

**COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN MEDICINE
PATIENT CARE ASSESSMENT (PCA) DIVISION**

INSTRUCTIONS FOR COMPLETING SAFETY AND QUALITY REVIEW FORM

(revised 08/05/08)

General Instructions

The Safety and Quality Review (SQR) Form replaces the Major Incident Report form. This is the prescribed form for reporting events that meet PCA “major incident” reporting requirements under 243 CMR 3.08. The information that you provide in the SQR is protected by statute from public disclosure. (Please see M.G.L .c. 111, §204 and 205.). The information is also not shared with the Board’s Enforcement Division, Data Repository Unit or any other parts of the Board that oversee the practice of physicians licensed in Massachusetts. You are not required to submit the names of physicians involved in the reported events

The decision whether an events meets PCA reporting requirements often is challenging because the regulatory language requires that the facility determine the degree of seriousness of the event and the patient’s outcome. (See 243 CMR 3.08). PCA Division staff is available for consultation should you have any questions about whether to report a certain unexpected event. Please review and complete all sections of the SQR. The form can be downloaded from the Board’s website and completed online at: www.massmedboard.org/pca. However, it is not yet possible to submit the form online. The original signature of the reporter is required on the form submitted to the PCA Division. Faxes are not accepted. If you have questions about whether to report an event or completing the reporting form, call the Board’s PCA Division at (781) 876-8255.

Section I. Report Identification

Indicate whether you are submitting an initial or a follow-up SQR. The same form is used for both. If you are completing a follow-up report, be sure to indicate the date on which you submitted the initial report.

SQRs must be submitted to the Board’s PCA Division on a quarterly basis, i.e., you must submit an initial SQR no later than 30 days following the quarter in which the unexpected event occurred. You may submit your SQRs once they are complete, rather than waiting to submit them collectively at the end of the quarterly reporting period. This allows PCA to avoid the “backlog” of SQRs that occurs four times a year and PCA can be more efficient with the follow-up reports back to facilities.

Some facilities will not have completed their internal reviews of the event or taken all appropriate corrective actions or performance improvement measures within the reporting time frame. If this is the case and a report is due, you should submit an initial SQR without waiting until your internal review is completed. When submitting the initial report, you should indicate in Section VIII that the investigation is still open and provide the date on which you believe the review will be completed. When the review has been completed, you must submit a follow-up report and provide any information that was not available at the time of the initial report.

You may submit as many follow-up reports as needed. However, please do not wait to submit a follow-up report until the PCA Division contacts you and requests it—you are responsible for submitting a follow-up report as soon as your facility's internal review has been completed. If you implement additional safety or performance improvement measures after submitting the first follow-up report, or you need to update the PCA Division on any other information pertaining to the event, please submit another follow-up report.

Section II. Reporting Health Care Facility

It is the responsibility of the facility's PCA Coordinator to ensure that the SQR is complete and submitted in a timely fashion. If the PCA Coordinator does not have a clinical background, sections VII (Nature of Event); VIII (Internal Review); and IX (Safety and Quality Improvement Measures) must be completed by someone who does. If a committee serves as the PCA Coordinator, the person completing the form should be a member of that committee and have a clinical background.

More than one health care facility may be responsible for submitting a SQR about the same event. Under some circumstances, a facility is responsible for reporting an event that may not have occurred on the premises but nonetheless originated at the institution. If, for example, a patient underwent an ambulatory procedure at your facility, was discharged, and died later at home or at another facility, the PCA Division expects that your quality assurance program would (or should) learn of the event, review the care your facility delivered to the patient and report the case. The same would apply, for example, to a delivery that took place at your facility after which the mother died at another institution from a cause related to the delivery.

In such cases, it is often through the patient's attending physician that a facility becomes aware of the unexpected outcome. Attending physicians should be aware of their responsibility to inform the PCA Coordinator of these events.

Section III. Date and Location of Event

Location code information is supplied via a drop-down menu on the form. If the event occurred somewhere that is not listed, please select "Other," and indicate the location in the specified location.

Section IV. Patient Involved in the Event

This section lists basic demographic information that PCA uses to track cases internally. In most cases, you will be providing the patient's date of admission. Health care facilities that normally do not "admit" patients (e.g., clinics) should indicate the patient's date of presentation. Presentation date should also be used by facilities in cases where the patient was not admitted but was seen by staff. These cases often involve the emergency room, e.g., a patient death that occurs in the emergency room; a transfer of a patient from the emergency room to another facility; or an event occurring at a patient's home or en route to or from the hospital after s/he was "discharged" from the emergency room. If multiple patients were involved in the event, please fill out a separate report for each patient.

Please select the most appropriate category from the drop-down bar when indicating race. Select a Hispanic Indicator, (i.e. whether or not the patient Hispanic, Latino or Spanish). Check all Ethnicity categories that are applicable to the patient involved in the reported event.

Section V. Facility Staff Involved in Event

Health care provider names are not required. The information you provide in this section is not used for disciplinary purposes but to ensure that your PCA program has a process for identifying and addressing individual health care provider issues. This information is confidential and not shared by the PCA Division with the Board's Enforcement Division, Data Repository Unit or other areas of the Board that oversee the practice of individual physicians licensed in Massachusetts.

The specialty of the provider and his or her relationship to the patient is provided in the drop-down bars.

