



Commonwealth of Massachusetts  
Board of Registration in Medicine  
**Quality and Patient Safety Division**

**HEALTH CARE FACILITY PATIENT CARE ASSESSMENT PROGRAMS**

**Introduction**

The Quality and Patient Safety Division (QPSD) of the Massachusetts Board of Registration in Medicine (Board) uses a unique approach to help health care facilities maintain the highest levels of health care quality. QPSD operates under the basic premise that the people who deliver excellent patient care every day — doctors, nurses, pharmacists, and other professionals — know what needs to be done to ensure that Massachusetts continues to have the highest health care quality in the world. Utilizing collaboration and data analysis, the QPSD brings vital tools and information to health care facilities to help them meet their patient safety and quality goals.

The QPSD function is unique among the nation's state licensing boards, as the legislature placed oversight of institutional quality assurance in an agency that licenses physicians, but not health care facilities. This rationale is compelling: institutional quality assurance will not succeed without meaningful physician leadership and participation.

QPSD activities differ from the Board's other, more traditional functions. The QPSD does not discipline individual physicians or regulate their licensure. While its ultimate responsibility is public protection, the QPSD operates to be collaborative and educational when working with health care facilities. The QPSD's purpose is to work with each health care facility to ensure high standards of quality.

**PCA Program Functions**

The QPSD oversees institutional systems of quality improvement, risk management, peer review, and credentialing. These activities are known collectively as the institution's "Patient Care Assessment (PCA) Program." The systems comprising a facility's PCA program must be overseen by both physician and corporate leadership and must actively involve all health care providers as well as other employees at the institution. A facility's PCA program must be described in a written plan.

Two general requirements are critical to the program's success. First, there must be a PCA Committee within each facility that has overall responsibility for the PCA program. It must be an integral component of the governing body of the facility. The facility's PCA Committee ensures that the program is an institutional priority. Second, every physician must participate in the PCA program established by the health care facility where s/he practices.

PCA information submitted to the QPSD is confidential and not subject to subpoena, discovery or introduction into evidence. The QPSD does not share its information with any of the Board's other functions or divisions.

**PCA Program Reporting - Safety and Quality Reviews**

The QPSD, by PCA regulations, requires submission of reports of unexpected patient outcomes — known as Safety and Quality Reviews (SQRs). There are four types of events that must be reported. The first three types of events are specific outcomes: (1) maternal death related to delivery; (2) death during or resulting from an elective ambulatory procedure; and (3) a wrong site procedure. The fourth type involves a death or "major or permanent impairment of bodily function" that was not ordinarily expected, based on the patient's condition upon presentation or admission to the facility.

When analyzing whether an event was “ordinarily expected,” the question to ask is not whether there was any chance that the event could happen. The question to consider is whether, in the ordinary course of events, the incident was expected to occur. There is a statistical chance that any patient, after entering a health care facility, might die or develop unanticipated complications. The relevant issue, however, is whether the incident would have been ordinarily expected, given the patient’s condition on presentation or admission.

When evaluating whether the patient experienced “major or permanent impairment of bodily function,” as a result of the event, consider whether the patient experienced a significant change in functional status, even if the change was temporary.

Identification of an event as one that must be reported as an SQR does not necessarily mean that the outcome was preventable or that it resulted from negligence or substandard care.

In a SQR report, the facility must provide a medically coherent description of the event; a clear and thorough account of the results of its investigation; and a description of all corrective or improvement measures taken in response to the event. Systems and provider issues may be identified and improved regardless of whether or not the event was preventable.

Keep in mind that the consequences of reporting are positive, that is - the report will provide the QPSD with evidence that your facility has a process for identifying, investigating and responding to unexpected patient events. The QPSD reviews the responses to determine that the facility thoroughly investigated the event and took appropriate follow-up action. QPSD uses these reports to evaluate the facility’s processes to identify and resolve existing weaknesses in the checks and balances that exist to prevent patient harm.

Often, the corrective actions taken by one institution can be replicated as “best practice guidelines” in other facilities. Occasionally, the QPSD will identify trends of similar “SQRs” in several different facilities. When this occurs, the QPSD is able to notify all facilities of the potential problem and recommend strategies to respond that have succeeded in other facilities. By serving as a central repository of the types of problems — and solutions — found in health care facilities throughout Massachusetts, the QPSD can share the experience and insight of thousands of health care professionals with colleagues in every health care facility in the Commonwealth.

### **PCA Program Reporting - Semi-Annual & Annual Reports**

A health care facility subject to PCA regulations must submit Semi-Annual and Annual Reports to the QPSD. These reports allow the QPSD to assess the facility’s systems for tracking and analyzing quality assurance data.

Semi-Annual Reports are intended to apprise the facility’s governing body of the operation of the facility’s PCA program. The report should demonstrate the facility administration and governance commitment to continuous quality improvement and patient safety efforts. By requiring review and approval by the governing body, a facility demonstrates its commitment to the PCA Program and its goals. Semi-Annual and Annual Reports should provide more than numbers from the data collected through the facility’s occurrence screening and reporting systems. The reports should contain the findings from analysis of the data identifying patterns or trends. The reports should also contain information about health care facility quality initiatives.

### **References**

The following are links to the PCA regulations on the Board’s website:

<http://www.mass.gov/eohhs/docs/borim/reg-243-cmr-3.pdf>

<http://www.mass.gov/eohhs/docs/borim/reg-243-cmr-3.doc>

The following are links to an expanded overview of the PCA regulations on the Board’s website:

<http://www.mass.gov/eohhs/docs/borim/physicians/qual-patient-safety-pca-report.pdf>

<http://www.mass.gov/eohhs/docs/borim/physicians/qual-patient-safety-pca-report.doc>