

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 29, 2018

Findings Date: March 29, 2018

Team Leader: Gloria C. Hale

Co-Signer: Lisa Pittman

COMPETITIVE REVIEW

Project ID #: F-11433-17

Facility: Novant Health Presbyterian Medical Center

FID #: 943501

County: Mecklenburg

Applicant: The Presbyterian Hospital

Project: Acquire one new fixed MRI scanner pursuant to the Need Determination in the 2017 SMFP

Project ID #: F-11425-17

Facility: Carolinas HealthCare System Pineville

FID #: 110878

County: Mecklenburg

Applicant: Mercy Hospital, Inc.

Project: Acquire a second fixed MRI scanner at Carolinas HealthCare System Pineville pursuant to a Need Determination in the 2017 SMFP

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health

service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NC – The Presbyterian Hospital
C – Mercy Hospital

Need Determination

The 2017 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional fixed MRI scanners by service area. Application of the need methodology in the 2017 SMFP identifies a need for one additional fixed MRI scanner in the Mecklenburg County MRI Service Area. Two applications were submitted to the Healthcare Planning and Certificate of Need Section, each proposing to acquire a fixed MRI scanner for Mecklenburg County.

Policies

There are two policies in the 2017 SMFP that are applicable to this review, *Policy GEN-3: Basic Principles*, and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, both on page 33.

Policy GEN-3 states:

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

Policy GEN-4 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. 131E184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

The Presbyterian Hospital d/b/a Novant Health Presbyterian Medical Center - proposes to acquire one fixed MRI scanner to be installed in the Radiology Department of Novant Health Presbyterian Medical Center (NHPMC) in renovated space. The Presbyterian Hospital owns and operates two fixed MRI scanners in the Radiology Department of NHPMC. The parent entity of The Presbyterian Hospital, Novant Health, Inc. (Novant Health), does not own or operate any mobile MRI scanners in Mecklenburg County.

Need Determination. The Presbyterian Hospital does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2017 SMFP for Mecklenburg County.

Policy GEN-3.

Promote Safety and Quality

The applicant describes how it believes its proposal would promote safety and quality in Section B.9, page 17, Section B.10, pages 18-22, and 28, Section N.2, pages 105-108, Section O.1, page 112-115, and Exhibits B-10, O-2 and O-3. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes its proposal would promote equitable access in Section B.10, pages 23-25, and 28, Section C.10, page 51-53, Section L, pages 95-101, Section N.2, pages 109-111, and Exhibit C-10. The discussion regarding access found in

Criterion (18a) is incorporated herein by reference. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes its proposal would maximize health care value in Section B.9, pages 17-18, Section B.10, pages 25-29, Section Q, pages 125-126, Section K.4, pages 91-92, Section N.2, page 105-106, and in Exhibits F-1 and K-4. However, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum value for resources expended.

Therefore, the application is not consistent with *Policy GEN-3*.

Policy GEN-4.

The proposed capital expenditure for this project is greater than \$2 million and less than \$5 million. The applicant describes how it will assure improved energy efficiency and water conservation in Section B.10, pages 28-29, Section K.4, page 92, and Exhibit B-10. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with *Policy GEN-4*.

Conclusion. The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 not conforming to this criterion for the following reason:

- The applicant does not adequately demonstrate that the proposal is consistent with *Policy GEN-3* for the following reasons:
 - The applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum value for resources expended. The discussion regarding revenues and costs found in Criterion (5) is incorporated herein by reference.
 - The applicant does not adequately demonstrate the need to acquire a fixed MRI scanner. The discussion regarding need found in Criterion (3) is incorporated herein by reference.

Mercy Hospital, Inc. (Mercy Hospital) – proposes to acquire one fixed MRI scanner to be installed at Carolinas HealthCare System Pineville (CHS Pineville) in renovated space adjacent to CHS Pineville’s existing fixed MRI scanner. The ultimate parent entity of Mercy Hospital is The Charlotte-Mecklenburg Hospital Authority (CMHA). Carolinas HealthCare Services (CHS) is owned by CMHA. Carolinas Imaging Services (CIS) is a joint venture of CMHA and Charlotte Radiology. CHS owns seven fixed MRI scanners and CIS owns two fixed MRI scanners for a total of nine CHS/CIS fixed MRI scanners in Mecklenburg County. In addition, CIS owns one mobile MRI scanner which services CIS-Huntersville in Mecklenburg County and St. Luke’s Hospital in Polk County.

Need Determination. Mercy Hospital does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2017 SMFP for Mecklenburg County.

Policy GEN-3.

Promote Safety and Quality

The applicant describes how it believes its proposal would promote safety and quality in Section B.10, pages 27-28, Section N.2, pages 103-104, Section O.1, pages 107-108, and Exhibits B.10-1, B.10-2 and B.10-3. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes its proposal would promote equitable access in Section B.10, pages 28-29, Section C.10, pages 57-58, Section L, pages 96-99, Section N.2, pages 104-105, and Exhibits B.10-4, B.10-5, L.4-1. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes its proposal would maximize health care value in Section B.10, page 29, Section K.4, pages 91-92, Section N.2, page 103, and in the applicant’s pro forma financial statements provided in Section Q. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how 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. Therefore, the application is consistent with *Policy GEN-3*.

Policy GEN-4.

The proposed capital expenditure for this project is greater than \$5 million. The applicant describes how it will assure improved energy efficiency and water conservation in Section B.11, pages 30-31, and Section K-4, page 91-92. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with *Policy GEN-4*.

Conclusion. The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 does not propose to acquire more MRI scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-3* for the following reason:
 - The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2017 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. The discussion regarding revenues and costs found in Criterion (5) is incorporated herein by reference.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-4* for the following reason:
 - The applicant adequately demonstrates how it plans to assure improved energy efficiency and water conservation.

Decision

The applications submitted by The Presbyterian Hospital and Mercy Hospital are conforming to the need determination in the 2017 SMFP for an additional MRI scanner in Mecklenburg County. However, the limit on the number of MRI scanners that may be

approved in this review is one MRI scanner. The application submitted by The Presbyterian Hospital is not conforming to *Policy GEN-3*. The application submitted by Mercy Hospital is conforming to *Policy GEN-3*. Both applications are conforming to *Policy GEN-4*. Therefore, the Mercy Hospital application is conforming to this criterion and The Presbyterian Hospital application is nonconforming to this criterion. 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.

NC – The Presbyterian Hospital
C - Mercy Hospital

The Presbyterian Hospital proposes to acquire one fixed MRI scanner to be installed in the Radiology Department in renovated space near its other two fixed MRI scanners.

Patient Origin

On page 146, the 2017 SMFP defines the service area for a fixed MRI scanner as “*a single county, except where there is no licensed acute care hospital located within the county.*” The definition of the service area for a fixed MRI scanner then explains how a service area is determined when there is no licensed acute care hospital located within the county. For the purpose of this review, however, Mecklenburg County is the service area since it has multiple licensed acute care hospitals. Facilities may also serve residents of counties not included in their service area.

In Section C.2, page 34, the applicant provides the historical patient origin for NHPMC’s MRI service for July 1, 2016 through June 30, 2017. In Section C.3, page 35, the applicant provides the projected patient origin for operating year one (OY1) of the proposed project, Fiscal Year (FY) 2021 (July 1, 2020 – June 30, 2021), and operating year two (OY2), FY2022 (July 1, 2021 – June 30, 2020). Historical and projected patient origin are illustrated in the table below:

**NHPMC's MRI Service
Historical and Projected Patient Origin
Percent of Total Patients**

County	Historical	Projected	
	FY2017 (7/1/16 – 6/30/17)	OY1, FY2021 (7/1/20-6/30/21)	OY2, FY2022 (7/1/21 – 6/30/22)
Mecklenburg	66.8%	66.8%	66.8%
Union	6.9%	6.9%	6.9%
Gaston	4.6%	4.6%	4.6%
York, SC	4.7%	4.7%	4.7%
Cabarrus	2.4%	2.4%	2.4%
Iredell	2.4%	2.4%	2.4%
Lincoln	1.7%	1.7%	1.7%
Lancaster, SC	1.6%	1.6%	1.6%
Rowan	1.6%	1.6%	1.6%
Cleveland	0.8%	0.8%	0.8%
Catawba	0.7%	0.7%	0.7%
Other*	5.7%	5.7%	5.7%
Total	100.0%	100.0%	100.0%

*Other includes patient origin from 36 other counties and the states of Georgia, Tennessee, Virginia and South Carolina. The Project Analyst assumes that South Carolina includes patient origin excluding York and Lancaster. See pages 34 and 36 for complete listing.

In Section C.3, page 36, the applicant provides the assumption used to project patient origin, stating that the projected patient origin is based on historical patient origin for the MRI service at NHPMC. The applicant's assumption is reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 37-49, the applicant explains why it believes the population projected to utilize the proposed fixed MRI scanner needs the proposed fixed MRI scanner at NHPMC. Novant Health is the parent company of NHPMC and of several other hospitals and health care facilities in Mecklenburg County and in other counties of the state. The applicant provides a table, on page 37, that shows that Novant Health's historical fixed MRI scanner volume at all of its acute care sites and all of its outpatient imaging sites that has increased an average of 4.9% from fiscal year 2014 through fiscal year 2017. In addition, the applicant states, on page 39, that its two existing fixed MRI scanners at NHPMC have reached maximum capacity and it expects growth of the MRI service at NHPMC to continue based on historical demand. The applicant summarizes the reasons for expected increases in demand for MRI services at NHPMC, and thus, the need for the proposed fixed MRI scanner, as follows:

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- Higher levels of patient acuity for both inpatient and outpatient MRI services performed at NHPMC [pages 40-41]
- Longer and more complex MRI procedures due to cases involving neurological, cardiac and pediatric patients [see pages 37-41]
- Increasing demand for MRI procedures from the Emergency Department [see pages 41-42]
- Expansion of services in neurosciences, heart and vascular, and pediatric services, along with increases in medical staff for these services who will make referrals for MRI procedures [see pages 42-45; 49]
- Increases in prostate MRI studies [see page 46 and Exhibit 4-C]
- The capability of the proposed MRI scanner to provide MRI procedures of the breast [see page 46]
- Projected population growth in Mecklenburg County, including the 65 and older population [see pages 47-48]

The information in the pages referenced above is reasonable and adequately supported for the following reasons:

- Historical MRI scan volume has grown at all Novant Health's fixed MRI sites,
- Access to MRI services at NHPMC is limited,
- Population growth, particularly among the elderly, is occurring in Mecklenburg County, and
- Demand for MRI services at NHPMC is expected to increase due to increased demand from several service lines.

