

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 19, 2014  
PROJECT ANALYST: Celia C. Inman  
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: K-10277-14/ DLP Person Memorial Hospital, LLC d/b/a Person Memorial Hospital/ Acquire one fixed MRI scanner / Person County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

### C

The 2014 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional fixed magnetic resonance imaging (MRI) scanners by service area. However, as noted on page 171 of the SMFP, the need determination in the Person County service area for one (1) fixed MRI scanner is not identified by applying the need methodology, but rather is in response to a petition that was approved by the State Health Coordinating Council.

DLP Person Memorial Hospital, LLC d/b/a Person Memorial Hospital (PMH) proposes to acquire one fixed MRI scanner to be located on the hospital campus. PMH currently provides MRI services three days a week through the mobile MRI vendor, Alliance Imaging. PMH does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2014 SMFP for Person County. Therefore, the application is consistent with the need determination.

In addition, there are two policies in the 2014 SMFP that are applicable to this review, Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities. Both policies are located on page 38 of the 2014 SMFP.

Policy GEN-3 states:

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

The applicant responds to Policy GEN-3 as follows:

Promote Safety and Quality

In Section III.2, page 66, the applicant discusses its safety and quality improvement plan. The applicant states that PMH continually promotes safety and quality in all areas of care. The applicant further states:

*“The proposed fixed MRI service will be incorporated in the hospital’s Service Excellence program whose policies and procedures include safety of patients and staff; patient privacy rights, hospital and medical staff performance quality, continuous reviews of patient outcomes and benchmarking to other LifePoint Hospitals.*

...

*The high-field, 1.5 tesla magnet, proposed will provide outstanding image quality.*

*Additionally, Person Memorial Hospital will promote safety and quality in the delivery of healthcare services by:*

- *Seeking accreditation through the American College of Radiology and through Joint Commission.*
- *Educating patients through verbal and written instructions related to safety prior to the MRI procedure.*
- *Implementing a regular maintenance schedule for the proposed equipment to ensure proper working order at all times.*
- *Adherence with applicable ADA and state / local policies related to the physical structure of the building.*
- *Quality interpretation of the MRI images by a board-certified radiologist.”*

Exhibit 2 contains excerpts from the PMH Service Excellence Policy.

The applicant adequately demonstrates that the proposal will promote safety and quality care.

#### Promote Equitable Access

In Section VI.2, page 95, the applicant discusses how the proposed project will promote equitable access. The applicant states:

*“DLP Person Memorial Hospital does not deny services to any patient because of economic, race, ethnicity, gender, age, handicap, or any other status. Please see Exhibit 20, for Patient Rights and Responsibilities Policy. Each of the groups in (a) through (f) above has access to the existing and proposed services through physician referral, emergency department admittance, and referral or transfer from other healthcare facilities. DLP Person Memorial Hospital accepts Medicare and Medicaid, and is subject to EMTALA regulations regarding access to care.”*

In Section III.2, page 67, the applicant discusses charity care and bad debt, stating that with the ageing service area:

*“Access to Medicare is important and charity and bad debt allowances will be equally important. As demonstrated in the payor mix information in Section VI.12, DLP Person Memorial Hospital provides high levels of access to self-pay, Medicare, Medicaid and Managed Care beneficiaries.”*

The applicant adequately demonstrates that the proposal will promote adequate access.

#### Maximize Healthcare Value

In Section III.2, page 67, the applicant states that the proposed project will maximize healthcare value, as follows:

*“Person Memorial Hospital policies of non-discrimination and history of charity care will sustain, making the proposed project an excellent value for patients.*

*For PMH, a safety net hospital, the direct unit costs for the full time service will be less than for the part time service.”*

The applicant states that the existing mobile MRI vendor service will be replaced by the proposed fixed MRI scanner, reducing PMH's unit operating cost and increasing the service's overhead contribution. Therefore, the applicant adequately demonstrates that the proposal will maximize healthcare value for resources expended.

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.”*

In Section III.2, page 68, the applicant addresses Policy GEN-4, stating:

*“Plans for energy conservation are described in Section XI.7. The MRI service involves little or no water consumption and the site changes involve no changes in water run-off.”*

In Section XI.7, page 136, the applicant discusses the methods that will be used by the facility to maintain efficient energy operations and contain costs of utilities. The applicant states that the proposed PDC Entrée pod housing the proposed MRI is designed specifically to work efficiently with the proposed MRI equipment, minimizing utility requirements and maximizing the performance functionality of the equipment. PMH further states the size of the pod and its integration with the hospital will provide efficiency in heating and cooling and save energy.

The applicant included a statement adequately 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 2014 SMFP and Policies GEN-3 and GEN-4. Consequently, the application is conforming to this criterion.

(2) Repealed effective July 1, 1987.

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

C

The applicant currently provides MRI services three days a week through Alliance Imaging, a mobile MRI service vendor. With this application, PMH proposes to acquire a fixed GE Optima MR360 Advance MRI scanner to replace its mobile MRI services. The applicant states that upon initiation of the proposed fixed MRI services, PMH will no longer lease mobile MRI services from Alliance Imaging.

Population to be Served

In Section III.4, page 70, the applicant provides the current patient origin for inpatient discharges and MRI services at PMH, as illustrated in the tables below:

**PMH Inpatient Patient Origin  
October 1, 2012 – September 30, 2013**

County	FFY2013 Number of Inpatients	FFY2013 Percent of Inpatients
Person	1,445	84.31%
Caswell	117	6.83%
Durham	54	3.15%
Virginia	44	2.57%
Other*	54	3.15%
<b>Total</b>	<b>1,714</b>	<b>100.00%</b>

\*Other includes 15 other NC counties and other states, each contributing less than 2%, as listed on page 70.

**PMH MRI Patient Origin  
October 1, 2012 – September 30, 2013**

County	FFY2013 Number of MRI Patients	FFY2013 Percent of MRI Patients
Person	629	79.02%
Caswell	98	12.31%
Durham	19	2.39%
Virginia	31	3.89%
Other*	19	2.39%
<b>Total</b>	<b>796</b>	<b>100.00%</b>

\*Other includes Alamance, Granville, Guilford, Orange, Vance and Wake counties.

In Section III.5(c), page 72, the applicant provides the projected patient origin for MRI services at PMH during the first two years of operation following completion of the project, as illustrated in the table below:

PMH Projected MRI Patient Origin

County	PY1 - CY2016 MRI Patients	PY1 - CY2016 Percent Patients	PY2 - CY2017 MRI Patients	PY2 - CY2017 Percent Patients
Person	891	81%	1,007	82%
Caswell	121	11%	119	10%
Other*	88	8%	98	8%
<b>Total</b>	<b>1,100</b>	<b>100%</b>	<b>1,223</b>	<b>100%</b>

Totals may not sum due to rounding.

\*Other includes Alamance, Granville, Guilford, Orange, Vance and Wake counties, per page 72 of application.

