

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

Date: May 22, 2008

Project: Proposal by St. Mary's Hospital

To: Catherine Cobb, Director of Licensing and Regulatory Services

Prepared by: Phyllis Powell, Certificate of Need Manager
Steven Keaten, Healthcare Financial Analyst
Larry Carbonneau, Healthcare Financial Analyst

Directly Affected Party: Central Maine Medical Center

Recommendation: Disapprove

	Proposed Per Applicant	Approved CON
Estimated Capital Expenditure	\$ 24,519,301	\$ 0
Maximum Contingency	\$ 1,025,032	\$ 0
Total Capital Expenditure with Contingency	\$ 25,544,333	\$ 0
Third Year Incremental Operating Costs	\$ 2,869,627	\$ 0
Capital Investment Fund (CIF) Impact:	\$ 2,115,034	\$ 0
CIF debit 2008	\$ 1,057,517	\$ 0
CIF debit 2009	\$ 1,057,517	\$ 0
Bureau of Insurance Impact Estimate	.799 %	

INTRODUCTION

“St. Mary's Regional Medical Center is a not-for-profit charitable corporation that operates a 233 bed community hospital in Lewiston, Maine.”

“St. Mary's Regional Medical Center proposes to expand and upgrade the Operating Room, Central Sterile, Lab and Pharmacy. The current physical plant housing these services is over fifteen years old, and the allocation and configuration of space does not meet current guidelines and standards. This project will add approximately 13,541 square feet to our existing Operating Room and Lab at the Main Building of St. Mary's on Campus Avenue in Lewiston. The project will also include renovation of 27,398 square feet of existing space related to the Operating Room, Central Sterile, Lab, and Pharmacy.”

“This project involves expansion and renovation of space on the lower level of the medical center in order to accommodate central sterile, the lab and pharmacy. This will then allow for expansion and renovation of the operating room on the level above. The 7 existing operating rooms will be expanded with a goal of at least 600 square feet for 2 of these rooms, and 500 square feet for another 2 rooms. The remaining 3 ORs will stay as is. The following upgrades will also occur: preoperative and postoperative holding areas, HVAC, equipment storage areas, pre-admission testing, and family waiting area. Existing issues with patient privacy and confidentiality will be addressed throughout this project.”

“The estimated capital expense for the project (including projected financing costs and movable equipment) totals \$25,544,333. This is higher than the estimate in our Letter of Intent. The increase is a result of several factors: more refined/detailed plans; an inflation adjustment that parallels our projected implementation schedule; inclusion of capitalized interest given the length of the project implementation. We estimate the incremental third-year operating costs associated with the project to be \$2,869,627. This project is identified as a priority in the SMRMC facility master plan completed in December 2004.”

“This project does not involve the addition of any new services, nor does it request an addition to the medical center's licensed bed capacity. Rather, our goal is to upgrade and modernize the physical plant housing these vital clinical services so as to meet current guidelines and standards. This will ultimately result in enhanced patient care and public health and safety as we create an environment that supports patient privacy and confidentiality, infection control, and operating rooms that can accommodate technological demands that did not exist fifteen years ago.”

I. Project Description

A. From Applicant

“The expansion and renovation of the St. Mary’s Operating Room, Central Sterile, Lab and Pharmacy was identified as a critical priority in the St. Mary’s Facility Master Plan completed in December 2004. These essential clinical services are housed in facilities that are over 15 years old. While each of these clinical services has grown significantly over the last 10 years, it is important to note that the principal driver for this project is not aggressive future growth and market share capture. Rather, our goal is a modernization project that will create facilities and an environment that can accommodate current volume, ensure patient safety and privacy, and provide adequate space to meet the programming and technological demands that did not exist when the current facilities were constructed in the early 1990s.”

“This project will add approximately 13,541 square feet to our existing Operating Room and Lab at the Main Building of St. Mary’s on Campus Avenue in Lewiston. The project will also include renovation of 27,398 square feet of existing space related to the Operating Room, Central Sterile, Lab, and Pharmacy.”

“The expansion and renovation will be designed to accommodate current OR volume of 4,829 cases and 499,103 billable lab tests (2007 projected volumes), plus future OR volume growth of 6% over the period 2008-2012, and annual lab growth of 8.5% over that same period of time. Current volumes represent 31% and 66% increases over 1997 volumes, and the growth trend has mirrored our growth in our primary care network over the same period of time. As we have created access to primary care, demand for surgical and ancillary services at St. Mary’s has increased as well. In addition, the nature of our surgical case mix has shifted. We continue to increase our volume of neurosurgical cases, and these cases run much longer than average surgical cases. The current space is completely inadequate for this level of activity. The current space creates tremendous inefficiency, and does not support the quality patient experience we wish to provide to all who seek our surgical or ancillary services.”

“The existing Operating Room, Central Sterile, Lab and Pharmacy at St. Mary’s Regional Medical Center was designed in 1988 and now, almost 20 years later, no longer meets contemporary standards. The operating rooms are significantly undersized, there is inadequate patient prep and recovery area and storage and support space is extremely limited. In addition to space and functional inadequacies the existing mechanical system does not provide temperature control and air exchanges to meet current code for operating suites. The lab layout is inefficient, it is not conducive to the nature and volume of testing conducted in this area, and the space does not allow for appropriate patient access and confidentiality. The pharmacy layout is also inefficient, with very cramped workspace for pharmacists and technicians and inadequate storage space for the myriad of pharmaceuticals required to be held in inventory. Photographs of current conditions are included under Tab D [on file CONU]. Renovation and expansion of these areas is the next critical step in the comprehensive master plan that St. Mary’s is in the

process of implementing. The Emergency Department project, also part of this master plan, is scheduled to start construction spring of 2008. This project will then logically follow the ED project bringing these two major program components up to contemporary healthcare standards.”

“The proposed Surgical Suite renovation provides the following:

- Dedicated public entrance for surgical services
- Pre Admission Testing relocated adjacent to the surgical suite
- 4 large OR's fully equipped
- 3 existing OR's fully equipped
- New Day Surgery/Phase 2 recovery suite
 - 2 isolation rooms
 - 10 stretcher bays
 - 6 recliner bays
 - Anesthesia Prep. Room
- New Post Anesthesia Care Unit (PACU)
 - 2 isolation rooms
 - 8 stretcher bays
- Larger equipment storage areas
- Larger anesthesia work area
- Improved office and support space
- New dedicated mechanical system”

“The existing surgical suite at St. Mary's is 14,050 square feet and supports 7 operating rooms. 6 of the existing operating rooms range in size from 350 s.f. to 400 s.f.; the 7th room is 490 s.f. These rooms do not adequately support many of the operations performed today that require large equipment and space to maneuver a sizable team of clinicians safely. The *2006 AIA Guidelines for Design and Construction of Health Care Facilities* stipulate 600 square feet for OR's where “orthopedic, neurological and other special procedures that require additional personnel and/or large equipment”. Sg2, a health care intelligence firm based out of Chicago, Illinois, has published work on the future design and operation of operating rooms throughout the United States. In their research study entitled Innovation in Operations, Strategic Technology Adoption for the OR, 2006, p.7 they make the following recommendations:

Organizations should appropriately upsize their ORs now.

- Existing and emerging OR technologies are increasing in volume and becoming more complex.
- The already-crowded 450-square-foot ORs common today will be unable to house the technologies of the future.
- A surgical robot alone requires about 200 square feet.
- ORs of the future will likely require a minimum of 650 square feet (adequate for an endovascular OR) and will range up to 1,200 square feet for super-sized image-guided ORs.

- Even with OR upsizing, no single OR will be able to accommodate all of the latest technologies.

The same study summarizes the issue in the Executive Summary on page 3:

- Hospitals planning replacement facilities or major retrofitting of their existing facilities risk creating operating rooms (ORs) that are outdated before their doors open. Tomorrow's ORs will bear little resemblance to the small, inefficient spaces that are typical today. Instead they will be packed with imaging, information management and robotic technologies demanded by surgery's high tech revolution.
- Technology space requirements will boost average OR sizes in the next 5 to 10 years by at least 50%, and some future ORs will exceed 1,000 square feet."

"We are already seeing this trend emerge here in Maine. The ORs approved in the Certificate of Need 2005/2006 cycle were at 600 square feet. A summary follows:

- Mercy Fore River 600 sf ORs
- MMC Scarborough Surgery Center 600 sf ORs
- MGMC Thayer Combination of 400 and 600 sf ORs
- MGMC Augusta Combination of 400 and 600 sf ORs"

"St. Mary's plans are consistent with these trends. The proposed plan maintains the same number of operating rooms but expands 2 of them to 600 square feet and 2 of them to 500 square feet. The total square footage of the proposed surgical suite is 24,867. To achieve this expansion it is necessary to relocate the central sterile program to the level below the surgical suite and build new clean and soiled service elevators to provide access between the surgical suite and central sterile. The relocation of central sterile to an area below the surgical suite in turn requires the relocation of the existing laboratory and pharmacy program. These programs can be accommodated in a combination of space on the first floor under the surgery addition and in existing renovated space. A summary of affected square footage is follows, and project designs and schematics are included under Tab E:

- New Surgical Suite: 24,867 s.f.
- Renovated Area for Central Sterile: 2,190 s.f.
- New Construction for Laboratory: 5,440 s.f.
- Renovated Area for Laboratory: 2,287 s.f.
- Renovated Area for Pharmacy: 2,583 s.f.
- New Construction for Public Corridor 1,534 s.f.
- Renovation of Public Corridor 2,038 s.f.
- Unchanged 537 s.f."

"St. Mary's Operating Room once renovated and expanded will support clinical excellence in an efficient work environment with adequately sized operating suites and support and storage space. The patient prep and recovery space will provide privacy and meet the needs of patients and their families. The new mechanical system will provide temperature control throughout the unit and the appropriate air exchanges to support the

procedures performed. Infection control standards, patient safety and family support will all be addressed.”

“The existing laboratory is significantly compromised and does not provide adequate space or infrastructure support for contemporary lab equipment. More and more automation is occurring in laboratories today and as a consequence open plan laboratories have become the standard. The current laboratory at St. Mary's is comprised of numerous small rooms. The compartmentalization of the existing space does not provide the flexibility to support automated analyzers. In addition, because the existing space is heavily partitioned staff cannot move freely from one lab modality to another. The current configuration reduces staff productivity. Many of the existing modalities of the lab are undersized including: the blood bank, specimen processing, hematology, histology and microbiology.”

“In addition to the deficiencies in the technical work areas, the existing lab does not support appropriate interface with patients. The waiting and blood-draw areas are more than 50% undersized. Often patients wait in the hallway for morning blood draws. It is difficult to maintain patient privacy in the current configuration. The new plan provides dedicated space for patient blood draw and specimen collection and also provides for an open plan laboratory for the analysis and processing of specimens. This new configuration will support automation, increase productivity and efficiency and provide a much better environment for patient care.”

“Renovations to support the pharmacy will allow full compliance with the latest USP 797 regulations developed by U.S. Pharmacopoeia, a JACHO mandated standard that governs pharmacies that prepare CSPs (Compounded Sterile Preparations). To eliminate any possible contamination of sensitive pharmaceuticals appropriate provisions will be made to bring designated areas of the pharmacy up to ISO class 7 cleanliness levels. In addition the delivery and pickup of pharmacy products will be clearly separated in accordance with USP protocols. Workflow will be streamlined. The ergonomics of the picking area will be significantly improved and pharmacy personnel workstations will be configured to support and enhance workplace safety and productivity.”

“The project will be designed to incorporate best practices in building construction, renovation and operation to minimize environmental impact. The design team selected for the project includes design professionals accredited by the U.S. Green Building Council LEED (Leadership in Energy and Environmental Design) program. They will assist St. Mary's with the development of the project that will be designed to operate efficiently using materials and resources that minimize environmental impacts.”

“Energy efficiency will be achieved through the use of:

- high performance heating, ventilation and air conditioning equipment
- variable speed drives
- heat recovery
- maximizing the use of natural light
- providing multiple options for controls of lighting and mechanical systems

- commissioning the building to ensure that systems are operating at optimal efficiencies.”

“Materials and resource consumption will be controlled by:

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

“Indoor Environmental Quality will be controlled by:

- requiring the contractor to replace filters and flush out the mechanical system prior to occupancy
- use of low-emitting materials
- providing a smoke-free environment
- providing occupants natural light and the ability to control artificial light and temperature”

“In summary the physical environment will be designed with sustainability and energy efficiency in mind, in keeping with St. Mary's commitment to the environment and to controlling the negative environmental impact of construction and on going hospital operations.”

