Department of Health and Human Services Division of Licensing and Regulatory Services State House 11; Augusta, ME Preliminary Analysis

Date: September 3, 2009

Project: Request for 16 Slice CT at Marshwood Imaging Center

Proposal by: InSight Premier Health, LLC d/b/a Marshwood Imaging Center

Prepared by: Phyllis Powell, Manager, Certificate of Need

Steven R. Keaten, Health Care Financial Analyst Larry D. Carbonneau, Health Care Financial Analyst Richard F. April, Health Care Financial Analyst

Directly Affected Party: None

Recommendation: Disapprove

	Proposed Per Applicant	Approved CON		
Estimated Capital Expenditure Maximum Contingency Total Capital Expenditure with Contingency Third Year Incremental Operating Costs	\$ 656,549 \$ 20,701 \$ 677,250 \$ 455,319	\$ 0 \$ 0 \$ 0 \$ 0		
Capital Investment Fund (CIF) Impact:	\$ 455,319	\$ 0		
Bureau of Insurance Regional Impact Estimate Bureau of Insurance Statewide Impact Estimate		.10 % .02 %		

I. Abstract

I. Abstract

A. From Applicant

PROJECT ABSTRACT

"InSight- Premier Health (IPH), LLC plans to purchase and place into service a 16 slice CT scanner at its Marshwood Imaging Center (MIC) located at 33 Gorham Road, Scarborough, ME 04074. This scanner will expand the MIC's services and complement its MRI capabilities."

"A 16 slice CT scanner will provide patients and physicians the option of having a scan at an independent diagnostic testing facility (IDTF), at less cost than other currently available locations without any degradation medical care and scan quality."

"IPH/MIC's proposed services will offer the opportunity for current and future demand for routine CT studies to shift from currently higher cost providers to the IDTF healthcare delivery model. This is expected to save the Maine employers at least \$404,000 in Year One and \$541,000 in Year Three (with similar annual savings continuing into future years.)"

"The capital cost of the proposed project will be \$677,250; \$420,000 for equipment (a refurbished, GE LightSpeed, 16-slice CT Scanner); \$ 200,000 for construction; and \$25,000 for other capitalized costs. The project will be implemented within existing space at MIC."

"Equipment acquisition and renovations for proposed project will commence within six months of notification of approval. Scanning is anticipated to commence as of January 1, 2010. The financial projections are based on calendar years 2010, 2011, and 2012. Anticipated volume will be 2394 scans in Year One, 3115 scans in Year Two, and 3208 scans in Year Three of operation."

"The Applicant will comply with applicable local construction permit requirements and inspections, e.g., electrical if required. No other zoning, environmental protection, local site plan review, or other construction requirements are anticipated."

"IPH/MIC has extensive quality and utilization mechanisms in place for MRI services and it will be extending its quality plan to cover CT services. The services that will be provided will be safe, timely, effective, and patient centered."

"The proposed services will not adversely effect the ability of current providers to continue services or to remain economically viable."

"There is no evidence that the Proposed Project will induce inappropriate utilization of services."

II. Fit, Willing and Able

II. Fit, Willing and Able

A. From Applicant

"Names, locations, and relationships of all affiliated entities/related parties":

"InSight Health Corp. was formed in June 1996 as a result of a merger between American Health Services Corporation and Maxum Health Corporation. InSight Health Corp. is headquartered in Lake Forest, California."

"Premier Health, LLC was organized in the State of Maine in June 2000 to pursue various business opportunities in Maine, including this joint venture with InSight Health Corp. Seventy five (75) individual investors, all of whom are current or former employees of Spectrum Medical Group and its affiliated companies comprise Premier Health."

"InSight-Premier Health, LLC was organized in the State of Maine in June 2000 to pursue various business opportunities in Maine, including this joint venture with Premier Health, LLC."

"Premier Health, LLC is located at the offices of Spectrum Medical Group, 300 Professional Drive, Scarborough, Maine 04074."

"InSight-Premier Health, LLC has been involved with the following health care facilities and services:

- i. Marshwood Imaging Center MRI & X-Ray Service
- ii. Open MRI of Bangor MRI & X-Ray Service
- iii. Open MRI of Brunswick MRI & X-Ray Service
- iv. Bridgton Hospital MRI Service
- v. Miles Memorial Hospital MRI service
- vi. Maine Medical Center MRI Service
- vii. Eastern Maine Medical Center MRI Service
- viii. Inland Hospital MRI Service
 - ix. Redington Fairview Hospital MRI Service
 - x. Franklin Memorial Hospital MRI Service (no longer servicing)
- xi. Parkview Hospital MRI Service (no longer servicing)
- xii. Intermed MRI Service
- xiii. Blue Hill Memorial Hospital—MRI Service"

"InSight Health Corp. has been involved with the following health care facilities and services:

- i. InSight Premier Health Partner
- ii. Maine Molecular Imaging Partner PETCT Services
 - a. Maine Health
 - b. Premier Health
 - c. Maine Medical Center

II. Fit, Willing and Able

- iii. Central Maine Imaging Center Partner Multi Modality Imaging Center
 - a. Androscoggin Inc (Central Maine Healthcare)
 - b. X-Ray Professional Association"

"Premier Health, LLC has been involved with the following health care facilities and services:

- i. Spectrum Medical Group"
- "An Organizational Chart showing the relationship of the entities is included in Exhibit A."

"Qualifications and Accreditations

Marshwood Imaging Center has been accredited by the American College of Radiology ("ACR") for MRI services since it opened in 1997. The ACR re-accreditation process for replacement equipment was completed in April of 2008 and it is valid through April 2011. A copy of the Accreditation Certificate is included in Exhibit B."

"A list of the radiologists who will perform the professional component for the CT services at MIC is included at Exhibit C. These Spectrum Medical Group radiologists currently perform the professional component for MRI services provided at MIC. Typically two radiologists are on site at MIC from 8:00 AM to 5:00 PM, Monday-Friday. Also included in Exhibit C are bio-sketches of key administrative staff."

B. CONU Discussion

i. CON Criteria

Relevant criteria for inclusion in this section are specific to the determination that the applicant is fit, willing and able to provide the proposed services at the proper standard of care as demonstrated by, among other factors, whether the quality of any health care provided in the past by the applicant or a related party under the applicant's control meets industry standards.

ii. <u>CON Analysis</u>

The Division of Licensing and Regulatory Services, Medical Facilities Unit confirmed that InSight-Premier Health, LLC's current MRI imaging facilities are not facilities that they are required to license. CT machines in Maine are required to be inspected and licensed by the Maine Center for Disease Control & Prevention, Division of Environmental Health, and Radiation Control Program for radiation safety. The applicant is accredited by the American College of Radiology for MRI services. Although this project, if approved would be the first CT imaging services offered by InSight in Maine, InSight Premier Health, LLC's parent corporation has affiliated entities that perform CT imaging in other states.

The applicant has shown a long standing ability to provide imaging procedures through an accredited program and is Medicare and MaineCare certified.

II. Fit, Willing and Able

iii. <u>Conclusion</u>

CONU recommends that the Commissioner find that InSight Premier is fit, willing and able to provide the proposed services at the proper standard of care as demonstrated by, among other factors, whether the quality of any health care provided in the past by the applicant or a related party under the applicant's control meets industry standards.

III. Economic Feasibility

A. From Applicant

"The financial projections for this project are attached as Exhibit D. Included in this Exhibit are notes related to the financial projections and the following documents":

"D1: Pro Forma Financial Projections for the Proposed Project for CY 2010, 2011, and 2012. This also includes the proposed capital costs, staffing, staffing cost assumptions and weighted revenue forecast. The weighted revenue forecast also includes identification of anticipated scans as defined by CPT codes."

"D2: A project statement of operations showing the financials for IPH for CY 2010, 2011, and 2012, with and without the inclusion of the Proposed Project. It also includes Pro Forma balance sheets for IPH that reflect the implementation of the Proposed Project the first three years of operation."