As illustrated in the table above, the applicant's project years for the MRI service run January through December, with the first full fiscal year of operation being January 1, 2016 - December 31, 2016 (CY2016). "Other" as identified above includes Alamance, Granville, Guilford, Orange, Vance and Wake counties. The applicant does not mention Virginia or Durham County, which together comprise 6% of the 2013 patient origin of MRI patients.

On page 64, the applicant states, "*Assumption: Percent of procedures from out of the service area will remain constant.*" From this statement, one would assume that MRI patients from Virginia and Durham County would be included in the 8% totaling "Other". In clarifying information requested by the Project Analyst in the expedited review of this project, the applicant confirmed a typographical error in the omission of Virginia and Durham County from the definition of "Other" on page 72 of the application.

The applicants adequately identified the population to be served.

#### Need Analysis

In Section III.1, page 50, the applicant states the need for the proposed fixed MRI scanner at Person Memorial Hospital is based on the following factors:

- The size and age of the population in the areas from which PMH MRI patients have come in recent years,
- The health status of the service area residents,
- The expected use rate for MRI procedures by the service area population,
- Advantages of having a service 24/7 over 24 to 30 hours a week for a limited number of days,
- The importance of proper equipment to physician retention in a rural area, and
- Cost advantages of fixed over mobile service for the hospital.

## Service Area Statistics

The applicant's proposed primary service area for PMH MRI services includes Person and Caswell counties, neither of which has a fixed MRI. On page 52, the applicant provides statistical data on the population growth of the service area, reaching 63,080 people by 2019, per the North Carolina Office of State Budget and Management (NCOSBM), prior to the April 24, 2014 update.

On page 50, the applicant provides information from the 2014 Health Rankings for North Carolina, a survey of personal health status conducted by the University of Wisconsin Population Health Institute in collaboration with the Robert Wood Johnson Foundation. This survey ranks Person County 32<sup>nd</sup> and Caswell County 62<sup>nd</sup> in health factors. The source offers the following interpretation of the statistics: *"The lowest score (best health) gets a rank of #1 for that state and the highest score (worst health) gets whatever rank corresponds to the number of units we rank in that state."*<sup>1</sup> Thus, Person is the 32<sup>nd</sup> healthiest county in the state, with 68 counties less healthy than Person. Accordingly, Caswell County is the 62<sup>nd</sup> healthiest, with 38 states less healthy than Caswell County. On page 54, the applicant further discusses the health of the population surrounding PMH, stating:

*"Although Person ranks 32<sup>nd</sup> among NC counties in health factors according to County Health Rankings, the county average is masked by the suburban population in the parts of the county that are closer to Durham County. Person Memorial Hospital had a Medicare case mix of 1.35 in 2012 compared to the LifePoint Hospital average of 1.32.<sup>2</sup> The hospital's combined payor mix for underserved populations exceeds 85 percent of total. Moreover, the statewide average is also skewed towards North Carolina's large healthy urban centers, Wake, Durham, and Mecklenburg which are ranked in the top 10 in County Health Rankings."*

The applicant discusses North Carolina and Person County MRI use rates on page 51, stating, *"Trends for the past four years show MRI use rates have declined, but appear to be stabilizing."* The applicant states the 2012 statewide use rate was 62 per 1,000 residents and the rate in the same year for Person County residents was 90 per 1,000 residents.

## Advantages of Availability of MRI Services 24/7

The applicant states that availability of full-time fixed MRI services will offer advantages for patients and referring physicians, overcoming the limitations of mobile MRI services, which include requiring patients to go out in the elements to access the mobile services, lack of access to MRI for emergency coverage and the complexity of keeping up with the mobile services' three day schedule. The applicant states that increased accessibility of MRI services at PMH will increase the percent of Person County residents that seek MRI services at PMH. Based on comparable hospital experience, PMH states its expectation to attract 33 percent of Person County MRI patients, rather than the current 20 percent.

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<sup>1</sup> <http://www.countyhealthrankings.org/ranking-methods/calculating-scores-and-ranks>

<sup>2</sup> LifePoint Hospitals Reports Fourth Quarter and Year-end 2012.

### Importance of Proper Equipment to Physician Retention

In Section III, page 51, the applicant states, “Merritt Hawkins, a top national physician recruiter identified appropriate equipment in the top 10 issues in a physician recruitment and retention plan.”

### Cost Advantages of Fixed Over Mobile MRI Services

The applicant states that cost per procedure will drop significantly when PMH changes from mobile to fixed MRI, as demonstrated in the proforma financial statements, page 143 (Total Expense / Total Procedures in 2015 compared to 2016, the first year of operation following completion of the project).

#### Cost per Procedure

	<b>CY2015</b>	<b>CY2016</b>
Total Expenses	\$ 608,835	\$ 699,778
Total Procedures	979	1,374
Cost per Procedure	\$ 621.89	\$ 509.30

### Statistical Data

The applicant provides an 18-step need methodology projecting MRI procedures at PMH on pages 52-64, including assumptions, as summarized below. Unless otherwise specified, the tables in the need methodology represent Full Federal Years (FFY) 2014-2019.

Step 1. Forecast Person and Caswell counties’ population through 2019. See excerpt from Table III.1, page 52, below.

#### Projected Population

<b>County</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
Person	39,418	39,430	39,538	39,549	39,660
Caswell	23,541	23,485	23,471	23,437	23,420
<b>Total</b>	<b>62,959</b>	<b>62,915</b>	<b>63,009</b>	<b>62,986</b>	<b>63,080</b>

Assumptions: Person and Caswell counties together represent more than 90% of the MRI patients at PMH.

Overall population of the service area will continue to grow and NCOSBM projections are reasonable.

Step 2. Obtain total number of MRI patients in the primary service area counties from 2008-2012 from DHSR MRI Patient Origin Reports (detail in Exhibit 23).



**MRI Patients**

<b>County</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>
Person	3,622	2,836	3,289	3,536
Caswell	1,125	937	1,314	1,167
<b>Total</b>	<b>4,747</b>	<b>3,773</b>	<b>4,603</b>	<b>4,703</b>

Assumption: Procedures in the Patient Origin Report are reasonably correct and are defined the same as in MRI Special Rules.

- Step 3. Calculate MRI use rate per 1,000 residents for each county and statewide by dividing the total number of MRI patients by the total population (Step 2 divided by Step 1).

**Historical MRI Use Rate**

<b>County</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2011/12 Average</b>
Person	92.64	71.90	83.04	89.76	86.40
Caswell	47.18	39.59	54.96	49.54	52.25
North Carolina	66.77	57.90	63.22	61.76	62.49

- Step 4. Project patient use rate per 1,000 Person County residents from 2014-2019 using the average patient use rate for Person County from 2011-2012 (Step 3). Person County resident MRI use rate is projected to be 90% of the 2011-12 two-year average.  $[(83.04 + 89.76) / 2 = 86.4 \times .90 = 77.76]$

Assumption: Use rate will decrease from current levels and stabilize at 90 percent of current level, remaining higher than the state average, because the population closer to PMH is less healthy.