“The proposed project will be implemented according to the following schedule. Assuming CON approval is obtained sometime during the summer of 2008, final design and engineering will be completed between September and February of 2009. Construction would then begin in March of 2009, and would likely continue over a 36-month period. Based on these premises, construction would be completed by summer 2012. The first full year of operation of the expanded facility would be 2013. Third year of operation of the expanded facility would be 2015.”

“St. Mary's is also aggressively implementing information technology. In October of 2005, St. Mary's implemented the Meditech electronic medical record (EMR) and immediately began electronic capture of patient demographics, registration, scheduling, order entry, and results reporting. The EMR is equipped with an HL7 interface. In March of 2006, surgical services implemented the OR patient management system. And in April 2006, the emergency department implemented clinical (nursing and physician) documentation.”

“The Meditech ORM (OR Management) module allows for electronic documentation of the operative visit. The patient is scheduled in the OR Management module and the operative visit is documented in conjunction with the scheduled appointment. The

ORM module links to ordered meds on patients, and allows staff to document meds dispensed from Pyxis machines in Day Surgery and PACU. The ORM module can also indicate to clinical staff when Lab results are complete on the patient, and allows staff seamless entry into the Meditech electronic medical record (EMR).”

“The Meditech Lab module offers the ability to order lab, blood bank, and microbiology tests from anywhere in the hospital that has a Meditech connection. The Lab module interfaces with many of the lab instruments and accepts test results from Mayo Medical Lab reference lab. The lab, blood bank, microbiology, and pathology results are immediately available in the Meditech EMR for all clinical users once they are verified and/or e-signed. The lab can set up test view groups that can be attached to certain procedures and medication orders. This ensures that appropriate lab tests were completed on patients prior to having a procedure performed or being administered a drug.”

“The Meditech Pharmacy module is used to create and maintain a patient’s medication profile. Medication orders are entered in the system which checks for appropriate dose, interactions, allergies, and other contraindications. This profile is used by nursing to create a Medication Administration Record (MAR) and also interfaced to medication dispensing machines (Pyxis) used by nurses to retrieve and administer verified doses to the patients.”

“Highlights of this module are:

- Reduce clinical errors with intelligent warnings, messages, and rejection notices
- Gain immediate access to clinical information from throughout the enterprise
- Access all relevant data from a single, centralized processing screen
- Minimize lost revenue with the option to charge on administration
- Enhance decision support using robust reporting tools
- Maintain proper inventory levels by linking to dispensing machines.”

“In January 2007, St. Mary’s also implemented an e-ICU – Vital Network’s VISCU remote monitoring system. St. Mary’s ICU patients are now provided 24-7 monitoring by critical care specialists in Portland. They continue to receive direct ICU services from St. Mary’s physicians and nursing staff, but the continuous monitoring by the critical care specialists in Portland raises the bar on quality of care for all patients in the intensive care unit.”

B. CONU Discussion

St. Mary's Hospital facilities are located on the southern side of Campus Avenue in Lewiston, Maine. The land mass is roughly triangular with the shortest side being an access road between Campus Avenue and Sabattus Street, the two major roads on which the hospital is located. This project proposes new physical space to provide a new entry for surgical services oriented closer to Sabattus Street.

The proposed construction occurs on two floors. On the upper floor there is currently the surgical suite and central sterile spaces. Central sterile will be relocated to the lower floor. The current physical space will include keeping a corner of the upper floor the same with four operating rooms. Along the outer perimeter, an older OR will be converted into a large storage area supporting two new OR's with additional storage space between them. A third new OR and additional storage space will be located adjacent to the opposite side of the space not being modified. A fourth new OR will be the only one located on the interior loop. The remainder of the current space will encompass 10 bays labeled "Pre/Post Op" and space for 6 reclining bays. Additionally, a post anesthesia care unit of 10 bays, with two units labeled isolation will be built. This appears to be the most significant change to the facility. It is unclear the number of "bays" the facility currently has from the information presented.

The new space on this floor is being used for staff lockers, a conference room, office space and a family and patient waiting area as well as pre-surgery testing areas. The hallway connecting the women's care unit on this level to the rest of the hospital will be re-routed around the periphery of the new waiting area as the current hallway will now connect the staff spaces to the OR suite.

The project proposes to renovate and expand 4 ORs to better meet patient needs based upon the type and number of surgeries performed. They cite the AIA Guidelines to support the size and point to other Maine hospitals that have experienced OR renovations as the basis for the design. Consistent with AIA Guidelines, and Hospital of the Future – Lessons for Inpatient Facility Planning and Strategy (The Advisory Board Company 2007) (later referred to as Hospital of the Future), establishes a "sweet spot" for ORs of 600 to 650 square feet. The OR renovations proposed in this application are consistent with these guidelines.

This project will maintain the same number of ORs while expanding their size. Hospital of the Future and AIA guidelines support that the existing square footage is undersized. With technological advances space needs in many OR's have increased. This is especially true for some types of surgical cases and services; however it is not clear if the actual surgical cases expected by St. Mary's are reflective of this trend. St. Mary's does not provide explicit evidence related to the development of the proposed plan or that the current number of surgeries could not be performed if the ORs were not expanded.

The ground floor currently houses the laboratory and pharmacy. The pharmacy is underneath the current central sterile area and will be renovated into the central sterile

area. Two elevators to transfer supplies from this floor to the surgical suite will be added. This space is listed in the construction budget at 2,255 square feet with an allocated cost of \$644,000.

The existing pharmacy will be relocated. This space is expected to be 2,583 square feet with an allocated cost of \$466,000. Currently the pharmacy is a long narrow corridor. The applicant did not state which construction guideline they used as a basis for the allocation of pharmacy space. According to Hospital of the Future, a standard for pharmacy net square feet is 7-8 square feet per inpatient bed and 5 -7 square feet per each outpatient bed. Lacking information from the applicant, based on Hospital of the Future it appears that the pharmacy space proposed is adequate for the 233 beds in this hospital. The present configuration and layout appear to present major operational challenges as the pharmacy is cramped and appears disorganized. How this will be improved as the space is reused as the Central Sterile area is not explained.

The current laboratory is located in three distinct spaces. A discreet space of 537 square feet will remain untouched on the east side (Campus Avenue) of the floor. The triangular wedge of 2,583 square feet will become the pharmacy area. The remaining 2,012 square feet of the existing lab will be renovated. The addition will house approximately 6,000 square feet. More than 1,400 square feet of space will be renovated to level the hallway that divides the current space from the space being constructed to the west. This hallway leveling is expected to cost about \$185,000.

The applicant states that the facilities proposed for renovations are between 15 and 20 years old. According to the Almanac of Hospital Financial and Operating Indicators (2008) there is a correlation between quality of care and age of plant. The applicant does not state what health efficiencies are negatively impacted by the age of the facility. This application is focused on facility improvement with little emphases on process or operational improvements relative to patient safety.

Statements relative to output, patient safety and privacy, and adequate space are addressed in other sections of this review.

II. Profile of the Applicant

A. From Applicant

“St. Mary’s Regional Medical Center is a not-for-profit charitable corporation that operates a 233 bed community hospital in Lewiston, Maine. St. Mary’s is state licensed and [Joint Commission] accredited. Copies of licenses, accreditation results, quality measures and statement of deficiencies with corrective action plans are attached under Tab A. St. Mary’s and its affiliates provide the following health care services, among others:

- primary and specialty care physician services
- prevention and community health assessment services
- community outreach services such as school-based health centers, food pantry and annual flu shot clinics
- emergency services
- acute care services including surgery, intensive care, medical/surgical care, obstetrics and gynecology, and behavioral care
- full service lab, imaging and rehabilitation services for both inpatients and outpatients”

“The medical center’s primary service area is Androscoggin County, with 72.7% of discharges originating from this region in 2006. The secondary service area also includes Franklin and Oxford counties. The St. Mary’s behavioral service has been designated a tertiary referral site by the State of Maine (identified as the primary behavioral provider for Androscoggin, Franklin, Oxford, and northern Cumberland counties), and draws a significant number of patients from this region.”

“St. Mary’s Regional Medical Center is a subsidiary of Sisters of Charity Health System (SOCHS). SOCHS is also a not-for-profit charitable corporation and is the parent company of St. Mary’s, Ste. Marguerite d’Youville Pavilion (a 210 bed long term care facility), and Maison Marcotte (a 128 apartment senior independent living facility). SOCHS also has a distinct relationship with Community Clinical Services (CCS), a Maine not-for-profit corporation that employs physicians and manages their practices. While CCS is an affiliate of SOCHS, it is not controlled by SOCHS. SOCHS provides management and administrative support to each of its subsidiaries and CCS. Together, SOCHS and its affiliates are collectively referred to as the “health system”.”

“Covenant Health Systems (CHS) is the sponsor and owner of SOCHS and its subsidiaries. CHS is a not-for-profit health care system formed in 1983 under the sponsorship of the Sisters of Charity of Montreal (Grey Nuns) to carry forth their century-long mission of providing value-driven, high quality health care services. Covenant Health Systems is based in Lexington, Massachusetts. SOCHS became an affiliate of CHS in 1992.”

“The mission of SOCHS and St. Mary’s is to continue the healing ministry of the Catholic Church in the spirit of Ste. Marguerite d’Youville by providing preventative,

curative, restorative and supportive services with compassion and respect for everyone. The health system attempts to identify community needs and to respond to these needs with innovative, high quality, cost effective programs and services. St. Mary's has served its community with distinction for over 100 years, and is part of a health care continuum unlike any other in the state. Primary care, emergency care, acute care, long term care and prevention and wellness services are all available through SOCHS and its subsidiaries and affiliates. This integrated health delivery system is a vital resource to the residents of central Maine. In 2006, SOCHS and its affiliates employed approximately 1,500 full time equivalents and returned over \$68 million in wages to the community. A copy of audited financial statements for the last two fiscal years is attached under Tab B." "Several key individuals will oversee implementation of the Operating Room, Central Sterile, Lab and Pharmacy Expansion and Renovation project. Michael Grimmer, VP Facilities, will provide direct oversight of construction. Susan Keiler, Chief Operating Officer, and Rosemary Henry, VP of Nursing, have provided clinical leadership during program design. They will ensure continuity and quality of care throughout implementation. Overall project management will be the responsibility of the Chief Operating Officer, Susan Keiler. A CV for each of these individuals is attached under Tab C."

B. CONU Discussion

i. Criterion

Relevant criterion 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

The applicant provided a copy of its license issued September 26, 2006 effective until March 31, 2008. On March 25, 2008 a new license was issued effective April 1, 2008 to March 31, 2009. Additionally, the Joint Commission accredited St. Mary's Regional Medical Center on July 13, 2006 for a period of 39 months.

The applicant provided a copy of "St. Mary's Regional Medical Center Performance and Patient Safety Improvement Plan 2007".

The Medical Facilities Unit of the Division of Licensing and Regulatory Services completed a site survey on March 2, 2006. St. Mary's plan of correction was deemed to be acceptable on May 12, 2006.

According to Maine Quality Forum, "It is noteworthy that the applicant describes in the application and otherwise shows evidence of attention to clinical quality. The institution has programs in place that attend to timely and equitable access to care. St. Mary's

website publicly reports on several quality indicators that the Maine Quality Forum collects but has yet to post.”

iii. Conclusion

CONU recommends that the Commissioner find 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.

III. Capital Expenditures & Financing

A. From Applicant

The applicant provided the following information in regards to proposed capital expenditures, availability of capital financing, staffing, financial feasibility, economic feasibility and the compliance with rules and regulations of local, State and Federal agencies.

The proposed capital expenditures as presented by the applicant for this project are as follows:

Land Surveys, Soil Tests, Borings	\$ 20,000
Architects' Basic Fees	1,250,000
Engineering Consultant Fees	1,000,000
Plans and Specifications	35,000
Project Supervision	100,000
Construction	14,361,654
Contingency Fees	1,025,032
Fixed Equipment	2,500,000
Movable Equipment	1,124,163
Interest during Construction	3,878,484
Financing Fees	250,000
Total Capital Costs	25,544,333

“Construction estimates and related costs were compiled with the assistance of H. P. Cummings Construction Co. and the architectural firm of SMRT. As described in further detail in Section VIII, the design team selected for this project includes design professionals accredited by the U.S. Green Building Council LEED (Leadership in Energy and Environmental Design) program. They will assist St. Mary's with the development of the project to ensure the design operates efficiently using materials and resources that minimize environmental impact.”