Projected Utilization of Existing Fixed MRI Scanners and Proposed MRI Scanner at NHPMC

In Section Q, pages 119 – 122, and in Exhibit C-4, the applicant provides three years of historical utilization of fixed MRI Services at NHPMC, Fiscal Years (FY) 2015 – 2017, (7/1/14 through 6/30/17), three years of interim utilization, (FY2018 - FY2020), and three years of projected utilization for operating years (OYs) one through three, (FY2021 – FY2023), illustrated as follows:

**NHPMC
Historical and Projected MRI Services Utilization**

Year	Historical Operating Year (OY) FY2015 7/1/14 – 6/30/15	Historical OY FY2016 7/1/15 – 6/30/16	Historical OY FY2017 7/1/16 – 6/30/17	Interim OY FY2018 7/1/17 – 6/30/18	Interim OY FY2019 7/1/18 – 6/30/19	Interim OY FY2020 7/1/19 – 6/30/20	OY1 FY2021 7/1/20 – 6/30/21	OY2 FY2022 7/1/21 – 6/30/22	OY3 FY2023 7/1/22 – 6/30/23
Number of MRI Scanners	2	2	2	2	2	2	3	3	3
Number of Unweighted Procedures	8,846	9,167	9,469	9,876	10,301	10,744	11,206	11,688	12,190
Number of Weighted Procedures	11,729	12,142	12,573	13,112	13,675	14,264	14,879	15,519	16,186

In Section Q, pages 122-123, and Exhibit C-4, the applicant provides its assumptions for projected utilization of NHPMC’s fixed MRI scanners, summarized as follows:

1. The number of MRI scanners, number of procedures, and number of weighted procedures were provided for the previous three fiscal years, FY2015 – FY2017.
2. The number of weighted procedures for FY2015 – FY2017 were based on the number of inpatient procedures without contrast and inpatient procedures with contrast, using the weighting factors listed in the 2017 SMFP for MRI scanners.
3. The number of weighted procedures for the interim years (FY2018 – FY2020) was determined as follows:

The historical MRI volume for FY2017 was broken down by patient scan category, illustrated in the following table:

**NHPMC’s Historical MRI Utilization by Patient Scan Category
FY2017**

	Number of Procedures	Percent of Total
Total Unweighted Procedures	9,469	100%
Inpatient Procedures	3,062	32.3%
Outpatient Procedures	6,407	67.7%
Procedures with Contrast	4,698	49.6%
Procedures without Contrast	4,771	50.4%

4. Next, the percentages for inpatient procedures and procedures with contrast for FY2017 were applied to the projected number of unweighted MRI procedures for each of the interim years. The number of weighted MRI procedures for each interim year were then determined by applying the formula below:

$$\text{(Inpatient Procedures} \times 0.4 \text{ weighting factor)} + \text{(Procedures with Contrast} \times 0.4 \text{ weighting factor)} + \text{Procedures without Contrast} \text{ [Total Unweighted Volume]} = \text{Weighted MRI Procedures}$$

- The projected utilization for the first three operating years (FY2021 – FY2023) was based on the MRI projections outlined in Section Q and include the addition of the proposed MRI scanner.

However, the applicant does not adequately demonstrate that its projected utilization is reasonable and adequately supported. In Section Q, pages 122-123, the applicant states that it uses historical MRI utilization to determine the projected number of *weighted* [emphasis added by the Agency] MRI procedures for the interim project years and the first three operating years of the project. As stated in the applicant's assumption number four, on page 122, the applicant uses historical percentages by patient [scan] category and applies these to the projected volume for the interim period to determine the weighted MRI volume. However, weighted MRI volume is necessarily based on unweighted MRI volume. The applicant neglects to state its methodology and assumptions for projecting unweighted MRI volume. Therefore, the Agency cannot determine if the applicant's projected MRI volume for the interim project years and projected operating years is reasonable or adequately supported. In addition, the applicant states, on page 10 of its response to comments received at the public hearing,

"...a portion of the assumptions related to the utilization methodology were inadvertently left out during the final copying process."

The applicant does provide its methodology for projecting MRI volume in its written response to comments. However, this information was not included in NHPMC's application, is an amendment to the application pursuant to 10A NCAC 14C .0204, and cannot be used by the Agency to determine conformance or nonconformance with statutory criteria. The Rule, 10A NCAC 14C .0204, Amendment to Applications states, "*An applicant may not amend an application.*" The applicant's written response to comments was submitted to the Team Leader [Project Analyst at the time] at the public hearing for this review that was conducted on December 19, 2017, after the application was received by the Agency.

Historical Utilization of Novant Health's Existing Fixed MRI Scanners

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In Section C, page 56, the applicant provides a table summarizing the total weighted MRI scanner volumes for each of Novant Health’s facilities with fixed MRI scanners in Mecklenburg County, from July 1, 2016 – June 30, 2017, summarized as follows:

**Novant Health Fixed MRI Scanner Volume
July 1, 2016 through June 30, 2017**

Acute Care Facilities*	NHPMC	NHCOH	NHMMC	NHHMC	Totals
Number of MRI Scanners	2	1	1	1	5
Total MRI Volume	9,469	2,794	7,072	6,963	26,298
Total Weighted MRI Volume	12,573	3,144	8,614	8,205	32,536
Outpatient Imaging Sites	Ballantyne	SouthPark	Museum		Totals
Number of MRI Scanners	1	1	1		3
Total MRI Volume	2,556	4,099	2,568		9,223
Total Weighted MRI Volume	2,831	4,395	2,948		10,174

*NHCOH is Novant Health Charlotte Orthopedic Hospital, NHMMC is Novant Health Matthews Medical Center, and NHHMC is Novant Health Huntersville Medical Center.

In Section C, pages 55-56, the applicant states that the average weighted fixed MRI scanner volume for its fixed MRI scanners in Mecklenburg County, from July 1, 2016 through June 30, 2017, was 5,339. This is illustrated as follows:

**Novant Health
Average Annual Fixed MRI Scanner Volume
July 1, 2016 through June 30, 2017**

	Total Weighted MRI Volume	Total Number of Fixed MRI Scanners	Average Weighted Fixed MRI Volume
Acute Care Facilities	32,536		
Outpatient Imaging Sites	10,174		
Total	42,710	8	5,339

Therefore, the applicant adequately demonstrates that its existing fixed MRI scanners in Mecklenburg County performed an average of at least 3,328 weighted MRI procedures in the most recent 12 month period for which it had data, as required in 10A NCAC 14C .2703(b)(1).

Projected Utilization of Novant Health’s Existing, Approved, and Proposed Fixed MRI Scanners

In Section C.4, page 37, the applicant provides a table of the historical, total unweighted fixed MRI volume and percentages of annual growth for all of Novant Health’s acute care facilities combined and all of its outpatient imaging facilities combined, from FY2014 through FY2017, illustrated as follows:

**Novant Health’s Fixed MRI Sites
Historical Unweighted MRI Volume**

Facility Type	7/1/13 – 6/30/14	7/1/14 – 6/30/15	7/1/15 – 6/30/16	7/1/16 – 6/30/17	Average Growth
Acute Care	23,202	24,615	24,924	26,298	
Percent Change		6.1%	1.3%	5.5%	4.3%
Outpatient Imaging	7,601	7,905	8,060	9,269	
Percent Change		4.0%	2.0%	15.0%	7.0%
Total	30,803	32,520	32,984	35,567	
Percent Change		5.6%	1.4%	7.8%	4.9%

Source: Novant Health internal data for stated time periods using July 1 – June 30.

In addition, the applicant provides a table in Section C, page 56, of historical MRI volumes for each of Novant Health’s acute care facilities and outpatient sites with fixed MRI scanners, for the period July 1, 2016 – June 30, 2017. The table on page 56 includes MRI volumes with contrast and without contrast, and weighted totals for each acute care facility and outpatient site. On page 56, the applicant states how it calculated the historical average weighted MRI volume for all of Novant Health’s fixed MRI scanners in Mecklenburg County, which is equal to 5,339.

Next, the applicant states, in Section C, page 57,

“Novant Health projects its annual average weighted MRI scan volume for each existing, approved, and proposed fixed MRI scanner owned and operated by Novant Health in Mecklenburg County to be 5,006 weighted MRI procedures per fixed MRI scanner in Project Year 3. This exceeds the threshold of 4,805 weighted MRI procedures per scanner.”

On page 57, the applicant states that utilization projections and assumptions can be found in Section Q of the application. However, in Section Q, pages 119-123, the applicant only provides projected utilization and assumptions for its two fixed MRI scanners and one proposed, fixed MRI scanner at NHPMC and does not provide its methodology, assumptions, or projected utilization for Novant Health's other existing and approved fixed MRI scanners it owns and operates at its other acute care facilities and outpatient sites in Mecklenburg County. Novant Health has two approved fixed MRI scanners that are not yet operational. Novant Health received approval, through a Declaratory Ruling issued by the Agency on August 17, 2015, to relocate an approved, fixed MRI scanner that has not been developed yet, from Novant Health Matthews Medical Center (NHMMC) to Novant Health Mint Hill Medical Center (NHMHMC). Likewise, Novant Health received approval through a settlement agreement to permanently locate and convert a mobile MRI scanner to a fixed MRI scanner at Novant Health Huntersville Medical Center (NHHMC). The settlement agreement states that NHHMC cannot operate the MRI scanner as a fixed MRI scanner until April 9, 2018.

However, projected utilization is not reasonable and adequately supported for the following reasons:

- The applicant does not provide its methodology, assumptions, or projected utilization for all of Novant Health's existing and approved fixed MRI scanners. Therefore, the applicant's average annual weighted MRI volume of 5,006 MRI procedures per fixed MRI scanner in project year three is not reasonable and adequately supported.

Therefore, the applicant does not adequately demonstrate that the annual average weighted MRI scan volume for each existing, approved, and proposed fixed MRI scanner owned and operated by Novant Health in Mecklenburg County will be at least 4,805 weighted MRI procedures in the third year of operation following completion of the proposed project, pursuant to 10A NCAC 14C .2703(b)(3).

Access

In Section C.10, page 51, the applicant states that NHPMC "*will provide services to all persons regardless of race, sex, age, religion, creed, disability, national origin or ability to pay, including the medically indigent, the uninsured, and the under insured.*" The applicant discusses Novant Health's policies to ensure access to services for the underserved on pages 51-53. In addition, the applicant provides copies of Novant Health's Patient Non-Discrimination Statement, Patient Bill of Rights and Responsibilities, and Charity Care, Uninsured Discount, Catastrophic Settlement policies in Exhibit C-10.

In Section L.1, page 95, the applicant provides percentages of categories of underserved populations NHPMC served in FY2017 compared to the percentages of these populations in Mecklenburg County on July 1, 2016, summarized as follows:

**NHPMC
 Service to Underserved Populations**

	Percentage Served FY2017	Percentage in Mecklenburg County July 1, 2016
Women	60.9%	51.2%
Age 65 and older	23.5%	10.6%
Racial Minorities*	53.2%	41.0%

*Includes non-white age groups.

On page 95, the applicant states that the percentages of underserved populations it has served exceeded the percentages of those populations residing in Mecklenburg County.

In Section L.1, page 96, and Section L.3, page 98, the applicant provides the historical payor mix for calendar year (CY) 2016 and projected payor mix during the second full fiscal year (FY) of operation following completion of the project, as illustrated in the following table:

**NHPMC
 Inpatient and Outpatient MRI Services**

Payor Source	Historical MRI Cases, Calendar Year (CY) 2016	Projected MRI Cases, FY2022
Self-Pay/Charity	5%	5%
Medicare*	41%	41%
Medicaid*	11%	11%
Insurance*	41%	41%
Other	2%	2%
Total	100%	100%

*Includes respective managed care plans, i.e. Medicare includes Medicare Managed Care Plans

The applicant provides its assumptions for the projected payor mix for NHPMC's MRI cases in Section L.3, pages 97-98, stating that payor mix in the future is based on historical payor mix and assumes it will not change.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 not conforming to this criterion for the following reasons:

- Projected utilization is not reasonable and is not adequately supported.
- The applicant does not adequately demonstrate that the existing, approved, and proposed fixed MRI scanners it owns and locates in Mecklenburg County are reasonably expected to perform an average annual of 4,805 weighted MRI procedures in the third year of operation following completion of the project, as required by 10A NCAC 14C .2703(b)(3).

Mercy Hospital

Mercy Hospital proposes to acquire one fixed MRI scanner to be installed in renovated space at CHS Pineville adjacent to the hospital's existing fixed MRI scanner.

Patient Origin

On page 146, the 2017 SMFP defines the service area for a fixed MRI scanner as “*a single county, except where there is no licensed acute care hospital located within the county.*” The definition of the service area for a fixed MRI scanner then explains how a service area is determined when there is no licensed acute care hospital located within the county. For the purpose of this review, however, Mecklenburg County is the service area since it has multiple licensed acute care hospitals. Facilities may serve residents of counties not included in their service area.