- Step 5. Project patient use rate per 1,000 residents for Caswell County, using the linear regression line  $y = 2.246*x + 42.203$  obtained from Caswell County patient use rate per 1,000 residents from 2009 through 2012 in Step 3.

Project North Carolina use rate using the linear regression line  $y = -0.9723*x + 64.983$  obtained from North Carolina patient use rate per 1,000 residents from 2009 through 2012 in Step 3.

Adjust Caswell's projected use rate to North Carolina's projected use rate when the trend line exceeds the North Carolina projected use rate. See the table below and on page 55 of the application.

**Projected Caswell County Use Rate**

<b>County</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
Caswell Linear Regression Projection	55.68	57.93	60.17	62.42	64.66	66.91
NC Linear Regression Projection	59.15	58.18	57.20	56.23	55.26	54.29
<b>Caswell Projection</b>	<b>55.68</b>	<b>57.93</b>	<b>57.20</b>	<b>56.23</b>	<b>55.26</b>	<b>54.29</b>

Assumptions: Use rate in Caswell County will continue to increase, reaching the state average.

X in the equations above represents the number of years since 2008.

The applicant did not discuss the related R<sup>2</sup> values for the linear regression equations provided above. The R<sup>2</sup> values calculated by the Project Analyst, 0.21 and 0.12 for Caswell County and the State, respectively, do not approach 1.0, a strong R<sup>2</sup> value. Therefore use of linear regression to forecast future MRI patient use rates for Caswell County and North Carolina would not appear to be the most reliable forecast tool. It does in fact yield a more aggressive forecast in the early years, and a less aggressive forecast in later years, than the compound average growth rate (CAGR) for Caswell County as compared below.

**Comparison of Caswell County Growth Rate Methodology for MRI Patient Use Rates**

<b>County</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
Caswell Linear Regression Projection	55.68	57.93	57.20	56.23	55.26	54.29
Caswell CAGR	51.18	52.02	52.88	53.74	54.63	55.53
<b>Difference</b>	<b>4.50</b>	<b>5.91</b>	<b>4.32</b>	<b>2.49</b>	<b>0.63</b>	<b>-1.24</b>

The linear regression forecast projected a more aggressive growth than the CAGR for North Carolina MRI patients as a whole as shown below.

**Comparison of North Carolina Growth Rate Methodology for MRI Patient Use Rates**

<b>North Carolina</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
Linear Regression Projection	59.15	58.18	57.20	56.23	55.26	54.29
CAGR	58.63	57.13	55.66	54.23	52.84	51.48
<b>Difference</b>	<b>0.52</b>	<b>1.05</b>	<b>1.54</b>	<b>2.00</b>	<b>2.42</b>	<b>2.81</b>

Step 6. Project total number of MRI patients in the service area 2014-2019. Multiply projected patient use rate in Person County (Step 4) and Caswell County (Step 5) by the projected population (Step 1) divided by 1,000; Sum the total number of patients for the primary service area (Person and Caswell counties). These calculations result in the following table presented on page 56 and below.

**Projected Number of MRI Patients in the PMH Primary Service Area  
As Projected by Applicant, Page 56**

County	2014	2015	2016	2017	2018	2019
Person	3,057	3,065	3,066	3,074	3,075	3,084
Caswell	1,311	1,364	1,343	1,320	1,295	1,271
<b>Total</b>	<b>4,367</b>	<b>4,429</b>	<b>4,409</b>	<b>4,394</b>	<b>4,370</b>	<b>4,355</b>

The following table provides the same projections using the CAGR for the two counties in the same process instead of the use rates projected by the applicant for Person and Caswell counties in Steps 4 and 5 above.

**Projected Number of MRI Patients in the PMH Primary Service Area  
Testing CAGR as Better Forecast Tool**

County	2014	2015	2016	2017	2018	2019
Person	3,455	3,428	3,393	3,367	3,333	3,307
Caswell	1,205	1,225	1,242	1,261	1,280	1,300
<b>Total</b>	<b>4,660</b>	<b>4,653</b>	<b>4,635</b>	<b>4,628</b>	<b>4,613</b>	<b>4,607</b>

As is apparent in the comparison of the previous two tables, the applicant's forecast of MRI patients in Person and Caswell counties using linear regression to project patient use rates results in a more conservative forecast than using the CAGR computed from the MRI patient use rates from 2009-2012. Therefore, the projection of total MRI patients in the primary service area appears conservative and reasonable.

Steps 7-9. Forecast PMH's Share of the Total Person County MRI Patients

On page 57, the applicant states the use of Halifax County's 2011-2012 two-year average market share (33.11%) of in-county MRI patients as a reasonable proxy for PMH to reach by 2019. The applicant projects its market share to increase annually, upon project completion, from PMH's 2011-2012 two-year average market share of 19.52% to 33.11% in 2019. The applicant states its belief that Halifax County, a rural hospital with 1 fixed MRI, should be representative of Person County when PMH receives a fixed MRI and that four years is a reasonable amount of time to stabilize at the new market share.

On page 58, the applicant applies its projected market share to the total MRI patients in Person County calculated in Step 6.

County	2014	2015	2016	2017	2018	2019
Projected Person MRI Patients.	3,057	3,065	3,066	3,074	3,075	3,084
Projected Market Share	19.52%	19.52%	26.32%	29.71%	31.41%	33.11%
<b>Projected MRI Patients from Person County at PMH</b>	<b>597</b>	<b>598</b>	<b>807</b>	<b>913</b>	<b>966</b>	<b>1,021</b>

Steps 10-11. Forecast PMH Share of the Total Caswell County MRI Patients

On page 58, the applicant forecasts the reasonable market share of PMH MRI patients from Caswell County as 9%, based on its market share from 2009-2012. On page 59, the applicant applies its projected market share to the total MRI patients in Caswell County calculated in Step 6.

<b>County</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
Projected Caswell MRI Patients.	1,311	1,364	1,343	1,320	1,295	1,271
Projected Market Share	9%	9%	9%	9%	9%	9%
<b>Projected MRI Patients from Caswell County at PMH</b>	<b>118</b>	<b>123</b>	<b>121</b>	<b>119</b>	<b>117</b>	<b>114</b>

Step 12. Forecast PMH MRI Patients from Primary Service Area

The applicant adds the projected MRI patients from Person and Caswell counties to calculate the total projected PMH primary service area MRI patients.

<b>County</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
Person MRI Patients at PMH	597	598	807	913	966	1,021
Caswell MRI Patients at PMH	118	123	121	119	117	114
<b>Total Primary SA MRI Patients at PMH</b>	<b>715</b>	<b>721</b>	<b>928</b>	<b>1,032</b>	<b>1,082</b>	<b>1,135</b>

In Section III, page 59, the applicant states that Steps 13-17 show the methodology for calculating the need for MRI procedures at PMH.

Step 13. Determine the historical number of MRI procedures per patient for PMH, Halifax County and Statewide.

