

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 4, 2015

Findings Date: December 4, 2015

Project Analyst: Mike McKillip

Assistant Chief: Martha Frisone

COMPETITIVE REVIEW

Project ID #: O-11060-15
Facility: Porters Neck Imaging
FID #: 050376
County: New Hanover
Applicant: Porters Neck Imaging, LLC
Project: Acquire one fixed MRI scanner

Project ID #: O-11063-15
Facility: Wilmington Health
FID #: 943565
County: New Hanover
Applicant: Wilmington Health, PLLC
Project: Acquire one fixed MRI scanner

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C – Both Applications

The 2015 State Medical Facilities Plan (2015 SMFP) includes a methodology for determining the need for additional fixed MRI scanners by service area. Application of the need methodology in the 2015 SMFP identified a need for one additional fixed MRI scanner in the New Hanover County MRI Service Area. Two applications were submitted to the Healthcare Planning and Certificate of Need Section (Agency), each proposing to acquire a fixed MRI scanner for New Hanover County. Each proposal is briefly described below.

Porters Neck Imaging, LLC [PNI] proposes to acquire one fixed MRI scanner to be located in a medical office building on Medical Center Drive in Wilmington in New Hanover County. PNI does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2015 SMFP for New Hanover County. Therefore, the application is consistent with the need determination.

Wilmington Health, PLLC [Wilmington Health] proposes to acquire one fixed MRI scanner to be located in a medical office building on Medical Center Drive in Wilmington in New Hanover County. Wilmington Health does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2015 SMFP for New Hanover County. Therefore, the application is consistent with the need determination.

Policies

There are two policies in the 2015 SMFP which are applicable to this review: Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-3: Basic Principles, states:

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

The applicants responded to Policy GEN-3 as follows:

PNI

Promote Safety and Quality - In Section II.6, page 34, and Section II.7, pages 35-38, Section V.7, pages 126-128, and Exhibit 12, the applicant describes how it believes the proposed

project would promote safety and quality. Exhibit 12 contains a copy of the applicant's "Performance Improvement Plan." 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 - In Section V.7, pages 129-130, Section VI, pages 134-141, and Exhibit 18, the applicant describes how it believes the project would promote equitable access to MRI scanner services. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will promote equitable access.

Maximizing Healthcare Value - The applicant describes how it believes the proposed project would maximize healthcare value in Section V.7, pages 131-132. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2015 SMFP. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference. The discussion regarding revenues and costs found in Criterion (5) is incorporated herein by reference. Therefore, the application is consistent with Policy GEN-3.

Wilmington Health

Promote Safety and Quality - In Sections II.5, II.6 and II.7, pages 19-20, Section III.2, pages 71-72, Section V.7, pages 87-88, and Exhibit 8, the applicant describes how it believes the proposed project would promote safety and quality. Exhibit 8 contains copies of the applicant's "Quality Policies." 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 - In Section III.2, pages 71-72, Section VI, pages 90-99, and Exhibit 13, the applicant describes how it believes the project would promote equitable access to MRI scanner services. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will promote equitable access.

Maximizing Healthcare Value - The applicant describes how it believes the proposed project would maximize healthcare value in Section V.7, pages 87-88. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need

identified in the 2015 SMFP. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference. The discussion regarding revenues and costs found in Criterion (5) is incorporated herein by reference. Therefore, the application is consistent with Policy GEN-3.

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, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

PNI – The proposed capital expenditure for this project is less than \$2 million. Therefore, Policy GEN-4 does not apply to the review of this application.

In summary, the application is consistent with the need determination in the 2015 SMFP and Policy GEN-3. Consequently, the application is conforming to this criterion.

Wilmington Health – The proposed capital expenditure for this project is greater than \$2 million. In Section III.2, page 72, the applicant states

“Wilmington Health has been implementing energy saving strategies at this facility in recent years to modernize the facility and provide cost savings to the end users. These include the addition of a main entrance vestibule, energy recovery ventilators, and LED and high output fluorescent lighting with dual level switching or occupancy sensors. High efficiency mechanical split heat pumps will be used to condition the air within the suite. Water saving toilet fixtures will incorporate metered sensors, and a closed loop chiller will be utilized to cool the magnet.”

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.

In summary, the application is consistent with the need determination in the 2015 SMFP, Policy GEN-3 and Policy GEN-4. Consequently, the application is conforming to this criterion.

Conclusion

In summary, both applicants adequately demonstrate that their proposal is consistent with the need determination in the 2015 SMFP for one fixed MRI scanner for New Hanover County. However, the limit on the number of MRI scanners that may be approved in this review is one MRI scanner. Collectively, the two applicants propose a total of two MRI scanners. Therefore, even if both applications are conforming to all statutory and regulatory review criteria, both applications cannot be approved.

Both applications are conforming to Policy GEN-3. Wilmington Health's application is conforming to Policy GEN-4. Policy GEN-4 is not applicable to PNI's application. Therefore, both applications are conforming to this criterion. See the Summary following the Comparative Analysis for the decision.

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

C – Both Applications

PNI. The applicant, Porters Neck Imaging, LLC, proposes to acquire one fixed MRI scanner to be located in 1,182 of renovated space in an existing medical office building, DR-Medical Center, which is located at 1025 Medical Center Drive in Wilmington. PNI is a joint venture company whose members are Delaney at MCD, LLC (Delaney) and New Hanover Regional Medical Center (NHRMC). Each member holds a fifty percent ownership interest in PNI. PNI will lease the space for the MRI scanner from Delaney, which owns the medical office building. Delaney Radiologists will manage the MRI scanner service. Since 2006, PNI has owned and operated one mobile MRI scanner which currently provides services at two Delaney Radiology office locations, including DR-Medical Center and DR-Ashton, which is located at 2800 Ashton Drive in Wilmington. In Section II.1, page 20, the applicant states,

“PNI proposes to upfit 1,182 SF in the DR-Medical Center at a cost of \$499,000. The up-fit will include the following rooms:

- *MRI Vault*
- *MRI Control and Support Equipment Room*
- *Control Booth*
- *Patient Prep Area (two curtained dressing rooms)*

The following rooms or areas will be shared with DR.

- *Reception*
- *Patient Waiting*
- *Toilet*

The space that will be up-fitting [sic] to accommodate the fixed MRI scanner is currently vacant space originally intended to either expand CT imaging, nuclear imaging, or add MRI services in the future.”

Population to be Served

On page 146, the 2015 SMFP defines the service area for fixed MRI scanners as *“a single county, except where there is no licensed acute care hospital located within the county.”* Thus, the service area consists of New Hanover County. Providers may serve residents of counties not included in their service area.

PNI currently owns and operates one mobile MRI scanner which provides services to two Delaney Radiology office locations in Wilmington, including DR-Medical Center. Also, InSight Imaging currently provides mobile MRI scanner services to DR-Medical Center. In Sections III.4 and III.5, pages 95-97, the applicant provides the current (FY2014) and projected (FY2017-FY2018) patient origin for MRI scanner services at DR-Medical Center, as summarized in the table below.

**PNI MRI Scanner Services
 Current and Projected Patient Origin**

County	Current (FY2014) Patient Origin Percent of Total Patients	Projected (FY2017-FY2018) Percent of Total Patients
Primary Service Area		
New Hanover	55.3%	55.3%
Brunswick	17.4%	17.4%
Pender	10.9%	10.9%
Secondary Service Area		
Columbus	4.8%	4.8%
Duplin	3.8%	3.8%
Onslow	3.7%	3.7%
In-migration	4.2%	4.2%
TOTAL	100.0%	100.0%

Source: Tables on pages 95 and 97.

In Section III.5, page 97, with regard to its assumptions for projected patient origin, the applicant states, “PNI expects projected patient origin to be similar to historical patient origin because MRI patients who are currently receiving an MRI scan on one of the two mobile MRI scanners at DR-Medical Center will now receive a MRI scan on the fixed MRI scanner.” The applicant adequately identified the population proposed to be served.

Analysis of Need

In Section III.1(a) and (b) of the application, the applicant describe the factors which it states support the need for the proposed project, including:

- Historical and projected growth in the service area population (pages 70-72).
- Commitments of referrals and support by service area physicians for the applicant’s MRI scanner services (pages 73-77).
- The historical utilization of MRI scanner services in North Carolina, and at NHRMC and PNI (pages 78-81).

Projected Utilization

In Section IV.1, page 101, the applicant provides the historical and projected utilization for its existing mobile MRI scanner and the proposed fixed MRI scanner through the first three years of operation following completion of the project (FY2017-FY2019), which is summarized below.

PNI's Historical and Projected MRI Scanner Utilization

Fiscal Year	Existing Mobile MRI Scanner	Proposed Fixed MRI Scanner	Total MRI Scans (Unweighted)	Percent Change
FY2013 Actual	3,632		3,632	---
FY2014 Actual	3,471		3,471	-5.2
FY2015 Projected*	3,852		3,852	11.0%
FY2016 Projected	3,941		3,941	2.3%
FY2017 Project Year 1	3,033	4,335	7,368	87.0%
FY2018 Project Year 2	3,103	4,435	7,538	2.3%
FY2019 Project Year 3	3,174	4,537	7,711	2.3%

Source: Table on page 101 of the application.

*Applicant states FY2015 was projected by annualizing actual volumes from October 1, 2014 through June 30, 2015.

As shown in the above table, the applicant projects the proposed fixed MRI scanner will perform 4,537 unweighted MRI scans in the third operating year. In Section III.1, page 116, the applicant projects the proposed fixed MRI scanner will perform 5,398 weighted MRI scans in the third operating year (FY2019), which exceeds the utilization standards required in 10A NCAC 14C .2703(b). The applicant describes the assumptions and methodology used to project utilization in Section IV.1(d), pages 102-116, which are summarized below.

“PNI identified the MRI scans performed at all PNI and NHRMC, a member company of PNI, locations and as reported in the 2014-2016 NHRMC License Renewal Applications and in the 2014-2016 Registration and Inventory of Medical Equipment forms for PNI, Alliance Healthcare, and InSight Imaging. PNI references the Alliance Healthcare and InSight Imaging forms because these two mobile providers are contracted to provide mobile MRI services at both NHRMC and DR sites. PNI also used current MRI scan volumes for the same locations for the time period 10/1/2014 through 6/30/15 to annualize the FY2015 MRI scan volumes. ... The following table shows growth over the last two years, which coincides with the improvement of several factors that had previously muted MRI scan growth.

***PNI and NHRMC
 Historical and Interim Year 1 MRI Scans***

Location			Hist Yr 1 FY2013	Hist Yr 2 FY2014	Int Yr 1 FY2015
<i>17th Street</i>	<i>2 fixed</i>	<i>NHRMC</i>	8,896	9,116	10,320
<i>Orthopedic Hospital</i>	<i>1 fixed</i>	<i>NHRMC</i>	2,308	2,133	216
<i>Med Mall</i>	<i>1 fixed</i>	<i>NHRMC</i>	1,669	1,822	1,861
<i>H&D – Military Cutoff</i>	<i>mobile</i>	<i>Alliance</i>	352	353	825
<i>H&D – Porters Neck/ED North</i>	<i>mobile</i>	<i>Alliance</i>	482	506	831
<i>DR – Ashton</i>	<i>mobile</i>	<i>PNI</i>	1,539	1,488	1,656
<i>DR – Medical Center</i>	<i>mobile</i>	<i>InSight</i>	2,331	2,430	2,677
<i>DR – Medical Center</i>	<i>mobile</i>	<i>PNI</i>	2,093	1,983	2,196
<i>Total</i>			19,670	19,831	20,582
<i>Annual Change</i>				0.82%	3.79%
<i>2-Year Average</i>					2.30%

Source: 2014-2016 NHRMC HLRAs, 2014-2106 PNI, Alliance Healthcare, InSight Imaging RIME forms.
 Note: The Orthopedic Hospital MRI scanner is in the process of being replaced and the replacement MRI scanner will become operational late 2nd quarter FY2016.