"D3: Insight-Premier Health Balance Sheets and Comparative Statements of Operations for FY 2007, 2008, and a six month period ending December 31, 2008. (Note: six months periods are provided to reconcile Fiscal Year operational statements to the proposed first three years of operation of the project, CYs 2010-2012.)"

"Note: The applicant is willing to provide copies of Insight's Forms 10Q and 10K, its Quarterly and Annual Reports filed with the Securities and Exchange Commission. This is over a hundred pages of documentation and is not being submitted with this Application. However, it will be provided upon request at any time during the project review."

"Additional Assumptions

The financial projections are based on the following assumptions which are consistent with data found in Exhibit D and other sections of this Application."

"Volume Forecast

Anticipate project volume was estimated by considering InSight's experience in other sites, where CT and MRI services are co-located, and the prevailing utilization patterns in the service area."

"It is InSight's experience in other free-stand sites that CT volume is approximately 80% of MRI volume in sites with fully matured implementation/operations. In hospital sites CT volumes may be greater than MRI volumes given the mix of inpatients and outpatients. However, given the currently available CT services in the service area, the area's prevailing utilization rates, and the additional steps that MIC will have in place to mitigate excess utilization, ISP/MIC estimates that CT Scans in Year Three of operation will be equal to 60% of MRI Scans. The estimates for years One and Two were derived by assuming incremental ramp-up volumes."

"The MIC anticipates MRI volume of 5347 scans in the third year of operation following implementation of CT services. The estimate for Third Year CT scans is 3208 scans (60% of 5347). Year One volume is estimated to be 2394 CT scans and Year Two volume is estimated to be 3115 CT scans."

"Capital Costs

Equipment: ISPH/MIC proposes to acquire a refurbished, GE LightSpeed, 16-slice CT Scanner. (See Exhibit E.) The capital cost of the proposed CT Scanner is \$420,000. The quoted price is for \$399,299. In the financial projections an estimate of \$420,000 is used to reflect a contingency factor."

"Construction/Renovations: Services will be provided in renovated space. Line drawings showing the existing and proposed facility floor plans are attached as Exhibit F. The construction costs of proposed project is estimated to be \$200,000. A contractor's estimate and details are also included in Exhibit F."

"Other Costs

The Applicant anticipates \$25,000 for capitalized costs of the CON Application."

"Availability of Resources, including health personnel, management personnel, and funds for capital and operating needs for the provision for the proposed services"

"Staffing

The Applicant requires an additional .5 FTE CT technologist in its first year of operation and .75 FTE in years two and three, .25 FTE front office administrative staff in all years, and .25 patient care assistant in all years. Staffing need projections and costs for the first three years of operation are found in Exhibit D. No additional radiologist staffing will be required. At least one radiologist (and usually two) will be on site from 8:00 AM to 5:00 PM, Monday through Friday. Back-up support is available during this time and for any additional needs through the Spectrum Medical Group."

"Given its current operations, the Applicant is very familiar with the availability of staff and anticipates no difficulty in attracting or retaining the anticipated personnel. The MIC Imaging Center has had minimal technologist turn-over in 5 years."

"Capital Costs and Working Capital Needs

The capital costs of the project and anticipated working capital needs will be financed internally by deferring distribution of earnings. The deferred distributions from operations anticipated from July 1, 2009 to December 31, 2009 will be used to complete the equipment acquisition and construction. The Applicant's ability to generate these resources is documented in balance sheets and statements of operation found in Exhibit D."

"Zoning, Environmental Protection Regulations, etc.

The Applicant will comply with applicable construction permit requirements. No other zoning, environmental protection, local site plan review, or other construction requirements are anticipated. The proposed CT Scanner will be registered with the Department of Human Services."

B. CONU Discussion

i. CON Criteria

Relevant criteria for inclusion in this section are specific to the determination that the economic feasibility of the proposed services is demonstrated in terms of the:

- Capacity of the applicant to support the project financially over its useful life, in light of the rates the applicant expects to be able to charge for the services to be provided by the project; and
- The applicant's ability to establish and operate the project in accordance with existing and reasonably anticipated future changes in federal, state and local licensure and other applicable or potentially applicable rules.

ii. <u>CON Analysis</u>

Financial Ratio Analysis

In an effort to sustain readability, additional financial ratios, as well as the financial projections are on file with CONU. The following discussion relies on the information presented by the applicant. At the technical assistance meeting held in January 2009, the applicant was presented a format with which to complete significant financial projections, including construction timelines and operating expenses. Fourteen ratios were developed with the applicant's submission to evaluate the current financial position of the organization and the impact of the proposed project on its operating and financial feasibility. The applicant worked with SMRT to develop a construction schedule.

The years presented are 2006 through 2008 (audited) and 2009 through 2012 (projected). We are presenting 2008 reported numbers for comparison to the project.

There are four areas of financial ratio analysis related to the ability of the project to be successful. These ratios are profitability, liquidity, capital structure and activity ratios.

Profitability ratios attempt to show how well the applicant does in achieving profit or providing a return. Generating profit is important to secure the resources necessary to update plant and equipment, implement strategic plans, or respond to emergent opportunities for investment. Losses, on the other hand, threaten liquidity, drain other investments, and may threaten the long-

term viability of the organization. The profitability ratios reported here include the operating margin, which measures the profitability from operations alone, the net margin (called total margin in some sources), which measures profitability including other sources of income, and the return on total assets.

Financial Performance Indicators

Profitability	2008	2009	2012
Operating Margin	18.44 %	19.22 %	27.35 %
Net Margin	18.44 %	19.22 %	27.35 %
Return on Total			
Assets	19.91 %	17.92 %	17.66 %

All three margins indicate that if the proposed project occurs then InSight would remain profitable. InSight has the means to take on additional expenses based upon net revenues.

The review of financial indicators is important because they can present a fair and equitable representation of the financial health of an organization and assist in presenting appropriate comparisons. This provides a sound basis for a determination of whether the organization has the ability to commit the financial resources to develop and sustain the project. While there are a number of indicators that are used in the industry, the ones applied to this review have been selected due to their direct relevance to the financial health of the applicant. The following analysis is based upon information provided by the applicant in its application.

Financial Performance Indicators

Profitability	2007	2008	2009	2012
Operating Income	\$ 1,161,383	\$ 2,037,242	\$ 2,107,674	\$ 3,349,496
Total Income	\$ 1,161,383	\$ 2,037,242	\$ 2,107,674	\$ 3,349,496

This table validates the assertion that InSight has the capacity to financially support this project.

Liquidity: Current ratios and acid test ratios are indicators of the ability of an organization to meet its short-term obligations. The acid test ratio is generally considered to be a more stringent measure because it recognizes only the most liquid assets as resources available for short-term debt; the current ratio assumes that inventory and accounts receivable can be liquidated sufficiently to meet short-term obligations. Days in accounts receivable and average payment period also are used to monitor liquidity. Respectively, they indicate the average length of time the organization takes to collect one dollar of receivables or pay one dollar of commercial credit. Together, they can provide a cursory indication of cash management performance.

Financial Performance Indicators

Liquidity	2008	2009	2012
Current Ratio	1.26	2.74	8.43
Days in Patient Accounts	41.68	65.70	71.17
Receivable	Days	Days	Days
	48.47	140.80	610.26
Days Cash on Hand	Days	Days	Days
Average Payment Period	75.72	77.86	82.13
	Days	Days	Days

In terms of liquidity, InSight currently (2008) has adequate liquidity, with a payment lag of 33 days between being paid and paying for services.

Liquidity measures an organization's ability to manage change and provide for short-term needs for cash. This liquidity alleviates the need for decision making to be focused on short-term goals and allows for more efficient planning and operations.

Days Cash On Hand is a ratio that is an industry accepted, easily calculated, method to determine an organization's ability to meet cash demands.

The impact of the proposed project is calculated to be an increase of 470 days cash on hand in the third operating year as compared to the non-CON operating projection (with and without this project). This is a major increase in days cash on hand. InSight should be able to adequately support this project.

