

August 21, 2008

HAND DELIVERED

Anne Flanagan, Assistant Director
Division of Licensing & Regulatory Services
41 Anthony Avenue
Augusta, Maine 04330

**RE: COMMENTS ON PROPOSED DHHS RULE CHAPTER 114,
RULES GOVERNING THE REPORTING OF SENTINEL EVENTS**

Dear Anne:

I am writing on behalf of the Maine Medical Association, a professional organization representing more than 2900 physicians, residents, and medical students whose mission is “to support Maine physicians, advance the quality of medicine in Maine, and promote the health of all Maine citizens.” The MMA appreciates the opportunity to comment on the proposed rule listed above.

MMA representatives participated in good faith with legislators on the Health & Human Services Committee, DHHS representatives, and stakeholders including the MHA and consumer/patient advocacy organizations in extensive negotiations during the course of two years of the 120th Maine Legislature to develop Maine’s sentinel event reporting law, P.L. 2001, Chapter 678. This law was a carefully crafted compromise that balanced the interests of all stakeholders.

In a number of material ways, proposed Rule 114 fails to meet the spirit of that compromise and, more importantly, exceeds the Division’s rulemaking authority specified in P.L. 2001, Chapter 678 (22 M.R.S.A., Chapter 1684). The following examples are ways in which the proposed rule exceeds the scope of the sentinel event reporting framework approved by the legislature.

- Reference to “potential” sentinel events in the proposed rule’s Purpose statement. The statute requires reporting of a specific list of sentinel

events defined in §8751(4), but it does not extend to “potential” sentinel events.

- Authority to determine the occurrence of a sentinel event. In §8753, the statute directs the health care facility to report sentinel events *it identifies* (emphasis supplied), so the MMA objects to the sentence in Section 2.2 of the proposed rule suggesting that the SET will determine whether a sentinel event is reportable. During the legislative debate about sentinel event reporting, the MMA clearly stated that its support for the new reporting framework depended on it being established as an educational initiative independent of the civil justice and state licensing systems, and that this new initiative not interfere with the long-standing peer review provisions of the Maine Health Security Act (24 M.R.S.A., Chapter 21). Maintaining strong peer review protections in Maine law is vitally important to ensuring physicians’ faith and trust in many of our quality improvement efforts today. The MMA objects to the expanded role of the SET and its interference in the protected peer review activities of Maine health care organizations that is suggested by Section 2.2 of the proposed rule.
- Scope of the written report required. In §8753(2), the statute identifies the specific data elements that a health care facility must include in a sentinel event report. These data elements were debated at length in the HHS Committee and upon the urging of the MHA and MMA, the data elements were intentionally specified as a subset of a facility’s work product constituting “professional competence review records.” The MMA objects to the inclusion of a definition of “root cause analysis” in Section 1.4 and the expansion of the reporting requirement in Section 2.4.5 to include a “thorough and credible root cause analysis.”

The MMA is willing to participate in a discussion about legislation your office might wish to pursue to amend the sentinel event reporting statute, but the provisions of the proposed rule cited above exceed the authority delegated to the Department in P.L. 2001, Chapter 678 (22 M.R.S.A., Chapter 1684) and we urge you to revise the proposal to remain within the statutory boundaries.

Thank you for considering the views of the MMA on the proposed DHHS Rule Chapter 114.

Sincerely,

Andrew B. MacLean