



## HEALTH CARE FACILITY PATIENT CARE ASSESSMENT PROGRAMS

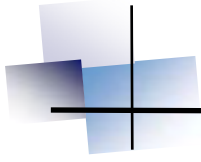
### **An Overview**

- Statutes & Regulations
- Health Care Facility Reporting Requirements
- Understanding Safety and Quality Reviews
- Frequently Asked Questions



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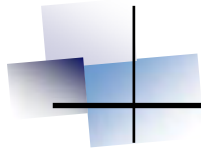


## Welcome

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 reviews unexpected patient outcomes — known as Safety and Quality Reviews (SQRs) — to ensure that the health care facility has taken all necessary steps to prevent a recurrence of an avoidable adverse event. QPSD looks at 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.

SQRs help the QPSD understand how an institution's quality assurance processes operate. 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.



## Quality and Patient Safety ...History of the PCA Program

The QPSD oversees institutional systems of quality assurance, 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.

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.

The QPSD Committee supports the work of the QPSD by working to ensure that health care facilities provide quality care and that physicians practicing within the facility are active participants. The QPSD Committee is made up of practicing physicians in various specialties, members of the Board of Registration in Nursing and Pharmacy, a hospital PCA Coordinator and a patient representative.

The QPSD and its Committee are also unique in the confidential nature of their activities. Soon after the inception of the QPSD function, the legislature passed a statute that afforded health care facility PCA Program information a high level of legal protection from disclosure. 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.**



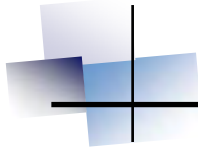
## PCA Program Overview

A health care facility's PCA program is an integrated system of peer review, risk management and credentialing with a goal of continuous improvement in the quality of health care services. A facility's PCA program must be described in a written plan. A physician may not practice at any health care facility without an approved PCA program; approval of the program is also a condition of hospital licensure.

### Basic Requirements of a PCA Program

The detailed requirements of a PCA program are in the PCA regulations and discussed in more detail on page 4. 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's impact is tied to the involvement of a facility's medical staff. Along with active participation of its medical staff, the facility must also have strong internal systems for physician credentialing; incident reporting; the processing of patient complaints; and acquisition of patients' informed consent.

The QPSD ensures that facility's have acceptable PCA programs in place by reviewing and approving their PCA plans. The PCA plan must describe in writing how the facility implements the requirements found in the PCA regulations. To ensure that the facility's PCA program is working, the QPSD requires three types of reports. Two of these reports, called the Semi-Annual and Annual Reports, must be submitted by the facility to its governing body, with copies furnished to the QPSD. The purpose of the QPSD Semi-Annual and Annual Reports is to apprise the health care facility's governing body and the QPSD of ongoing PCA program activities. The third type of report required by the QPSD, perhaps the most critical of all, is the SQR Report. SQR Reports are discussed in detail in this handbook on page 6.



## Reference Guide

### Statutory References

The PCA function was created by the Medical Malpractice Reform Act of 1986. This legislation was drafted in response to the rising number of patient injuries and the associated medical malpractice claims, which, in turn, increased insurance premiums.

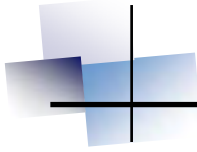
The legislation was also a response to criticism at the time that health care facilities ignored substandard performance by physicians. These statutes require participation in PCA programs as conditions of hospital and physician licensure. Among the key provisions of the Massachusetts General Laws dealing with oversight of institutional quality assurance are [M.G.L. c.111, § 203\(d\)](#) and [M.G.L. c.112, § 5](#).



The full text of these laws can be found on the state website at: [www.mass.gov](http://www.mass.gov). Just follow the links to the web pages related to the Massachusetts legislature to use the search engine for all Massachusetts General Laws.

### Regulations

Following the enactment of these statutes, the Board promulgated regulations to carry out its mandate of overseeing institutional quality assurance. The PCA Regulations can be found at 243 CMR 3.00. They specify, in detail, the requirements broadly set out in the 1986 legislation. The regulations apply to all health care facilities, ranging from hospitals to HMOs to physicians' office settings. The regulations prohibit Massachusetts physicians from practicing at facilities without approved PCA programs. The full text of these regulations can be found by visiting the Board's website at: [www.mass.gov/massmedboard](http://www.mass.gov/massmedboard).



## Glossary of Terms

### Safety and Quality Reviews (SQRs)

Reports that describe unexpected patient outcomes that meet specific criteria described in the Board's PCA regulations for reporting "major incidents" at 243 CMR 3.08. These reports detail the event itself, the facility's investigation and response.

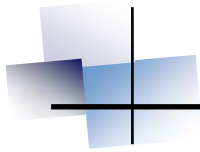
### Annual & Semi-Annual Reports

Updates from health care facilities that must be submitted to the QPSD. Requirements for submission are at the Board's website: [www.mass.gov/massmedboard](http://www.mass.gov/massmedboard).

