BRIEFING MEMO

Central Maine Medical Center
Emergency Department and Laboratory Expansion

DATE: December 2, 2008

TO: Brenda M. Harvey, Commissioner, DHHS

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

FROM: Phyllis Powell, Manager, Certificate of Need Unit
Steven R. Keaten, Health Care Financial Analyst
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SUBJECT: Proposal by Central Maine Medical Center to expand their Emergency Department and Laboratory via new construction and renovations at their hospital campus in Lewiston, Maine at an estimated capital cost of $46,466,089.

ISSUE ACTIVATED BY: The referenced proposal requires Certificate of Need (CON) approval as defined in "The Maine Certificate of Need Act of 2002," 22 MRSA Section 326 et seq., as amended.

REGISTERED AFFECTED PARTIES: St. Mary's Regional Medical Center

I. BACKGROUND:

- Central Maine Medical Center (CMMC) is a not-for-profit corporation and is a subsidiary of Central Maine Medical Family (CMMF), also a not-for-profit corporation. CMMC is licensed for 250 beds. CMMC is verified as a Level II trauma center by the American College of Surgeons and is one of three state designated trauma centers in Maine.

- The Division of Licensing and Regulatory Services, Medical Facilities Unit, confirms that CMMC is a general hospital licensed in the State of Maine and is MaineCare and Medicare certified. CMMC is accredited by the Joint Commission.

- In 2000 and 2001, CMMC received CON approval to create a cardiac surgery program. The approval contained additional shell space to be used for a later project. The final approved capital cost for this project was $8,113,879.

- In 2006, CMMC received CON approval to relocate their critical care unit into the empty shell space approved in their 2000 and 2001 cardiac surgery program. The final approved capital cost for this project was $7,166,875.

- The application was received and certified complete, by the applicant, on December 20, 2007. CONU released the Preliminary Analysis recommending disapproval on May 22, 2008. CON review was suspended, by the applicant, on June 11, 2008. On August 9, 2008, the applicant unsuspended the review.

II. PROJECT DESCRIPTION:

The project under CON review proposes an expansion of the hospital's ED and clinical laboratory space via a construction and renovation project. In addition, this project involves the relocation of some existing ancillary departments that will be displaced and relocated as a result of the expansion

of the ED and clinical laboratory. These ancillary departments include radiology, pastoral care, employee health, red-cross blood donor center, support services, on call rooms and storage.

The current ED consists of a 31-bed unit that is separated into multiple geographic areas located in 2 different buildings comprised of 15 acute care beds in the main ED, 7 beds in the ED annex and 9 beds in First Care.

The proposal calls for the consolidation of the current ED that is presently housed in three separate locations within the hospital. This project also includes a 15-bed expansion to 46 total ED beds (44 rooms) into one geographical location comprised of 3 treatment zones. The 3 treatment zones include a critical care zone with 10-universal exam beds (10 rooms), 4-trauma beds (2 rooms) and 1-safe bed (1 room); an ambulatory zone with 17-universal exam beds (17 rooms); and an observation/surge treatment zone with 8-universal exam beds (8 rooms) and 6-clinical decision unit/observation beds (6 rooms).

This project will include a partial demolition of 13,380 sq. ft. to the current Memorial Building which is currently 95,875 sq. ft. New construction will add 38,905 sq. ft. to the remaining Memorial Building increasing its total square footage to 121,400.

This application does not propose any new services.

The Preliminary Review by CONU staff, dated May 22, 2008, concluded that this application failed the following CON review criteria which are later addressed in additional comments received from the applicant. See Section V.

Capital Expenditure & Financing

- Did not provide specific information in the form of a budget narrative.
- Did not provide financial forecasts that correspond with stated goals of the project, namely reducing ED visit growth through the inclusion of a preventive component.
- Did not develop an acceptable rationale for explaining how this project will not expand utilization of services in the ED and consequently in the OR and inpatient services.
- Did not provide financial forecasts that correspond to the stated goals of increasing efficiency and savings in per unit costs.
- Did not provide an explanation for how an ED that is “approaching maximum capacity” will still be able to serve an additional 16,000 ED visits in its current physical situation.

