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

Date: June 2, 2009

Project: Add an additional Linear Accelerator to the Scarborough Campus

Proposal by: Maine Medical Center

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Directly Affected Party: None

Recommendation: Disapprove

	Proposed Per Applicant	**Approved CON**
Estimated Capital Expenditure	$ 5,018,095	$ 0
Maximum Contingency	$ 250,905	$ 0
Total Capital Expenditure with Contingency	$ 5,269,000	$ 0
Third Year Incremental Operating Costs	$ 1,265,679	$ 0
Capital Investment Fund (CIF) Impact:	$ 1,123,835	$ 0
CIF debit 2009	$ 1,123,835	$ 0
Bureau of Insurance Regional Impact Estimate		0.101%

I. Abstract

A. From Applicant

Overview

"Maine Medical Center (MMC) proposes adding a linear accelerator to be located at its Scarborough campus to MMC Radiation Therapy Program."

"This project will maintain appropriate timely access to external beam radiation therapy, a necessary service for treating most forms of cancer. Without the additional capacity, timely access to this needed service will be unduly diminished, which is a proven risk to patient safety."

"The increase in capacity is necessary due to the introduction of Image Guided Radiation Therapy (IGRT), the most advanced form of radiation therapy. Research demonstrates that IGRT provides the best treatment outcomes with fewer, less severe side effects. IGRT involves obtaining daily high resolution imagery in the linear accelerator vault immediately preceding treatment, which significantly impacts the amount of time each patient spends in the vault. The average in-vault time per IGRT patient visit is 40 minutes in comparison to 16 minutes per visit for non-IGRT patients."

"Please refer to Exhibit 1-A for an overview of radiation therapy, three-dimensional conformal radiation therapy, intensity modultated radiation therapy and image guided radiation therapy."

"The estimated capital expenditure associated with this project is five million two hundred sixty nine thousand dollars ($5,269,000). The estimated incremental third year expense is one million three hundred fifty five thousand seven hundred eighty five dollars ($1,355,785). The Capital Investment Fund debit is eight hundred six thousand nine hundred eighty one dollars ($806,981)."

"MaineHealth and MMC are launching a new major clinical integration initiative focusing on cancer, which is designed to improve access to specialty care, clinical trials and genetic counseling; provide patient navigation and survivorship programs; disseminate evidence-based care guidelines; support each MaineHealth organization achieving the appropriate accreditation and credentialing; and improve the Network Registry to support increased access and data review for outcomes and quality metrics. The investment in this initiative for FYE 2009 is three hundred seventy three thousand dollars ($373,000)."

I. Abstract

MMC Radiation Therapy Program

"MMC provides external-beam (linear accelerator-based) radiation therapy services at four sites within its service area: Scarborough, Portland, Bath and Sanford (in cooperation with Southern Maine Medical Center and Goodall Hospital). Current and proposed linear accelerator capacity at MMC's sites is presented in the following table:

MMC Radiation Therapy Program Sites	**Current Capacity**	**Proposed Capacity**
MMC Outpatient Campus, Scarborough	2	3
MMC Inpatient Campus, Portland	1	1
MMC Coastal Cancer Treatment Center, Bath	1	1
Cancer Care Center of York County, Sanford	1	1
MMC Radiation Therapy Program	**5**	**6**

"Please refer to Exhibit 1-B for an overview of MMC Radiation Therapy Program."

MMC's Scarborough Outpatient Facility, 98 Campus Drive, Scarborough, Maine

"Adding a Linear Accelerator requires the construction of a new vault and associated support functions at MMC's Scarborough outpatient facility. MMC engaged SMRT Architects, Portland, Maine to develop the functional and space program, and the schematic design for this project."

Functional and Space Program

"The project program calls for 3,700 square feet of new construction and 2,600 square feet of renovation."

"Please refer to Exhibit 1-C for the proposed functional and space program."

Schematic Design

"The proposed design involves two small, single-story, masonry-sided additions to 98 Campus Drive:

1. A linear accelerator vault, control room and corridor, and
2. An administrative suite with a mix of open-architecture and enclosed office space."

"The proposed design also calls for renovations to:

1. Enlarge patient waiting and exam functions, and
2. Relocate and enlarge an office suite for physicians, physicists and dosimetrists displaced by the expansion of these patient areas."

I. Abstract

"Please refer to Exhibit 1-D for the existing facility plan and to Exhibit 1-E for the proposed facility schematic design."

Preliminary Project Schedule

"The project schedule anticipates that the new linear accelerator would be ready for patient treatments by October 1, 2010, the beginning of MMC's Fiscal Year 2011."

"Please refer to Exhibit 1-F for the preliminary project schedule."

II. Fit, Willing and Able

A. From Applicant

Overview

"Maine Medical Center (MMC) is a not-for-profit, 650-bed, State-licensed, Joint Commission on the Accreditation of Health Care Organizations (JCAHO) accredited hospital located in Portland, Maine. MMC is a subsidiary of MaineHealth, a nonprofit organization located in Portland, Maine."

"MMC Cancer Institute - Commission on Cancer Accreditation – MMC Cancer Institute is the only program in Maine accredited by the American College of Surgeon's (ACoS) Commission on Cancer (CoC) as a "Teaching Hospital Cancer Program" with commendation. "Teaching Hospital" is the highest level of CoC accreditation; CoC commendation recognizes MMC Cancer Institute as being in the top five percent of programs its size. MMC Cancer Institute was one of only two programs in New England to receive the CoC's Outstanding Achievement Award for exceptional performance in 2007. CoC accreditation is recognized by the Maine Cancer Consortium as an indicator that a cancer program meets industry standards."

"MMC Radiation Therapy Program is the only radiation therapy program in Maine accredited by the American College of Radiology."

"MMC Radiation Therapy Program also is an Active Affiliate Member of the Radiation Therapy Oncology Group (RTOG), a national clinical cooperative group for the purpose of conducting radiation therapy research and cooperative clinical investigations."

"MMC Cancer Institute's Genitourinary Cancer Program was selected in 2008 as one of five model prostate cancer programs nationally by the Association of Community Cancer Centers."

"Maine Medical Center
22 Bramhall Street
Portland, Maine 04102

http://www.mmc.org"

"Maine Medical Center (MMC) is a voluntary non-profit 501 (c) (3) organization and is a subsidiary of MaineHealth, a nonprofit organization. MMC is licensed for 650 beds including 42 newborn beds."

"Please refer to Exhibit 2-A: MaineHealth"

II. Fit, Willing and Able

Mission:

"The Maine Medical Center is dedicated to maintaining and improving the health of the communities it serves by:

- caring for the community by providing high quality, caring, cost effective health services;
- educating tomorrow's care givers; and
- researching new ways to provide care."

"MMC Service Area:

Primary: Cumberland and York counties;

Secondary: Androscoggin, Franklin, Kennebec, Knox, Lincoln, Oxford, Sagadahoc, Somerset and Waldo counties;

Tertiary: Aroostook, Hancock, Penobscot, Piscataquis and Washington counties."

"MMC Radiation Therapy Program Service Area:

Primary: Cumberland, Lincoln, Sagadahoc and York counties.

Secondary: Androscoggin, Franklin, Kennebec, Knox, Oxford, Somerset and Waldo counties.

Tertiary: Aroostook, Hancock, Penobscot, Piscataquis and Washington counties."

"MMC Radiation Therapy Program Service Area's definition varies from MMC's general definition of service areas; Lincoln and Sagadahoc counties, usually identified as parts of MMC's secondary service area, are included in MMC Radiation Therapy Program's primary service area due to the location of MMC's Coastal Cancer Treatment Center in Bath, Maine and its service to residents of those counties."

Licenses, Certifications & Accreditations

"MMC is licensed by the State of Maine, certified to participate in Medicare and accredited by the Joint Commission on the Accreditation of Health Care Organizations (JCAHO)."

"MMC's "Statements of Deficiencies" and site visit reports from the previous three years are on file with the Department of Health and Human Services' Division of Licensing and Regulatory Services."

"Please refer to Exhibit 2-B: MMC Quality of Care."

II. Fit, Willing and Able

"Please refer to Exhibit 2-C: MMC's General Hospital License issued by the Maine Department of Health and Human Services."

"Please refer to Exhibit 2-D: MMC's Certificate of Accreditation issued by the Joint Commission on Accreditation of Healthcare Organizations."

"MMC Cancer Institute - Commission on Cancer Accreditation – MMC Cancer Institute is the only program in Maine accredited by the American College of Surgeon's (ACoS) Commission on Cancer (CoC) as a "Teaching Hospital Cancer Program" with commendation. "Teaching Hospital" is the highest level of CoC accreditation; CoC commendation recognizes MMC Cancer Institute as being in the top five percent of programs its size. MMC Cancer Institute was one of only two programs in New England to receive the CoC's Outstanding Achievement Award for exceptional performance in 2007. Commission on Cancer accreditation is recognized by the Maine Cancer Consortium as an indicator that a cancer program meets industry standards. (See Section VI State Health Plan of this application for more details on the Maine Cancer Consortium and the Maine Comprehensive Cancer Control Plan 2006 – 2010.)"

"Please refer to Exhibit 2-E: MMC Cancer Institute."

"Please refer to Exhibit 2-F: MMC Cancer Institute's Commission on Cancer Accreditation with Commendation."

"MMC Radiation Therapy Program - American College of Radiology Accreditation - MMC is the only radiation therapy program in Maine accredited by the American College of Radiology (ACR). The goals of the ACR accreditation program are to provide impartial, third-party peer review; to recognize quality radiation oncology practices through accreditation; to make recommendations for improvement in practice and patient outcomes according to the recognized standards of the scientific community; and to provide a referral list for patients."

"ACR accreditation recognizes a program's achievement of high practice standards after a peer-review evaluation of its practice. Image quality and procedure evaluations are conducted by board-certified radiologists and medical physicists who are experts in the field. The program evaluates personnel qualifications to perform and interpret medical images and administer radiation therapy treatments; adequacy of facility equipment, quality control procedures and quality assurance programs. ACR certification establishes that the facility meets or exceeds quality assurance and safety guidelines."

"Please refer to Exhibit 2-G: MMC's American College of Radiology accreditation letter."

"MMC Radiation Therapy Program - Radiation Therapy Oncology Group Membership – MMC Radiation Therapy Program has attained Active Affiliate Member status with the Radiation Therapy Oncology Group (RTOG), a Radiation Therapy-specific indicator of high quality care."

II. Fit, Willing and Able

"RTOG is a national clinical cooperative group for the purpose of conducting radiation therapy research and cooperative clinical investigations. RTOG provides an infrastructure for clinical investigators from the United States and Canada to seek more effective treatments for cancer. RTOG pursues studies identifying new therapies which can be transferred to the community as standard treatment for the 21st century."

"RTOG emphasizes a common understanding of quality assurance requirements to achieve the most effective care throughout the general medical community for standard as well as new modalities. The RTOG has established mechanisms to assure its members' compliance with protocols in all aspects of radiation therapy, dose prescription and delivery."

"Please refer to Exhibit 2-H: MMC's RTOG membership letter."

"MMC Cancer Institute's Genitourinary Cancer Program was selected in 2008 as one of five model prostate cancer programs nationally by the Association of Community Cancer Centers."

MMC's Board-Certified Radiation Oncology Physicians

"100% of the radiation oncologists with staff privileges at MMC are board certified by the American Board of Radiology. To be certified a candidate must finish a prescribed and approved period of training and study, and pass computer-based and oral examinations, demonstrating an adequate level of knowledge and ability in radiation oncology in accordance with American Board of Radiology standards."

MMC's Board-Certified and Board-Eligible Physicists and Dosimetrists

"All of MMC's physicists and dosimetrists are American Board of Radiation (physicists) or American Board of Medical Dosimetrists (dosimetrists) Board-certified or Board-eligible. In the case of Board-eligible staff, the Boards require a minimum number of years to elapse after degree matriculation before the individual can sit for the written and oral exams. By the end of 2010 all current MMC physicists and dosimetrists will be Board-certified."

MMC's Certified Registered Nurses

"71% of the RNs involved with MMC's Radiation Oncology Program at the Scarborough campus are oncology certified nurses; 66% of the RNs working in the outpatient oncology clinics are certified. These nurses have met or exceeded requirements for practice in cancer care, completed education in oncology nursing, and possess a tested knowledge of the specialty. Certification in oncology nursing is based on current professional practice, so it validates a nurse's knowledge is up-to-date. Pending test results, 88% of the RNs involved with MMC's Outpatient I-V Therapy at Scarborough will be oncology certified by early 2009."

II. Fit, Willing and Able

Key Personnel and Organizational Chart

"Miriam Leonard, Vice President of Operations, oversees the MMC Cancer Institute and serves as MMC's Oncology Clinical Service Coordinator with physicians and other providers. Prior to her current position, Ms. Leonard served as Associate Vice President, Operations and as Administrative Director, Oncology Services at MMC. She previously was a Senior Manager with Newman/Noyes (formerly Ernst & Young) and Manager with Deloitte/Haskins. Ms. Leonard also served as Assistant Director of Pharmacy for both Children's Hospital Medical Center, Cincinnati, Ohio and St. Mary's Hospital, Athens, Georgia."

"Jacquelyn Hedlund, MD, MMC Cancer Institute Medical Director, is Board-certified in hematology and internal medicine, and Fellowship trained in hematology."

"Cornelius McGinn, MD, Medical Director for MMC Department of Radiation Therapy, is Board-certified in radiation therapy, and has held a variety of academic positions with University of Michigan Department of Radiation Oncology program."

"Administrative Director, MMC Cancer Institute, This position is presently vacant."

"Leslie Weeks, Business Manager, MMC Cancer Institute. Prior to her current position, Ms. Weeks has served as MMC Radiation Therapy's Chief Therapist, Senior Therapist and Staff Therapist. In her current position Ms. Weeks will continue to oversee MMC's Department of Radiation Therapy."

"Steven Ryan, Chief Radiation Physicist, MMC Department of Radiation Therapy, is Board-certified in therapeutic radiology physics. Mr. Ryan also serves as an Instructor in Southern Maine Community College's Radiation Therapist Program. Prior to his current position Mr. Ryan served as a staff Radiation Physicist."

"Donna Akerson Green, RN, Clinical Manager, Outpatient Oncology Services, is Oncology-certified. Prior to her current position, Ms. Green has held various nursing leadership and staff positions with MMC's breast care, outpatient oncology, radiation therapy and gynecological oncology services."

"Please refer to Exhibit 2-I: MMC's organizational chart."

II. Fit, Willing and Able

B. CONU Discussion

i. 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. Analysis

Maine Medical Center (MMC) has submitted a proposal to add one additional linear accelerator to be located on their Scarborough campus for the outpatient Radiation Therapy Program located there. This proposal would allow Image Guided Radiation Therapy (IGRT) to be delivered with more precision than was previously possible. The applicant has provided volumes of information considered by CONU and referenced where appropriate. All information is on file at CONU. This project consists of 3,700 square feet of new construction and 2,600 square feet of renovations.

This proposal is not a new service for MMC as they currently provide radiation therapy at their Scarborough campus. The applicant already performs this type of radiation therapy (IGRT), but on a limited basis. MMC is accredited by the American College of Surgeon's (ACoS) Commission on Cancer (CoC) and the American College of Radiology.

The Division of Licensing and Regulatory Services, Medical Facilities Unit confirms that Maine Medical Center is a fully licensed acute care hospital in the State of Maine and is MaineCare and Medicare certified. The Division's most recent survey was completed on July 10, 2006. No major deficiencies were cited that would affect licensure. MMC was cited for numerous life safety code deficiencies. CMS notified MMC on August 30, 2006 that the deficiencies were standard level code deficiencies and a plan of correction was not required. MMC submitted a plan of correction on October 31, 2006 even though it was not necessary. The last Joint Commission report was completed in August 2008. In that report, MMC had no cancer treatment requirements for improvements. MMC was fully accredited by the Joint Commission on August 13, 2008.

The applicant has shown a long-standing ability to provide hospital-based services within licensing standards.

iii. Conclusion

CONU recommends that the Commissioner find that Maine Medical Center 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

Capital Costs

Construction Costs:	
Estimate	$2,008,000
Estimating Margin @ 10%	$201,000
Construction Costs	$2,209,000
Architect & Engineer Costs:	
A/E Fees @ 12%	$241,000
A/E Reimbursable Expenses	$18,000
General Expenses/Permits	$60,000
Testing	$20,000
Commissioning	$11,000
Estimating Margin	$18,000
A&E Costs	$368,000
Other Costs:	
Insurance	$20,000
CON Filing Fee	$6,000
Other Costs	$26,000
Furniture, Furnishings & Equipment	
Furniture, Furnishings, Minor Equipment	$176,000
Linear Accelerator and Associated Equipment	$2,268,000
Information & Telecommunications	$160,000
Signage (allowance)	$5,000
FFE Costs	$2,609,000
Owner's Associated Costs:	
Project Manager Fee	$29,000
Purchasing Department Fee	$15,000
I.S. Telecomm Fee	$13,000
Owner's Associated Costs	$57,000
Total Project Costs	**$5,269,000**

Basis for Estimates

"These capital expenditure estimates have been developed by MMC Departments of Radiation Therapy, Facilities Development, Planning, Purchasing, Information Services and Financial Planning in cooperation with SMRT Architects (project architect and design engineers), Sebago Technics (project site architect and civil engineer), and Langford & Lowe (project construction manager)."

