Maine Medical Center
MaineHealth

June 17, 2009
Via email; hard copy to follow

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

RE: Maine Medical Center
Additional Linear Accelerator
Response to Preliminary Analysis

Dear Ms. Powell:

The purpose of this letter is to respond to the Certificate of Need Unit's Preliminary Analysis of Maine Medical Center (MMC) proposal to add a linear accelerator to be located at its Scarborough campus to MMC Radiation Therapy Program dated June 2, 2009.

Maine Medical Center is responding to the concerns, issues, questions and allegation of facts contrary to those in the application made by the department and others during the course of the Department's January 2009 hospital large project review cycle. Our comments are enclosed.

MMC is requesting a twelve-month suspension of this proposal's application process in order to ascertain whether installation of current and next generation linear accelerators as replacement equipment mitigates MMC's need for additional linear accelerator capacity.

Please feel free to contact me; I may be reached by telephone at 207-662-2451 or via email at linehr@mmc.org .

Sincerely,

Rich Linehan
Director of Planning
Maine Medical Center

c.c.: Steven Keaten, Certificate of Need Unit

II. Fit, Willing and Able

Maine Medical Center (MMC) concurs with the Certificate of Need Unit (CONU) recommendation that the Commissioner find that Maine Medical Center is fit, willing and able to provide the proposed services at the proper standard of care as demonstrated by, among other factors, whether the quality of any health care provided in the past by the applicant or a related party under the applicant's control meets industry standards.

III. Economic Feasibility

MMC concurs with the CONU recommendation that the Commissioner determine that Maine Medical Center has met the burden to demonstrate the economic feasibility of the proposed services in terms of: (1) the capacity of the applicant to support the project financially over its useful life, in light of the rates the applicant expects to be able to charge for the services to be provided by the project; and (2) the applicant's ability to establish and operate the project in accordance with existing and reasonably anticipated future changes in federal, state and local licensure and other applicable or potentially applicable rules.

IV. Public Need

MMC provides the following information in response to CONU and Maine Quality Forum comments, analysis and conclusion related to MMC's effort to demonstrate public need for the proposed project.

Need Forecasting

2004 Maine County-specific Cancer Incidence Rates

CONU raises questions concerning the differences among service area cancer incidence rates and notes that MMC did not use Maine Center for Disease Control District Profiles in assessing need.

MMC uses county-specific incidence rates published by the National Cancer Institute accessed via the internet at statecancerprofiles.cancer.gov. Variations in area incidence rates are to be expected due to populations having differing demographic characteristics, environmental risk factors, health behaviors and lifestyle choices.

The Maine Center for Disease Control (CDC) Division of Chronic Disease Maine Cancer Registry publishes a series of annual reports of cancer incidence and mortality rates by site (part of the body), gender, year and county without discussion of differences. MMC takes a similar approach, using county-specific incidence rates for its need forecast without discussion of differences.

Other than the Aroostook, Cumberland and York Maine CDC Districts, the remaining districts are composed of multiple counties. Available county-specific incidence rates offer a greater level of specificity. MMC believes that providing more specific information when available is preferable.

Both the National Cancer Institute reports and Maine CDC District profiles rely on the same data source, the Maine Cancer Registry. Therefore, any variations resulting from developing county-level rather than district-level forecasts should be insignificant.

MMC uses age-adjusted rates for its need projection. The National Cancer Institute defines age-adjusted rate as:

> *(A) weighted average of the age-specific incidence or mortality rates where the weights are the proportions of persons in the corresponding age groups of a standard million population. Age adjustment minimizes the effect of a difference in age distributions when comparing rates. For State Cancer Profiles, all incidence and mortality rates are age-adjusted to the 2000 US standard million population to facilitate comparison of rates across geographic areas and demographic groups.*

Maine's state-wide crude (unadjusted) rate is 607.5 as a result of its higher than standard percentage of elderly residents. Maine's age-adjusted rate is 527.2 (Source: North American Association of Central Cancer Registries, Additional Linear Accelerator Application, p. 13.).

The age-adjusted rate methodology minimizes the effect of varying age distributions. This is significant when applying such rates to Maine's population, since Maine has one of the oldest populations in the nation. MMC's use of standardized age-adjusted incidence rates for Maine counties applied to Maine's population understates need by approximately 15%. MMC's approach results in a conservative forecast of need.

MMC Market Share

CONU raises questions regarding the market share information contained in MMC's application.

MMC adjusts its presumed market share to reflect the significant amount of time that its full compliment of linear accelerators was off line during the 2005 to 2008 period. MMC believes that it is reasonable to adjust its market share to reflect full capacity and unencumbered access; otherwise, customary demand for MMC radiation therapy service would be underrepresented. MMC's linear accelerator capacity is reduced by 15 months of accelerator capacity during the period in question.

MMC states:

> *MMC uses the 3 highest volume years during the 2005 to 2008 period to adjust for the times when MMC's linear accelerators were off line for replacement/upgrade to IGRT capabilities and for Cancer Care Center of York County's (CCCYC) partial first year of operation. Coastal Cancer Treatment Center's linear accelerator was off line for 5 months during FY 2005, Cancer Care Center of York County provided radiation therapy services for seven months during FY 2006 and one of the Scarborough linear accelerators was off line for 5 months during FY 2008.*
>
> Additional Linear Accelerator Application, p. 19.

