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Division of Licensing and  
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Maine Medical Center  
MaineHealth

May 11, 2009

Phyllis Powell, Assistant Director  
Division of Licensing and Regulatory Services  
Certificate of Need Unit  
Department of Health and Human Services  
State House Station # 11  
Augusta, Maine 04333-0011

RE: Maine Medical Center  
Simulation Center  
Letter of Intent

Dear Ms. Powell:

Maine Medical Center (MMC) is requesting a ruling from the Department regarding the applicability of the Certificate of Need Program to MMC's proposed project to develop a Simulation Center on its Brighton Avenue, Portland, Maine campus. The capital expenditure for this project is estimated to be approximately six million dollars (\$6,000,000). Third year operating expenses are estimated to be approximately three million dollars (\$3,000,000).

If the Department determines that this project is subject to Certificate of Need review and approval, MMC respectfully requests that the Department deem the project to be qualified for the simplified review and approval process as described in the Maine Certificate of Need Act of 2002, 22 M.R.S.A. § 336.

There is no development or offering of new health services. There is no change in MMC's licensed bed complement. The only change is the introduction of simulation-based education technology to MMC's existing medical education programs. The proposed project is for the education of health professionals, not clinical care. The equipment acquired will be used for simulation-based education, not clinical services.

The capital expenditure is needed to comply with current and anticipated Accreditation Council for Graduate Medical Education standards for the teaching and training of graduate medical students (residents and fellows); and supports MMC's continued eligibility to receive Center for Medicare and Medicaid Services' reimbursement as a teaching hospital.

MMC anticipates submitting a completed application for review in August. If the Department determines that the proposed project qualifies for a simplified review, analysis of the application can commence immediately upon submission.

### **Simulation-based Education**

MMC's Simulation Center will address Accreditation Council for Graduate Medical Education (ACGME) requirements to incorporate simulation-based education into residency and fellowship curricula. ACGME increasingly is requiring graduate medical education residency and fellowship programs to incorporate simulation-based education into their curricula to maintain accreditation.

Simulation technologies advance the science, safety, and cost effectiveness of medical practice. Until recently the apprenticeship model, practicing on cadavers, laboratory animals, or real patients, has been the only way to teach doctors, nurses, and other health professionals about anatomy and how to practice medicine. Simulation-based education helps move medicine from this old "see one, do one, teach one" method to a contemporary "see one, practice many, do one" model for success.

Simulation-based education is a teaching method in which learners practice tasks and processes in lifelike circumstances using sophisticated models, with feedback from observers, peers and video cameras to improve skills. This approach is similar to the flight simulators used to train pilots in which the pilot is immersed in a complete replica of the cockpit environment.

Medical simulators allow individuals to review and practice procedures as often as required to reach proficiency without involving actual patients. High fidelity simulation environments allow newly trained health professionals to practice procedural interventions and critical medical decision making on human-like patient simulators literally hundreds of times before ever touching a real patient.

### **MMC Simulation Center**

The project involves reusing the Ambulatory Surgery Suite on the 3<sup>rd</sup> floor of MMC's facility located on its Brighton Avenue, Portland, Maine campus. This Suite was vacated when MMC opened the Scarborough Surgery Center.

The Simulation Center will include three fully equipped, accurate replicas of clinical environments: an Operating Room, an Emergency Department Trauma Bay / Intensive Care Room and a Medical / Surgical Patient Room. These rooms will be equipped and furnished in much the same fashion as MMC's actual clinical settings. The operating room will be a replica of an operating room in MMC's recently constructed Scarborough Surgery Center; the trauma bay, which will support intensive care scenarios, will resemble the trauma bays in MMC's newly expanded Emergency Department. The medical / surgical room will be comparable to recently refurbished and equipped patient care rooms.

These high resolution simulation rooms will contain sophisticated mannequins, known as patient simulators. Patient simulators provide health care professionals with a computer-based patient that breathes, responds to drugs, talks, and exhibits human physiology. The simulators come in newborn, infant, pediatric and adult configurations; and can mimic both male and female anatomies.

The Center will contain a Skills Lab with task trainers to teach students and residents specific clinical tasks; e.g., how to utilize laparoscopic, minimally invasive surgical instruments, how to give a smallpox inoculation or how to insert a chest tube.

Observation / debriefing rooms, a simulation control room, technical workshop, administrative offices and support functions are included in the space program.

The Center will have a dedicated staff including a Manager, Medical Director (part-time), Nurse Coordinator, Simulation Technicians, Information System Analyst, Audio-Visual Coordinator and Administrative Associates.