In Section C.2, pages 35-36, the applicant provides its current and projected patient origin for MRI services at CHS Pineville, summarized as follows:

**CHS Pineville
Current and Projected MRI Services**

County	Current Patient Origin* CY2016	Projected Patient Origin** CY2019-CY2021
Mecklenburg	46.7%	46.7%
York, SC	28.6%	28.6%
Lancaster, SC	10.0%	10.0%
Union	6.8%	6.8%
Gaston	1.9%	1.9%
Other***	6.0%	6.0%
Total	100.0%	100.0%

*Includes fixed and mobile MRI procedures.

**Includes fixed MRI procedures only.

***Other includes other counties in the state and other states. See page 35 for a complete listing.

In Section B.3, page 37, the applicant provides the assumptions and methodology used to project its patient origin, stating that it does not expect projected patient origin to change from historical patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, page 37-55, the applicant explains why it believes the population projected to utilize the proposed MRI scanner needs the proposed fixed MRI scanner at CHS Pineville, summarized as follows:

- 2017 SMFP’s need determination for one additional fixed MRI scanner in Mecklenburg County. [see pages 37-39]
- Growth in MRI utilization throughout Carolinas HealthCare System (CHS) and Carolinas Imaging Services (CIS), is occurring primarily due to increases in physician recruitment, and the development of cancer and cardiology services. [see pages 39-43]
- The compound average growth rate (CAGR) for CHS Pineville’s MRI volume, from CY2014 through CY2017 annualized was 2.5% and it had the highest weighted MRI procedures per fixed MRI unit in the state for federal fiscal year 2016. [see pages 44-45, 48]
- CHS Pineville operates its existing fixed MRI scanner on extended hours to accommodate demand - 19 hours a day, Monday through Saturday, and 10 hours on Sunday, and contracts with mobile MRI services each Monday and every other Wednesday. [page 46]

- CHS Pineville’s use of contracted mobile MRI services to accommodate demand has drawbacks in quality, safety, cost, and efficiency. [page 46]
- CHS Pineville’s inpatient MRI volume has grown at a higher rate than its outpatient MRI volume, from CY2014-CY2017 annualized. [page 48]
- CHS Pineville’s growth in MRI volume for emergency and observation patients, from CY2014-CY2017 annualized. [page 49]
- Constraints in serving patients needing MRI procedures requiring sedation across all CHS facilities, but especially CHS Pineville, due to high MRI utilization. [page 50]
- Projected growth in the overall population and in persons aged 65 and older in Mecklenburg County, and in the overall population in the southern Charlotte region. [pages 53-55]

Historical MRI Utilization CHS Pineville

In Section Q, Form C, page 1, the applicant provides the total historical utilization of CHS Pineville’s MRI services, and respective compound annual growth rates (CAGRs), illustrated as follows:

**CHS Pineville
Historical MRI Utilization**

	CY2014	CY2015	CY2016	CY2017 Annualized*	CAGR
Outpatient No Contrast	4,164	4,310	4,210	4,505	2.7%
Outpatient With Contrast	1,608	1,833	1,996	1,483	-2.7%
Inpatient No Contrast	1,872	1,893	2,006	2,129	4.4%
Inpatient With Contrast	431	405	506	559	9.0%
Total	8,075	8,441	8,718	8,676	2.4%
Total Weighted	9,812	10,255	10,724	10,568	2.5%

*Based on July year-to-date data.

In Section C.4, page 46, the applicant states that a contracted mobile MRI scanner is utilized at CHS Pineville each Monday and every other Wednesday to supplement MRI services capacity. The applicant further states, on page 46, that the mobile MRI scanner was also used as a temporary replacement for the fixed MRI scanner when it suffered a catastrophic failure. In Section Q, page 1, the applicant states that the temporary replacement of the fixed MRI scanner with the mobile MRI scanner was utilized from December 12, 2016 to July 7, 2017. The applicant states, in Section C.4, page 46, that its MRI utilization was constrained in CY2017 due to the additional time it took to undertake each mobile MRI procedure, given patient transport time to and from the hospital building to the mobile MRI unit housed in a truck adjacent to the hospital.

Projected MRI Utilization at CHS Pineville

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The applicant states, in Section Q, page 2, that CHS Pineville’s projected utilization will increase by 1.2% annually, which is half of 2.4%, the CAGR for total historical utilization for CY2014 through CY2017 annualized. In addition, the applicant states that it assumes the distribution of MRI procedures by category, i.e. inpatient without contrast, inpatient with contrast, outpatient without contrast, outpatient with contrast, will be equal to the distribution of MRI procedures by category for CY2017 annualized. The applicant further states, on page 2, that the application of this distribution is reasonable even though patient acuity has increased historically. The applicant provides its total projected MRI utilization, including both fixed and mobile MRI services, from page 2, as follows:

	CY2017 Annualized*	Percent Distribution	CY2018**	CY2019	CY2020	CY2021	CAGR
Outpatient No Contrast	4,505	51.9%	4,560	4,615	4,671	4,727	1.2%
Outpatient With Contrast	1,483	17.1%	1,501	1,519	1,537	1,556	1.2%
Inpatient No Contrast	2,129	24.5%	2,155	2,181	2,207	2,234	1.2%
Inpatient With Contrast	559	6.4%	566	572	579	586	1.2%
Total	8,676		8,781	8,887	8,995	9,104	1.2%
Total Weighted	10,568		10,696	10,825	10,956	11,089	1.2%

CHS Pineville Total Projected MRI Utilization

*Based on July year-to-date data

**Includes Alliance mobile MRI scanner utilization

The applicant states, on page 2, that it will cease utilizing the mobile MRI scanner once the proposed fixed MRI scanner becomes operational and is providing sufficient capacity. The applicant states, on page 2, that due to the limited capacity of its existing fixed MRI scanner, the applicant projects that in CY2018 the existing fixed MRI scanner will perform all inpatient MRI procedures, the outpatient MRI procedures performed on the existing fixed MRI scanner will remain constant, and the Alliance mobile MRI scanner will perform all of the remaining outpatient MRI procedures. In Section Q, page 3, the applicant states that when the proposed fixed MRI scanner becomes operational in CY2019, all of the CHS Pineville’s MRI procedures will be performed on its two fixed MRI scanners. The applicant provides tables illustrating these projections in Section Q, page 3.

The applicant provides CHS Pineville’s projected average, weighted fixed MRI utilization for interim year CY2018, and for the first three operating years of the project, CY2019 through CY2021, in a table in Section Q, page 3, summarized as follows:

**CHS Pineville
Projected Utilization of Fixed MRI Services, CY2018 – CY2021**

	CY2018	CY2019	CY2020	CY2021
Total MRI Procedures	8,110	8,887	8,995	9,104
Total Weighted MRI Procedures	9,892	10,825	10,956	11,089
Fixed MRI Units	1	2	2	2
Average per Fixed MRI Unit	9,892	5,413	5,478	5,545

The applicant states, as illustrated above, that the average weighted number of MRI procedures per fixed MRI scanner in the proposed project’s third year of operation will be 5,545 (11,089/2).

Historical Utilization of CHS/CIS’ Existing Fixed MRI Scanners

In Section C.11, page 62, the applicant provides a table illustrating the historical utilization for each CHS/CIS facility’s fixed MRI scanners from August 2016 through July 2017, summarized as follows:

**CHS/CIS Fixed MRI Scanner Volume by Facility
August 2016 through July 2017**

	Total Unweighted MRI Procedures	Total Weighted MRI Procedures	Number of MRI Scanners	Total Average Weighted MRI Procedures
CHS Pineville	8,068	9,894	1	
CMC	18,802	25,576	4	
CMC-Mercy	5,281	6,581	1	
CHS University	5,569	6,788	1	
CIS-Ballantyne	3,988	4,443	1	
CIS-SouthPark	3,670	4,308	1	
Total	45,378	57,589	9	6,399

The applicant states, on page 62, that the average annual weighted MRI procedures for all of its fixed MRI scanners in Mecklenburg County was 6,399 from August 2016 through July 2017.

Therefore, the applicant adequately demonstrates that its existing fixed MRI scanners in Mecklenburg County performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which it had data, as required in 10A NCAC 14C .2703(b)(1).

Projected Utilization of CHS/CIS’ Existing, Approved, and Proposed Fixed MRI Scanners

In Exhibit C.11-1, pages 1-13, the applicant provides the assumptions and methodology used to project the average annual MRI procedures for its existing, approved and proposed fixed MRI scanners in Mecklenburg County, summarized as follows:

The applicant uses the following approach to determine projected utilization for each CHS and CIS facility with an existing or approved fixed MRI scanner, with the exception of CIS-Huntersville:

- Use historical utilization to determine the CAGR,
- Project utilization based on one-half the historical CAGR,
- Project weighted MRI volume based on historical distribution by category, i.e. inpatient no contrast, outpatient with contrast, etc., and
- Apply any anticipated future shifts of MRI volume

To project CMC’s utilization of its four existing fixed MRI scanners, the applicant applies a CAGR of 1.6% annually, which is one-half of its historical CAGR, and subtracts projected shifts in MRI volume to CIS-Huntersville (Project ID #F-11182-16), CIS mobile MRI scanner (Project ID #F-11182-16), and CMC’s iMRI scanner (Project ID #F-11210-16), as stated in Exhibit C.11-1, pages 4-8. On page 8, the applicant provides its projected utilization for CMC, summarized as follows:

CMC Projected MRI Utilization

	CY2018	CY2019	CY2020	CY2021
Baseline Total Weighted MRI Procedures	26,031	26,441	26,856	27,279
Total Weighted MRI Procedures After Shifts	23,009	22,985	23,301	23,690
Number of Fixed Units	4	4	4	4
Average Weighted MRI Procedures per MRI Scanner	5,752	5,746	5,825	5,923

To project CMC-Mercy’s utilization of its one fixed MRI scanner, the applicant applies a CAGR of 1.2% annually, which is one-half of its historical CAGR, and subtracts shifts of MRI volume to CIS-Huntersville (Project ID #F-11182-16), as stated in Exhibit C.11-1, pages 9-10, summarized as follows:

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CMC-Mercy Projected MRI Utilization

	CY2018	CY2019	CY2020	CY2021
Baseline Total Weighted MRI Procedures	6,599	6,678	6,758	6,838
Total Weighted MRI Procedures After Shifts	6,421	6,465	6,506	6,570
Number of Fixed Units	1	1	1	1
Average Weighted MRI Procedures per MRI Scanner	6,421	6,465	6,506	6,570

To project CHS University’s utilization of its one fixed MRI scanner, the applicant applies a CAGR of 2.1% annually, which is one-half of its historical CAGR, and subtracts shifts to CIS-Huntersville (Project ID #F-11182-16), as stated in Exhibit C.11-1, pages 10-11, summarized as follows:

CHS University Projected MRI Utilization

	CY2018	CY2019	CY2020	CY2021
Baseline Total Weighted MRI Procedures	6,958	7,102	7,248	7,398
Total Weighted MRI Procedures After Shifts	6,611	6,686	6,757	6,875
Number of Fixed Units	1	1	1	1
Average Weighted MRI Procedures per MRI Scanner	6,611	6,686	6,757	6,875

To project CIS-Ballantyne’s utilization of its one fixed MRI scanner, the applicant applies a CAGR of 6.6% annually, which is one-half of its historical CAGR, as stated in Exhibit C.11-1, page 11. The applicant states there are no expected shifts in utilization. Projected utilization for CIS-Ballantyne is summarized as follows from page 12:

CIS-Ballantyne Projected MRI Utilization

	CY2018	CY2019	CY2020	CY2021
Number of Fixed Units	1	1	1	1
Average Weighted MRI Procedures per MRI Scanner	4,770	5,087	5,425	5,786

To project CIS-South Park’s utilization of its one fixed MRI scanner, the applicant applies a CAGR of 5.7% annually, which is one-half of its historical CAGR, as stated in Exhibit C.11-1, page 12. The applicant states there are no expected shifts in utilization. Projected utilization for CIS-South Park is summarized as follows from page 12:

CIS-South Park Projected MRI Utilization

	CY2018	CY2019	CY2020	CY2021
Number of Fixed Units	1	1	1	1
Average Weighted MRI Procedures per MRI Scanner	4,660	4,926	5,208	5,505

To project CIS-Huntersville’s utilization of its one approved, fixed MRI scanner, the applicant states, in Exhibit C.11-1, page 2, that it uses the same assumptions it used in Project ID #F-11182-16. In Exhibit C.11-2, page 54, the applicant provides a table of CIS-Huntersville’s historical MRI volume performed on a CIS mobile MRI scanner, from CY2013 through CY2015, and also includes CAGR’s for outpatient no contrast MRI procedures, outpatient with contrast MRI procedures, total unweighted MRI procedures and total weighted MRI procedures. To project weighted MRI procedures at CIS Huntersville, the applicant states, on page 55, it applies one-quarter of the CAGR for outpatient no contrast MRI procedures and one-quarter of the CAGR for outpatient with contrast MRI procedures to CIS-Huntersville’s MRI volumes in CY2015 through CY2020. In Exhibit C.11-1, pages 2-3, the applicant states that shifted MRI procedures from CMC, CMC-Mercy, and CHS University, also discussed in Project ID #F-11182-16, were added to the projected MRI volumes. The applicant provides tables in Exhibit C.11-1, pages 2-4, illustrating the projected MRI shift from each of three hospitals, CMC, CMC-Mercy, and CHS University, to CIS-Huntersville. CIS-Huntersville’s projected utilization is summarized as follows:

CIS-Huntersville Projected MRI Utilization

	CY2018	CY2019	CY2020	CY2021
Number of Fixed Units	1	1	1	1
Average Weighted MRI Procedures per MRI Scanner	4,359	4,782	5,242	5,584

The applicant provides a table summarizing projected utilization for each of the CHS and CIS’ fixed MRI scanners in Exhibit C.11-1, page 13, as follows:

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CHS/CIS Projected Weighted MRI Procedures

	CY2018	CY2019	CY2020	CY2021
CHS Pineville	9,892	10,825	10,956	11,089
CMC	23,009	22,985	23,301	23,690
CMC-Mercy	6,421	6,465	6,506	6,570
CHS University	6,611	6,686	6,757	6,875
CIS-Ballantyne	4,770	5,087	5,425	5,786
CIS-South Park	4,660	4,926	5,208	5,505
CIS-Huntersville	4,359	4,782	5,242	5,584
Total	59,722	61,758	63,396	65,100
# of Fixed Units	10*	11^	11	11
Average per Unit	5,972	5,614	5,763	5,918

*CHS/CIS currently operates nine fixed MRI units in Mecklenburg County and CIS has been approved to develop one additional fixed MRI unit at CIS-Huntersville (Project ID #F-11182-16), thereby making the total number of fixed MRI scanners in CY2018 equal to 10.
^The proposed additional fixed MRI scanner at Mercy Hospital will be the 11th fixed MRI scanner owned and operated by CHS/CIS.

The average annual utilization of CHS/CIS’ existing, approved and proposed fixed MRI scanners located in Mecklenburg County are reasonably expected to perform 5,918 weighted MRI procedures in the third year of operation following completion of the proposed project.

Therefore, the applicant adequately demonstrates that CHS/CIS’ existing, approved, and proposed fixed MRI scanners are reasonably expected to perform more than 4,805 weighted MRI procedures in Mecklenburg County in the third year of operation following the completion of the proposed project, as required in 10A NCAC 14C .2703(b)(3).

Historical Utilization of CIS’ Mobile MRI Scanner

The applicant states, in Section C.11, page 63, that CIS operates one mobile MRI scanner in Mecklenburg County. In Section C.11, page 63, the applicant provides the historical MRI utilization for its CIS mobile MRI scanner from August 2016 to July 2017, which serves CIS-Huntersville five days per week and St. Luke’s Hospital in Polk County one day per week, summarized as follows:

**CIS Mobile MRI Utilization
August 2016 through July 2017**

	CIS-Huntersville	St. Luke's Hospital	Total
Total MRI Procedures	2,817	815	3,632
Total Weighted MRI Procedures	3,189	877	4,066

The applicant states its CIS mobile MRI scanner performed 4,066 weighted MRI procedures from August 2016 through July 2017. Therefore, the applicant demonstrates that its existing mobile MRI scanner which it operates in Mecklenburg County performed over 3,328 weighted MRI procedures in the most recent 12 month period for which it had data, as required in 10A NCAC 14C .2703(b)(2).

Projected Utilization of CIS' Mobile MRI Scanner

In Exhibit C.11-1, pages 5-8, 13-15, the applicant provides its methodology and assumptions for projecting utilization of the one CIS mobile MRI scanner it owns and operates in Mecklenburg County, summarized as follows:

In Exhibit C.11-1, page 13, the applicant states that its mobile MRI scanner, operating for five days per week at CIS-Huntersville, will be replaced by a fixed MRI scanner (Project I.D. #F-11182-16) in January 2018. At that time, the mobile MRI scanner will no longer operate at CIS-Huntersville and will begin operating for three days per week at CMC. In Exhibit C.11-1, page 5, the applicant states that the mobile MRI scanner will be utilized at CMC for scheduled outpatient MRI procedures which will, in turn, address the need for increased capacity for inpatient MRI procedures at CMC.

Step 1:

The applicant states, in Exhibit C.11-1, pages 5-6, that the mobile MRI scanner performed 2,465 MRI procedures annually for five days per week or 493 MRI procedures each of the five days per week. On page 6, the applicant states that the mobile MRI scanner will perform 493 MRI procedures per day, three days a week at CMC, for a total of 1,479 outpatient procedures annually.

Step 2:

The applicant applies CMC's historical, CY2017, outpatient contrast/no contrast distribution to the projected 1,479 mobile MRI procedures, as illustrated in Exhibit C.11-1, page 6, for a total of 1,820 weighted mobile MRI procedures for each of the project years, CY2018 through CY2021 as summarized in a table provided in Exhibit C.11-1, page 14.

The applicant's projected number of weighted mobile MRI procedures for CY2018 through CY2021 to be performed at CMC is reasonable and adequately supported as follows:

The applicant states, in Exhibit C.11-1, page 5, that the number of total weighted procedures for CMC's four fixed MRI scanners was 25,576, or 6,394 weighted procedures per fixed MRI scanner in the most recent 12 month period. Therefore, CMC exceeded the performance standard threshold of the average annual number of weighted MRI procedures per fixed MRI scanner of 4,805 for Mecklenburg County, demonstrating there was sufficient MRI volume for a mobile MRI scanner. Furthermore, in Exhibit C.11-1, page 4, the applicant states that from CY2014 through CY2017 annualized, the CAGR for CMC's total weighted MRI procedures was 4.0%. However, the applicant states it applies one-half the CAGR annually, or 1.6%, to project MRI utilization and uses the CY2017 distribution by type of MRI scan, i.e. contrast/no contrast, etc. to project weighted MRI procedures for CY2018. In Exhibit C.11-1, page 8, the applicant provides a table summarizing projected shifts of MRI procedures from CMC to CIS-Huntersville (Project ID #F-11182-16), the CIS mobile MRI (Project ID #F-11182-16), and the iMRI scanner (Project ID #F-11210-16) to be located at CMC, from CY2018 through CY2021. CMC is projected to provide an average of 5,923 weighted MRI procedures per fixed MRI scanner in CY2021 after all shifted MRI procedures, including those shifted to the CIS mobile MRI scanner, which is above the performance standard of 4,805 weighted MRI procedures. Therefore, the Agency concludes that the applicant adequately demonstrates that there will be sufficient MRI volume at CMC to accommodate the projected mobile MRI volume to be provided at CMC three days per week.

Step 3:

In Exhibit C.11-1, page 14, the applicant states that the mobile MRI scanner will provide services two days per week at Carolinas Neurological Clinic (CNC) which had formerly been serviced by the CIS mobile MRI scanner in federal fiscal year (FFY) 2015 and FFY2016 until early May of 2016. The applicant states that Alliance Healthcare Services, a contracted MRI service provider, currently provides mobile MRI services at CNC, however the number of MRI procedures it has performed at CNC has not been published in the SMFP. The applicant states, on page 14, that its CIS mobile MRI scanner performed 1,152 weighted MRI procedures at CNC in FY2015 and 986 weighted MRI procedures in FY2016 through May 5, 2016. The applicant projects, on page 14, that its mobile MRI scanner will perform 1,152 weighted MRI procedures each year from CY2018 through CY2021.

The Agency concluded that this projection is reasonable and conservative given that the CAGR for weighted MRI volume from FY2013 through FY2015 was 16.9%. Application of the CAGR of 16.9% results in 1,347 weighted MRI procedures in FY2016 and 1,575 weighted MRI procedures in FY2017.

Step 4:

In Exhibit C.11-1, pages 14-15, the applicant states that its mobile MRI scanner will continue to serve St. Luke's Hospital in Polk County one day per week and assumes no

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growth in the number of weighted MRI procedures from the most recent 12 months of utilization. The applicant states that the total number of weighted mobile MRI procedures at St. Luke's Hospital is projected to be 877 each year from CY2018 through CY2021.

The Agency concluded that this projection is reasonable and conservative because based on application of the CAGR for weighted MRI procedures for the mobile MRI scanner used at St. Luke's Hospital, from FY2013 through FY2016, the number of weighted MRI procedures would equal 1,371.

Step 5:

In Exhibit C.11-1, page 15, the applicant provides a table summarizing projected utilization of its CIS mobile MRI scanner, as follows:

**CIS Mobile MRI Unit
Projected Weighted MRI Procedures by Facility**

	CY2018	CY2019	CY2020	CY2021
CMC Weighted MRI Procedures	1,820	1,820	1,820	1,820
CNC Weighted MRI Procedures	1,152	1,152	1,152	1,152
St. Luke's Hospital Weighted MRI Procedures	877	877	877	877
Total Weighted MRI Procedures	3,848	3,848	3,848	3,848

The assumptions and methodology used by the applicant for projecting its mobile MRI scanner utilization in Mecklenburg County during the proposed project's interim year of development, CY2018, and for each of the first three operating years following completion of the proposed project, CY2019 through CY2021, are reasonable and adequately supported.

Therefore, the applicant adequately demonstrates that the one mobile MRI scanner it owns and operates in Mecklenburg County is reasonably expected to perform at least 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project, as required in 10A NCAC 14C .2703(b)(5).

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

- The applicant adequately demonstrates that its existing fixed MRI scanners in Mecklenburg County performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which it had data, as required in 10A NCAC 14C .2703(b)(1).
- The applicant adequately demonstrates that CHS/CIS' existing, approved, and proposed fixed MRI scanners are reasonably expected to perform more than 4,805 weighted MRI procedures in Mecklenburg County in the third year of operation following the completion of the proposed project, as required in 10A NCAC 14C .2703(b)(3).

- The applicant adequately demonstrates that its existing mobile MRI scanner which it operates in Mecklenburg County performed over 3,328 weighted MRI procedures in the most recent 12 month period for which it had data, as required in 10A NCAC 14C .2703(b)(2).
- The applicant adequately demonstrates that the one mobile MRI scanner it owns and operates in Mecklenburg County is reasonably expected to perform at least 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project, as required in 10A NCAC 14C .2703(b)(5).

Access

In Section C.10, page 57, the applicant states, that CHS 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.*” The applicant provides CHS’s Non-Discrimination Policy in Exhibit B.10 and its Hospital Coverage Assistance and Financial Assistance Policy in Exhibit L.4. In addition, on page 57, the applicant provides a table of percentages of categories of underserved populations CHS Pineville served in CY2016 compared to the percentages of these populations in Mecklenburg County, summarized as follows:

**CHS Pineville
Service to Underserved Populations**

	Percentage Served CY2017	Percentage in Mecklenburg County*
Women	57.9%	51.4%
Age 65 and older	25.6%	11.1%
Racial Minorities	36.9%	47.7%

*The Project Analyst cannot determine the date or timeframe used.