III. Economic Feasibility

Depreciation Schedule

"The project's annual depreciation expense for building, improvements, equipment and furniture is based on American Hospital Association's Estimated Useful Lives of Depreciable Hospital Assets (American Hospital Publishing, Chicago, 2008)."

"Annual depreciation expense is estimated to be $458,698."

Sources & Uses

Uses	
Construction, Fees & Equipment	**$5,269,000**
Sources	
Debt	$0
Equity	$5,269,000
TOTAL	**$5,269,000**

"This project will be funded through MMC equity reserves. MMC's most recent audited financial statements clearly demonstrate MMC's ability to support the capital project as proposed in this application."

"Please refer to Exhibit 3-A for MMC's most recent audited financial statements."

Staffing

"MMC proposes the following additional staff positions to support the new linear accelerator:

Department	**Position**	**FTEs**
Radiation Therapy	Therapist	1.50
Radiation Therapy - Nursing	Registered Nurse	.75
Radiation Therapy - Physics	Dosimetrist	.50
Radiation Therapy - Physics	Physicist	.50
Ultrasound	Technologist	.03
Environmental Services	Housekeeper	.50
TOTAL	**ALL**	**3.78"**

"As one of the largest private employers in Maine, MMC has a full-service Human Resources department to recruit staff. MMC recruits over 800 new/replacement staff each year. MMC annually reviews its employee compensation and benefit plans and makes the adjustments necessary to remain competitive in the relevant labor market."

III. Economic Feasibility

Operating Expenses

"MMC identifies the following incremental annual operating expenses for this project:

Incremental Operating Expenses (Inflation Adjusted) Cost Center	**2011**	**2012**	**2013**
Salaries & Wages	$323,045	$340,004	$358,631
Employee Benefits	87,868	92,481	97,548
Salary, Wages, Benefits	$410,914	$432,485	$456,179
Non-Salary Expenses	134,008	334,491	350,802
Depreciation	458,698	458,698	458,698
Bad Debt	68,006	76,090	90,106
Total Operating Expenses	$1,071,625	$1,301,764	$1,355,785"

Capital Investment Fund Impact

"Based on the information contained in the completed CONU Financial Module for this project, the estimated Capital Investment Fund debit for this project, if approved, is eight hundred six thousand nine hundred eighty one dollars ($806,981)."

"Please refer to Exhibit 3-B for the completed CONU Financial Module for this Project."

B. CONU Discussion

i. 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:

a. 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

b. 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.

III. Economic Feasibility

ii. Analysis

Inconsistencies and Omissions

Maine Medical Center recently completed two other CON applications. Both applications related to other hospitals becoming members of MaineHealth. Neither application affects the financial numbers presented for this project and as a consequence are not reflected in the financial analysis presented below. Several questions in the financial module were answered incorrectly for this project. The consequence of this is that in the original submission the debit to the Capital Investment Fund (CIF) was calculated and reported incorrectly. The questions in the module were corrected and the analysis reflects those changes.

The capital expenditure provided by the applicant included the following information:

Construction Costs		
1	New Construction	$ 1,726,053
2	Renovation	377,757
3	Site Work	-
4	Fixed Equipment	-
5	Design/Building Contingency (auto-5%)	105,191
6	Additional Requested Contingency (no more than 3%)	-
7	Construction Manager Fee	-
8	Other (please specify in *Assumptions*)	-
	Subtotal	$ 2,209,001
Related Project Costs		Table
1	Major Moveable Equipment	
2	Furnishings, Fixtures & other Equipment	2,546,285
3	Architectural/Engineering Fees	368,000
4	Land Acquisition	-
5	Purchase of Buildings	
6	Administrative Expenses & Permits	-
7	Debt Financing Expenses	0
8	Debt Service Reserve Fund	
9	Contingency (auto-5%)	145,714
10	Working Capital	
11	Other (please specify in *Assumptions*)	
	Subtotal	$ 3,060,000
Total Project Costs		$ 5,269,000

Several inconsistencies were noted by CON in the financial module as compared to the comments provided by the applicant. The applicant included estimating margins of $219,000 while in the financial module the contingency is $250,905. Other identified capital expenditures by the applicant are $5,018,095 in the module as compared to $5,050,000 as described in the narrative above. Overall, these discrepancies do not change the total possible expenditures (estimated expenditures + contingency) of $5,269,000. The difference would have affected the allowable contingency as an approved CON is allowed a minimum 5% contingency. The allowable contingency can be increased to 8% for portions of a project related to construction if requested by the applicant. Maine Medical Center did not request this additional contingency.

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 October 2008, the applicant was presented a format with which to complete significant financial projections, including construction timelines and operating expenses. Twenty-three ratios were developed with the applicant's submission to help elucidate the current financial position of the hospital and the impact of the proposed project on its operating and financial feasibility. The applicant worked with HP Cummings to develop a construction schedule and cost estimate based on the specific nature of the project which involves a significant amount of renovation to critical hospital areas as well as new construction.

The years presented are 2003 through 2007 (audited) and 2008 through 2013 (projected). Also, since the third operating year of the proposed project is 2013, that year is presented as modified for the effects of the CON on hospital operations. A final column related to the difference between the third year with CON compared to third year results without the CON project is also presented. The source for Maine Industry Medians and Northeast Regional Medians is the 2009 Almanac of Hospital Financial and Operating Indicators. We are presenting 2007 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 hospital does in achieving an excess of revenues over expenditures or providing a return. Generating revenue in excess of expenditures 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.

III. Economic Feasibility

Financial Performance Indicators

Profitability	2007	2010	2013	2007 ME State Median	2007 Northeast US Median
Operating Margin	7.94 %	6.61 %	7.09 %	1.97 %	1.88 %
Net Margin	11.66 %	9.99 %	11.29 %	4.30 %	2.70 %
Return on Total Assets	6.81 %	6.38 %	6.78 %	3.94 %	3.62 %

All three margins indicate that if the proposed project occurs then Maine Medical Center would remain profitable. However, comparing operating year 2006 and 2007 indicates that operating margins were decidedly higher in 2007 (7.94%) than in 2006 (6.00%). Maine Medical Center has continued to outperform hospitals in the largest peer group regarding profitability. The 2008 operating margin is projected to be 6.24%. A projected operating margin of 6.99% without this project in 2013 is reasonable given the range that Maine Medical Center has operated in from 2003 through 2007. Maine Medical Center has the means to take on additional expenses based upon excess of revenues over expenditures.

The CONU financial analysis considers information contained in the 2009 Almanac of Hospital Financial and Operating Indicators and generally accepted accounting standards in determining the financial capability of a hospital to support a proposed project.

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 hospital 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. One item of terminology needs to be defined. Throughout the analysis a comparison of high-performance and low-performance hospitals is referenced. These groups are based on the uppermost and lowermost quartiles of hospitals based on their return on investments. This analysis chose to not specifically discuss return on investment but decided instead to use that ratio to group all hospitals in regards to making a comparison to the particular project and applicant.

Non-profit hospitals need to perform at financially sustainable levels in order to carry out their public missions. An adequate operating margin is a key indicator of the financial health of a hospital. Of great concern to CONU is the determination of the reasonableness of the methodology the applicant has used in determining the appropriateness of the timing and scope of the project. Over time, capital expenditures can and need to be made in order to meet the goals expressed in the State Health Plan. CONU evaluates the applicant's ability to organize and respond to its challenges in improving and maintaining the health care system.

III. Economic Feasibility

Operating margins in the high performing hospital group have seen greater improvements in margins while hospitals in the low performing group continue to slide further apart. High performing hospitals are doing better now than five years ago. Over the same time, lower performing hospitals are generally doing worse than five years ago. There is a widening gap between high and low performing hospitals. Improvement in median operating profits for high-performing hospitals drives this widening performance gap. Larger hospitals tend to have an increasing ability to perform at least at a near profitable level as even the lowest 25 percentile large revenue hospitals had a positive operating margin unlike any of the other peer groups based on operating revenues. As a comparison, operating margins in the Northeast Region continue to be considerably lower than in other regions.

The Maine State average for operating margin in 2007 was 1.97%. Maine Medical Center in 2007 was 7.94%, which puts them in the 90th percentile of hospitals in Maine.

The trend for operating margin in the State of Maine has been improving from a low of 1.33% in 2003 to the high of 3.52% in 2006 but the trend lowered to 1.97% in 2007 for the reporting hospitals. Maine Medical Center for the past four operating years including 2007 averaged above 7.0%. 2005 was 11.51% which helped to offset the 4.41% Maine Medical Center reported in 2004. Over the course of the projection through 2013 it is projected that the hospital will have an operating margin rising to 6.99% in 2013 from 6.24% in 2008 (7.09% in 2013 if the project is approved).

The effect of this project on operating margins, as projected by the applicant, is an increase from 6.99% to 7.09% in 2013. This project is not expected to cause a significant impact on the operating margin on the hospital.

Financial Performance Indicators

Profitability	2006	2007	2008	2010	2013
Operating Surplus	$ 33,413,000	$ 46,577,000	$ 39,101,000	$ 48,948,000	$ 61,666,970
Total Surplus	$ 52,547,000	$ 68,394,000	$ 43,428,000	$ 73,979,000	$ 98,190,970

This table validates that Maine Medical Center has the capacity to financially support this project as this project only encumbers 6.75% of the total surplus in 2010.

Liquidity: Current ratios and acid test ratios are indicators of the ability of a hospital 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 hospital

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	2007	2010	2013	2007 ME State Median	2007 Northeast US Median
Current Ratio	2.42	2.64	3.65	1.93	1.53
Days in Patient Accounts Receivable	20.27 Days	24.51 Days	22.90 Days	50.3 Days	46.8 Days
Days Cash on Hand	247.04 Days	216.47 Days	319.96 Days	87.0 Days	68.9 Days
Average Payment Period	117.01 Days	90.44 Days	82.29 Days	48.4 Days	60.7 Days

In terms of liquidity, Maine Medical Center currently (2007) has adequate liquidity, with a payment lag of 97 days between being paid and paying for services. It is interesting to note that the projection indicates a decreasing lag over the forecasted period. The average payment period expanded in 2007 to 117 days from a low in 2004 of 86 days. Forecasted average payment periods are 82 days with or without the project, this strengthens the assurance that cash needs can be met as this hospital has shown significant payment lags in its reported figures before. Days in accounts receivable increased by 4 days in the same period. Days cash on hand was in a range of 202-247 days in the 2003-2007 periods and is projected to increase significantly to more than 322 days by 2013 (320 days if the project is approved).

Liquidity measures a hospital'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 of a hospital.

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

The year 2007 marked an increase of cash on hand nationally. Hospitals with revenue of greater than $150 million have 107 days cash on hand. Maine Medical Center with net patient service revenue of $600 million and days cash on hand of 247 days in 2007 clearly has significantly more cash on hand than the average hospital in its peer group. Interestingly, S & P Bond ratings showed no clear distinction between ratings and days cash on hand for investment grade ratings. This may mean that high performing hospitals do attempt to control excess levels of on-hand cash.

In 2007, the average days cash on hand for all sources for hospitals in the State of Maine was 87 days. Calculated days cash on hand for Maine Medical Center in 2007 was approximately 247 days indicating that Maine Medical Center was in the 90-100th percentile.

According to the same source, between 2003 and 2007 the average days cash on hand remained about 78 days in the Northeast. In 2007, days cash on hand improved from 2006. Between 2003 and 2013 average days cash on hand for Maine Medical Center is projected to increase by 120 days. In 2004, Maine had 5 less days cash on hand than the Northeast Region at 79 days. In 2007, Maine hospitals had increased their days cash on hand by 14 days in three years to be 18 days above the regional average.

The impact of the proposed project is calculated to be a decrease of 2 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 minor decrease in days cash on hand. Based upon source information this hospital is projected to be in greater than the 90th percentile for days cash on hand, compared to today's industry averages, with or without the project. This project will not have a substantial impact on Maine Medical Center's operating ability to meet its cash demands. Even if actual cash on hand is lower, based on additional investments in programs and technology, Maine Medical Center 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 is reviewed in greater detail. Debt Service coverage measures the ability of a hospital to cover its current year interest and balance payments.

Financial Performance Indicators

Solvency	2007	2010	2013	2007 ME State Median	2007 Northeast US Median
Equity Financing	64.7 %	71 %	75 %	59.7 %	48.3 %
Debt Service Coverage	10.86	8.86	11.75	3.34	3.52
Cash Flow to Total Debt	28.4 %	38 %	47 %	22.1 %	17.8 %
Fixed Asset Financing	54.7 %	35 %	39 %	56.9 %	64.0 %

Many long term creditors and bond rating agencies evaluate capital structure ratios to determine the hospital's ability to increase its amount of financing. During the past 20 years, the hospital industry has radically increased its percentage of debt financing. This trend makes capital structure ratios important to hospital management because these ratios are widely used by

outside creditors. Values for these ratios ultimately determine the amount of financing available for a hospital. Debt service coverage is the most widely used capital structure ratio. Debt service coverage minimums are often seen as loan requirements when obtaining financing. Debt service coverage is the ratio of earnings plus depreciation and interest expense to debt service requirements. In 2007, the median Maine hospital's debt service coverage (DSC) was 3.34x.

Maine Medical Center had a DSC in 2007 of 10.86x which places it in the range of 90-100th percentile of Maine hospitals. The trend statewide for 2003-2007 has been increasing with a low of 3.07 in 2003 and a high of 3.71 in 2004. The trend for Maine Medical Center has been increasing for the last 5 years from 5.57x in 2003 to 10.86x in 2007. The trend as projected by Maine Medical Center for this project 2008-2013 is that DSC is expected to increase from 6.73x to 11.68x (11.75x with the project).

Maine Medical Center has the capacity and the ability to have adequate debt service coverage. If Maine Medical Center were to maintain its debt service coverage at a ratio consistent with its recent history, a positive change of 0.07x would not impact its ability to service its loans.

The first two operating years in the projection (2011 and 2012) show debt service coverage of approximately 9.6x, this will increase dramatically in 2013 to 11.68x. Most of the change is related to a 25% decrease in debt service payments in 2013 compared to 2012. Even if actual results are more consistent with years one and two, the debt service coverage would be extremely favorable and is not a cause for concern related to the financial viability of this project.

The 2009 Almanac commented: "We expect fixed asset financing ratios to continue to remain stable during the next five years as hospitals curtail their growth in new capital expenditures and reduce their reliance on long term debt."

The Northeast has considerably higher rates in financing fixed assets than other regions. The 2007 average for hospitals in the State of Maine was 57% in regards to fixed asset financing. In 2007, Maine Medical Center was at 55% which is the 25th-50th percentile for the State of Maine. For the years 2003-2007, for hospitals with revenues similar to Maine Medical Center, 67% is about the average.

The fixed asset financing ratio over the past five years has remained relatively consistent in the State of Maine.

The proposed financing is consistent with the way Maine Medical Center is spending the funds on fixed assets. It appears that MMC is expecting a significant portion of its fixed asset growth to be financed through equity. Total debt in year three of the project (2013) is expected to be approximately $10 million more than 2006. Since last year's projections expected 2012's total debt to be about the same as 2004 this does represent a significant change in planning. While these changes are not unreasonable, they do point out that Maine Medical Center is expanding its capital footprint.

III. Economic Feasibility

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

Financial Performance Indicators

Efficiency	2007	2010	2013	2007 ME State Median	2007 Northeast US Median
Total Asset Turnover	0.58	0.64	0.60	1.16	1.14
Fixed Asset Turnover	1.67	1.49	1.72	2.73	2.86
Current Asset Turnover	1.49	1.77	1.44	3.88	4.25

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. Larger hospitals usually have lower values for turnover than smaller hospitals. This can be attributed to two factors: (1) larger hospitals are most likely to have newer physical plants; and (2) capital intensity is often greater in larger hospitals due to more special services and higher levels of technology.

In 2007, according to the source cited above Maine hospitals had a TAT of 1.16 while Maine Medical Center had a TAT of 0.58. This is indicative of the capital intensive procedures that occur at MMC, its status as the largest most comprehensive medical facility and as a teaching hospital.

In the period of 2004 – 2007 there has been a steady increase in the TAT for Maine hospitals. The expected trend for Maine Medical Center is for TAT to remain stable during the time frame of this project 2009 – 2013. This is reflective of a hospital planning to spend significant funds for capital improvements or investments in technology. This project is not a capital intensive project; however, its impact is slight on the hospital's financial turnover.

Operating Costs in the third operating year are expected to increase by $1,265,679. For the Bureau of Insurance this amount is adjusted to a current value of $1,133,457 in order to calculate the impact of this project on commercial insurance premiums. The impact on the CIF, if approved, would be $1,123,835. The $1,265,679 includes $458,698 in depreciation costs and $806,981 additional costs for staffing and supplies in 2013 dollars. These costs are adjusted to reflect the original costs presented in the application as the financial forecast module was resubmitted to reflect some changes.

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 adequate to support projected operations. Financing and turnover ratios show little impact on the organization as a whole from successfully engaging in this project. The hospital has shown current earnings which are not expected to be significantly impacted by this project.

III. Economic Feasibility

The capital expenditures for this project reflect costs for additional space requirements and renovations to existing space. The additional space requirements reflect the costs of $476 per square foot and renovation costs of $145 per square foot. This is considered to be a reasonable cost estimate according to industry sources due to the special requirements for a cement vault that contains radiation. Construction is slated to take 3 months according to the construction time table submitted by the applicant.