The Center will be used initially for MMC residents, fellows and nurses. It is anticipated that attending physicians, interdisciplinary clinical care teams and other allied health professionals will start using simulation-based education in the near future.

### **Qualification for Simplified Review as a Maintenance Project**

MMC believes that this project qualifies for simplified review since it primarily involves the maintenance of a health facility as defined in 22 M.R.S.A. § 336 (1). The proposed project is for the education of health professionals, not clinical care. The equipment acquired will be used for simulation-based education, not clinical services. There is no development or offering of new health services. There is no change in MMC's licensed bed complement. The only change is the introduction of simulation-based education technology to MMC's existing medical education programs.

The project addresses the requirements (in emboldened, italicized text) to qualify for simplified review as a maintenance project in the following manner:

***(A) Will result in no or a minimal additional expense to the public or to the health care facility's clients.***

MMC estimates that the cost of operating the Simulation Center to be approximately \$3,000,000 in annual operating expense. This includes Simulation Center staff, additional faculty time and general expenses. This is less than ½ of one percent (0.5%) increase in MMC's annual operating expenses.

***(B) Will be in compliance with other applicable State and local laws and regulations.***

MMC currently operates in compliance with applicable State and local laws and regulations; this project will not change that compliance. The project will be in compliance with applicable State and local laws and regulations.

***(C) Will significantly improve or, in the alternative, not significantly adversely affect the health and welfare of any person currently being served by the health care facility.***

The Institute of Medicine (IOM) identifies preventable adverse events as a leading cause of death in the United States. The IOM recommends simulation-based education as a key element in reducing practitioner errors and enhancing patient safety:

*Health care organizations and teaching institutions should participate in the development and use of simulation for training novice practitioners, problem solving, and crisis management, especially when new and potentially hazardous procedures and equipment are introduced.*

(Institute of Medicine, To Err Is Human: Building a Safer Health System, National Academies Press, Washington, D.C., 1999)

The IOM makes several notable recommendations with regard to medical simulation:

- Establish interdisciplinary team training programs, such as simulation, that incorporate proven methods of team management.
- Health care organizations should use and rely on proficiency-based credentialing and privileging to identify, retrain, remove, or redirect physicians, nurses, pharmacists, or others who cannot competently perform their responsibilities.
- Use procedures to mitigate injury through simulation training.
- Create a learning environment. “Use simulations whenever possible.”

Simulation-based education will significantly improve the health and welfare of persons currently being served by MMC as well as other health care facilities in which its residents will practice in the future. Simulation-based education significantly improves patient safety by:

- Removing a substantial amount of the early education process from the bedside, which reduces unnecessary risks to patient safety;
- Providing an “error-tolerant”, “risk-free” environment in which practitioners can safely practice skills and procedures until they gain proficiency;
- Creating an environment that is conducive to teaching evidence-based best practices;
- Enabling practitioners to repeatedly experience and respond to high risk clinical situations without adverse consequences; and
- Presenting the opportunity to demonstrate, measure and document learner competency and proficiency using objective, standardized clinical scenarios.

### **Qualification for Simplified Review as a Capital Expenditure**

MMC believes that this project qualifies for simplified review as a capital expenditure as defined in 22 M.R.S.A. § 336 (4). The proposed project is required so that MMC complies with Accreditation Council for Graduate Medical Education (ACGME) accreditation standards that must be met in order for MMC to qualify for Centers for Medicare and Medicaid Services’ reimbursement as a teaching hospital.

The project addresses the requirements (in emboldened, italicized text) for simplified review as a capital expenditure in the following manner:

- (A) ***The capital expenditure is required to eliminate or prevent imminent safety hazards, as defined by applicable fire, building or life safety codes and regulations; to comply with State licensure standards; or to comply with accreditation or certification standards that must be met to receive reimbursement under the United States Social Security Act, Title XVIII or payments under a State plan for medical assistance approved under Title XIX of that Act.***

The capital expenditure is needed to comply with current and anticipated Accreditation Council for Graduate Medical Education accreditation standards for the teaching and training of graduate medical students (residents and fellows). As a teaching hospital, MMC must comply with ACGME standards to remain eligible for Center for Medicare and Medicaid Services' reimbursement for medical education.

- (B) ***The economic feasibility of the project is demonstrated in terms of its effects on the operating budget of the applicant, including its existing rate structure.***

MMC estimates that the cost of operating the Simulation Center to be approximately \$3,000,000 in annual operating expense. This includes Simulation Center staff, faculty and general expenses. This represents less than ½ of one percent (0.5%) increase to MMC's annual operating expenses.