Timely access to radiation therapy is more highly desirable than proximity. It is to be expected that patients would be redirected to other providers when MMC was experiencing capacity constraints to assure timely access to treatment. The fluctuation in market share is most pronounced in MMC's primary service area. Residents of MMC's secondary and tertiary service

areas often must receive treatment at MMC due to their need for subspecialty radiation therapy not available elsewhere in Maine.

IGRT and IMRT

Image Guided Radiation Therapy (IGRT) is a technological enhancement to Intensity Modulated Radiation Therapy (IMRT), not a substitute. New generation linear accelerators incorporate both IMRT and IGRT capabilities; accelerators without IGRT capability are being phased out of manufacturing and soon will be unavailable.

Once the imaging procedure is performed via IGRT-capability and the tumor site is precisely located, the patient receives IMRT. Therefore, the effectiveness of the underlying treatment is the same for both IGRT and IMRT. What differs significantly is the precision and accuracy of the dosing, and the avoidance of collateral damage to healthy tissue due to IGRT's more precise guidance.

In essence, IGRT significantly improves the anatomical accuracy of IMRT dosing and reduces radiation toxicity. The technology is being demonstrated as effective with certain tumor sites. This is similar to the progression that occurred as radiation treatment technology migrated from Three-Dimensional Conformal Radiation Therapy to IMRT.

The published research (circa 2006-2007) presents evidence supporting the use of IGRT for prostate, head and neck tumors. (Additional Linear Accelerator Application, Exhibit 1-A Radiation Therapy Overview.) MMC's Radiation Therapy Program limits its practice to these evidence-based applications.

Clinical data are emerging to support the use of IGRT in patient receiving treatment for breast cancer, although the acceptance of these data is not been uniform, nor is the routine use of IGRT in patients with breast cancer. There are no other data to support the routine use of IGRT in other patient populations. While it is very likely that data demonstrating increased effectiveness and/or reduced toxicity with IGRT in other patient populations will still mature over time, to date there is no definitive evidence for these applications; as a result, MMC does not include such applications in its radiation therapy practice.

Demand Forecasting

Distribution of IGRT and Non-IGRT Cases

CONU raises questions regarding the increase in the percent of patients qualifying for IGRT.

MMC and its radiation oncologists anticipate that clinician "learning curve" will take time for MMC Radiation Therapy to attain proficiency in IGRT and fully extend their practice. MMC anticipates that evidence supporting IGRT use for treating breast and lung tumors continues to be published and gains acceptance during the forecast period.

As noted above, emerging clinical data tend to support IGRT application for breast cancer; MMC forecasts additional data being published and more generally accepted. MMC expects a similar process to occur with IGRT applications for lung cancer.

The Maine Quality Forum Assessment states that the clinical rationale "is based on the evolving need for image-guided radiation therapy (IGRT) for most radiation oncology applications." (CONU Preliminary Analysis, p.73.)

MMC does not assume that all or most tumors benefit from IGRT. MMC concurs with Dr. Cutler's concerns that IGRT is not a panacea for every tumor. MMC anticipates that at program maturation 21% of MMC's patients would benefit from IGRT.

MMC emphasizes that this is a forecast based on the assumption that further data supporting IGRT use for certain tumor sites continue to be published and gain acceptance. MMC does not and will not vary from its commitment to an evidence-based radiation therapy practice.

Average IGRT Procedure Time

CONU questions whether the average IGRT procedure time improves with staff experience.

The average time per procedure is based on actual MMC experience prior to submission of the application. The throughput duration is and continues to be more directly related to the technology than to staff proficiency.

Early generation IGRT-capable linear accelerators at MMC's Bath and Scarborough campuses, and the Cancer Care Center of York County Sanford campus require 35 to 45 minutes to acquire images and provide radiation treatment. The newly installed IGRT-capable linear accelerators at MMC's Scarborough and Portland campuses (replacement equipment) appear to have significantly faster throughput than the early generation accelerators.

The generation of linear accelerators now being installed nationwide appears to provide shorter treatment times and more rapid throughput. Cyclical replacement of MMC's older generation linear accelerators may provide adequate capacity to deliver IMRT/IGRT to the appropriate patient populations for the foreseeable future.

The Bath and Sanford IGRT-converted linear accelerators currently provide adequate capacity to deliver IMRT/IGRT at those sites. However, the Bath linear accelerator tends to run at or just above capacity. MMC continues to monitor this situation to gauge reasonable geographic and timely access to radiation therapy.

MMC is requesting a twelve-month suspension of this proposal's application process in order to ascertain whether installation of current and next generation linear accelerators mitigates MMC's need for additional linear accelerator capacity.

Linear Accelerator Efficiency

CONU raises questions regarding the annual treatment time per linear accelerator contained in MMC's application.

