

BRIEFING MEMO

St. Mary's Regional Medical Center **Expansion/Renovation of Operating Rooms, Central Sterile, Laboratory and** **Pharmacy** **To Campus Avenue Lewiston, Maine**

DATE: August 6, 2008

TO: Brenda M. Harvey, Commissioner, DHHS

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

FROM: Phyllis Powell, CONU Manager
Steven Keaten, Health Care Financial Analyst
Larry Carboneau, Health Care Financial Analyst

SUBJECT: Proposal by St. Mary's Regional Medical Center to expand and renovate its surgical suite, central sterile, laboratory and pharmacy departments located at their facility located on Campus Avenue in Lewiston, Maine at an estimated capital expenditure of \$25,544,333 including contingency. Third year operating costs are \$2,869,627 (2012). The debit to the Capital Investment Fund will be \$2,115,034.

ISSUE ACTIVATED BY: The subject proposal requires Certificate of Need approval in accordance with 22 M.R.S.A. Section 326 of "The Maine Certificate of Need Act of 2002".

REGISTERED AFFECTED PARTIES: Central Maine Medical Center

INTRODUCTION:

The preliminary analysis of St. Mary's Regional Medical Center's application recommended that a CON be disapproved because it was deemed to not meet the following criteria: Public Need, Orderly and Economic Development, State Health Plan, Outcomes and Community Impact and Service Utilization. The applicant has presented clarifying information that substantially satisfies these criterions and, with the conditions set forth in this memo, will meet CON review standards.

BACKGROUND:

- St. Mary's Regional Medical Center (SMRMC) is a 233 bed, not-for-profit corporation and is a subsidiary of Sisters of Charity Health Systems (SOCHS), also a not-for-profit corporation. SMRMC is licensed as a General Hospital and is designated as a tertiary referral site by the State of Maine for behavioral health services. SMRMC primary service area is Androscoggin County with a secondary service area that includes Franklin and Oxford Counties. Based upon the 2005 U.S. Census, the population of the total service area is projected at 194,371.
- The *Division of Licensing and Regulatory Services, Medical Facilities Unit*, confirmed that St. Mary's Regional Medical Center is a General Hospital, licensed in the State of Maine, and is MaineCare and Medicare certified. SMRMC is also certified by the Joint Commission.
- SMRMC obtained a CON in 2007 for the expansion/renovation of their Emergency Department (ED). That project was estimated to cost \$8,508,492. The approved project proposed that 10,445

gross square feet of new construction be added to the existing facility. The expanded 19,375 square foot ED includes specialized intake rooms for emergency behavioral health services. Construction is expected to be completed by December 2009.

- The proposed project (2008), under CON review, involves the expansion and renovation of SMRMC's surgical suite, central sterile, laboratory and pharmacy departments at the Campus Avenue facility located in Lewiston, Maine. It proposes 13,541 square feet of new construction and renovations of 27,398 square feet to accomplish the following:
 - Ground Floor – Relocation of central sterile facilities; relocation/expansion of laboratory; and relocation of pharmacy.
 - First Floor – Replaces three suboptimal ORs with four ORs and renovates two small ORs into one OR. This does not increase the total number of ORs.

HIGHLIGHTS:

Letter of Intent dated September 25, 2007

Subject to CON review letter issued September 27, 2007

Technical Assistance Meeting held on October 19, 2007

Application filed and certified as complete on December 17, 2007

Application placed in review cycle on January 1, 2008

Applicant's Public Informational Meeting held on January 16, 2008

Public Hearing held on March 4, 2008

Preliminary Analysis released on May 22, 2008

Preliminary Analysis published in newspapers on May 28, 2008

Record closed on June 11, 2008

PUBLIC COMMENTS RECEIVED IN RESPONSE TO THE PRELIMINARY ANALYSIS:

No public comments were received by the CON Unit in reference to this application.