The applicant sources its data from the 2011-2014 State Medical Facilities Plans (SMFPs) and the 2009-2012 MRI Services Patient Origin Reports developed by the Division of Health Service Regulation (DHSR) Planning Branch. The MRI patient origin reports provide data on the number of MRI patients served by county of residence and by facility. The applicant includes the patient origin data used in the analysis in Exhibit 23. The step on pages 60-61 results in an MRI procedure to patient ratio of 1.10 for years 2014 and 2015, based on PMH's historical average ratio and 1.33 for the years following the project completion, based on North Carolina's historical average ratio.

Step 14. Projected MRI Procedures from PMH's Proposed Primary Service Area

**Total Primary Service Area (Person and Caswell Counties) Projected Procedures**

	2014	2015	2016	2017	2018	2019
Total PSA Patients	715	721	928	1032	1082	1135
Procedures per Patient	1.10	1.10	1.33	1.33	1.33	1.33
<b>Projected PSA Procedures</b>	<b>784</b>	<b>791</b>	<b>1,230</b>	<b>1,368</b>	<b>1,435</b>	<b>1,505</b>

Totals may not sum due to rounding.

Assumption: The number of procedures per patient will match the state average when a new hospital fixed MRI is installed.

Using the North Carolina average provides a more conservative estimate than using Halifax County ratios; and the state average has been consistent for four years.

Steps 15 and 16. Determine Distribution of Unweighted MRI Procedures by Procedure Type

The applicant states it compared the percentages of MRI procedure types (outpatient no contrast, outpatient with contrast, inpatient no contrast, and inpatient with contrast) reported as performed in Person County, Halifax County and Statewide. The applicant determined it was reasonable to use the Person County distribution for the years prior to project implementation and the Halifax County distribution for the years following project implementation, resulting in the following procedures.

Procedure Type	2014	2015	2016	2017	2018	2019	Person Co. Distribution	Halifax Co. Distribution
Total Projected Procedures	784	791	1230	1368	1435	1505	100%	100%
Outpatient No Contrast	517	521	844	939	984	1032	66%	69%
Outpatient with Contrast	194	195	207	230	241	253	25%	17%
Inpatient No Contrast	42	42	114	127	133	140	5%	9%
Inpatient with Contrast	32	32	65	73	76	80	4%	5%

Assumption: With a new MRI installed, Person County’s distribution of procedures will match the average of the Halifax distribution.

Steps 17. Project Weighted MRI Procedures from the Primary Service Area at PMH

<b>Procedure Type</b>	<b>Weighting Factor</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
Outpatient No Contrast	1	517	521	844	939	984	1032
Outpatient with Contrast	1.4	271	273	290	321	337	354
Inpatient No Contrast	1.4	59	58	159	178	186	197
Inpatient with Contrast	1.8	58	57	118	132	136	144
<b>Total Weighted Procedures From Primary Service Area</b>		<b>903</b>	<b>912</b>	<b>1,410</b>	<b>1,569</b>	<b>1,645</b>	<b>1,726</b>

Steps 18 and 19. Estimate the Need for MRI Procedures by Persons Outside the Primary Service Area

The applicant states it determined the average percent of MRI patients at PMH originating from outside of Person and Caswell counties. According to the applicant, an examination of MRI Patient Origin Reports and PMH License Renewal Applications from 2009 through 2013 reveals an average of eight percent of patients originating from outside the primary service area during those years. Thus, the projected number of PMH MRI procedures from within the primary service area, as calculated in Step 14, is 92% of the total PMH MRI procedures to be performed. The following table shows the total projected number of unweighted MRI procedures to be performed at PMH.

	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
Projected PMH Unweighted MRI Procedures	852	859	1,336	1,487	1,559	1,635

Assumption: Percent of procedures from outside the primary service area will remain constant.

The applicant adequately demonstrates the need the proposed service area population has for the proposed PMH MRI services.

Projected Utilization

In Section IV.1, page 77, the applicant states:

*“The methodology and assumptions for determining the number of patients and procedures from the PMH primary service area are described in Section III.1.b, Steps 1 through 17. Total procedures for the first three project years, were estimated using the following methodology and assumptions.”*

The applicant uses the number of primary service area MRI patients calculated in Section III, Step 12 and above and the historical percent of MRI patients (8%) from outside the primary service area calculated in Section III, Step 18 and above to project the total number of MRI patients at PMH for FFY 2014-2019, as shown below. Thus, the primary service area patients are 92% of the projected total number of MRI patients at PMH, as shown in Table IV.3 of the application and below.

**Projected PMH MRI Patients  
October 1, 2014 through September 30, 2019**

	2014	2015	2016	2017	2018	2019
Projected PSA MRI Patients	715	721	928	1,032	1,082	1,135
Projected Out of PSA MRI Patients	62	63	80	90	94	98
<b>Total Projected PMH MRI Patients</b>	<b>777</b>	<b>784</b>	<b>1,008</b>	<b>1,122</b>	<b>1,176</b>	<b>1,234</b>

In Section IV.1, Table IV.4, page 79, the applicant forecasts the total MRI procedures at PMH, as shown in the table below, based on the calculations shown in the table above and the assumptions in Section III, Step 14 for the number of procedures per patient.

**Projected PMH MRI Procedures  
October 1, 2014 through September 30, 2019**

	2014	2015	2016	2017	2018	2019
Total Projected PMH MRI Patients	777	784	1,008	1,122	1,176	1,234
Procedure to Patient Ratio	1.10	1.10	1.33	1.33	1.33	1.33
<b>Projected MRI Procedures</b>	<b>852</b>	<b>859</b>	<b>1,336</b>	<b>1,487</b>	<b>1,559</b>	<b>1,635</b>

On page 80, the applicant distributes the total projected MRI procedures by procedure type for FFY 2014-2019, calculated using the methodology in Steps 15 and 16 of Section III.1, page 62-63, and shown above.

**Projected PMH MRI Procedures by Type  
October 1, 2014 through September 30, 2019**

Procedure Type	2014	2015	2016	2017	2018	2019	Person Co. Distribution	Halifax Co. Distribution
Total Projected Procedures	852	859	1,336	1,487	1,559	1,635	100%	100%
Outpatient No Contrast	562	567	917	1,020	1,070	1,122	66%	69%
Outpatient with Contrast	210	212	225	250	262	275	25%	17%
Inpatient No Contrast	45	46	124	138	145	152	5%	9%
Inpatient with Contrast	35	35	71	79	83	87	4%	5%

The applicant then provides, on page 81, Table IV.6, total weighted MRI procedures projected to be performed at PMH, using the need methodology and assumptions provided in Section III.1 Step 17, page 63 and discussed above. The applicant's table contains numerous typographical errors; specifically, the table shows incorrect individual values for the projections by procedure type for each year for "Outpatient With Contrast, Inpatient No Contrast and Inpatient With

Contrast”; however, the total annual weighted procedure figures are correct. The table below provides the correct projections for individual procedures by type.