In Section L.1, page 97, and Section L.3, page 98, the applicant provides the historical and projected payor mix for MRI services at CHS Pineville, respectively, as follows:

**CHS Pineville
MRI Services**

Payor Source	Historical MRI Services, CY2016	Projected MRI Services, FY2020
Self-Pay/Charity	4.9%	4.9%
Medicare	45.6%	45.6%
Medicaid	5.6%	5.6%
Commercial/Managed Care	42.6%	42.6%
Other*	1.3%	1.3%
Total	100.0%	100%

*Includes worker's compensation and other payors.

The applicant provides its assumptions for the projected payor mix for CHS Pineville's MRI services in Section L.3, page 98, stating that it assumes the payor mix will be consistent with historical payor mix since it is unclear how much patient shift will occur in the future due to healthcare reform efforts.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 supports its 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 – Both Applications

Neither applicant proposes to reduce or eliminate a service, nor relocate a facility or a service. Therefore, Criterion (3a) is not applicable to this review.

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

NC – The Presbyterian Hospital
C – Mercy Hospital

The Presbyterian Hospital proposes to acquire one fixed MRI scanner to be installed in the Radiology Department of NHPMC in renovated space.

In Section E.2, pages 65-67, 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:

- 1) Maintain the Status Quo – the applicant determined that this was not an effective alternative because the existing two MRI scanners are operating at practical capacity and the number of referrals for MRI procedures is increasing due to an increase in medical staff. Therefore, the limited availability of the existing MRI scanners is impacting patient access to MRI services.
- 2) Contract with a Mobile MRI Vendor – the applicant states that this alternative is not the most effective or least costly alternative because of several limitations. The applicant states that NHPMC has no suitable mobile pad located on the campus, transporting very ill or complex inpatients outside to a mobile site can be risky, mobile MRI scanners may not have the needed coils for specialized procedures, and the cost of using a mobile MRI scanner over time would be much higher than purchasing its own MRI scanner.
- 3) Replace One Existing MRI Scanner – the applicant states that this alternative would not be feasible since it would not address the increasing number of MRI scan referrals being made by increasing medical staff. Therefore, this is not an effective alternative.

- 4) Shift Some MRI Volume to Novant Health Charlotte Orthopedic Hospital (NHCOH) – the applicant states that there are several limitations to the use of NHCOH’s fixed MRI scanner for patients at NHPMC. Patients at NHPMC would need to be transported to NHCOH by ambulance due to its location across the street from NHPMC. This, in turn, may compromise patient safety and would be costly. In addition, NHCOH’s MRI scanner cannot accommodate specialized MRI procedures, including neurological procedures which account for more than half of NHPMC’s MRI procedures.

On page 66, the applicant states that its proposal is the most effective alternative because developing a fixed MRI scanner in renovated space at NHPMC would result in less capital cost than constructing new space and would allow for all of the hospital’s fixed MRI scanners to be in close proximity, thereby improving patient flow and operational efficiency. The applicant states that for these reasons and the reasons noted in the descriptions of the alternatives considered, the proposed project is the most effective alternative to meet the need.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need because the application is not conforming to all other applicable statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above.

Mercy Hospital – proposes to acquire one fixed MRI scanner to be installed at CHS Pineville in renovated space adjacent to CHS Pineville’s existing fixed MRI scanner. In Section E.2, pages 71-72, 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:

- 1) Maintain the status quo – the applicant states that this is not a realistic alternative because it would result in continued cost, inconveniences, and inefficiencies that result from the existing fixed MRI scanner’s high utilization. In addition, acutely ill patients would need to be transported to the mobile unit if the existing fixed MRI scanner was not functioning. Moreover, options for addressing future growth would be limited. Therefore, this is not an effective alternative.
- 2) Choose an alternate location – the applicant states that CHS Pineville has the highest utilization not only within CHS and CIS, but also statewide. Therefore, choosing to develop the additional fixed MRI scanner at a different location would not be the most effective alternative.
- 3) Develop a freestanding facility – the applicant states that it considered developing the fixed MRI scanner at a freestanding facility, however it determined that while this alternative would offer outpatients convenience and lower cost, there are several existing freestanding MRI services in Mecklenburg County that have available capacity and CHS Pineville has a need for a hospital-based fixed MRI scanner to serve inpatients, emergency patients, observation patients, and outpatients with co-morbidities. Therefore, this is not the most effective alternative.

On page 72, the applicant states that its proposal is the most effective alternative because CHS Pineville has the highest utilization in the county and that,

“CHS Pineville is the most highly utilized fixed MRI provider in the state and its need is driven by a large percentage of patients who are most appropriately served in a hospital-based setting.”

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 applicant has demonstrated a need for an additional fixed MRI scanner based on reasonable and adequately supported assumptions and methodology.
- The applicant has adequately demonstrated that other alternatives would be more costly, less efficient, and would not meet the need demonstrated at CHS Pineville.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing

- Responses to comments
 - Information which was publicly available during the review and used by the Agency.
- (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.

NC – The Presbyterian Hospital
C – Mercy Hospital

The Presbyterian Hospital proposes to acquire one fixed MRI scanner to be installed in the Radiology Department of NHPMC in renovated space.

Capital and Working Capital Costs

In Section Q, page 125, the applicant projects the total capital cost of the project as shown in the table below:

Construction Contract	\$1,430,436
Construction Contingency	\$ 143,044
Architect and Engineering Fees plus Reimbursables	\$ 142,500
Medical Equipment and Furniture	\$1,420,506
Consultant Fees	\$ 21,000
Other*	\$ 377,508
Total Capital Cost	\$3,534,994

*Other includes information technology, nurse call system, project contingency, and other miscellaneous costs listed on page 125.

In Section F.3, page 70, the applicant projects there will be no start-up or initial operating expenses for the project because it currently staffs and operates the facility's existing MRI service.

Availability of Funds

In Section F.2, page 69, the applicant states that the capital cost will be funded with accumulated reserves of Novant Health, Inc. Exhibit F-2 contains a letter dated October 5, 2017 from the Senior Vice President of Finance, Novant Health, Inc., documenting the availability of accumulated reserves to fund the capital costs for the proposed project.

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Exhibit F-2 contains audited financial statements for Novant Health, Inc. and Affiliates for the years ending December 31, 2016 and December 31, 2015. As of December 31, 2016, Novant Health had \$260,988,000 in cash and cash equivalents, total assets of \$5,847,532,000 and total liabilities of \$2,399,195,000. Net assets were equal to \$3,448,337,000 (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project in Section Q, pages 129-138. In Form F.4, page 133, the applicant projects that revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below:

NHPMC Fixed MRI Services

	1st Full Fiscal Year 7/01/2020- 6/30/2021	2nd Full Fiscal Year 7/01/2021- 6/30/2022	3rd Full Fiscal Year 7/01/2022-6/30/2023
Total Projected # of Unweighted Procedures	11,206	11,688	12,190
Total Gross Revenues (Charges)	\$ 9,962,084	\$ 42,198,076	\$ 44,560,598
Total Net Revenue	\$ 12,919,050	\$ 13,747,393	\$ 14,627,902
Average Net Revenue per Procedure	\$ 1,153	\$ 1,176	\$ 1,200
Total Operating Expenses (Costs)	\$ 2,586,076	\$ 2,769,104	\$ 2,374,363[2,900,544]
Average Operating Expense per Procedure	\$ 231	\$ 237	\$ 195 [238]
Net Income	\$ 10,332,974	\$ 10,978,289	\$ 12,253,538 [11,727, 358]

Note: the Agency's corrections are shown in brackets.

As shown in the table above, the applicant projects a positive net income in all three initial operating years of the proposed project. However, the Agency notes that the pro forma in Form F.4 contains errors. The applicant made errors adding up its Direct Expenses for the third full fiscal year, calculating dollar amounts for staffing and payroll taxes in PY1, and in calculating other line item operating expenses as follows: the applicant did not apply its annual inflation rate correctly, based on the assumptions it provided, from the partial interim year to the first full fiscal year of the proposed project, resulting in an under estimation of operating expenses in the first full fiscal year. Consequently, projected operating expenses for full fiscal years two and three were also under estimated. Furthermore, as a result of this error, net income is over stated for the first three full fiscal years of the proposed project. In addition, the applicant does not explain why professional fees increase 50 percent in the third full fiscal year of operation.

The applicant projects a positive net income for Novant Health in each of the first three operating years of the project.

However, the assumptions used by the applicant in preparation of the pro forma financial statements are not reasonable and adequately supported because projected utilization is questionable. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, since projected revenues and expenses are based at least in part on projected utilization, projected revenues and expenses are also questionable.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 not conforming to this criterion because the applicant does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Mercy Hospital – proposes to acquire one fixed MRI scanner to be installed at CHS Pineville in renovated space adjacent to CHS Pineville’s existing fixed MRI scanner.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects the capital cost of the project as shown in the table below:

CHS Pineville Fixed MRI Scanner Capital Cost	
Construction Contract	\$ 1,800,000
Architect/Engineering Fees	\$ 170,000
Equipment and Furniture	\$ 2,995,000
Consultant Fees	\$ 125,000
Other*	\$ 110,000
Total Capital Cost	\$ 5,200,000

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F.3, pages 76-77, the applicant projects that no start-up expenses or initial operating expenses for the project since the proposed project is not a new service.

Availability of Funds

In Section F.2, page 75, the applicant states that the project will be funded with owner’s equity/accumulated reserves of CMHA [The Charlotte-Mecklenburg Hospital Authority]. Exhibit F.2 contains a letter, dated October 16, 2017, from the Executive Vice President and Chief Financial Officer of CHS stating that it will fund the capital costs of the proposed project from existing capital cash reserves. In addition, the letter states that the availability of funds can be verified in the audited financial statements included with the application. Exhibit F.2 contains the audited financial statements for CMHA for December 31, 2016 and December 31, 2015. As of December 31, 2016, CMHA had \$142,725,000 in cash and cash equivalents, \$7,997,897,000 in total assets, and \$4,027,806,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q, Form F-3, the applicant projects that revenues will exceed operating expenses in each of the first three full fiscal years of the project, as illustrated in the table below:

CHS Pineville Fixed MRI Services

	Project Year 1 CY2019	Project Year 2 CY2020	Project Year 3 CY2021
Total Projected # of Unweighted Procedures	8,887	8,995	9,104
Total Gross Revenues (Charges)	\$ 30,105,559	\$ 31,384,208	\$ 32,717,164
Total Net Revenue	\$ 5,811,520	\$ 5,909,945	\$ 6,004,677
Average Net Revenue per Unweighted Procedure	\$ 654	\$ 657	\$ 660
Total Operating Expenses (Costs)	\$ 2,244,489	\$ 2,335,515	\$ 2,377,768
Average Operating Expenses per Unweighted Procedure	\$ 253	\$ 260	\$ 261
Net Income	\$ 3,567,031	\$ 3,574,430	\$ 3,626,909

The applicant also projects a positive net income for the entire facility in each of the first three operating years. 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
- Written comments
- Remarks made at the public hearing
- 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 demonstrates availability of sufficient funds for the capital and working 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.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

NC – The Presbyterian Hospital
C – Mercy Hospital

On page 146, the 2017 SMFP defines the service area for a fixed MRI scanner as “*a single county, except where there is no licensed acute care hospital located within the county.*” The definition of the service area for a fixed MRI scanner then explains how a service area is determined when there is no licensed acute care hospital located within the county. For the purpose of this review, however, Mecklenburg County is the service area since it has multiple licensed acute care hospitals. Facilities may also serve residents of counties not included in their service area.