### Advisories

By their reviews of SQRs, the QPSD is in a unique position to identify quality assurance problems in health care that require broad, state-wide attention. When such problems are identified, advisories are distributed to all hospitals in the Commonwealth alerting facilities about the issue, describing the problem and offering solutions. Copies of all advisories are on the Board's website: [www.mass.gov/massmedboard](http://www.mass.gov/massmedboard).





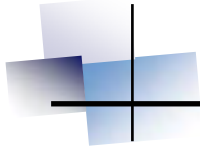
## SQR Reports

SQR reporting to the QPSD is a required component of a Massachusetts health care facility's overall incident reporting system. Reports of most incidents identified and tracked by a health care facility are internal matters and remain within the institution. However, the details of some incidents that are designated as ("major"), because they result in severe adverse patient outcomes, are required to be reported to the QPSD. 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 serious injury that was not ordinarily expected, based on the patient's condition upon presentation or admission to the facility. The four types of events are described in the PCA regulations at 243 CMR 3.08.

**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.** Through its review of SQR reports, the QPSD evaluates how a facility's PCA program responds to a serious unexpected outcome. Indeed, the reason SQRs must be submitted to the QPSD on a quarterly basis, and not immediately following an event, is to allow the facility's own PCA program to investigate what happened and to formulate an institutional response.

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. Following its review of the event, the facility may find that the event, while unexpected, could not have been prevented. Alternatively, the facility may uncover circumstances that caused or contributed to the event and identify opportunities to improve. Systems and provider issues may be identified and improved regardless of whether or not the event was preventable. The QPSD reviews the responses to determine that the facility thoroughly investigated the event and took appropriate follow-up action.





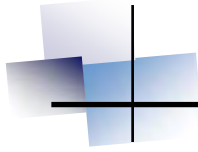
## Type 4 Events ....Deciding Whether to Report

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 suffer serious injury. The relevant issue, however, is whether the incident would have been *ordinarily* expected, given the patient’s condition on presentation or admission.

The starting point of the above analysis is the patient’s condition on admission or presentation, not immediately prior to the event. For example, consider a patient admitted in good condition for an elective laparoscopic cholecystectomy. During the procedure, the bowel is perforated, but the perforation is not diagnosed. Later, the patient requires a return to surgery for additional surgical intervention. In determining whether this event is reportable, think about the patient’s condition at admission, not after the complication occurred. While perforation is a recognized complication, the diagnosis and treatment of the complication is the critical issue.

If it appears very likely when the patient is first seen that s/he will die (for example, because of terminal cancer or severe trauma secondary to a motor vehicle accident) and the patient does, in fact, die but from an unexpected cause (e.g., an air embolism secondary to line placement), that is a reportable event. But if the patient dies, as expected, of the underlying medical condition, that would not be reportable. *If there are questions about whether a specific case is reportable, call the QPSD at (781) 876-8296 for assistance.*





## Semi-Annual & Annual Reports

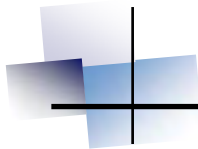
A health care facility subject to PCA regulations must submit Semi-Annual and Annual Reports to the QPSD. These reports allow the QPSD to assess the facility's systems for tracking and analyzing quality assurance data.



The Semi-Annual Report is required by 243 CMR 3.07 (3)(g). It must be submitted to a health care facility's governing body (for example its Board of Trustees or Board of Directors) with a copy filed with the QPSD not later than 30 days after the end of the applicable six-month period. Once a year, the facility's PCA Program Annual Report is to be submitted. The Annual Report is required by 243 CMR 3.11(4).

Semi-Annual Reports are intended to apprise the 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.



## Advisories & Newsletters

By their reviews of SQRs, the QPSD is in a unique position to identify quality assurance problems in health care that require broad based attention.

When such problems are identified, advisories are distributed to health care facilities in the Commonwealth. The advisories alert the facilities about the issue, describe the problem and offer potential solutions.

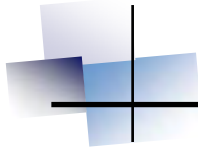
The advisories draw upon the experiences and reports of health care facilities across the Commonwealth. These communications represent the cornerstone of the QPSD philosophy: the collaborative use of carefully analyzed data to drive improvements in health care quality. The QPSD and its Committee can identify trends that cut across several institutions, because the QPSD receives reports from all facilities. Full and timely reporting from institutions allows the QPSD Committee to offer this valuable service to all health care facilities. Advisories can be found on the Board's website.

Of greatest importance, the advisories can share valuable quality improvement measures and "best practices" of institutions whose internal PCA functions identified and responded to a problem. It is this practical approach to patient safety and health care quality that prevents avoidable harm to patients.