The annual operating costs of this project are driven in large part by:

1) $458,698 in depreciation;
2) $456,179 in salaries and benefits related to the addition of 3.78 full time equivalent positions required to operate the new linear accelerator; and
3) $350,802 in additional supplies and other expenses.

Changing Laws and Regulations

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

iii. Conclusion

CONU recommends that the Commissioner determine that Maine Medical Center has met their burden to demonstrate the economic feasibility of the proposed services in terms of: (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

Overview

"The MMC Radiation Therapy Program Primary Service Area encompasses Cumberland, Lincoln, Sagadahoc and York counties. The MMC Radiation Therapy Program currently includes five linear accelerators: two on the MMC Scarborough campus; and one each on MMC Bramhall, Bath and Cancer Care Center of York County campuses."

"The addition of a linear accelerator to MMC Radiation Therapy Program is necessary in order to meet existing and projected demand, provide timely access for patients, and maintain state of the art facilities and equipment."

"Ongoing demand for radiation treatment time is projected to increase due to aging of the population, which results in a higher incidence of cancer per capita, as well as population growth and increased treatment time per patient."

"Image Guided Radiation Therapy (IGRT) technology, the most advanced form of radiation therapy, provides the best treatment outcomes with less side effects. IGRT significantly impacts the amount of time each patient spends in the vault in order to obtain the necessary daily imaging and to receive the radiation therapy. Average in-vault time per IGRT patient visit is 40 minutes in comparison to 16 minutes per visit for non-IGRT patients."

"Geographic access to radiation therapy throughout the primary service area appears to be reasonable."

"Timely access is hampered due to extended in-vault time associated with the introduction of IGRT."

"Regarding financial access, MMC provides radiation therapy to patients regardless of ability to pay for the service."

Area to be Served

"MMC Radiation Therapy Program's Service Area is:

- Primary: Cumberland, Lincoln, Sagadahoc and York counties.
- Secondary: Androscoggin, Franklin, Kennebec, Knox, Oxford, Somerset and Waldo counties.
- Tertiary: Aroostook, Hancock, Penobscot, Piscataquis and Washington counties; and other states."

IV. Public Need

"MMC Radiation Therapy Program service area definition varies from MMC's general definition of service area; Lincoln and Sagadahoc counties, usually identified as parts of MMC's secondary service area, are included in MMC Radiation Therapy Program's primary service area due to the location of MMC's Coastal Cancer Treatment Center in Bath, Maine and its service to residents of those counties."

Health Need to be Addressed

"Cancers are diseases of the elderly; and, as a result, it would be expected that Maine would have a higher incidence rate of cancer than the national or other New England states' incidence rates due to Maine's demographic profile as one of the oldest populations in the nation the state."

"Maine's elderly population is not the sole factor driving its high rate of cancer diseases. Whether Maine's cancer incidence rate is age adjusted or not, Maine has the highest incidence rate of Invasive Cancer in the Nation and has higher than national average incidence rates for every one of the ten most frequently reported cancers by site. Maine has more underlying cancer disease than the nation."

"The North American Association of Central Cancer Registries identifies Maine as having the highest invasive cancer incidence rate (both crude and age-adjusted rates) in the nation. See http://www.cancer-rates.info/naaccr."

"The National Cancer Institute reports that Maine has higher than average incidence rates for every one of the ten most frequently reported cancers by site."

"See www.cancer.gov"

"The Maine Cancer Consortium, Maine's statewide comprehensive cancer control partnership, declares that cancer is the leading cause of death in Maine."

"See www.mainecancerconsortium.org"

Invasive Cancer Incidence Rates by State/Province in North America				
All Sites, 2001-2005				
State/Province	Population at Risk	Cases	Crude Rate	Age-adjusted Rate
Maine	6522528	39626	607.53	527.24
New Jersey	43095612	233951	542.87	515.70
Massachusetts	32146928	176375	548.65	514.93
Rhode Island	5354370	30157	563.22	514.51
Kentucky	20584144	108913	529.11	512.75
Michigan	50303950	259546	515.96	509.07
Connecticut	17368048	95803	551.60	508.33
Delaware	4088405	21867	534.85	507.31
New Hampshire	6423076	33424	520.37	506.99
Pennsylvania	61751683	363215	588.19	503.64
Washington	30693330	148642	484.28	498.97
Louisiana	20164270	97041	481.25	497.68
Nova Scotia	4677532	26073	557.41	493.79

IV. Public Need

West Virginia	9039206	52781	583.91	490.46
New York	96108703	490219	510.07	489.10
Illinois	63248419	302062	477.58	487.40
Prince Edward Island	686983	3707	539.61	484.64
Iowa	14728719	79655	540.81	481.03
Minnesota	25290487	120409	476.10	480.98
Montana	4594780	24186	526.38	477.61
South Carolina	20745833	101430	488.92	475.23
South Dakota	3827381	19828	518.06	474.53
Nebraska	8688515	43092	495.97	474.38
Oregon	17786906	88432	497.17	472.85
Nevada	11250934	50828	451.77	471.65
Florida	85153562	495408	581.78	470.34
Indiana	30962159	146523	473.23	469.48
Missouri	28586410	141845	496.20	467.68
Oklahoma	17525750	85632	488.61	466.43
Alaska	3240619	10700	330.18	466.07
Georgia	43839923	177638	405.20	465.47
Idaho	6857031	30030	437.94	462.19
North Dakota	3173071	16189	510.20	458.66
Alberta	15818977	64566	408.16	456.23
Arkansas	13644039	67634	495.70	455.36
Manitoba	5813388	28359	487.82	455.35
Texas	99236566	386554	389.53	454.89
Alabama	20230892	96079	474.91	449.23
Wyoming	2508862	11409	454.75	447.89
New Brunswick	3755000	18739	499.04	447.73
Colorado	22736443	89574	393.97	447.06
California	177036749	710810	401.50	446.20
Saskatchewan	4975597	24266	487.70	436.18
Hawaii	6232851	28677	460.09	426.78
New Mexico	9392339	38991	415.14	420.99
Utah	11881914	36869	310.30	411.82
Note: All rates are per 100,000. Rates are age-adjusted to the 2000 U.S. Standard Population.				
Created Dec 16, 2008				
Source: Data as of December 2007 reported by NAACCR as meeting high quality standards for 2001-2005 and include data from state and provincial cancer registries participating in SEER, NPCR, or both, in the US and the Canadian Cancer Registry in Canada. To account for population anomalies caused by Hurricane Katrina in 2005, statistics for AL, LA, and TX are based on cases diagnosed through June 2005.				

Comparison of National and Maine 2004 Age-Adjusted Invasive Cancer Incidence Rates/100,000

Site	Maine	U.S.
1. Prostate	167.4	145.3
2. Female Breast	123.0	117.7
3. Lung & Bronchus	79.1	67.4
4. Colon & Rectum	56.2	49.5
5. Urinary/Bladder	27.8	21.3
6. Corpus & Uterus	26.9	23.1
7. Non-Hodgkin Lymphoma	22.3	19.0
8. Melanomas of the Skin	22.0	17.1
9. Kidney & Renal Pelvis	15.0	14.1

IV. Public Need

10. Leukemia	14.6	11.7

Source: National Cancer Institute, 2004 United States Cancer Statistics

"The Maine Cancer Consortium, Maine's statewide comprehensive cancer control partnership, states:

> *Cancer has become the leading cause of death in our state and leaves no family untouched. It is estimated that 7,910 Mainers will be told, "You have cancer" in 2006. They will join the thousands of individuals in the state who are already living with the disease. By the end of the year, family, friends, and co-workers will mourn the loss of over 3,000 people to cancer.*
>
> *Cancer takes a huge toll on Maine and its people. For the first time in history, cancer is the leading cause of death in Maine. At the end of each day, twenty-two Mainers will have been diagnosed with cancer, and nine will have died from the disease. It is a significant public health issue in terms of personal suffering, increased medical costs, premature deaths, and loss of productive years of life. However, the good news is that cancer mortality is on the decline so fewer Mainers are dying from cancer than ever before.*
>
> *Cancer is a costly disease. In 2004, 7,778 hospitalizations occurred in Maine as a result of cancer with direct and indirect costs of cancer totaling nearly $700 million. The economic, psychological, and social burden of cancer on individuals, families, and communities is beyond measure. This burden can be dramatically reduced if proven advances in prevention, early detection, and care are made available to all Mainers.*
>
> Maine Comprehensive Cancer Control Plan, 2006 – 2010 (American Cancer Society – Maine Chapter, Topsham, Maine, 2006.)"

Population's Need for Service

"MMC presents a need projection for external-beam radiation therapy treatment based on the following data sources and assumptions:

- General Population: Maine State Planning Office, 2000 to 2020 Town Age Forecast.
- Cancer Incidence Population: National Cancer Institute, 2004 United States Cancer Statistics, county-specific age-adjusted incidence rates applied to Maine State Planning Office population projections.
- Radiation Therapy Population: 67% of cancer incidence population. (Source: American Society for Therapeutic Radiology and Oncology, Fact Sheet www.astro.org)

Note: All population projections are rounded to hundreds."

IV. Public Need

"The forecast indicates that Maine's greatest increase in radiation therapy need occurs in MMC's primary service area. Between 2005 and 2015 the primary service area's need grows by 300 radiation therapy cases, and MMC's secondary and tertiary service areas' needs grow by 100 cases each. (Total new cases = 500.)"

"The county-specific age-adjusted incidence rates are based on historical incidence. As a result, these rates do not reflect likely increases in cancer incidence rates due to Maine's continuing increase in ethnic, cultural and racial diversity, especially in southern and central Maine counties."

"The risk of cancer increases with age. Cancer is essentially a disease of the elderly. Maine, already with one of the nation's oldest populations, is forecast to become even older. Holding 2004 age-adjusted incidence rates constant throughout the forecast period does not reflect likely increases in cancer incidence rates due to the aging of Maine's population. County level age cohort specific incidence rates are not published."

"A substantial proportion of cancers are preventable. Changes in lifestyles, health behaviors and environmental factors can reduce the incidence of cancer. Holding 2004 incidence rates constant throughout the forecast period does not reflect potential decreases in cancer incidence rates as a result of significant shifts in Maine residents' lifestyle and health behaviors, or major improvements in environmental factors."

"The introduction of Image Guided Radiation Therapy (IGRT) technology enables more precise targeting of cancerous cells and minimizes damage to adjacent healthy cells. IGRT allows for reduced treatment field margins and dose escalation, and addresses anatomically challenging cancerous tumors that are often found in chronic, ongoing disease processes. This technological advance may enable radiation oncologists to achieve improved clinical outcomes and/or to expand the applicability of radiation therapy to additional cancers. Holding the percent of cancer patients appropriate for radiation therapy constant throughout the forecast period does not reflect likely increases in radiation therapy rates due to technological advances."

IV. Public Need

MAINE MEDICAL CENTER RADIATION THERAPY NEED FORECAST 2005 - 2015

Projected General Population (Maine State Planning Office)

Service Area	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Primary	601,800	607,400	614,700	621,600	628,100	636,300	644,300	650,300	659,900	667,900	675,700
Secondary	488,600	491,400	494,000	498,900	501,300	504,800	507,900	510,900	513,700	518,100	523,600
Tertiary	348,200	347,500	348,200	348,400	349,400	349,300	350,900	351,700	353,000	353,900	354,300
Maine	**1,438,600**	**1,446,300**	**1,456,900**	**1,468,900**	**1,478,800**	**1,490,400**	**1,503,100**	**1,512,900**	**1,526,600**	**1,539,900**	**1,553,600**

New Cancer Cases (National Cancer Institute 2004 County-specific Incidence Rates)

Service Area	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Primary	3,000	3,000	3,100	3,200	3,200	3,200	3,200	3,300	3,300	3,300	3,400
Secondary	2,500	2,500	2,500	2,500	2,500	2,500	2,500	2,600	2,600	2,600	2,600
Tertiary	1,900	1,900	1,900	1,900	1,900	1,900	1,900	1,900	2,000	2,000	2,000
Maine	**7,400**	**7,400**	**7,500**	**7,600**	**7,600**	**7,600**	**7,600**	**7,800**	**7,900**	**7,900**	**8,000**

New Radiation Therapy Cases (American Society for Therapeutic Radiology and Oncology Rate)

Service Area	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Primary	1,900	1,900	2,000	2,100	2,100	2,100	2,100	2,200	2,200	2,200	2,200
Secondary	1,600	1,600	1,600	1,600	1,600	1,600	1,600	1,700	1,700	1,700	1,700
Tertiary	1,300	1,300	1,300	1,300	1,300	1,300	1,300	1,300	1,400	1,400	1,400
Maine	**4,800**	**4,800**	**4,900**	**5,000**	**5,000**	**5,000**	**5,000**	**5,200**	**5,300**	**5,300**	**5,300**

IV. Public Need

Service Area Population's Access to Radiation Therapy

Timely access

"As demonstrated throughout this application the introduction of IGRT involves extended in-vault time, which hampers timely access to care. It is not increased patient volume, changes in market share or improved geographic access that drive the need for this additional linear accelerator, rather it is the need for continued timely access."

Financial Access

"MMC provides radiation therapy to patients regardless of ability to pay for the service."

Geographic access

"Geographic access to radiation therapy throughout MMC's primary service area appears to be reasonable. MMC uses reasonable travel time to the nearest Radiation Therapy site as an indicator of geographic access. Patients may travel to a more distant radiation therapy site due to a variety of reasons including patient choice, referring physician's preference or subspecialty needs, i.e., pediatric patients. With the exception of subspecialty care, these are mostly matters of physician and patient choice, not access. Proximity defines geographic access."

"MMC's primary service area is served by MMC and other radiation therapy providers who are in close proximity to MMC's primary service area. The following table identifies all the Radiation Therapy sites that are within reasonable travel distance of MMC's primary service area."

Site	Provider	Location
MMC-Aligned Sites		
MMC Cancer Institute	MMC	Scarborough
Southern Maine RT Institute	MMC	Portland
Coastal Cancer Treatment Center	MMC	Bath
Cancer Care Center of York County	Southern Maine Medical Center, Goodall Hospital & MMC	Sanford
Other Sites		
Cynthia Rydholm Center	Central Maine Medical Center	Lewiston
Harold Alfond Center	MaineGeneral Medical Center	Augusta
Seacoast Cancer Center	Wentworth Douglass Hospital	Dover, NH

"For purposes of determining reasonable travel time MMC excludes its Southern Maine Radiation Therapy Institute (SMRTI) from the analysis. MMC typically schedules radiation therapy outpatients to the Scarborough, Bath and Sanford sites."

IV. Public Need

"SMRTI is located on MMC's main campus on Bramhall Street in Portland. MMC continues its efforts to decompress its main campus. SMRTI serves as a special purpose Radiation Therapy site. The SMRTI linear accelerator is used for:

- Stereotactic radiosurgery - These procedures often are two to three hours in duration.
- Inpatient radiation treatment - These patients' cancers typically have metastasized and require multiple site treatments at a time resulting in prolonged treatment times.
- Pediatric radiation treatment – These patients are often sedated to prevent movement during treatment, which also results in extended treatment times."

"MMC engaged NBT Solutions to perform a drive time analysis to determine the primary service area population's proximity to radiation therapy services, whether provided by MMC or another provider."

"NBT Solutions used block level information on travel time and population for this analysis. This level of information is the smallest geographic unit for which this information is available."

"The analysis indicates that slightly less than 90% of the primary service area population is within a thirty-minute drive of radiation therapy services, and nearly 65% are within a twenty-minute drive."

"Less than 3% of the service area population is more than 45 minutes from a radiation therapy site. These residents live in the remote northwestern reaches of Cumberland and York counties; easternmost portion of Lincoln County; and Chebeague, Cliff, Cousin, Long and Peaks islands."

"The issue needing to be addressed is not improving geographic access; rather the issue is timely access."

"Please refer to Exhibit 4-A: MMC Primary Service Area Drive Times to RT Sites for a map showing the drive time bands."

MMC RT Primary Service Area Population's Geographic Access Analysis

		Travel Time				
Year	**Age Group**	**w/i 20 min**	**20-30 min**	**30-45 min**	**45 + min**	**TOTAL**
2008	All Ages	362,400	136,000	47,500	14,800	560,700
	% of All Ages	64.6%	88.9%	97.4%	2.6%	
	45 & Older	158,100	61,400	22,500	7,300	249,300
	% of 45+	63.4%	88.0%	97.1%	2.9%	
2013	All Ages	377,700	142,200	49,200	15,200	584,200
	% of All Ages	64.7%	89.0%	97.4%	2.6%	
	45 & Older	174,700	68,000	24,400	8,000	275,100
	% of 45+	63.5%	88.2%	97.1%	2.9%	

IV. Public Need

NOTES:

"Drive time band population figures are non-duplicated. Primary service area existing site rings above show 362,400 people within a 20 minute drive of existing RT sites, and 136,000 people between 20 and 30 minutes drive. These numbers are added together to make a total of 498,400 people within a 30 minute drive time. Percentages reflect this combined total divided by the total service area population."

"Population Estimates source: Applied Geographic Solutions (AGS) block group level estimates and projections."

"Drive-time source: Applied Spatial Technologies' DriveZone application."