The 2017 SMFP identifies a need determination for one fixed MRI scanner in Mecklenburg County. There are 20 existing fixed MRI scanners in Mecklenburg County according to the 2017 SMFP. The following table provides the number of fixed MRI scanners, total weighted MRI procedures, and average weighted MRI procedures per MRI scanner for each of the fixed MRI scanners, summarized from Table 9P of the 2017 SMFP (based on FFY 2015 utilization data submitted by providers).

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Fixed MRI Scanners in Mecklenburg County

Facility	# of Fixed MRI Scanners	Total Weighted MRI Procedures	Average Weighted MRI Procedures per MRI Scanner*
Carolinas Medical Center (CMC)	5	31,354	6,270
Carolinas Healthcare System (CHS) - Pineville	1	10,866	10,866
CHS-University	1	6,437	6,437
Novant Health Huntersville Medical Center	1	7,431	7,431
Novant Health Imaging (NHI) - Museum	1	2,471	2,471
NHMMC**	2	7,666	3,833
NHPMC***	3	15,428	5,143
Carolinas Imaging Services (CIS) - Ballantyne	1	3,513	3,513
CIS-South Park	1	3,317	3,317
NHI Ballantyne	1	2,628	2,628
NHI South Park	1	3,713	3,713
OrthoCarolina Spine Center	1	9,320	9,320
OrthoCarolina Ballantyne	1	0	0

*Average weighted MRI procedures per MRI scanner are rounded to nearest whole number.

**A Declaratory Ruling was issued by the Agency on August 17, 2015, approving the relocation of one undeveloped, fixed MRI scanner from NHMMC to NHMHMC. The fixed MRI scanner at NHMHMC is expected to be operational in mid-2018.

***One of NHPMC's fixed MRI scanners is located at Novant Health Charlotte Orthopedic Hospital which is on the license of NHCPM but is located across the street from NHPMC.

The Presbyterian Hospital proposes to acquire one fixed MRI scanner to be located in the Radiology Department of NHPMC in renovated space. The Presbyterian Hospital does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2017 SMFP for Mecklenburg County. In Section G.3, page 77, the applicant explains why it believes its proposal would not result in an unnecessary duplication of existing or approved services in the service area. The applicant states,

“The existing two MRI units performed 12,573 weighted procedures in the last year which indicates a need for 2.6 MRI scanners (12,573/4,805=2.62).

...NHPMC is unable to accept non-emergent, routine outpatient MRI cases and are currently sending those patients to other Novant facilities or other providers in Mecklenburg County. The ability to improve accessibility at NHPMC for its patients will not result in an unnecessary duplication of MRI services in the service area.”

However, the applicant does not 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:

- The applicant does not adequately demonstrate that the fixed MRI scanner it proposes to develop in Mecklenburg County is needed in addition to the existing and approved fixed MRI scanners in Mecklenburg County. The discussion regarding analysis of need, including historical and projected utilization, found in Criterion (3) is incorporated herein by reference.
- The applicant does not adequately demonstrate that the existing, approved, and proposed fixed MRI scanners it owns in Mecklenburg County are reasonably expected to perform an average annual of 4,805 weighted MRI procedures in the third year of operation following completion of the proposed project. The discussion regarding analysis of need, including historical and projected utilization, found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above.

Mercy Hospital proposes to acquire one fixed MRI scanner to be located in renovated space at CHS Pineville adjacent to the hospital's existing fixed MRI scanner. Mercy Hospital does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2017 SMFP for Mecklenburg County. In Section G.3, pages 82-83, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in Mecklenburg County. The applicant states, on page 82,

“CHS Pineville has historically operated the most highly utilized fixed MRI unit in North Carolina. As such, additional capacity at CHS Pineville could not be reasonably considered to be unnecessary duplication, particularly since its current volume supports more than two fixed scanners.”

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 2017 SMFP for the proposed fixed MRI scanner.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to its existing or approved fixed MRI scanners in Mecklenburg County. 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
- Remarks made at the public hearing
- Responses to comments
- Information which was 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.

- (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 – Both Applications

The Presbyterian Hospital. In Section Q, page 148, the applicant provides the current and projected staffing for the proposed services as illustrated in the following table:

Position	Current	Projected		
	9/27/17	1 st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
MRI Supervisor	1.0	1.0	1.0	1.0
MRI Technician Lead	1.0	1.0	1.0	1.0
MRI Technician	6.0	10.0	10.0	10.0
TOTAL	8.0	12.0	12.0	12.0

Source: Section Q, Form H, of the application.

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.4, which is found in Section Q. In Section H, pages 78-79, the applicant describes the methods used to recruit or fill new positions and on

pages 80-81 it describes its existing training and continuing education programs. Exhibit H-4 contains a letter from David Altman, M.D., indicating his intent to continue to serve as Medical Director for the proposed service.

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
- Information which was 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.

Mercy Hospital. In Section Q, Form H, the applicant provides current and projected staffing for the proposed services as illustrated in the following table:

Position	Current	Projected		
	CY2016	1 st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
MRI Technician	5.7	7.7	7.7	7.7
TOTAL	5.7	7.7	7.7	7.7

Source: Section Q, Form H of the application.

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 84-85, the applicant describes the methods used to recruit new positions and its existing training and continuing education programs. In Section H, page 85, the applicant identifies the current medical director of the MRI service. In Exhibit H.4, the applicant provides a letter from Dr. Peter Hindel indicating his intent to continue to serve as medical director for the MRI service.

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
- Information which was 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.

- (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 – Both Applications

The Presbyterian Hospital. In Section I.1, pages 84-85, the applicant provides a listing of necessary ancillary and support services it will continue to have for its MRI services, including the proposed fixed MRI scanner. On pages 84-85, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I-1 which contains a copy of a letter from the Vice President of Professional and Support Services at NHPMC stating that all necessary ancillary and support services will continue to be provided for the existing MRI services and the projected, additional fixed MRI scanner.

In Section I.2, pages 85-86, the applicant provides a list of various local health and social service programs with whom it has working relationships. Exhibit I-2 contains a copy of a letter from the President and Chief Operating Officer of NHPMC which confirms these existing working relationships. In addition, Exhibits H-4 and C-4 contain letters of support from referring physicians representing a variety of specialties.

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
- Information which was 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.

Mercy Hospital. In Section I, page 87, the applicant states that all necessary ancillary and support services are already in place to support the hospital's MRI service and will continue to be provided upon completion of the proposed project. The necessary ancillary and support services include, but are not limited to, patient scheduling, registration and billing, medical records, and housekeeping. Exhibit I.1 contains a letter from the President of CHS Pineville confirming the availability of all necessary ancillary and support services for the proposed project.

In Section I.2, page 87, the applicant states that CHS Pineville, as an existing healthcare facility, has established relationships with other local healthcare and social service providers and provides supporting documentation in Exhibit I.2 from area physicians.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing healthcare system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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.

- (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

Neither applicant projects 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, neither applicant projects 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. Therefore, Criterion (9) is not applicable to this review.

- (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

Neither applicant is an HMO. Therefore, Criterion (10) is not applicable to this review.

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

C – Both Applications

The Presbyterian Hospital. In Section K, pages 91-92, the applicant states that the project involves renovating 1,050 square feet of existing space in the Radiology Department of NHPMC. Line drawings are provided in Exhibit K-2.

On page 91, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit K-4.

On page 92, 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 92, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit B-10.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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.

Mercy Hospital. In Section K, pages 90-91, the applicant states that the project involves renovating 3,131 square feet of existing space adjacent to the existing fixed MRI scanner at CHS Pineville. Line drawings are provided in Exhibit C.1-3.

On page 91, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 91, 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 91-92, 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
- Information which was 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.

- (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 – Both Applications

The Presbyterian Hospital. In Section L.1, page 96, the applicant provides the historical payor mix during CY2016 for the existing MRI services at NHPMC, as shown in the table below:

**NHPMC
 Inpatient and Outpatient MRI Services**

Payor Category	MRI Services as Percent of Total, CY2016
Self-Pay/Charity	5%
Medicare*	41%
Medicaid*	11%
Insurance*	41%
Other	2%
Total	100%

*Includes respective managed care plans, i.e. Medicare includes Medicare Managed Care Plans.

In Section L.1, page 95, the applicant provides the following comparison.

**NHPMC
 Service to Underserved Populations**

	Percentage of Total Patients Served by the Facility during FY2017	Percentage of the Population in Mecklenburg County July 1, 2016
Women	60.9%	51.2%
Age 65 and older	23.5%	10.6%
Racial Minorities*	53.2%	41.0%

*Includes non-white age groups.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

Mercy Hospital. In Section L.1, page 97, the applicant provides the historical payor mix during CY2016 for the existing MRI services at CHS Pineville, as shown in the table below:

CHS Pineville

MRI Services

Payor Category	MRI Services as Percent of Total, CY 2016
Self-Pay/Charity	4.9%
Medicare	45.6%
Medicaid	5.6%
Commercial/ Managed Care	42.6%
Other	1.3%
Total	100.0%

*Includes worker's comp. and other payors.

In Section L.1, page 96, the applicant provides the following comparison:

**CHS Pineville
 Service to Underserved Populations**

	Percentage of Total Patients Served by the Facility during CY2016	Percentage of the Population in Mecklenburg County
Women	57.9%	51.4%
Age 65 and older	25.6%	11.1%
Racial Minorities	36.9%	47.7%

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents 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. 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 – Both Applications

The Presbyterian Hospital. Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.1, page 96, the applicant states that it exceeded its obligations for uncompensated care pursuant to the Hill-Burton Act many years ago, but continues to provide community benefit dollars and care to all persons, regardless of their ability to pay. In addition, the applicant provides a copy of Novant Health's Charity Care and related policies in Exhibit C-10.

In Section L, page 97, the applicant states that during the last five years no civil rights access complaints have been filed against Novant Health or any of its affiliated facilities located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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.

Mercy Hospital. Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.1, page 97, the applicant states that it has had no obligations to provide uncompensated care in any specified amount, community service, or access by medically underserved persons during the last three years. However, the applicant states that it provides and will continue to provide services to all persons in need of medical care, including medically underserved persons.

In Section L, page 98, the applicant states that during the last five years no civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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.

- (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 – Both Applications

The Presbyterian Hospital. In Section L.3, page 97, the applicant projects 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:

**NHPMC
Inpatient and Outpatient MRI Services**

Payor Category	MRI Services as Percent of Total, FY2022
Self-Pay/Charity	5%
Medicare*	41%
Medicaid*	11%
Insurance*	41%
Other	2%
Total	100%

*Includes respective managed care plans, i.e.
Medicare includes Medicare Managed Care Plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 5% of total services will be provided to self-pay/charity patients, 41% to Medicare patients and 11% to Medicaid patients.

On pages 96-98, 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 because it is based on historical payor mix and the applicant states it assumes it will remain the same as historical payor mix.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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.

Mercy Hospital. In Section L.3, page 98, the applicant projects 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:

**CHS Pineville
MRI Services**

Payor Source	Projected MRI Cases, CY2020
Self-Pay	4.9%
Medicare	45.6%
Medicaid	5.6%
Commercial/ Managed Care	42.6%
Other*	1.3%
Total	100.0%

* Includes worker's comp. and other payors.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 4.9% of total services will be provided to self-pay patients, 45.6% to Medicare patients and 5.6% to Medicaid patients.

On page 97, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on historical payor mix for its MRI services and the applicant does not expect payor mix for its MRI services to change.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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.

- (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 – Both Applications

The Presbyterian Hospital. In Section L.5, page 101, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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.

Mercy Hospital. In Section L.5, page 99, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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.

- (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 – Both Applications

The Presbyterian Hospital. In Section M.1, page 102, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

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.

Mercy Hospital. In Section M.1, pages 101-102, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

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.

(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.