**Projected PMH MRI Procedures by Type (Weighted)  
October 1, 2014 through September 30, 2019**

<b>Procedure Type</b>	<b>Weighting Factor</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
Outpatient No Contrast	1	562	567	917	1,020	1,070	1,122
Outpatient with Contrast	1.4	294	297	315	350	367	385
Inpatient No Contrast	1.4	62	64	174	193	203	213
Inpatient with Contrast	1.8	63	64	127	143	149	156
<b>Total Weighted Procedures From Primary Service Area</b>		<b>982</b>	<b>991</b>	<b>1,532</b>	<b>1,705</b>	<b>1,788</b>	<b>1,875</b>

The applicant’s final step in its utilization projection is to convert its federal fiscal year projections, which run from October 1 – September 30, to PMH fiscal years which are the calendar year (CY) January 1 – December 31. On page 81, the applicant explains its methodology as “taking 75 percent of the value of the federal fiscal year and adding it to 25 percent of the value for the following federal fiscal year.” The applicant’s methodology results in the following projected procedure utilization for the correlating PMH fiscal years and Project Years (PY) 1-3.

	<b>FFY2014</b>	<b>FFY2015</b>	<b>FFY2016</b>	<b>FFY2017</b>	<b>FFY2018</b>	<b>FFY2019</b>
	<b>10/13-9/14</b>	<b>10/14-9/15</b>	<b>10/15-9/16</b>	<b>10/16-9/17</b>	<b>10/17-9/18</b>	<b>10/18-9/19</b>
FFY Unweighted Procedures	852	859	1,336	1,487	1,559	1,635
FFY Weighted Procedures	982	991	1,532	1,705	1,788	1,875
	<b>PMH FY2014</b>	<b>PMH FY2015</b>	<b>PMH FY2016</b>	<b>PMH FY2017</b>	<b>PMH FY2018</b>	
	<b>1/14-12/14</b>	<b>1/15-12/15</b>	<b>1/16-12/16</b>	<b>1/17-12/17</b>	<b>1/18-12/18</b>	
			<b>PY 1</b>	<b>PY 2</b>	<b>PY 3</b>	
PMH FY Unweighted Procedures	854	979	1,374	1,505	1,578	
PMH FY Weighted Procedures	984	1,126	1,576	1,726	1,810	

The applicant adequately demonstrates projected utilization of the proposed fixed MRI scanner is based upon reasonable, credible and supported assumptions.

Access

In Section VI, pages 95-106, the applicant discusses access to services at Person Memorial Hospital. On page 95, the applicant states:

*“DLP Person Memorial Hospital does not deny services to any patients because of economic, race, ethnicity, gender, age, handicap, or any other status. ... DLP Person Memorial Hospital accepts Medicare and Medicaid, and is subject to EMTALA regulations regarding access to care.”*



On page 97, the applicant states, “DLP Person Memorial Hospital makes every effort to make services easily accessible to all persons.” See further discussion on access in Criteria (13) and (18a) which is hereby incorporated as if set forth fully herein.

The applicant adequately demonstrates 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 proposed services.

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need the population to be served has for the proposed fixed MRI scanner, and demonstrates that all residents of the area will have adequate 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

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

CA

In Section III.3, pages 68-69, the applicant discusses the alternatives considered, which include:

1. Status Quo - continue limited access to mobile MRI services – the applicant concluded that with this alternative, PMH will continue to see providers refer 75% of Person County MRI patients out of Person County. The applicant believes such outmigration will increase the cost associated with care coordination and add travel costs for residents of the service area. The applicant further believes the added cost in time and money will cause many patients to delay or defer treatment. The applicant states:

*“Moreover, high costs to offer MRI will continue to put pressure on the hospital’s operating margin. This is not a good alternative.”*

2. Additional mobile services – the applicant states that additional mobile days will come at a high price, requiring contracting for full days of service regardless of use. The applicant states that though this could result in a reduction of outmigration, there is no guarantee that the increased utilization would be sufficient to offset the very high cost of this alternative.

3. Joint Venture / Partnership - The applicant states that it found no reasonable joint venture partnership for this project.
4. Purchase a fixed MRI scanner for location at PMH – The applicant provides an analysis of the incremental cost per scan for fixed MRI services on page 69. Based on the analysis, the applicant states:

*“A review of the costs of a new, refurbished MRI indicates that the applicant’s total cost per scan for a full time will be only \$34 more than for part time service.*

...

*Clearly, the fixed scanner provides the better long term value.”*

The applicant adequately demonstrates that acquiring the fixed MRI scanner to be located on the PMH campus is its most effective alternative to meet the need for fixed MRI services in Person County.

Furthermore, the application is conforming to all other applicable statutory review criteria. Therefore, the application is approvable. An application that cannot be approved is not an effective alternative.

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

1. **DLP Person Memorial Hospital, LLC shall materially comply with all representations made in its certificate of need application and the supplemental information received June 9, 2014. In those instances where representations conflict, DLP Person Memorial Hospital shall materially comply with the last made representation.**
2. **DLP Person Memorial Hospital, LLC shall acquire no more than one fixed MRI scanner for a total of no more than one fixed MRI scanners.**
3. **DLP Person Memorial Hospital, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.**
4. **DLP Person Memorial Hospital, LLC shall obtain accreditation from 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.**

**5. DLP Person Memorial Hospital, LLC 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.**

- (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

In Section VIII.1, pages 120-121, the applicant states that the total capital cost of the project will be \$2,192,266, including \$55,000 for site costs, \$588,364 for construction costs, \$1,350,798 for fixed equipment purchase/lease, \$10,000 for architect/engineering fees, \$12,500 for equipment certification, and a contingency of \$175,604. In Section IX, page 127, the applicant states that there will be no start up or initial operating expenses associated with the proposed project. In Section VIII.3, page 122, the applicant states that the project will be funded by the cash reserves of its parent company, LifePoint Hospitals, Inc. Exhibit 9 contains an April 11, 2014 letter signed by the President of the Eastern Group of the LifePoint Hospitals, Inc., which states:

*“This letter is to confirm that Person Memorial Hospital plans to utilize cash reserves to fund the proposed addition of a fixed Magnetic Resonance Imaging scanner and pod unit. As President-Eastern Group, I have the authority to obligate funds up to \$2.2 million to finance the proposed MRI scanner, subject to our normal and customary internal review process. This amount is sufficient to cover the estimated capital costs and working capital.*

*Please accept this letter as indication that there are necessary funds to develop this project subject to the aforementioned review process. These funds are not committed to another project, and will be available at the end of the agency review and in subsequent months.”*

Exhibit 9 also contains a letter date April 11, 2014 from the CEO of DLP Person Memorial Hospital confirming PMH’s intent to use LifePoint Hospitals, Inc. cash reserves to fund the project.

Exhibit 7 contains an unaudited LifePoint Hospitals, Inc. Balance Sheet and Income Statement as of December 31, 2013 and December 31, 2012, showing “Cash and Cash Equivalents” of \$637.9 million on December 31, 2013.