CLARIFYING INFORMATION RECEIVED FROM APPLICANT IN RESPONSE TO THE PRELIMINARY ANALYSIS (condensed):

1) Needs to be Met

The applicant provided quantifiable data on need, including:

The applicant provided recent documentation from The College of American Pathologists that cited them for inadequate laboratory space in the chemistry-toxicology and hematology-urinalysis sections of the laboratory. The applicant provided laboratory errors rates, blood culture contamination rates, data regarding laboratory turn-around time. They also provided quarterly improvement reports for the laboratory.

The applicant provided supporting documentation that the project would lower the risk of HIPAA non-compliance and that the workplace design would improve work flow, reduce wait times, increase patient satisfaction and improve worker satisfaction/quality. The applicant will measure the impact of the facility changes through monitoring of employee satisfaction and retention rates, as well as tracking of departmental quality metrics such as laboratory error rates, laboratory turn-around time and pharmacy medication variances. The applicant will target a 5% improvement in these measures following implementation of this project.

The applicant has identified that Androscoggin County exceeds the targeted benchmarks for tobacco use and obesity as identified in *Healthy Maine 2010* and *Healthy People 2010*.

St. Mary's plan is to expand the scope of their health status evaluations for its surgical patients by expanding its Pre-Admission Testing program. A risk assessment/profile for each surgical candidate will be shared with both patient and primary provider. This expansion is being implemented to foster positive clinical outcomes. St. Mary's will develop a tracking tool that will measure and track the number of referrals that resulted in actual patient enrollment in supportive services.

The applicant references the study *The Role of the Physical Environment in the Hospital of the 21st Century: A Once in a Lifetime Opportunity*. This study suggests that in the advent of evidence-based medicine hospitals should implement evidence-based design. Research finds that evidence-based design helps create hospitals that actually help patients recover, be safer and helps staff do their job better. St. Mary's makes the commitment to apply evidence-based design principles to this project and the recently approved ED project. St. Mary's seeks to make important HVAC upgrades to improve air quality in the OR. The applicant states that the air quality is compromised. This is a threat to patient safety. Also, patients are held before surgery and recover after surgery in cramped quarters where the risk of infection is maximized. Surgical site infections in the OR range from 1-2% in 2007. The goal is to reduce infection rate by 50% once this project is completed.

2) **Alternatives Considered**

The applicant provided a feasibility study entitled *Clinical Diagnostic and Anatomic Laboratory Services Proposal December 2007* conducted with NorDx Labs that demonstrated a collaborative effort to reduce costs. Upon completion of the study it was determined that an integration of laboratory activities would lead to an increase of \$600,000+ in annual operating costs for St. Mary's were they to outsource laboratory services.

The applicant has stated a commitment to value engineering as part of its architectural and engineering design process.

St. Mary's reported on its collaboration with Central Maine Orthopedics, an independent physician's group which operates an ambulatory surgical unit in the service area. Over the past several years, significant outpatient orthopedic volume moved from the St. Mary's OR to this ambulatory setting. St. Mary's worked collaboratively with this physician group to identify the need for joint sponsorship of St. Mary's Center for Joint Replacement in October 2007. A unit of the hospital was renovated to accommodate joint patients. Evidence-based protocols were developed to address the comprehensive needs of this population.

St. Mary's has stated that under State participation in Medicaid, the State has an obligation to cover Medicaid approved expenditures.

The applicant states that ORs, laboratory, pharmacy and central sterile are units that will remain core components for community hospitals.

3) **State Health Plan**

The applicant asserts that this project meets the State Health Plan in the following areas:

- Projects that protect public health and safety;
- Projects that center on a redirection of resources and focus toward population-based health and prevention;
- Projects that contribute to lower costs of care and increased efficiencies;

- Projects that advance access to services and reflect a collaborative, evidence-based strategy for introducing new services and technologies;
- Projects that include a complementary preventive component that will lead to a reduced need for services at the population level;
- Construction that employs green building methods;
- Investment in the MHINT project and also investments in electronic medical records systems, such as HL7;
- Projects that exercise less than .05% increase on regional insurance premiums.