Activity and Capital Structure: Activity ratios indicate the efficiency with which an organization uses its resources, typically in an attempt to generate revenue. Activity ratios can present a complicated picture because they are influenced both by revenues and the value of assets owned by the organization. The total asset turnover ratio compares revenues to total assets. Total assets may rise (or fall) disproportionately in a year of heavy (dis)investment in plant and equipment, or decrease steadily with annual depreciation. Thus, it is helpful to view total asset turnover at the same time as age of plant. Debt service coverage (DSC) is reviewed in greater detail. DSC measures the ability of an organization to cover its current year interest and balance payments.

Financial Performance Indicators

	V		
Solvency	2008	2009	2012
Equity Financing	52.7 %	63.8 %	83 %
Debt Service Coverage	3.52	2.87	3.97
Cash Flow to Total Debt	73.3 %	85.9 %	136 %
Fixed Asset Financing	70.8 %	70.3 %	627 %

Many long term creditors and bond rating agencies evaluate capital structure ratios to determine the organization's ability to increase its amount of financing. Values for these ratios ultimately determine the amount of financing available for an organization. DSC is the most widely used capital structure ratio. DSC minimums are often seen as loan requirements when obtaining financing. DSC is the ratio of earnings plus depreciation and interest expense to debt service requirements.

InSight had a DSC in 2008 of 3.52x. This is well above minimum standards for lending. DSC is expected to remain at this level throughout the period of the analysis. InSight has the capacity and the ability to have adequate debt service coverage.

The large increase in fixed asset financing seen by 2012 is because of a difference between Insight's repayment of borrowings and the depreciated value of the equipment being purchased with those borrowed funds. Unlike typical commercial lending, the financing source for this project is from one of the owners of Insight Premier Health and not a bank. Funds borrowed for this project may be paid back earlier as cash balances allow. InSight Premier is not conducting an arms-length transaction. As this agreement is not between two disassociated parties, Insight Premier may also easily come into an agreement with the lender to repay the funds in a different manner than typically seen in a commercial lending arrangement. The parent corporation would show these funds as an inter-company transfer and not as a loan. From Insight Premier's perspective, it has elected to show this as a loan so interest expense would be reflected through the financial presentation.

Efficiency Ratios: Efficiency ratios measure various assets and how many times annual revenues exceed these assets.

Financial Performance Indicators

Efficiency	2009	2009	2012
m . 1 A m	1.00	0.02	0.65
Total Asset Turnover	1.08	0.93	0.65
Fixed Asset Turnover	2.39	2.86	56.82
Current Asset Turnover	5 65	2.56	0.81
Current Asset Turnover	5.65	2.56	0.81

Total asset turnover (TAT) provides an index of the number of operating revenue dollars generated per dollar of asset investment. Higher values for this ratio imply greater generation of revenue from the existing investments of assets.

The increase in fixed asset turnover is related to the value of the new equipment being depreciated over the expected useful life of the equipment.

Operating costs in the third operating year are expected to increase by \$454,144. For the Bureau of Insurance this amount is adjusted to a current value of \$423,425 in order to calculate the impact of this project on commercial insurance premiums. The impact on the CIF, if approved, would be \$424,986.

In completing this section of the analysis, the CONU concludes that, as proposed, the applicant can financially support the project. Demands on liquidity and capital structure are expected to be minimal in support of projected operations. Financing and turnover ratios show no negative impact on the organization as a whole from successfully engaging in this project. The organization has shown strong current earnings which would be expected to significantly increase.

Changing Laws and Regulations

CONU staff is not aware of any imminent or proposed changes in laws and regulations that would impact the project. InSight presently has the organizational strength to adjust to reasonable changes in laws and regulations.

iii. Conclusion

CONU recommends that the Commissioner determine that InSight Premier has met their burden to demonstrate: (1) the capacity of the applicant to support the project financially over its useful life, in light of the rates the applicant expects to be able to charge for the services to be provided by the project; and (2) the applicant's ability to establish and operate the project in accordance with existing and reasonably anticipated future changes in federal, state and local licensure and other applicable or potentially applicable rules.

IV. Public Need

A. From Applicant

"The Applicant is addressing several aspects of Public Need in this Application including: 1) The clinical efficacy of CT scanning, 2) Proposed diagnostic studies and the clinical appropriateness of CT services at MIC versus alternatives, 3) The definition of the proposed service area, 4) Anticipated community need for CT Scans, anticipated volume and payer distribution, 5) Determination of currently available CT scanning capacity in the proposed service area and the determination of public need, 6) The "Public Need" to reduce health care costs and the proposed costs at MIC versus alternative locations, and 7) Demonstrated support from payers and referring physicians."

"Many of the factors defining need are also referenced in Section V, Orderly and Economic Development; Section VI State Health Plan; Section VII, Outcomes and Community Impacts; and Section VIII, Service Utilization."

"1a) Clinical Efficacy and Description of the Proposed Services

CT Scanning is a recognized diagnostic tool fundamental to the diagnosis and treatment of a wide range of conditions. The clinical efficacy of this technology has been established in numerous, previous CON applications."

"2) Proposed Diagnostic Studies and the Clinical Appropriateness of CT Services as Proposed at MIC Versus Alternatives"

"Anticipated Diagnostic Studies

Based on the extensive expertise of its radiologists and experience at other InSight sites, ISP/MIC proposes to provide CT scans consistent with the list of CPT codes and descriptions found in Exhibit D1. (weighted average revenue analysis)"

"Clinical Appropriateness of CT Services as Proposed at MIC Versus Alternative Locations Within the range of proposed CPT codes, scans provided to ambulatory patients will provide appropriate clinical information for radiologist interpretation. Based on the experience of the IPH/MIC radiologists, the Applicant believes that for at least 90% of outpatient CT scans; there is no evidence that scanners with greater slice capacity or located in hospitals will provide meaningful or significant increases in clinical quality."

"The differences in a 16 slice versus a 64 slice scans have to do with the degree of spatial and temporal resolution. The 16 slice scanner produces excellent images, although the 64 slice scanner will have higher resolution. The only CT procedures that will benefit significantly from a higher slice scanner are cardiac studies. Although some cardiac imaging can be done on a 16 slice scanner, when a scanner with great resolution is available, as is the case in the Portland service area, scans involving motion are preferably done on those units. IPH/MIC does not

propose to do cardiac imaging. As such, there is no need for a scanner with greater that 16 slice capacity. Please note the attached article "Slice Selection" in Exhibit L."

"3) The Definition of the Proposed Service Area

Patients currently serviced by MIC's MRI unit are typically ambulatory patients referred by physicians from their offices. The vast majority of patients reside in the greater Portland, Maine service area. The Applicant will be building utilization of its services on relationships with currently referring physicians and expects patients to be referred from approximately the same service area. See Exhibit G (Map and patient zip code dispersion for MRI and proposed CT service area.)"

"Based on future market development, the number of practices that will be sources of referrals will likely expand. However, it is unlikely that patients will live beyond the specified service area. There will be no restrictions on the sources of referrals or patient residence."

"Also included in Exhibit G is data that estimates the utilization of CT service in the service area. This was provided by the Advisory Board and Insight. It shows estimates of total market utilization, hospital-based utilization, with projections for 2007, 2012, and 2017 based on CT practice pattern trends. CT utilization is projected to increase approximately 6% per year overall with hospital-based utilization increasing approximately 4.3% per year."

"4) Anticipated Community Need for CT Scans, Anticipated Volume and Payer Distribution, and
 5) <u>Determination of Currently Available CT Scanning Capacity in the Proposed Service Area</u> and the Determination of Public Need"

"Inadequate access to essential services and speculative growth assumptions are not the compelling arguments for the Application. The rationale for public need is that there is a public interest in the development of a lower cost alternative to existing services, in order to reduce the health costs of area patients and employers (including the State of Maine)."

"The intent of the project is for MIC to be a reliable, lower cost option for the most routine scans by improving the ability of physicians and payers to match the clinically appropriate level of diagnostic equipment and cost with clinical needs."