On page 146, the 2017 SMFP defines the service area for a fixed MRI scanner as “*a single county, except where there is no licensed acute care hospital located within the county.*” The definition of the service area for a fixed MRI scanner then explains how a service area is determined when there is no licensed acute care hospital located within the county. For the purpose of this review, however, Mecklenburg County is the service area since it has multiple licensed acute care hospitals. Facilities may also serve residents of counties not included in their service area.

The 2017 SMFP identifies a need determination for one fixed MRI scanner in Mecklenburg County. There are 20 existing fixed MRI scanners in Mecklenburg County according to the 2017 SMFP. The following table provides the number of fixed MRI scanners, the number of total weighted MRI procedures, and the average weighted MRI procedures per MRI scanner, summarized from Table 9P of the 2017 SMFP (based on FFY2015 utilization data submitted by providers).

Fixed MRI Scanners in Mecklenburg County

Facility	# of Fixed MRI Scanners	Total Weighted MRI Procedures	Average Weighted MRI Procedures per MRI Scanner*
Carolinas Medical Center (CMC)	5	31,354	6,270
Carolinas Healthcare System (CHS) - Pineville	1	10,866	10,866
CHS-University	1	6,437	6,437
Novant Health Huntersville Medical Center	1	7,431	7,431
Novant Health Imaging (NHI) - Museum	1	2,471	2,471
NHMMC**	2	7,666	3,833
NHPMC***	3	15,428	5,143
Carolinas Imaging Services (CIS) - Ballantyne	1	3,513	3,513
CIS-South Park	1	3,317	3,317
NHI Ballantyne	1	2,628	2,628
NHI South Park	1	3,713	3,713
OrthoCarolina Spine Center	1	9,320	9,320
OrthoCarolina Ballantyne	1	0	0

*Average weighted MRI procedures per MRI scanner are rounded to nearest whole number.

**A Declaratory Ruling was issued by the Agency on August 17, 2015, approving the relocation of one undeveloped, fixed MRI scanner from NHMMC to NHMHMC. The fixed MRI scanner at NHMHMC is expected to be operational in mid-2018.

***One of NHPMC's fixed MRI scanners is located at Novant Health Orthopedic Medical Center which is on the license of NHPMC but is located across the street from NHPMC.

The Presbyterian Hospital proposes to acquire one fixed MRI scanner to be located in renovated space in NHPMC's Radiology Department.

In Section N, pages 105-111, 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 service. On page 105, the applicant states,

"The additional MRI capacity at NHPMC will provide [sic] the facility to improve accessibility for patients in need of specialized care that is provided at NHPMC.

...allow NHPMC to continue recruiting physicians specializing in neurological studies, cardiac care, oncology care and pediatrics in order to present a high quality option for these specialized services in Mecklenburg County.

...

Novant Health has formed a value-based strategy team launched to accelerate strategies for assuming risk and shifting further towards a value-based case and payment models to demonstrate greater value for the patients we serve.”

The applicant does not adequately describe the expected effects of the proposed services on competition in the service area and does not adequately demonstrate:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 not conforming to this criterion for the reasons stated above.

Mercy Hospital proposes to acquire one fixed MRI scanner to be located in renovated space adjacent to its existing fixed MRI scanner at CHS Pineville.

In Section N, pages 103-105, the applicant describes the expected effects of the proposed services on competition in the serve area and discusses how any enhanced competition in the service area will promote the cost effectiveness, quality and access to MRI services in Mecklenburg County.

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
- Written comments
- Remarks made at the public hearing
- 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.

C – Both Applications

The Presbyterian Hospital. In Section O.3, page 113, the applicant identifies the hospitals located in North Carolina that are owned, operated or managed by Novant Health or a related entity. The applicant identifies a total of 14 of this type of facility located in North Carolina.

In Section O, page 114, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities. The applicant states that all of the problems have been corrected. However, according to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the submittal of the application through the date of this decision, an incident related to quality of care occurred in one of these facilities and has not yet been deemed to be back in compliance. 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 14 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Mercy Hospital. In Exhibit O.3, the applicant identifies the hospitals located in North Carolina that are owned, operated or managed by CMHA or a related entity. The applicant identifies a total of 12 of this type of facility located in North Carolina.

In Section O, pages 109-110, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. However, according to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months

immediately preceding the submittal of the application through the date of this decision, four incidents related to quality of care occurred in three of these facilities and they have not yet been deemed to be back in compliance. 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 12 facilities, the applicant 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.

NC – The Presbyterian Hospital
C – Mercy Hospital

The Presbyterian Hospital. The application submitted by The Presbyterian Hospital was found to not be in conformity with all applicable Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700.

Mercy Hospital. The application submitted by Mercy Hospital was determined to be conforming with all applicable Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700.

The specific criteria for both applications are discussed below.

SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER

10A NCAC 14C .2703 PERFORMANCE STANDARDS

- (a) *An applicant proposing to acquire a mobile magnetic resonance imaging (MRI) scanner shall:*
- (1) *demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the mobile MRI region in which the proposed equipment will be located, except temporary MRI scanners, performed 3,328*

weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; with the exception that in the event an existing mobile MRI scanner has been in operation less than 12 months at the time the application is filed, the applicant shall demonstrate that this mobile MRI scanner performed an average of at least 277 weighted MRI procedures per month for the period in which it has been in operation;

- (2) demonstrate annual utilization in the third year of operation is reasonably projected to be at least 3328 weighted MRI procedures on each of the existing, approved and proposed mobile MRI scanners owned by the applicant or a related entity to be operated in the mobile MRI region in which the proposed equipment will be located [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; and*
- (3) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- Neither of the applicants propose to acquire a mobile MRI scanner. Therefore, this rule is not applicable to this review.

(b) An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner, except for fixed MRI scanners described in Paragraphs (c) and (d) of this Rule, shall:

- (1) demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data;*

-C- **The Presbyterian Hospital.** In Section C, pages 55-56, the applicant states that Novant Health's fixed MRI scanners in Mecklenburg County performed an average of 5,339 weighted MRI procedures from July 1, 2016 through June 30, 2017.

-C- **Mercy Hospital.** In Section C, page 62, the applicant states that CHS/CIS' fixed MRI scanners in Mecklenburg County performed an average of 6,399 weighted MRI procedures from August 2016 through July 2017.

- (2) demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners,*

performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.];

- NA- **The Presbyterian Hospital.** The applicant does not currently own or have a controlling interest in any mobile MRI scanners operated in Mecklenburg County. Therefore, this Rule is not applicable to this application.

- C- **Mercy Hospital.** The applicant states, in Section C, page 63, that it operates one mobile MRI scanner in the service area which services two sites, CIS-Huntersville in Mecklenburg County and St. Luke’s Hospital in Polk County. The applicant provides the historical utilization for the mobile MRI scanner for the period, August 2016 through July 2017, on page 63, illustrated as follows:

**CIS Mobile MRI Scanner Weighted MRI Procedures
August 2016 through July 2017**

	CIS-Huntersville	St. Luke’s	Total
Total Weighted MRI Procedures	3,189	877	4,066

(3) demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:

- (A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*
- (B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*
- (C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*
- (D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*
- (E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

The 2017 SMFP shows that there are more than four (4) fixed MRI scanners located in the fixed MRI service area of Mecklenburg County. Therefore, each applicant must demonstrate that the average annual utilization for the existing, approved and proposed fixed MRI scanners

which the applicant or a related entity owns and locates in Mecklenburg County will be at least 4,805 weighted MRI procedures in the third operating year.

-NC- **The Presbyterian Hospital.** The applicant states, in Section C, page 57, that it projects its annual average weighted MRI scan volume for each of its existing, approved, and proposed fixed MRI scanners to be 5,006 weighted MRI procedures per fixed MRI scanner in project year three. However, the applicant does not provide its methodology, assumptions, or projected utilization for all of Novant Health's existing and approved fixed MRI scanners it owns and operates at its acute care facilities and outpatient sites in Mecklenburg County. Therefore, the applicant does not adequately demonstrate that the annual average weighted MRI scan volume for each existing, approved, and proposed fixed MRI scanner owned and operated by Novant Health in Mecklenburg County will be at least 4,805 weighted MRI procedures in the third year of operation following completion of the proposed project, pursuant to 10A NCAC 14C .2703(b)(3).

-C- **Mercy Hospital.** In a table provided in Section C.11, page 64, the applicant states that the average annual weighted MRI procedures that all CHS/CIS existing, approved, and proposed fixed MRI scanners are projected to perform in the third year of operation of the proposed project is 5,918.

(4) if the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:

(A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,

(B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,

(C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,

(D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or

(E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;

-NA- **Both Applications.** Neither applicant proposes to locate an additional fixed MRI scanner at a different site from any of the existing or approved

MRI scanners owned by the applicant or a related entity. Therefore, this Rule is not applicable this review.

(5) demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project [Note: This is not the average number of weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.]; and

-NA- **The Presbyterian Hospital.** The applicant does not own any mobile MRI scanners in Mecklenburg County. Therefore, this Rule is not applicable to this review.

-C- **Mercy Hospital.** In Section C.11, page 65, and Exhibit C.11-1, page 15, the applicant projects the annual utilization of its one existing mobile MRI scanner located in Mecklenburg County will perform 3,848 weighted MRI procedures in CY2021, the third year of operation of the proposed project.

(6) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.

-NC- **The Presbyterian Hospital.** The applicant's assumptions and data supporting the methodology used for the projection required in 10 A NCAC 14C .2703(b)(1) are provided in Section C, pages 55-56. However, the applicant does not provide assumptions nor data supporting a methodology used for the projection required in 10A NCAC 14C .2703(b)(3). Therefore, the application is not conforming to this Rule.

-C- **Mercy Hospital.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q, page 1, Section C.11, page 63, Section Q, page 2-3, and Exhibit C.11-1, pages 1-15.

(c) An applicant proposing to acquire a fixed dedicated breast magnetic resonance imaging (MRI) scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:

(1) demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 1,664 weighted MRI procedures which is .80 times 1 procedure per hour times 40 hours per week times 52 weeks per year; and

(2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- Neither of the applicants propose the acquisition of a dedicated fixed breast MRI scanner. Therefore, this Rule is not applicable to this review.

(d) *An applicant proposing to acquire a fixed extremity MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*

(1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(f)(7); and*

(2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- Neither of the applicants propose the acquisition of a fixed extremity MRI scanner. Therefore, this Rule is not applicable to this review.

(e) *An applicant proposing to acquire a fixed multi-position MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for a demonstration project shall:*

(1) *demonstrate annual utilization of the proposed multi-position MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(g)(7); and*

(2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- Neither of the applicants propose the acquisition of a fixed multi-position MRI scanner. Therefore, this Rule is not applicable to this review.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2017 SMFP, no more than one additional fixed MRI scanner may be approved in this review for Mecklenburg County. Because the two applications in this review collectively propose to acquire two additional fixed MRI scanners, only one of the applications can be approved. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the Agency conducted a comparative analysis of the proposals to decide which proposal should be approved. For the reasons set forth below and in the rest of the findings, the application submitted by Mercy Hospital, Inc. is approved and the other application, submitted by The Presbyterian Hospital, is denied.

Geographic Distribution

The 2017 SMFP identifies the need for one fixed MRI scanner in Mecklenburg County. The following table identifies the location of the existing and approved fixed MRI scanners in Mecklenburg County.