Needs to be Met

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

Alternatives Considered

- The application does not address in detail opportunities for collaboration, as specified in the State Health Plan (SHP), in either emergency services (recently expanded at St. Mary's Regional Medical Center) or in Laboratory services (St. Mary's currently has a CON for enlarged laboratory space). An assessment indicating how the two neighboring institutions could combine resources to improve services in their area with less impact would be appropriate.

State Health Plan

- The applicant did not provide quantifiable data that "unambiguously and directly" supports the assertion that this application is necessary to protect public health and safety, specifically patient safety. This application provides inputs and outputs but does not speak to quantifiable patient safety outcomes.

- The application contains statements of the applicant's determination that certain priorities have been satisfied or are not applicable from the applicant's perspective. The statements do not contain supporting documentation and where supporting documentation is referenced, it is not evidence-based. The applicant has not met the burden to substantiate the statements.

- The impact on regional insurance premiums was determined by the Bureau of Insurance (BOI) to be greater than 0.5%.

Outcomes and Community Impact

- The applicant states that this project will not have any negative effects on any other hospital in Maine. The applicant also states that they are including Behavioral Health dedicated beds in the ED. This is a duplication of services in their service area since Behavioral Health consumers are currently being directed to St. Mary's and TriCounty. A consultation with DHHS Office of Adult Mental Health Services revealed that there is no record of CMMC coordinating with the Department about a need in the area for additional Behavioral Health beds. CMMC did not indicate, in the application, any discussions of need with St. Mary's, NAMI, or other Behavioral Health Care providers.

Service Utilization

- The application did not address this specific criteria.

Funding in Capital Investment Fund

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

III. HIGHLIGHTS:

Letter of Intent dated March 12, 2007
Subject to CON review letter issued April 4, 2007
Technical Assistance Meeting held on October 19, 2007
Application filed and certified as complete on December 20, 2007
Application placed in review cycle on January 1, 2008
Applicant's public informational meeting held on January 22, 2008
A public hearing was 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
Applicant suspended review on June 11, 2008

Applicant unsuspended review on August 9, 2008
Record reopened and was published in newspapers on September 12, 2008
Record closed on September 26, 2008

IV. PUBLIC COMMENTS RECEIVED IN RESPONSE TO THE PRELIMINARY ANALYSIS:

Following release of the Preliminary Analysis, numerous public comments were received in support of the project including support letters from medical organizations, politicians, etc. No opposing comments were received.

V. CONU ANALYSIS/CMMC COMMENTS (condensed):

1) Capital Expenditures

The applicant provided additional financial data to their application indicating the scope of the application. The initial application indicated a third year operating ED growth rate of 4%. The applicant has now indicated their volume growth projections to be 0%. As indicated by the applicant, this is a result of organizational strategies executed in the last few years that includes:

- the addition of 9 primary care physicians in 2007;
- the launch of an acute care clinic designed to handle overflow or excess from employed physician practices, implementation of "best practice" scheduling procedures; and
- supported expansion of existing prevention, community education and chronic disease management initiatives.

ED volume remained relatively unchanged in FY 2008 vs. FY 2007. CMMC has forecasted no increased volume contrary to other recently CON approved ED expansions and national data that suggest projected increases in ED visits.

2) Financing

The applicant has decided to commit an equity contribution towards the project of roughly 20%. This is a substantial modification. Originally no equity contribution was proposed. This has little to no affect on third year operating cost or the CIF since the initial application failed to show additional costs for utilities which, when added, offset each other. The capital costs of the project remain unchanged.

CONU has determined that the applicant has the financial capacity to proceed with this project.

3) Needs to be Met

i. The applicant provided several additional attachments and letters of support to justify need. These include letters of support from several municipalities and ambulance companies. The applicant provided research data that provided national patient characteristics involving ED usage.

Of particular interest, the applicant provided research data from the American College of Emergency Physicians (ACEP) that explains the impact of ED crowding. The research document titled "Emergency Department Crowding: High-Impact Solutions" (April 2008) (Attachment D-4) gives the consequences of crowding strategies and proposed solutions to crowding. Crowding leads to boarding which leads to increases in length of stay, increases in

walkouts, increases to medical errors, causes ambulance diversions, causes death, interferes with the patient care model, and increases medical negligence claims which increases health insurance costs to everyone. The research data provided strategies that will improve ED access and flow that the applicant listed are underway at its facility. These include redesign of ED staff model; extend First Care hours; use of an adult hospitalist program to expedite admission and discharge processes for inpatients; and incorporate observation rooms, etc. An additional recommendation is to have an appropriate sized ED. Having appropriate space and staff to match the volume of emergency patients is considered critical to the proper functioning of the ED.