"Where drive-times cover partial block-groups, a geographic proportion count is allocated."

Population's Demand for MMC Radiation Therapy Service

"MMC presents a demand forecast for MMC Radiation Therapy service based on the following data sources and assumptions:

- MMC's actual radiation therapy patients by town and service area for the period 2005 – 2008 – MMC internal data.
- Developing MMC's presumed radiation therapy Maine market share for the period 2005 through 2008 based on the following formula for each town: MMC Actual Patients / Projected Maine Radiation Therapy Population = MMC Market Share. Town-specific information is rolled up into county and service area composites.
  Note: MMC uses the 3 highest volume years during the 2005 to 2008 period to adjust for the times when MMC's linear accelerators were off line for replacement/upgrade to IGRT capabilities and for Cancer Care Center of York County's (CCCYC) partial first year of operation. Coastal Cancer Treatment Center's linear accelerator was off line for 5 months during FY 2005, Cancer Care Center of York County provided radiation therapy services for seven months during FY 2006 and one of the Scarborough linear accelerators was off line for 5 months during FY 2008.
- Applying that market share to the projected annual radiation therapy patient population to forecast MMC Radiation Therapy Population. This market share is held constant throughout the forecast period."

Impact of Image Guided Radiation Therapy on Linear Accelerator Operations

"MMC presents a forecast of IGRT impact on MMC's Linear Accelerator Operations based on the following data sources and assumptions:

- MMC percent of patients receiving IGRT - MMC internal data.
- Annual increase in percent of patients receiving IGRT –As MMC clinicians become more familiar with IGRT, they continue to expand the IGRT applications that they provide.

MMC IGRT applications are anticipated to become consistent with the experience of other mature IGRT providers over time. Note: The need forecast holds the percent of cancer patients suitable for radiation therapy constant. The demand forecast changes the proportion of radiation therapy patients receiving IGRT.

- MMC actual average number of visits per non-IGRT and IGRT patients - MMC internal data.
- MMC anticipated changes in average visits per non-IGRT and IGRT patients – forecast changes in patient population as more cancer sites are treated using IGRT technology.
- MMC actual average time per treatment for non-IGRT IMRT– MMC internal data.
- MMC actual average time per treatment for IGRT – MMC internal data."

Conservative Forecast

"MMC's forecast is conservative. Overall population need for radiation therapy may increase due to continuing technological advances. Increased precision may enable practitioners to treat a higher percentage of cancer cases. Research related to IGRT may demonstrate its applicability to a higher percentage of cancer cases. Cancers of the lung and esophagus are currently being actively investigated. Pelvic cancers (rectal, bladder and uterus) are potential sites for IGRT future investigations and applications as well."

MAINE MEDICAL CENTER RADIATION THERAPY MMC DEMAND ACTUAL 2005-2008 FORECAST 2009 - 2015

MMC Radiation Therapy Cases

	Actual				Projected						
Service Area	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**
Primary	860	820	860	820	950	950	950	990	990	990	990
Secondary	90	110	110	90	100	100	100	110	110	110	110
Tertiary	50	40	40	50	50	50	50	50	50	50	50
TOTAL	**1,000**	**970**	**1,010**	**960**	**1,100**	**1,100**	**1,100**	**1,150**	**1,150**	**1,150**	**1,150**

MMC Radiation Therapy Cases - Distribution of IGRT & Non-IGRT Treatment Cases

	Actual				Projected						
	2005	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**
IGRT				50	85	125	160	180	215	245	245
Non-IGRT	1,000	970	1,010	910	1,015	975	940	970	935	905	905
TOTAL	**1,000**	**970**	**1,010**	**960**	**1,100**	**1,100**	**1,100**	**1,150**	**1,150**	**1,150**	**1,150**

MMC Radiation Therapy Cases - Distribution of IGRT & Non-IGRT Treatment Visits

	Actual				Projected						
	2005	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**
IGRT Visits / Patient				34.1	34.1	34.1	34.1	33.9	33.5	33.5	33.5
Non-IGRT Visits / Patient	28.8	32.3	31.5	27.1	26.4	26.4	26.4	26.4	26.4	26.4	26.4
IGRT Visits				1,700	2,900	4,260	5,450	6,100	7,200	8,200	8,200
Non-IGRT Visits	28,760	31,290	31,780	26,320	26,790	25,740	24,810	21,910	20,820	19,810	19,810
TOTAL VISITS	**28,760**	**31,290**	**31,780**	**28,020**	**29,690**	**30,000**	**30,260**	**28,010**	**28,120**	**28,010**	**28,010**

MMC IGRT/Non-IGRT Distribution of Visits & Duration of Visits in Hours

	Actual				Projected						
	2005	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**
IGRT % of Visits	0%	0%	0%	6%	11%	14%	18%	22%	26%	29%	29%
Treatment Time											
IGRT (40 min/visit)	-	-	-	1,140	2,190	2,850	3,650	4,090	4,820	5,490	5,490
Non-IGRT (16 min/visit)	7,600	8520	8,460	7,050	7,170	6,890	6,640	5,860	5,570	5,300	5,300
TOTAL HOURS	**7,600**	**8,520**	**8,460**	**8,190**	**9,360**	**9,740**	**10,290**	**9,950**	**10,390**	**10,790**	**10,790**

IV. Public Need

"Based on these actual and projected treatment hours, and 1,700 annual treatment hours per linear accelerator (250 days x 8 hrs/day x 85% efficiency), MMC developed a demand based capacity and compares that capacity to MMC's actual and proposed linear accelerator capacity. MMC believes that this comparison demonstrates that MMC request for an additional linear accelerator is reasonable."

MMC RADIATION THERAPY DEMAND FORECAST
MMC Radiation Therapy Program Demand Based, Actual and Proposed Number of Linear Accelerators

	Actual				**Projected**						
	2005	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**
Demand Based	4.8	5.0	5.0	4.8	5.5	5.7	6.1	5.9	6.1	6.3	6.3
Actual/Proposed	4	5	5	5	5	5	6	6	6	6	6

Determining the Appropriate Site for New Linear Accelerator

"MMC's primary service area covers four counties with different population demographics and densities, different projected changes in population, different county-specific incidences of overall cancer, and varying site-specific rates of cancer. (Note: IGRT is not appropriate or necessary for treating neoplasms in all body sites.)"

"MMC does not provide radiation therapy to 100% of the radiation therapy service population, some patients due to personal choice, referring physician preference, proximity and other reasons choose to receive their treatment at non-MMC aligned radiation therapy sites."

"As a result of these factors, service demand by MMC Radiation Therapy Program site varies, and it is as critically important to locate capacity to provide geographic and timely access to treatment. Determining where to install a linear accelerator needs to consider both these access factors as well as how efficiently a linear accelerator will be used."

"MMC projected how patient demand and vault time would be distributed among its four sites. MMC then developed a capacity needs per site based on each accelerator operating 1,700 annual treatment hours (250 days x 8 hrs/day x 85% efficiency) to determine the best distribution of capacity among its sites."

IV. Public Need

MMC FORECAST PATIENT & VAULT HOURS DEMAND AND CAPACITY NEED BY TOTAL PROGRAM AND INDIVIDUAL SITE

	2011				
	All Sites	**Bramhall**	**Scarborough**	**Bath**	**Sanford**
Patients	1,100	215	500	245	140
Vault Hours	10,290	2,010	4,675	2,290	1,310
Capacity	6.1	1.2	2.8	1.3	0.8
	2012				
	All Sites	**Bramhall**	**Scarborough**	**Bath**	**Sanford**
Patients	1,150	215	515	255	165
Vault Hours	9,950	1,860	4,460		1,430
Capacity	5.9	1.1	2.6	1.3	0.8
	2013				
	All Sites	**Bramhall**	**Scarborough**	**Bath**	**Sanford**
Patients	1,150	220	520	245	165
Vault Hours	10,390	1,990	4,700	2,300	1,490
Capacity	6.1	1.2	2.8	1.3	0.9
	2014				
	All Sites	**Bramhall**	**Scarborough**	**Bath**	**Sanford**
Patients	1,150	220	520	245	165
Vault Hours	10,790	2,070	4,880	2,300	1,550
Capacity	6.3	1.2	2.9	1.3	0.9
	2015				
	All Sites	**Bramhall**	**Scarborough**	**Bath**	**Sanford**
Patients	1,150	220	520	245	165
Vault Hours	10,790	2,070	4,880	2,300	1,550
Capacity	6.3	1.2	2.9	1.3	0.9

"At maturity, currently projected to be in the 2013 – 2015 timeframe, MMC's projected linear accelerator capacity need and proposed capacity by site are:

MMC FORECAST NEEDED AND PROPOSED CAPACITY BY SITE

	All Sites	**Bramhall**	**Scarborough**	**Bath**	**Sanford**
Needed Capacity	6.1	1.2	2.9	1.3	0.9
Proposed Capacity	6.0	1	3	1	1"

"MMC's Bramhall linear accelerator serves highly specialized functions, including inpatients. Therefore, the Bramhall site is able to extend its hours of operation (evenings and/or weekends) and treat inpatients without causing hardship since the inpatient population is not traveling to and from treatment on a daily basis. Maintaining capacity of a single linear accelerator for the Bramhall campus appears appropriate."

IV. Public Need

"CCCYC's Sanford site serves central and southern York County, and nearby New Hampshire border towns. Based on current projections, at maturity this site will continue to have available capacity during regular business hours to treat additional patients. Maintaining capacity of a single linear accelerator for the Sanford site appears appropriate."

"MMC's Bath site serves northeastern Cumberland, Lincoln and Sagadahoc counties; and also serves a significant role in meeting the treatment needs of Knox and Waldo county residents. Demand at this site, projected to continue increasing, already is straining a single linear accelerator's capacity to meet need. However, based on current projections, this site would use only 30% of available time to meet demand; adding a second linear accelerator at this site would result in 70% slack capacity, an unwarranted inefficiency."

"MMC's Scarborough site serves central and northern York County and Cumberland County. Based on current projections, adding a third accelerator at this site addresses projected demand and does not result in significant slack capacity or inefficiencies."

"MMC is proposing to locate the new linear accelerator at its Scarborough site."

"MMC believes this proposal represents the best alignment of need, demand and capacity."

2005 Estimated Cancer Incidence

"In November 2008 the American Cancer Society released its 2008 report and noted a national decrease in the incidence and mortality rates for cancer. (American Cancer Society. *Cancer Facts & Figures 2008*. Atlanta: American Cancer Society; 2008.)"

"On December 1, 2008 MMC obtained a prepublication draft of the Maine cancer incidence report under review by the Maine Center for Disease Control and Prevention, Division of Chronic Disease. (Maine Department of Health and Human Services. *2005 Cancer Incidence Report, Maine Cancer Registry*. Augusta, Maine: Maine Department of Health and Human Services, unpublished.) This report contains 2005 county-specific estimated cancer incidence rates, which vary from the 2004 rates used in the series of analyses presented in this application. MMC reran this series of analyses using these unpublished data. There is no material difference between the results of the two analyses, as demonstrated in the following table."

FORECAST NEEDED CAPACITY BY SITE, 2005 INCIDENCE RATES

	All Sites	Bramhall	Scarborough	Bath	Sanford
Needed Capacity	6.3	1.2	3.0	1.4	0.8
Proposed Capacity	6.0	1	3	1	1

IV. Public Need

B. CONU Discussion

i. Criteria

Relevant criterion 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. Analysis

The applicant is proposing additional space to add an additional linear accelerator to their Scarborough campus. This project involves 3,700 square feet of construction and 2,600 of existing square feet will be renovated.

MMC has asserted that there is a need for an additional linear accelerator in the 2013-2015 timeframe as IGRT becomes MMC's treatment of choice. IGRT significantly impacts the amount of time each patient spends in the vault in order to obtain the necessary daily imaging and to receive the radiation therapy. The average in-vault time per IGRT visit is 40 minutes in comparison to 16 minutes per visit for non-IGRT visits. Outcomes were not shown to be improved with IGRT treatments. The demonstration of improved quality and outcome measures is necessary to show the quantifiable need for an additional linear accelerator.

Primarily, MMC uses IGRT to treat prostate cancer and head/neck cancer. MMC is expecting IGRT will be further developed to be used to treat other cancers in the near future. MMC has indicated that they will need an additional linear accelerator due to the change in the distribution of visits between IGRT and non-IGRT visits. The applicant did not provide measurable outcomes specific to the current use of IGRT. Dr. Dora Mills, in her State Health Plan assessment to CONU, stated that no evidence was presented that mortality is reduced as a result of IGRT. Dr. Josh Cutler raises several issues in his assessment to CONU questioning clinical outcomes.

At the public informational meeting MMC indicated that their hours of operation are from 6:15 AM and are able to go as late as 6:00 PM, often flexing with the volume.

IV. Public Need

MMC has looked at extending hours past 6:00 PM; however, with the majority of patients being elderly, the early morning appointments are preferred due to driving difficulties and less accessible transportation during evening hours.

Need Forecasting

The needs assessment is based on several different assumptions. CONU did not review all of the underlying data; however, CONU has the following concerns about the applicant's needs assessment: (1) the capacity of the linear accelerator equipment; (2) the ability to replicate some of the information presented by the applicant; and (3) the completeness of the information provided by the applicant.

The following discussion is related to the three charts the applicant presented that are on page 28 of this report.

The applicant presented a chart entitled Projected General Population (Maine State Planning Office) shown on page 28 of this report. This chart shows the population of the three service areas totaling 1,438,600 individuals in 2005 and increasing to 1,553,600 individuals by 2015. The increase in population is an 8% increase in the ten years. This totaling line is labeled "Maine." According to 2005-2007 data from the U.S. Census Bureau (www.census.gov), Maine's population is approximately 1,314,780 individuals. This is a difference of 6%. It is unclear if MMC is including populations outside of Maine inside its widest service area.

The chart entitled New Cancer Cases is based on the 2004 county-specific incidence rate. CONU determined the service area incident rates by comparing new cases to population. The result of that comparison is that residents of MMC's primary service area have a 10% lower incidence rate of cancer than its tertiary service area (0.50% compared to 0.55%). This difference was not discussed.

The final chart on the same page entitled New Radiation Therapy Cases is based on the American Society for Therapeutic Radiology and Oncology rate. The chart indicates a higher percentage of new cancer cases treated with Radiation Therapy for tertiary areas than for MMC's primary service area. The chart also reflects an increase of 2% in radiation therapy as a treatment modality for cancer in this time frame. CONU noted that the new cancers and radiation treatment incidence numbers are rounded off to the nearest hundred. The rounding of the number of radiation therapy causes significant percentage changes from year to year in the assumptions.

The applicant did not address the Maine CDC's District Health Profiles in regards to its assessment of need. The Cumberland District Health Profile indicates that the cancer incident rate for males is 571.4 per 100,000 and for females is 453.9 per 100,000. The applicant suggests that the combined incident rate is 514.8 per 100,000.

IV. Public Need

Market Share

It is not clear in the applicant's presentation how the number of new cases in the "state" is related to a different chart, entitled MMC Radiation Therapy Cases. CONU divided the 860 primary service area MMC cases by the 1,900 statewide cases and determined that the "market share" was 45% in 2005. Market share decreased to 39% in 2008. The projected portion of the chart is consistent with a 45% "market share" for primary service area patients. The remaining market shares are consistently 6% and 4% respectively.

The applicant suggests that its forecast is conservative. CONU can point to several reasons why it does not agree with that characterization. The Maine Quality Forum cited a lack of evidence in the application towards improved quality. Dr. Cutler in his review noted that the utilization of image-guided radiation therapy (IGRT) increases the duration of therapy visits (40 minutes for an average IGRT therapy session vs. 16 minutes for an average non-IGRT therapy session). This has the potential of reducing access by patients to services by 60%; each treatment is increased by 250%.

Intensity-modulated radiation therapy (IMRT) has been used for a longer period of time than IGRT. There is a body of evidence to support its utilization. There are studies of IMRT that demonstrate prolonged survival rates in patients with a variety of cancerous conditions. Evidence demonstrates that radiation toxicity is reduced when dosing is anatomically accurate with IMRT. CONU has not been presented with evidence that utilization of IGRT technology has added to the quality of clinical outcomes, namely fewer radiation side-effects. Evidence supporting its effectiveness on treating specific types of tumors, compared with the more traditional treatment methods would be helpful to form an opinion on how the benefits of IGRT treatment exceed its costs.

Demand

The applicant noted significant off-line time for replacement upgrades to IGRT capability and for a partial first year for CCCYC. This rationale was used to explain why market share was adjusted upwards from the stated methodology to its highest percentage of the four years presented in the chart. This is the **first** of **five** assumptions that affect the determination of the demand for linear accelerators.

MMC did not discuss alternative providers. No explanation was given for where treatment occurred, or what steps were taken to expand hours of service if an accelerator was off-line. This is problematic in regards to the assertion that the "market share" is 45%.

The applicant presented a distribution of IGRT and non-IGRT treatment cases. These two treatment methodologies reflect a **second** significant assumption that increases demand for linear accelerators. The assumption is that the proportion of IGRT radiation therapy cases will increase from 1 in 20 (5%) to more than 1 in 5 (21%) in the next six years. This assumption is questionable based on the comments from the Maine Quality Forum.

IV. Public Need

According to the applicant, the increasing shift from non-IGRT to IGRT treatment stops in 2015.