“Movable equipment related to this project totals \$1,124,163. A general inventory of this equipment is included below:

• 1 each Anesthesia Supply System, Mobile	\$185,000	\$ 185,000
• 7 each Anesthesia Machine	\$ 80,000	\$ 560,000
• 7 each Surgical Table	\$ 40,000	\$ 280,000
• 7 each Electrosurgical Unit	\$ 7,500	\$ 52,500
• 1 each Laboratory Hood System	\$ 46,663	\$ 46,663

Total Moveable Equipment \$1,124,163”

“St. Mary's projected consolidated financial statements are included under Tab F. These include eight-year pro forma projections, service volumes, capital and operating

assumptions, and revenue, expense and income figures for St. Mary's. Given current and anticipated service volumes and prevailing payment mechanisms, the proposed project is financially and economically feasible since it can be implemented and financially sustained while at the same time maintaining pricing for consumers at competitive rates. No rate increases are planned to support this expansion and any future increases in rates will be driven by external factors other than this project. We assume our rates will increase 6% per year on average regardless of this project."

"The project will be financed with a \$23,000,000 million loan for 30 years at 5%. St. Mary's understands tax-exempt bond financing is available through the Maine Health and Higher Educational Facilities Authority (MHHEFA) if the project receives Certificate of Need approval. The remaining \$2,544,333 in capital will be funded through an equity contribution from operating cash. There is no fundraising assumption for this project. Based upon the St. Mary's projected consolidated financial statements, St. Mary's has adequate debt capacity to add the additional debt required to finance this project as proposed."

"Given the magnitude of the capital investment, the project itself will lose money during its first three years of operation. However, the St. Mary's targeted bottom-line of 4% and the SOCHS targeted bottom-line of 2% will be maintained throughout the project."

"The staffing plan and incremental operating costs associated with this project are included under Tab G. Third year operating costs are projected to be \$2,869,627. As the analysis indicates, the incremental operating costs associated with this project are driven in large part by \$1,956,561 in interest and depreciation, \$137,000 in salaries and benefits related to the addition of 1 Operating Room RN FTE and 1.2 additional FTEs in housekeeping once the project is complete, and \$684,757 in additional OR supplies related to the increase in surgical cases."

"St. Mary's ultimate objective is always to focus on quality patient care and safety. To ensure quality, the Operating Room and Lab each track several performance indicators. Current quality reports are included under Tab H. Also included under Tab H is the St. Mary's 2007 Performance and Safety Quality Indicator Plan and current data on the measurement of these quality metrics."

"Throughout 2007, St. Mary's has worked on the implementation of Midas quality tracking and monitoring software. We expect to be live with this product by early 2008. This will provide another tool to measure the effectiveness of our quality and patient safety indicators. St. Mary's also believes in total transparency, reporting on key quality indicators on the hospital's website, www.stmarysmaine.com."

"St. Mary's projected consolidated financial statements are included under Tab F. These include eight-year pro forma projections, service volumes, capital and operating assumptions, and revenue, expense and income figures for St. Mary's. Given current and anticipated service volumes and prevailing payment mechanisms, the proposed project is

financially and economically feasible since it can be implemented and financially sustained while at the same time maintaining pricing for consumers at competitive rates. No rate increases are planned to support this expansion and any future increases in rates will be driven by external factors other than this project. We assume our rates will increase 6% per year on average regardless of this project.”

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“Given the magnitude of the capital investment, the project itself will lose money during its first three years of operation. However, the St. Mary's targeted bottom-line of 4% and the SOCHS targeted bottom-line of 2% will be maintained throughout the project.”

“St. Mary's Regional Medical Center is licensed by the State of Maine and accredited by JCAHO. St. Mary's is also a certified Medicare and MaineCare provider. As such, the Medical Center is mandated by these agencies to meet pertinent standards of care.”

“In addition, Goal 1 of St. Mary's Strategic Plan (Board Approved, June 2005) articulates the organization's commitment to patient safety and quality of care and adherence to all applicable standards:

Performance Improvement and Patient Safety Goals

Goal 1: Support and sustain an organizational culture that proactively addresses performance improvement opportunities and patient safety initiatives through a comprehensive system-wide strategy.

- A. Assure regular communication and oversight of the quality of patient care and continuous performance and patient safety improvement efforts by the medical staff, administration and board.**
- B. Utilize knowledge learned from experiences and best practices to proactively improve our services.**
- C. Maximize patient safety by reducing the opportunity for medical/ health system errors.**
- D. Promote collaborative efforts among physicians, nurses, clinical professionals, support staff and administrators to advance patient care and safety.**
- E. Develop and support valid data systems that can be used to measure and assess the organization's performance both internally and in comparison to external data sources.**

- F. Promote customer service excellence and improve patient satisfaction as well as employee, physician and provider job satisfaction.**
- G. Develop and adhere to processes that assure compliance with State, Federal and other regulatory/accrediting requirements.”**

“The proposed Operating Room, Central Sterile, Lab and Pharmacy Expansion and Renovation will be operated in accordance with the same standards now utilized in these clinical departments, but will permit us to more readily achieve the above goals through the many improvements described elsewhere in the filing. Mechanical upgrades, additional square footage and improved clinical flow will only serve to enhance patient safety and quality.”

“There are mechanical and HVAC facilities that are currently out of compliance that will be addressed. AIA provides guidelines related to size of operating rooms, privacy and safety, HIPAA, air exchange requirements, etc. These guidelines are significantly more stringent than those in place at the time the current departments were built in the early 1990's. Through this project the operating rooms, central sterile, lab and pharmacy will be brought into compliance with the current AIA hospital guidelines.”

“St. Mary's has engaged SMRT of Portland, Maine to design the Operating Room, Central Sterile, Lab and Pharmacy Expansion and Renovation project to comply with all applicable standards and to fulfill our programmatic needs. The firm has been involved in several projects at St. Mary's, and it was chosen because it has an excellent awareness of municipal, state and federal ordinances, statutes, life safety codes and other regulations. The design of the project incorporates all of these requirements, and necessary approvals will all be obtained prior to the start of construction.”

“The project will include a building addition on land immediately adjacent to the existing pharmacy. No additional land will need to be acquired as the expanded facility will be developed on existing hospital property. Consequently there will be no sprawl into abutting neighborhoods.”

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;

ii. Analysis

In 2007, St. Mary's Regional Medical Center applied for a Certificate of Need to build and renovate their emergency department. This was approved. In the interim they also notified the CONU of their intentions to construct a medical office building for \$5,112,500. St. Mary's projects approximately \$4M in capitalized expenses each year not related to any of these three projects. In total the amount of capitalized assets is expected to increase from 29MM to 62MM in the time frame of this project. This doubling of capital assets represents a significant investment in the health care delivery model and should not be treated lightly. The importance of maintaining a consistent operating margin with increased fixed costs cannot be underestimated. This proposed project will have a significant impact on the hospital's ability to adjust to changes that may negatively affect its performance margins.

In last year's CON project St. Mary's proposed to finance a significant portion of the project through fundraising. A question regarding the ability to fund the capital portion of the ED project was related to the ability of the hospital to raise the \$2 Million in contributions. A feasibility study was commissioned and the report, while not provided to CONU, concluded in part: "Our findings demonstrate a minimum goal of \$3 million is achievable. If the project secures a few 6-figure lead gifts, a \$3.5 to \$4 million goal is attainable. Several gifts at the \$250,000 to \$1 million level would be required to raise \$5 million, and this level of giving does not appear to be present. SOCHS will need to ultimately decide, 'what is the right goal, based on needs and the collective willingness of the Board to aggressively pursue goal achievement'." St. Mary's then commented, "Following receipt of this report, the Board of the health system voted to pursue a fundraising Campaign with a goal of \$3.0 million, viewing this figure to be achievable, but also recognizing that until the goal is achieved, it remains a goal and not a matter of certainty. Against this background we believe our proposed equity contribution of \$2.0 million from this source is realistic and conservative." For this project St. Mary's estimates a need for 90% financing meaning a capital contribution of 2.5MM will be necessary. Unlike the previous proposal St. Mary's believes that there is adequate operating capital to fund this project. The capital contribution is roughly 22% of current liquid assets. As a follow-up to this project CONU is assuming that fundraising remains on schedule. A change in fundraising goals would impact the previous CON.

Since St. Mary's finances are dependent on the completion of the CON approved last year, it is recommended that this CON, if approved, bear the condition that the construction related to the 2007 CON for the Emergency Room project be completed before this project exceeds \$4,000,000 in expenditures. This amount represents the construction costs for the addition and the leveling of the corridor, projects that are scheduled to be started in 2009. This will assure completion of the 2007 CON.

Financial Ratio Analysis

In an effort to sustain readability, additional financial ratios, as well as 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 2007, 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 2004 through 2006 (audited) and 2007 through 2015 (projected). Also, since the third operating year of the proposed project is 2015, 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 2008 Almanac of Hospital Financial and Operating Indicators. We are presenting 2006 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.

Financial Performance Indicators

Profitability	2006	2012	2015	2006 ME State Median	2006 Northeast US Median
Operating Margin	3.41 %	5.57 %	3.90 %	3.80 %	1.83 %
Net Margin	5.78 %	7.18 %	5.36 %	3.90 %	3.00 %
Return on Total Assets	7.08 %	7.18 %	5.35 %	5.26 %	2.28 %

All three margins indicate that if the proposed project occur that St. Mary's would remain profitable. However, the comparison between operating year 2004 and 2005 indicates that operating margins were decidedly higher in 2004 than in 2005. 2006 for St. Mary's was more in line with what is expected for a facility of its size and purpose in Maine. The 2007 operating margin is projected at 7.41%. A projected operating margin of 5.57 in 2012 is consistent with the range that St. Mary's has experienced in 2004-2007. St. Mary's has the means to take on additional expenses based upon excess of revenues over expenditures.

The CONU financial analysis considers information contained in the 2008 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.

Operating margins in the high performing hospital group have seen greater improvements in margins while hospitals in the low performing group are sliding. 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 operating profits for high-performing hospitals drives this widening performance gap. As a comparison, operating margins in the Northeast Region are considerably lower than in other regions.

The Maine State average for operating margin in 2006 was 3.80%. St. Mary's in 2006 was 3.40, which puts them nearly in the middle of hospitals in Maine.

The trend for operating margin in the State of Maine has been improving from a low of -1.35 to the present high of 3.8. St. Mary's for the past four operating years including 2007 averaged 6.0%. 2005 was 15.90% which helped to offset the -0.54% St. Mary's reported in 2004. Over the course of the projection through 2015 it is projected that the hospital will have an operating margin rising to greater than 5.5% before dropping through 2015 to 4.41% (3.90% if the project is approved) This is consistent with the CON presented last year and should be noted that combined the two projects decrease operating margin by nearly 20%.

The effect of this project on operating margins, as projected by the applicant, is a decrease from 4.41 to 3.90. This project is not expected to cause a significant impact on the operating margin on the hospital by itself. With the layout suggesting the potential for greater throughput the enrollment of more doctors in surgical services at St. Mary's there could eventually be a significant increase in revenues.

Financial Performance Indicators

Profitability	2005	2006	2007	2012	2015
Operating Surplus	\$ 18,921,154	\$ 3,781,203	\$ 9,064,382	\$ 8,235,968	\$ 6,361,642
Total Surplus	\$ 20,536,947	\$ 6,424,944	\$ 12,050,943	\$ 10,628,833	\$ 8,754,507

This table validates that St. Mary's has the capacity to financially support this project.

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	2006	2012	2015	2006 ME State Median	2006 Northeast US Median
Current Ratio	4.34	4.87	5.99	1.67	1.53
Days in Patient	36.17	34.65	34.65	49.17	44.3

Accounts Receivable	Days	Days	Days	Days	Days
	104.24	122.58	152.72	97.9	67.7
Days Cash on Hand	Days	Days	Days	Days	Days
Average Payment Period	28.49	23.60	22.86	63.4	53.6
	Days	Days	Days	Days	Days

In terms of liquidity, St. Mary's Hospital currently has adequate liquidity, with a payment lag of 8 days between being paid and paying for services. It is interesting to note that the projection indicates an increasing lag over the forecasted period. The average payment period rebounded in 2004 to 27 days from a high in 2003 of 35 days. Forecasted average payment periods are a very aggressive 22 days, this strengthens the assurance that cash needs can be met. Days in accounts receivable increased by 9 days in the same period. Days cash on hand was in a range of 50-60 days in the 2002-2006 periods and is projected to increase significantly to more than 150 days during the course of the project.