The applicant provided attachment H-1 also from the ACEP titled "Emergency Department Design" "A Practical Guide to Planning for the Future". This resource data included a chart estimating the right size design of an ED using the projected annual visits expected. The chart projected square foot need, bed quantity need and estimated number of observation/clinical decision bed quantities need based on a low range vs. high range operating ED. The documentation also defined a set of criteria to be used to determine parameters match on projected future ED will be on a scale of low range to high range. It is understood that the applicant has assumed a high range use since low range use criteria does not include observation/ clinical decision beds. The applicant has included observation/clinical decision beds in their projections as depicted in the comparison chart below:

	ACEP	CMMC	EMMC	MMC
Current ED visits at time of application	50,000	52,498 (FY2007)	44,000 (FY2007)	54,000 (FY2006)
Proposed ED by 3rd year of operation	---	52,000 (FY2013)	47,060 (FY2015)	60,500 (FY2012)
Prior to CON Application # of beds	---	31	26	34
Proposed # of beds (w/o CDU)	40	40	26	54
Proposed CDU beds	8-10	6	8	8
Prior to CON visits/bed	---	1,693	1,692	1,588
Proposed visits/bed	---	1,300	1,810	1,120
Proposed visits/bed including CDU	1,250	1,130	1,471	976

A comparison of the two other tertiary centers in Maine located in Portland (MMC) and Bangor (EMMC) that have had recent CON approved ED expansions is represented in the table above.

	ACEP	St. Mary's
Current ED visits at time of application	30,000	31,000
Proposed ED by 3rd year of operation	---	37,000
Proposed # of beds (w/o CDU)	26	18
Proposed CDU beds	4-6	4
Proposed Behavioral Health beds	---	8
Proposed visits/bed	---	1,766*
Proposed visits/bed including CDU	1,154	1,445*
Proposed visits/beds including Behavioral beds	---	1,233

* Visits reduced to 31,800 visits per year (37,000 projected total ED visits minus 5,200 projected Behavioral Health visits as stated in St. Mary's 2006 CON application).

The applicant projects no increase in ED volume through 2012 thus projecting a flat utilization at 52,000 ED patient visits per year. According to the ACEP, page 6, charts

52,000 ED annual visit falls between criteria from the chart of 50,000 annual ED visits to 60,000 annual ED visits or in the range of 34,000 to 39,950 square footage, 40-47 total bed quantity and 8-12 observation/ clinical decision beds. The applicant is proposing an ED consisting of 34,000 square feet, 46 total bed quantity and 6 observation/clinical bed quantity. CONU has determined that the applicant is within the ACEP and ED design literature recommended guidelines from the presented research data they provided.

ii. Average Length of Stay in the ED: In the initial application, CONU interpreted that the ED Length of Stay (LOS) as 2.78 hours. The applicant provided clarifying information stating that this was the combination of ED and First Care. The applicant provided clarifying information that the current ED LOS is 3.03 hours and the LOS for First Care is 1.93 hours. This project aims to lower the ED LOS from 3.03 hours to less than 2.5 hours.

iii. ED Patients per bed: Currently visits per ED bed is 1,625 per year. CMMC proposes 52,000 patients and 46 beds which equals 1,130 visits per bed. CMMC's original application forecasted a 4% increase in ED volume. As indicated in the additional information provided by the applicant, CMMC is now projecting ED volume to remain constant at 52,000 visits per year due to increase preventative care initiatives in the community, including the addition of several primary care physicians. ED actual visits from FY 2007 were 52,498. The applicant's new projections are to remain stable through 2013 at 52,000 visits per year. The current ED space is inadequate and outdated to serve the volume of the ED. The current ED space was developed for 25,000 patient visits 17 years ago and is currently receiving more than 52,000 patients per year. The applicant is proposing single patient rooms to achieve HIPAA compliance as well as define separate areas for staff and patients.