A **third** significant assumption related to demand is the 25% increase in the number of visits each individual patient would make to a facility. This significant change in patient comfort and convenience was not discussed in the application. The increase in visits from one treatment modality to another increase to 29% more IGRT and then decreases to 27%. Part of this may be attributable to the types of cancer being treated, but it is not indicated in the application.

Despite the shift to IGRT and more visits per patient the applicant projects the number of Treatment visits to first increase and then decrease. CONU recalculated these projected visits and found errors in the original calculation. 2008 visits appear to be over reported by 1,654 and 2012 – 2015 appear to be under reported by 4,090 visits annually.

The applicant states that IGRT treatments average 40 minutes per visit while non-IGRT treatments are 16 minutes in duration. This is a **fourth** significant assumption. The assumption does not consider increased efficiency over time due to operator efficiencies common from repeating a new methodology. The calculation error explained above was determined by CONU staff to be related to the determination of non-IGRT treatments and duration. CONU's calculation of IGRT treatment hours is the same as the applicant. The applicant appears to overstate year 2008 hours by 446 hours and the applicant appears to understate 2012-2015 hours by 985 to 1,084 hours.

The **fifth** significant assumption is that the linear accelerators will only be available for 85% efficiency per 8 hours per day. The applicant did not provide information regarding the reliability history of linear accelerators in general or their experience with their current operations. CONU research indicated that a 5% reliability factor was the goal. Preventative maintenance of 3-4 hours weekly with 2-4 days of scheduled shut down maintenance should be included in the annual schedule. Without more detailed information on the specific reliability of the applicant's current equipment, CONU can only compare the divergent results and report the information as a range.

The applicant suggests that treatment hours per accelerator are limited to 1,700 hours annually. CONU calculates availability of an accelerator to 2,325 hours (249 days less 4 days of maintenance at 10 hours per day with 95% availability). This is a significant deviation.

IV. Public Need

The following chart is presented to indicate the range of "needed capacity".

Radiation Therapy Demand Forecast Corrected

	2008	*2009*	*2010*	*2011*	*2012*	*2013*	*2014*	*2015*
Original Demand	**4.8**	**5.5**	**5.7**	**6.1**	**5.9**	**6.1**	**6.3**	**6.3**
Hours Available	1700	1700	1700	1700	1700	1700	1700	1700
Demand - Applicant Adjusted	**4.5**	**5.3**	**5.7**	**6.0**	**6.4**	**6.7**	**7.0**	**7.0**
Hours Available - CONU	2325	2325	2325	2325	2325	2325	2325	2325
CONU Demand	**3.3**	**3.9**	**4.2**	**4.4**	**4.7**	**4.9**	**5.1**	**5.1**

These errors and inconsistencies as described above are a critical to the need determination application. Reliance on further projections is not appropriate until clarifying information is presented by the applicant.

The remaining analysis is presented so CONU can make clear its concerns regarding the presentation of the remainder of the applicant's methodology for determining needed capacity.

The Bramhall location serves highly specialized functions including inpatients. Including the Bramhall location in a chart presenting forecasted need by location is not appropriate because its patients and uses are different. The chart also included Bath as part of its service area. The applicant explained that a 30 minute radius included 500,000 individuals. The applicant did not show that the Bath location (42 miles from Scarborough) was a reasonable alternative to the Scarborough location. CONU considers the Scarborough and Sanford locations to be poor alternatives for Portland residents (considering travel time) but a reasonable alternative for much of the service area around Scarborough.

Sensitivity Analysis

A sensitivity analysis of the project shows that the revenues would exceed all expenses even if revenues were decreased to 60% of the forecasted values while expenses remained the same. This would allow for an acceptable range of need for services to be 60-100% of the forecasted amount of vault hours without negatively impacting overall profitability of the hospital.

Accessibility

Currently, MMC is considered a preferred hospital under the state employee insurance plan, effective February 1, 2009. MMC has previously provided CONU with information regarding their Free Care Policy and 990 forms.

IV. Public Need

iii. Conclusion

CONU recommends that the Commissioner find that Maine Medical Center 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

A. From Applicant

Impact on Total Health Care Expenditures

"For the January 2009 Hospital Large Project Cycle the Bureau of Insurance methodology estimates a project's impact based on the project's incremental 3rd year operating costs adjusted to the year ending June 30, 2008. The computation is contained in the Financial Module."

"Please refer to Exhibit 3-B: CONU Financial Module."

Availability of State Funds

"Approval of this project has no impact on MaineCare. MaineCare currently reimburses MMC for radiation therapy services at a rate that is below MMC's current cost of providing care. Additional costs as a result of this project will not be reimbursed by MaineCare, whose rate setting is independent of MMC's fee schedule and costs of care. MaineCare, Maine's Medicaid program, accounts for approximately 3% of MMC Radiation Therapy Program's payer mix."

Alternatives Considered

1. THE PROPOSED ALTERNATIVE: Locate the Additional Linear Accelerator at MMC Scarborough Campus

"MMC's Scarborough site serves central and northern York County and Cumberland County. Based on current projections, adding a third accelerator at this site addresses projected demand and does not result in significant slack capacity or inefficiencies."

"MMC Radiation Therapy Program operates as a "hub and spoke" program. The hub is MMC Radiation Therapy Program on the Scarborough campus. Placement of this linear accelerator at the hub of MMC Radiation Therapy Program improves access for the greatest number of patients."

"MMC believes that this alternative results in appropriate access both in terms of hours of operation and travel distance for the patient populations that it serves."

2. Maintain Current Operations

"Maintaining the current locations, number and scheduled hours of MMC Radiation Therapy Program does not provide patients the appropriate timely access to a necessary cancer treatment service. Delays in scheduling create an undesirable risk

of untimely access to treatment or, in some cases, a patient's decision to defer or forego treatment altogether. These are direct risks to patient safety."

"Delays in treatment increase the risk that a neoplasm becomes more widely disseminated. The more widely disseminated a neoplasm becomes, the more difficult its cure. Those cancers most amenable to cure are those which are confined to a single organ or to one region of the body. Once cancers become disseminated, treatment is generally palliative rather than curative. Untreated, malignant neoplasms almost always prove fatal in spite of the fact that their growth rates may vary widely."

3. Extend Hours and Days of Service

"MMC's principal radiation therapy site in Scarborough with two linear accelerators already operates ten hours per day (7:00 am to 5:00 pm) with the ability to flex hours to provide emergency treatments, accommodate peak volume periods and/or absorb complex procedures. Emergency treatments are performed on Saturdays/Sundays on an as needed basis."

"These hours of operation are tailored to the needs of an elderly treatment population. Elderly patients prefer early morning treatments, and often have difficulties driving after dark or finding a reliable transportation during evening hours. Current hours of operation in radiation therapy also allow patients who are working to obtain treatment before their workday starts, during their lunch break, or on their commute home."

"Consecutive treatments are required in order to be effective, with a 2 day break per week in order to provide normal cells the time needed to repair themselves from radiation exposure. The average number of treatments per patient is 29."

"MMC's other radiation therapy sites typically operate 8 ½ hour daily schedules with the ability to flex hours to provide emergency treatments, accommodate peak volume periods and/or absorb complex procedures. Emergency treatments are performed on Saturdays/Sundays on an as needed basis."

4. Defer Increase in Linear Accelerator Capacity

"The need and demand forecast demonstrate that the additional capacity is necessary to maintain the current level of service and timely access. Delaying this project diminishes timely access to a necessary service."

5. Locate the Additional Linear Accelerator at MMC Bramhall Campus

"MMC's Bramhall linear accelerator serves highly specialized functions, including inpatients. Therefore, the Bramhall site is able to extend its hours of operation and treat inpatients later in the day without causing hardship since the inpatient population

is not traveling to and from treatment on a daily basis. Maintaining capacity of a single linear accelerator for the Bramhall campus appears appropriate."

"MMC continues relocating more outpatient services to sites away from the Bramhall campus to help alleviate traffic and congestion at its main campus, which are ongoing concerns."

"Space on the Bramhall campus is at a premium. Attempting to locate an additional accelerator adjacent to the existing Bramhall linear accelerator would involve substantial excavation and/or disruption of other services since the vault is located completely below grade. While possible, this option is cost prohibitive. Locating an additional vault elsewhere on the Bramhall campus would be inefficient, since staff and support functions would need to be duplicated to each linear accelerator if the Department operated in two physically separated suites."

6. **Locate the Additional Linear Accelerator at MMC Bath or Sanford Satellite Campus**

"Locating the linear accelerator at one of MMC Radiation Therapy satellite campuses (Bath or Sanford) does not address the timely access issues present at MMC's Scarborough site, nor does either of these options make efficient use of an additional linear accelerator."

"CCCYC's Sanford site serves central and southern York County, and nearby New Hampshire border towns. Based on current projections, at maturity this site will continue to have available capacity during regular business hours to treat additional patients. Maintaining capacity of a single linear accelerator for the Sanford site appears appropriate."

"MMC's Bath site serves northeastern Cumberland, Lincoln and Sagadahoc counties; and also serves a significant role in meeting the needs of Knox and Waldo county residents. Demand at this site, projected to continue increasing, already is straining a single linear accelerator's capacity to meet need. Based on current projections, adding a second linear accelerator at this site would result in significant slack capacity, an unwarranted inefficiency."

7. Develop another Satellite campus

"MMC's analysis (See Section IV Need) demonstrates that the primary service area has reasonable geographic access to radiation therapy services, whether provided by MMC or another provider. The issue needing to be addressed is not improving geographic access; rather the issue is timely access, a need most acutely experienced at MMC's Scarborough site."

V. Orderly and Economic Development

"Developing another satellite campus for the additional accelerator would create the same undesirable access concerns as placing it at either existing satellite campus. This option would also require additional capital to purchase and develop a site, and to build the full complement of functional space needed for a stand-alone unit."

8. Install an Alternative Technology

"Proton beam radiotherapy is a well-established alternative to x-ray (photon) radiotherapy. Photon radiotherapy deposits dose along the entire energy beam path to the tumor as well as beyond the depth of the tumor. Proton radiotherapy deposits most of its energy at a specific depth and then stops entirely. This allows the physician to tailor the deposition of dose to the specific depth and shape of the tumor while simultaneously reducing the damage to surrounding normal tissue. The advantages of proton radiotherapy over conventional radiotherapy are emphasized in areas of the body with critical adjacent structures (e.g. eye, brain, base of the skull, spine, and prostate) as well as in pediatric tumors."

"Current proton beam radiotherapy technology involves the use of large-scale cyclotrons originally developed for research that cost $100 to $150 million, weigh hundreds of tons and require extraordinary shielding (18-ft walls). About twenty institutions around the world, seven of which are located in the United States, have installed proton therapy systems."

"Massachusetts Institute of Technology and Still River Systems are developing and introducing a smaller, less complex, less costly particle accelerator designed specifically for hospital radiation therapy programs. The first installations in the United States are scheduled to begin in 2008 or when FDA approval is secured. As of December 1, 2008 this system is awaiting FDA approval. These installations are estimated to range in cost between $15 and $20 million. In comparison, the addition of a linear accelerator at MMC Scarborough campus is estimated to cost less than $6 million."

V. Orderly and Economic Development

B. CONU Discussion

i. Criteria

Relevant criterions 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. Analysis

The utilization of image-guided radiation therapy (IGRT) increases the duration of therapy visits (40 minutes for an average IGRT therapy session vs. 16 minutes for an average non-IGRT therapy session). This has the potential of reducing access by patients to services by 60%; each treatment is increased by 250%. The traditional intensity-modulated radiation therapy (IMRT) has been used for a longer period of time. There is a body of evidence to support its utilization. There are studies of IMRT that demonstrate prolonged survival rates in patients with a variety of cancerous conditions. There is also evidence demonstrating that radiation toxicity is reduced when dosing is anatomically accurate with IMRT.

CONU has not been presented with evidence that utilization of IGRT technology has added to the quality of clinical outcomes, namely fewer radiation side-effects or a decrease in mortality rates. Given the increased time required to perform IGRT therapy sessions, it would require that it not be applied to all types of tumors. Evidence supporting its effectiveness on treating specific types of tumors, compared with the more traditional treatment methods help demonstrates how the benefits outweigh the disadvantages of IGRT treatment.

Total 3rd year operating costs are projected to be $1,265,679 and of that amount MaineCare’s 3rd year cost is $25,314 ($1,265,679 x 2.0%), which is both the Federal and State portions combined. Currently the impact to the Maine budget per year would be approximately $8,860 ($25,314 x 35% (State Portion)). The applicant estimates that the actual costs to the MaineCare budget are minimal. Due to the increased duration of treatment sessions and the lack of evidence demonstrating the advantages of IGRT over

more traditional radiation therapy treatments, CONU cannot justify yearly increase to the state budget.

The applicant has not demonstrated that IGRT is more efficient or effective than IMRT treatments. The applicant states that there are no alternative considerations available to this project that are less costly. MMC is the principal radiation therapy center in the Portland Hospital Service Area.

Until MMC has demonstrated the benefits of the project, as discussed in Section IV above, CONU cannot comprehensively compare the costs and benefits of the project to conclude that this proposed project is consistent with the economic development of health facilities and health resources for the State.

iii. Conclusion

CONU recommends that the Commissioner find that Maine Medical Center 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

Please indicate which State Health Plan goals are being met. Please ONLY complete the description sections on the priorities that pertain to your application/project.

State Health Plan goals targeted by Applicant

☒ The applicant is redirecting resources and focus toward population-based health and prevention.

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

☒ 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 consideration and for the other services throughout the hospital.

☒ 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 applicant has regularly met the Dirigo voluntary cost control targets.

☒ 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.

☒ 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 LEEDS certified-architect that incorporate "green" best practices in building construction, renovation and operation to minimize environmental impact both internally and externally.

VI. State Health Plan

A. From the Applicant

Overview

"MMC, as an applicant, and its proposed project to add a linear accelerator to MMC Radiation Therapy Program are consistent with the intent, goals and objectives of Maine's 2008 – 2009 State Health Plan and the Maine Comprehensive Cancer Control Plan 2006 – 2010, a disease-specific health plan recognized by the State Health Plan."

Maine's 2008 – 2009 State Health Plan

"The Governor's Office of Health Planning and Finance's Maine's 2008 – 2009 State Health Plan (pp. 78-80) declares that projects that meet more of the following attributes shall receive higher priority than projects that meet fewer of these attributes in the Certificate of Need review process."

1. ***The applicant is redirecting resources and focus toward population based health and prevention.***

a. Applicant's Discussion on Priority

MaineHealth Cancer Initiative

"MaineHealth has launched a new major initiative focusing on cancer. The investment in this initiative for FYE 2009 is three hundred seventy three thousand dollars ($373,000). Goals for this new initiative include:

- For the five most prevalent cancers, adopt evidence-based clinical care guidelines, identify quality metrics and reporting methodology, and provide a range of educational supports to promote consistent use of guidelines.
- Support each MaineHealth organization in attaining or maintaining the appropriate level of cancer care accreditation, including appropriate level of credentialing necessary for delivering care in accordance with desired accreditation (e.g. Board-certified surgeons, surgeons with sentinel node training.)
- Improve access to clinical trials.
- Improve access to genetic counseling services.
- Support the development of patient navigation and survivorship programs to improve patient access, engagement, and satisfaction.
- Improve the Network Registry to support increased access and data review for outcomes and quality metrics.
- Coordinate services regionally to provide maximum access to care (i.e. improve access to specialists.)"

VI. State Health Plan

Other MaineHealth Population-based Initiatives

"Maine Medical Center actively participates in MaineHealth initiatives in chronic disease and case management. The mission of MaineHealth is "Working together so our communities are the healthiest in America". We have made financial and human resource commitments to this mission which is based on the following beliefs:

- Health care costs in Maine(and nationally) will continue to increase due to demographic, technological and normal inflation factors which are generally beyond our control;
- If healthcare is to remain affordable to the vast majority of our citizens, changes will need to be made to the manner in which we currently provide and finance that care;
- The long-term solution to balancing increased utilization is to improve the health of the people of Maine;
- The "health care challenge" requires short-term solutions which improve the quality (both care delivery and outcomes), cost-efficiency (both clinical and administrative) and access to health care."

"MaineHealth's approach to improving the health of its communities focuses on two major types of initiatives:

- Health status improvement initiatives which address a health issue which is amenable to intervention based on specific, scientifically based programs
- Clinical integration initiatives which seek to improve the delivery of coordinated, integrated services to selected populations, particularly those with chronic diseases or for conditions where clinical guidelines and protocols have been demonstrated to improve outcomes."

"Management of populations with chronic diseases has become a major focus of our clinical integration initiatives. From 2010 to 2025, the population in Maine over the age of 65 will double. Based on national studies we can expect that 60% of the population will have at least one chronic condition and 40% will have two or more. A recent study by researchers at Johns Hopkins, the US HHS Agency for Health Research and Quality and the University of Pennsylvania predicts that by 2030, 87% of the population will be overweight, 51% will be obese and the prevalence of overweight children will nearly double. Since 1998, MaineHealth has been building health status improvement and clinical integration initiatives to address these challenges, funding them through a combination of MaineHealth dues, investment income and grants. Below are the MaineHealth budgets for these initiatives for FY 2008 and 2009."