Exhibit 8 contains an unaudited PMH Balance Sheet and Income Statement for the years ending December 31, 2013 and December 31, 2012. The applicant states the most recent audited financial statements for LifePoint Hospitals, Inc. are for the years ending 2011 and 2012, which are available in the 2012 Annual Report at <http://www.lifepointhospitals.com/investor-relations/>.

The applicant provides pro forma financial statements for the first three years of the project for the proposed fixed MRI scanner. In Form C, the applicant projects revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below.

	<b>Project Year 1 CY2016</b>	<b>Project Year 2 CY2017</b>	<b>Project Year 3 CY2018</b>
Projected # of Unweighted MRI Procedures	1,374	1,505	1,578
Projected Average Charge (Gross Patient Revenue/ Projected # of Procedures)	\$ 3,002	\$ 3,092	\$ 3,185
Gross Patient Revenue	\$ 4,124,483	\$ 4,653,124	\$ 5,026,272
Deductions from Gross Patient Revenue	\$ 3,259,206	\$ 3,721,005	\$ 4,067,000
Net Patient Revenue	\$ 865,277	\$ 932,119	\$ 959,272
Total Expenses	\$ 699,778	\$ 831,757	\$ 845,520
Net Income	\$ 165,499	\$ 100,361	\$ 113,752

The applicant also projects a positive net income for the entire hospital in the third operating year of the project. 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 for the assumptions regarding cost and charges. See Criterion (3) for discussion of utilization projections which is hereby incorporated as if set forth fully herein. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges, and therefore, the application is conforming to this criterion.

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

C

The 2014 SMFP identifies a need for one fixed MRI scanner in Person County. The applicant proposes to acquire one fixed MRI scanner. The applicant adequately demonstrates the need to replace the mobile MRI services leased through Alliance Imaging with a fixed MRI scanner, based on reasonable, credible and supported projected utilization. See Criterion (3) for discussion of need which is hereby incorporated as if set forth fully herein. Thus, the applicant adequately demonstrates the acquisition of a fixed scanner to replace contracted mobile services will not result in the unnecessary duplication of MRI services in Person County. Consequently, the application is conforming to this criterion.

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

C

In Section VII.1(b), pages 110-112, the applicant provides the projected staffing for the proposed fixed MRI scanner at PMH. The applicant projects to employ 2.50 full-time equivalents (FTEs) for the proposed MRI project. The positions include 2.0 FTE MRI technologist positions, 0.25 FTE RN, and 0.25 FTE administrative positions. In Section VII.6, page 115, the applicant discusses its experience in the recruitment and retention of staff. In Exhibit 22, the applicant provides a letter from William Hall, MD, which states, *“I am writing this letter to express my willingness to serve as Medical Director Person Memorial Hospital’s proposed fixed MRI expansion program.”*

The applicant adequately demonstrates the availability of health manpower and management personnel for the provision of 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

PMH is an existing hospital which currently contracts with Alliance Imaging to provide mobile MRI services on its campus. In Section II.2(a), page 22, the applicant identifies the necessary ancillary and support services for the MRI service as follows:

- Administration
- Medical Records
- Transcription
- Scheduling / Registration / Billing
- Maintenance / Engineering
- Material Services
- Housekeeping
- Security
- Quality, Risk Management and other ancillary and support services

In Section II.2(b), page 22, the applicant states that the project does not propose a new service for PMH. The applicant states that replacement of its existing mobile MRI services with fixed MRI services, is supported by current PMH departments. The applicant further states, *“Service support will continue with the new unit.”* Exhibit 11 contains a letter from PMH CEO, confirming existing staff and committing to support MRI services.

In Section V.2, page 90, the applicant identifies the facilities with which they have transfer agreements, as follows:

*“DLP Person Memorial Hospital has existing transfer arrangements with the following hospitals:*

- *Duke University Medical Center*
- *Roxboro Healthcare and Rehabilitation Center”*

Policies in Exhibit 27 govern PHM patient transfers to other hospitals.

Exhibit 38 contains copies of physician support and referral letters. Exhibit 39 contains letters from physicians and community leaders supporting PMH in its Summer 2013 petition to adjust the 2014 SMFP to identify the need for one Magnetic Resonance Imaging scanner in Person County.

The applicant adequately demonstrates the availability of the necessary ancillary and support services and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Section XI.4, pages 134-135, the applicant states:

*“DLP Person Memorial Hospital is proposing to install a PDC MR Cassette to house the new MRI scanner. This is an installation which will require no construction or renovation to existing space within the hospital.*

...

*The “pod” will be installed on the current pad used by the mobile MRI unit. ”*

The applicant discusses the proposed equipment, the MRI pod and its installation in Section II, pages 18-21. Exhibit 30 of the application contains the vendor quote.

In Section XI.7, page 136, the applicant addresses energy efficiency, stating:

*“As described in Exhibit 36, the PDC Entrée pod is designed specifically to work efficiently with the proposed MRI equipment. This will minimize utility requirements and maximize the performance functionality of the equipment. The pod will be integrated with the hospital and will not require special lifts to bring persons on stretchers into the MRI. This will save energy. The small size of the pod will provide efficiency in heating and cooling.”*

The applicant adequately demonstrates that the cost, design, and means of construction represent the most reasonable alternative for the proposed project and that replacing the contracted mobile MRI services with fixed MRI services will not unduly increase the costs and charges of providing MRI services. See Criterion (5) for discussion of costs and charges which is hereby incorporated as if set forth fully herein. Therefore, the application is conforming to this criterion.

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

C

In Section VI.12, page 103, the applicant provides the payor mix for the entire facility based on percent of patient days utilized during Federal Fiscal Year 2013, as illustrated in the table below:

	<b>Percent of Patient Days</b>
Self Pay/Indigent/Charity	11.1%
Medicare/Medicare Managed Care	44.0%
Medicaid	12.5%
Commercial Insurance	7.5%
Managed Care	24.9%
Other	0.0%
Total	100.0%

In Section VI.13, page 104, the applicant provides the payor mix for the MRI service during the Calendar Year 2013 as a percent of total MRI revenue, as illustrated in the table below:

	<b>Percent of MRI Service Revenue</b>
Self Pay/Indigent/Charity	2.4%
Medicare	40.2%
Medicaid	12.4%
Commercial Insurance	41.1%
Managed Care	2.7%
Other	1.2%
Total	100.0%

In Section VI.2, page 95, the applicant states:

*“DLP Person Memorial Hospital does not deny services to any patient because of economic, race, ethnicity, gender, age, handicap, or any other status. Please see Exhibit 20, for Patient Rights and Responsibilities policy. Each of the groups in (a) through (f) above has access to the existing and proposed services through physician referral, emergency department admittance, and referral or transfer from other healthcare facilities. DLP Person Memorial Hospital accepts Medicare and Medicaid, and is subject to EMTALA regulations regarding access to care.”*

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



following table illustrates those percentages for Person and Caswell counties and statewide.

	<b>June 2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>June 2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>CY2008-09 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Person	18%	8.31%	18.0%
Caswell	21%	10.76%	20.0%
Statewide	17%	6.71%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group would not typically utilize the health 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 payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations have adequate access to existing services; therefore, the application is conforming to this criterion.