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 2006 marked a steep decline of cash on hand nationally. Hospitals with revenue of \$100M-150M have 56 days cash on hand. St. Mary's with Net patient service revenue of \$110M and cash on hand of 104 days in 2006 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 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 2006 the average days cash on hand for all sources for hospitals in the State of Maine was 97.9 days. Calculated days cash on hand for St. Mary's in 2006 was approximately 104 days indicating that St. Mary's was in the 50-75th percentile.

According to the same source, between 2000 and 2004 the average days cash on hand remained about 68 days. In 2006 cash on hand reached a five year low. Between 2004 and 2015 average days cash on hand for St. Mary's is projected to increase by 95 days. In 2004, Maine had 15% less days cash on hand than the Northeast Region at 80 days, 12 days more than the Maine average. In 2006, Maine hospitals had increased their cash on hand by 50% in two years to be 30 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. Therefore

this project will not have a substantial impact on St. Mary's operating ability to meet its cash demands. Even if actual cash on hand is lower, based on additional investments in programs and technology, St. Mary's 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	2006	2012	2015	2006 ME State Median	2006 Northeast US Median
Equity Financing	66.2 %	65 %	71 %	58 %	47.4 %
Debt Service Coverage	5.27	5.22	4.34	3.48	3.45
Cash Flow to Total Debt	35.3 %	29 %	32 %	23.8 %	18.2 %
Fixed Asset Financing	77.2 %	65 %	61 %	52.0 %	65.3 %

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 2006 the median Maine hospital's debt service coverage (DSC) was 3.48x.

St. Mary's Hospital had a DSC in 2006 of 5.27x which places it in the range of 50-75th percentile. The trend has been statewide for 2002-2006 has been increasing with a low of 2.36 in 2002 and a high of 3.71 in 2004. The trend for St. Mary's has been increasing for the last 4 years from 3.15x to 5.27x and to a combined 7.0x for 2004 and 2005. The trend as projected by St. Mary's for this project 2008-2015 is that DSC is expected to stay about the same with 2015 being projected to be 4.34x. This is much different from last year's numbers which suggested 2012 to have Debt service coverage to improve to

greater than 6.25x by 2012. As compared to the non-CON projection DSC is expected to decrease by 1.16x.

St. Mary's has the capacity and the ability to have adequate debt service coverage. If St. Mary's were to maintain its debt service coverage at a ratio consistent with its recent history, a change of 1.16x would not significantly impact its ability to service its loans.

The 2008 Almanac commented: "Low performance hospitals have historically used more debt to finance net fixed assets than high performance hospitals. With the removal of capital cost pass through, long term debt will become most costly relative to equity. High performance hospitals are restructuring their capital positions to reflect this shift in the relative costs of debt and equity capital. However, we expect fixed asset financing ratios to continue to remain stable during the next 5 (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 2006 average for hospitals in the State of Maine was 52 percent in regards to fixed asset financing. In 2006 St. Mary's was at 77.2 percent which is the 75th-90th percentile for the State of Maine. For the years 2002-2006, for hospitals with revenues similar to St. Mary's, 63 percent is about the average.

The fixed asset financing ratio over the past 5 years has remained relatively consistent in the State of Maine.

The proposed financing is consistent with the way St. Mary's is spending the funds on fixed assets. This is because a significant portion of St. Mary's existing debt is expected to be repaid during the next five years. Total debt in year three of the project (2015) is expected to be approximately 10MM 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 the St. Mary's is expanding its capital footprint, this represents stress to the organization that previously was not there to maintain financial performance at a higher level. SOCHS has a goal of 2% operating margin and St. Mary's has a goal of 4%.

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

Financial Performance Indicators

Efficiency	2006	2012	2015	2006 ME State Median	2006 Northeast US Median
Total Asset Turnover	1.22	1.00	1.00	1.12	1.13
Fixed Asset Turnover	3.79	2.24	2.63	2.74	2.77
Current Asset Turnover	3.18	3.46	2.89	4.19	4.15

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. First, larger hospitals are most likely to have newer physical plants. Second, capital intensity is often greater in larger hospitals due to more special services and higher levels of technology.

In 2004, according to the source cited above Maine hospitals had a TAT of 1.12.

For 2004 St. Mary's had a TAT of 1.34. This is indicative of the relative age of the hospital and expected because of the lack of significant hospital improvements over the past decade.

In the period of 2000 – 2004 there has been a steady increase in the TAT for Maine hospitals. The expected trend for St. Mary's is for TAT to lower during the time frame of this project 2009-2015. This is reflective of a hospital planning to spend significant funds for capital improvements or investments in technology. This is a capital intensive project. The capital nature of this project is indicated by the fact that revenues are expected to increase by only 5 percent of the increase investment in assets.

Operating Costs in the third operating year are expected to increase by \$2,869,627. For the Bureau of Insurance this amount is adjusted to a current value of \$2,075,146 in order to calculate the impact of this project on commercial insurance premiums. The impact on the CIF if approved would be \$2,115,034. The \$2,869,627 includes \$910,421 in depreciation and \$1,046,140 in interest expense. Additional costs for staffing and supplies amounts to \$913,066 in 2015 dollars.

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.

The capital expenditures for this project reflect costs on the pharmacy, laboratory and central sterile level of \$120-\$150 per square foot and for the surgical suite of \$330 per square foot. This is considered to be a reasonable cost estimate according to industry sources. Because of the nature of the spaces, construction is expected to take a significantly longer time than other construction projects and incur significantly larger construction interest charges. Construction is slated to take 38 months. As proposed this project is expected to allow an additional 1.3 surgeries daily based on 250 operating days annually.

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

- 1) interest and depreciation;
- 2) \$137,076 in salaries and benefits related to the addition of 1.0 full time equivalent Operating Room registered nurse FTE and 1.2 additional FTEs in housekeeping once the project is complete and;
- 3) \$775,990 in additional OR supplies and other expenses related to the increase in surgical cases.

Changing Laws and Regulations

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

iii. Conclusion

The applicant has demonstrated the financial capacity to support the project over its useful life and the organizational strength to adjust to reasonable changes in laws and rules.

CONU recommends that the Commissioner determine that St. Mary's has met its burden to show that the proposed project demonstrates economic feasibility. However, as discussed below, CONU recommends disapproval of this project. Should the Commissioner disagree with this recommendation, CONU recommends this CON, if approved, bear the condition that the construction related to the 2007 CON for the Emergency Room project be completed before this project exceeds \$4,000,000 in expenditures.

IV. Needs to be Met

A. From Applicant

“The service area to be served by this project is St. Mary’s primary service area of Androscoggin County, as well as the secondary service area of Oxford and Franklin counties. According to the U.S. Census Bureau 2005 Population Estimates, Androscoggin county population is 108,039. Oxford and Franklin county population is 56,628 and 29,704 respectively. Therefore, total service area population is 194,371. During 2006, 86% of St. Mary’s medical/surgical inpatient volume was from the tri-county area.”

“Medical/surgical use rates calculated using the Maine Hospital Association 2006 Inpatient Origin Report and the U.S. Census Bureau 2005 Population Estimates are as follows:

Androscoggin county	93 discharges/1000 population
Oxford county	101 discharges /1000 population
Franklin county	95 discharges/1000 population”

“St. Mary’s historical use patterns relative to the project are as follows:

Surgical Cases

1997	3,668
1998	3,718
1999	3,938
2000	4,421
2001	4,839
2002	4,548
2003	4,357
2004	4,671
2005	4,404
2006	4,545
2007	4,829 projected
2008	4,799 projected
2009	4,830 projected
2010	4,862 projected
2011	4,918 projected
2012	4,970 projected
2013	5,020 projected
2014	5,070 projected
2015	5,121 projected”

“Over the last 10 years (1997-2007), St. Mary’s surgical cases have increased by 31.65%. This increase in surgical volume has paralleled our investment in our primary care network. As the primary care network is now closer to maturity, we expect surgical

volume to moderate, and we are projecting an overall increase in surgical volume of only 6% through 2015.”

“Our 1990 operating room/surgical service configuration is woefully inadequate to meet our current and projected level of surgical volume. In addition to the pure volume concerns, we are challenged to meet the new technological and patient safety demands that did not exist in the early 1990's.”

“Patient privacy and confidentiality are now legally mandated patient rights, and every day we struggle to honor our patients' privacy. Our OR holding area is so small it necessitates lining patients up, side by side. OR staff (surgeons, anesthesiologists, nursing) all need to converse with patients in this area as they prepare them for entry into the OR, and it is impossible not to overhear these private conversations. The post anesthesia care unit presents similar challenges. In addition, locating patients in such tight, crammed quarters increases the risk of infection. There is also no private space for surgeons to speak with families, and this makes for uncomfortable conversations for all parties involved.”

“As our volume has increased, we have also seen a shift in the mix of cases we are seeing. In the early 1990s, we were seeing very few neurosurgery cases and far fewer orthopedic cases. Those we were seeing were far less complex than today. In 2006, 20% of our surgical cases were either neurosurgical or orthopedic. That percentage has increased to 23% in 2007. In addition, 43% of our operating room hours are attributable to these services, with the average neurosurgery case 3.2 hours and the average orthopedic case 2 hours. This has dramatic impact on the OR. These cases make scheduling of the ORs very difficult, especially when the rooms are not adequately sized to accommodate the technological and medical equipment demands these cases require.”

“In addition to addressing the need for larger ORs and appropriate support space for OR holding, post anesthesia care, and family waiting and consult, the new plans will provide desperately needed storage. The OR equipment and supply needs have expanded exponentially, and St. Mary's is currently forced to store equipment and supplies on carts in the hallways. This negatively impacts efficiency, as the hallways and corridors are difficult to navigate with patients on stretchers, and it is often very difficult to procure needed supplies and equipment in a timely manner. Finally, the current predicament with storage jeopardizes St. Mary's compliance with applicable codes and regulations defining the proper storage of such equipment.”

“Central Sterile volume is directly correlated to surgical volume, and that space is being relocated in order to accommodate the required expansion of the Operating Room. Current space will be modestly increased and moved to the lower level with access to the OR through an elevator system.”

“The St. Mary’s lab has seen even more significant growth over the last 10 years.

Lab Billable Tests

1997	299,621
1998	333,717
1999	286,437
2000	307,064
2001	347,434
2002	356,383
2003	384,023
2004	410,543
2005	448,371
2006	496,609
2007	499,103 projected
2008	504,998 projected
2009	510,048 projected
2010	515,148 projected
2011	520,299 projected
2012	525,502 projected
2013	530,757 projected
2014	536,065 projected
2015	541,426 projected”

“Again, we believe this increase of 66.6% (1997 – 2007) is related to the growth we have experienced in our primary care network over the last 10 years. In addition, we have experienced dramatic growth in our outpatient medical oncology/infusion therapy practice. St. Mary’s will pursue automation of the lab over the next year or two, and this will help accommodate the current and total projected volume increase of 8.5% through 2015, however, this level of volume can simply not be accommodated in the current space. The new lab space will be designed to accommodate automation, and will provide needed space for staff to accomplish their work in a safe, properly configured environment. We will also be able to provide more private space for lab registration and blood draw. This is currently accomplished in two under-sized discrete, fractured spaces that are not conducive to patient privacy and comfort.”

“The St. Mary’s pharmacy provides a critical service to the entire hospital. It also represents one of our higher risk areas, and therefore, necessitates an environment that supports very focused, detailed work on the part of pharmacists, pharmacy techs and support staff. It also requires adequate storage space for the clear, organized inventory of the pharmaceuticals as the margin for error is virtually non-existent in this essential health care service. The current hospital pharmacy provides neither adequate work nor storage space. This is less a matter of volume, and more a matter of patient safety.”

“It is difficult for St. Mary’s to present meaningful volume trend data for the pharmacy. In 2005, the hospital underwent a major conversion of its hospital information system.

This conversion required a change in the manner in which pharmacy volume was measured, and new volume numbers are no longer comparable to the old. However, current and projected pharmacy volumes are provided below, and we are projecting that this volume will be relatively constant through 2015:

Pharmacy STD Hours

2007	28,625 projected
2008	28,625 projected
2009	28,625 projected
2010	28,625 projected
2011	28,625 projected
2012	28,625 projected
2013	28,625 projected
2014	28,625 projected
2015	28,625 projected"

"Tab A contains the Statement of Deficiencies that resulted from the state licensing survey conducted in March 2006. This report details some of the facility issues of concern that will be addressed by this project."