As shown in the table above, the applicant calculates the average annual rate of increase in MRI scanner utilization as 2.3 percent based on the historical utilization of all the MRI scanners operated at NHRMC and PNI sites, including the mobile MRI scanners contracted through Alliance and InSight Imaging, over the period from FY2013 to FY2015. The applicant then projects utilization for all the MRI scanners operated at NHRMC and PNI sites will continue to increase at annual rate of 2.3 percent from FY2015 through FY2019, as summarized in the following table.

Projected Total MRI Scanner Utilization at all NHRMC and PNI MRI Sites

	FY2015	FY2016	FY2017	FY2018	FY2019
Total MRI Scans	20,582	21,056	21,541	22,037	22,544
Annual Rate of Change		2.3%	2.3%	2.3%	2.3%

Source: Table on page 106 of the application.

On page 106, the applicant states the assumption that total MRI scanner utilization will continue to increase at the rate of 2.3 percent per year during the four-year period from FY2016 to FY2019 is “reasonable because unemployment has decreased in New Hanover County and surrounding counties [See table on page 106], the number of uninsured has decreased due to the Affordable Care Act [See table on page 106], continued growth in the service area population and key demographics (pages 70-72), increased familiarity with pre-certification requirements for MRI scan utilization, and neither NHRMC nor PNI are self-referring imaging centers.”

On page 107, the applicant states,

“The projected Interim Year 2 and Project Years 1-3 total MRI scans, calculated in Step 2, were divided among the locations operated by PNI and NHRMC. Central scheduling systems allow patients to decide where their MRI scan will be obtain [sic], but these decisions are typically based on hours of operation, proximity to physician’s office, location of medical treatment, proximity to home, etc.

***PNI and NHRMC
 Interim Year 2 and Projected Year 1-3
 By Location***

<i>Location</i>			<i>Int Yr 2 FY2016</i>	<i>Year 1 FY2017</i>	<i>Year 2 FY2018</i>	<i>Year 3 FY2019</i>
<i>17th Street</i>	<i>2 fixed</i>	<i>NHRMC</i>	<i>9,502</i>	<i>9,721</i>	<i>9,945</i>	<i>10,174</i>
<i>Orthopedic Hospital</i>	<i>1 fixed</i>	<i>NHRMC</i>	<i>1,277</i>	<i>2,504</i>	<i>2,562</i>	<i>2,621</i>
<i>Med Mall</i>	<i>1 fixed</i>	<i>NHRMC</i>	<i>1,904</i>	<i>1,948</i>	<i>1,993</i>	<i>2,038</i>
<i>H&D – Military Cutoff</i>	<i>mobile</i>	<i>Alliance</i>	<i>844</i>			
<i>H&D – Military Cutoff</i>	<i>mobile</i>	<i>PNI</i>		<i>863</i>	<i>883</i>	<i>904</i>
<i>H&D – ED North</i>	<i>mobile</i>	<i>Alliance</i>	<i>850</i>			
<i>H&D – ED North</i>	<i>mobile</i>	<i>Alliance</i>		<i>870</i>	<i>890</i>	<i>910</i>
<i>DR – Ashton</i>	<i>mobile</i>	<i>PNI</i>	<i>1,694</i>	<i>1,300</i>	<i>1,330</i>	<i>1,360</i>
<i>DR – Medical Center</i>	<i>mobile</i>	<i>InSight</i>	<i>2,739</i>			
<i>DR – Medical Center</i>	<i>mobile</i>	<i>PNI</i>	<i>2,247</i>			
<i>DR – Medical Center</i>	<i>Fixed</i>	<i>PNI</i>		<i>4,335</i>	<i>4,435</i>	<i>4,537</i>
<i>Total</i>			<i>21,056</i>	<i>21,541</i>	<i>22,037</i>	<i>22,544</i>

Additional table assumptions:

- Orthopedic Hospital replacement MRI scanner will become operational late 2nd quarter FY2016.*
- InSight Imaging and Alliance Healthcare mobile MRI contracts will end after FY2016.*
- The PNI mobile MRI scanner will no longer provide services at DR-Medical Center after FY2016.*
- The PNI mobile MRI scanner will begin providing services at H&D-Military Cutoff and at H&D-ED North in FY2017.*
- Decreased days of mobile MRI operation at DR-Ashton will decrease MRI scans performed at this site by 25% and will be reallocated to other PNI member company locations including Orthopedic Hospital.*
- Replacing the existing MRI scanner at the Orthopedic Hospital will result in 15% of outpatient MRI scans to be reallocated from DR-Medical Center.”*

On pages 108-111, the applicant describes its projections (Steps 4-6) of the percentages of MRI scans it will perform by the categories of MRI scan in the weighting system described in the 2015 SMFP (page 147). The applicant states it calculated the percentage of scans at each location by type of scan based on its historical (FY2015 annualized) experience, with two adjustments. The applicant states,

“PNI calculated the MRI scan type breakdown by annualizing the MRI scans performed at each PNI and NHRMC MRI scan location in FY2015. Next, PNI divided the MRI scan volume by type by the total annualized MR scans [See tables on page 108]. ... PNI used the annualized FY2015 MRI scan by type breakdown percentages, calculated in Step 4, to project the FY2016-Interim Year 2 MRI scan by type breakdown. ... In projecting Project Years 1-3 MRI scan by type breakdowns, PNI had to make two adjustments in the MRI scan by type breakdown percentages calculated in Step 4. ... To calculate the MRI scan by type breakdown percentages for the Orthopedic Hospital [Underline in original], PNI allocated 25% of the MRI scan by type breakdown percentage that were performed on the PNI mobile MRI scanner at DR-Ashton and 15% of the MRI scan by type breakdown percentage that were performed on the PNI mobile MRI scanner at DR-Medical Center to Orthopedic Hospital, as shown [in the table on page 110]. ... To project the MRI scan by type breakdown percentage for the fixed MRI scanner to operate at DR-Medical Center [Underline in original], PNI added the MRI scan by type breakdown percentages that were performed on the InSight Healthcare mobile MRI scanner to the remaining values from the PNI mobile MRI scanner at DR-Medical Center after the previous calculation.”

On page 111, the applicant provides a table showing its projections of percentages MRI scans by type and location for the first three operating years for the project (FY2017-FY2019), which is summarized below.

**PNI’s Projected Percentage MRI Scanner Utilization by Type and Location
 Project Years 1-3 (FY2017-FY2019)**

Location	Provider	Inpatient With Sedation/ Contrast	Inpatient Without Sedation/ Contrast	Outpatient With Sedation/ Contrast	Outpatient Without Sedation/ Contrast	Total
17 th Street	NHRMC	19.9%	22.0%	26.1%	31.9%	100%
Orthopedic Hospital	NHRMC	1.4%	1.0%	45.0%	52.6%	100%
Med Mall	NHRMC	0.3%	0.2%	58.0%	41.4%	100%
H&D – Military Cutoff	Alliance			44.8%	55.2%	100%
H&D – ED North	Alliance			39.8%	60.2%	100%
DR – Ashton	PNI				100.0%	100%
DR – Medical Center	PNI			47.7%	52.3%	100%

The applicant multiplied the projected percentages of MRI scans by type shown in the table above by the projected MRI scans by location from a previous step to calculate the projected number of MRI scans by type and by location for each of the first three years of operation [See tables on pages 112-113]. The applicant then multiplied the projected number of MRI scans by type and by location by the corresponding MRI weights for each MRI scan type to calculate the total projected weighted MRI scans for each location for the two interim years (FY2015-FY2016) and each of the first three years of operation (FY2017-FY2019) [See tables on pages 114-116].

The applicant's total projected unweighted MRI scans by location and year are summarized below:

PNI's Projected Unweighted MRI Scanner Utilization by Location

Location	Provider	FY2015	FY2016	FY2017	FY2018	FY2019
17 th Street	NHRMC	10,320	9,502	9,721	9,945	10,174
Orthopedic Hospital	NHRMC	216	1,277	2,504	2,562	2,621
Med Mall	NHRMC	1,861	1,904	1,948	1,993	2,038
H&D – Military Cutoff	Alliance	825	844	863	883	904
H&D – ED North	Alliance	831	850	870	890	910
DR – Ashton	PNI	1,656	1,694	1,300	1,330	1,360
DR – Medical Center	InSight	2,677	2,793	0	0	0
DR – Medical Center	PNI	2,196	2,247	4,335	4,435	4,537
Totals		20,582	21,111	21,541	22,038	22,544

Source: Tables on pages 108-113 of the application.

The applicant's total projected weighted MRI scans by location and year are summarized below:

PNI's Projected Weighted MRI Scanner Utilization by Location

Location	Provider	FY2015	FY2016	FY2017	FY2018	FY2019
17 th Street	NHRMC	13,952	12,846	13,142	13,445	13,754
Orthopedic Hospital	NHRMC	269	1,591	2,993	3,062	3,132
Med Mall	NHRMC	2,299	2,352	2,407	2,462	2,519
H&D – Military Cutoff	Alliance	973	995	1,018	1,042	1,066
H&D – ED North	Alliance	986	986	1,008	1,031	1,055
DR – Ashton	PNI	1,656	1,694	1,300	1,330	1,360
DR – Medical Center	InSight	3,227	3,301	0	0	0
DR – Medical Center	PNI	2,578	2,638	5,158	5,277	5,398
Totals		25,940	26,403	27,026	27,649	28,284

Source: Tables on pages 114-116 of the application.

In FY2014, the two existing mobile MRI scanners operating at the applicant's DR-Medical Center site performed at total of 4,413 unweighted MRI scans and 5,216 weighted MRI scans. Based on utilization data for the period from October 1, 2014 through June, 30, 2015, the applicant projects the two existing mobile MRI scanners operating the DR-Medical Center site will perform 4,873 unweighted MRI scans and 5,805 weighted MRI scans in FY2015. As shown above, the applicants' utilization projections are based on the historical utilization of PNI's and NHRMC's existing fixed and mobile MRI scanner sites from FY2013 to FY2015, as well as the utilization of the InSight Imaging mobile MRI scanner currently operating at the DR-Medical Center location, and is supported by the projected growth and aging of the service area population, recent trends toward lower unemployment rates resulting from the economic recovery, and expanded health insurance coverage resulting from implementation of the Affordable Care Act. Exhibit 32 contains letters from physicians in the proposed service area expressing support for the proposed project and their intention to

refer patients to the proposed service. Projected utilization is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrated the need to acquire a fixed MRI scanner.