"Traditional arguments justifying the need for expanded technology and services, in this case CT Scanning, look at the service area's population, anticipated need (procedures or scans/1000 residents), available resources and their capacity (number and type of existing scanners and their operational capacity e.g., scans/hour X hours of scanning time available) to derive an assessment of gaps in availability and access for the defined population. Applicants then demonstrate how their projects will meet unmet needs. In the case of this Application, this approach is neither reasonably possible nor specifically applicable. IPH/MIC is not arguing that the area has insufficient resources. It is arguing that there should be lower cost alternatives."

"In addition, criteria applied to the determination of need also included consideration of:

a) Whether, and 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;

In the short term, other than inducing cost savings and possibly lowering barriers to care due to cost, this project will not substantially effect any specific health needs that are unmet in the service area. In the long term, as use of CT scanning grows and the demand for 64 slice scanners increases <u>for clinical advanced applications</u>, this project may improve overall community access by freeing up time on these scanners. However, the proposed need for this project is not based on this assumption.

b) Whether the project will have a positive impact on the health status indicators of the population to be served;

Other than lowering barriers to care due to cost, this project will not measurably change any health status indicators related to the population in the service area.

c) Whether the services affected by the project will be accessible to all residents of the area proposed to be served;

The proposed project will be accessible to all residents of the service area including patients from all payer classifications.

d) Whether the project will provide demonstrable improvement in quality and outcome measures applicable to the services proposed in the project.

It is unlikely that the project will provide demonstrable improvements in quality and outcome. It may facilitate easier access to services and reduce financial barriers to care for a limited number of patients. However, these impacts will not be measurable."

"Discussion of Area Needs and Limitations on Forecasting

ISP/MIC believes that it has identified the number, types and locations of CT scanners in its proposed service area, as reflected in the following table."

CT Scanners in Southern Maine	Vendor	Slice	Location
Maine Medical Center	GE	64	Main Campus
Maine Medical Center	GE	64	Brighton Campus
Maine Medical Center	GE	64	Scarborough
Southern Maine Medical Center	GE	64	Biddeford
Prime Care	GE	16	Biddeford
Intermed	Siemens	16	So. Portland

Mercy	GE	64	Main Campus
Mercy	GE	32	Fore River
Maine Centers for Healthcare	GE	Single Slice	Westbrook
Portland Urologic Associates	Siemens	2	So. Portland

"Although IPH/MIC can identify these locations, there is insufficient availability and transparency to the data necessary to access the current utilization of these units, their operational capacities, their charges, and more significantly their costs to payers. There is insufficient data available to assess the scope of the population's current utilization and there are no known studies that address the utilization of services that would be applicable to a defined population, if all care was being provided at established "standards of care". Thus, defining population need, comparing it to available capacity and then assessing the reasonableness of current utilization patterns, gaps, and appropriate levels of cost would yield at best highly speculative results."

"In trying to address the overall population's utilization, the Applicant has turned to a study conducted by the Maine Quality Forum "Initial Analysis of Maine Paid Claims Database". This study provided as an appendix and sub-study a "Geographic Variation Analysis of Advanced Imaging Services". The overall study and the advanced imaging analysis point to numerous findings, including the observations that there is significant variation in the utilization of the referenced imaging services in different areas of the State (without explanation); and that there is great difficulty is accessing data that is necessary to conduct thorough evaluations of utilization variances. ISP/MIC concurs."

"Nonetheless, the Geographic Variation Analysis did indicate that between January 2003 and June 2005, for the CT studies that were cited (Abdominal/Pelvic CT and Lumbar CT) the overall use rate for CT scans was 94% of the state average and the Z score indicated that this was substantially lower that the state rate. The Applicant does not argue that these rates are indicative of underutilization and that the proposed project should be approved to increase the number of scanner available in Portland."

"However, IPH/MIC believes that the use rates are indicative of conservative practice patterns and thoughtful efforts to manage utilization appropriately. Although the utilization rates are most specifically related to the practice patterns of ordering physicians, the radiologists associated with this CON are significant contributors to the development of the local standards of care and thus to the lower use rates."

"The Applicant also believes that there will be continuing grow in the use of CT scanning based on further expansion of clinical applications in conjunction with population growth and an aging population that will occur in the service area. Looking further ahead, as indicated in Exhibit G, the demand for CT services is expected to grow at a rate of approximately 6% per year overall.

¹ Maine Quality Forum "Initial Analysis of Maine Paid Claims Database", February 2, 2007. The Geographic Variation Analysis of Advanced Imaging Services is found on pages 75-112.

Growth in hospitals is expected to be approximately 4%. As CT scans continue to be utilized for expanding clinical indications(particularly cardiac imaging), ISP/MIC expects the demand for the 64 slice and higher CT scanners to increase. We further expect continued pressure on the hospital-based system to treat acute inpatient and cardiac patients. The growth in this demand will replace some of the ambulatory volume that may be lost by current providers to MIC."

"Concerns That More Technology Stimulates Excess Utilization

There is no evidence that the number of scanners in the greater Portland area during the Quality Forum study period contributed to excess utilization rates, even though CT scanning is often consider a "supply sensitive" service. Data is currently unavailable to address any changes in total area CT scanning subsequent to the expansion of services at Mercy Hospital and Maine Medical Center."

"ISP/MIC appreciates and shares the concern expressed in the State Health Plan and the Quality Forum study about "supply sensitive care" and specifically imaging procedures. The proposed CT services will draw patients to lower cost alternative, particularly if use of these services is advocated by payers and employers to reduce employer health care cost. This shift of utilization is not anticipated to increase overall utilization rates in the service area. While a few physicians may be more willing to order a CT scan if they know that the cost is appreciably less, IPH/MIC has no evidence that there are physicians avoiding referrals for scans due to cost. The are no anecdotal observations to this effect from physicians who refer to MIC. The conservative practice patterns and thoughtful efforts to manage utilization cited above should continue to prevail. However, ISP/MIC will have several tools in place to mitigate the risk of inappropriate utilization of its services. The tools build on existing practices already in place for MRI scanning and include the following:

- All requests from referring physicians will require a written order.
- All scans requested will be reviewed by the radiologist prior to the patient being scanned and the guidelines for the specific scan clearly stated following established protocols. ² The protocols will be the same as used at Maine Medical Center by Spectrum radiologists. The protocols reflect national and community's established standards of care. This is a similar process used in most academic institutions. Protocols will be reviewed at least quarterly. Any specific payer-requested review criteria will be incorporated into the protocols.
- Payer pre-authorization procedures will be followed. (See Exhibit H: Anthem Imaging Quality Management Program Procedures)
- Inappropriate orders will be monitored by the MIC manager. The manager will review findings with the radiologists and the radiologists will contact the referring physician to discuss ordering practices if necessary.
- The radiologists and the manager will provide more in-depth targeted review of inappropriate referrals with any physicians demonstrating on-going, inappropriate ordering.

² For example, depending on the area of coverage (chest, chest-abdomen-pelvis, pelvis, abdomen) was well as the clinical question and the patient renal status specific guidelines determine the patient's need for contrast agents, contrast administration timing, positioning, bowel preparation, etc.

- Referring physicians will be provided continuing education regarding CT services through
 in-services offered every quarter. This will include education on the types of indications that
 are appropriate for a CT exams. In-services will be carried out by the MIC account
 representative in conjunction with the MIC's radiologists. This process will build on ongoing educational steps that are currently taken for MRI services
- List of appropriate CPT codes will be supplied to the referring physicians.
- The on-sight availability of radiologists will provide timely access to consultations for referring physicians regarding the type of scan that may be warranted as well as timely reporting of results.
- ISP/MIC will continue to participate in the development of PACS systems and electronic medical records systems to avoid inappropriate or duplicative testing.
- ISP/MIC will make CT Scan charge schedules available to referring physicians as requested."

"Note: scanning will be occurring in an Independent Diagnostic Testing Facility (IDTF) setting, as opposed to physician practice-based diagnostic model. The nature of this testing structure, where physicians are not ordering procedures on their equipment, is less likely to promote inappropriate or over-utilization."