B. CONU Discussion

i. Criterion

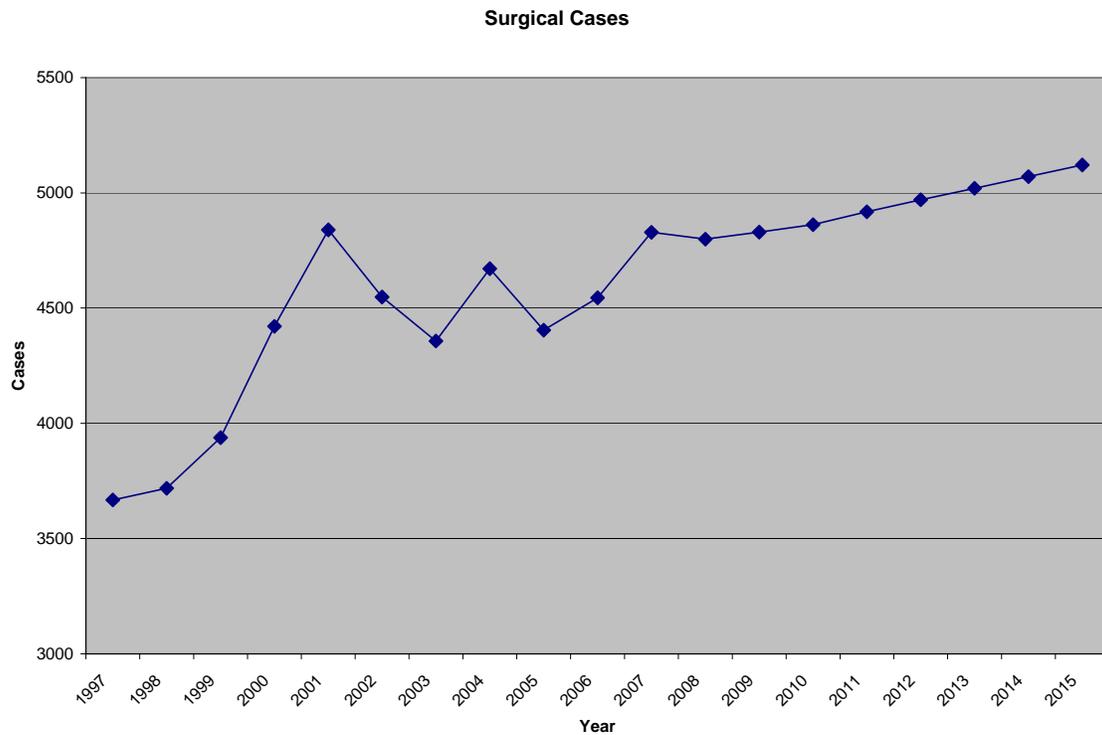
Relevant criterion for inclusion in this section are specific to the determination there is a public need for the proposed services as demonstrated by certain factors, including, but not limited to:

- 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 provided historical use patterns relative to the project. According to the applicant there has been a 31.65% reported increase in surgical volume that reportedly paralleled their investment in primary care network. Future growth is projected at 6% through 2015. It is not clear what the 6% growth projection is based upon.

The following charts were graphed by CONU using data provided from the applicant.



The applicant, in response to questions submitted by CONU in regards to its original application, was asked to discuss the marked changes in surgical cases as represented in the chart above.

In a letter dated April 3, 2008, they responded by saying, “St. Mary’s has increased its primary care base, and this has generated an increase in surgical referrals. Community Clinical Services, an FQHC affiliated with St. Mary’s currently employs 29 internal and family practice providers at 16 sites throughout the community. The hospital payer mix is 20% MaineCare.”

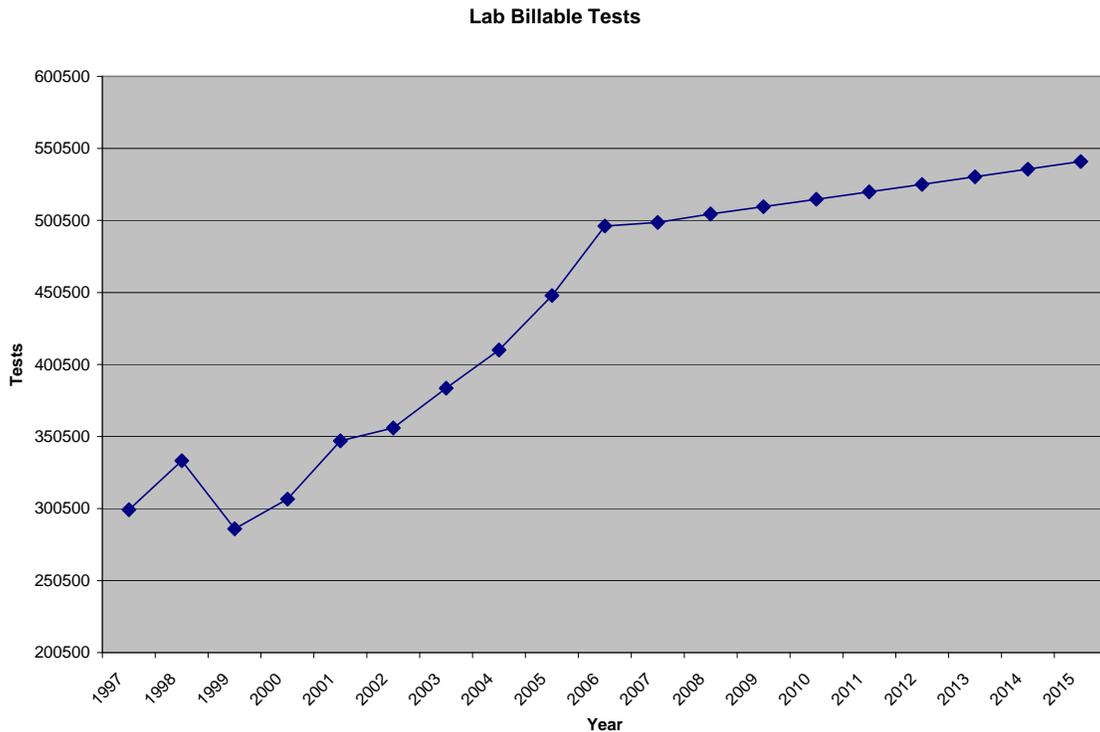
“The population is aging and there are higher surgical use rates among the population 55+.”

“St. Mary’s has developed a center of excellence in orthopedic joint surgery, and this has led to an increase in volume (29% over the last year).”

“St. Mary’s neurosurgery program has provided outreach to Togus, and this previously underserved population now has access to neurosurgery services at St. Mary’s. (23% increase over the last year).”

“St. Mary’s as developed a multidisciplinary chest oncology program that allows patients to undergo thoracic cancer surgery in their home community (27% increase over the last year).”

It is interesting to note that the surgical case load does correspond to these changes in staffing. However, CONU lacks information to determine if these activities are related to treating underserved areas or merely a shifting of hospital services from one community to another or one hospital to another. Additionally the applicant projected a 6% increase growth rate over 6 years. This projection appears to assume little additional need.



This application speaks to the physical plant needs of the facility but fails to address specific health problems to be addressed by the project as measured by health needs in the services area. For example, the applicant speaks about the risk of infection but provides no details relative to the type or frequency of infections and what reduction will occur as a result of this project. Infection reduction procedures were not discussed. What actions have they employed to reduce infections and how effective have the processes been were not included. In addition, the District Health Profile, Western Maine District, December 2007 includes public health indicators for this service area.

The applicant failed to discuss the impact of this project on health status indicators of the population to be served. CONU concludes that the applicant failed to meet its burden to show specific and measurable health needs and outcome measures.

At the Public Hearing on March 4, 2008, the applicant noted that they “have HVAC mechanical costs that are part of that 14.3 million.” “These are costs that we would need to incur in any case whether we went forward with this project or not.”

St. Mary's is a not-for-profit hospital and, thereby, its services are accessible to all residents of the area.

The applicant failed to meet its burden to demonstrate improvements in patient quality and outcome measures were quantified.

iii. Conclusion

The project encompasses improvements to a facility that has certain challenges due to its age, changes in technology and an increased provider network. The operating rooms are undersized by today's standards (AIA & Hospital of the Future). However, the applicant failed demonstrate that there is a public need for the proposed services for patients in the Lewiston service area because of the lack of OR space or laboratory or pharmacy expansion. Because of the lack of measurable patient outcomes and health indicators the applicant has failed to show that this CON criterion has been satisfied.

CONU recommends that the Commissioner determine that St. Mary's has failed to meet its burden to show that the proposed project meets the public need.

V. Alternatives Considered

A. From Applicant

“The services included within the scope of this project (the Operating Room, Central Sterile, Lab and Pharmacy) are all essential clinical services that are integral to any full service community hospital. According to inpatient market share statistics provided by the Maine Health Information Center, St. Mary's served the health care needs of 37% of the Androscoggin county population in 2006. While reliable, consistent outpatient data is not available, we can fairly assume that the outpatient market share mirrored this percentage given our share of affiliated primary care providers. Therefore, a significant portion of our community counts on St. Mary's to be available when they have health care needs that require either inpatient or outpatient surgical care and related ancillary services. Consequently, eliminating any of these essential services was never considered a viable option. On the contrary, these critically important services must be maintained and enhanced to meet current technological and patient demands, and fulfill all applicable standards.”

“Because addressing the shortcomings that are being addressed by this project was identified as a priority in the St. Mary's Facility Master Plan completed in December 2004, several alternatives were explored before concluding that expansion and renovation of space was the only viable option.”

“Recently, St. Mary's has made a concerted effort to accommodate demands with the current physical plant. Within the last year, ophthalmology procedures were relocated to two minor procedure rooms in the outpatient department. This has helped to somewhat mitigate issues related to OR scheduling, patient holding, patient privacy and storage to a minor extent, but the challenges continue. In addition, this was at best a short-term fix that is not sustainable over time. We also attempted to alleviate space issues in our lab by converting a conference room to a lab registration office. Again, this offered some immediate relief, but did nothing to address inherent inefficiencies in our current lab and pharmacy configurations. Therefore, these temporary fixes were not an acceptable alternative to proceeding with the project described in this application.”

“St. Mary's also considered simply reconfiguring the current space so as to avoid adding any additional square footage. This option, however, was quickly rejected when we were faced with expanding at least 4 of our current operating rooms to 500 - 600 square feet in accordance with AIA standards. We simply did not have the square footage required to accomplish this, nor did we have adequate space to properly accommodate patient privacy in the holding area, an integrated preadmission testing area, infection and patient safety concerns, and required storage areas needed to meet code and licensing requirements. There was also a lack of available space on the lower level of the medical center to create an efficient lab and pharmacy configuration that could meet modern demands of clinical workflow, technology and patient privacy and safety.”

“Therefore, St. Mary’s presents this application as the only real alternative worthy of further consideration.”

B. CONU Discussion

i. Criteria

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

- The impact of the project on total health care expenditures after taking into account, to the extent practical, both the costs and benefits of the project and the competing demands in the local service area and statewide for available resources for health care;
- The availability of state funds to cover any increase in state costs associated with utilization of the project’s services; and
- The likelihood that more effective, more accessible or less costly alternative technologies or methods of service delivery may become available;

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.

ii. Analysis

Alternatives discussed in the application are: Not viable to eliminate services; internal space adjustments; reconfiguring space. The applicant failed to present information relative to the impact of the project on total health care expenditures in the service area and statewide. Nor did the applicant present specific cost information to the alternatives that they considered.

Initially the applicant did not discuss the option of collaborating with Central Maine Medical Center to identify areas of mutual need or system efficiencies. In a letter dated April 3, 2008, the applicant stated that while conversations with Central Maine Medical Center regarding combining Laboratory space have taken place, “we both feel strongly that we need to maintain our own hospital-based lab services for the following reasons:

- 1) We need to maintain our ability to support critical clinical services that require immediate lab testing/response. Key areas include:

- a. OR: critical to minimize patient anesthesia exposure; quick turn around time to maintain patient vital signs, blood usage and electrolytes; need for STAT micro results for orthopedic joint replacements.
 - b. ER: provide immediate results in order to make diagnosis and begin treatment, minimizing time in ER.
 - c. Oncology: STAT results needed for outpatient treatment/infusion therapy dosing.
 - d. ICU/CCU: required to maintain cardiac and intensive care plans for critically ill patients.
- 2) St. Mary's and CMMC have already created appropriate opportunities for collaboration (short of a combined lab)
- a. CMMC serves as the regional depot for the American Red Cross to provide additional blood products in emergency situations.
 - b. Regular sharing of supplies, reagents and equipment.
 - c. Both labs serve as back-ups to each other; eliminates the need for costly back-up equipment, ensuring patient access to needed services during a hospital-specific downtime, as well as a larger regional emergency/disaster.
- 3) St. Mary's has fully evaluated the option of outsourcing lab services. It was concluded that continuing a hospital-based lab (with appropriate usage of outside reference labs for esoteric testing) was the most cost-effective option."

