DATE: April 30, 2010

TO: Brenda M. Harvey, Commissioner, DHHS

THROUGH: Catherine Cobb, Director, Division of Licensing and Regulatory Services

FROM: Phyllis Powell, Assistant Director, Planning, Development and Quality
       Steven R. Keaten, Health Care Financial Analyst

SUBJECT: Proposal by InSight Premier Health, LLC to place a 16-Slice CT Scanner at their
          Marshwood Imaging Center in Scarborough, Maine at an estimated capital cost of $677,250.


REGISTERED AFFECTED PARTIES: NONE

I. BACKGROUND:

- InSight Premier Health, LLC is a for-profit corporation and was organized in the State of Maine in June 2000 to pursue various business opportunities together with Premier Health, LLC, a group of individual investors who are current or former employees of Spectrum Medical Group. Premier Health, LLC is also in a joint venture with InSight Health Corp. headquartered in Lake Forrest, California. InSight Health Corp. is involved with CT imaging services in other States.
- InSight Premier Health, LLC operates several facilities that provide MRI imaging including facilities in Waterville, Skowhegan, Bangor and Scarborough. The Scarborough facility is owned and operated by Marshwood Imaging Center (MIC), a wholly owned subsidiary of Insight Premier Health, LLC. The MIC serves the Southern Cumberland County service area.
- The Division of Licensing and Regulatory Services, CONU, confirms that The Marshwood Imaging Center (MIC) is MaineCare and Medicare certified and accredited by the American College of Radiology (ACR) and has a valid ACR license through April 2011.

II. PROJECT DESCRIPTION:

The project under CON review proposes to place a 16-Slice CT Scanner at MIC in Scarborough, Maine. Currently, only MRI services are performed at the Scarborough location. InSight believes offering CT services would compliment the site and give physicians and patients a lower cost alternative to hospital-based outpatient CT services. InSight has stated that approximately 90% of all ambulatory CT scans can be performed by a 16-slice scanner, without a loss of appropriate clinical quality and at a lower cost to the patient or insurance provider.

This project is considered a new service for MIC and is expected to provide service in the Southern Cumberland County area. This project will be located within existing space at MIC. Capital costs consist of $677,250 ($420,000 equipment, $200,000 renovations and $57,250 for other capitalized costs).
The Preliminary Review by CONU staff, dated September 3, 2009, concluded that this application failed to meet the following six CON review criteria which are later addressed in additional comments received from the applicant. See Section V.

**Needs to be Met**
- The applicant did not meet its burden to demonstrate that the project meets the following factors used to determine if a public need exists:
  - the extent to which the project will substantially address specific health problems, as measured by health needs in the area to be served by the project;
  - whether the project will have a positive impact on the health status indicators of the population to be served; and
  - whether the project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project.

**Orderly and Economic Development**
- The applicant did not meet their burden to demonstrate that the proposed project is consistent with the orderly and economic development of health facilities and health resources for the State.
- The applicant did not demonstrate the following criteria:
  - The impact of the project on total healthcare expenditures after taking into account, to the extent practical, both the costs and benefits of the project and the competing demands in the local service area and statewide for available resources for health care;
  - The availability of state funds to cover any increase in state costs associated with utilization of the project’s services; and
  - The likelihood that more effective, more accessible or less costly alternative technologies or methods of service delivery may become available.

**State Health Plan**
- Even though the applicant met some of the priorities of the State Health Plan CONU concluded that the project is not consistent with the State Health Plan priorities.

The applicant met the following priorities:
- The applicant demonstrates a culture of patient safety, that it has a quality improvement plan, uses evidence-based protocols, and/or has a public and/or patient safety improvement strategy for the project under construction and for other services throughout the hospital.
- Applicants (other than those already participating in the HealthInfoNet Pilot) who have employed or have concrete plans to employ electronic health information systems to enhance care quality and patient safety.
- Projects done in consultation with a LEED certified-architect that incorporate “green” best practices in building construction, renovation and operation to minimize environmental impact both internally and externally.

The applicant was found not to have met the following priorities:
- The applicant has a plan to reduce non-emergent ER use.
- The project leads to lower costs of care/increased efficiency through such approaches as collaboration, consolidation, and/or other means.
- The project improves access to necessary services for the population.
- The impact of the project on regional and statewide health insurance premiums, determined by BOI, given the benefits of the project, as determined by CONU.
Outcomes and Community Impact
- The project ensures high-quality outcomes but may negatively affect the quality of care delivered by existing service providers.

Service Utilization
- The applicant did not meet their burden to demonstrate that the project does not result in inappropriate increases in service utilization, according to the principles of evidenced-based medicine adopted by the Maine Quality Forum.

Funding in Capital Investment Fund
- Although there is sufficient funds in the Capital Investment Fund (CIF), CONU recommends that the project not be funded within the CIF as all CON criteria have not been recommended for approval.