MMC estimates that operating the Simulation Center could result in an increase its rate structure by a cumulative  $\frac{7}{10}$  of one percent (0.7%) over the first three full years of operation if no other sources of revenue are available. This is a "worse case" scenario that does not attempt to identify additional sources of revenue to support this endeavor.

The Accreditation Council for Graduate Medical Education is requiring that simulation be incorporated into graduate medical education curricula. At the same time the Center for Medicare and Medicaid Services (CMS) has capped both the number of funded resident slots and the funding for those slots. In effect simulation-based education is an unfunded mandate.

The Council on Graduate Medical Education (COGME), which advises the Federal Secretary of Health and the Congress on graduate medical education (GME), is recommending a 15% increase in GME positions and an increase in funding levels for current positions to address an anticipated significant gap between expected physician supply and demand.

Medicare-supported residency training slots have been frozen at 1996 levels since the passage of the Balanced Budget Act of 1997. The President has announced his intent to improve health care access, which will increase the demand for physicians. In May Majority Leader Senator Harry Reid (D-Nev.), Senator Bill Nelson (D-Fla.) and Senator Charles Schumer (D-N.Y.) introduced a Bill to increase Medicare-sponsored residency slots by 15% and to allow for unused

positions to be redirected to other institutions. Passage of this Bill could increase the revenue stream available to MMC to support its medical education program.

To date simulation-based education has been focused mostly on undergraduate and graduate medical student, and nurse education. Interest in its applications for continuing medical education is emerging.

The American Board of Medical Specialties (ABMS) represents twenty-four member boards that cover board-certification for 145 medical specialties and subspecialties. ABMS is emphasizing a commitment to quality healthcare, transparency in physician accountability and enhanced professional development activities to improve the ABMS life-long learning evaluation.

By 2010, ABMS Member Boards will require physician diplomates to provide evidence of participation in practice assessment and quality improvement every two to five years. With the national movement toward performance measurement, evaluation of physician activities should include evidence of practice changes to improve quality and re-evaluation to determine the effect of a change in the practice process or structure of care.

The ABMS initiative may provide an opportunity to use simulation technologies to demonstrate practice proficiency and to generate additional revenue to offset the operation of the Simulation Center. The President of ABMS calls simulation-based education the future of continuing medical education.

Simulation-based education is making significant inroads in Nursing Education, Allied Health Professional Education and High-functioning Team Training (Surgery, Trauma, Emergency, Intensive Care and Rapid Response Teams). The Joint Commission on Accreditation of Healthcare Organizations recommends that simulation-based education is beneficial in the training of such teams.

As simulation-based education proliferates, the research agenda is evolving. Research issues include demonstrating the validity of simulation-based education, determining the optimal applications of simulation, developing simulation-based education outcome-based criteria and curricula, and integrating simulation-based education with the apprenticeship model.

The National Institutes of Health recently released a request for proposals for simulation-based education research projects. The Maine Medical Center Research Institute has demonstrated its capabilities of securing funding support for MMC's research initiatives in other areas. Until the Simulation Center is established, MMC efforts to pursue grant funding related to simulation-based education and research are severely hampered.

**(C) *There remains a public need for the service to be provided;***

In his State of the State Address (March 10, 2009) Governor John Elias Baldacci stated:

*We also know that good health requires having enough high quality doctors and health care providers available when you need them. Doctors and nurses are the lifeblood of good health, and Maine doesn't have enough of them.*

*...(W)e will provide needed scholarships for Maine residents to support their medical education at Maine Medical Center, Eastern Maine Medical Center or the University of New England.*

*Research shows that doctors tend to settle near the hospitals where they complete their training. And I know that given the chance young doctors will stay in Maine.*

(Transcript accessed Maine.gov, Governor's Office, Speeches)

Residency and Fellowship programs are a critical element in recruiting and retaining an adequate supply of physicians to practice in Maine. Once medical students complete their four-year undergraduate studies, they enroll in residency programs to complete their studies. MMC's Graduate Medical Education Program will enable these medical students to complete their studies in Maine and will encourage them to stay in Maine to practice. Providing medical students the opportunity to complete their education in-state dramatically improves the likelihood that they will choose to practice in-state.

The Maine Department of Labor states:

*(L)imited residency opportunities will have a dramatic effect on the supply of these healthcare professionals. After completion of medical school, three to eight years of internship and residency, depending on the specialty are required. Residency opportunities will have a dramatic effect on the supply of physicians and surgeons in Maine...*

*Importantly, the residency programs report that 50% or more of their graduates remain in state after residency; this retention is paramount in ensuring an adequate supply of these healthcare professionals.*

(Kruk, 2006 Healthcare Occupations Report, Maine Department of Labor, January 21, 2007, pp. 30-1.)

