, Inc., Mercy Health Services, Inc., and The Charlotte-Mecklenburg Hospital Authority shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
5. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Mercy Hospital, Inc., Mercy Health Services, Inc., and The Charlotte-Mecklenburg Hospital Authority shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
    a. Payor mix for the services authorized in this certificate of need.
    b. Utilization of the services authorized in this certificate of need.
    c. Revenues and operating costs for the services authorized in this certificate of need.
    d. Average gross revenue per unit of service.
    e. Average net revenue per unit of service.
    f. Average operating cost per unit of service.

6. Mercy Hospital, Inc., Mercy Health Services, Inc., and The Charlotte-Mecklenburg Hospital Authority shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.
7. Mercy Hospital, Inc., Mercy Health Services, Inc., and The Charlotte-Mecklenburg Hospital Authority shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.