The applicant does not provide any detailed data showing that an on-site laboratory is more cost effective. Hospitals of the Future suggest that some laboratory and pharmacy functions can be decentralized as follows:

	<u>Centralized</u>	<u>Decentralized</u>
Laboratory	Routine chemistry Immunoassay Hematology testing Anatomical pathology Molecular diagnostics	Glucose testing Cardiac markers Toxicology/drug screening Coagulation testing Electrolyte testing Blood gas testing
Pharmacy	Unit dose preparation First dose delivery Sterile medication preparation	Narcotics storage Maintenance storage Emergency medications

Additionally the Maine Quality Forum analysis states: "the application does not address in detail opportunities for collaboration, as specified in the State Health Plan, in laboratory services (Central Maine Medical Center currently has a CON application for enlarged laboratory space). An in depth assessment of ways in which the two neighboring

institutions could combine resources to improve services in their area with less cost impact would be appropriate.”

Additionally the applicant failed to include information that indicates any effort with Central Maine Medical Center, Central Maine Orthopedics Ambulatory Surgery Center, or other area providers to quantify total needs in the service area or how the orderly and economic development of health care facilities and health care resources could meet those needs.

Recent information received by CONU also raises important issues regarding Operating Room expansions. A Delicate Balance: Managing The Inpatient Enterprise Across Time “Avoiding A Field of Dreams” presents several lessons learned and conclusions relative to hospital growth, including:

- Lesson #12: “Answer-First Facilities Planning”

“Conclusion #28 Finding of Greatest Concern in the Research: Hospitals often seeing the need for new inpatient capacity, even investing the capital, but getting their investments wrong; two problems worth avoiding.”

“Conclusion #29: Problem #1: Investing where physical capacity is “apparent”, not actual short supply; too many hospitals are expanding their ED’s and ORs when the real capacity shortage is further downstream in critical care or med/surg beds.”

Treating the Symptoms, Not the Cause

Symptom	“First Blush” Cause	Actual Cause
Surgery delays worsening	OR turnaround too slow	PACU, inpatient beds full
Referral/Transfer denials increasing	ORs overtaxed, critical care beds full	PACU, inpatient beds full

- “Lesson #13: Add Capacity From Back To Front
Conclusion #31: For many hospitals ED overcrowding and OR delays are merely symptoms of a bottleneck further downstream; root cause problem is too few critical care beds and (even more important) too few med/surg beds-no solving access problems without investing on the back end first.”

The applicant also failed to discuss the availability of state funds to cover any increase in state costs associated with utilization of the project. CONU analyst estimates such costs as follows: Total projected 3rd year incremental operating costs are projected to be \$2,869,627 and of that amount MaineCare’s 3rd year cost is \$455,123 (\$2,869,627 x 15.86 % (MaineCare payor mix projected by the applicant for CON project type of

services only)), which is both the Federal and State portions combined. Currently the impact to the State portion of the budget by the third year of operation (2015) would be approximately \$159,293 ($\$455,123 \times 35\%$).

The applicant also failed to address the likelihood that more effective, more accessible or less costly alternative technologies or methods of service delivery may become available.

CONU concludes that St. Mary's has not met its burden to show that the project is consistent with the orderly and economic development of health care facilities and health care resources for the state.

iii. Conclusion

CONU recommends that the Commissioner determine that St. Mary's has failed to meet its 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

i. Introduction

This section includes information presented in the application relative to how the proposed project specifically relates to priorities in the State Health Plan (SHP). The applicant's comments, as well as input received from the Maine CDC/DHHS, and CONU findings are incorporated under the respective priorities for the SHP. The complete text of the Public Health Assessment by the Maine CDC/DHHS is contained in the CONU record.

This year, Certificate of Need (CON) applicants were provided with two items that provided clarifying information regarding the State Health Plan.

The first item is a memo to Potential CON Applicants dated October 9, 2007. This memo was developed by the Advisory Council on Health Systems Development to provide clarification and guidance relative to the State Health Plan Priority "projects that directly and unambiguously protect the public's health and safety," more specifically: 1) "projects that have as a primary, overriding objective the elimination of threats to patient safety" and 2) "projects that center on a redirection of resources and focus toward population-based health and prevention; such efforts address our state's greatest area of need . . ." The criteria and definitions contained in this memo will be used to evaluate the applications consistency with the State Health Plan. A copy of this memo is on file with CONU. It was included in packets distributed to attendees at the Technical Assistance Training, October 19, 2007.

The second item is a letter to CON Applicants dated January 10, 2008. This letter was developed to provide clarification specific to which State Health Plan guides the 2008 CON review process. The letter states that the current State Health Plan will guide the CON review.

Relevant criterion for inclusion in this section is specific to the determination that the project is consistent with the goals and priorities of the State Health Plan.

It is important to note that priorities are further defined within the CON section of the SHP. The CONU review of consistency with the SHP follows and is organized by priority.

A. From Applicant

“We understand that DHHS will be evaluating this project and other proposals from other hospitals against the criteria and priorities set forth in the State Health Plan (“SHP”) – and will be applying the priorities that are set forth at Chapter 10(1)(E) of the December 2004 CON Procedures Manual (based on earlier SHP), as well as the SHP of 2006/2007. Based on the October 19, 2007 Technical Assistance Meeting, and subsequent e-mail exchanges with Ms. Powell, we have been informed that the Chapter 10(1)(E) standards will take precedence over those in the most recent SHP. We therefore offer the following in response to the specific priorities in Chapter 10(E) of the Manual. We will also address other priorities described at pages 56-60 of the current SHP.”

“At a December 13, 2007 meeting with Ms. Powell on another subject, our counsel was informed that this prioritization determination was being further examined, and that an additional clarifying communication would likely be forthcoming, and could serve to elevate the priority status of the current SHP. Ms. Powell advised that should this new determination be made, all applicants would be given an opportunity to supplement their filings for this section. We will await any further clarifications, and if forthcoming, we will determine whether and to what extent we should supplement this portion of our filing.”

ii. Analysis

Priority: Projects that protect public health and safety are of utmost importance.

Projects that have as a primary, overriding objective the elimination of specific threats to patient safety.

a. Applicant's Discussion on Priority

“We understand that projects that protect the public's health and safety are assigned the highest priority. We feel our project directly reflects this priority, and in many ways is the actual driving force behind the project. It is directed toward “eliminating threats to patient safety” in many respects.”

“The Operating Room, Lab and Pharmacy represent some of the most high risk areas of the clinical enterprise. In order to ensure public health and safety, it is absolutely essential that we deliver these services in a facility that meets current codes and requirements. Anything less is unacceptable, and would contradict our culture of always pursuing excellence in quality of care.”

“In the Operating Room, we will be addressing a host of issues including: undersized operating rooms that are unable to accommodate the current technological demands, especially in the areas of orthopedics and neurosurgery; air handling and mechanical systems that are currently unable to adjust appropriately for high humidity, thereby causing visibility issues for providers; less than optimal access to needed surgical

instruments and supplies given substandard storage; inadequate holding areas causing confusion and chaos for providers and patients; and lack of integrated pre-admission testing service causing inefficiencies and confusion for providers and patients. Addressing all of these issues contribute to a higher quality and safer experience for surgical patients.”

“In the 20 years since the existing OR was designed contemporary healthcare facilities have evolved with the recognition that positive clinical outcomes are linked to the environment of care. A healthcare environment that provides patients privacy, choices, space and amenities for family members, access to information and technology, positive distractions, natural light and reduction of noise and commotion will significantly enhance the patient experience. Although the number of OR's in the proposed project remains the same the patient prep and recovery space and the family support and waiting space is more than doubling in size. Expanding these spaces will allow patients and their families to be treated with dignity and respect in an environment that balances the needs of the clinical team and the patient making provisions for the needs of all stakeholders involved.”

“In the Lab, we will be redesigning space to improve efficiency and to support the lab automation currently underway. It is critical that our lab staff have well-designed, efficient space as their work requires absolute precision and quick response. We will also provide more private/confidential space for lab registration and blood draw.”

“And in the pharmacy we will also develop more efficient space that will support clinicians and the appropriate, safe storage of the pharmaceutical inventories. The pharmacy staff assumes responsibility for the accurate dispensing of many very powerful pharmaceuticals, and it is essential that they have a work environment that allows them to safely conduct this work.”

b. Maine CDC/DHHS Assessment

“The applicant states that this project addresses public health and safety because of the following issues:

- OR insufficiencies: inability for the OR to accommodate current technologies, equipment, and demand - almost doubling the space by adding 13,541 sf to the OR that was designed in 1988 and build 15 years ago, and to accommodate the increase volume from ~3,700 patients to 4,800 in 2007; the need for modernized air handling and related systems; inadequate storage space and patient holding areas; and lack of integrated pre-admission testing.
- Lab insufficiencies: the project will address inefficiencies, especially related to space – the project proposes 5,440 new sf and 2,287 sf of renovated space for the lab to accommodate the increase in volume from about 300,000 billable tests to 500,000 in 10 years.
- Pharmacy insufficiencies: 2,583 sf of renovate space to include changes that will improve the overall safety of the pharmacy.”

“There could be more measurements of health needs being addressed by the project.”

“There could be a stated measured quality and outcomes measures.”

c. CONU Discussion

The Public Health Advisory Committee issued a clarifying memo on October 9, 2007 to potential Certificate of Need applicants. This memo provided clarification on certain portions of the Maine State Health Plan.

Item #2 in this memo addresses this priority as follows: “Applicants that assert that they are meeting this priority must demonstrate that the project unambiguously protects patient safety. The burden rests with the applicant to demonstrate that the project is evidence-based and to demonstrate the need for the project for patients treated at their facility and quantify, if possible, effects on patient safety.”

In this application, St. Mary's fails to meet its burden to provide quantifiable data that “unambiguously and directly” support the assertion that this application is necessary to protect public health and safety. The narrative related to this priority is focused on patient safety, but does not provide specific data or references. St. Mary's fails to provide measurable clinical outcomes.

Efficiencies in the OR cites in the application are not quantified and also do not include performance measurements.

Projects that center on a redirection of resources and focus toward population-based health and prevention.

a. Applicant's Discussion on Priority

“In addition, St. Mary's is committed to developing health services and programs that are consistent with the orderly and economic development of health facilities and health resources for the entire state of Maine, and in a manner that is consistent with the State Health Plan (SHP). To this end, St. Mary's Strategic Plan (Board approved June 2005) includes St. Mary's commitment to the following public health initiatives (many of which mirror the goals and objectives of the SHP):”

Public Health and Community Reinvestment Goals

“Goal 9: Pursue specific strategic initiatives that serve to improve the overall health of the general public, and are consistent with state public health objectives/ Dirigo Health Plan.”

- A. “Ensure direct access to quality healthcare, disease prevention and health promotion services for potentially underserved populations through sponsorship of Bates Street Family Health Center, FQHC, School-based Health Centers, and Take Charge! Community Screening Program.”**

- B. "Sponsor or actively participate in outreach activities that promote the common good of underserved members of our community: lead screening, healthy families home visitation, Food Pantry, Lots to Gardens, Neighborhood Housing Initiative, cultural diversity initiatives."**
- C. "Heighten awareness of state public health priorities through participation in the Healthy Androscoggin Project."**
- D. "Work closely with area employers in order to assist them in maintaining the good health of the populations they employ."**
- E. "Pursue activities that demonstrate SOCHS' commitment to maintaining the health and wellness of its own employees."**
- F. "Ensure that all SOCHS entities clearly understand their particular role in emergency preparedness, and that employees are adequately trained to respond appropriately in the case of either a regional or national medical emergency."**

"St. Mary's has committed significant organizational resources towards these initiatives. The preventative efforts detailed in items A-E above have specifically impacted the health and wellness of the communities we serve. In recognition of these accomplishments, in January 2007 St. Mary's was formally recognized as one of the American Hospital Association's four finalists for the coveted Foster McGaw Prize for Excellence in Community Service. Some of the health system's accomplishments highlighted in St. Mary's achieving finalist status for this award included:"

"Making Healthcare Affordable: FQHC and the B Street Health Center"

"In the fall of 2003, our downtown Lewiston medical practice became a central component of the newly created *B Street Community Center*. Located in the heart of a federally designated Enterprise Community, the Community Center houses 12 agencies that provide services to the city's poor. The Health Center is a true medical practice where one would not normally be found. It accepts all patients, though many are MaineCare - (Medicaid) -eligible and sliding scale self-pay clients. It provides comprehensive primary care as well as behavioral healthcare in an innovative primary-care mental-health collaborative with the Common Ties Mental Health Coalition. This initiative integrates a range of targeted specialty mental health services with primary care medical services in a multidisciplinary treatment team model. It is driven by the need to address all the issues that present in a primary care setting."

