Massachusetts Board of Registration in Medicine
Quality & Patient Safety Division

Patient Care Assessment Program Overview

Updated November 2024

Overview of the Patient Care Assessment Program

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QPSD Mission is to assist Massachusetts healthcare facilities in maintaining and improving systems for patient care that are evidence and team based, sustainable, safe, and inclusive. We achieve this by reviewing data, listening, collaborating, and educating teams in healthcare facilities throughout the state.

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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. The QPSD works collaboratively with healthcare facilities in the Commonwealth to ensure that healthcare facilities continues to improve quality and patient safety within their organizations.

The QPSD reviews unexpected patient outcomes, known as Safety and Quality Review (SQR) reports, to confirm that the health care facility has taken all possible steps to prevent a recurrence of an avoidable adverse event. QPSD reviews the facility's processes to identify potential gaps and possible opportunities to prevent patient harm. Often, the corrective actions taken by one healthcare facility can be replicated as "best practice guidelines" in other facilities.

SQR reports help the QPSD understand how a healthcare facility's quality assurance processes operate. Occasionally, the QPSD will identify trends of similar SQR reports in several different facilities. When this occurs, the QPSD can provide an alert to 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 other health care professionals with colleagues in every healthcare facility in the Commonwealth.

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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 organization.

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

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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. A link to the regulations may be found here: Physician Regulations, Policies, and Guidelines | Mass.gov.

Two general requirements are critical to the program's success:

1. 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.
2. Every physician must participate in the PCA program established by the health care facility where they 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 facilities 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. Guidance for writing and submitting a PCA Plan may be found here: Submit Patient Care Assessment Reports | Mass.gov

To ensure that the facility's PCA program is working, the QPSD requires two types of reports:

1. Quality assurance reports, called the Semiannual and Annual Reports, must be submitted by the facility to its governing body, with copies furnished to the QPSD. The purpose of the QPSD Semiannual and Annual Reports is to apprise the health care facility's governing body and the QPSD of ongoing PCA program activities. In September of 2023, the QPSC approved a new policy, allowing facilities to submit one Patient Care Assessment Quality Assurance (PCA-QA) report annually in lieu of the above mentioned Semiannual and Annual Reports.
2. Safety and Quality Review (SQR) Reports which are reports of unexpected patient outcomes. SQR Reports are discussed in detail in this handbook on page 7.

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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. Please 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 institutions 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 ambulatory surgery centers to clinics. 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:
Physician Regulations, Policies, and Guidelines | Mass.gov

Online Reporting Support:

Online support for reporting Patient Care Assessment activities may be found here:
Submit Patient Care Assessment Reports | Mass.gov

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Safety and Quality Review (SQR) Reports

SQR reporting to the QPSD is a required component of a Massachusetts health care facility's overall incident reporting system pursuant to 243 CMR 3.08. Events that result in adverse patient outcomes may be required to be reported to the QPSD. There are four types of events that must be reported:

(I) Maternal deaths that are related to delivery.

(II) Death in the course of, or resulting from, elective ambulatory procedures.

(III) Any invasive diagnostic procedure or surgical intervention performed on the wrong organ, extremity or body part.

(IV) All deaths or major or permanent impairments of bodily functions other than those reported in 243 CMR 3.08(2)(a) through (c) that are not ordinarily expected as a result of the patient's condition on presentation.

Identification of an event as one that must be reported as a SQR report 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 SQR reports 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 organizational response.

In a SQR report, the facility must provide a medically coherent, detailed 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, and de-identified provider metrics for any provider involved in an event if applicable. Following its review of the event, the healthcare 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 for process improvement . Systems issues may be identified and improved regardless of whether the event was preventable. The QPSD reviews the responses to determine that the facility thoroughly investigated the event and took appropriate follow-up action.

Health care facilities shall file major incident reports with the Board on a quarterly basis. When reporting a SQR report, health care facilities shall use the Board's online reporting portal. Users of the portal must be approved in writing by the healthcare facility's Patient Care Assessment Coordinator, Chief Medical Officer, or Medical Director, AND be authorized by the QPSD.

A link to the portal may be found on the website: Submit Patient Care Assessment Reports | Mass.gov

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SQR Reports-Type IV Events

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.

Preventability should not impact reporting. Whether an event is determined to be preventable or non-preventable, opportunities for improvement may be identified. Reporting of near-miss events is not required, however, if the near-miss events resulted in a significant process improvement or initiative, QPSD recommends reporting of the event as a near-miss event.