Access

In Section VI.2, page 134, the applicant states it is committed to provide services to all patients who need the services regardless of their ability to pay, racial/ethnic origin, age, gender, physical or mental conditions or other conditions that would classify them as underserved. In Section VI.15, page 141, the applicant projects that 38 percent of patients to be served will be Medicare beneficiaries and 4 percent will be Medicaid recipients. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

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

Wilmington Health. The applicant, Wilmington Health, PLLC, proposes to acquire one fixed MRI scanner to be located in a 967 square foot addition to the existing medical office building, which is located at 1202 Medical Center Drive in Wilmington. Wilmington Health is multi-specialty medical group practice which currently provides MRI scanner services at the Medical Center Drive location with a mobile MRI scanner under contract with Alliance Imaging. In Section II.1, pages 13-15, the applicant states,

“As previously noted, Wilmington Health has been providing MRI services to its patients through its existing mobile MRI agreement with Alliance for 15 years, since September 2000. The mobile MRI unit remains continually parked at Wilmington Health’s location at 1202 Medical Center Drive and does not travel to any other locations. ... The design for the proposed project involves the construction of a new addition within the building alcove that is currently used to access the mobile unit, clearly visible in the [photograph on page 14 of the application]. The new addition will house the magnet and control room, allowing for the specialized needs of the equipment to be within space that provides floor recess to accommodate shielding below the magnet as well as additional structural height. Ancillary spaces such as the equipment support room, dressing room, private toilet, and storage will be located in space to be renovated within the existing medical office building, adjacent to the new construction.”

Population to be Served

On page 146, the 2015 SMFP defines the service area for fixed MRI scanners as “a single county, except where there is no licensed acute care hospital located within the county.” Thus, the service area consists of New Hanover County. Providers may serve residents of counties not included in their service area.

Wilmington Health currently provides MRI services at the Medical Center Drive location through a contract for a mobile MRI scanner with Alliance Imaging. In Sections III.4 and III.5, pages 75-77, the applicant provides Wilmington Health’s current and projected (CY2017-CY2018) patient origin for MRI scanner services, as summarized in the table below.

**Wilmington Health MRI Scanner Services
 Current and Projected Patient Origin**

County	Current Patient Origin Percent of Total Patients	Projected (CY2017-CY2018) Percent of Total Patients
New Hanover	51.5%	51.5%
Brunswick	21.3%	21.3%
Pender	12.0%	12.0%
Onslow	5.5%	5.5%
Columbus	3.7%	3.7%
Duplin	2.8%	2.8%
Bladen	1.0%	1.0%
Other*	2.3%	2.3%
TOTAL	100.0%	100.0%

Source: Tables on pages 75 and 77.

*Applicant provides a list of counties included in the “Other” category on pages 75 and 77.

In Section III.5, page 77, with regard to its assumptions for projected patient origin, the applicant states, “Wilmington Health projected its patient origin for the proposed fixed MRI scanner based on current patient origin for MRI services.” The applicant adequately identified the population proposed to be served.

Analysis of Need

In Section III.1(a) and (b) of the application, the applicant describe the factors which it states support the need for the proposed project, including:

- The operational problems and constraints associated with the existing mobile MRI scanner service provided through contract with Alliance (pages 50-51).
- The cost-savings of converting from a contracted mobile MRI scanner to a provider-owned fixed MRI scanner and the need to meet the requirements of Accountable Care Organizations (ACO) with which Wilmington Health participates (pages 53-55).

- The high historical utilization of the existing Alliance mobile MRI scanner operating at the Wilmington Health location in comparison with other New Hanover County providers (pages 56-61).
- Historical and projected growth and aging of the service area population (pages 61-62).

Projected Utilization

In Section IV.1, pages 81-82, the applicant provides the historical and projected utilization for the existing mobile MRI scanner (under contract with Alliance Imaging) and the proposed fixed MRI scanner through the first three years of operation following completion of the project (CY2017-CY2019), which is summarized below. The applicant proposes to terminate the contract for the existing mobile MRI scanner with Alliance upon completion of the project and the offering of services with the proposed fixed MRI scanner.

Wilmington Health’s Historical and Projected MRI Scanner Utilization

Calendar Year	Existing Mobile MRI Scanner	Proposed Fixed MRI Scanner	Total MRI Scans	Percent Change
CY2013 Actual	2,986		2,986	---
CY2014 Actual	2,901		2,901	-2.8%
CY2015 Projected	2,900		2,900	0.0%
CY2016 Projected	2,931		2,931	1.1%
CY2017 Project Year 1	0	4,065	4,065	38.7%
CY2018 Project Year 2	0	4,108	4,108	1.1%
CY2019 Project Year 3	0	4,152	4,152	1.1%

Source: Tables on pages 81-82 of the application.

As shown in the above table, the applicant projects the proposed fixed MRI scanner will perform 4,152 unweighted MRI scans in the third operating year. In Section IV.1, page 81, the applicant projects the proposed fixed MRI scanner will perform 4,954 weighted MRI scans in the third operating year (CY2019), which exceeds the utilization standards required in 10A NCAC 14C .2703(b). The applicant describes the assumptions and methodology used to project utilization in Section III.1(b), pages 62-70. On pages 62-63, the applicant states,

“Wilmington Health providers make referrals for 4,421 MRI scans (unweighted) annually according to 2015 year-to-date internal data. Wilmington Health estimates that these scans are equivalent to 5,275 weighted scans based on its historical ratio of scans with contrast. This level of utilization exceeds the performance standard of 4,805 weighted scans annually for a fixed MRI unit in New Hanover County by 10 percent. Thus, based on its historical and current MRI referral volumes, Wilmington Health needs the proposed fixed MRI to serve its patient population.

Nearly two-thirds of these scans are provided on a mobile MRI unit operated by Alliance Healthcare Services (Alliance) at Wilmington Health’s Medical Center Drive

location. According to Wilmington Health’s internal billing data, the number of weighted MRI scans performed on this mobile MRI unit has increased at a compound annual growth rate (CAGR) of 1.5 percent since 2011....

**Wilmington Health MRI Referrals
 Provided at Wilmington Health Mobile MRI**

	CY11	CY12	CY13	CY14	CY15*	CAGR
<i>With Contrast</i>	1,059	1,060	1,177	1,263	1,400	7.2%
<i>Without Contrast</i>	1,782	1,772	1,809	1,638	1,500	-4.2%
Total	2,841	2,832	2,986	2,901	2,900	0.5%
Weighted Total	3,265	3,256	3,457	3,406	3,460	1.5%
<i>Ratio of Weighted Total to Total Scans</i>	1.15	1.15	1.16	1.17	1.19	0.9%

**CY15 based on six months annualized.
 Source: Wilmington Health internal data.*

Also, due to the constraints of the mobile MRI scanner such as its outdoors location, older technology, physically small spaces, and limited hours of operation, the applicant states Wilmington Health physicians have historically referred patients to other area providers of MRI services, including New Hanover Regional Medical Center, which is approximately one mile from the applicant’s Medical Center Drive location. On page 64, the applicant states, “Because of the multiple issues with the mobile unit, Wilmington Health providers must refer 1,521 outpatient MRI scans to other MRI providers, annually, based on 2015 year-to-date internal data.” Therefore, based on six months of actual experience, the applicant projects Wilmington Health will refer 2,900 patients for MRI scans at the on-site Alliance mobile MRI scanner, and 1,521 patients for MRI scans at other MRI service providers, for a total of 4,421 MRI scans, in CY2015. On pages 65-66, the applicant states,

In order to estimate the number of MRI scans that it projects to refer in the future, Wilmington Health examined historical data for MRI providers in New Hanover County. According to data presented in the 2013 to Proposed 2016 State Medical Facilities Plan, MRI scans (unweighted) in New Hanover County have grown 1.07 percent annually since 2011 and weighted scans have growth [sic] 1.21 percent annually.

**All New Hanover County Providers
 Total MRI Scans**

	2011	2012	2013	2014	CAGR
<i>Total Scans (Unweighted)</i>	27,708	26,867	28,344	28,607	1.07%
Weighted Scans Total	33,468	32,562	34,342	34,695	1.21%

Source: 2013 to Proposed 2016 State Medical Facilities Plan.

Wilmington Health conservatively estimates that its MRI referrals will grow 1.07 percent annually through 2019, a rate equivalent to the 2011 to 2014 compound annual growth rate (CAGR) for MRI scans in New Hanover County, which is lower

*than the practice's historical growth in weighted scan referrals to its mobile scanner."*¹

Based on the assumption that total referrals for MRI scans from Wilmington Health physicians will increase by 1.07 percent per year from 2015 through 2019, the applicant projects total MRI referrals as follows:

Projected Wilmington Health MRI Scanner Referrals

	CY2015	CY2016	CY2017	CY2018	CY2019
Total MRI Referrals	4,421	4,468	4,516	4,564	4,613
Annual Rate of Change		1.07%	1.07%	1.07%	1.07%

Source: Table on page 66 of the application.

To project total weighted MRI scans, the applicant assumes a ratio of 1.19 weighted MRI scans to total scans, based on Wilmington Health's experience in the first six months of CY2015. The applicant's projections of weighted MRI scans by year are shown in the following table.

Projected Wilmington Health MRI Referrals/Scans and Weighted MRI Scans

	2015	2016	2017	2018	2019	CAGR
Total MRI Referrals	4,421	4,468	4,516	4,564	4,613	1.07%
Ratio of Weighted to Total MRI Scans	1.19	1.19	1.19	1.19	1.19	0.0%
Total Weighted Scans	5,275	5,331	5,388	5,446	5,504	1.07%

Source: Table on page 67 of the application.

The applicant then assumes a 10 percent reduction in its projected number of weighted MRI scans in each of the first three operating years of the proposed project. On page 67, the applicant states,

"As shown in the table above, the resulting projected CAGR for Wilmington Health's weighted scans of 1.07 percent is less than its historical CAGR (2011 to 2015) for weighted scans of 1.5 percent. Ideally, each one of Wilmington Health [sic] 5,504 projected weighted MRI scans in 2019 would be performed on the proposed fixed MRI unit. In order to remain conservative, Wilmington Health projects that its

¹ The total number of weighted MRI scans performed in New Hanover County as published in Table 9P of the 2015 SMFP is overstated by 1,571 scans. New Hanover Regional Medical Center and Alliance Healthcare Services reported the same mobile MRI scans in their 2014 Hospital License Renewal Application and 2014 Registration and Inventory, respectively, and the Agency double counted these scans. However, the Agency was not aware of the error until October 2015 when Alliance Healthcare Services submitted written comments regarding the Wilmington Health application. The Agency assumes that Wilmington Health was not aware of the error. Reliance upon the published data is reasonable.

proposed fixed MRI unit will provide ten percent fewer scans than those projections. This ten percent reduction is to account for patients that may receive their scan at another provider due to any number of unique circumstances (schedule, location, etc.) and to account for potential fluctuations in the number of providers that are part of Wilmington Health. The following table demonstrates the projected number of scans to be performed at Wilmington Health during the three project years.

***Wilmington Health MRI Referrals
 Performed on Proposed Fixed MRI Unit***

	2017	2018	2019
<i>Total MRI Referrals</i>	4,517	4,564	4,613
<i>Total MRI Scans Performed at Wilmington Health (includes 10% Reduction)</i>	4,065	4,108	4,152
<i>Ratio of Weighted to Total Scans</i>	1.19	1.19	1.19
<i>Weighted Scans Total</i>	5,388	5,446	5,504
<i>Total Weighted Scans Performed at Wilmington Health (includes 10% Reduction)</i>	4,849	4,901	4,954

As described above, the applicant’s utilization projections are based on the its historical volume of referrals for MRI services to the existing Alliance mobile MRI scanner operated at Wilmington Health’s Medical Center Drive location and the historical volume of referrals from Wilmington Health physicians to other providers of MRI services, and is supported by the projected growth and aging of the service area population.