III. HIGHLIGHTS:
- Letter of Intent dated December 29, 2008
- Subject to CON review letter issued January 5, 2009
- Technical Assistance Meeting held on January 14, 2009
- Application filed and certified as complete on March 20, 2009
- Application placed in review cycle on April 1, 2009
- Applicant’s public informational meeting held on April 14, 2009
- Public comment period ended on May 14, 2009
- A public hearing was not requested or held
- Preliminary analysis released on September 3, 2009
- Preliminary analysis published in newspapers on September 11, 2009
- Comments were received from the applicant on September 24, 2009
- Record closed on September 25, 2009
- Applicant suspended review on October 13, 2009
- Applicant unsuspended review on January 29, 2010
- Record reopened and was published in newspapers on February 9, 2010
- Record closed on February 25, 2010

IV. PUBLIC COMMENTS RECEIVED IN RESPONSE TO THE PRELIMINARY ANALYSIS:
- Following release of the Preliminary Analysis, there were no public comments. The only comments received during the comment period following the release of the preliminary record were from the applicant in support of the project dated September 24, 2009.

V. SUSPENSION OF THE REVIEW AND PUBLIC COMMENTS IN RESPONSE TO REOPENING THE RECORD:
- The applicant suspended the review in accordance with the Maine Certificate of Need Procedures Manual (Chapter 5 Section 9) on October 13, 2009. On January 29, 2010, the applicant requested that the application be reactivated and that significant materials from the applicant received by CONU on January 11, 2010 be included in the record. The record was reopened and public comments were received from Mercy Hospital on February 25, 2010 stating their opposition to the project.
Mercy Hospital COMMENTS (condensed):
- The applicant has not demonstrated a public need for an additional CT scanner as current existing capacity is adequate for the area to be served.
- The proposal is inconsistent with the State Health Plan as the project shows no significant health impact and Mercy Hospital would be unable to compete against a for-profit entity.
- The project conflicts with the orderly and economic development of health facilities and resources for the state as it (i) represents a duplication of services, (ii) it may negatively impact existing service providers by shifting volumes in the service area, and (iii) it may inappropriately increase service utilization.

The comments received by CONU from Mercy Hospital were given careful consideration; however, because the comments were not accompanied by supporting data, the commenter did not elaborate on its opinions, and several of the comments were speculative (note use of operative word “may”), these comments did not provide much evidentiary material in light of the support from the insurance providers.

Two letters were received from Aetna, Inc and MedSolutions, Inc. which support InSight’s addition of an outpatient CT facility. During the period when the record was reopened, the applicant provided additional data on insurance reimbursement rates in support of the application.

CONU ANALYSIS/InSight COMMENTS (condensed):

1) Needs to be Met

i. The applicant provided two additional letters of support from Aetna, Inc and MedSolutions, Inc. which support InSight’s addition of an outpatient CT facility. Both letters included comments suggesting that the project “would provide increased access and a lower cost alternative for Maine residents”. Aetna, Inc is a health insurance company whereas MedSolutions, Inc. helps manage all high-tech radiology services in Maine on behalf of Cigna Healthcare and Aetna. The original application also had a letter of support from Anthem Blue Cross Blue Shield.

ii. The applicant provided information from the Maine Health Data Organization’s Claims website on the “estimate of combined payments” from Aetna Health, Inc., Anthem, and Cigna for CT-Head (without contrast material), CT-chest, CT-abdomen and CT-pelvis for several hospitals in their service area: Maine Medical Center, Mercy Hospital, Southern Maine Medical Center, etc. This service area is referred to herein as the Southern Cumberland County service area. The applicant proposes to charge and receive reimbursement on CT scans at a rate up to 50% lower than some providers are currently receiving in the service area. In addition, InSight clarified that they anticipated savings of $541,000 for service payors by year three of operations; this is net of the $455,319 to implement this service.

iii. The applicant has demonstrated this project will not negatively affect the quality of care delivered by existing service providers. It is expected that this project will reduce the number of CT scans delivered by existing service providers because of the lower cost alternative but not enough to affect the quality of care by those same service providers. The existing service providers will still have quality plans in place with certified licensed technicians and Radiologists available to read the CT Scans. CONU has concluded that this project should not reduce the quality of care provided by existing service providers.

iv. In information provided by the applicant, 90% of CT services performed in a hospital setting can be done with a lower strength 16-slice CT scanner. In comments regarding the Cost
Driver Study performed at the behest of the ACHSD, recommendations included the implementation of cheaper less costly alternatives, namely mid-level practitioners, including dental hygienists and physician assistants. This low-level scanner has a place in today’s diagnostic “tool-box” as a mid-level alternative to hospital based CT machines that need to be replaced with stronger machines to meet the needs of the minority of cases that need a higher strength machine. Since the need of the 16-slice CT machine has been demonstrated by the applicant it is the recommendation that the Certificate of Need including the following condition:

**Condition 1:** The certificate holder will be limited to providing CT services with a 16-slice CT scanner. The certificate holder may apply for a subsequent review to replace the machine at the end of the machines useful life.

v. The applicant provided information which demonstrated that there is a public need for the proposed service as demonstrated by the availability of a demonstrably lower cost of care alternative, while increasing access and maintaining quality outcomes for this proposed service.