"Estimated Payer Distribution

The Applicant anticipates that the initial payer distribution for CT scans will be the same as for its existing MRI services. However, given the anticipated cost per scan, there may be some growth in the percentage of patients covered by private insurance. To the extent that this occurs it will increase the public cost savings attributable to this project."

"Current MRI and Initial Payer distribution is as follows:

Medicare 32%
Maine Care 18%
Private Insurance 42%
Self Pay 2%
Free Care 6 %"

"Charity Care Policy

The Applicant in a for-profit organization. However, it maintains a charity care policy that will be applicable to CT scanning. A copy of this Policy is attached as Exhibit I. MIC does not limit referrals to its facility based on ability to pay. For the last six months of CY 2008, MIC provided \$19,055 of free care and IPH provided \$76,411."

"6) The "Public Need" to Reduce Health Care Costs

Hospitals in the greater Portland, Maine service area have moved and are moving to 64 slice and higher CT scanners to accommodate very high end non-routine CT scan needs. Associated technology cost more than the technology needed to provide most CT scans. In addition, the operating costs and hospitals' reimbursement expectations associated with scans provided in hospitals are much higher than scans provided in non-hospital settings. *As indicated*,

approximately 90% of all ambulatory CT scans can be performed by a 16 slice scanner, at an independent diagnostic testing facility, at comparatively lower cost, without a loss of appropriate clinical quality."

"Based on Insight's experience IPH/MIC estimates that its proposed reimbursement from private payers will be not more than half of what the payers are paying for the same CPT code-specific scans when they are "purchasing" them from hospitals in the service area. At the estimated volumes, this would result in a Year One savings to Payers (Anthem, Aetna, and Other/Managed Care) of at least \$404,000 and a Year Three savings of approximately \$541,000. This estimate assumes that the payers will be paying hospitals twice as much as they will be paying MIC (as shown in Exhibit D-CT Volume and revenue projections) and that Year Three volumes are 34% greater than Year One as reflected in the volume projection.)"

"There is a critical public need to find options for providing care at lower costs when that care can be provided without detrimentally compromising clinical quality. The Proposed Project is consistent with this goal. This cost reduction strategy is supported by Anthem and Aetna on behalf of the employers that they insure; employers which include the State of Maine."

"Also see Section V, Orderly Economic Development, Section VI, State Health Plan."

"7) Demonstrated Support

Exhibit J includes several letters of support for this project from a sample of currently referring physicians, who have addressed access, quality and their positive working relationships with MIC for MRI scanning."

"Letters of support for this project from Aetna and Anthem are also included. This support from two key area insurers is a critical recognition of the need for alternative, lower cost services and reflects not only the insurers' interests but the interests of their covered employers."

B. <u>CONU Discussion</u>

i. <u>CON Criteria</u>

Relevant criteria for inclusion in this section are specific to the determination there is a public need for the proposed services as demonstrated by certain factors, including, but not limited to:

- Whether, and 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;
- Whether the services affected by the project will be accessible to all residents of the area proposed to be served; and
- Whether the project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project.

ii. <u>CON Analysis</u>

The applicant states this project does not 1) substantially address specific health problems as measured by health needs in the area to be serviced; 2) have a positive impact on the health status indicators of the population to be served; or 3) provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project. The applicant states this project will reduce payments made by insurance companies for CT service. They also cite the potential for increasing utilization by lowering barriers to access by reducing the fee charged for the service.

InSight estimates that there are savings to payors by switching to a lower cost provider. These savings are projected by the applicant to be \$541,000 in the 3rd year of operation. Incremental operating costs associated with this project, as projected by InSight, are \$454,144. It is not clear if the savings projected by InSight are net of the additional costs that would be incurred if this project would be approved. InSight estimates savings despite not providing information regarding what other providers are currently being reimbursed for services.

InSight has received support letters from several area physicians and two insurance companies stating this project would increase access and provide a lower cost alternative to hospital-based CT services. The project received opposition from another provider (Mercy Hospital, Portland, ME) citing, among many things, the effect on them as an existing service provider in the area, duplication of services and inappropriate increases in service volume. Mercy Hospital states that the "existing capacity is adequate to meet current needs" and "to the extent that future demand

for CT services will create a need for an additional CT scanner in the service area, that need has already been addressed by the recently installed CT scanner at Mercy's new Fore River campus."

The proposed services appear to be accessible to all residents of the service area. InSight Premier currently has a Free Care Policy in place even though it is not required since InSight is not a hospital. Marshwood Imaging Center provided \$19,055 of Free Care during the last 6 months of Calendar year 2008 and InSight Premier provided \$76,411 during the same time frame.

The applicant did not provide any information relative to health status indicators or their ability to monitor or positively impact quality and outcome measures.

iii. Conclusion

CONU recommends that the Commissioner find that InSight Premier has not met their burden to show that there is a public need for the proposed project as demonstrated by certain factors, including, but not limited to: (1) Whether, and 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; (2) Whether the project will have a positive impact on the health status indicators of the population to be served; (3) Whether the services affected by the project will be accessible to all residents of the area proposed to be served; and (4) Whether the project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project.

V. Orderly and Economic Development

V. Orderly and Economic Development

A. From Applicant

"As discussed in the public need section, this project should reduce health care costs in the service area by at least \$404,000 in Year One and \$541,000/year by Year Three. (Savings will also continue in future years.)"

"Existing providers are likely to be able to replace some of their lost volume as the overall market expands and as the demand for cardiac studies increases. The proposed MIC Year One volume of 2394 scans is estimated to be approximately 2.9 % of 2010 hospital-based volume of 83,965 scans (estimated 2007 volume of 74,005 scans inflated by 4.3%/year to 2010). (As reflected Exhibit G.) This loss of 2.9 % of volume in Year One increases to 3.5% by Year Three, but this "loss" should be partially off-set by anticipated hospital-based growth in each year. There should be minimal effect on hospitals (except to free up more time for appropriate scans, which in turn may stabilize their revenues). The proposed project may also mitigate the need for the expansion of further hospital-affiliated capacity."

"The transition to MIC of some CT scans, now provided by hospitals in particular, will not be significant enough to compromise the quality of services that existing providers can offer."

"If the volume of CT scanning in the service area does not increase as expected, existing providers, now providing scanning at higher than necessary cost, may have to reduce their profits."

"Given that the charges paid by MaineCare and Medicare will be the same at MIC as they are at hospitals, there should be no increase in MaineCare costs (assuming that the project does not induce unnecessary utilization). IPH/MIC believes that significant barriers to inappropriate utilization are in place, as is discussed above."

"The Applicant does not anticipate that alternative technologies will replace the appropriateness of CT scanning as proposed."

"As an alternative to the proposed program of services, IHP/MIC could choose to exclusively serve commercially insured patients, excluding Medicare, MaineCare, self-pay, and non-paying patients. There is certainly sufficient volume in the service area now to develop a marketing plan to exclusively sell services to insurers, employers, and commercially insured patients, based on being a lower cost option. This strategy could lead to much greater profit and greater decreases in health systems cost than proposed. However, this approach would be inconsistent with IPH/MIC philosophy of supporting the established relationships with physicians now referring for MRI scans and all of their patients, as well as the needs of the broader health system."

V. Orderly and Economic Development

"Another alternative to the proposed project would be for existing providers to lower their charges and their expected reimbursement to the level proposed by IPH/MCI. It is not anticipated that this will happen."

B. CONU Discussion

i. CON Criteria

Relevant criteria for inclusion in this section are specific to the determination that the proposed services are consistent with the orderly and economic development of health facilities and health resources for the State as demonstrated by:

- The impact of the project on total health care 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.

ii. CON Analysis

InSight estimates that there are savings to payors by switching to a lower cost provider. These savings are projected by the applicant to be \$541,000 in the 3rd year of operation. Incremental operating costs associated with this project, as projected by InSight, are \$454,144. It is not clear if the savings projected by InSight are net of the additional costs that would be incurred if this project is approved. InSight estimates savings despite not having information regarding what other providers are currently being reimbursed for services.