In FY2014, the existing mobile MRI scanner operated by Alliance at the applicant’s Medical Center Drive site performed at total of 2,856 unweighted MRI scans and 3,332 weighted MRI scans. Based on utilization data for the period from January 1, 2015 through June, 30, 2015, the applicant projects the existing Alliance mobile MRI scanner operating at the Medical Center Drive site will perform 2,900 unweighted MRI scans and 3,460 weighted MRI scans in CY2015.

Based on data from the first six months of CY2015, the applicant projects Wilmington Health physicians will refer 1,521 patients for MRI scans at other MRI service providers, in addition to the 2,900 patients Wilmington Health projects to refer for MRI scans at the on-site Alliance mobile MRI scanner, for a total of 4,421 referrals for MRI scans in CY2015. The applicant assumes that annual MRI referral volumes from Wilmington Health physicians will increase by 1.07 percent per year from CY2015 through CY2019. In comparison, from CY2011 to CY2015, the applicant reports that its MRI referrals to the Alliance mobile MRI scanner located at the Medical Center Drive location increased by an average of 0.5 percent per year, and that total weighted MRI scans increased by an average of 1.5 percent per year. Exhibit 20 contains letters from Wilmington Health physicians expressing support for the proposed project and their intention to refer patients to the proposed service. Projected utilization is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrated the need to acquire a fixed MRI scanner.

Access

In Section VI.2, page 90, the applicant states it is committed to provide services to all patients who need the services regardless of their ability to pay, racial/ethnic origin, age, gender, physical or mental conditions or other conditions that would classify them as underserved. In Section VI.15, page 99, the applicant projects that 44.7 percent of patients to be served will be Medicare beneficiaries and 5.9 percent will be Medicaid recipients. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

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

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

NA – Both Applications

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

C – Both Applications

PNI. In Section III.3, pages 89-94, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative because it would not meet the need for one additional fixed MRI scanner identified in the 2015 SMFP, and would not address PNI’s need for additional MRI capacity.
- Locate the MRI Scanner in Another Part of the County – The applicant states that after considering factors such as strategic fit, operational challenges, financial concerns, timing issues and projected utilization, PNI determined that DR-Medical Center was the best location for the proposed fixed MRI scanner.
- Develop the MRI Scanner in a New Freestanding Facility – The applicant states that developing the MRI scanner in a new facility is not the most effective alternative due to the higher capital and operational costs.

- NHRMC Acquire a Fifth MRI Scanner – The applicant states this alternative is less effective because NHRMC has adequate MRI scanner capacity.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

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

Wilmington Health. In Section III.3, pages 72-74, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative because it would not address the problems and constraints associated with the existing mobile MRI scanner operated under contract with Alliance.
- Locate the MRI Scanner in Vacated Laboratory Space – The applicant states that after consulting with architects and contractors, Wilmington Health determined that the space was inadequate to meet the requirements of the fixed MRI scanner.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

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

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

C – Both Applications

PNI. In Section VIII.1, page 150, the applicant states the total capital cost is projected to be as follows:

PNI MRI Scanner Project Capital Cost

Site Costs	\$0
Construction/Renovation Costs	\$499,000
Equipment/Miscellaneous	\$1,320,138
TOTAL CAPITAL COST	\$1,819,138

Source: Table on page 150 of the application.

In Section IX.1, page 155, the applicant states there will be \$26,024 in start-up expenses and no initial operating expenses associated with the project.

Availability of Funds

In Section VIII.3, page 151, the applicant states that \$82,151 of the project capital costs will be funded by the accumulated reserves of PNI, LLC and \$1,736,987 will be funded by the members of PNI, LLC. In Section IX.2, page 155, the applicant states that the working capital will be funded by the unrestricted cash of PNI, LLC. In Exhibit 27, the applicant provides a letter dated August 6, 2015, from the President of PNI, documenting its intention to fund the capital and working capital costs for the proposed project. Also, Exhibit 27 contains copies of letters from the two members companies of PNI, NHRMC and Delaney at MCD, LLC, documenting the intention of each member to fund 50 percent of capital and working capital costs for the proposed projects. Exhibit 28 contains the NHRMC consolidated balance sheets (“*Statement of Net Position*”) which indicate that as of September 30, 2014, NHRMC had \$71.3 million in cash and cash equivalents. Exhibit 29 contains an August 1, 2015 letter from First Citizens Bank documenting its intention to extend a line of credit to Delaney at MCD, LLC to fund the capital and working capital costs for the proposed project. The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

In the pro forma financial statements for PNI’s MRI services (Form B), including the existing mobile MRI scanner and the proposed fixed MRI scanner, the applicant projects that revenues will exceed operating expenses in each of the first three operating years of the project, as shown in the table below.

**PNI MRI Services
 (Includes Existing Mobile MRI Scanner and Proposed Fixed MRI Scanner)**

	FY2017	FY2018	FY2019
Total Net Revenues	\$4,736,619	\$4,845,905	\$4,957,121
Total Operating Expenses	\$3,406,150	\$3,630,359	\$3,705,091
Net Income (Loss)	\$1,330,468	\$1,215,547	\$1,252,029

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

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

Wilmington Health. In Section VIII.1, pages 109-110, the applicant states the total capital cost is projected to be as follows:

Site Costs	\$17,500
Construction/Renovation Costs	\$650,580
Equipment/Miscellaneous	\$1,473,912
TOTAL CAPITAL COST	\$2,141,992

Source: Tables on pages 109-110 of the application.

In Section IX.1, page 114, the applicant states there will be no start-up expenses and no initial operating expenses associated with the project.

Availability of Funds

In Section VIII.3, page 110, the applicant states that \$720,080 of the project capital costs will be funded by the accumulated reserves of Wilmington Health and \$1,421,912 will be funded by a capital lease. In Exhibit 15, the applicant provides a letter dated August 17, 2015, from the Chief Financial Officer of Wilmington Health documenting its intention to fund the capital costs for the proposed project. Exhibit 16 contains the Wilmington Health consolidated balance sheets which indicate that as of December 31, 2013, Wilmington Health had \$2.3 million in cash and cash equivalents. Exhibit 4 contains a copy of a capital lease agreement between Wilmington Health and General Electric Capital Corporation for \$1,421,912 for the MRI scanner. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

In the pro forma financial statements for Wilmington Health’s MRI services (Form C), the applicant projects that revenues will exceed operating expenses in each of the first three operating years of the project, as shown in the table below.

Wilmington Health MRI Services

	FY2017	FY2018	FY2019
Total Net Revenues	\$1,763,199	\$1,782,066	\$1,801,134
Total Operating Expenses	\$1,041,381	\$939,721	\$953,104
Net Income (Loss)	\$721,819	\$842,345	\$848,030

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

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C – Both Applications

The 2015 SMFP includes a methodology for determining the need for additional fixed MRI scanners by service area. Application of the need methodology in the 2015 SMFP identified a need for one additional fixed MRI scanner in the New Hanover County MRI Service Area.

On page 146, the 2015 SMFP defines the service area for fixed MRI scanners as *“a single county, except where there is no licensed acute care hospital located within the county.”* Thus, the service area consists of New Hanover County. Providers may serve residents of counties not included in their service area.

There are five existing fixed MRI scanners in New Hanover County. The following table identifies the provider, number, and average utilization of each of the fixed MRI scanners, summarized from Table 9P of the Proposed 2016 SMFP.

	Fixed MRI Scanners	Total Weighted MRI Scans	Average Weighted MRI Scans Per MRI Scanner
New Hanover Regional Medical Center	4	17,421	4,355
OrthoWilmington	1	4,520	4,520

Source: Proposed 2016 SMFP, Table 9P, pages 175-176. The data in the Proposed 2016 SMFP is from the hospital's 2015 License Renewal Application submitted in late 2014 and OrthoWilmington's 2014 Registration and Inventory form submitted in early 2015.

PNI. The applicant, PNI, proposes to acquire one fixed MRI scanner to replace mobile MRI scanner services provided at its Medical Center Drive location. The applicant adequately demonstrates in its application that the fixed MRI scanner it proposes to develop in New Hanover County is needed in addition to the existing fixed MRI scanners in New Hanover County. The applicant adequately demonstrates that its projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved fixed MRI scanner services in New Hanover County. Therefore, the application is conforming to this criterion.

Wilmington Health. The applicant, Wilmington Health, proposes to acquire one fixed MRI scanner to replace mobile MRI scanner services provided at its Medical Center Drive location. The applicant adequately demonstrates in its application that the fixed MRI scanner it proposes to develop in New Hanover County is needed in addition to the existing fixed MRI scanners in New Hanover County. The applicant adequately demonstrates that its projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved fixed MRI scanner services in New Hanover County. Therefore, the application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C – Both Applications

PNI. In Section VII.1, page 142, the applicant states that it currently employs 3.0 full-time equivalent (FTE) MRI technologists to staff the existing mobile MRI scanner, and that it projects to employ a total of 6.0 FTE MRI technologists to staff both the existing mobile MRI scanner and the proposed fixed MRI scanner in the second year of the project. In Section VII.3, page 144, the applicant describes its experience and process for recruiting and retaining staff. Exhibit 21 contains a copy of a letter from Joseph Wehner, M.D., expressing

his interest in serving as the Medical Director for the proposed service. Exhibit 32 of the application contains copies of letters from area physicians and other healthcare providers expressing support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

Wilmington Health. In Section VII.2, page 100, the applicant provides the proposed staffing for the fixed MRI scanner in operating year 2 (FY2018), as shown in the table below.

Position	Number of Full-Time Equivalent (FTE) Positions
MRI Technologists	4.00
Patient Representative	0.50
Manager	0.25
TOTAL	4.75

Source: Table VII.1, page 100.

In Section VII.3, page 101, the applicant describes its experience and process for recruiting and retaining staff. Exhibit 12 contains a copy of a letter from Jonathan Hines, M.D., expressing his interest in serving as the Medical Director for the proposed service. Exhibit 20 of the application contains copies of letters from area physicians and other healthcare providers expressing support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C – Both Applications

PNI. In Section II.2, page 26, the applicant describes the manner in which it will provide the necessary ancillary and support services. Exhibit 32 contains letters of support from physicians and other health care providers. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

Wilmington Health. In Section II.2, page 18, the applicant describes the manner in which it will provide the necessary ancillary and support services. Exhibit 20 contains letters of support from physicians and other health care providers. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

C – Both Applications

PNI. The applicant proposes to develop the fixed MRI scanner in 1,182 square feet of renovated space in the existing medical office building located at 1025 Medical Center Drive. Exhibit 25 contains a letter from an architect that estimates construction costs that are consistent with the project capital cost projections provided by the applicant in Section VIII.1, page 150 of the application. In Section XI.7, page 167, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction

cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

Wilmington Health. The applicant proposes to develop the fixed MRI scanner in a 967 square foot addition to the existing medical office building located at 1202 Medical Center Drive. Exhibit 18 contains a letter from an architect that estimates site preparation and construction costs that are consistent with the project capital cost projections provided by the applicant in Section VIII.1, page 109 of the application. In Section XI.7, page 123, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C – Both Applications

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. More current data, particularly with regard to the estimated uninsured percentages, was not available.