Projects that protect public health and safety

The applicant employs a quality model that defines quality along four dimensions: clinical outcomes, patient/employee satisfaction, value and patient/employee safety. Current space constraints have the potential to increase infections rates, medication error rates and lower turn-around times of laboratory tests. Presently these spaces are constrained. St. Mary's uses Avatar patient satisfaction surveys to measure patient satisfaction. Patient satisfaction in these surveys has declined from 92.43 % in 1992 to 90.37 % in 2008. The goal is to reach 93 % with this project. Employees were surveyed in 2006 utilizing the AHRO Patient Safety Survey - only 64 % agreed/strongly agreed whether St. Mary's procedures and systems were good at preventing errors from happening. St. Mary's goal is 80 % by implementing this project. In the same survey only 72 % agreed/strongly agreed that hospital management provided a work climate that promotes patient safety. St. Mary's goal is to reach 90 % by implementing this project. The study previously cited indicated that evidence-based design will positively affect patient quality.

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

The Surgical Pre-Admission Testing program as noted above will be enhanced and expanded which will reinforce important prevention messages by conducting a risk assessment/profile for each surgical candidate to be shared with both the patient and primary care provider.

Those patients without a primary care provider will be immediately referred to one. Patients will be screened for obesity, smoking, hypertension, diabetes, mental health and depression. In addition, patients will be screened for latent heart disease via a baseline cardiac assessment. Appropriate referrals to services will be made to community resources that are available. The critical first step to improving health status is to increase participation in prevention and wellness activities.

Projects that contribute to lower costs of care and increased efficiencies

The enhanced Surgical Pre-Admission Testing program will include a tracking tool that will measure the number of referrals from the program to supportive resources in the health system and community. The tracking will include how many referrals resulted in actual patient enrollment in supportive services.

Workplace design has been shown to improve work-flow, reduce wait times and increase patient satisfaction with the service. The applicant states this project will also improve patient and family way finding to surgical services. Current physical access to the surgical department is difficult and stressful for patients. A source of increased efficiency will be the imbedded savings of staff hours not spent directing patients to services within the hospital.

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

St. Mary's proposes that the Surgical Pre-Admission Testing meets these criteria that will positively advance access to prevention services using a collaborative, interdisciplinary approach. St. Mary's proposes to track the results of the Surgical Pre-Admission testing.

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

The applicant states that the Surgical Pre-Admission Testing meets this criteria. In targeting obesity, St. Mary's will be making an incremental investment of \$250,000 over the next three years to focus on nutrition education for individuals with specific health issues such as diabetes, coronary artery disease, allergies, etc.

Construction that employs green building methods

The applicant has made a firm commitment to using USGBC LEED building standards. St. Mary's has already engaged LEED certified architects from SMRT and is required by Covenant Health Systems to engage in LEED building standards as detailed in the Sustainable Design, Construction and Building Renovation policy.

Investment in the MHINT project and also investments in electronic medical records systems, such as HL7

St Mary's provided early and ongoing support for HealthInfoNet (HIN) since 2004. The applicant through its clinical affiliation with MaineHealth will have access to HIN and is committed to participate fully with HIN following completion of the pilot program.

Projects that exercise less than .05% increase on regional insurance premiums

The applicant understands this criteria is considered a priority under the 2006/2007 State Health Plan.

4) Outcome and Community Impact

St. Mary's restated that this project is not predicated on a market shift from CMMC to St. Mary's. This is documented by the modest growth in services they project. Market share has remained constant over the last five years between CMMC and St. Mary's as each hospital has its own discrete primary care physician network and referral patterns tend to follow these specialty care networks. Both hospitals have had upgrades to services over the past several years. As results indicate, the market share for each hospital has been stable. "Market share trends have held at 37% St. Mary's and 44% CMMC over the last 5 years (MHIC Annual Market Share Data)."