Research supports the Governor's and Department of Labor's statements that physicians tend to practice near the hospitals in which they complete their training. The most recent data on active physicians (allopathic and osteopathic) demonstrate that physicians that complete just their graduate studies in a state will practice in that state at a greater rate than those physicians who only complete their undergraduate education in a state, and that physicians who complete both

their undergraduate and graduate education in a state are the most likely to remain in that state to practice.

**Active Physicians Practicing in the Same State in which They Trained**

Extent of In-State Training	United States	Maine
Undergraduate Medical School Only	29%	7%
Graduate Medical School Only	45%	21%
Both Undergraduate & Graduate Medical School	66%	73%

Center for Workforce Studies, 2007 State Physician Workforce Data Book, (American Association of Medical Colleges, Washington, DC, December 2007).

The Council on Graduate Medical Education (COGME), which advises the Federal Secretary of Health and the Congress on graduate medical education, is forecasting a significant gap between physician supply and demand over the next 15 years. COGME recommends a 15% increase in Graduate Medical Education positions to address this gap between supply and demand. The gaps between supply and demand are forecast to be most pronounced in specialist services and specialties that predominately serve the elderly.

Eastern Maine Medical Center, Central Maine Medical Center and Maine General Medical Center in combination currently provide 82 allopathic resident positions in two specialties, Family Medicine and Geriatrics.

The University of New England in cooperation with Mercy Hospital and Southern Maine Medical Center provides osteopathic residency programs in Family Medicine, Geriatrics, Neuromusculoskeletal Medicine, and Osteopathic Manipulative Medicine.

Primary care specialties are not the only specialties that are needed in Maine. MMC's Graduate Medical Education Program is vital to recruitment and retention efforts to assure an adequate supply of physicians in various specialties choose to practice in Maine.

By mid-2010 MMC will increase its residency and fellowship programs from 207 to 241 positions (a 16% increase) in such specialties as Anesthesiology, Cardiology, Emergency Medicine, Family Medicine, Gastroenterology, Geriatrics, Internal Medicine, Obstetrics & Gynecology, Pediatrics, Pulmonary & Critical Care, Psychiatry (Adult and Child), Radiology, Surgery and Urology.

MMC believes that there is a demonstrated, ongoing need for graduate medical education capacity including MMC's residency programs and that simulation-based education is becoming a core element of resident education.

**(D) *The corrective action proposed by the applicant is the most cost effective alternative available under the circumstances.***

MMC believes that reusing vacant space for this purpose is the most cost effective alternative. Further, locating this program on MMC's Brighton campus helps with ongoing efforts to decompress the Bramhall campus.

As the Accreditation Council for Graduate Medical Education increases the requirements for simulation-based education, MMC residency and fellowship programs will need convenient, priority access to high-resolution simulated clinical areas for significant numbers of residents and fellows. The ability to replicate the MMC clinical settings in which MMC's residents and fellows will be practicing and the extent of this needed access support MMC proposal to operate its own Simulation Center.

The Center will improve MMC's ability to recruit and retain highly qualified medical students and residents. Medical student and resident expectations regarding simulation-based education are outpacing the introduction of ACGME requirements. Simulation-based education is already a key factor in the program selection decisions of many prospective medical students and residents. Today institutions without simulation-based education programs are at a distinct disadvantage in their student and resident recruitment efforts; this disadvantage is becoming more pronounced as more GME programs introduce simulation-based education to their curricula.

MMC residency programs currently have limited access to the University of New England (UNE) Simulation Center (Emergency Medicine) and travel to Boston for simulation training (Anesthesiology). UNE's program does not have the high-resolution clinical environments that are an important element of simulation-based education. Travel to Boston is an inefficient way to provide simulation-based education; the logistics limit MMC's utilization of these resources. Neither of these approaches provides the unencumbered access that MMC teaching programs require, or that medical students and residents expect.

**Maine Medical Center Research Institute Expansion Project as a Precedent**

MMC believes that the Department's recent determination that Maine Medical Center Research Institute (MMCRI) Expansion met the requirements for a simplified review provides a precedent for a similar determination regarding this project. (October 25, 2005 letter from C. Cobb to R. Linehan and February 6, 2007 letter from P. Powell to R. Linehan)

The similarities between the two projects include the following:

- **Both projects have little or no direct impact on MMC's present clinical services.**

The Simulation Center's purpose is to educate health professionals; no clinical services are involved. MMCRI's research endeavors do not have a direct or immediate effect on MMC's clinical services.