"Androscoggin Country is a designated dental health professional shortage area (HPSA). In April 2004 we opened a pediatric dental program providing a range of dental services to underserved youth. We are staffed with one dental hygienist and one dental assistant 4 days per week for cleanings, sealants, fluoride treatments and education. Of those clients coming in for routine care, at least 20 percent require additional complex care that requires them to be seen by a dentist. Serving the dental needs of the B Street Center clients has proved rewarding and frustrating, with an average rate of 25 percent no shows. One day per week a dentist sees patients with complex dental health issues. Some visits require up to 2 hours."

“Delivering healthcare to the downtown immigrant population has presented special challenges that involve meeting their physical needs as well as assisting them with their complex social needs. Through a series of focus groups with Somali women, we have learned much about their cultural health and nutrition practices, such as:

- How to schedule appointments with people who have not used clocks
- How to ensure safe, full-term pregnancies for women who fast during a month-long religious holiday and stop eating in the seventh month so that their babies will not grow too large
- How to deliver the babies of women who have had female circumcision
- How to respond when they ask that the circumcision be repaired”

“One way we have addressed these challenges is through partnerships with other agencies. For example, working with both the March of Dimes and the Women Infants and Children (WIC) program, we provide a Somali-speaking woman who works side-by-side with our practitioners and WIC counselors to translate and coach women on Western health practices, prenatal care, and nutrition.”

“Six to eight hundred clients visit the B Street Health Center every month. Since May 2004 when the dental portion of the Health Center opened, through 800 visits we have served over 500 children from Lewiston-Auburn’s poorest families who might otherwise never see a dentist. Since October 2004, over 15 Somali women have received prenatal care through the March of Dimes partnership program. At B Street, 59 percent of all patients seen at the clinic receive a mental health diagnosis, with 33 percent of those patients having an addiction-related diagnosis. All of this care was provided in a primary care setting, rather than the emergency department.”

“Take Charge! Identifying Risk”

“*Take Charge!*, a comprehensive health screening program established in 2001, changes the way people receive health information. It eliminates the barrier of health insurance coverage, and reduces the barriers of cost, and transportation. Maine has some of the nation’s highest chronic disease rates, which *Take Charge!* addresses in a way that is both low-cost and preventive.”

“The screening takes about 30 minutes and involves answering 18 questions, providing a finger-stick blood sample and breathing into a machine. Based on this information, a report is generated detailing the individual’s complete lipid profile (cholesterol); glucose measurement (diabetes); pulmonary function measurement (lungs); blood pressure; sleep habits; body mass index; smoking impact; and physical activity levels.”

“At the end of that 30 minutes, a medical professional discusses the results and as appropriate makes referrals to a primary care doctor, or a community-based prevention-related services (e.g. a smoking clinic or exercise program. If more immediate action is necessary, *Take Charge!* clinicians refer the person directly to a specialist. A cardiologist

reviews and follows up on all at-risk results and often refers people back to a primary care physician (a reversal of the traditional healthcare referral process).”

“Individuals requiring ongoing cardiac care are invited to become part of a research study by Androscoggin Cardiology Associates with access to low-cost medications and case management. People with e-mail receive a monthly prevention-related newsletter.”

“These screenings are held throughout the community and in locations where people are likely to be – including at St. Mary’s Regional Medical Center. Businesses have increasingly begun scheduling screenings at their locations and paying for their employees to have these tests done. In these instances, *Take Charge!* also aggregates results and provides them to employers so they may target prevention strategies to areas of highest employee health need.”

“For individuals, any cost can be a barrier to seeking health information. *Take Charge!* uses the income from company-sponsored workplace screenings to fund lower-cost and free community mini-screenings and referrals.”

“Recently, Maine largest Tertiary care hospital (Maine Medical Center) has begun offering this program both independently of St. Mary’s, and in conjunction. They are achieving similar results, which attests to the replicability of this program.”

“To date, approximately 4500 individuals have gone through the screen, 60% female, 40% male. Of those, 77% were of working age, and the average age was 49. 65% of individuals are classified as either moderate or high risk (ACSM), most have cholesterol levels greater than desirable, 26% have elevated glucose levels, about the same number have elevated blood pressure, and a majority have a BMI that is considered either overweight or obese. In 3-6 month follow-up surveys on lifestyle changes after the screening, 57% report they have made changes since the screening, with a slightly higher percentage (61%) among moderate to high-risk individuals doing so. About 67% report dietary changes, and 22 % report increased physical activity following the screening. Just as important, 71% report having followed up with their physician as recommended, with a slightly higher percentage (83%) among moderate or high risk individuals doing so. *Take Charge!* works.”

**“Malnutrition and Obesity: Prescription: Food and Exercise
The Sisters of Charity Food Pantry and Lots to Gardens at work in our community”**

“The Sisters of Charity Food Pantry has been providing emergency food assistance to residents of the greater Androscoggin County for over 25 years. Originally known as Lewiston/Auburn Emergency Food Pantry, the Sisters of Charity Food Pantry was founded in 1981 by the Good Shepherd Food-Bank. In 2002, the Food Bank, needing to focus more on its mission of state-wide food distribution, asked Sisters of Charity Health System to assume operation of the Pantry. The Food Pantry is conveniently located in the heart of downtown Lewiston. It operates 5 days a week. The primary focus of the Food Pantry is to obtain and distribute food to individuals seeking assistance from the Pantry

and educate families on food purchasing, nutritious eating, and cooking. In addition, we direct clients to alternative sources of assistance, both financial and supportive.”

“Local service agencies, churches, hospitals, and schools regularly refer clients to the Food Pantry. Furthermore, the Sisters of Charity medical staff and physician groups distribute Food Pantry vouchers to needy patients.”

“*Lots to Gardens* was started in 2000 with youth and community members to create community gardens and green spaces in Lewiston. Heading into our sixth season, we have gardens and weekly programs focused on healthy eating. The purpose of *Lots to Gardens* is to empower people to develop the skills and knowledge to produce and access fresh and nutritious food at the community level. We help families and youth develop skills for lifelong and community-wide change. Through this program, participants eat more fresh and nutritious food, support local growers and farmers, share meals with neighbors, and are actively involved in physical activity that brings them outdoors. In partnership with Coastal Enterprises Inc., we were instrumental in starting the Lewiston Farmers’ Market, which provides outlets for excess produce from the gardens as well as a place for people who aren’t gardening to purchase fresh nutritious food. At every level, we develop existing skills in the community to teach each other. Participants gain many job and life skills, become knowledgeable in agriculture and nutrition, and become valuable leaders in their community.”

“The Food Pantry currently distributes 12,980 boxes of food annually to over 26,000 people. Seventy percent of those served are families with children under the age of 12. Recent trends also show that many are elderly or “working poor,” individuals holding paying jobs yet not earning enough to meet their family’s basic needs.”

“*Lots to Gardens* has 14 seasonal gardens supplying food to 50 families. Over 120 youth and 100 adult volunteers help in the gardens and workshops. Another 700 individuals a year participate in workshops, veggie stands and cooking classes. In 2006, *Lots to Gardens* provided over 7000 pounds of food to the Good Shepherd Food Pantry and other emergency food distributors in the community.”

b. Maine CDC/DHHS Assessment

“The applicant discusses the various prevention and community health investments it has made over the years and on an ongoing basis, including: support for Bates Street Family Health Center; Take Charge chronic disease screening Program; B Street Community Center with an imbedded medical practice, pediatric dental practice, Somali-focused maternal child health clinics; and support for the food pantry. There are no new or redirected resources mentioned.”

“There could be a commitment to re-directing resources to prevention initiatives that work collaboratively with the existing local public health infrastructure.”

c. CONU Findings

While the applicant states what prevention initiatives they have in the past and currently are involved in, the applicant did not state how this project would contribute to population-based health and prevention efforts.

d. Determination

CONU finds that the applicant fails to meet its burden to demonstrate that this project will directly and unambiguously protect patient safety.

Priority: Projects that contribute to lower costs of care and increased efficiencies.

Projects that clearly demonstrate they will generate cost savings either through verifiable increased operational efficiencies or through strategies that will lead to lower demand for high cost services in the near or long term.

a. Applicant's Discussion on Priority

“St. Mary's and its affiliated organizations offer a full continuum of care. The health system attempts to ensure that individuals always seek care at the appropriate point on the care continuum. We have expanded access to primary care and prevention/wellness services, and have addressed related aspects of health such as nutrition and housing. While these initiatives minimize the need for many costly services, the demand for high quality surgical, lab and pharmacy services will always exist. The goal of this project is not to expand these serves through aggressive growth and market share capture. Rather, we are attempting to meet current demands most efficiently through modernization of our facilities. As noted above in the immediately preceding section, many efficiencies will be fostered in each of these services.”

b. Maine CDC/DHHS Assessment

“The applicant states that modernizing their OR, Lab, and pharmacy will help improve efficiencies. However, there is no claim that this will lead to lowering the demand for high cost services.”

c. CONU Findings

This application fails to provide documentation for cost savings or efficiency outcomes to support this priority.

Projects that physically consolidate hospitals or services that serve all or part of the same area that demonstrate an appropriate, cost effective use for the “abandoned” infrastructure, that do not result in increased costs to the health care system and that, in accordance with state policy as expressed in Maine's Growth Management Act, do not contribute to sprawl.

a. **Applicant's Discussion on Priority**

The applicant did not address this specific priority.

b. **Maine CDC/DHHS Assessment**

"This project does not result in abandoned infrastructure."

c. **CONU Findings**

CONU concurs with Dr. Mills' comment that this project does not result in abandoned infrastructure.

Telemedicine projects that facilitate improvements and cost-efficiencies in the quality of diagnosis and treatment in smaller, rural communities.

a. **Applicant's Discussion on Priority**

The applicant did not address this specific priority as this is not a telemedicine project.

b. **Maine CDC/DHHS Assessment**

"This is no a telemedicine project."

c. **CONU Findings**

This is not a telemedicine project.

Priority: Projects that advance access to services and reflect a collaborative, evidence-based strategy for introducing new services and technologies

a. **Applicant's Discussion on Priority**

"The Operating Room, Central Sterile, Lab and Pharmacy are core program components of the health care continuum offered by St. Mary's. This project does not involve the introduction of a new service or new clinical technology, but rather, ensures continued access to these services for patients affiliated with St. Mary's."

b. **Maine CDC/DHHS Assessment**

"This project does not introduce new services."

c. **CONU Findings**

CONU finds that this priority does not apply to this project as no new services are being introduced.

Priority: Projects that include a complementary preventive components that will lead to a reduced need for services at the population level.

a. **Applicant's Discussion on Priority**

"St. Mary's is committed to continued development of the primary care network, prevention and wellness initiatives, and aggressive management of chronic illnesses."

b. **Maine CDC/DHHS Assessment**

"This project does not appear to include a complementary prevention program."

c. **CONU Findings**

In a memo dated October 9, 2007, issued by the Public Health Criteria Advisory Committee to Potential Certificate of Need Applicants the following guidance is offered: *"At a minimum, priority projects will devote a portion of the total "value" or cost of the project to new investment in a related public health effort that is aimed at reducing the demand for the service proposed under the application at the population level."*

d. **Determination**

CONU recommends that the Commissioner determine that St. Mary's has not met its burden to demonstrate that they will devote a portion of the total value or cost of the project to an investment as specified by the State Health Plan.

Priority: Construction that employs green building methods

a. **Applicant's Discussion on Priority**

"Chapter 10(1)(E) and the State Plan also prioritizes projects that "demonstrate best practices in building construction, renovation and operation to minimize environmental impact both internally and externally (e.g. "green energy".)" (Chapter 10(1)(e)(1). The St. Mary's Operating Room, Central Sterile, Lab and Pharmacy Expansion and Renovation project will be designed to incorporate best practices in building construction, renovation and operation to minimize environmental impact. The design team selected for the project includes design professionals accredited by the U.S. Green Building Council LEED (Leadership in Energy and Environmental Design) program. They will assist St. Mary's with the development of the project that will be designed to operate efficiently using materials and resources that minimize environmental impacts."