County	Total # of Medicaid Eligibles as % of Total Population June 2010	Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010	% Uninsured CY2008-2009 (Estimate by Cecil G. Sheps Center)
New Hanover	13%	5.7%	20.4%
Statewide	17%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the MRI scanner services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

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

PNI. In Section VI.13, page 139, the applicant reports the following payer mix for PNI's MRI services for FY2014:

Payer Category	MRI Scanner Services Procedures as Percent of Total
Self Pay/Charity	0.5%
Medicare/Medicare Managed Care	35.2%
Medicaid	4.3%
Commercial Insurance	41.4%
Managed Care	8.2%
Other (Government)	10.4%
Total	100.0%

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services and is conforming to this criterion.

Wilmington Health. In Section VI.13, page 98, the applicant reports the following payer mix for Wilmington Health's MRI services for CY2014:

Payer Category	MRI Scanner Services Procedures as Percent of Total
Self Pay/Indigent/Charity	0.4%
Medicare/Medicare Managed Care	44.7%
Medicaid	5.9%
Commercial Insurance/Managed Care	44.1%
Other (Government)	4.9%
Total	100.0%

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant’s existing services and 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

PNI. Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 138, the applicant states, *“As a North Carolina limited liability company, PNI does not have any public obligation under Federal regulations to provide uncompensated care, community service, or access by minorities or handicapped persons. However, as previously stated, PNI does and will provide equal access to MRI services through uncompensated care (charity) and bad debt write-offs.”* In Section VI.10 (a), page 137, the applicant states that no civil rights access complaints have been filed against it in last five years. The application is conforming to this criterion.

Wilmington Health. In Section VI.11, page 97, the applicant states, *“Wilmington Health has no federal obligation to provide uncompensated care. The practice will continue to comply with all access requirements for the American [sic] with Disabilities Act.”* In Section VI.10 (a), page 97, the applicant states that no civil rights access complaints have been filed against it in last five years. 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

PNI. In Section VI.15, page 141, the applicant projects the following payer mix for PNI's MRI services during the second operating year (FY2018):

Payer Category	MRI Scanner Services Procedures as Percent of Total
Self Pay/Charity	1.0%
Medicare/Medicare Managed Care	38.0%
Medicaid	4.0%
Commercial Insurance	41.0%
Managed Care	8.0%
Other (Government)	8.0%
Total	100.0%

On page 141, the applicant states, *“PNI assumes a slight change in payer mix due to a different payer mix of patients who previously received an MRI scan on one of the two mobile MRI scanners that currently serve DR, which includes an InSight Imaging mobile MRI scanner.”* The applicant demonstrated that the medically underserved population will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

Wilmington Health. In Section VI.15, page 99, the applicant projects the following payer mix for Wilmington Health's MRI services during the second operating year (CY2018):

Payer Category	MRI Scanner Services Procedures as Percent of Total
Self Pay/Indigent/Charity	0.4%
Medicare/Medicare Managed Care	44.7%
Medicaid	5.9%
Commercial Insurance/Managed Care	44.1%
Other (Government)	4.9%
Total	100.0%

On page 99, the applicant states, *“Wilmington Health has based its projected payor mix on its historical data and does not anticipate any change in payor mix as a result of this project.”* The applicant demonstrated that the medically underserved population will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C – Both Applications

PNI. In Section VI.9, page 137, the applicant describes the range of means by which a person will have access to PNI's MRI services. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

Wilmington Health. In Section VI.9, pages 95-96, the applicant describes the range of means by which a person will have access to Wilmington Health's MRI services. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C – Both Applications

PNI. In Section V.1, page 118, the applicant states that it already has established relationships with health professional training programs. Exhibit 20 contains a copy of a clinical training agreement between the applicant and Cape Fear Community College. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

Wilmington Health. In Section V.1, page 83, the applicant states that it already has established relationships with health professional training programs, including the South East Area Health Education Center and Cape Fear Community College. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

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

applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C – Both Applications

The 2015 SMFP includes a methodology for determining the need for additional fixed MRI scanners by service area. Application of the need methodology in the 2015 SMFP identified a need for one additional fixed MRI scanner in the New Hanover County MRI Service Area.

On page 146, the 2015 SMFP defines the service area for fixed MRI scanners as “a single county, except where there is no licensed acute care hospital located within the county.” Thus, the service area consists of New Hanover County. Providers may serve residents of counties not included in their service area.

There are five existing fixed MRI scanners in New Hanover County. The following table identifies the provider, number, and average utilization of each of the fixed MRI scanners, summarized from Table 9P of the Proposed 2016 SMFP.

	Fixed MRI Scanners	Total Weighted MRI Scans	Average Weighted MRI Scans Per MRI Scanner
New Hanover Regional Medical Center	4	17,421	4,355
OrthoWilmington	1	4,520	4,520

Source: Proposed 2016 SMFP, Table 9P, pages 175-176. The data in the Proposed 2016 SMFP is from the hospital’s 2015 License Renewal Application submitted in late 2014 and OrthoWilmington’s 2014 Registration and Inventory form submitted in early 2015.

PNI. The applicant, PNI, proposes to acquire one fixed MRI scanner to replace mobile MRI scanner services provided at its Medical Center Drive location in Wilmington. In Section V.7, pages 126-132, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

“The PNI project will foster competition by promoting cost effectiveness, quality, and access to fixed MRI services.... PNI is committed to developing and carrying out a performance improvement plan to ensure safety and quality. The objective is to make certain a mechanism is in place which will ensure the occurrence of an ongoing evaluation of various aspects of the operation of the MRI scanner, both medical and non-medical....

The PNI fixed MRI scanner will be readily accessible to any resident of Wilmington with access to the Cape Fear Public Transportation Authority, operating as Wave Transit. ... PNI attempts to address the barriers to access in its daily operation. PNI does not discriminate against any class of patient based on age, sex, religion, race, handicap, ethnicity, or ability to pay. ... PNI actively participates in both the Medicaid and Medicare programs....

With the acquisition and operation of the fixed MRI scanner at DR-Medical Center, PNI will be able to charge patients freestanding-based MRI charges. These charges extend to the patient on both the fixed MRI scanner and the mobile MRI scanner. The average gross MRI scan charge will be \$1,533 through Year 3. The average cost per fixed MRI scan is estimated to be \$483 in Year 3. The free-standing-based MRI charge will lead to a decreased insurer payments, patient deductible payments and copayments. The lower freestanding-based charges will lead to lower healthcare expenditure and hopefully result in lower health insurance premiums [All underlining in original].”

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

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

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

Therefore, the application is conforming to this criterion.

Wilmington Health. The applicant, Wilmington Health, proposes to acquire one fixed MRI scanner to replace mobile MRI scanner services provided at its Medical Center Drive location in Wilmington. In Section V.7, pages 87-88, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

“As discussed in Section III.1, the proposed project will result in improved quality, access, and value. The proposed project will allow Wilmington Health to replace its existing mobile MRI service with a new state-of-the-art fixed MRI scanner that has the latest technology, thereby improving the quality of the scans produced and the overall quality of the MRI service offered. The quality of the patient experience will be greatly enhanced as a result of the proposed project as the addition of new construction within the building alcove to house the proposed scanner will alleviate the need for patients to leave the medical office building to access the MRI scanner while exposed to the elements. Further, the proposed scanner and the space within which the scanner will be located are both significantly larger than the existing scanner and space, which will

prevent Wilmington Health from having to refer larger and/or claustrophobic patients to other providers for MRI procedures, and will also allow patients' family members to accompany them. The project will also enhance access by allowing Wilmington Health to control the staffing and scheduling of the MRI service, thereby eliminating the existing inconvenience of a six-day scheduling delay. As stated above, the proposed project will eliminate the need to refer patients requiring a larger scanner to other more costly providers, thereby also having a positive impact on value."

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

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

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

Therefore, the application is conforming to this criterion.

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

C – Both Applications

PNI. In Section II.7, pages 35-38, the applicant describes the methods used by PNI to insure and maintain quality care. In Section II.7(c), page 38, the applicant states that none of the licensed health service facilities owned or operated by the applicant, as identified by the applicant in Section I.12, pages 13-14, have had their licenses revoked or had their Medicare or Medicaid provider agreements revoked. The information provided by the applicant is reasonable and supports the determination that the applicant is conforming to this criterion.

Wilmington Health. In Section II.6, page 20, and Exhibit 8, the applicant describes the methods used by Wilmington Health to insure and maintain quality care. In Section II.7, pages 20-21, the applicant indicates that there have been no quality of care issues at the healthcare facilities identified in Section I.12, page 11. The information provided by the

applicant is reasonable and supports the determination that the applicant is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C – Both Applications

The applications submitted by PNI and Wilmington Health are conforming with all applicable Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700. The specific criteria are discussed below.

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

10A NCAC 14C .2702 INFORMATION REQUIRED OF APPLICANT

- (a) *An applicant proposing to acquire an MRI scanner, including a mobile MRI scanner, shall use the Acute Care Facility/Medical Equipment application form.*
- C- **Both Applicants** used the Acute Care/Medical Equipment application form.
- (b) *Except for proposals to acquire mobile MRI scanners that serve two or more host facilities, both the applicant and the person billing the patients for the MRI service shall be named as co-applicants in the application form.*
- C- **PNI.** In Section II.8, page 42, the applicant states, “*PNI is the applicant and the biller of the MRI service.*”
- C- **Wilmington Health.** In Section II.8, page 25, the applicant states, “*Wilmington Health is the entity that will bill patients for MRI services and is the sole applicant.*”
- (c) *An applicant proposing to acquire a magnetic resonance imaging scanner, including a mobile MRI scanner, shall provide the following information:*

- (1) *documentation that the proposed fixed MRI scanner, excluding fixed extremity and breast MRI scanners, will be available and staffed for use at least 66 hours per week;*
- C- **PNI.** In Section II.8, page 42, the applicant states that the proposed MRI scanner will be available and staffed for at least 66 hours per week.
- C- **Wilmington Health.** In Section II.8, page 25, the applicant states that the proposed MRI scanner will be available and staffed for at least 66 hours per week.
- (2) *documentation that the proposed mobile MRI scanner will be available and staffed for use at least 40 hours per week;*
- NA- **Both Applicants.** Neither applicant proposes to acquire a mobile MRI scanner.
- (3) *documentation that the proposed fixed extremity or dedicated breast MRI scanner shall be available and staffed for use at least 40 hours per week;*
- NA- **Both Applicants.** Neither applicant proposes to acquire a fixed extremity or dedicated breast MRI scanner.
- (4) *the average charge to the patient, regardless of who bills the patient, for each of the 20 most frequent MRI procedures to be performed for each of the first three years of operation after completion of the project and a description of items included in the charge; if the professional fee is included in the charge, provide the dollar amount for the professional*
- C- **PNI.** In Section II.8, page 42, the applicant states, “PNI charges a global fee, which includes both technical and professional fees.” On pages 43-45, the applicant provides tables of projected charges for the 20 most frequent MRI procedures to be performed in the first three years of operation (FY2017-FY2019).
- C- **Wilmington Health.** In Section II.8, page 26, the applicant states, “Exhibit 9 includes projected charges for the technical, component, professional fee, and global charge.” In Exhibit 9, the applicant provides tables of projected charges for the 20 most frequent MRI procedures to be performed in the first three years of operation (CY2017-CY2019).
- (5) *if the proposed MRI service will be provided pursuant to a service agreement, the dollar amount of the service contract fee billed by the*

applicant to the contracting party for each of the first three years of operation;