- **Both projects support major State initiatives.**

The Simulation Center supports the State of Maine's Physician Recruitment and Retention Initiative. The MMCRI project supports the State's Research-based Economic Development Initiative.

The alternative to providing simulation-based education is for MMC residency and fellowship programs to risk the loss of ACGME accreditation. This poses an unnecessary and undesirable risk to Maine's efforts to recruit and retain an adequate supply of physicians to practice in Maine, a major initiative outlined in the Governor's State of the State address.

The Certificate of Need Unit recognized that the alternative to the MMCRI expansion project had potentially dire consequences for the State's research-based economic development initiative:

*There are no alternative considerations available to this project except for research teams to take their research projects to another facility possibly out-of-state and then the State of Maine would lose that economic development that is important to the State and community. (MMCRI Expansion CON Preliminary Analysis, p 21.)*

- **Both projects address Accreditation Council for Graduate Medical Education accreditation standards.**

Simulation-based education is needed to maintain Accreditation Council for Graduate Medical Education accreditation. ACGME accreditation requires a research program. This requirement was a factor in MMC's MMCRI Expansion project proposal and Certificate of Need Unit's review:

*MMC currently supports over 200 residents and fellows in 11 residencies and 8 fellowships approved by the Accreditation Council for Graduate Medical Education. Residency and Fellowship accreditation require a strong, viable research program. (MMCRI Expansion CON Application, p 11.)*

- **Both projects have no impact on Medicare or MaineCare costs.**

Medicare and MaineCare will not incur additional costs as MMC increases expenses for its Residency Programs. CMS has capped both the number of funded resident slots and the funding for those slots.

This is similar to the zero-impact of research expenses on these two programs:

*MMC's research expenses appear on its Medicare/MaineCare Cost Report as nonreimbursable expenses. Neither Medicare nor MaineCare pay these expenses... (MMCRI Expansion CON Application, p 12.)*

Until CMS acts on COGME funding recommendations, there will not be any additional federal funding for medical education.

- **Both projects are subsidized by MMC operating revenue.**

The special purpose Centers for Medicare and Medicaid Services' teaching hospital revenue, which MMC receives for its Medical Education Program, is insufficient to support the program. As a result, MMC subsidizes its medical education endeavors with operating revenue just as it subsidizes its research activities with operating revenue.

The incremental impact of the Medical Education Simulation Center on MMC's operating budget is estimated to be approximately \$3,000,000 per year, less than MMC's annual subsidy for research activities.

*MMC supports its research initiatives with excess operating revenue...; MMC support is approximately \$3,500,000 per year. MMC's commitment to research is expected to increase to \$5,800,000 during the forecast period as MMCRI's annual budget grows to approximately \$27,000,000. (MMCRI Expansion CON Application, p 12.)*

### **Other Considerations**

Educational institutions, which are not regulated by CON, are able to easily introduce this educational technology while MMC is constrained from offering the service without CON authorization. The University of New England provides simulation-based education as an integral aspect of its undergraduate and graduate health professions programs; the University of Southern Maine is introducing simulation-based education as part of its undergraduate and graduate nursing programs.

The proposed project schedule is economically and logistically advantageous. MMC has other projects under construction on its Brighton campus. The opportunity to coordinate this project's construction schedule with those other projects avoids the inefficiencies and added costs of demobilizing and remobilizing, allowing the Construction Manager to keep work crews and subcontractors on site and working. The estimated capital expenditure is based on this construction approach and schedule.

MMC anticipates submitting a completed application for review in August. If the Department determines that the proposed project qualifies for a simplified review, analysis of the application can commence immediately upon submission. Delays in the schedule to place the application into a Capital Investment Fund review cycle would add premium construction costs and underlying inflation to the project's estimated capital cost. Current estimates place the resulting increase in capital costs in the \$250,000 to \$300,000 range.

### **Technical Assistance Meeting**

MMC seeks to arrange a Technical Assistance Meeting within the next 30 days of this Letter of Intent as required by the Maine Certificate of Need Act of 2002, 22 M.R.S.A. § 337; and the Maine Certificate of Need Procedures Manual for Health Care Facilities (other than Nursing Facilities) Chapter 2, Subsection 2 (2). The purposes of the Technical Assistance Meeting with the Department staff are to assist the Department in understanding the application and to receive technical assistance concerning the nature, extent and format of the documentary evidence, statistical data and financial data required for the Department to evaluate the proposal.

Please feel free to contact me if you have any questions; I may be reached by telephone at 207-662-2451 or by email at [linehr@mmc.org](mailto:linehr@mmc.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Richard M. Linehan". The signature is fluid and cursive, with a long horizontal stroke at the end.

Richard M. Linehan  
Director of Planning