According to the applicant, this proposal will reduce surgical site infections from a range of 1-2 % to its goal of 0.5 %. HVAC upgrades will improve air quality in the OR and will reduce the risk of patients contracting infectious diseases from other patients due to airborne and surface contamination. This is validated by research cited by the applicant. Keeping patients in close proximity before and after surgery in cramped quarters leads to a greater risk of infections. The space upgrades to the surgical suite will minimize these infections.

St. Mary's laboratory was cited by the American College of Pathologists for space constraints. Over-crowded conditions lead to medication error rates and increased laboratory turn-around times. The applicant cited sources that report that the process of improving systems and processes

to reduce medical errors in hospitals should include an assessment of the environment in which the staff members perform their activities. By implementing evidence-based design, the applicant is expecting a 5 % improvement in all measures following the implementation of this project. These measures include monitoring of employee satisfaction and retention rates, tracking quality metrics such as laboratory error rates, laboratory turn around times and pharmacy medication variances.

This project also considers HIPAA concerns. Confidentiality is a priority issue that physicians and nurses frequently breach by talking in spaces where they are overheard by other patients or persons. In its current set-up, there are no available spaces for confidential conversations.

5) Service Utilization Impact

While service utilization has increased within the last few years due to the addition of added surgical programs such as orthopedic joint surgery, etc., growth trends, independent of past projects, have been consistent with the trends the Health Care Advisory Board as seen around the country. The number of OR's in this project are not increasing to handle extra volume other than the modest growth rate estimated. St. Mary's has partnered with Medical Rehab Associates (MRA) and New England Neurosurgery to develop a spine center that ensures that no referrals are made directly to surgery without a prior assessment from MRA. This is to ensure that medical/non-invasive interventions have first been considered/attempted/ruled out.

This is the end of additional comments by applicant (condensed).

CONU COMMENT:

1) Needs to be Met

The applicant has justified and addressed the physical plant needs, identified specific health problems in the community this project would focus on and has determined measurable patient outcomes and health indicators this application will target. The proposed surgical suit, laboratory and pharmacy configuration are properly sized according to AIA Guidelines and Hospital of the Future-Lessons for Inpatient Facility Planning and Strategy (The Advisory Board 2007) (referred to as Hospital of the Future). This project does not add ORs, rather it right-sizes the existing OR space and provides necessary storage space adjacent to the ORs. Present ORs range from 300 square feet to 400 square feet with one at 490 square feet. The reconfigured space will have two rooms with 600 square feet; two rooms with 500 square feet while three rooms will remain the same. The sizes of the new rooms are consistent with AIA Guidelines and the orthopedic, neurological, and other special procedures that require additional personnel and/or large equipment. The HVAC system does not adequately service the ORs or other areas of the facility.

This proposed project will focus on reducing heart disease and diabetes by expanding its Pre-Admission Testing program for all surgical cases and will be making an incremental investment of \$250,000 over the next three years to focus on nutrition education. The applicant has targeted improving the following quality standards: employee satisfaction and retention rates, laboratory error rates, laboratory test turn-around times, pharmacy medication error rates, patient satisfaction rates as it relates to patient safety and lowering infection rates from surgical cases. The applicant will be asked to report these outcomes as a condition of approval.

2) Alternatives Considered

In the CONU's preliminary analysis, we noted that the applicant failed to collaborate with Central Maine Medical Center in regards that both hospitals have submitted applications in this review cycle to expand their laboratories. As an alternative, St. Mary's demonstrated that they had

explored a collaborative effort with NorDx Labs. This would have increased St. Mary's costs to operate their laboratory department by over \$600,000 annually and was not determined to be a feasible alternative to the expansion of St. Mary's laboratory. Additionally, findings by the American College of Pathologists require timely response and action. CONU consulted with the CLIA Program (DLRS) regarding the specific findings of The College and they were affirmed.

Based on information provided by the applicant, CONU has determined that St. Mary's total approved 3rd year 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 for the third year of operation (2012) would be approximately \$159,293 (\$455,123 x 35%). Funds should be available to cover these additional expenditures.

This project appears to be the best approach to enable the applicant to solve the undersized surgical suite, and to assure that laboratory and pharmacy departments come into compliance with today's space standards.