QPSD is primarily focused on a healthcare facility's review and response to the event rather than the event itself. The following questions may be helpful in determining whether to report:

- Did the event meet the criteria for a Serious Reportable Event (SRE)?
- Was there a gap in process, communication, and/or coordination of care that may have led to a delay in diagnosis/treatment or a missed finding?
- Did the event involve clinicians who did not adhere to process, protocol, or evidence-based practice?
- Did the event result in a change in your systems?
- Did the event uncover ineffective processes in your systems, providers, or employees?

As of September, 2023, The Quality and Patient Safety Committee approved a new PCA Policy which permits healthcare facilities to omit submission of SQR reports of patient falls and pressure injuries provided that:

- The Healthcare facility has submitted a semiannual or PCA-QA report within the last 24 months that documents the existence and implementation of comprehensive prevention programs and/or protocols for prevention of patient falls and pressure injuries, and
- The specific patient fall or pressure injury incident is not inclusive of other adverse events.

If it is uncertain whether an event should be reported as a SQR, guidance may be obtained from the QPSD.

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Quality Assurance Reports

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

The Semiannual 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).

Semiannual 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.

Semiannual 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.

*****As of September, 2023, The Board's Quality and Patient Safety Committee approved a new PCA Policy which allows the QPSD to accept reports that meet the following criteria in lieu of the traditional reports:**

a. Pursuant to 243 CMR 3.07(g) and 243 CMR 3.11(4), Annual and Semiannual Reports are required to be submitted as three distinct reports each year. 243 CMR 3.07(g), sets different reporting periods and due dates for the Annual and Semiannual Reports, dependent upon the healthcare facility type.
   In satisfaction of the foregoing reporting requirements, the Board's Quality and Patient Safety Division will now accept a single, annual submission to be referred to as the Patient Care Assessment Quality Assurance Report (PCA-QA Report), provided that it includes the following elements:

   i. A copy of the facility's Patient Care Assessment Plan, which shall be reviewed, updated, and submitted annually.

   ii. Patient complaint data:

      1. Total volume of patient and family complaints for the reporting period, with the total volume of complaints in each of the top three categories of patient and family complaints.

      2. Analysis, recommendations, and plans for corrective measures for any trends

indicated by data.

iii. Performance Improvement Activities (Major Tasks Completed).

iv. Internal Reporting and Screening Systems:

1. Focused Occurrence *Screening* Criteria data, analysis, and recommendations.
2. Focused Occurrence *Reporting* Criteria data, analysis, and recommendations.
3. Internal Incident Reporting System Data:
    a. Total number of incident reports for the reporting period, with the total number of incident reports in each of the top three categories of incident reports.
    b. Analysis, recommendations, and plans for corrective measures for any trends indicated by data.

v. Attestation that the following elements are in place and available upon request:

1. Policy/protocol regarding the distribution of detailed written instructions regarding operational procedures relevant to patient care assessment and compliance with 243 CMR 3.00.
2. Policy/protocol regarding the handling of impaired physicians.

vi. The reporting period is inclusive of the calendar year prior to the report's due date.

vii. The PCA-QA Report must be submitted annually on or before the following due dates:

1. March 30th for ambulatory clinics and outpatient sites, and
2. April 30th for hospitals.

For assistance in writing and/or submitting a PCA QA Report, please visit the online video tutorial link:
mass.gov/doc/patient-care-assessment-quality-assurance-pca-qa-report-video-tutorial/download

PCA Policy Link: Patient Care Assessment (PCA) Policy - September 2023 | Mass.gov

For assistance in writing and/or submitting the traditional Annual and Semiannual Reports, please use one of the following links:
Patient Care Assessment Program Guidance for Hospitals | Mass.gov

Patient Care Assessment Program Guidance for Licensed Ambulatory Surgical Centers & Clinics | Mass.gov

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Newsletters

Spotlight on Quality & Patient Safety is issued by the Massachusetts Board of Registration in Medicine Quality & Patient Safety Division (QPSD) to share aggregate Safety and Quality Review (SQR) report data and to share performance improvement initiatives being achieved by some of the hospitals, ambulatory surgery centers, and ambulatory clinics in the Commonwealth. *Spotlight* highlights individual hospital's successful innovations in patient safety and quality improvement and has replaced the previous FIRST Do No Harm newsletters. Publication of this newsletter does not constitute an endorsement by the Board of any studies or practices described in the newsletters and none should be inferred.

The link to the most recent issue of *Spotlight* and the newsletter archive may be found here:

Quality and Patient Safety Newsletters | Mass.gov

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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. They can also be submitted on a rolling basis once the investigation and committee review is completed.

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 follow-up on the 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?

You can submit communication with the QPSD through the online portal by choosing the "Communication" tile and indicating that your facility did not have reportable events in that quarter.

