A. Policy Statement

The purpose of this policy directive is to protect the health and safety of patients by assuring that certain incidents, called Sentinel Events, are reviewed and investigated in a timely manner and to create a process for analyzing Sentinel Event information to ensure that necessary systemic corrective actions and opportunities for improvement are taken.

This policy directive applies to all State operated inpatient and residential programs, whether a Sentinel Event occurs on-site or off-site. It also applies to State-operated outpatient programs, (such as PMHP, clinic treatment, day treatment, or crisis services), when a Sentinel Event occurs on the site or grounds of the outpatient program.

As noted in the body of this document, no State-operated facility is to notify the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) directly about a Sentinel Event. This decision must be made in conjunction with the Director of the OMH Office of Quality Management.

This policy directive supersedes QA-510, as it relates to Sentinel Events.

B. Relevant Statutes and Standards

Mental Hygiene Law, sections 7.21 (b), 29.29, and 45.19
Civil Service Law, section 75
14 NYCRR Parts 37, 524, 540 and 541
OMH Official Policy Manual sections QA-510, QA-515, QA-520 and QA 530
OMH Manual for Special Investigations
JCAHO Sentinel Event Policy

C. Definitions As used in this policy directive:

1) Accreditation Watch means an attribute of an organization’s Joint Commission accreditation status which is applicable when a Sentinel Event for which a root cause analysis is required has occurred and has come to the Joint Commission’s attention, and a thorough and credible root cause analysis of the Sentinel Event and action plan have not been completed within a specified time frame.

2) Action Plan means the product of the root cause analysis that identifies the strategies that the organization intends to implement to reduce the risk of similar events occurring in the future. The plan should address responsibility for implementation, oversight, pilot testing (as appropriate), time lines, and strategies for measuring the effectiveness of the actions. An action plan will be considered acceptable if:
a) it identifies changes that can be implemented to reduce risk, or formulates a rationale for not undertaking such changes; and

b) where improvement actions are planned, it identifies who is responsible for implementation, when the action will be implemented (including any pilot testing), and how the effectiveness of the actions will be evaluated.

3) **Cause-and-Effect Diagrams** mean charts which show the many casual relationships between various actions or events leading to a specific outcome. Also called *Ishikawa diagrams* (for their inventor) or *fishbone diagrams* (because of their shape), cause-and-effect diagrams are helpful in the improvement process because they present a clear picture of the relationships between various factors and their outcomes.

4) **Common-cause variation** is inherent in every process and is a consequence of the way the process is designed to work. A process which varies only because of common causes is said to be stable.

5) **Flow chart** means a graphic representation of the path a process follows from start to finish.

6) **Major Permanent Loss of Function** means sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment or life-style change. When “major permanent loss of function” cannot be immediately determined, reporting is not expected until either the patient is discharged with continued major loss of function, or two weeks have elapsed with persistent major loss of function, whichever occurs first.

7) **Non-Consensual Sexual Contact** means **Sexual Contact**, as defined in this policy directive¹, in any of the following situations:

   a) a person is involved who is less than 17 years of age, and/or who is a patient of any age receiving services from an inpatient, outpatient, or residential program of a State-operated Children’s Psychiatric Center or a Children and Youth Unit of a State-operated Psychiatric Center.

   b) the Sexual Contact is between an employee and a patient;

   c) the involved individuals are adults, at least one of whom indicates he or she did not consent to the Sexual Contact; or

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¹For purposes of this policy directive, sexual contact that rises to the level of a Sentinel Event is defined in D(3)(a)(i)(3), as involving skin to skin contact. This is distinguished, for example, from briefly touching outside the clothing, which may constitute “inappropriate sexual contact,” which is reportable as an incident in accordance with OMH Official Policy QA-510 C(16), but which does not require reporting as a Sentinel Event under this policy directive.
d) the involved individuals are adults and, based on an evaluation by a psychiatrist or New York State licensed psychologist, it is determined that one or both individuals are incapable of consent.

8) **Pareto chart** means a special form of vertical bar graph that is used to compare events, problems, or causes according to their relative frequency or magnitude.