- NA- **Both Applicants.** The applicants do not propose to provide MRI services pursuant to a service agreement.
 - (6) *letters from physicians indicating their intent to refer patients to the proposed magnetic resonance imaging scanner and their estimate of the number of patients proposed to be referred per year, which is based on the physicians' historical number of referrals;*
- C- **PNI.** Exhibit 32 contains letters from physicians indicating their intent to refer patients to the proposed fixed MRI scanner, and their estimate of the number of patients proposed to be referred for MRI services.
- C- **Wilmington Health.** Exhibit 20 contains letters from physicians indicating their intent to refer patients to the proposed fixed MRI scanner, and their estimate of the number of patients proposed to be referred for MRI services.
 - (7) *for each location in the MRI service area at which the applicant or a related entity will provide MRI services, utilizing existing, approved, or proposed fixed MRI scanners, the number of fixed MRI scanners operated or to be operated at each location;*
- C- **PNI.** In Section II.8, page 46, the applicant states that PNI proposes to operate one fixed MRI scanner at the DR-Medical Center location in Wilmington, and that NHRMC will continue to operate four existing fixed MRI scanners in Wilmington, including two located at NHRMC's 17th Street main campus, one at NHRMC Orthopedic Hospital, and one at the NHRMC Health and Diagnostics - Medical Mall.
- C- **Wilmington Health.** In Section II.8, page 27, the applicant states that Wilmington Health proposes to operate one fixed MRI scanner at the Medical Center Drive location in Wilmington, and that it does not operate any other fixed MRI scanners.
 - (8) *for each location in the MRI service area at which the applicant or a related entity will provide MRI services, utilizing existing, approved, or proposed fixed MRI scanners, projections of the annual number of unweighted MRI procedures to be performed for each of the four types of MRI procedures, as identified in the SMFP, for each of the first three years of operation after completion of the project;*
- C- **PNI.** In Section II.8, pages 47-48, the applicant provides the projected number of unweighted annual MRI procedures to be performed for each of the four

types of MRI procedures, for each of its facilities with existing or proposed fixed MRI scanners, for each of the first three years of operation following completion of the proposed project, as shown in the table below. See the discussion regarding the reasonableness of the projected utilization in Criterion (3).

Projected Annual Unweighted MRI Procedures

	Year 1 FY2017	Year 2 FY2018	Year 3 FY2019
PNI DR-Medical Center			
Inpatient with contrast			
Inpatient without contrast			
Outpatient with contrast	2,069	2,117	2,165
Outpatient without contrast	2,266	2,318	2,371
Total	4,335	4,435	4,537
NHRMC Main Campus*			
Inpatient with contrast	1,937	1,981	2,027
Inpatient without contrast	2,141	2,190	2,241
Outpatient with contrast	2,539	2,598	2,658
Outpatient without contrast	3,104	3,175	3,248
Total	9,721	9,945	10,174
NHRMC Orthopedic Hospital			
Inpatient with contrast	34	35	36
Inpatient without contrast	25	26	26
Outpatient with contrast	1,128	1,154	1,181
Outpatient without contrast	1,317	1,348	1,379
Total	2,504	2,562	2,621
NHRMC Medical Mall			
Inpatient with contrast	6	6	7
Inpatient without contrast	4	4	4
Outpatient with contrast	1,130	1,156	1,183
Outpatient without contrast	807	825	845
Total	1,948	1,993	2,038

*NHRMC main campus operates two fixed MRI scanners.

- C- **Wilmington Health.** In Section II.8, page 27, the applicant provides the projected number of unweighted annual MRI procedures to be performed for each of the four types of MRI procedures for the proposed fixed MRI scanner to be located at its Medical Center Drive location in Wilmington for each of the first three years of operation following completion of the proposed project, as shown in the table below. See the discussion regarding the reasonableness of the projected utilization in Criterion (3).

Projected Annual Unweighted MRI Procedures

	Year 1 CY2017	Year 2 CY2018	Year 3 CY2019
Inpatient with contrast			
Inpatient without contrast			
Outpatient with contrast	1,962	1,983	2,004
Outpatient without contrast	2,102	2,125	2,148
Total	4,065	4,108	4,152

(9) *for each location in the MRI service area at which the applicant or a related entity will provide services, utilizing existing, approved, or proposed fixed MRI scanners, projections of the annual number of weighted MRI procedures to be performed for each of the four types of MRI procedures, as identified in the SMFP, for each of the first three years of operation after completion of the project;*

-C- **PNI.** In Section II.8, pages 49-50, the applicant provides the projected number of annual weighted MRI procedures to be performed for each of the four types of MRI procedures, for each of its facilities with existing or proposed fixed MRI scanners, for each of the first three years of operation following completion of the proposed project, as shown in the table below. See the discussion regarding the reasonableness of the projected utilization in Criterion (3).

Projected Annual Weighted MRI Procedures

	Year 1 FY2017	Year 2 FY2018	Year 3 FY2019
PNI DR-Medical Center			
Inpatient with contrast			
Inpatient without contrast			
Outpatient with contrast	2,897	2,963	3,032
Outpatient without contrast	2,266	2,318	2,371
Total	5,163	5,282	5,403
NHRMC Main Campus*			
Inpatient with contrast	3,486	3,566	3,648
Inpatient without contrast	2,997	3,066	3,137
Outpatient with contrast	3,555	3,637	3,721
Outpatient without contrast	3,104	3,175	3,248
Total	13,142	13,445	13,754
NHRMC Orthopedic Hospital			
Inpatient with contrast	61	63	64
Inpatient without contrast	35	36	37
Outpatient with contrast	1,579	1,616	1,653
Outpatient without contrast	1,317	1,348	1,379
Total	2,993	3,062	3,132
NHRMC Medical Mall			
Inpatient with contrast	11	12	12
Inpatient without contrast	6	6	6
Outpatient with contrast	1,582	1,619	1,656
Outpatient without contrast	807	825	845
Total	2,407	2,462	2,519

*NHRMC main campus operates two fixed MRI scanners.

- C- **Wilmington Health.** In Section II.8, page 28, the applicant provides the projected number of annual weighted MRI procedures to be performed for each of the four types of MRI procedures for the proposed fixed MRI scanner to be located at its Medical Center Drive location in Wilmington for each of the first three years of operation following completion of the proposed project, as shown in the table below. See the discussion regarding the reasonableness of the projected utilization in Criterion (3).

Projected Annual Weighted MRI Procedures

	Year 1 CY2017	Year 2 CY2018	Year 3 CY2019
Inpatient with contrast			
Inpatient without contrast			
Outpatient with contrast	2,747	2,776	2,806
Outpatient without contrast	2,102	2,125	2,148
Total	4,849	4,901	4,954

(10) *a detailed description of the methodology and assumptions used to project the number of unweighted MRI procedures to be performed at each location, including the number of contrast versus non-contrast procedures, sedation versus non-sedation procedures, and inpatient versus outpatient procedures;*

-C- **PNI.** The applicant’s methodology and assumptions used to project the number of unweighted MRI procedures are described in Section IV.1, pages 101-116.

-C- **Wilmington Health.** The applicant’s methodology and assumptions used to project the number of unweighted MRI procedures are described in Section III.1, pages 62-69.

(11) *a detailed description of the methodology and assumptions used to project the number of weighted MRI procedures to be performed at each location;*

-C- **PNI.** The applicant’s methodology and assumptions used to project the number of weighted MRI procedures are described in Section IV.1, pages 101-116.

-C- **Wilmington Health.** The applicant’s methodology and assumptions used to project the number of weighted MRI procedures are described in Section III.1, pages 62-69.

(12) *for each existing, approved or proposed mobile MRI scanner owned by the applicant or a related entity and operated in North Carolina in the month the application is submitted, the vendor, tesla strength, serial number or vehicle identification number, CON project identification number, and host sites;*

-C- **PNI.** The applicant provides the required information for PNI’s existing mobile MRI scanner in Section II.8, page 51.

-NA- **Wilmington Health.** In Section II.8, page 29, the applicant states that neither Wilmington Health nor any related entities owns or operates any mobile MRI scanners.

(13) *for each host site in the mobile MRI region in which the applicant or a related entity will provide the proposed mobile MRI services, utilizing existing, approved, or proposed mobile MRI scanners, projections of the annual number of unweighted and weighted MRI procedures to be performed for each of the four types of MRI procedures, as identified in the SMFP, for each of the first three years of operation after completion of the project;*

-C- **PNI.** In Section II.8, pages 52-53, the applicant provides the projected annual number of unweighted and weighted MRI procedures to be performed at each host site for each of the four types of MRI procedures for its existing mobile MRI scanner for each of the first three years of operation following completion of the proposed project, as shown in the tables below.

**PNI's Existing Mobile MRI Scanner
 Projected Annual Unweighted MRI Procedures**

	Year 1 FY2017	Year 2 FY2018	Year 3 FY2019
H&D-Military Cutoff			
Inpatient with contrast			
Inpatient without contrast			
Outpatient with contrast	387	396	405
Outpatient without contrast	476	487	498
Total	863	883	904
H&D-ED North			
Inpatient with contrast			
Inpatient without contrast			
Outpatient with contrast	346	354	363
Outpatient without contrast	523	535	548
Total	870	890	910
DR-Ashton			
Inpatient with contrast			
Inpatient without contrast			
Outpatient with contrast			
Outpatient without contrast	1,300	1,330	1,360
Total	1,300	1,330	1,360
Total All Sites	3,033	3,103	3,174

**PNI's Existing Mobile MRI Scanner
 Projected Annual Weighted MRI Procedures**

	Year 1 FY2017	Year 2 FY2018	Year 3 FY2019
H&D-Military Cutoff			
Inpatient with contrast			
Inpatient without contrast			
Outpatient with contrast	542	555	567
Outpatient without contrast	476	487	498
Total	1,018	1,042	1,066
H&D-ED North			
Inpatient with contrast			
Inpatient without contrast			
Outpatient with contrast	485	496	508
Outpatient without contrast	523	535	548
Total	1,008	1,031	1,055
DR-Ashton			
Inpatient with contrast			
Inpatient without contrast			
Outpatient with contrast			
Outpatient without contrast	1,300	1,330	1,360
Total	1,300	1,330	1,360
Total All Sites	3,326	3,403	3,481

(14) *if proposing to acquire a mobile MRI scanner, an explanation of the basis for selection of the proposed host sites if the host sites are not located in MRI service areas that lack a fixed MRI scanner; and*

-NA- **Both Applicants.** The applicants do not propose to acquire a mobile MRI scanner.

(15) *identity of the accreditation authority the applicant proposes to use.*

-C- **PNI.** The applicant identifies the accreditation authority it proposes to use in Section II.8, page 54 of the application.

-C- **Wilmington Health.** The applicant identifies the accreditation authority it proposes to use in Section II.8, page 29 of the application.

(d) *An applicant proposing to acquire a mobile MRI scanner shall provide copies of letters of intent from, and proposed contracts with, all of the proposed host facilities of the new MRI scanner.*

-NA- **Both Applicants.** The applicants do not propose the acquisition of a mobile MRI scanner.