Based on the above comparison table, CMMC's proposed additional ED beds are within range of the other two recently CON approved tertiary hospitals in Maine, as well as within ACEP suggested guidelines. CMMC's First Care ED visits are included in their total visits per year. MMC's First Care visits are not included because the First Care department is not located at their main hospital. EMMC is undetermined whether the numbers include First Care or not.

St. Mary's Regional Medical Center was also recently approved to add Behavioral Health beds to their ED. Their recently approved ED included 26 beds and 4 CDU beds for a total of 30 beds. It is important to note that the ACEP figures below do not account for Behavioral Health beds.

The applicant is proposing to add two dedicated trauma rooms (4 beds) to their ED. Currently, CMMC does not have any dedicated trauma rooms/beds in their ED. CMMC has been designated as a tertiary care center in this area and should have dedicated trauma rooms.

iv. Behavioral Room: CMMC has further clarified the intent for one "safe room" designed for Behavioral Health patients when they present themselves to CMMC. CMMC has an on-going relationship with St. Mary's to transfer these patients.

v. Laboratory: CMMC continues to forecast a 3% growth in laboratory tests from 740,159 actual tests (FY2007) to 982,802 projected tests (FY2013).

CMMC states that the American College of Pathologists cited them in a recent survey report dated 8/4/08 for ten phase II deficiencies related to laboratory space violations. This report was included in the response information from CMMC. The applicant is proposing to correct these space deficiencies with this project in order to bring their Laboratory up to current standards.

4) Alternatives

i. Outsourcing the Laboratory/Collaboration: The applicant included a recent study dated 7/11/08 conducted by an independent laboratory consultant regarding an evaluation of long term options for their laboratory. The study concluded that of the three options explored, the least expensive in capital costs was the option to fully consolidate lab services within the hospital. The other two options included collaborating with St. Mary's or splitting lab functions and moving "those items not needed for 'stat' procedures onto an offsite laboratory." The option chosen by CMMC shows a reduction in capital costs by +$2M over the other two options.

ii. ED congestion factors: CMMC provided short-term and intermediate-term strategies for increasing CMMC's inpatient capacity. The applicant "believes the threshold problem is too few CMMC ED treatment rooms for the volume of patients treated regardless of any inpatient capacity issues." While the applicant does have future plans to invest several millions of dollars for their inpatient capacity, the CMMC Board of Trustees believes that by consolidating their ED now, is the best solution to improve quality measures including average length of stay.

5) State Health Plan

The SHP is broken down into various priorities which CONU has addressed individually in the following sections.

i. Projects that protect public health and safety are of utmost importance;

An example of such a project includes: Projects that have, as a primary over-riding objective, the elimination of specific threats to patient safety.

The applicant states the project will lower threats to public health and safety by eliminating ED overcrowding that will eliminate diversions and lower door to completion, door to bed, door to physician and length of stay. The applicant is proposing single occupancy patient rooms which will improve infectious cross-contamination among patients. The applicant states this project will also improve HIPAA compliance.

The laboratory portion of the project will abate staff safety risks and address known areas of risk of medical errors due to overcrowding and prevent interruption of laboratory services. This will prevent the loss of CAP accreditation in CMMC's lab.

The applicant will be creating one safe room within their ED which will provide a safe environment especially designed for Behavioral Health patients. To ensure the safety of all patients, CMMC has a protocol agreement with the Lewiston Police Department regarding persons who may be in need of involuntary commitment to a mental health institution. The applicant has also stated that CMMC has a full-time dedicated psychiatrist and a psychiatric nurse practitioner on their campus serving patients.

CONU has determined the applicant has demonstrated this project will protect public health and safety.

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

The applicant is committed to a new $3 million Community Health Initiative Fund and is already working collaboratively with the local Lewiston/Auburn public health infrastructure. The applicant has seen an influx of approximately 5,000 Somali/Somali Bantu immigrants. CMMC received a grant that enabled them to produce a DVD which explains the healthcare system to the Somali and Somali/Bantu communities. This video titled "Just Ask" covers access to CMMC services in three languages including English, Somali and Maay Maay. CMMC staff and Healthy Androscoggin have narrowed the focus of their obesity initiatives to that of youth obesity. A pilot program is underway to identify children and adolescents to participate in a program using the Maine Youth Overweight Collaborative model. CONU has determined this project will directly and unambiguously protect public safety.

iii. Projects that contribute to lower costs of care and increased efficiencies;

The applicant has modified their projected ED volume use from a 4 % annual growth to a 0 % annual ED volume growth due to several organizational strategies that include hiring several new primary care physicians in the past year to implement "best practice" measures that reduce ED patient volume. CONU has determined that by lowering ED volume to a flat rate of 52,000 patients a year, this project will now contribute to lower cost of care and increased efficiencies in the ED. The applicant quantified a decrease in costs by providing an updated financial module, which lowered the 3rd year incremental operating costs.