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

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 102, the applicant states:

*“As a hospital that accepts Medicare and Medicaid, DLP Person Memorial is obligated to abide by EMTALA regulations. Its acquisition agreement commits to retain the charity policies in effect at Person Memorial Hospital, Inc. for five years from 2011.*

*DLP Person Memorial Hospital, LLC is in good standing and EMTALA compliant with CMS and it has retained the same charity policies that were in place with Person Memorial Hospital, Inc. None of the agreements require specific amounts of charity care.”*

In Section VI.2 and VI.3, pages 95-97, the applicant states:

*“DLP Person Memorial Hospital accepts Medicare and Medicaid, and is subject to EMTALA regulations regarding access to care.*

...

*It does not discriminate on the basis of race or ethnicity.*

...

*Services are provided in compliance with standards set by the American with Disabilities act (ADA).*

...

*The medically indigent and other underserved populations will have access to DLP Person Memorial Hospital’s MRI services. The applicant’s charity care, [sic] policies involve adjustments for medically indigent persons.*

...

*DLP Person Memorial Hospital is in compliance with:*

- *Title VI of Civil Rights Act of 1963*
- *Section 504 of Rehabilitation Act of 1973*
- *The Age Discrimination Act of 1975”*

In Section VI.10, page 102, the applicant states, *“There have been no civil rights complaints filed against the applicant, or against any of the facilities managed or operated by the applicant’s managers or corporate members.”*

The application is conforming to this criterion.

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

C

In Section VI.2 and VI.3, pages 96-97, the applicant states:

*“The facility will accept persons regardless of age.*

...

*The medically indigent and other underserved populations will have access to DLP Person Memorial Hospital’s MRI services.*

...

*Parts of the hospital are grandfathered, but all new construction and renovation incorporates ADA Standards; and the proposed pod unit and renovation will be in compliance with these standards.”*

In Section VI.14, page 105, and Section VI.15, page 106, the applicant provides the projected payor mix for the entire facility and the proposed fixed MRI service during the second operating year, as illustrated in the table below:

PMH Facility Payor Mix  
PY 2 / CY 2017

	<b>Percent of Patient Days</b>
Self Pay/Indigent/Charity	11.1%
Medicare/Medicare Managed Care	44.0%
Medicaid	12.5%
Commercial Insurance	7.5%
Managed Care	24.9%
Other	0.0%
Total	100.0%

PMH MRI Service Payor Mix  
PY 2 / CY 2017

	<b>Percent of MRI Service Revenue</b>
Self Pay/Indigent/Charity	2.4%
Medicare	40.2%
Medicaid	12.4%
Commercial Insurance	41.1%

Managed Care	2.7%
Other	1.2%
Total	100.0%

In Section VI.15, page 106, the applicant states, *“The applicant assumes no change in payor mix. The above projection is based on historical experience.”*

The application is conforming with this criterion.

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

C

In Section VI.9(a), page 101, the applicant states.

*“Patients are referred by their physicians to the DLP Person Memorial Hospital MRI Services. The referring physician need not be a member of the applicant’s medical staff. The MRI radiologist evaluates each case for appropriateness prior to authorizing the scan.”*

The applicant adequately demonstrates it will provide a range of means by which patients will have access to the proposed services. Therefore, the application is conforming with this criterion.

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

C

In Section V.1(a)(b)(c), page 89, the applicant provides documentation that they will continue to accommodate the clinical needs of area health professional training programs. PMH has existing clinical training program agreements with Piedmont Community College and Vance-Granville Community College. Exhibit 35 contains letters sent to other area training programs offering PMH as a training site. The information provided is reasonable and credible and supports a finding of conformity with this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact

upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

PMH proposes to acquire one fixed MRI scanner to be located on the hospital campus. PMH currently provides MRI services three days a week through the mobile MRI vendor, Alliance Imaging. There is no other provider of MRI services in Person or Caswell counties.

In Section V.7, pages 93-94, the applicant explains why it believes PMH's proposal to acquire a fixed MRI scanner to be located on the hospital campus will enhance competition by promoting cost effectiveness, quality and access to MRI services in Person County, stating:

*"A Full-time MRI scanner at DLP Person Memorial Hospital will be cost effective for both provider and consumer; it will reduce local travel, have lower charges than other nearby hospitals, build local equity and develop local technical skills and job opportunities.*

...

*The MRI is and will continue to be part of the extensive Service Excellence program at DLP Person Memorial Hospital.*

...

*Services will be available without discrimination to all appropriate patients."*

See also Sections II, III, VI and VII of the application for additional discussion by the applicant about the impact of its proposal on cost effectiveness, quality and access to MRI services in Person County.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition in the service area include a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to acquire a fixed MRI scanner and that it is a cost-effective alternative;
- The applicant adequately demonstrates that it will continue to provide quality services; and
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations.

The application is conforming to this criterion.

- (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

According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, no incidents occurred within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

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

C

The application submitted by Pender Memorial Hospital is 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- The applicant 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- In Section II.8, 30, the applicant states, “DLP Person Memorial Hospital will own, operate, and bill patients for the proposed service.”

- (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- In Section II.8, page 30, the applicant states that the proposed MRI scanner will be available and staffed for at least 66 hours per week, scheduling patients 8 am to 5 pm, Monday through Friday. The applicant further states, “*Dually trained CT/MRI Techs will staff the emergency room and cover unscheduled MRI in the other hours.*” On call coverage will be staffed seven days a week at all times.
- (2) *documentation that the proposed mobile MRI scanner will be available and staffed for use at least 40 hours per week;*
- NA- PMH does not propose 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- PMH does not propose 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- In Section II.8, page 31, the applicant states, “*The applicant has estimated the charges for the 20 most frequent MRI procedures. Professional fee is not included.*” The applicant also provides a table of projected charges for the 20 most frequent procedures to be performed in the first three years of operation after completion of the project.
- (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- The applicant does 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- Exhibit 38 contains letters from two Person Memorial Hospital physicians indicating their support for the project, their intent to refer patients to the proposed fixed MRI 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 for MRI studies. Exhibit 37 contains a list of physicians who have historically referred outpatients to PMH 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- In Section II, page 32, the applicant states that according to the definition in 10A NCAC .2701(13), the service area for MRI services is defined in the 2014 SMFP. Person Memorial Hospital's MRI service area is shown as Person County on page 162 of the 2014 SMFP. The applicant further states:

*"DLP Person Memorial Hospital is proposing to operate one MRI scanner in Person County. Neither the applicant nor its parent company has any approved or existing scanners in this service area."*

(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- In Section II.8, page 32, the applicant states:

*"For projections of annual MRI procedures to be performed by the proposed MRI scanner at DLP Person Memorial Hospital, please see Section IV.2.d, Steps 5 and 7."*

The applicant provides its projected utilization steps in Section IV.1(d). Step 5, page 80 provides the projected annual number of unweighted MRI procedures by type for Federal Fiscal Years 2014 through 2019. Step 7, page 81, converts the total annual number of projected MRI procedures from the federal fiscal years (October 1-September 30) to the MRI project years (January 1-December 31). The application does not show "*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*", as required in this rule. In clarifying information



requested by the Project Analyst in the expedited review of this project, the applicant provided the following table showing the unweighted MRI procedures by type to be performed in the first three years of operation after completion of the project.