	FYE 2008	FYE 2009
Clinical Integration	$3,325,000	$4,597,000
Health Status Improvement	2,736,000	3,055,000
Community Education	1,041,000	1,242,000
Total	$7,102,000	$8,894,000
% of MaineHealth Total Budget	32%	32%

VI. State Health Plan

"Beginning in FY 2006, MaineHealth began providing partial support for these initiatives through fund balance transfers from member organizations. At the time, a limit for such transfers was set at 0.4% of each organization's net assets. The actual amounts provided through this process increased from $385,000 in FY 2006 to $1,058,000 in FY 2007 and FY 2008 (representing 0.06%, 0.14% and 0.12% respectively of members' net assets). We have not asked for more than we thought could be well used and we have continued to be successful in securing other support through grants. As part of a recently completed strategic planning process, MaineHealth adopted a strategy that recognized that, while it has been reasonably successful in its initiatives, MaineHealth must step up the scope and pace of these initiatives by committing over the next several years up to 1% of its net assets annually to support these initiatives. At present, 1% of members' net assets would represent a commitment of $7 million which would be added to commitments of dues revenue, investment income and grant support."

"Presented below are brief summaries of the major health status improvement and clinical integration initiatives supported by these resources. Detailed descriptions of these initiatives and the outcomes they have produced to date to improve the health of communities we serve are on file with the Certificate of Need Unit as part of the public record associated with MaineHealth and Waldo County Healthcare certificate of need application for WCHI Membership in MaineHealth and are included in this application by reference."

- "AH! Asthma Health – a comprehensive patient and family education and care management program targeting childhood asthma initially and now expanded to include adults;
- Target Diabetes – a comprehensive diabetes education and care management program;
- Caring for ME – designed to improve the ability of primary care providers to care for patients with depression and to educate patients and families on their roles in self management;
- Healthy Hearts – designed to improve the care of patients with congestive heart failure and to educate patients and families on their roles in self management;
- Clinical Improvement Registry - a computer based system provided to primary care practices in the MMC Physician-Hospital Organization and several other hospital physician organizations. The Registry provides patients and physicians with data on the management of chronic illnesses including asthma, diabetes, cardiovascular disease, depression and heart failure;
- MMC Physician Hospital Organization Clinical Improvement Plan – the Plan includes funding 23 practice based registered nurse care managers which support 265 physicians in 71 primary care practices, currently they are focusing on diabetes, depression and asthma;
- Raising Readers – a health and literacy project that provides books to all Maine Children from birth to age five at their Well Child visits;
- Care Partners – provides free physician and hospital care, drugs and care management to over 1,000 adults in Cumberland, Kennebec and Lincoln counties who do not qualify for federal and state programs.
- Center for Tobacco Independence – MaineHealth through a contract with the State manages the statewide smoking cessation program.

VI. State Health Plan

- Acute Myocardial Infarction/Primary Coronary Intervention Project - collaborative effort of 11 southern, central and western Maine hospitals, and their medical staffs that standardizes and improves the care of patients experiencing a heart attack.
- Stroke Program - assures that all patients with stroke receive the most up to date, high quality, efficient care; provides a coordinated system of care for stroke patients who must be transferred to another facility.
- Emergency Department Psychiatric Care - follows a medical clearance protocol for patients seen in the ED who need hospitalization; follows medication recommendations for agitated patients; and decreases the need for restraints and seclusion, including training ED staff how best to work with agitated patients.
- Healthy Weight Initiative – addresses adult and youth obesity, including a 12 step action plan ("Preventing Obesity: A Regional Approach to Reducing Risk and Improving Youth and Adult Health").
- Youth Overweight - MaineHealth and MMC have joined with several other organizations including Hannaford, United Way, Unum, Anthem and TD Banknorth, to design and implement a 5 year initiative on youth overweight."

"MaineHealth believes that these initiatives are entirely consistent with the goals of the State Health Plan regarding how to approach chronic disease. Evidence from our programs demonstrates that the Chronic Care Model can and does work."

"Please refer to Exhibit 6-A: Letourneau, Korsen, Osgood, Schwartz, "Rural Communities Improving Quality through Collaboration," Journal for Healthcare Quality, (National Association for Healthcare Quality, Vol. 28, No. 5, pp. 15-27)."

b. Maine CDC/DHHS Assessment

"The applicant makes strong investments in population-based health and prevention, though no redirection is mentioned. No such new investment is mentioned. No such plan for collecting data or evaluating is mentioned."

c. CONU Findings

The applicant has provided information on its numerous initiatives. In addition, MaineHealth, the parent of MMC has launched a new major initiative focusing on cancer. The investment in this initiative for FYE 2009 is $373,000. It is not clear how much, if any, of this investment is focused on population-based health and prevention.

VI. State Health Plan

2. ***The applicant has a plan to reduce non-emergent ER use.***

a. Applicant's Discussion on Priority

Portland Hospital Service Area Emergency Service Utilization

"The available evidence indicates that Portland Hospital Service Area (HSA) exhibits appropriate emergency services utilization. MMC provided the Certificate of Need Unit a series of analyses in its Bramhall Emergency Department Expansion certificate of need application, which demonstrate that Portland HSA residents' utilization of Emergency Medical Services visits per capita rate is comparable to the national per capita rate; and is significantly below the rates for New England, Maine and other Maine HSAs."

"The results are summarized in the accompanying table."

Comparison of 2003 Emergency Visit Per Capita Use Rates

Geographic Area	Per Capita Use Rate
Portland HSA	**384.2**
Total United States	382.0
US Census Division 1: New England	441.9
Maine	542.5

"Sources: American Hospital Association, AHA Hospital Statistics, 2006 Edition, (Health Forum, Chicago, 2006) Table 3, p. 11; Table 5, p. 31, Table 6, p. 87; Maine Health Data Organization's hospital inpatient database; and Maine Health Information Center's Outpatient Hospital Utilization Report Package, Report # 4."

"Please refer to Exhibit 6-B: MMC's Bramhall Emergency Department Expansion CON Application Excerpts."

MaineHealth and MMC Initiatives Influencing Emergency Service Utilization

"Maine's 2008 – 2009 State Health Plan identifies the following as some of the issues likely to be influencing the over-utilization of emergency services:

- Unavailability of primary care doctors after office hours.
- Patients without a primary care doctor.
- Availability of full service care in one stop – imaging, lab, specialists.
- Ease of ED-use – no need to make a doctor's appointment.
- Lack of available services for people suffering from alcoholism, drug addiction, and/or mental health problems.
- Ineffective chronic care management, resulting in complications. (SHP, p. 54)"

"Long term reductions in use of emergency services are directly related to: (1) the development of initiatives to improve the health status of the population and control chronic disease: and (2) ensure there is convenient, timely and affordable access to physicians. As described above,

VI. State Health Plan

MaineHealth has developed and is implementing across the region a broad base of health status improvement and chronic disease management initiatives, to address such conditions as asthma, diabetes, depression, congestive heart failure and obesity. Expansion of these programs into all of MaineHealth's eleven county service area is a priority and will be funded through the net asset transfer mechanism described above. MaineHealth has also implemented its CarePartners Program which provides primary care, referrals to specialists and care management to low income adults who are not eligible for state and federal programs. The program currently serves residents of Cumberland, Lincoln and Kennebec Counties and has demonstrated its ability to reduce emergency services utilization."

"MMC's participation in MaineHealth disease and care management initiatives, and MMC's community access initiatives appear to be having a positive effect on local emergency services utilization."

Primary care physicians' availability after hours

"MMC operates Family Practice Centers, large primary care practices, at two locations: Portland and Falmouth. The Portland Center provides extended evening hours (5 pm to 8 pm) three evenings per week. The Falmouth Center is open until 8 pm Monday through Thursday and from 10 am to 2 pm on Saturday."

Patients without a primary care physician

"CarePartners, made possible through MaineHealth, Maine Medical Center, and volunteer providers throughout the community, is a health care access program for adults in the Greater Portland Area who do not have or are not eligible for any other health care coverage, and meet certain financial guidelines. CarePartners works with volunteer physicians and other service providers to facilitate and coordinate health care services to eligible members, assisting members by completing applications to patient assistance programs through the various pharmaceutical programs, accessing network specialists, and working with patients to access community resources and programs as appropriate."

"MMC's Outpatient Clinics provide comprehensive, primary medical care, as well as specialized care to specific patient populations. These clinics include: Adult Cystic Fibrosis, Infectious Disease, General Pediatric, Enterostomal, International, Pediatric G.I., Endocrine, Lipid, NICU Follow-up, Nerve Block, Primary Care (Medical), Pediatric Continuity, Surgical, Urgent Care, Pediatric Pulmonary, Burn Wound Care, Spina Bifida, Cardiac, Broncho-Pulmonary Dysplasia, TB, Dermatology, Colposcopy, Teen Pregnancy, G.I., Cystic Fibrosis, Teen Clinic, Muscular Dystrophy, Cleft Lip and Palate, Developmental, Spasmodic Sysphonia, Musculoskeletal, and Feeding."

"MMC's Emergency Department Primary Care Linkage Program links ED patients with MMC Physician Hospital Organization and CarePartners primary care providers in the community. Referral to these programs is especially beneficial for ED patients with chronic conditions; both

programs embrace MaineHealth's Chronic Disease Model. This program provides patients with access to community-based services, reducing inappropriate ED utilization."

"Availability of full service care in one stop – imaging, lab, specialists, and Ease of ED-use – no need to make a doctor's appointment."

"MMC's Brighton FirstCare is a Fast Track / Urgent Care Unit, open from 9 a.m. to 9 p.m. every day. This program provides the same features of convenient, one-stop, on-demand service with a less costly charge structure than the Bramhall Emergency Department, further encouraging people to use this service instead of the main Emergency Department. All patient visits to this location are reported as emergency visits."

"Lack of available services for people suffering from alcoholism, drug addiction, and/or mental health problems"

"MMC's Outpatient Psychiatry Department provides a spectrum of psychiatric services to patients of all ages; serves as a training site for psychiatric residents, medical, nursing, social work, and psychology students; and engages in a number of innovative research projects, contributing state of the art knowledge to the field. Services include: the Adult, Child, and Geriatric Divisions at McGeachey Hall; Intensive Outpatient and Partial Hospital Programs at McGeachey Hall; the Anchor Program, PIER Program, and Psychology Division at 932 Congress Street; and the Access and Access Diversion Teams at 576 St. Johns Street."

"MMC's Geriatric Center offers medical and memory impairment assessments. All medical assessments involve a Geriatrician, Occupational Therapist, and Social Worker; memory impairment assessments are conducted by a team involving a Geriatric Psychiatrist, Advanced Practice Psychiatric Nurse, Geriatrician, Occupational Therapist, and Social Worker. The team manages any psychiatric issues relating to the aging process in cooperation with the primary doctor and family. All team members are either Board Certified or licensed."

"Ineffective chronic care management, resulting in complications"

"MMC has implemented MaineHealth initiatives in chronic disease and care management described elsewhere in this proposal. All of these programs improve the ability of patients to manage these diseases, thereby reducing the need for emergency department visits and hospital admissions where these chronic diseases cause acute episodes. As noted in Exhibit 6-A, evidence from our programs demonstrates that the Chronic Care Model can and does work."

b. Maine CDC/DHHS Assessment

"The applicant does include their existing plan for reducing ER use."

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c. CONU Findings

The applicant has provided information about ED Services. However, this is not an ED project and the applicant provided no information that adding an additional linear accelerator would have an effect on reducing ED services.

3. ***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 consideration and for other services throughout the hospital, as well as a plan – to be specified in the application – to quantifiably track the effect of such strategies using standardized measures deemed appropriate by the Maine Quality Forum.***

a. Applicant's Discussion on Priority

Commitment to Quality

"MaineHealth is committed to being recognized by patients, payors and providers as the benchmark for quality and safety, patient and family experience and evidence based use of resources. On a quarterly basis the MaineHealth board reviews quality performance measures for all member and affiliate organizations, including:

- National Quality Forum hospitals measures
- Performance of participants in the MaineHealth Vital Network (electronic ICU monitoring system)
- Home health clinical measures
- Long term care clinical measures"

"In 2007, the MaineHealth Board adopted the following 10 year vision for quality and safety:

> *In 2017 MaineHealth will be a nationally recognized leader in health care quality and safe patient and family centered care. We will achieve that status not because we seek national prominence for its sake but rather it will be founded on an unwavering system level commitment to quality and safety and continuously improving the health of the communities we serve. Achieving and sustaining excellence starts with our belief that every single patient in the communities we serve deserves the highest quality health care services that we can provide in an efficient and cost effective manner. We will communicate publicly our quality, safety and cost information to aid patients and their families in making informed choices when seeking health care services. The core of our success will be our boards and management teams focusing at all levels on quality and safety as the critical elements driving strategic planning. Across the continuum of care our physicians, nurses, staff, patients and their families will collaborate to set high standards, monitor performance, openly share results and work together to continuously improve quality and safety."*

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"In order to implement that vision, MaineHealth has established its Center for Quality and Patient Safety under the direction of Dr. Vance Brown, MaineHealth Chief Medical Officer. The Center will focus on:

- Board Engagement – All MaineHealth and member board members will complete a core curriculum in quality and safety developed by the Center. That training will enable every board member to better understand quality, safety and performance improvement and enable them to take a greater role in ensuring quality and safety in their organization
- Education and Consultation – Center staff will provide support and expertise to member organizations in developing and implementing quality and safety initiatives. Ownership and responsibility for quality improvement and monitoring will remain at the local level
- Performance Measurement and Reporting – Member organizations are overwhelmed at present by the number of organizations requesting quality and safety performance information. The Center will provide support for data collection, measurement and reporting allowing members to focus on actual quality and performance improvement.
- Accreditation and Regulatory Support – The Center will provide the support and expertise to ensure member organizations attain and maintain all appropriate licensure and accreditation standards
- System Wide Performance Targets – Working with members, MaineHealth will identify system wide performance targets to ensure consistency and accountability for major clinical processes. Included in these efforts will be clinical decision support systems that facilitate the monitoring of performance."

"Please refer for additional information to Section VII Outcomes and Community Impact and Exhibit 2-L MMC Performance Improvement Plan of this application."

b. <u>Maine CDC/DHHS Assessment</u>

"The applicant includes such a plan indicating a culture of safety."

c. <u>CONU Findings</u>

The applicant has demonstrated a commitment to quality and has a plan to approve upon that commitment.

4. ***The project leads to lower cost of care / increased efficiency through such approaches as collaboration, consolidation, and/or other means.***

a. <u>Applicant's Discussion on Priority</u>

"This project experiences economic advantage due to MMC Radiation Therapy Program's scale. The Program assures the availability of certified physicians, physicists, dosimetrists and nurses. Overhead costs do not increase with the addition of this linear accelerator. Locating the linear

accelerator on the Scarborough campus reduces the need for additional staff. Placement of the vault adjacent to an existing vault eliminates the need to build the 4th vault wall, reducing capital requirements."

"MMC has a long history of collaboration, especially in oncology services. Major oncology-related collaborative efforts include:

- Southern Maine Radiation Therapy Institute – Cooperative effort involving 17 Maine hospitals, establishing a consolidated radiation therapy in Portland.
- Coastal Cancer Treatment Center – Cooperative effort involving 6 Maine hospitals, establishing a radiation therapy site in Bath.
- Cancer Care Center of York County - Joint venture involving 3 Maine hospitals, establishing a medical oncology and radiation therapy site in Sanford.
- MaineHealth Cancer Initiative – This newly launched Clinical Integration Initiative is available to any and all practitioners and providers desiring to participate.
- OneMaine Health Community Clinical Oncology Program Grant -MaineHealth is leading an OneMaine Health (MaineHealth, Eastern Maine Health and MaineGeneral Health) initiative to write a Community Clinical Oncology Program (CCOP) grant for increased statewide access to National Cancer Institute clinical trials."

b. Maine CDC/DHHS Assessment

"The applicant mentions overall cancer treatment collaboratives, though it is unclear if patients seen in other programs would have easy access to the new accelerator."

c. CONU Findings

The applicant has demonstrated a commitment to collaboration through the cancer care projects it is involved in. The applicant has expressed a commitment to consolidation by adding the additional linear accelerator to its existing facility in Scarborough that actually reduces costs by eliminating the need to build a 4th vault wall by building adjacent to the other existing vaults. It is unclear is patients seen in other programs would have easy access to the new accelerator.

5. ***The project improves access to necessary services for the population.***

a. Applicant's Discussion on Priority

"The current proposal to add a linear accelerator to MMC Radiation Therapy Program maintains appropriate timely access to this necessary service. This accelerator is necessary to due to the introduction of Image Guided Radiation Therapy. Without the additional capacity, timely access to this needed service is diminished. Delays in radiation therapy present a clear and direct risk to patient safety."

"Maine Health and Human Services Commissioners have approved each of MMC's linear accelerator Certificates of Need. In every case the Commissioner found that the service was necessary and that the project improved access."

"MMC provides access to its radiation therapy program regardless of ability to pay."

b. Maine CDC/DHHS Assessment

"It is unclear from the materials presented if this service is necessary for the population."

c. CONU Findings

The applicant has shown a commitment to access. The outpatient radiation therapy program was moved to the Scarborough campus to reduce the need for additional space at the Bramhall campus thereby creating greater access and parking availability for its patients. The outpatient radiation therapy program is available to all residents of the service area regardless of their ability to pay. It is not clear that IGRT technology is a necessary service for the population.