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

The applicant states the commitment to a new $3 million Community Health Prevention program that will address adult and childhood obesity. CONU has determined the applicant has demonstrated a complementary preventive component that will lead to a reduced need for services at the population level.

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

Central Maine Healthcare is one of the Demonstrated Phase Participating Organizations in the HealthInfoNet Project. In addition, CMMC currently has several electronic medical record systems in place that they are currently using. CONU has determined the applicant has demonstrated their commitment to this technology.

vi. Construction that employs green building methods;

The applicant has shown a commitment to a LEED auditing process that includes an interdisciplinary review of LEED credit opportunities. The applicant states this audit will be presented to CMMC for direction to proceed with specific components identified in the LEED audit. CONU has determined that the applicant has firmly stated a commitment to using USGBC LEED building standards.

vii. Projects that exercise less than 0.5% increase on regional insurance premiums shall be given priority consideration under the CON review process.

The applicant's initial application showed a regional insurance impact of .514%. CONU requested that the BOI re-evaluate the impact on regional premiums based on 0% growth in ED volumes.

The BOI provided the following assessment: "I estimate that the maximum impact of this CON project on private health insurance premiums in Central Maine Medical Center's service area for the project's third year of operation will be approximately 0.457% ($0.457 per $100) of premium. I further estimate that this project, in its third year of operation, will have an impact on statewide private health insurance premiums of approximately 0.069% ($0.069 per $100) of premium."

CONU has determined that the applicant has met this priority under the SHP.

6) Outcomes and Community Impact

i. Outcomes: The applicant states that this project will ensure high-quality outcomes by;

1. adhering to HIPAA compliance regulations;
2. reduce door to completion of triage time from 14 minutes to 7 minutes;
3. reduce door to bed time by an average of 29 minutes to 10 minutes;
4. reduce door to physician time from 61 minutes to 20 minutes;
5. reduce length of stay from 177 to 92 minutes;
6. eliminating ED overcrowding;
7. abatement of ED patient and staff safety risks;
8. abatement of Laboratory Department staff safety risks;
9. improve employee satisfaction and morale;
10. avoidance of medical errors; and
11. prevent interruptions of CMMC Laboratory services.

ii. Community Impact:

CMMC states that this project will not have any negative affect on other service providers. CMMC states that it collaborates with St. Mary's Regional Medical Center for the transfer of all Behavioral Health patients. The applicant will not be providing any additional services as a result of this project.

7) Service Utilization

i. Utilization:

The applicant has changed their projected ED growth from 4% per year to 0% growth per year. The applicant attributes this change to their additional initiatives in prevention care and the recent addition of several primary care physicians. This project includes no assumptions of increased service utilization.

VI. CONCLUSION:

Concluding Statement:

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

VII. RECOMMENDATION:

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

1) As a condition of approval, the applicant must provide CONU with the results of the following outcomes through the third year of operation:

   - Ambulance diversions
   - Patient boarding
   - Length of stay in ED
   - Left without being seen rates
   - Medical Error rates as presented in the application
   - Employee satisfaction
   - Patient satisfaction

2) As a condition of approval, the applicant is to provide evidence of corrective actions taken specific to the American College of Pathologists survey deficiencies.

3) As a condition of approval, the applicant will report lab test growth rate for a period of 3 years following project implementation.

Capital Costs	
$ 43,662,600	Capital costs as Approved
$ 1,536,000	Contingency
$ 45,198,600	Total Approved Capital Costs

Incremental 3rd Year Costs	
$3,847,102	Approved Incremental Costs

Capital Investment Fund	
$2,804,961	Approved CIF
$1,402,481	Charge for FYE 2008
$1,402,481	Charge for FYE 2009
$2,804,962	