COMMONWEALTH OF MASSACHUSETTS

BOARD OF REGISTRATION IN MEDICINE
QUALITY AND PATIENT SAFETY (QPS) DIVISION

INSTRUCTIONS FOR COMPLETING SAFETY AND QUALITY REVIEW FORM

(revised 10/2012)

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 "major incident" reporting requirements under the Patient Care Assessment (PCA) regulations, 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 areas 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 event 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.) The QPS 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: http://www.mass.gov/eohhs/gov/departments/borim/. (Click on the Quality and Patient Safety link.) 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 QPS Division. Faxes or emailed forms are not accepted. If you have questions about whether to report an event or completing the reporting form, call the Board's QPS Division at (781) 876-8296.

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 QPS 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 the QPS Division to avoid the "backlog" of SQRs that occurs four times a year and the QPS Division 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 for the QPS Division to contact you to request the follow-up report - 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 QPS 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 QPS Division expects that your PCA 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, followed by maternal death 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 section of the report.

Section IV. Patient Involved in the Event

This section lists basic demographic information that the QPS Division 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 is 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 QPS 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 impairment (temporary or permanent) of bodily function. We define "major 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 of the described events would be considered Serious Reportable Events in Health Care ("SREs"), as identified and published by the National Quality Forum (NQF). (See Serious Reportable Events in Healthcare – 2011 Update at http://www.qualityforum.org/Publications/2011/12/Serious_Reportable_Events_in_Healthcare_2011.aspx.

For further guidance, please see the QPS Division "*Advisory on PCA Reporting*" *(March 2010)* at the Quality and Patient Safety link at the Board's website: http://www.mass.gov/eohhs/gov/departments/borim/. (Click on the Guidelines/Advisory section.)

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 on the Basis Code list, available in the SQR section at the Board's website (QPS link). Select the basis code(s) that best describe(s) the nature of the event. Choose as many as apply, but no more than ten. These codes are intended to facilitate the QPS Division's research. So, for example, the codes RR04 and RR05 (interventional radiology) were used to research the QPS database for cases involving interventional procedures, which were the impetus for the QPS 2011 Advisory on Interventional Radiology complications.

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. If the sequence or timing of events is relevant, please include that information, as well. While the QPS 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 check those boxes that best describe your internal review findings. You may check as many categories as apply. In section D, use as much space as needed in an attachment (in the PDF version) to describe the results of your facility's internal review of the event. Include a description of the internal review findings identified in section C.

The primary focus of the QPS 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 cause of the patient's outcome. The facts provided in the description of the event should support your facility's conclusions about the care provided. For example, if it is determined that "diagnosis and treatment" were timely; the narrative should include the dates, times and other factors that would support that statement.

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; and, most importantly, the "lessons learned" from the review of the case. Please include the results of the facility's review of both systems and individual health care provider issues.

If your facility conducted a Root Cause Analysis (RCA) of the event, please submit a copy of the RCA or describe the RCA findings in this section.

Section IX. Safety and Quality Improvement Actions

The QPS 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; or 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 action. That referral is part of the facility's internal review and should be described in Section VIII, above.

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.

The QPSD encourages health care facilities to implement actions that will be effective in preventing a recurrence and will improve the quality of care and patient safety.

Section A asks you to please select the types of safety and quality improvement actions 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 actions taken by your facility. Please include a description of the plan for implementation and monitoring of any recommended improvements or changes to systems or processes.

Section C asks you to consider the "strength" of each action taken and indicate on the form whether you consider the action to be a "stronger, intermediate or weaker action." This section is intended to encourage health care facilities to evaluate their actions, with the goal of identifying solutions that have the highest likelihood of success.

The QPSD describes the rationale for including this information on the form in its Advisory - *Assessing the Strength of Health Care Facility Improvement Actions at* the Quality and Patient Safety link at the Board's website: http://www.mass.gov/eohhs/gov/departments/borim/ (Click on the Guidelines/Advisory section.) We provide, as a guide, an evidence-based cognitive aid developed by the Department of Veterans Affairs, National Center for Patient Safety (NCPS), as part of its Root Cause Analysis Tool. (See the NCPS Root Cause Analysis tool: www.patientsafety.gov/CogAids/RCA/index.html. The cognitive aid for measuring strength of actions is in the "Actions and Outcomes" section of the RCA tool.)

Some actions, combined, can result in a stronger action and you can group those actions in the boxes provided. For example, if your review results in a recommendation for additional staff training, the training alone may be considered to be a "weaker" action. However, training coupled with periodic competency assessments might be considered to be a "stronger" action. Another example of a combined "stronger" action might be "development of a checklist" ("intermediate" on the cognitive aid), with random audit of compliance.

An example of how this section might be completed in response to a medication error follows.

"Type" of Action	**"Strength" of Action**
Training and Periodic Competency Assessment	☒Stronger ☐ Intermediate ☐Weaker
Reinforcement of double check system/random audit for compliance	☒Stronger ☐ Intermediate ☐Weaker
Leadership support of additional staffing for xx unit	☒Stronger ☐ Intermediate ☐Weaker
Addition of new medication alert for xx drug	☐Stronger ☒ Intermediate ☐Weaker
Purchase of new smart pumps for xx medication administration	☒Stronger ☒ Intermediate ☐Weaker

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 QPS Division *Guidelines for Collection, Analysis and Reporting of Performance Data (May 2010)* at the Quality and Patient Safety link at the Board's website: http://www.mass.gov/eohhs/gov/departments/borim (Click on the Guidelines/Advisory section.)

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
Quality and Patient Safety Division
200 Harvard Mill Square, Suite 330
Wakefield, MA 01880