(e) *An applicant proposing to acquire a dedicated fixed breast MRI scanner shall demonstrate that:*

- (1) *it has an existing and ongoing working relationship with a breast-imaging radiologist or radiology practice group that has experience interpreting breast images provided by mammography, ultrasound, and MRI scanner equipment, and that is trained to interpret images produced by a MRI scanner configured exclusively for mammographic studies;*
- (2) *for the last 12 months it has performed the following services, without interruption in the provision of these services: breast MRI procedures on a fixed MRI scanner with a breast coil, mammograms, breast ultrasound procedures, breast needle core biopsies, breast cyst aspirations, and pre-surgical breast needle localizations;*
- (3) *its existing mammography equipment, breast ultrasound equipment, and the proposed dedicated breast MRI scanner is in compliance with the federal Mammography Quality Standards Act;*
- (4) *it is part of an existing healthcare system that provides comprehensive cancer care, including radiation oncology, medical oncology, surgical oncology and an established breast cancer treatment program that is based in the geographic area proposed to be served by the applicant; and,*
- (5) *it has an existing relationship with an established collaborative team for the treatment of breast cancer that includes, radiologists, pathologists, radiation oncologists, hematologists/oncologists, surgeons, obstetricians/gynecologists, and primary care providers.*

-NA- **Both Applicants.** The applicants do not propose the acquisition of a dedicated fixed breast MRI scanner.

(f) *An applicant proposing to acquire an extremity MRI scanner, pursuant to a need determination in the State Medical Facilities Plan for a demonstration project, shall:*

- (1) *provide a detailed description of the scope of the research studies that will be conducted to demonstrate the convenience, cost effectiveness and improved access resulting from utilization of extremity MRI scanning;*
- (2) *provide projections of estimated cost savings from utilization of an extremity MRI scanner based on comparison of "total dollars received per procedure" performed on the proposed scanner in comparison to "total dollars received per procedure" performed on whole body scanners;*

- (3) *provide projections of estimated cost savings to the patient from utilization of an extremity MRI scanner;*
- (4) *commit to prepare an annual report at the end of each of the first three operating years, to be submitted to the Medical Facilities Planning Section and the Certificate of Need Section, that will include:*
 - (A) *a detailed description of the research studies completed;*
 - (B) *a description of the results of the studies;*
 - (C) *the cost per procedure to the patient and billing entity;*
 - (D) *the cost savings to the patient attributed to utilization of an extremity MRI scanner;*
 - (E) *an analysis of "total dollars received per procedure" performed on the extremity MRI scanner in comparison to "total dollars received per procedure" performed on whole body scanners; and*
 - (F) *the annual volume of unweighted and weighted MRI procedures performed, by CPT code;*
- (5) *identify the operating hours of the proposed scanner;*
- (6) *provide a description of the capabilities of the proposed scanner;*
- (7) *provide documentation of the capacity of the proposed scanner based on the number of days to be operated each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of unweighted MRI procedures the scanner is capable of performing each hour;*
- (8) *identify the types of MRI procedures by CPT code that are appropriate to be performed on an extremity MRI scanner as opposed to a whole body MRI scanner;*
- (9) *provide copies of the operational and safety requirements set by the manufacturer; and*
- (10) *describe the criteria and methodology to be implemented for utilization review to ensure the medical necessity of the procedures performed.*

-NA- **Both Applicants.** The applicants do not propose the acquisition of an extremity MRI scanner.

- (g) *An applicant proposing to acquire a multi-position MRI scanner, pursuant to a need determination in the State Medical Facilities Plan for a demonstration project, shall:*
 - (1) *commit to prepare an annual report at the end of each of the first three operating years, to be submitted to the Medical Facilities Planning Section and the Certificate of Need Section, that will include:*
 - (A) *the number of exams by CPT code performed on the multi-position MRI scanner in an upright or nonstandard position;*
 - (B) *the total number of examinations by CPT code performed on the multi-position MRI scanner in any position;*

- (C) *the number of doctors by specialty that referred patients for an MRI scan in an upright or nonstandard position;*
 - (D) *documentation to demonstrate compliance with the Basic Principles policy included in the State Medical Facilities Plan;*
 - (E) *a detailed description of the unique information that was acquired only by use of the multi-position capability of the multi-position MRI scanner; and*
 - (F) *the number of insured, underinsured, and uninsured patients served by type of payment category;*
- (2) *provide the specific criteria that will be used to determine which patients will be examined in other than routine supine or prone imaging positions;*
 - (3) *project the number of exams by CPT code performed on the multi-position MRI scanner in an upright or nonstandard position;*
 - (4) *project the total number of examinations by CPT code performed on the multi-position MRI scanner in any position;*
 - (5) *demonstrate that access to the multi-position MRI scanner will be made available to all spine surgeons in the proposed service area, regardless of ownership in the applicant's facility;*
 - (6) *demonstrate that at least 50 percent of the patients to be served on the multi-position MRI scanner will be spine patients who are examined in an upright or nonstandard position; and*
 - (7) *provide documentation of the capacity of the proposed fixed multi-position MRI scanner based on the number of days to be operated each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of unweighted MRI procedures the scanner is capable of performing each hour.*

-NA- **Both Applicants.** The applicants do not propose the acquisition of a multi-position MRI 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- **Both Applicants.** The applicants do not propose the acquisition of a mobile MRI scanner.

(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- **PNI.** In Section II.8, page 59, the applicant states that NHRMC's four existing fixed MRI scanners performed an average of 4,255 weighted MRI procedures in most recent 12 month period (July 2014 – June 2015).

-NA- **Wilmington Health.** In Section II.8, page 35, the applicant states that neither Wilmington Health nor a related entity owns a controlling interest in any fixed MRI scanners.

- (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.];*

-C- **PNI.** In Section II.8, page 60, the applicant states that PNI's existing mobile MRI scanner performed 4,108 weighted MRI procedures in most recent 12 month period (July 2014 – June 2015).

-NA- **Wilmington Health.** In Section II.8, page 35, the applicant states that neither Wilmington Health nor a related entity, owns a controlling interest in any mobile MRI scanners.

(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 2015 SMFP shows that there are more than four (4) fixed MRI scanners located in the MRI service area of New Hanover 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 New Hanover County is reasonably expected to perform 4,805 weighted MRI procedures in the third operating year.

-C- **PNI.** In Section II.8, page 61, the applicant states its average annual weighted MRI scan volume for NHRMC's four existing fixed MRI scanners is projected to be 4,851 weighted MRI procedures per MRI scanner in the third operating year. In Section II.8, page 62, the applicant states its annual weighted MRI scan volume for PNI's proposed fixed MRI scanner is projected to be 5,403 weighted MRI procedures in the third operating year. The application is conforming to this Rule.

-C- **Wilmington Health.** In Section II.8, page 36, the applicant states its annual weighted MRI scan volume for Wilmington Health's proposed fixed MRI scanner is projected to be 4,954 weighted MRI procedures in the third operating year. The application is conforming to this Rule.

(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;*

-C- **PNI.** In Section II.8, page 62, the applicant states its annual weighted MRI scan volume for PNI's proposed fixed MRI scanner is projected to be 5,403 weighted MRI procedures in the third operating year.

-NA- **Wilmington Health.** In Section II.8, page 37, the applicant states Wilmington Health does not own or operate any other MRI scanners.

- (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*

-C- **PNI.** In Section II.8, page 63, the applicant states the annual weighted MRI scan volume for PNI's existing mobile MRI scanner is projected to be 3,481 weighted MRI procedures in the third operating year. The application is conforming to this Rule.

-C- **Wilmington Health.** In Section II.8, page 38, the applicant states that neither Wilmington Health nor a related entity, owns a controlling interest in any mobile MRI scanners.

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

-C- **PNI.** The applicant's methodology and assumptions used for these projections are described in Section IV.1, pages 101-116.

- C- **Wilmington Health.** The applicant's methodology and assumptions used for these projections are described in Section III.1, pages 62-69.
- (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- **Both Applicants.** The applicants do not propose the acquisition of a fixed dedicated breast MRI scanner.
- (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- **Both Applicants.** The applicants do not propose the acquisition of a fixed extremity MRI scanner.
- (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- **Both Applicants.** The applicants do not propose the acquisition of a fixed multi-position MRI scanner.

- (a) *An applicant proposing to acquire a mobile MRI scanner shall provide referral agreements between each host site and at least one other provider of MRI services in the geographic area to be served by the host site, to document the availability of MRI services if patients require them when the mobile unit is not in service at that host site.*
- NA- **Both Applicants.** The applicants do not propose the acquisition of a mobile MRI scanner.
- (b) *An applicant proposing to acquire a fixed or mobile MRI scanner shall obtain accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the American College of Radiology or a comparable accreditation authority, as determined by the Certificate of Need Section, for magnetic resonance imaging within two years following operation of the proposed MRI scanner.*
- C- **PNI.** In Section II.8, page 65, the applicant states that it intends to obtain accreditation for the fixed MRI scanner from the American College of Radiology.
- C- **Wilmington Health.** In Section II.8, pages 40-41, the applicant states that it intends to obtain accreditation for the fixed MRI scanner from the Intersocietal Accreditation Commission.

10A NCAC 14C .2705 STAFFING AND STAFF TRAINING

- (a) *An applicant proposing to acquire an MRI scanner, including extremity and breast MRI scanners, shall demonstrate that one diagnostic radiologist certified by the American Board of Radiologists shall be available to interpret the images who has had:*
- (1) *training in magnetic resonance imaging as an integral part of his or her residency training program; or*
 - (2) *six months of supervised MRI experience under the direction of a certified diagnostic radiologist; or*
 - (3) *at least six months of fellowship training, or its equivalent, in MRI; or*
 - (4) *a combination of MRI experience and fellowship training equivalent to Subparagraph (a)(1), (2) or (3) of this Rule.*
- C- **PNI.** Exhibit 15 contains a letter from L. Neal Beard, M.D., President of Delaney Radiologists, stating that Delaney Radiologists will continue to provide professional MRI interpretation services for the proposed fixed MRI scanner. Exhibit 14 contains documentation indicating the physicians of Delaney Radiologists have the training and experience to meet the requirements of this Rule.

- C- **Wilmington Health.** Exhibit 5 contains a letter from L. Neal Beard, M.D., President of Delaney Radiologists, stating that Delaney Radiologist have the required training and experience, and will continue to provide professional MRI interpretation services for the proposed fixed MRI scanner.

- (b) *An applicant proposing to acquire a dedicated breast MRI scanner shall provide documentation that:*
 - (1) *the radiologist is trained and has expertise in breast imaging, including mammography, breast ultrasound and breast MRI procedures; and*
 - (2) *two full time MRI technologists or two mammography technologists are available with training in breast MRI imaging and that one of these technologists shall be present during the hours operation of the dedicated breast MRI scanner.*

- NA- **Both Applicants.** The applicants do not propose the acquisition of a dedicated breast MRI scanner.

- (c) *An applicant proposing to acquire a MRI scanner, including extremity but excluding dedicated breast MRI scanners, shall provide evidence of the availability of two full-time MRI technologist-radiographers and that one of these technologists shall be present during the hours of operation of the MRI scanner.*

- C- **PNI.** In Section II.8, page 66, the applicant states that 3.0 FTE MRI technologists will be added to staff the proposed fixed MRI scanner, for a total of 6.0 FTE MRI technologists to staff both the existing mobile MRI scanner and the proposed fixed MRI scanner.