3) **State Health Plan**

St Mary's Regional Medical Center has provided additional quantifiable information to CONU regarding criteria to establish priorities to the State Health Plan as noted above. CONU is in agreement that the applicant has met the following priorities:

- Projects that protect public health and safety;
- Projects that center on a redirection of resources and focus toward population-based health and prevention;
- Projects that contribute to lower costs of care and increased efficiencies;
- Projects that include a complementary preventive components that will lead to a reduced need for services at the population level;
- Construction that employs green building methods;
- Investment in the MHINT project and also investments in electronic medical records systems, such as HL7;

This project does not include any new services, therefore the priority stating: Projects that advance access to services and reflect a collaborative, evidence-based strategy for introducing new services and technologies, does not apply.

The State Health Plan requires an assessment by the Bureau of Insurance to determine both the Regional and Statewide impact on insurance premiums. The limit established in the SHP is 0.50% for a project to be considered a priority project. The BOI assessment states, in part, "we estimate 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 health insurance premiums approximately 0.045% (\$0.045 per \$100) of premium." Although this is not considered a priority project for the purpose of the SHP, the benefits of this project appear to outweigh the impact on regional insurance premiums.

4) **Outcome and Community Impact**

The applicant has provided additional information on the quality outcome measurements this project will employ. The applicant has also demonstrated that the improvements made from this proposed project will not impact other service providers.

5) Service Utilization Impact

CONU acknowledges growth rates projected by the applicant are within acceptable level of growth given past historical data and future projections. The number of OR's are not being increased but reconfigured to better accommodate the surgical cases being performed at St. Mary's. The renovations to the OR are adequate for the procedures being performed, but not excessive in size.

6) Capital Investment Fund

The CONU has determined that this project can be funded within the Capital Investment Fund (CIF). An amount of \$1,057,517 would be charged against the CIF from the hospital large review cycle for FYE 2008 and \$1,057,517 for FYE 2009 for a total of \$2,115,034.

CONCLUSION:

The Preliminary Analysis by CONU staff, dated May 22, 2008, concluded that this application failed the following criteria: public need, orderly and economic development of health facilities and resources for the State, low priority relative to the State Health Plan, ensuring high-quality outcomes and not negatively affecting quality of care delivered by existing service providers, and inappropriate increases in service utilization. Subsequent information provided by the applicant has satisfied concerns raised in the Preliminary Analysis.

For all the reasons set forth in the Preliminary Analysis, in the record, and considering the clarifying information provided by the applicant, we now conclude that the review criteria have been satisfied. CONU recommends the approval of a CON with conditions.

RECOMMENDATION:

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

- 1) That the construction related to the 2007 approved CON for the Emergency Room project be completed before this project exceeds \$4,000,000 in expenditures. Due to the timing of expenditures between the two projects, this will ensure adequate funding for both projects to be completed without introducing financial stress for St. Mary's;
- 2) That the applicant take immediate, interim measures to mitigate the findings of the College of American Pathologists and provide documentation to CONU;
- 3) That the applicant be required to report for the first full three years of operation the following measurable improvements to quality standards;
 - Employee satisfaction and retention rates
 - Laboratory error rates
 - Laboratory turn-around time
 - Pharmacy medication error rates
 - Patient satisfaction rates as it relates to patient safety
 - Infection rates from surgical cases
 - Report results of the Surgical Pre-Admission Testing program

<u>Capital Costs</u>	
\$ 24,519,301	Capital Costs As Proposed
<u>\$ 1,025,032</u>	Contingency
\$ 25,544,333	Total Approved Capital Costs

<u>Incremental 3rd Year Costs</u>	
\$ 2,869,627	Approved Incremental Costs as Proposed

<u>Capital Investment Fund</u>	
\$ 2,115,034	Approved CIF as Proposed

\$ 1,057,517	Charge for FYE 2007
<u>\$ 1,057,517</u>	Charge for FYE 2008
\$ 2,115,034	Total CIF Approved