Total 3^{rd} year operating costs are projected to be \$454,144 and of that amount MaineCare's 3^{rd} year cost would be \$23,207 (\$454,144 x 5.11%), which is both the Federal and State portions combined. Currently the impact to the Maine budget per year would be approximately \$8,122 (\$23,207 x 35% (State Portion). It does not appear that these funds are readily available. Absent a demonstration of public need CONU cannot justify any increase to the State budget.

CONU cannot comprehensively compare the costs and benefits of the project or conclude that this proposed project is consistent with the economic development of health facilities and health resources for the State. The applicant did not present any quantifiable data that this project is consistent with the orderly and economic development of health facilities and health resources for the State.

V. Orderly and Economic Development

iii. Conclusion

CONU recommends that the Commissioner find that InSight Premier has not met 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.

VI. State Health Plan

The Maine CDC/DHHS did not provide an assessment on individual priorities. On July 17, 2009, Dr. Dora A. Mills provided the following: "At this time, I do not see any significant health impact [this application has]."

PRIORITY: The applicant has a plan to reduce non-emergent ER use.

a. Applicant's Discussion on Priority

"The expanded community availability of non-hospital-based CT scanning, the concerted education of physicians who may refer to these services, facilitated scheduling for high priority referrals, and the availability of on-site radiologists may reduce unnecessary Emergency Room Utilization. This would reduce the cost per scan and the cost of the overall episode of care in the ER. Please see the discussion of utilization management found in Section VIII, Service Utilization."

"The Applicant anticipates developing linkages to physicians office that will facilitate the referral and timely completion of diagnostic studies for non-emergency cases that might otherwise be sent to a hospital and treated as urgent or emergent care in order to obtain "quicker" access than might otherwise be available through normal hospital scheduling."

b. **CONU Findings**

The proposal states that the project would allow physicians to schedule non-emergent CT services with a non-hospital provider that would otherwise require referrals to more costly non-emergent ER use. The applicant did not quantify the impact; therefore, the applicant does not satisfy this priority.

PRIORITY: 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.

a. Applicant's Discussion on Priority

"The MIC Imaging Center and Insight-Premier are committed to providing services with a culture that emphasizes patient safety and quality. The applicable quality assurance/quality improvement plans are discussed in Section VIII and further documented in Exhibit L, Quality and Performance Improvement Strategies."

b. <u>CONU Findings</u>

The applicant has a quality control program that identifies and documents quality control issues. The applicant then acts to correct any necessary changes. The applicant has met this priority.

PRIORITY: The project leads to lower costs of care/increased efficiency through such approaches as collaboration, consolidation, and/or other means.

a. Applicant's Discussion on Priority

"Through expanded price competition and easy outpatient access, coupled with appropriately defined and monitored quality, this project leads to a reduction in the cost of care for commercial insurance payers by providing patients, physicians, and payers a lower cost option for a considerable range of CT scans."

b. <u>CONU Findings</u>

This project would allow physicians to refer patients to a lower cost provider other than at a hospital setting where costs are typically higher. The applicant states that they do not have the information available to quantify this statement. The applicant does not know what hospitals are currently charging or being reimbursed for CT services. The applicant did not provide data related to savings from this project. The applicant did not satisfy this priority.

PRIORITY: The project improves access to necessary services for the population.

a. Applicant's Discussion on Priority

"The project provides expanded access to services that are recognized as necessary to diagnose identified conditions, at lower costs than are current available in hospital settings. This may decrease cost-of-care barriers, but this impact is likely to be minimal and not measurable."

"The project does increase access to necessary services to the extent that "necessary services" are defined as "services that offer lower cost alternatives to existing services"."

b. **CONU Findings**

The project would expand access to services which are only currently available in a hospital setting or a large medical office practice. InSight has a charity care policy that does not limit access to care based on availability to pay. The applicant did not quantify that access is an issue for this service in the greater Portland area. Mercy Hospital has stated that the need is sufficiently being served with the 10 existing CT scanners already in operation in the greater Portland area. The applicant did not satisfy this priority.

PRIORITY: The impact of the project on regional and statewide health insurance premiums, as determined by BOI, given the benefits of the project, as determined by CONU.

a. Applicant's Discussion on Priority

"Previous evaluation by the Bureau of Insurance (BOI) of a similar but withdrawn CON proposal submitted by the Applicant indicated that the cost of the proposed services did not significant increase premium cost to employers."

"The BOI did not evaluate that extent to which the project will lower cost to some payers. The applicant encourages this evaluation based on the submitted Application. The impacts on payers should be a reduction in premium costs rather than an increase."

b. <u>Bureau of Insurance Assessment</u>

"The Bureau of Insurance applied an enhanced version of the assessment model that was previously developed internally with support from its consultant, Milliman, Inc., of Minneapolis, MN, in order to develop an estimate of the impact that this CON project is likely to have on private health insurance premiums in the applicant's service area and in the entire state of Maine. I have worked with you and your staff at the CON Unit, using data and support from the U.S Census Bureau, the Centers for Medicare & Medicaid Services, the State Planning Office, the Office of Integrated Access and Support, the Certificate of Need Unit of the Department of Licensing and Regulatory Services, the Bureau of Insurance, and information submitted by the applicant through your agency to perform this assessment."

"The assessment compares the CON project's Year 3 estimated average per capita incremental premium [based on 2012 estimated population and service volume, adjusted to a 2009 incremental revenue (insurance cost) current value] to the estimated private health insurance average premium per capita for the current period (Y/E 12/31/2009), which corresponds to the period for which the current capital investment fund has been established. As a result, I estimate that the potential impact of this CON project on private health insurance premiums in Marshwood Imaging Center's service area for the project's third year of operation will be approximately \$0.0010 per \$100 (0.10%) of premium. I further estimate that this project, in its third year of operation, will have an impact on statewide private health insurance premiums of approximately \$0.0002 per \$100 (0.02%) of premium. To the extent, however, that any of the underlying data or information sources identified above is inaccurate or incomplete, the results of this assessment may likewise be inaccurate or incomplete."

c. <u>CONU Findings</u>

The additional impacts to regional and statewide insurance premiums are minimal; however, any increase in insurance premiums is not warranted absent a demonstration of the proposed project meeting the other CON criteria.

PRIORITY: 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.

a. Applicant's Discussion on Priority

"Marshwood Imaging Center will integrate CT services into it on-going participation in the CI PACs system at Maine Medical Center supported by Maine Health. This system has been in place for the MRI imaging at MIC since late 2003. MIC and other InSight Premier sites were some of the first "non-MMC" users of the integrated PACs system. Additionally, MIC participates in the regular CI PACs user group meetings in order to make sure patient and physician needs are being coordinated and appropriately met. MIC is currently working with MMC on plans for another system upgrade. The CI PACs system and MIC's participation in it has benefited the medical community. The radiologists that are located at MIC Imaging Center not only support MIC but they are able to provide radiological services for all CI PACS participants. InSight Premier's Marshwood Imaging Center is very proud of its ability to be a significant contributor in this endeavor."

"Similar to the CI PACs, MIC plans to participate in the EMR project hosted by Maine Health. MIC has had preliminary discussions to this end and looks forward to a more integrated medical record system."

b. **CONU Findings**

Currently the Marshwood Imaging Center's PAC system is available and works with its MRI services. InSight would incorporate CT imaging into its already existing PAC system. The applicant has met this priority.

PRIORITY: Projects done in consultation with a LEEDS certified-architect that incorporate "green" best practices in building construction, renovation and operation to minimize environmental impact both internally and externally.

a. Applicant's Discussion on Priority

"Opportunities to incorporate "green" best practices in this project are limited. Nonetheless, this project will be implemented with these practices in mind."

"InSight Premier has used SMRT, 144 Fore Street, PO Box 618 Portland, Maine 04104 as its architect for this project. SMRT indicates the intent to utilize "green" best practices in the renovations required for this project in the following comments":

"The project will be designed to incorporate best practices in building construction, renovation and operation to minimize environmental impact. The design team selected for the project includes design professionals accredited by the U.S. Green Building Council LEED (Leadership

in Energy and Environmental Design) program. They will assist Marshwood Imaging Center with the development of the project that will be designed to operate efficiently using materials and resources that minimize environmental impacts."