CONU states that it is reasonable to plan for annual accelerator availability of 245 days, 10 hours, 95% on line or 2,325 hours per year. In the application MMC presents treatment time as 85% of 250 days, 8 hours or 1,700 hours per year. (Application, pp. 20-21)

CONU and MMC take two differing approaches to efficiency that are complimentary. CONU presents a forecast of availability; MMC presents a forecast of treatment utilization when an accelerator is available.

While availability can be relatively constant (scheduled hours, increased hours for peak demand, need for maintenance or repair), treatment utilization fluctuates with the number of patients presenting and receiving treatment when the accelerator is available. There are days when there are open treatment slots and other days when hours need to be expanded.

In addition to variations in the number of patients referred for treatment throughout a year, cancellations occur when patients are too ill to travel (a common occurrence with this patient population), patients inadvertently miss an appointment, or road conditions make travel difficult.

MMC's utilization approach takes these factors into account.

V. Orderly and Economic Development

CONU raises concerns that MMC has not demonstrated public need for IGRT technology and as a result the project is not consistent with the orderly and economic development of Maine's health care system.

MMC believes that there is sufficient clinical evidence to support limited applications of IGRT to treatment tumors of the prostate, head and neck. The National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology – version 2.2009 for Prostate Cancer makes the global change in its Prostate Treatment guidelines 1.2008 version: *"3D-CRT was changed to 3D-CRT/IMRT with IGRT."* Most NCCN guidelines, including this global change, are *"based on lower-level evidence and there is uniform NCCN consensus."*

Contemporary linear accelerators incorporate both IMRT and IGRT capabilities; accelerators without IGRT capability are being phased out of manufacturing and soon will be unavailable. Manufacturers claim that these newly introduced linear accelerators are making significant advances in reducing the throughput involved with IGRT procedures.

MMC notes that if these new generation accelerators deliver the claimed shorter throughput times, the need for additional linear accelerators will be lessened.

VI. State Health Plan

MMC concurs with CONU findings that MMC has demonstrated a commitment to quality, collaboration and consolidation.

CONU questions the applicability of MMC's emergency service reduction efforts to this project stating that "*The applicant has provided information about ED Services. However, this is not an ED project and the applicant provided no information that adding an additional linear accelerator would have an effect on reducing ED services.*"

MMC notes that the State Health Plan goal for applicants states that "*The applicant has a plan to reduce non-emergent ER use.*" MMC believes that the goal as stated is not project-specific and refers to the applicant regardless of the nature of the proposed project. MMC does not claim that this particular project has a direct effect on emergency service usage.

CONU raises a question regarding patients in other programs having access to the proposed accelerator.

MMC is committed to providing all patients with access to the available, appropriate technology to address their health care needs.

CONU raises a concern regarding MMC's commitment to the Dirigo target of 3% operating margin.

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

MMC notes that the financial forecast module submitted as part of the application (Additional Linear Accelerator Application, Exhibit 3-B.) relates to MMC's hospital operation only and does not include the activity of other subsidiary operations of MMC. MMC calculates the operating margin limit based on consolidated operations. As a result, the operating margin of the hospital activity, on both a historical basis and forecast basis, exceeds the 3% limit on operating margins. The additional hospital operating margin is required to cover MMC investments to provide access to certain to physician services in the community which are part of MMC's consolidated operations.

MMC believes that the financial forecast module submission is completed in accordance with the instructions provided by CONU staff. Further, the historical operating margins of the consolidated operations of MMC can be calculated from the audited consolidated financial statements that are contained in the CON application (Additional Linear Accelerator Application, Exhibit 3-A.).

MMC concurs with CONU findings that MMC has demonstrated a commitment to electronic medical records and a commitment to environmentally-sensitive facility design.

VII. Outcomes and Community Impact

CONU states:

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

MMC concurs with CONU's finding that the proposed project does not negatively affect the quality of care delivered by existing service providers.

MMC notes that current and future generation linear accelerators have both IGRT and IMRT capabilities. IMRT-only accelerators will no longer be available from manufacturers.

MMC believes that there is sufficient clinical evidence to support limited applications of IGRT to treatment tumors of the prostate, head and neck. The National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology – version 2.2009 for Prostate Cancer makes the global change in its Prostate Treatment guidelines 1.2008 version: *"3D-CRT was changed to 3D-CRT/IMRT with IGRT."* Most NCCN guidelines, including this global change, are *"based on lower-level evidence and there is uniform NCCN consensus."*

VIII. Service Utilization

MMC concurs with the CONU recommendation that the Commissioner find that the applicant has met their burden to demonstrate that the project does not result in inappropriate increases in service utilization, according to the principles of evidence-based medicine adopted by the Maine Quality Forum.

Conclusion

Linear accelerator technology continues to evolve; research demonstrating IMRT and IGRT benefits is being published; national guidelines are beginning to recommend IGRT for some tumor sites. The generation of linear accelerators now being installed nationwide appears to provide shorter treatment times and more rapid throughput than earlier generation IGRT accelerators.

MMC is requesting a twelve-month suspension of this proposal's application process in order to ascertain whether installation of current and next generation linear accelerators mitigates MMC's need for additional linear accelerator capacity.