<b>Procedure Type</b>	<b>PY1- CY 2016</b>	<b>PY2- CY 2017</b>	<b>PY3- CY 2018</b>
Outpatient No Contrast	943	1032	1083
Outpatient with Contrast	231	253	265
Inpatient No Contrast	128	140	147
Inpatient with Contrast	73	80	84
<b>Total Unweighted Procedures</b>	<b>1,374</b>	<b>1,505</b>	<b>1,578</b>

The application is conforming to this rule.

- (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- In Section II.9, page 33, the applicant states:

*“For projections of annual weighted MRI procedures to be performed by the proposed MRI scanner at DLP Person Memorial Hospital, please see Section IV.2.d, Steps 6 and 7.”*

The applicant provides its projected utilization steps in Section IV.1(d). Step 6, page 81 provides the projected annual number of weighted MRI procedures by type for Federal Fiscal Years 2014 through 2019. Step 7, page 81, converts the total annual number of projected MRI procedures from the federal fiscal years (October 1-September 30) to the MRI project years (January 1-December 31). The application does not show *“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”*, as required in this rule. In clarifying information requested by the Project Analyst in the expedited review of this project, the applicant provided the following table showing the weighted MRI procedures by type to be performed in the first three years of operation after completion of the project.

<b>Procedure Type</b>	<b>CY 2016</b>	<b>CY 2017</b>	<b>CY 2018</b>
Outpatient No Contrast	943	1032	1083
Outpatient with Contrast	323	354	371
Inpatient No Contrast	179	196	206

Inpatient with Contrast	131	144	151
Total Weighted Procedures	1,576	1,726	1,810

The application is conforming to this Rule.

(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- The applicant's methodology and assumptions used to project the number of unweighted MRI procedures are described in Section IV, pages 77-81, and in clarifying information requested by the Project Analyst during the expedited review of this project. The application is conforming to this Rule.

(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- The applicant projects MRI patients and procedures for the primary service area in Section III.1(b), Steps 1-17. The applicant's methodology and assumptions used to project the number of weighted MRI procedures are described in Section IV, pages 77-81, and in clarifying information requested by the Project Analyst during the expedited review of this project. The application is conforming to this Rule.

(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- In Section II.8, page 34, the applicant states that it does not currently own or operate a mobile MRI scanner in North Carolina. PMH leases mobile MRI services from Alliance Imaging three days a week. PMH provides the information requested above on the leased Alliance Imaging scanners on page 34.

(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;*

-NA- This applicant does not propose to provide mobile MRI services.

*(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- The applicant does not propose the acquisition of a mobile MRI scanner.

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

-C- The applicant identifies the accreditation authority it proposes to use in Section II.8, page 35 of the application. The applicant states:

*“DLP Person Memorial Hospital is Joint Commission (JC) accredited and will continue to pursue JC accreditation in the future. PMH will also apply for accreditation of its MRI services by American College of Radiology.”*

*(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- The applicant does 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- The applicant does 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- The applicant does 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- The application does 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- The applicant does 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;*

-NA- In Section II.8, page 40, the applicant states, “*The applicant does not currently own or operate a fixed MRI scanner.*”

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

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

-NA- The applicant states that neither PMH, nor a related entity, owns a controlling interest in any mobile MRI scanners in the service area as defined by 10A NCAC 14C .2701(13).

(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;*

-C- Person County is the service area as defined by 10A NCAC 14C .2701(13). PMH proposes that its primary service area includes Person and Caswell counties. The 2014 SMFP shows there are no fixed MRI scanners located in Person County or Caswell County. Therefore, the applicant must demonstrate that the average annual utilization for the proposed MRI scanner to be located in Person County is reasonably expected to perform 1,716 weighted MRI procedures in the third operating year. The applicant's proposed scanner is projected to perform 1,810 weighted procedures in its third operating year. The applicant adequately demonstrates that projected utilization is based on reasonable, credible and supported assumptions. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein.

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

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

-NA- The applicant does not own or operate any MRI scanners in Person County. Upon approval of the project, the applicant will only own and operate one fixed MRI scanner in Person County.

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

-NA- The applicant does not own or operate any MRI scanners in Person County. Upon approval of the project, the applicant will only own and operate one fixed MRI scanner in Person County.

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

-C- The applicant's assumptions and data used to support the methodology for each projection required by this Rule are described in Section III.1, pages 50-63, Section IV, pages 77-81, and clarifying information requested by the Project Analyst in the expedited review of this application. The assumptions and data used to support the methodology for each projection are reasonable, credible and supported. See Criterion (3) for discussion regarding the applicant's assumptions and data used to support the methodology for each projection which is incorporated hereby as if set forth fully herein.

(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- The applicant does 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- The applicant does 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- The application does not propose the acquisition of a fixed multi-position MRI scanner.

**10A NCAC 14C .2704      SUPPORT SERVICES**

- (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- The applicant does 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- In Section II.8, page 35 of the application. The applicant states:

*“DLP Person Memorial Hospital is Joint commission (JC) accredited and will continue to pursue JC accreditation in the future. PMH will also apply for accreditation of its MRI services by American College of Radiology.”*

**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- In Section II.8, page 46, the applicant states that William Hall, M.D. provides MRI radiology coverage for PMH and will continue to interpret images for the proposed scanner. The applicant states Dr. Hall is certified by the American Board of Radiologists and meets the required training as outlined above. See Exhibit 14 for Dr. Hall’s CV and Exhibit 22 for a letter from Dr. Hall documenting his training and intent to serve as the Medical Director.

(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- The proposed project does not involve 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- In Section II, page 47, the applicant states,
- “The proposed MRI service will make at least two full-time MRI technologists available for the proposed services. One technologist shall be present during the hours of operation of the MRI scanner. See staffing table in the proforma in Tab 13. Please see Section VII.3(b) for research of staff availability.”*
- (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- In Section II, page 47, the applicant states that PMH requires all MRI clinical staff to maintain certification in cardiopulmonary resuscitation and basic cardiac life support. Exhibits 18, 28 and 29 contain PMH related policies.
- (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- In Section II, page 48, the applicant states that job descriptions in Exhibit 29 and PMH staff policies in Exhibit 28 require that all staff members maintain proficiency and current licenses in their respective fields. The applicant further states it has budgeted funds for continuous staff education. *“Moreover, through its relationships with LifePoint and Duke University Medical Center, and through the vendor package for the new equipment,”* the applicant states, *“DLP Person Memorial Hospital has provided for improvement in technique and proper training of new personnel.”*
- (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- The applicant is 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- The applicant is 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- The applicant is not proposing to perform cardiac MRI procedures at this time.