"Energy efficiency will be achieved through the use of:

- -high performance heating, ventilation and air conditioning equipment
- -variable speed drives
- -heat recovery
- -maximizing the use of natural light
- -providing multiple options for controls of lighting and mechanical systems
- -commissioning the building to ensure that systems are operating at optimal efficiencies."

"Materials and resource consumption will be controlled by:

- -limiting the area of new construction and renovating as much of the existing building as is practicable
- -using locally available materials where possible to reduce the environmental impact of transportation
- -using rapidly renewable materials and materials with high recycled content where possible
- -requiring the contractor to recycle construction waste
- -requiring the contractor to salvage materials where possible
- -providing adequate areas for waste recycling"

"Indoor Environmental Quality will be controlled by:

- -requiring the contractor to replace filters and flush out the mechanical system prior to occupancy
- -use of low-emitting materials
- -providing a smoke-free environment
- -providing occupants natural light and the ability to control artificial light and temperature In summary the physical environment will be designed with sustainability and energy efficiency in mind, in keeping with Marshwood Imaging Center's commitment to the environment and to controlling the negative environmental impact of construction and on going hospital operations."

b. **CONU Findings**

The applicant has hired a LEED-accredited firm committed to designing this project to satisfy this priority.

iii. Conclusion

CONU recommends that the Commissioner find that the project is not consistent with the State Health Plan priorities.

VII. Outcomes and Community Impact

VII. Outcomes and Community Impact

A. From Applicant

"Many of the specifics of the Proposed Project that related to Outcomes and Community Impacts have already been discussed in the preceding sections."

"Community cost impact is discussed in preceding sections."

"As indicated in Section II (Fit, Willing and Able), MIC has in place extensive quality measures consistent with its accreditation by the American College of Radiology. These measures will be extended to CT services."

"Care will be provided using well-recognized protocols that reflect national and local standards of care. Additional steps that will be taken to assure appropriate utilization of services are documented in Section 4 as part of the discussion of Public Need."

"IPH/MIC has taken steps to enhance its ability to deliver quality of care and to avoid unnecessary duplication of services by participating in the development of PACS and electronic medical record technology."

"MIC has multiple clinical policies in place for MRI scanning that meet accreditation standards. The same policies, where applicable, will be used for CT and additional policies, such as those applicable to the administration of CT contrast agents, monitoring the image quality of the scanner, and CT radiation exposure, will be in place prior to initiation of services. The total MRI policy book is not being submitted with this Application, but ISP/MIC is willing to provide any specific policy statements that the Department feels would be helpful in demonstrating the IPH/MIC performs with a culture and tools that promote quality and is willing to share any CT-specific policies prior to implementation of services."

"IPH/MIC operates using the Quality of Care Plan of InSight. A Copy of this Plan is attached as Exhibit K."

"IPH/MIC now conducts quarterly patient surveys to assess patient perceptions of its services. Surveying will be extended to CT services. All survey results have not been provided. However, IPH/MIC is willing to share more results for MRI scanning if the CON Unit feels that they would be helpful in assessing the quality of care that IPH/MIC provides. The following charts reflect sample findings for a survey of 91 patients conducted during the last quarter of 2008."

VII. Outcomes and Community Impact

For the next set of questions, please check 1 = poor, 4 = excellent: How well did the radiology staff technologist explain your exam to you?

Response	Count		
2 fair	7	7%	
3 good	17	18%	
4 excellent	67		73%
Total:	91		

For the next set of questions, please check 1 = poor, 4 = excellent: How would you rate our facility to a friend or relative who needed an exam?

Response	Count		
2 fair	2	2%	
3 good	15	16%	
4 excellent	74		81%
Total:	91		

If you were given a choice, would you return to our facility if you needed another exam?

Response	Count	
<u>Yes</u>	91	100%
Total:	91	

"An account executive/physician liaison specialist is currently in daily contact with physicians and their office staff to facilitate the resolution of MRI issues. Any dissatisfaction expressed by the referring physicians, is reviewed immediately with the MIC manager and radiologists as necessary. This services will be extended to CT scanning."

"The Applicant has extensive experience in Maine with providing high quality services. The radiologists involved with this project are recognized as providing appropriate levels of quality."

"The transition to MIC of some CT scans now provided by hospitals in particular, will not be significant enough to compromise the quality of services that existing providers can offer."

"The "Outcome" that high quality CT scans will be available at lower cost has been clearly demonstrated."

VII. Outcomes and Community Impact

"The support of Anthem and Aetna for this project reflects their assessment that MIC is currently a quality provider of MRI services and that it will provide similar quality for CT services. (See Exhibit J.)"

B. CONU Discussion

i. CON Criteria

Relevant criteria for inclusion in this section are specific to the determination that the project ensures high-quality outcomes and does not negatively affect the quality of care delivered by existing service providers.

ii. <u>CON Analysis</u>

InSight has a quality control program in place that would insure high quality outcomes. InSight provided a copy of their Quality Control Plan as well as a copy of their client satisfaction survey results.

Existing service providers have the potential to lose some volume if this project were approved; however, it is not known whether this project would negatively affect the quality of care delivered by existing service providers. Comments received by Mercy Hospital, dated May 16, 2009, state the following:

"The project conflicts with the orderly and economic development of health facilities and resources for the State on the basis that: (i) it represents a duplication of services, (ii) it will negatively impact existing service providers by shifting volumes in the service area, and (iii) it will inappropriately increase service utilization because there is no need for an additional CT scanner in the service area."

"In sum, the granting of the applicant's proposal and the introduction of their CT scanner into the service area is likely to result in many of the important adverse consequences that the CON Act and the State Health Plan are intended to avoid."

While Mercy Hospital did not quantify the extent that this proposal may negatively impact the quality of care delivered by their facility, the applicant has not met their burden to demonstrate that the quality of care delivered by existing service providers will not be negatively affected.

iii. Conclusion

CONU recommends that the Commissioner find that InSight Premier has met their burden to demonstrate that this project will ensure high-quality outcomes but may negatively affect the quality of care delivered by existing service providers.

VIII. Service Utilization

VIII. Service Utilization

A. From Applicant

"Other sections of this application contain documentation that IPH/MIC is capable of providing and will provide safe, timely, effective, and patient centered CT services. IPH/MIC's proposed approach is consistent with the criteria of Maine Quality Forum's and the principals recommended by the National Institute of Health."

"The Quality Forum and the Maine Center for Disease Control have in the past expressed concerns that the development of additional CT scanning services in the Portland area could result in "supply sensitive" excess CT scanning utilization. IPH/MIC believes that this possibility is minimal and that this issue has been addressed in Sections 4 and 5. In summary:

- At least to the extent expressed in the Quality Forum study "Geographic Variation Analysis of Advanced Imaging Services," the Portland service area's use rates are below state averages and reflect conservative utilization practices when compared to many areas of the State. IPH/MIC believes that this reflects both the culture of the medical community and steps that have been taken by radiologists and hospitals, as well as other physicians to constrain inappropriate use. The introduction of CT services provided through IPH/MIC is not expected to change this pattern.
- IHP/MIC has indicated multiple steps that it will take to mitigate inappropriate utilization of services at its facility and that it documented its ability to provide appropriate services.
- IHP/MIC believes that its primary referring physicians (those currently referring for MRI scans) will shift service from current providers to the lower cost CT services and that this will not lead to an increase in their use of CT.
- The will be natural grow in the use of CT services in the foreseeable future. The natural growth will off set some of the losses of volume at local hospitals, and mitigate inappropriate growth of utilization.
- IPH/MIC provides scans to physicians based on referral. The radiologists who provide professional services to MIC's patients do not control the referral volume like physicians who may refer to services within their own practices. Thus, the risk of over-utilization at MIC is less.
- IPH/MIC is unaware of any documented findings that indicate that the greater Portland area has experienced inappropriate "supply sensitive" excess CT scanning utilization. Particularly given the preceding points, there is no local evidence to support a conclusion, this project will stimulate inappropriate use of services."