6. ***The applicant has regularly met the Dirigo voluntary cost control targets.***

a. Applicant's Discussion on Priority

"MMC has responded positively to the annual allowable increases in the Dirigo Cost Per Adjusted Discharge and the 3% limit on operating margins."

b. Maine CDC/DHHS Assessment

"The applicant says it's met the cost control targets of Dirigo."

c. CONU Findings

The applicant did not provide CONU with the historical data necessary to judge this priority. From the financial forecast module the applicant submitted, the 3% limit on operating margins have been exceeded since 2003 and is forecasted to exceed the 3% limit on operating margins through 2013.

7. ***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

"The Bureau of Insurance (BOI) and the Certificate of Need Unit (CONU) make this determination. MMC is happy to respond to any concern, issue, question or request for additional information to assist BOI and/or CONU in making this determination."

"Please see Exhibit 3-B the Certificate of Need Financial Module for this project."

VI. State Health Plan

b. Bureau of Insurance Assessment

"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 Maine Medical Center'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 (DHHS), 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 methodology compares the CON project's Year 3 incremental operating and capital costs (adjusted to the year ending December 31, 2009) to the estimated private health insurance average premium per person for the same period. Based on the model, I estimate that the maximum impact of this CON project on private health insurance premiums in Maine Medical Center's service area for the project's third year of operation will be approximately 0.101% ($0.101 per $100) 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 0.033% ($0.033 per $100) of premium."

c. CONU Findings

The additional impact to regional and statewide insurance premiums are minimal. Any increase in insurance premiums is not warranted absent a demonstration of public need for the proposed project.

8. ***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

Inpatient Electronic Medical Record

"Beginning in 2002, MMC has been implementing its electronic inpatient medical record/patient management system, which includes computerized order entry and results reporting for medication, lab and imaging. It provides clinical decision support, e.g., drug interactions, standing orders/protocol sets. Physicians at the hospital, in their offices and at home have access to an electronic version of the record which is updated after discharge."

Ambulatory Electronic Medical Record

"In 2007, the MaineHealth Board approved a plan recommended by management to make available an ambulatory electronic medical record system to employed and independent

physicians on the medical staffs of all MaineHealth member hospitals. The system is also being offered to physicians on the medical staffs of MaineHealth's affiliate hospitals. The plan calls for bringing 400 physicians (180 employed and 220 independent) at Maine Medical Center, Miles Memorial Hospital, St. Andrews Hospital, Stephens Memorial Hospital and Spring Harbor Hospital on to the system by 2010. MaineHealth is investing $10.4 million, its member hospitals $2.5 million and the independent physicians $2.7 million ($15 million total) to bring these 400 physicians on to the system. First year (FY 2008) implementation is underway at several practice sites."

"MaineHealth has selected Epic, one of the nation's leading information technology organizations, as its strategic partner to implement the MaineHealth ambulatory electronic medical record. Epic allows healthcare providers the ability to address a variety of information needs, and will help MaineHealth, and its member organizations, build strong relationships with patients, facilitate an exchange of information across episodes of care, and allow anytime/anywhere data access for physicians. Epic is consistently ranked as the top EMR in its category by respected industry evaluators. The system allows clinicians to improve care, protect patient safety and enhance financial performance. With Epic, providers have the right information at the right time."

Picture Archiving and Communications System

"MaineHealth has developed a PACS (imaging archiving and retrieval system) project for Maine Medical Center, Stephens Memorial Hospital, Miles Memorial Hospital, St. Andrews Hospital, Maine Medical Center Regional Medical Center, Southern Maine Medical Center and 12 other sites."

MaineHealth VitalNetwork (Electronic ICU Monitoring)

"In 2005, MaineHealth began offering to Maine hospitals an electronic system for monitoring real time patients in intensive care units. The system is staffed at a central location by critical care trained/certified physicians and nurses. The Leap Frog Group has determined that electronic monitoring systems satisfy its quality/safety standard for care of ICU patients by Board Certified critical care physicians. The system provides continuous monitoring of selected patient conditions and has a video system which allows the VitalNetwork Staff to view the patients. Because of its capabilities, the system has been proven to reduce ICU mortality. (Kuzniewicz MW, Vasilevskis EE, Lane R, et al., Impact of Methods of Assessment and Variation in ICU Risk-Adjusted Mortality: Potential Confounders. Chest 2008:133; pp. 1319-1327.) MaineHealth was the first health care system in New England to implement the system, and has invested in excess of $ 4 million in the project."

"Currently, the VitalNetwork is operational for all critical care beds (except neonates) at Maine Medical Center, Miles Memorial Hospital, Maine Medical Center Regional Medical Center, Waldo County General Hospital, Pen Bay Medical Center, Franklin Memorial Hospital and Southern Maine Medical Center. Implementation is in the planning stages at MaineGeneral Medical Center and Mercy Hospital."

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HealthInfoNet

"MaineHealth has supported HealthInfoNet since its inception:

- MaineHealth leaders were active participants in developing the HealthInfoNet.
- MaineHealth has contributed $ 250,000 over two years to underwrite the project.
- Bill Caron and Frank McGinty MaineHealth's President and Executive Vice President have served on the Board of Directors of HealthInfoNet.
- MaineHealth acted as the guarantor for the initial eighteen-month engagement of the HealthInfoNet's Executive Director.
- MaineHealth is negotiating to make its proprietary MaineHealth information system available to HealthInfoNet."

"OneMaineHealth (MaineHealth, MaineGeneral and Eastern Maine Health) selected and funded HealthInfoNet as the data bank for medical records to share statewide patient information such as medications, allergies and health problems regardless of where care is delivered."

b. Maine CDC/DHHS Assessment

"The applicant has implanted a number of EMRs and has fully participated in HealthInfoNet."

c. CONU Findings

MMC and MaineHealth are one of the original founding sponsors of the HealthInfoNet Pilot and has committed significant resources to the project.

9. ***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

"MMC has engaged SMRT as the project's architectural firm. The design team includes professionals who are Leadership in Energy and Environmental Design (LEED) accredited by US Green Building Council. The building is being designed and constructed in manner to minimize environmental impacts. Factors being addressed include energy efficiency, material/resource consumption and indoor environmental quality to the extent possible and practical given the nature and scope of the project."

b. Maine CDC/DHHS Assessment

"The project is being done with a LEDDS certified architect according to the applicant."

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c. CONU Findings

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

Maine Comprehensive Cancer Control Plan 2006 – 2010

"Maine's 2008 – 2009 State Health Plan recognizes the Maine Cancer Consortium's Maine Comprehensive Cancer Control Plan 2006 – 2010 (MCCCP) as a disease-specific State Health Plan. (See SHP, Appendix III - Links to Recent Maine State Government Health Plans and Reports.)"

MCCCP Cancer Early Detection

"Several national organizations, including the U.S. Preventive Services Task Force and the American Cancer Society, have developed screening guidelines for several types of cancer. These guidelines set the standard for cancer screening and represent the best in scientific knowledge and clinical practice to date. *(MCCCP, p. 46)"*

MaineHealth promotes use of evidence-based Screening Guidelines

"Evidence based screening guidelines have been adopted or are under development by MaineHealth work groups for colon cancer, breast cancer and prostate cancer. The guidelines are based largely on guidelines developed by NCCN, USPSTF or other professional review organizations."

"MaineHealth takes the position that patient decision aids should be made available whenever possible to help patients make screening decisions. This position is noted within the MaineHealth screening guidelines. MaineHealth actively seeks patient decision aids to recommend patients and families."

"MaineHealth's Clinical Integration Division formed Site-specific Workgroups comprised of primary care physicians, gastroenterologists, cancer genetic specialists, data analysts and administrative support staff who are affiliated with MaineHealth and its member and affiliate hospitals."

"These workgroups reviewed the professional literature, achieved consensus regarding the appropriate, evidence-based screening guidelines, and developed resources to assist physicians and to maximize the screening of eligible patients across Maine. The guideline materials currently are being distributed to physicians throughout the MaineHealth system. Work groups are being convened to address two additional site-specific protocols."

"Increase the number of referrals by 100% for cancer genetic services by 2010. Baseline: 284 referrals and 138 consultations to cancer genetic services. *(MCCCP, p. 60)"*

"MaineHealth and MMC are committed to providing improved access to genetic counseling services. Genetic counseling services are available in Maine, yet underutilized. Primary care providers and specialists are unfamiliar with specific criteria for identifying patients with a possible hereditary cancer. Criteria need to be disseminated to community providers supported by ongoing education to assure optimum rates of testing and referral for counseling. Community based genetics counseling may be achieved through telemedicine efforts for patient convenience and most efficient use of scarce expert resources. Currently counseling is available primarily in Portland and sparsely available in other communities."

"MaineHealth is supporting publication and dissemination of guidelines for identifying patients at risk for familial cancer syndromes and in need of genetic counseling and/or testing. MaineHealth is assessing demand for genetic screening in the region and necessary resources, and is seeking grant funding for telemedicine or other pilot(s) to enable genetic counseling where unavailable."

MCCCP Cancer Treatment

"MCCCP presents the following objectives to assure that all Maine residents have access to high-quality cancer treatment information and services. (pp. 68-9.)"

"Objective 1: Increase the use of national treatment guidelines among professionals in Maine by 2010."

MMC Radiation Therapy Oncology Group Membership

"MMC Radiation Therapy Program has attained Active Affiliate Member status with the Radiation Therapy Oncology Group (RTOG), a Radiation Therapy-specific indicator of high quality care. RTOG members are committed to complying with RTOG published clinical protocols and treatment guidelines in all aspects of radiation therapy, dose prescription and delivery."

"Objective 2: Increase by 15% oncology certification of health care professionals by 2010."

MMC Radiation Oncologists

"100% of MMC Radiation Therapy Program's Radiation Oncologists are board certified by the American Board of Radiology."

MMC Physicists and Dosimetrists

"All of MMC's physicists and dosimetrists are American Board of Radiation (physicists) or American Board of Medical Dosimetrists (dosimetrists) Board-certified or Board-eligible."

VI. State Health Plan

MMC's Certified Registered Nurses

"71% of the RNs involved with MMC's Radiation Oncology Program at the Scarborough campus are oncology certified nurses; 66% of the RNs working in the outpatient oncology clinics are certified. Pending test results, 88% of the RNs involved with MMC's Outpatient I-V Therapy at Scarborough will also be oncology certified by early 2009."

"Objective 3: Increase patient utilization of cancer treatment education resources by 2010. Strategy # 5: Promote recruitment and enrollment of Mainers in state and national level clinical trial"

MMC Clinical Trials Patient Accrual Rate

"MMC is Maine's leader in patient accruals to cancer clinical trials, with approximately 400 patients enrolled in various studies during 2006 and 2007. This accrual rate is nearly double the national benchmark for hospitals of comparable size."

Community Clinical Oncology Program Clinical Trials

"MaineHealth is leading an OneMaine Health initiative to write a Community Clinical Oncology Program (CCOP) grant for increased statewide access to National Cancer Institute clinical trials. The CCOP is a large network that enables patients and physicians to participate in clinical trials across the United States and in Puerto Rico. Additionally a grant has short and longer term benefits including structural options that may address Institutional Research Board concerns of smaller hospitals as well as staffing and knowledge management issues."

Children's Oncology Group (COG) Clinical Trials

"The Maine Children's Cancer Program participates in the national Children's Oncology Group (COG) Clinical Trials, and employs an on-site research team that manages the program's participation in the trials."

MMC Radiation Therapy Program Radiation Therapy Oncology Group Membership

"MMC Radiation Therapy Program has attained Active Affiliate Member status with the Radiation Therapy Oncology Group (RTOG), a Radiation Therapy-specific indicator of high quality care. RTOG members are committed to complying with RTOG published clinical protocols and treatment guidelines in all aspects of radiation therapy, dose prescription and delivery. The Department participates in a number of RTOG clinical trials. The presence of Board-certified Radiation Oncologists and Image Guided Radiation Therapy is imperative for MMC to participate in these clinical trials, offering cutting-edge radiation therapy to MMC patients."

"The Maine Center for Cancer Medicine and Blood Disorders is a private medical group practice composed of oncologists and hematologists, including Jacquelyn Hedlund, MD, MMC Cancer

Institute's Medical Director. MCCM provides access to clinical trials, and integrated cancer care with other healthcare professionals."

"MMC's three-fold mission involves patient care, provider education and research. The Maine Medical Center Research Institute (MMCRI) is MMC's focal point for its efforts to advance clinical and translational research to improve patient care outcomes and, ultimately, the nation's health."

"The Research Institute's cancer-related activities involve grants, clinical trials and clinical laboratory research. These activities have been performed in conjunction with: National Institute of Health, National Children's Oncology Group, Radiation Therapy Oncology Group, American Cancer Society, American Heart Association, Center for Innovation in Biotechnology, Agency for Health Care Research & Quality, Dana-Farber Cancer Institute, St. Elizabeth's Medical Center, New York University Medical School, Duke University Medical School, University of California, and University of Louisville, as well as a number of pharmaceutical companies including Abbott Labs, Amgen, Eli Lily, and Schering-Plough."

"Currently MMCRI has 271 clinical trials that have enrolled approximately 3,000 patients. Twenty-five (25%) of those trials include the evaluation and assessment of best practices and treatments for cancer patients, both adult and children. The overall objectives of many of these trials are to test the hypothesis that drugs and/or radiation therapy is the best treatment for patients with specific cancers."

"Please refer to Exhibit 6-C: Maine Medical Center Research Institute, Active Cancer Radiation Therapy-specific Clinical Studies, 2008."

"Objective 4: Increase by three the number of hospitals in Maine accredited by the American College of Surgeons Commission on Cancer by 2010. Baseline: 11 hospitals."

"Commission on Cancer (CoC) accreditation is an indicator that a cancer program meets industry standards. The Maine Cancer Consortium states:

> *One indicator of high quality care is accreditation through the American College of Surgeons (ACoS) Commission on Cancer. Accredited hospitals ensure quality care through various cancer-related programs, including prevention, detection, pretreatment evaluation, staging, optimal treatment, rehabilitation, surveillance for recurrent disease, support services, and end-or-life care.* (MCCCP, p. 65)"

Commission on Cancer Accreditation

"MaineHealth and MMC are providing support to each MaineHealth member and affiliate hospital in attaining or maintaining the appropriate level of CoC accreditation, including appropriate level of credentialing necessary for delivering care in accordance with desired accreditation (e.g. Board-certified surgeons, surgeons with sentinel node training."

VI. State Health Plan

"MMC Cancer Institute is the only program in Maine accredited by the American College of Surgeon's (ACoS) Commission on Cancer as a "Teaching Hospital Cancer Program"."

"Other MaineHealth member and affiliate hospitals that are already accredited are MaineGeneral – Augusta & Waterville, Penobscot Bay Medical Center, Southern Maine Medical Center, Maine Medical Center Regional Medical Center and Stephens Memorial Hospital. Each is accredited at the "Community Hospital" level."

"MaineHealth member and affiliate hospitals yet to be accredited are Mid Coast Hospital, Miles Memorial Hospital, St Andrews Hospital and Waldo County General Hospital. By the end of FY 2009 MaineHealth plans to identify the most appropriate level of accreditation for each hospital and work with hospitals to develop a plan to achieve and maintain accreditation. Following the initial plan MaineHealth will determine needs and develop a plan for critical access hospitals to become affiliates of nearby community accredited hospitals."

MMC Cancer Institute assistance to Maine hospitals seeking Accreditation
"MMC Cancer Institute has provided Stephens Memorial Hospital, Henrietta Goodall Hospital and Southern Maine Medical Center with assistance and support during their respective successful accreditation processes."

"All CoC accredited hospitals have a tumor registry function populating a database from which statewide tracking of incidence and other data occur. Maine Medical Center Cancer Institute's Network Registry is a richer database that enables MaineHealth to understand the rates of recurrence, survivor issues, and other information."

"The Network Registry is currently utilized by Maine Medical Center, Southern Maine Medical Center, Goodall Hospital and CCCYC. MaineGeneral and Mid Coast Hospital are considering using the Network Registry."

"Priorities for the Network Registry are:

- Establish a governance structure for the registry to establish standards for data entry, review, reporting, metrics, and other issues.
- Expand the registry to accommodate more data, improved reporting, review criteria, and other criteria.
- Assure that all MaineHealth hospitals use the Network Registry.
- Provide support through human resources for data entry and analysis."

"MMC Radiation Therapy Program American College of Radiology Accreditation - MMC is the only radiation therapy program in Maine accredited by the American College of Radiology (ACR). The goals of the ACR accreditation program are to provide impartial, third-party peer review; to recognize quality radiation oncology practices through accreditation; to make recommendations for improvement in practice and patient outcomes according to the recognized standards of the scientific community; and to provide a referral list for patients."

VI. State Health Plan

MMC Radiation Therapy Program Oncology Group Membership

"MMC Radiation Therapy Program has attained Active Affiliate Member status with the Radiation Therapy Oncology Group (RTOG), a Radiation Therapy-specific indicator of high quality care. RTOG members adhere to a common understanding of quality assurance and established mechanisms to assure compliance with protocols in all aspects of radiation therapy, dose prescription and delivery."

"Objective 5: Provide culturally appropriate pain and symptom management and supportive services that enhance quality of life by 2010."

MCCCP Rehabilitation & Survivorship Services

"MCCCP includes a goal to increase awareness and utilization of rehabilitation/survivorship services throughout Maine by 2010. (pp. 73-5.)"

