



## RM Mailbag

- Hospital RM asks if risk management process is compliant with Incident Reporting Regulations – effective 7/1/09 – outlined in the December 2008 Kansas Board of Pharmacy newsletter?

**Response:** After researching the requirements and talking with the Board of Pharmacy, the change mainly includes pharmacists outside of those under risk management – those not working in a medical facility. The Kansas State Board of Pharmacy regulatory reference is KAR 68-7-12b.

Just as some of your risk management activities also meet other regulatory requirements, this should also apply to these pharmacy requirements. Recommendation: Continue to process pharmacy/pharmacist related incidents through RM as required by RM statutes and regulations and through QAPI, as warranted.

If the reports are requested during a Board of Pharmacy inspection, then you can choose whether or not you release the information. If you elect not to release the information, you will have nothing to prove compliance with the Board of Pharmacy requirements and may be cited.

If the reports are requested as a result of you reporting a staff member to the Board of Pharmacy, then you are to release applicable information per RM statute, KSA 65-4925(e).

- Multiple Risk Manager's asked how long to keep risk management documentation.

**Response:** KAR 28-52-2(c) Incident reports, investigational tools, minutes of risk management committees, and other documentation of clinical analysis for each reported incident shall be maintained by the facility for not less than one year following completion of the investigation.

The requirement is to retain the risk management documentation for at least one year following completion of the investigation. **Not** that they must destroy the documentation after a year, *unless that is what their risk management plan specifies*. (For facilities that have incidents they never completed - guess they have to keep them forever!)

Surveyors should check the facility's risk management plan for any specific retention requirements that exceed regulatory requirements and hold the facility to those requirements. Facilities may retain the risk management documentation for as long as they desire. It is privileged and confidential. The risk factor is that should there be a breach making their risk management information discoverable or the risk management laws get changed and privileged and confidential is lost.

It is recommended that the facility maintain risk management documentation related to actual/potential litigation, including incidents involving minors, for as long as their legal consultant advises.

- Many questions asked about how to determine who is "involved."

### Examples of involvement determination:

\*\*Wrong site surgery: everyone responsible to participate in the time out (usually everyone on the team); everyone who prepared wrong area; everyone who did surgery on wrong site (usually just the surgeon).

\*\*Medication error secondary to transcription error: individual who made transcription error; pharmacy personnel supplying medication (if applicable); individual responsible for 24 hour check/reviewing MAR (if applicable); each staff member who made med error, per wrong medication administration.

\*\*Surgical complication (perforation): individual who made perforation (usually only the surgeon); other individuals may become involved, if surgeon fails to take appropriate action and they are knowledgeable of failure. Sometimes a perforation occurs when the cautery is not set properly or malfunctions. In those cases, whoever is responsible for the cautery would also be involved.

Rarely is the physician who was notified of the incident "involved," unless they fail to take warranted action, once they are aware of a situation needing their attention. Then there would be another issue to address - physician failure to provide services.

Staff member(s) who come upon the scene become involved, just like the first person on the scene of an accident. Additionally, supervising staff may be involved if they fail to adequately supervise/provide direction and an incident or near miss occurs.

Bottom line: Go to the root cause(s) - issues - and see which individual(s) was involved, or should have been.