The QPSD also publishes newsletters that highlight individual hospital's successful innovations in patient safety and quality improvement.

### *Advisories*

- *SQR & SRE Reporting*
- *Glacial Acetic Acid*
- *Hydromorphone vs. Morphine*
- *Sharing of Patient Information for Quality Improvement Purposes*
- *Post-op Management of Weight Loss Surgery Patients*
- *Gastric Bypass Complications*
- *DVT and PE with Knee Injuries*
- *Patient-Controlled Analgesia*
- *Complications in Patients Receiving Neuraxial Anesthesia/Analgesia*
- *Unread Electrocardiograms*
- *Radiology Coverage in Emergency Rooms*
- *Laparoscopic Injuries*
- *Adrenocortical Insufficiency Secondary to Previous Treatment with Adrenal Corticosteroids*
- *Pediatric Neurosurgical Procedures*
- *Oncology Drug Administration*



## Frequently Asked Questions

### When are SQR reports due?

A health care facility has 30 days following the end of the calendar quarter in which the incident occurred to submit a SQR to the QPSD.

### Should I wait until the investigation of the event is complete before filing a report?

No. File the SQR within the required time period. You may indicate on the report that the investigation is not complete. You must then submit a follow-up report at the completion of the investigation.

### If no reportable events occur in a particular calendar quarter, do I have to submit some kind of report stating so?

It is not necessary to do so. You must, however, indicate the total number of SQRs for the entire year in the Annual Report.

### What should I include in the SQR?

A clear and concise description of the event, a complete report on the results of the review of the incident, and any corrective actions or quality improvement measures taken in response to the event. When applicable, the report should also include an analysis of credentialed provider performance data as compared to the department and benchmarks. Healthcare provider identifying information is not required. The SQR form and instructions are available at the Board's website: <http://www.mass.gov/massmedboard>.



## Frequently Asked Questions ....continued

### **There is a new PCA Coordinator at our health care facility. Do we have to do anything?**

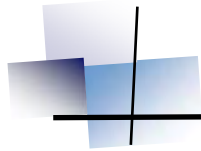
The PCA regulations require (at 243 CMR 3.06(2)) a health care facility to report the name of the PCA Coordinator to the QPSD within ten days of designation or replacement.

### **When are my facility's Semi-Annual and Annual Reports due? Are there formats or forms for these reports?**

There is a format for Semi-Annual Reports. There is no form per se for the Annual Report, however, the information that must be contained in the report can be found at 243 CMR 3.11(4). The Board's website has available : (1) the recommended format for the Semi-Annual Report; (2) the information that must be included in the Annual Report; and (3) a reporting schedule for Semi-Annual and Annual reporting. <http://www.mass.gov/massmedboard>.

### **I am confused about Annual reporting —is it the same as the Annual Disciplinary Action Summary report?**

The Annual Report differs from the Board's Annual Disciplinary Action Summary report. The latter report summarizes information about physicians disciplined by the health care facility in the previous year. This report goes to the Data Repository Unit, a totally separate unit at the Board.



## Frequently Asked Questions ....continued

If I report a serious reportable event to the Department of Public Health (DPH), do I have to report it to QPSD?

You need to carefully review the SQR reporting requirements. The event may satisfy reporting requirements under both DPH and PCA regulations and policies. If the event meets the PCA regulatory requirements (243 CMR 3.08), you need to report the incident to QPSD, using the form and following the instructions for SQR reporting. Instructions for reporting SQRs are at <http://www.mass.gov/massmedboard>. QPSD does not share your report with DPH.

Why do you ask for credentialed health care provider performance data in the SQRs?

A health care facility must have systems for peer review and credentialing that are integrated and overseen by the facility's corporate and physician leadership. QPSD does not request this information for the purpose of identifying the involved individuals, but to assure that an assessment by the health care facility of individual provider performance was part of the investigation of an adverse or unexpected event. QPSD needs to be assured that the health care facility is ensuring that its professional staff is competent and meeting all applicable patient care standards. The QPSD Committee never asks for names of the involved individuals. As with all PCA information submitted to the QPSD, this information is confidential.





## Frequently Asked Questions ....continued

Sometimes our facility receives a letter from the QPSD asking about a DPH report of an investigation that DPH conducted in a response to a patient complaint or hospital “serious incident report.” Why?

QPSD reviews DPH reports of investigations because, like the SQRs and Semi-Annual and Annual Reports, the DPH reports provide insight into a health care facility’s quality improvement and patient safety program. QPSD staff may send a letter to the hospital asking for more information about the event described in the DPH report. QPSD does not focus on the involvement of individual health care providers and in fact, reviews “de-identified” DPH reports.





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*Striving to Ensure High Quality and Safe Patient Care*