Section VI. Type of Event

On the reporting form, check the box for the appropriate "type" of "major incident" that took place. If the event is either a Type 3 or Type 4 Event, indicate whether the patient died, or suffered a major or permanent impairment of bodily function. We define "major or permanent impairment" as a significant change in the patient's functional status, either physically or mentally. If none of these three choices apply, indicate "other" and provide a brief explanation. You should base your selection on what you know about the patient's condition at the time you are completing the report.

We are tracking our SQRs to determine how many describe events that would be considered Serious Reportable Events in Health Care ("SREs") as identified and published by the National Quality Forum. The most recent list of NQF Serious Reportable Events, are available at <http://www.qualityforum.org/pdf/news/txSREReportAppeals10-15-06.pdf>. For further guidance on what types of events should be categorized as SREs, please also see Department of Public Health Circular Letter DHCQ 08-06-489 at http://www.mass.gov/Eeohhs2/docs/dph/quality/hcq_circular_letters/hospital_hai_0806489.pdf. If you determine that the event you are reporting as a "Major Incident" can also be categorized as a Serious Reportable Event (SRE), check "yes" and indicate the "type of event," using the drop down lists provided.

VII. Nature of Event

Basis codes can be found at Table III (attached). Select the basis code(s) that best describe(s) the nature of the event. Choose as many as apply, but no more than ten.

In section B, Narrative Description of Event, please provide a brief one paragraph (or less) summary of the event. In section C, we ask you to please submit as an attachment (in the PDF version) a more detailed narrative of the event, which should include all relevant clinical information.

When describing an event, keep in mind that the report will be analyzed by physicians, nurses and others with a clinical background. While knowledgeable in a range of clinical issues, these analysts do not know anything (at least initially) about the patient or the events leading up to the unexpected event other than what you include in the narrative description. You therefore need to describe the event as fully and completely as possible, answering the basic question of "what happened?" Other information to provide, if applicable, includes the patient's condition prior to medical intervention or treatment, a description of the intervention or treatment, and the patient's subsequent condition. While the PCA Division's review of the event is directed more to your facility's response to the event than to the event itself, it is difficult to evaluate the response without understanding what

happened to the patient. It is usually better to err on providing too much information rather than too little. Please do not copy and paste the patient's discharge summary, operative reports or other parts of the medical record into this section.

Section VIII. Internal Review

If the internal review is still open at the time of the initial report, please provide the date (even if it is only approximate) on which the review is scheduled to be completed. Once it is completed, be sure to submit the results of the review in a follow-up SQR.

In section B, please indicate the titles of individuals or names of committees who were involved in the review of the event (names are not required).

In section C, please describe the results of your facility's internal review of the event in an attachment to the report. The primary focus of the PCA Division's review of the SQR is to evaluate the thoroughness and completeness of the facility's internal review of an unexpected patient outcome. This section should summarize the internal review process and provide a complete description of the results of the internal review. Information should include the areas or issues that were examined (including medical care, nursing care, pharmacy and all systemic processes) and determinations made about the ultimate cause of the patient's outcome. Ultimate conclusions regarding the quality of care delivered to the patient and whether the event could have been prevented should be provided. However, regardless of whether or not the event was determined to be preventable, the facility should describe all factors that may have caused or contributed to the patient's unexpected outcome. Please include the results of the facility's review of both systems and individual health care provider issues.

Section IX. Safety and Quality Improvement Measures

Section A asks you to please select the types of safety and quality improvement measures (including "corrective actions," if any), that were taken during the course of the review. Please select as many categories as apply. Section B asks you to use as much space as you need in an attachment (in the PDF version) to describe the measures taken by your facility.

The PCA Division expects that a facility review of an unexpected patient outcome will result in the identification of opportunities to improve care for future patients. This would include, for example, system changes or improvements, implementation of new policies or changes to existing policies; staff education, training or other actions to improve individual health care provider performance. Referral of a matter to another committee or department for additional review is not a safety or performance improvement measure. That referral is part of the facility's internal review and should be described in Section VIII, above; the results of that review should be described in this section.

If the facility's investigation is not yet complete at the time of the initial report, you may need to submit one or more follow-up reports to complete this section in order to provide information on all actions taken or to include updated information on an already described action.

If policies, procedures or protocols were changed as a result of the event, these materials should be included as an attachment to the report. Please list the Attachments in Section XI. It is helpful to know how new policies or procedures differ from those that were in place at the time of the event-

either explain how the revised procedures differ from the old or submit copies of the old and new, highlighting the changes.

Section X. Credentialed Health Care Provider Data and Findings

When applicable, please provide performance data and analysis for involved credentialed health care providers. For guidance on what to submit in this section, please see the PCA Guidelines for Collection, Analysis and Reporting of Performance Data at the following link:
http://www.massmedboard.org/pca/pca_updates.shtm.

Section XI. Attachments

Please indicate if you have attached a detailed description of the event, the results of the Internal Review, Corrective Actions or Safety and Quality Improvement Measures, and the credentialed Health Care Provider Data (if applicable). Please also list or describe any additional attachments that you are submitting with the report.

Submit completed form to:

*Massachusetts Board of Registration in Medicine
Patient Care Assessment Division
200 Harvard Mill Square, Suite 330
Wakefield, MA 01880*