“Energy efficiency will be achieved through the use of:

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

“Materials and resource consumption will be controlled by:

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

“Indoor Environmental Quality will be controlled by:

- requiring the contractor to replace filters and flush out the mechanical system prior to occupancy
- use of low-emitting materials
- providing a smoke-free environment
- providing occupants natural light and the ability to control artificial light and temperature”

b. Maine CDC/DHHS Assessment

“The design team is stated to include LEED accredited professionals who are committed to design the project with sustainability and energy efficiency in mind. There is no firm commitment stated to using these standards.”

“There could be a stated commitment to using USGBC LEED building standards.”

c. CONU Findings

CONU concurs with Dr. Mills' comment that there could be a more firmly stated commitment to using USGBC LEED building standards.

d. Determination

CONU recommends that the Commissioner determine that St. Mary's did not meet its burden to demonstrate that the project satisfies the requirements of this priority.

Priority: Investments in the MHINT project and also investments in electronic medical records systems, such as HL7, will receive a higher priority ranking than those applicants failing to make such investments.

a. Applicant's Discussion on Priority

"Other aspects of the project entitle St. Mary's to priority under Chapter 10(1)(E) criteria. St. Mary's is also aggressively implementing information technology. In October of 2005, St. Mary's implemented the Meditech electronic medical record (EMR) and immediately began electronic capture of patient demographics, registration, scheduling, order entry, and results reporting. The EMR is equipped with an HL7 interface. In March of 2006, surgical services implemented the OR patient management system. And in April 2006, the emergency department implemented clinical (nursing and physician) documentation."

"The Meditech ORM (OR Management) module allows for electronic documentation of the operative visit. The patient is scheduled in the OR Management module and the operative visit is documented in conjunction with the scheduled appointment. The ORM module links to ordered meds on patients, and allows staff to document meds dispensed from Pyxis machines in Day Surgery and PACU. The ORM module can also indicate to clinical staff when Lab results are complete on the patient, and allows staff seamless entry into the Meditech EMR."

"The Meditech Lab module offers the ability to order lab, blood bank, and microbiology tests from anywhere in the hospital that has a Meditech connection. The Lab module interfaces with many of the lab instruments and accepts test results from Mayo Medical Lab reference lab. The lab, blood bank, microbiology, and pathology results are immediately available in the Meditech EMR for all clinical users once they are verified and/or e-signed. The lab can set up test view groups that can be attached to certain procedures and medication orders. This ensures that appropriate lab tests were completed on patients prior to having a procedure performed or being administered a drug."

"The Meditech Pharmacy module is used to create and maintain a patient's medication profile. Medication orders are entered in the system which checks for appropriate dose, interactions, allergies, and other contraindications. This profile is used by nursing to create a Medication Administration Record (MAR) and also interfaced to medication dispensing machines (Pyxis) used by nurses to retrieve and administer verified doses to the patients."

“Highlights of this module are:

- Reduce clinical errors with intelligent warnings, messages, and rejection notices
- Gain immediate access to clinical information from throughout the enterprise
- Access all relevant data from a single, centralized processing screen
- Minimize lost revenue with the option to charge on administration
- Enhance decision support using robust reporting tools
- Maintain proper inventory levels by linking to dispensing machines.”

“In January 2007, St. Mary's also implemented an e-ICU – Vital Network's VISCU remote monitoring system. St. Mary's ICU patients are now provided 24-7 monitoring by critical care specialists in Portland. They continue to receive direct ICU services from St. Mary's physicians and nursing staff, but the continuous monitoring by the critical care specialists in Portland raises the bar on quality of care for all patients in the intensive care unit.”

“Approximately 85% of St. Mary's providers affiliated through Community Clinical Services utilize an ambulatory EMR. These providers utilize Centricity, which is interfaced with Meditech for efficient flow of information between the two systems. The Medical center also has RIS/PACS (radiology information system/picture archiving and communication system) that interfaces to these systems as well.”

“St. Mary's has heavily invested in information technology throughout its entities, and looks forward to developments spearheaded by the MHINT to promote interoperability and integration throughout the state.”

b. Maine CDC/DHHS Assessment

“As of 2005 St. Mary's invested in the Meditech EMR with HL7 interface. This has been implemented in the several settings, including the OR, ED, Lab, pharmacy, and most outpatient practices affiliated with the applicant. They also have an e-ICU with Maine Medical Center.”

“There could be a stated commitment to participating with HealthInfoNet.”

c. CONU Findings

The applicant demonstrates an ongoing commitment to medical technologies, although this is not a medical technology application. The applicant has demonstrated that they have committed to various investments, such as HL7 and e-ICU.

d. Determination

CONU recommends that the Commissioner determine that St. Mary's has failed to meet its burden to demonstrate that they meet the requirements of this priority.

Priority: Projects that exercise less than 0.5% increase on regional insurance premiums.

a. Applicant's Discussion on Priority

“This analysis will be completed by the Bureau of Insurance and submitted to the CONU. No rate increases are planned to support this expansion and any future increase in rates will be driven by external factors other than this project. St. Mary's assumes current reimbursement methodologies continue through 2015. We perceive fulfillment of this standard to be a substitute for the reference in Chapter 10(1)(E) to seeking “evidence of good faith efforts in meeting the price and cost targets established by the Dirigo Health Reform Act, P.L. 469.” These targets, by their terms, applied only to hospital fiscal years ending in 2004.”

b. Bureau of Insurance Assessment

“Estimate[s] that the maximum impact of this CON project on private health insurance premiums in St. Mary's Regional Medical Center's service area for the project's third year of operation will be approximately 0.799% (\$0.799 per \$100) of premium. We further estimate that this project, in its third year of operation, will have an impact on statewide private health insurance premiums of approximately 0.045% (\$0.045 per \$100) of premium.”

c. Determination

Since the impact for regional insurance premiums exceeds 0.5% this project shall not be considered a priority project.

iii. Conclusion

The applicant has satisfied a few of the State Health Plan priorities. However, based upon the assessment by the Maine CDC/DHHS, the Bureau of Insurance and the number of priorities not satisfied, CONU recommends that the Commissioner determine that this applicant has not met its burden to show that this project is consistent with the State Health Plan.

VII. Outcomes and Community Impact

A. From Applicant

Although this application did not contain a section on outcomes and community impact, they did make the following comment:

“Rather, our goal is a modernization project that will create facilities and an environment that can accommodate current volume, ensure patient safety and privacy, and provide adequate space to meet the programming and technological demands that did not exist when the current facilities were constructed in the early 1990s.”

B. CONU Discussion

i. Criteria

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

ii. Analysis

This application failed to provide measurable outcomes expected from the project or specific information on the impact to the community or on other providers in the community anticipated by the project.

According to the Maine Quality Forum, “The project itself is mainly directed at structural indicators of quality, mainly emphasizing the characteristics of patient safety that will be improved by larger laboratory and pharmacy spaces. For evidence that these characteristics are important, the applicant cites American Institute of Architecture (AIA) specifications for appropriate operating room size and JCAHO standards for sterile pharmaceutical preparation spaces. There is limited if any evidence available to link these specifications to better clinical outcomes, and the application cites none.”

iii. Conclusion

CONU recommends that the Commissioner determine that St. Mary's has failed to meet its burden to demonstrate that this project will ensure high-quality outcomes and will not negatively affect the quality of care delivered by existing service providers.

VIII. Service Utilization

A. From Applicant

Although this application did not contain a section on service utilization, they did present historic and projected surgical case utilization and projections in section 4 "Needs to be Addressed." This section also included types of services and area demographics to support the project. Additionally, this section included historical information specific to billable tests and pharmacy STD hours.

B. CONU Discussion

i. Criterion

Relevant criterion for inclusion in this section is 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. Analysis

According to the Maine Quality Forum:

"The above application was reviewed for quality considerations, with reference to the Institute of Medicine definition of quality attributes (safe, timely, efficient, effective, equitable, and patient-centered) and the three domains of structure, process, and outcome."

"It is noteworthy that the applicant describes in the application and otherwise shows evidence of attention to clinical quality. The institution has programs in place that attend to timely and equitable access to care. St. Mary's website publicly reports on several quality indicators that the Maine Quality Forum collects but has yet to post."

"The project itself is mainly directed at structural indicators of quality, mainly emphasizing the characteristics of patient safety that will be improved by larger laboratory and pharmacy spaces, the characteristic of efficiency that will be improved by larger operating room space. For evidence that these characteristics are important, the applicant cites American Institute of Architecture (AIA) specifications for appropriate operating room size and JCAHO standards for sterile pharmaceutical preparation spaces. There is limited if any evidence available to link these specifications to better clinical outcomes, and the application cites none."

"The application cites the need for larger operating spaces as a primary driver of the project. The application specifies an increasing number of orthopedic and neurosurgical procedures in the institution, which require particularly large rooms. MHDO discharge data from 1998-2002 shows that the rate of lumbar fusion for back problems in Lewiston compared to other hospital service areas in the state was 124% higher than the statewide

average (see http://www.mainequalityforum.gov/chart_011p.html). Back and neck surgery rates in the Lewiston service area during that period were 37% higher than the state average. The rate of hysterectomy for noncancerous conditions in Lewiston was 9% above the state average, and the rate of carotid endarterectomy was 40% higher. Rates of total hip replacement and total knee replacement were not significantly different than the state average. These data have not been updated for more recent time periods, but the information does raise the question of need for more facilities for orthopedic and neurosurgical procedures in the Lewiston area, particularly since the approach to clinical problems of low back pain and noncancerous uterine conditions represent preference-sensitive and supply-sensitive care. (Carotid endarterectomy is less preference-sensitive, since clear anatomic guidelines for its application now exist.)”

“Finally, the application does not address in detail opportunities for collaboration, as specified in the State Health Plan, in laboratory services (Central Maine Medical Center currently has a CON application for enlarged laboratory space). An assessment of ways in which the two neighboring institutions could combine resources to improve services in their area with less cost impact would be appropriate.”

iii. Conclusion

The CONU recommends that the Commissioner determine that the St. Mary's has not met its burden to demonstrate that inappropriate increases in service utilization will not occur.

IX. Funding in Capital Investment Fund

A. From Applicant

The applicant did not discuss this project's effect on the Capital Investment Fund.

B. CONU Discussion

i. Criterion

Relevant criterion for inclusion in this section is 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 capital investment fund 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.

iii. Conclusion

Although there are sufficient funds in the Capital Investment Fund (CIF), CONU recommends that the project not be funded within the CIF.

X. Timely Notice

A. From Applicant

“St. Mary’s filed a Letter of Intent for this project on September 25, 2007. This is attached under Tab I. Upon notification of CON applicability, a technical assistance conference was scheduled. This conference occurred on October 19, 2007. St. Mary’s was represented by St. Mary’s COO Susan Keiler, SOCHS Director of Finance Joe Wood, and Attorneys John Doyle and John Geismar. The format of the technical assistance was changed, and representatives from all facilities with applications in the January 1, 2008 cycle were present. CONU staff provided general filing information in the morning session, and individual applicants had an opportunity to solicit information relevant to their particular projects in the afternoon session. St. Mary’s representatives provided an overview of the proposed project, and CON representatives highlighted key issues to be addressed in the CON application. The technical assistance meeting proved beneficial to St. Mary’s staff, and the feedback provided has been incorporated throughout the application.”

B. CONU Discussion

Letter of Intent filed:	September 25, 2007
Subject to CON review letter issued:	September 27, 2007
Technical assistance meeting held:	October 19, 2007
CON application filed	December 17, 2007
CON certified as complete:	December 17, 2007
Public informational meeting held	January 16, 2008
Public Hearing held	March 4, 2008
Public comment period ended	April 3, 2008

XI. Findings and Recommendations

Based on the preceding analysis and the record, the CONU recommends that the Commissioner make the following findings and recommendations:

- 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 certain factors, including, but not limited to;
 - 1. The project will not 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 services affected by the project will be accessible to all residents of the area proposed to be served; and
 - 4. The applicant has not demonstrated that the project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project;

- D. The applicant has not demonstrated that the proposed services are consistent with the orderly and economic development of health facilities and health resources for the State as demonstrated by:
 - 1. The applicant has not demonstrated what 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 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 not result in inappropriate increases in service utilization, according to the principles of evidence-based medicine adopted by the Maine Quality Forum; and
- H. That the project can be funded within the Capital Investment Fund.

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