Palliative Care

"MMC Center for Pain and Palliative Care is staffed by experts in symptom management. These providers provide treatment to ease the pain and suffering associated with advanced illnesses even when the underlying illness cannot be cured."

Patient Navigators

"MaineHealth and MMC support the development of patient navigation service(s) throughout the regional system to assist patients and their family members in accessing information and services."

"MMC provides a Registered Nurse-based Clinical Patient Navigator Service at no charge. Key elements of the Clinical Patient Navigator's role include:

- Guiding patients through the health care system, establishing rapport with newly diagnosed cancer patients and/or family members, loved ones or caregivers;
- Help in scheduling consultations with appropriate specialists and other resources, and conducting meaningful discussions with patients following their initial consultations;
- Providing an objective, balanced explanation of different treatment options for cancers, including benefits, risks, and side effects, and where treatments are available;
- Actively identifying and addressing barriers to care that might keep the patient from receiving timely and appropriate treatment for their cancer diagnosis (barriers may include health insurance/financial concerns, transportation to and from treatment, physical/psychosocial needs, communication/cultural needs or disease management);
- Connecting patients with resources, healthcare and support services in their communities;
- Assisting the patient and oncology physicians in the transition from active treatment to survivorship."

VI. State Health Plan

"Maine Medical Center Cancer Institute and the American Cancer Society (ACS) have introduced the first ACS Patient Navigator Program in Maine. This free, confidential program helps cancer patients, their families, and caregivers by finding local and hospital resources; being a supportive listener; acknowledging cultural differences to both doctors and patients; and providing guidance and support as they face the emotional, logistical, and financial challenges of their unique cancer experience."

"The ACS Patient Navigator Program provides cancer patients, survivors and caregivers with social services and programs, as well as resources tailored to the local community. Navigators seek to improve quality of life for cancer patients, families and caregivers throughout the continuum - from time of diagnosis, through treatment, into survivorship."

"The American Cancer Society's innovative Patient Navigator Program – a comprehensive initiative launched in 2005, links people affected by cancer to patient navigators who serve as personal guides for patients. ACS Patient Navigators receive national-level training through the American Cancer Society, in collaboration with the National Cancer Institute Patient Navigation Research Program Navigators, as well as localized training and opportunities for ongoing education."

"There are currently 84 American Cancer Society Patient Navigator program sites across the U.S., including four in New England. The American Cancer Society Patient Navigator Program is a component of the American Cancer Society Cancer Resource Network, a free, comprehensive resource to help patients and their caregivers manage the impact of cancer on their lives."

"The ACS Patient Navigator Program helps guide patients through the cancer care system and links them to appropriate programs and resources. Typical issues that are addressed include:

- Language or cultural barriers,
- Transportation and childcare needs,
- Lack of financial resources,
- Insurance difficulties,
- Access to support groups or classes, and
- Links to home health, respite care or hospice."

<u>Survivorship Services</u>

"MaineHealth and MMC support the development of survivorship service(s) throughout the regional system to improve support to patients and to better understand the issues facing survivors. MaineHealth is currently researching the needs of child and adult survivors, and their families. The research is taking into consideration the most recent evidence as well as the opinions of our own patients and family members."

VI. State Health Plan

b. Maine CDC/DHHS Assessment

"The applicant states this proposal will address rising demands for cancer treatment because of the aging population and because of Maine's underlying high cancer rates."

"There is some evidence that IGRT enables more precise targeting of cancer cells and minimizes damage to other cells. There is no evidence presented that mortality is reduced."

c. CONU Findings

This project addresses cancer care, one of the most significant health challenges facing Maine, a priority under the State Health Plan. The CONU concurs with the assessment from Dr. Dora Mills and cannot make a recommendation at this time that the project is consistent with the State Health Plan priorities until more documentation is presented on clinical outcomes.

iii. Conclusion

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

VII. Outcomes and Community Impact

A. From Applicant

High Quality Outcomes

MMC Institutional Measures

"MMC participates in the following Institutional-wide Patient Safety and Quality Initiatives: Specific Initiatives at MMC to Prevent Errors."

"Blame-free reporting: Example: cardiovascular surgeons all receive their own numbers and self-monitor."

"Robotics in the Pharmacy: Automated dispensing system with an error rate of less than 1%."

"Computerized Physician Order Entry: This major investment in information systems achieved 100% of orders entered by physicians by 10/01. Part of $3 million Sunrise Clinical Manager initiative, also operational by 10/01. Better records, automatic "flags" for problems, physician access from outside hospital for better monitoring of care."

"Adverse Drug Event Analysis: 1,200 each year out of 3 million doses"

"Root Cause Analysis: Determining the actual cause(s) of errors"

"Nursing Screening of High-Risk Patients: Example: patients at risk for bedsores."

"Improved Communications Models in the Operating Rooms: Modeled on lessons learned in the airline industry that have increased safety in the cockpit."

"Maryland Quality Indicators Initiative: MMC participates."

"Sentinel Events Monitoring and Root Cause Analysis: Part of JCAHO standards."

MMC Radiation Oncology Specific Measures

"All patients receiving radiation therapy are identified through 2 means of positive patient identification. Additionally, patients receiving IGRT have daily imaging of the target tissues prior to treatment delivery. The location of the target and the central axis of the treatment fields are then determined, and compared with the location of the target and central axis of the treatment field as determined at the time of treatment planning. The patient is then shifted in any of three dimensions such that the daily position matches that of the pretreatment plan, to ensure that the targeted tissues are accurately treated (and uninvolved normal tissues avoided)."

VII. Outcomes and Community Impact

"The Radiation Therapists are provided with a standard protocol, developed by the Radiation Oncologists, including the parameters by which the daily location is considered acceptable for treatment (without shifting the patient), the parameters by which a shift accomplished by the therapists can be performed to meet acceptable criteria, and the parameters by which a physician needs to be contacted to review the images and determine if additional shifting is required or re-evaluation is needed prior to continuation of treatment. Final images are obtained prior to delivery of treatment. These images are reviewed by the physicians and compared with the images obtained at the time of treatment planning on a daily bases."

"Daily adjustments, if needed, are documented in the radiation therapy treatment record and reviewed by a physician at least once weekly. Custom patient immobilization / repositioning devices, created at the time of treatment planning under the guidance of the physician, aid in the initial daily patient positioning. A record and verify system allows for ongoing verification of patient specific parameters on the treatment unit and captures all details of the actual treatment in an electronic treatment delivery record for each patient."

Quality Assurance:

"MMC follows the American College of Radiology Practice Guidelines. A board-certified medical physicist maintains and manages the QA program for the entire IMRT/IGRT system, which includes the treatment planning system, treatment delivery system, and the interface between these systems. The physicist also participates in review of all IMRT/IGRT treatment plans for technical accuracy and precision, as well as providing physical measurements for verification of the plan. Patient specific quality assurance includes treatment unit verification data, image based verification data, and dose delivery verification data by physical measurement."

Quality Improvement:

"MMC follows the American College of Radiology Practice Guidelines. Patient and personnel safety are addressed by documentation of beam leakage and scatter measurements at the time of IMRT/IGRT commissioning, and periodically over the equipment's lifespan."

"Physician peer review of patient treatment plan, positioning, and documentation occurs at the start of treatment and on an as needed basis throughout the patient's course."

"Registered Oncology Nurses provide specific patient education to all IMRT/IGRT patients in the form of printed and verbal materials."

"With the introduction of IGRT, MMC Radiation Therapy Program began performing baseline and subsequent symptom assessments, comparing the previous treatment delivery to IGRT technology. Side effects and recurrent disease rates are being collected and reported."

"A database has been established by the Radiation Oncology Department and the Chief Therapist. The Nurse Coordinator and Chief Therapist are responsible for gathering and

collating data, including clinical measures, demographic information, and general data. Annual reporting in the form of a written summary and analysis is submitted to both the Radiation Oncology Quality Improvement Committee and the Oncology Steering Committee."
"Please refer to Section II Fit, Willing and Able; and Section VI State Health Plan of this application for additional information that demonstrates MMC's and MaineHealth's commitment to quality."

Potential Impact on Other Providers

"Approval of this project does not negatively affect the volume of services, quality of care and/or costs of other existing service providers. The project does not envision any impact on current practice patterns. MMC is the sole radiation therapy provider located within its primary service area."

- "IGRT increases in the vault time per visit drive the need for an additional linear accelerator in MMC Radiation Therapy Program. The project does not anticipate a change in market share and/or demand that would have any effect on other radiation therapy providers in Maine.
- MMC has a demonstrated record of collaborating with other providers in addressing cancer, especially in the radiation therapy arena.
- MMC is committed to supporting other providers in their efforts to qualify for Commission on Cancer accreditation, an indicator that their programs meet industry standards of care."

Current and Projected Utilization

"Please refer to Section IV Public Need of this application for information on:

- The population's current and projected utilization, need and demand forecast data sources and methodology;
- MMC Radiation Therapy Program's primary and secondary service areas' definition and the rationale for the definition of service area; and
- The region's existing and proposed radiation therapy capacity."

B. CONU Discussion

i. Criteria

Relevant criterions 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. Maine Quality Forum/DHHS Assessment

"The clinical rationale for the installation of a third linear accelerator at the Maine Medical Center outpatient campus in Scarborough is based on the evolving need for image-guided radiation therapy (IGRT) for most radiation oncology applications. Since the addition of

imaging before, during, and after radiation therapy increases the duration of therapy visits, access by patients to the service is diminished through decreased availability. The need for IGRT itself is based on its advantages in limiting radiation dose to surrounding healthy tissues through frequent observation of organ motion and imaging of radiation effect on the tumor."

"The clinical quality of the applicant institution and its public recognition are adequately documented in the application. These comments will be limited to the need for IGRT capability by the applicant based on timely access to the service by patients and the issue of whether or not improved clinical outcomes from the application of IGRT justify its expense. However, the application does reflect an emphasis on quality care in the institution generally and evidence of an integrated, patient-centered approach to oncology care specifically."

"The impact on time necessary for treatment by IGRT is substantial (40 minutes vs. 16 minutes for average encounter without IGRT) and diminishes the availability of radiation therapy by 60%. Its advantages are enumerated in the application. There is considerable patient and tissue movement due to body habitus, position, breathing, and effects of accumulating dosage on the tumor. Better direction of the radiation dose to the target tumor while minimizing the incidental dose to adjacent organs is achieved through IGRT in combination with intensity-modulated radiation therapy (IMRT). There is a body of evidence to support anatomically accurate dosing through the use of IMRT. It includes studies showing increased survival in medulloblastoma patients and longer duration of undetectable PSA levels in prostate cancer patients treated with IMRT. There is also evidence showing that radiation toxicity is reduced when dosing is anatomically accurate. However, although the advantages of IGRT are intuitively apparent, I could find no evidence that the use of IGRT in addition to other methods of dose control and placement added to the quality of clinical outcomes (including that of fewer side-effects, important because of its relationship to level of function, patient satisfaction, and likely diminished rehospitalization rates)."

"As was pointed out in one of the review articles cited in the application, *"Pursuit of fully online adaptive replanning might be tempting, but the desire for sub-millimetre technical precision needs to be balanced with risk of chasing only modest clinical gains and the possibility of imposing an unacceptable workload on radiotherapy planning, delivery, and review processes. Clinical needs and infrastructure, human resources, the quality of imaging in the sites at which it is needed, and the efficiency, ease of use, and support for technology all need to be considered in the development of an image-guidance strategy."* (Dawson LA, Sharpe MB, Image-guided radiotherapy, rationale, benefits, and limitations. Lancet Oncol 2006;7:848-58) (italics added). This raises the need for cost-benefit analysis in the evaluation of need for this technology."

"In summary, although the application accurately reflects the possible and conjectural advantages of IGRT, there is room for a discussion of the evidence for its justification of the initial and ongoing capital and operating costs on the basis of improved patient outcomes over those achieved with more conventional radiation therapy methods including intensity-modulated radiation therapy. I would submit the following questions for this discussion:

VII. Outcomes and Community Impact

- Is there evidence that IGRT positively affects clinical outcomes compared to IMRT without on-line imaging?
- If so, are these outcomes related to favorable effect on prognosis and/or survival, or to clear reduction in toxicity and radiation of nontarget tissues?
- The addition of IGRT to conventional RT increases the time of each encounter by a factor of 2.5 (16' vs. 40'). Economical use of IGRT would require that it not be applied to all types of tumors. Are the advantages of IGRT greater for some types of tumors than for others? If so, where are these advantages greatest, and how does this distribution affect the demand for IGRT?"

iii. CONU Analysis

This project will not negatively affect the quality of care delivered by existing service providers. MMC is the only provider of radiation therapy in its service area. However, as noted by both CDC and MQF, the applicant has failed to demonstrate that installation of an IGRT linear accelerator ensures higher-quality outcomes when compared to an IMRT linear accelerator.

iv. Conclusion

CONU recommends that the Commissioner find that Maine Medical Center has not met their burden to demonstrate that this project will ensure high-quality outcomes and does not negatively affect the quality of care delivered by existing service providers subject to a condition that it reports on quality outcomes.

VIII. Service Utilization

A. From Applicant

"Maine experiences a high rate of cancer. Cancers are diseases of the elderly, and Maine's demographic profile as one of the oldest populations in the nation results in the state having higher incidences of cancer than national or other New England states' incidence rates."

"Even when Maine's cancer incidence rates are age adjusted, Maine continues to have the highest cancer incidence rate in the nation and higher incidence rates than the national average for every one of the ten most frequently reported cancers by site. Maine has more underlying cancer disease than the nation."

"Maine's aging population, its population increases in the older age groups and its high incidence rate of cancer will result in an ongoing, increasing need for cancer services, including radiation therapy. It is this need that influences the utilization of cancer treatment services, including radiation therapy. Approximately 67% of cancer patients are appropriate for radiation therapy."

"The introduction of Image Guided Radiation Therapy (IGRT) has improved patient safety and outcomes, and has reduced side effects. The technology enables precise targeting of cancerous cells and minimizes damage to adjacent healthy cells. IGRT allows for reduced treatment field margins and dose escalation, and addresses anatomically challenging cancerous tumors that are often found in chronic, ongoing disease processes. This technological advance may enable radiation oncologists to achieve improved clinical outcomes and/or to expand the applicability of radiation therapy to additional cancers."

"As described in Section VI State Health Plan of this application, MaineHealth has just launched a major new population-based cancer initiative. This initiative includes adopting evidence-based clinical care guidelines, identifying quality metrics and reporting methodology, and providing a range of educational supports to promote consistent use of guidelines. These efforts should result in appropriate, evidence-based service utilization."

B. CONU Discussion

i. Criteria

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/DHHS Assessment

The Maine Quality Forum did not comment on this section.

VIII. Service Utilization

iii. CONU Analysis

Service Utilization is not expected to increase as a result of this project. The additional linear accelerator is requested due to increased treatment time of current patients being treated.

The applicant is not expecting to see an increase in patients. The applicants are expecting to see a shift in treatment type which will increase treatment time. Although the applicant has not projected an increase in utilization, they have not demonstrated an increase in capacity.

iv. Conclusion

The CONU recommends that the Commissioner find that the applicant has 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

A. From Applicant

"Based on the information contained in the completed CONU Financial Module for this project (Exhibit 3-B), the estimated Capital Investment Fund debit for the project, if approved, is eight hundred six thousand nine hundred eighty one dollars ($806,981)."

B. CONU Discussion

i. Criteria

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. Analysis

The large hospital project cycle is a competitive cycle. The CIF has been introduced to limit the development of hospital 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 approved in 2009 has yet to be determined although it is expected to be adequate to fund this project if it were approved.

X. Timely Notice

A. From Applicant

"MMC has incurred and continues to incur obligations for predevelopment activities associated with this project. The total capital obligations for these activities while MMC awaits the Department's decision are estimated to be less than the Maine Certificate of Need threshold currently in effect."

"MMC has followed the appropriate procedures regarding timely submission of the Letter of Intent, scheduling of the mandatory Technical Assistance meeting, submission of the Application and certifying the Application Completeness outlined in the Maine Certificate of Need Procedures Manual for this type of project."

"MMC will cooperate with the Department in arranging the required Public Informational Meeting."

"MMC is willing and reserves the right to submit information that is responsive to any concern, issue, question or allegation of facts contrary to those in the application made by the department or any other person."

"For informational purposes MMC presents the following schedule based on requirements outlined in the Maine Certificate of Need Manual currently in effect."

Responsible Party	Task	Due Date	Actual Date
MMC	File Letter of Intent:	Oct. 3, 2008	Sep. 26, 2008
MMC / DHHS	Hold technical assistance meeting:	Nov. 2, 2008	Oct. 10, 2009
MMC	File a certified complete application and filing fee:	Dec. 19, 2008	Dec. 19, 2008
DHHS	Review Cycle commences:	Jan. 1, 2009	

B. CONU Analysis

Letter of Intent	September 30, 2008
Technical Assistance Meeting	October 10, 2008
Application filed	December 19, 2008
Application certified complete	December 19, 2008
Public Informational Meeting	January 14, 2009
Record Closes	February 13, 2009

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 not 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 not 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;

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 not demonstrated that the project ensures high-quality outcomes and does not negatively affect the quality of care delivered by existing service providers;

G. The applicant has not demonstrated that the project does 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 can be funded within the Capital Investment Fund if it were approved.

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.**