- C- **Wilmington Health.** In Section II.8, page 42, the applicant states that 4.0 FTE MRI technologists will be available to staff the proposed MRI scanner.

- (d) *An applicant proposing to acquire an MRI scanner, including extremity and breast MRI scanners, shall demonstrate that the following staff training is provided:*
 - (1) *American Red Cross or American Heart Association certification in cardiopulmonary resuscitation (CPR) and basic cardiac life support; and*

- C- **PNI.** In Section II.8, page 67, the applicant states that PNI requires all MRI technologists to maintain certification in cardiopulmonary resuscitation and basic cardiac life support. Exhibit 16 contains PNI policies documenting this staff training requirement.

- C- **Wilmington Health.** In Exhibit 2, the applicant states that Wilmington Health requires staff to maintain certification in cardiopulmonary resuscitation and basic cardiac life support. Exhibit 10 contains Wilmington Health policies documenting this staff training requirement.
 - (2) *the availability of an organized program of staff education and training which is integral to the services program and ensures improvement in technique and the proper training of new personnel.*
- C- **PNI.** In Section II.8, page 67, the applicant states that PNI has an organized program of staff education and training. Exhibit 16 contains PNI policies documenting a program of staff training.
- C- **Wilmington Health.** In Exhibit 2, the applicant states that Wilmington Health has an organized program of staff education and training. Exhibit 10 contains Wilmington Health policies documenting a program of staff training.
 - (e) *An applicant proposing to acquire a mobile MRI scanner shall document that the requirements in Paragraph (a) of this Rule shall be met at each host facility, and that one full time MRI technologist-radiographer shall be present at each host facility during all hours of operation of the proposed mobile MRI scanner.*
- NA- **Both Applicants.** The applicants are not proposing to acquire a mobile MRI scanner.
 - (f) *An applicant proposing to acquire an extremity MRI scanner, pursuant to a need determination in the State Medical Facilities Plan for a demonstration project, also shall provide:*
 - (1) *evidence that at least one licensed physician shall be on-site during the hours of operation of the proposed MRI scanner;*
 - (2) *a description of a research group for the project including a radiologist, orthopaedic surgeon, and research coordinator; and*
 - (3) *letters from the proposed members of the research group indicating their qualifications, experience and willingness to participate on the research team.*
- NA- **Both Applicants.** The applicants are not proposing to acquire an extremity MRI scanner.
 - (g) *An applicant proposing to perform cardiac MRI procedures shall provide documentation of the availability of a radiologist, certified by the American Board of Radiology, with training and experience in interpreting images produced by an MRI scanner configured to perform cardiac MRI studies.*

-NA- **Both Applicants.** The applicants are not proposing to perform cardiac MRI procedures.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2015 State Medical Facilities Plan, no more than one additional fixed MRI scanner may be approved in this review for New Hanover 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 Project Analyst 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 Wilmington Health, Project I.D. #O-11063-15, is approved and the other application, submitted by PNI, is denied.

Geographic Accessibility

The 2015 SMFP identifies the need for one fixed MRI scanner in New Hanover County. The following table identifies the location of the existing fixed MRI scanners in New Hanover County.

Facility	City/Town	Number of Existing Fixed MRI Units
New Hanover Regional Medical Center	Wilmington	2
NHRMC Orthopedic Hospital	Wilmington	1
NHRMC Health & Diagnostic-Medical Mall	Wilmington	1
OrthoWilmington	Wilmington	1
Total		5

As shown in the table above, there are five existing fixed MRI scanners located in New Hanover County, all of which are located in Wilmington. The two applicants, PNI and Wilmington Health, both propose to locate the fixed MRI scanner in Wilmington. Indeed, both sites are located on Medical Center Drive less than one half mile from each other. Therefore, with regard to improving geographic accessibility to fixed MRI scanner services in New Hanover County, the two proposals are comparable.

Access by Underserved Groups

The following table shows each applicant’s projected percentages of MRI procedures to be provided to Medicaid and Medicare recipients in the second full fiscal year of operation following completion of the project, based on the information provided by the applicants in Section VI.15(a) of the applications. Generally, the application proposing to serve the higher percentages of Medicare and Medicaid patients is the more effective alternative with regard to this comparative factor.

APPLICANT	Projected Percentage of Total Procedures Provided to Medicare Recipients	Projected Percentage of Total Procedures Provided to Medicaid Recipients
PNI	38.0%	4.0%
Wilmington Health	44.7%	5.9%

As shown in the table above, Wilmington Health projects the highest percentage of services to be provided to Medicare recipients, and the highest percentage of services to be provided to Medicaid recipients. Therefore, the application submitted by Wilmington Health is the most effective alternative with regard to access by underserved groups.

Ownership of Fixed MRI Scanners in New Hanover County

There are five existing fixed MRI scanners in New Hanover County. The following table identifies the provider, number, and average utilization of each of the fixed MRI scanners, summarized from Table 9P of the Proposed 2016 SMFP.

	Fixed MRI Scanners	Total Weighted MRI Scans	Average Weighted MRI Scans Per Scanner
New Hanover Regional Medical Center	4	17,421	4,355
OrthoWilmington	1	4,520	4,520

Source: Proposed 2016 SMFP, Table 9P, pages 175-176. The data in the Proposed 2016 SMFP is from the hospital's 2015 License Renewal Application submitted in late 2014 and OrthoWilmington's 2014 Registration and Inventory form submitted in early 2015.

As shown in the table above, New Hanover Regional Medical Center (NHRMC) owns four of the five existing fixed MRI scanners located in New Hanover County. NHRMC is a member of PNI (50%). The Agency is not aware of any relationship between OrthoWilmington and either applicant or any of the applicant's members.

PNI owns an existing mobile MRI scanner which operates at several sites in New Hanover County. Wilmington Health does not own a mobile MRI scanner. Both PNI and Wilmington Health contract with unrelated providers (Alliance Healthcare Services and / or Insight) for mobile MRI services.

With regard to fixed MRI scanners, the proposal submitted by Wilmington Health would offer a third provider in New Hanover County. Given that NHRMC owns 50% of PNI, the proposal submitted by PNI would mean that NHRMC would own four of the six fixed MRI scanners outright and would own 50% of a fifth fixed MRI scanner. The proposal submitted by Wilmington Health is the more effective alternative with regard to increasing the number of providers of fixed MRI scanner services in New Hanover County.

Projected Average Gross Revenue per MRI Procedure

The following table shows the projected gross revenue per MRI procedure in the third year of operation for each of the applicants, based on the information provided in the applicants’ pro forma financial statements (Form C). Generally, the application proposing the lowest average gross revenue per MRI procedure is the more effective alternative with regard to this comparative factor.

Third Operating Year	PNI	Wilmington Health
Gross Patient Revenue	\$6,995,221	\$5,617,398
Deduct Professional Fees	(\$896,585)	NA
Gross Revenue less Professional Fees	\$6,058,636	\$5,617,398
Unweighted MRI Procedures	4,537	4,152
Gross Revenue/Procedure	\$1,335	\$1,353

Source: PNI projected revenues, professional fees, and MRI procedures are from Form C, pages 179-180 of the application. Wilmington Health projected revenues and MRI procedures are from Form C, page 130 of the application.

As shown in the table above, PNI projects the lowest average gross revenue per MRI procedure in the third operating year. The application submitted by PNI is the most effective alternative with regard to projected average gross revenue per MRI procedure.

Projected Average Net Revenue per MRI Procedure

The following table shows the projected net revenue per MRI procedure in the third year of operation for each of the applicants, based on the information provided in the applicants’ pro forma financial statements (Form C). Generally, the application proposing the lowest average net revenue per MRI procedure is the more effective alternative with regard to this comparative factor.

Third Operating Year	PNI	Wilmington Health
Net Patient Revenue	\$2,916,672	\$1,801,134
Deduct Professional Fees	(\$896,585)	NA
Net Revenue Less Professional Fees	\$2,020,087	\$1,801,134
Unweighted MRI Procedures	4,537	4,152
Net Revenue/Procedure	\$445	\$434

Source: PNI projected revenues, professional fees, and MRI procedures are from Form C, pages 179-180 of the application. Wilmington Health projected revenues and MRI procedures are from Form C, page 130 of the application.

As shown in the table above, Wilmington Health projects the lowest average net revenue per MRI procedure in the third operating year. The application submitted by Wilmington Health is the most effective alternative with regard to projected average net revenue per MRI procedure.

Projected Average Operating Expense per MRI Procedure

The following table shows the projected average operating expense per MRI procedure in the third year of operation for each of the applicants, based on the information provided in the applicants' pro forma financial statements (Form C). Generally, the application proposing the lowest average operating expense per MRI procedure is the more effective alternative with regard to this comparative factor.

Third Operating Year	PNI	Wilmington Health
Total Operating Expenses	\$2,182,973	\$953,104
Deduct Professional Fees	(\$896,585)	NA
Operating Expenses less Professional Fees	\$1,286,388	\$953,104
Unweighted MRI Procedures	4,537	4,152
Operating Expense/Procedure	\$284	\$230

Source: PNI projected operating expenses, professional fees, and MRI procedures are from Form C, pages 179-180 of the application. Wilmington Health projected operating expenses and MRI procedures are from Form C, page 130 of the application.

As shown in the table above, Wilmington Health projects the lowest average operating expense per MRI procedure in the third operating year. The application submitted by Wilmington Health is the most effective alternative with regard to projected average operating expense per MRI procedure.

SUMMARY

The following is a summary of the reasons the proposal submitted by Wilmington Health is determined to be the most effective alternative in this review:

- The proposal submitted by Wilmington Health results in a third provider of fixed MRI services.
- Wilmington Health projects the highest percentage of MRI procedures for Medicare and Medicaid recipients.
- Wilmington Health projects the lowest average net revenue per MRI procedure in the third operating year. See Comparative Analysis for discussion.
- Wilmington Health projects the lowest average operating cost per MRI procedure in the third operating year. See Comparative Analysis for discussion.

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

- The proposal submitted by PNI would mean NHRMC would own four of the six fixed MRI scanners outright and would own 50% of a fifth fixed MRI scanner.
- PNI projects the lowest percentage of MRI procedures for Medicare and Medicaid recipients.

- PNI projects the highest average net revenue per MRI procedure in the third operating year. See Comparative Analysis for discussion.
- PNI projects the highest average operating cost per MRI procedure in the third operating year. See Comparative Analysis for discussion.

CONCLUSION

The Agency determined that the application submitted by Wilmington Health, Project I.D. #O-11063-15, is the most effective alternative proposed in this review for the additional fixed MRI scanner for the New Hanover County service area and is approved. The approval of the application submitted by PNI would result in fixed MRI scanners in excess of the need determination for New Hanover County. Consequently, the application submitted by PNI is denied.

The application submitted by Wilmington Health is approved subject to the following conditions.

- 1. Wilmington Health, PLLC shall materially comply with all representations made in the certificate of need application.**
- 2. Wilmington Health, PLLC shall acquire no more than one fixed MRI scanner as part of this project.**
- 3. Wilmington Health, PLLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section VII of the application and that would otherwise require a certificate of need.**
- 4. Wilmington Health, PLLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**