What should I include in the SQR?

A clear and detailed 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 de-identified credentialed provider performance data as compared to the department and benchmarks. The online portal is to be used for SQR submission unless an exemption from online reporting has been granted.

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.

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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, which is a separate and distinct unit at the Board. The QPSD does not share any of the documents submitted as part of a Patient Care Assessment program with any other division of the Board.

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,

The 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.

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Glossary of Terminology

Board: The Board of Registration in Medicine, including, but not limited to, its Data Repository, Disciplinary Unit, Patient Care Assessment Unit, Legal Unit, Licensing Unit, and its agents and employees.

Governing Body: the trustees, governing board or other persons responsible for establishing policy, maintaining quality patient care and providing for institutional management and planning at a health care facility.

Health Care Facility: any entity licensed pursuant to M.G.L. c. 111, § 51; any nursing home, within the meaning of M.G.L. c. 111, § 203(d); any state, county or municipal hospital; any entity maintaining more than one primary or episodic walk-in center; and any health maintenance organization within the meaning of M.G.L. c. 176G, § 1. The application of 243 CMR 3.00 to nursing homes and health maintenance organizations is limited as per 243 CMR 3.13 and 3.14.

Health Care Provider: As defined under M.G.L. c. 111, § 1, any doctor of medicine, osteopathy, or dental science, or a registered nurse licensed under the provisions of M.G.L. c. 112, or an intern, resident, fellow, or medical officer licensed under M.G.L. c. 112, a medical student, or a hospital, clinic or nursing home licensed under the provisions of M.G.L. c. 111 or a health maintenance organization within the meaning of M.G.L. c. 176G, § 1, and its licensed health professionals with employment, practice, association or privileges.

Licensee: a person holding any type of license issued pursuant to M.G.L. c. 112, §§ 2 through 9B.

Medical Peer Review Committee: consistent with M.G.L. c. 111, § 1, a committee of a state or local professional society of health care providers or of a medical staff of a licensed hospital, nursing home, or other health care facility, provided the medical staff operates pursuant to written by-laws that have been approved by the governing board of the hospital, nursing home, or other health care facility, which committee has as its function the evaluation or improvement of the quality of health care rendered by providers of health care services, the determination whether health care services were performed in compliance with the applicable standards of care, determination whether the cost of health care services rendered was considered reasonable by the providers of health services in the area, the determination of whether a health care provider's actions call into question such health care provider's fitness to provide health care services, or the evaluation and assistance of health care providers impaired or allegedly impaired by reason of alcohol, drugs, physical disability, mental instability or otherwise.

Patient Care Assessment Committee: a medical peer review committee, as defined by 243 CMR 3.02, and consistent with M.G.L. c. 111, §§ 1 and 204, that is created by the bylaws at the governing body level of a health care facility and which includes among its members not less than one governing body member, and other senior personnel essential to the quality of patient care, for example, higher level nursing administrators.

Patient Care Assessment Coordinator: a qualified physician or non-physician designated by a health care facility to implement and coordinate the facility's Qualified Patient Care Assessment Program established pursuant to 243 CMR 3.00. To be qualified, the Patient Care Assessment Coordinator shall evidence by education, training or experience the ability to carry out the functions and activities of the Patient Care

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Assessment Program. In lieu of appointing a single Patient Care Assessment Coordinator, the governing body of a health care facility may designate a committee to carry out the Patient Care Assessment Coordinator's functions as enumerated in 243 CMR 3.00. Thus, upon election of the health care facility's governing body, all references to Patient Care Assessment Coordinator may include Patient Care Assessment Committee.

Qualified Patient Care Assessment Program: A health care facility's rules, standards and procedures, adopted pursuant to the facility's bylaws (unless otherwise required by statute), designed to establish effective programs in quality assurance, risk management, peer review, identification and prevention of substandard practice, and maximization of patient care assessment and thus minimization of loss, and which meet or exceed the rules, procedures and standards set forth in 243 CMR 3.00. A Qualified Patient Care Assessment Program is a "risk management program" established by the Board of Registration in Medicine pursuant to M.G.L. c. 111, § 203(d) and recognized as a "risk management program" within the meaning of M.G.L. c. 112, § 5.

Qualified Patient Safety Division: The division of the Board of Registration in Medicine responsible for overseeing Patient Care Assessment activities in the Commonwealth.

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Quality and Patient Safety Division

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This overview is provided by the Board of Registration in Medicine (BORIM), Division of Quality and Patient Safety (QPSD).

Questions and comments may be directed to:
Quality & Patient Safety Division
Massachusetts Board of Registration in Medicine

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