Commonwealth of Massachusetts
BOARD OF REGISTRATION IN MEDICINE

PATIENT CARE ASSESSMENT DIVISION

ADVISORY MARCH 2010

Safety and Quality Reviews and Serious Reportable Events in Healthcare

This Advisory is intended to reinforce the Patient Care Assessment Division's (PCA) expectations for health care facility reporting of unexpected patient outcomes that meet both Massachusetts Department of Public Health (DPH) and PCA reporting requirements. PCA is working closely with DPH on strategies to address health care facility concerns about reporting the same event to more than one agency. PCA appreciates the participation of health care facility leaders in these efforts.

The following information is provided for clarification.

Reports describing serious unexpected patient outcomes that are submitted by health care facilities to PCA are called Safety and Quality Reviews (SQRs). The PCA regulations specifically require health care facilities to report the following types of events:

1. Maternal deaths that are related to delivery;
2. Death in the course of, or resulting from, elective ambulatory procedures;
3. Any invasive diagnostic procedure or surgical intervention performed on the wrong organ, extremity or body part; and
4. All deaths or major or permanent impairments of bodily functions (other than those reported above) that are not ordinarily expected as a result of the patient's condition on presentation.[i]

Included in these events, in most cases, are events that are also reportable to DPH under their regulations requiring hospitals to report Serious Reportable Events in Healthcare (SREs).[ii]

In August 2009, the Joint Commission advised hospitals that it would not require them to submit a Root Cause Analysis (RCA) for any of the events identified in the report *Serious Reportable Events in Massachusetts Acute Care Facilities* published by the DPH in February 2009.[iii] This decision followed a meeting between Joint Commission representatives and PCA staff, during which PCA was able to demonstrate to the Joint Commission that Massachusetts has a method for follow-up with the hospitals identified in the February 2009 public report. The Joint Commission's decision was in keeping with its commitment to encourage transparency in patient safety improvement efforts, while at the same time avoiding burden and unnecessary duplication for hospitals.

The Joint Commission's decision acknowledged the efforts in Massachusetts to ensure quality patient care through robust, transparent reporting systems. PCA joins the hospitals in their commitment to continue to demonstrate the effectiveness of the Commonwealth's reporting systems. In doing so, PCA asks all health care facilities to review their internal processes for identifying cases for reporting to PCA, using the guidance offered in this Advisory. Health Care Facilities are reminded that reports to PCA are provided statutory confidentiality protections.[iv] They are also not shared with DPH, even if the event described was also reported to DPH.

If you have any questions about reporting SREs to PCA, or any other questions concerning this Advisory, please contact Maureen Keenan, RN, JD, Associate Director of the PCA Division at maureen.keenan@state.ma.us or (781) 876-8255.

---

[i] 243 CMR 3.08
[ii] 105 CMR 130.332
[iii] *Serious Reportable Events in Massachusetts Acute Care Facilities*
http://www.mass.gov/Eeohhs2/docs/dph/quality/healthcare/sre_acute_care_hospitals.pdf
[iv] MGL. c. 111, §§ 204 & 205; 243 CMR 3.04