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Existing and Approved Fixed MRI Scanners by Location in Mecklenburg County (FY2016)

Facility	City/Town	# of Existing and Approved Fixed MRI Units
Carolinas Medical Center	Charlotte	5
Carolinas HealthCare System (CHS) – Pineville	Charlotte	1
CHS – University	Charlotte	1
Novant Health Huntersville Medical Center*	Huntersville	2
Novant Health Imaging (NHI) Museum	Charlotte	1
Novant Health Matthews Medical Center	Matthews	2
Novant Health Presbyterian Medical Center	Charlotte	3
Carolina Neurosurgery and Spine Associates**	Charlotte	1
Carolinas Imaging Services (CIS) – Huntersville^	Huntersville	1
CIS – Ballantyne	Charlotte	1
CIS – Southpark	Charlotte	1
NHI Ballantyne	Charlotte	1
NHI Southpark	Charlotte	1
OrthoCarolina Spine Center	Charlotte	1
OrthoCarolina Ballantyne	Charlotte	1
Novant Health Mint Hill Medical Center^^	Charlotte	1
Total		24

Sources: 2018 SMFP, 2016 Registration and Inventory of Medical Equipment forms, and Findings for 2016 Mecklenburg Fixed MRI Scanner Review.

*Pursuant to a settlement agreement, a CON will be reissued for F-8237-08, converting a mobile MRI scanner to a fixed MRI scanner to be located at Novant Health Huntersville Medical Center.

**The multi-positional fixed MRI scanner operated at Carolina Neurosurgery and Spine Associates as a demonstration project has been added to the inventory.

^An approved fixed MRI scanner will be developed and located at CIS-Huntersville.

^^An approved fixed MRI scanner will be located at Novant Health Mint Hill Medical Center and is expected to become operational in 2018.

As shown in the table above, there are 24 existing and approved fixed MRI scanners located in Mecklenburg County. Nineteen are located in Charlotte, two are located in Huntersville, and one is located in Matthews. There are no fixed MRI scanners located in other Mecklenburg County cities.

Both applicants propose to locate an additional fixed MRI scanner in Charlotte, Mecklenburg County. Thus, with respect to geographic distribution, the proposals submitted by The Presbyterian Hospital and Mercy Hospital, Inc. are equally effective alternatives.

Demonstration of Need

Mercy Hospital adequately demonstrates that projected utilization of the proposed fixed MRI scanner was reasonable, adequately documents its assumptions and methodologies, and

demonstrates the need the population it projects to serve has for the proposed fixed MRI scanner. The Presbyterian Hospital does not adequately demonstrate the need the population it proposes to serve has for the proposed fixed MRI scanner. The discussion regarding demonstration of need found in Criterion (3) is incorporated herein by reference. Therefore, the application submitted by Mercy Hospital is the most effective alternative with regard to demonstration of need.

Ownership of Fixed MRI Scanners in Mecklenburg County

According to the 2018 SMFP, there are 24 existing and approved fixed MRI scanners in Mecklenburg County, owned by four different providers. The following table identifies the provider, number of MRI scanners, and average utilization of each of the fixed MRI scanners.

Ownership of Existing and Approved Fixed MRI Scanners in Mecklenburg County (FY 2016)			
Provider	Number of Fixed MRI Scanners	Total Number of Weighted Scans	Average Weighted Scans per Scanner
CHS/CIS	10	57,860	5,786
Novant Health	11	39,729	3,612
OrthoCarolina	2	8,591	4,296
Carolina Neurosurgery and Spine Associates	1	4,385	4,385
Total	24	110,565	18,079

Source: Table 9P, 2018 SMFP

Currently, fifteen of the 24 existing Mecklenburg County fixed MRI scanners are hospital-based (sixteen once NHMHMC opens in mid-2018) and nine are in freestanding outpatient imaging centers (eleven upon development of one approved fixed MRI scanner each at CIS-Huntersville and NHI-Huntersville). Hospital-based MRI procedures are provided at eight different hospital sites¹ (nine, once NHMHMC opens in mid-2018) and freestanding outpatient MRI procedures are currently provided at six different sites (nine different sites upon development and operation of one approved fixed MRI scanner each at CIS-Huntersville and NHI-Huntersville, and operation of one fixed MRI scanner at OrthoCarolina Ballantyne). In addition, mobile MRI services are offered at 15 sites in Mecklenburg County.

According to the 2018 SMFP, CHS/CIS owns 10 of the 24 existing and approved fixed MRI scanners in Mecklenburg County. Novant Health owns 11 of the 24 existing and approved fixed MRI scanners in Mecklenburg County but has one additional approved fixed MRI scanner projected to be operational in 2018. CIS provides both fixed and mobile MRI scanner services at various locations in Mecklenburg County, and Novant Health provides fixed MRI scanner services and contracted mobile MRI scanner services at various locations in Mecklenburg County. Each location proposed for the fixed MRI scanner currently provides fixed MRI

¹ According to NHPMC’s 2016 License Renewal Application, two of the three fixed MRI scanners on NHPMC’s hospital license are located at NHPMC and one is located at Novant Health Orthopedic Hospital on the same campus.

scanner access. There will be no change in the number of providers of MRI scanner services. Therefore, with regard to improving accessibility to an increased number of unique providers of MRI services in Mecklenburg County, both proposals are comparable.

Access by Underserved Groups

The following table illustrates the number and percentage of MRI procedures projected to be reimbursed by Medicaid and Medicare, and the number and percentage of MRI services projected to be Self-Pay in Project Year 2, as stated in Section L.3 of The Presbyterian Hospital’s and Mercy Hospital’s respective applications,

Application	Number and Percentage of MRI Procedures to Medicaid Recipients	Number and Percentage of MRI Procedures to Medicare Recipients	Number and Percentage of MRI Procedures to be Provided as Self-Pay*
The Presbyterian Hospital	1,286 (11.0%)	4,792 (41.0%)	584 (5.0%)
Mercy Hospital	504 (5.6%)	4,102 (45.6%)	441 (4.9%)

*The Presbyterian Hospital lists its payor category as Self-Pay/Charity Care on page 96 of its application. Mercy Hospital lists its payor category as Self-Pay on page 98 of its application.

As shown in the table above, The Presbyterian Hospital proposes to have the highest number and percentage of Medicaid recipients, the highest number of Medicare recipients, and the highest number and percentage of Self-Pay patients. Mercy Hospital proposes to serve the highest percentage of Medicare recipients. The Presbyterian Hospital describes its charity care policies in Section L.4, pages 98-101, and Exhibit C-10. In its pro forma financial statement, Form F.4, The Presbyterian Hospital lists the payor category self-pay/indigent/charity care and provides gross revenues for that line item. However, The Presbyterian Hospital lists the same payor category in its deductions from gross revenues. Mercy Hospital describes its charity care policies in Section L.4, page 99 and Exhibit L.4. In its pro forma financial statement, Form F.4, and its assumptions, Mercy Hospital combines charity care with self-pay for gross revenues and deducts charity care from gross revenues. The applicants provide different titles for their respective self-pay payor categories as described in the table above. Therefore, the Agency cannot determine whether the self-pay payor categories for both applicants are comparable. However, The Presbyterian Hospital did not adequately demonstrate the need to acquire a fixed MRI scanner to be located in Mecklenburg County and therefore cannot be approved. The discussion regarding need and projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application submitted by Mercy Hospital is the most effective alternative with regard to access by underserved groups.

Projected Average Gross Revenue per MRI Procedure

The following table shows the projected average gross revenue per MRI procedure for the second year of operation for The Presbyterian Hospital (FY2022) and the third year of operation

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for Mercy Hospital (CY2021), based on the information provided in the applicants' pro forma financial statements in Section Q. Both applicants deduct bad debt from gross revenue.

Application	Gross Revenue*	# of Unweighted MRI Procedures	Ave. Gross Revenue Per Procedure
The Presbyterian Hospital (OY2: 7/1/21 - 6/30/22)	\$42,198,076	11,688	\$3,606
Mercy Hospital (OY3: 1/1/21 – 12/31/21)	\$32,717,164	9,104	\$3,594

*The Presbyterian Hospital lists professional fees amounts in Form F.4 of its pro forma financial statement as Indirect Expenses. Mercy Hospital does not list professional fees amounts in Form F.4 of its pro forma financial statements and states in its assumptions that professional fees are billed separately.

As shown in the table above, Mercy Hospital projects a slightly lower average gross revenue per MRI procedure. However, with regard to projected average gross revenue per MRI procedure, the proposals are comparable.

Projected Average Net Revenue per MRI Procedure

The following table shows the projected net revenue per MRI procedure for the second year of operation for The Presbyterian Hospital (FY2022) and the third year of operation for Mercy Hospital (CY2021), based on the information provided in the applicants' pro forma financial statements (Section Q).

Application	Net Revenue*	# of Unweighted MRI Procedures	Average Net Revenue Per Procedure
The Presbyterian Hospital (OY2: 7/1/21-6/30/22)	\$13,747,393	11,688	\$1,172
Mercy Hospital (OY3: 1/1/21 – 12/31/21)	\$6,004,677	9,104	\$660

*The Presbyterian Hospital lists professional fees as an Indirect Expense in Form F.4 of its pro forma financial statements. Mercy Hospital does not list professional fees amounts in Form F.4 of its pro forma financial statements and states in its assumptions for Form F.4 that professional fees are billed separately.

As shown in the table above, Mercy Hospital projects the lowest average net revenue per MRI procedure. Therefore, with regard to projected average net revenue per procedure, the proposal submitted by Mercy Hospital is the most effective alternative.

Projected Average Operating Expense per MRI Procedure

The following table shows the projected average operating expense per MRI procedure for the second year of operation for The Presbyterian Hospital (FY2022) and the third year of operation for Mercy Hospital (CY2021), based on the information provided in the applicants’ pro forma financial statements (Section Q).

Application	Total Operating Expenses	Unweighted MRI Procedures	Average Operating Expense Per Procedure
The Presbyterian Hospital (OY2: 7/1/21-6/30/22)	\$2,769,104	11,688	\$237
Mercy Hospital (OY3: 1/1/21 – 12/31/21)	\$2,377,768	9,104	\$261

As shown in the table above, The Presbyterian Hospital projects the lowest average operating expense per MRI procedure. However, The Presbyterian Hospital made errors in its calculation of its operating expenses, based on its assumptions, resulting in an under estimation of operating expenses for the first three full fiscal operating years of the proposed project. In addition, an error was made in calculating operating expenses in operating year three based on an addition error. Therefore, the applicant’s operating expenses in the table above are questionable. In addition, the application submitted by The Presbyterian Hospital is not approvable. The Presbyterian Hospital did not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding demonstration of need in Criterion (3) is incorporated herein by reference. Therefore, with regard to projected average operating expense per procedure, the proposal submitted by Mercy Hospital is the most effective alternative.

SUMMARY

For each of the comparative analysis factors listed below, the application submitted by Mercy Hospital is determined to be the most effective alternative in this review:

- Demonstration of need
- Average net revenue per MRI procedure
- The application submitted by Mercy Hospital was determined to be conforming to all applicable statutory and regulatory review criteria.

The following is a summary of the reasons the proposal submitted by The Presbyterian Hospital is determined to be a less effective alternative in this review than the approved applicant:

- The application submitted by The Presbyterian Hospital is determined to be nonconforming to Criteria (1), (3), (4), (5), (6) and (18a).

- The application submitted by The Presbyterian Hospital is determined to be nonconforming to 10A NCAC 14C .2703(b)(3) and 10A NCAC 14C .2703(b)(6).

CONCLUSION

Both of the applications are conforming to the need determination in the 2017 SMFP for one fixed MRI scanner in Mecklenburg County. N.C.G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed MRI scanners that can be approved by the Agency. The Agency determined that the application submitted by Mercy Hospital is the most effective alternative proposed in this review for one additional fixed MRI scanner for Mecklenburg County and is approved. The approval of any other application would result in the approval of MRI scanners in excess of the need determination in the 2017 SMFP and therefore, the application submitted by The Presbyterian Hospital is denied.

The application submitted by Mercy Hospital is approved subject to the following conditions:

- 1. Mercy Hospital, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Mercy Hospital, Inc. shall acquire no more than one additional fixed MRI scanner, for a total of two fixed MRI scanners, to be located at CHS Pineville.**
- 3. Mercy Hospital, Inc. 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.**
- 4. Mercy Hospital, Inc. 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.**
- 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. 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. 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.**