2) **Orderly and Economic Development**

i. In conjunction with the comments received above in regards to need, the applicant has demonstrated that the proposed service is consistent with the orderly and economic development of health resources for the State.

ii. The applicant has demonstrated that the project would provide a cost savings to insurers in Maine. In light of the limited expenditures involved in the project and the relatively significant savings, but a continued concern from other providers regarding competing demands for available resources, CONU believes that it is in the State’s best interest for CONU to closely monitor results of this project. Accordingly, it is recommended that the following two conditions be included to better ensure that this project demonstrates that the benefits of this project outweigh the costs of the project.

**Condition 2:** Following the first year of operations and annually thereafter, within 60 days of completion of each fiscal year of MIC, the applicant will submit a report to include the number of procedures performed and the entity’s profit and loss statement prepared to report CT services for each operating year.

**Condition 3:** The applicant will be limited to provide services at MIC for the service area as described in the application, namely the Southern Cumberland County service area.

3) **State Health Plan**

i. This is not a hospital project; therefore, it is not designed to reduce non-emergent ER use.

ii. The project leads to lower costs of care and increased efficiency through such approaches as collaboration, consolidation, and/or other means by allowing insurance companies a lower cost alternative for services that should reduce insurance premiums.

iii. The project improves access to necessary services for the population as it provides a lower cost alternative for CT scanning services.

iv. In light of the demonstrable savings and the comments from the insurance company, CONU has determined that the project is consistent with the State Health Plan.
4) Outcomes and Community Impact

i. The population of the area to be serviced will benefit from this lower cost alternative. According to information provided by the applicant up to 90% of CT services performed in a hospital setting can be done with a lower strength 16-Slice CT scanner verses the 32- and 64-slice CT scanner currently in service in hospitals. Referring physicians have the expertise and knowledge to know which level of scan is more appropriate for their patient and make referral decisions based on that knowledge. Other providers of this service have equipped their facilities with higher-detailed machines that perform better for certain tests and are more appropriately used in those cases.

ii. The applicant has demonstrated that the project ensures high-quality outcomes and does not negatively affect the quality of care delivered by existing service providers.

5) Service Utilization

i. The applicant proposed to report the number of referrals for CT services from all Spectrum Medical Group physicians.

ii. The combination of historically lower utilization in the Southern Cumberland County service area as reported in the MQF report included in the preliminary analysis of the Certificate of Need for the outpatient “Mall” in Bangor, as compared to other regions of the State, coupled with controls on utilization proposed by the applicant and those used by payers should mitigate any unnecessary increase in service utilization.

iii. InSight is partially owned by current and former members of The Spectrum Medical Group whose physicians may refer patients to this new service.

iv. The CONU recommends that the following condition be included to better ensure that the project will not result in unnecessary increases in service utilization:

**Condition 4:** The applicant will be required to report the number of referrals for CT services from all Spectrum Medical Group physicians and/or owners of Insight, Insight Premier Health or related parties annually for a period not less than three years from the approval of this Certificate of Need.

6) Funding in Capital Investment Fund

i. There are sufficient funds in the Capital Investment Fund.

ii. The applicant has demonstrated that they have satisfied all of the other criteria for a Certificate of Need. This project is now eligible to be considered to be included for funding by the CIF.

iii. CONU recommends that the project be funded in the CIF for $455,319.

VI. CONCLUSION:

For all the reasons set forth in the Preliminary Analysis, in the information contained in the record, and considering both the additional information provided by the applicant and the public comments
received, CONU concludes that the applicant has met its burden to demonstrate that the project and the applicant meet all the review criteria.

VII. RECOMMENDATION:

The CONU recommends this proposal be **Approved with the following conditions**:

1. The certificate holder will be limited to providing CT services with a 16-slice CT scanner. The certificate holder may apply for a subsequent review to replace the machine at the end of the machines useful life.

2. Following the first year of operations and annually thereafter, within 60 days of completion of each fiscal year of MIC, the applicant will submit a report to include the number of procedures performed and the entity’s profit and loss statement prepared to report CT services for each operating year.

3. The applicant will be limited to provide services at MIC for the service area as described in the application, namely the Southern Cumberland County service area.

4. The applicant will be required to report the number of referrals for CT services from all Spectrum Medical Group physicians and/or owners of Insight, Insight Premier Health or related parties annually for a period not less than three years.

<table>
<thead>
<tr>
<th>Capital Costs</th>
<th>$666,549 Capital costs as Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contingency</td>
<td>$20,701 Contingency</td>
</tr>
<tr>
<td>Total Approved</td>
<td>$677,250 Total Approved Capital Costs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Incremental 3rd Year Costs</th>
<th>$455,319 Approved Incremental Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capital Investment Fund</td>
<td>$455,319 Approved CIF 2009</td>
</tr>
</tbody>
</table>