VIII. Service Utilization

B. CONU Discussion

i. <u>CON Criteria</u>

Relevant criterion for inclusion in this section are specific to the determination that the project does not result in inappropriate increases in service utilization, according to the principles of evidence-based medicine adopted by the Maine Quality Forum.

ii. Maine Quality Forum Analysis

"This application was reviewed for quality considerations with emphasis on the five characteristics of quality care (safe, timely, effective, efficient, equitable, and patient-centered) within the three domains of structure, process, and outcome. The applicant seeks to add a 16-slice CT scanner to its diagnostic imaging center in Scarborough."

"Normally, a request for the addition of scanning capacity would be made on the basis of a need for a higher level of technology or because the scanning capacity in the region is insufficient. The first addresses effectiveness and the second timeliness and patient-centered care (decrease in wait times, decrease in cancellations)."

"The scanner proposed does not represent a higher level of technology. Only 2 of the 10 CT scanners in the greater Portland and Biddeford areas are less than 16 slice instruments."

"No evidence is presented that demonstrates that patient needs are not being met by the current capacity in the area. As the applicant states, "Inadequate access to essential services and speculative growth assumptions are not the compelling arguments for the Application...IPH/MIC is not arguing that the area has insufficient resources." (application pp 8-9)."

"The applicant does cite previous work by the Maine Quality Forum examining advanced imaging utilization in healthcare service areas in the state. A more recent claims analysis (*All-Payer Analysis of Variation in Healthcare in Maine, April 2009*), examining services in the period 11/1/05-10/31/06 shows that advanced imaging (CT and MRI) is a high-cost, highly variable (in utilization) service, accounting for 5.1% of total outpatient costs. For the insured populations analyzed, advanced imaging costs in the Portland area were at the state average for commercially insured population (costs were below average for Medicare and substantially below average for MaineCare populations). In the Biddeford service area, advanced imaging costs were slightly below the state average for the commercially insured population (below average for Medicare and at the average for the MaineCare populations). In general, total costs of services were more a function utilization than of price."

"The applicant appears to be suitable in other domains of quality. Certainly the structural descriptors of the services it provides are good. However, as the applicant points out, system capacity is one driver of utilization, so there is a possibility that utilization could increase as a

VIII. Service Utilization

result of this proposed increase. There is no evidence that increased utilization would correct a problem of under use in the region. The possibility that increased capacity would lead to lower price is conjectural; this has not always been observed in health care markets. One might ask whether the ten scanners present in the regional southern Maine market have already lowered prices."

iii. CON Analysis

CT services fall in the category of supply sensitive care where utilization of services is in part driven by supply. InSight noted the procedures they would follow to make sure inappropriate scanning would not take place.

New data from "All-Payer Analysis of Variation in Healthcare in Maine" completed by Maine Quality Forum and the Advisory Council on Health Systems Development and reported to the Legislature in April 2009 suggests that "total cost is a function of volume of services (utilization) and price per service." The report indicated that the volume of services was the more powerful determinant of cost. Outpatient scanning accounts for 5.1% of outpatient spending. The applicant states that they would provide a less costly service; however, the applicant failed to demonstrate the amount of cost savings. CONU concurs with Joshua Cutler, MD that there is no evidence stating that prices in the southern Maine market are not already lower.

InSight states that this project will not cause over utilization because InSight will not be directly responsible for the number of scans performed. InSight states that their policy is to only perform scans as ordered by a physician. InSight is projecting that the addition of a CT scanner in this area will not likely be the reason for an increase in the number of scans ordered by physicians. CONU recognizes that system capacity has been identified as one of the drivers for utilization. CONU concurs with the Maine Quality Forum analysis that states, in part, "No evidence is presented that demonstrates that patient needs are not being met by the current capacity in the area." The applicant has not met their burden to demonstrate that the risk of inappropriate increases in service utilization will be minimal.

iv. <u>Conclusion</u>

CONU recommends that the Commissioner find that the InSight Premier, LLC has not met their burden to demonstrate that the project does not result in inappropriate increases in service utilization, according to the principles of evidence-based medicine adopted by the Maine Quality Forum.

IX. Capital Investment Fund

IX. Capital Investment Fund

A. From Applicant

"The impact on the Capital Investment Fund is anticipated to be less than \$500,000."

"The CON unit has indicated that there is no issues with the Capital Investment fund as this project is the only project in the small projects category for the current cycle."

B. <u>CONU Discussion</u>

i. <u>CON Criteria</u>

Relevant criteria for inclusion in this section are related to the needed determination that the project can be funded within the Capital Investment Fund.

ii. CON Analysis

The small non-hospital project is a non-competitive cycle as this application was the only proposal received. The CIF has been introduced to limit the development of healthcare facility projects to a level sustainable in regards to its impact on the growth of healthcare costs. The CONU has determined that, if approved, this project can be funded within the CIF.

iii. Conclusion

CONU has determined that there are incremental operating costs to the healthcare system that will affect the Capital Investment Fund (CIF) dollars needed to implement this application. The current CIF calculation for projects in 2009 is adequate to fund this project if it was approved.

X. Timely Notice

X. Timely Notice

A. From Applicant

"Letter of Intent filed: December 28, 2008

Technical Assistance Meeting Held: January 14, 2009

CON application Filed: March 20, 2009

CON certified as complete: Date to be determined by State"

B. <u>CONU Discussion</u>

Letter of Intent filed:

Technical Assistance meeting held:

CON application filed:

CON certified as complete:

March 20, 2009

Public Information Meeting Held:

Public comment period ended:

December 29, 2008

January 14, 2009

March 20, 2009

April 14, 2009

May 14, 2009

XI. Findings and Recommendations

XI. Findings and Recommendations

Based on the preceding analysis, including information contained in the record, the CONU recommends that the Commissioner make the following findings and recommendations subject to the conditions below:

- A. That the applicant is fit, willing and able to provide the proposed services at the proper standard of care as demonstrated by, among other factors, whether the quality of any health care provided in the past by the applicant or a related party under the applicant's control meets industry standards.
- B. The economic feasibility of the proposed services is demonstrated in terms of the:
- 1. Capacity of the applicant to support the project financially over its useful life, in light of the rates the applicant expects to be able to charge for the services to be provided by the project; and
- 2. The applicant's ability to establish and operate the project in accordance with existing and reasonably anticipated future changes in federal, state and local licensure and other applicable or potentially applicable rules;
- C. The applicant has not demonstrated that there is a public need for the proposed services as demonstrated by certain factors, including, but not limited to;
- 1. 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;
- 2. The project has demonstrated that it will have a positive impact on the health status indicators of the population to be served;
 - 3. The project will be accessible to all residents of the area proposed to be served; and
- 4. The project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project;
- D. The applicant has not demonstrated that the proposed services are consistent with the orderly and economic development of health facilities and health resources for the State as demonstrated by:
- 1. The impact of the project on total health care 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;

XI. Findings and Recommendations

- 2. The availability of State funds to cover any increase in state costs associated with utilization of the project's services; and
- 3. The likelihood that more effective, more accessible or less costly alternative technologies or methods of service delivery may become available was not demonstrated by the applicant;

In making a determination under this subsection, the commissioner shall use data available in the state health plan under Title 2, section 103, data from the Maine Health Data Organization established in chapter 1683 and other information available to the commissioner. Particular weight must be given to information that indicates that the proposed health services are innovations in high quality health care delivery, that the proposed health services are not reasonably available in the proposed area and that the facility proposing the new health services is designed to provide excellent quality health care.

- E. The applicant has not demonstrated that the project is consistent with and furthers the goals of the State Health Plan;
- F. The applicant has demonstrated that the project ensures high-quality outcomes but may negatively affect the quality of care delivered by existing service providers;
- G. The applicant has not demonstrated that the project does not result in inappropriate increases in service utilization, according to the principles of evidence-based medicine adopted by the Maine Quality Forum; and
- H. That the project should not be funded within the Capital Investment Fund.

For all the reasons contained in the preliminary analysis and in the record, CONU recommends that the Commissioner determine that this project should be **disapproved.**