9) **Process** means a goal-directed, interrelated series of actions, events, mechanisms or steps.

10) **Risk** means any variation in process for which a recurrence would carry a significant chance of a serious adverse outcome.

11) **Root Cause Analysis** means the process for identifying the basic or causal factor(s) that underlie variation in performance, including the occurrence or possible occurrence of a Sentinel Event.

12) **Sentinel Event** means an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function (e.g., the use of the limb).

13) **Sexual Assault** means a sexual attack including but not limited to those that result in vaginal, anal, or oral penetration, e.g.: rape or attempted rape; sodomy or attempted sodomy; and/or any sexual contact between a person who is 18 years old or more and a person who is less than 15 years old, or between a person who is 21 years of age or older and a person who is less than 17 years old.

14) **Sexual Contact** means any touching of the sexual or other intimate parts of a person’s body, with the intent of gratifying sexual desire of either party.

15) **Special-cause variation** arises from unusual circumstances or events that may be difficult to anticipate and may result in marked variations and an unstable process.

16) **Variation** means the difference in results obtained in measuring the same phenomenon more than once.

D. **Body of the Directive**

1) **Responding to a Sentinel Event**

   a) A determination should be made that the incident is a Sentinel Event, as defined in this policy directive, regardless of whether or not a Root Cause Analysis is required, as specified in D)3) of this directive. This determination should be made by the facility Executive Director or Designee, or a determination may be made in conjunction with, or solely by, the Director of the OMH Office of Quality Management or designee. The Director of the OMH Office of Quality Management may also consult with the OMH Chief Medical Officer or other OMH Executive staff in
making this decision. The facility Executive Director shall be responsible for the final Root Cause Analysis and the implementation of the Action Plan.

b) Facility responses to Sentinel Events should be consistent with the Official OMH Policy Manual, sections QA-510, QA-515, QA-520 and QA-530. Generally, in addition to the specific actions required by this policy directive, staff should take the following actions:

i) provide immediate, prompt, appropriate care for the affected patient or patients;

ii) contain the risk of an immediate recurrence of the event;

iii) take all appropriate steps to preserve evidence;

iv) commence an investigation; and

v) notify appropriate parties.

2) Notification Time Frames

The JCAHO encourages the voluntary reporting of Sentinel Events within five (5) business days, as well as the preparation and submission of a thorough and credible root cause analysis and an acceptable action plan within forty-five (45) days of the Sentinel Event. Failure to complete an acceptable root cause analysis may result in the facility being placed on Accreditation Watch.

OMH Clinical Risk Management and Risk Management Plans policy (QA-510) calls for immediate notification to OMH Central Office when serious incidents occur. This requirement remains in effect, however, a decision must be made, in conjunction with the Director of the OMH Office of Quality Management, within five (5) business days as to whether an incident qualifies as a Sentinel Event. If appropriate, notification to JCAHO will be made by the Director of the OMH Office of Quality Management, who may consult with the OMH Chief Medical Officer or other OMH Executive staff. However, all investigatory steps (e.g., special investigation), systems reviews (including Root Cause Analysis), subsequent implementation of improvements to reduce risk, and monitoring of the effectiveness of those improvements remain the responsibility of the facility Executive Director.

Current JCAHO policy allows for JCAHO examination of Sentinel Event materials on-site, or the facility may choose to send the materials to JCAHO. Facilities shall consult with the Director of the OMH Office of Quality Management in deciding which option, if any, to pursue when this situation occurs. The Office of Quality Management must approve all materials prior to forwarding to JCAHO.

Notification time frames, regardless of whether an incident has been classified as a Sentinel Event, should also be consistent with the Official OMH Policy

3) **Root Cause Analysis**

A root cause is the most fundamental reason that an adverse event has occurred. A Root Cause Analysis focuses primarily on systems and processes, not individual(s) performance. The analysis encompasses both clinical and operational areas, generally progressing from the special causes of variation to the common causes of variation contributing to the adverse outcome. It identifies changes which could be made in systems and processes, either through redesign or development of new systems and processes that would reduce the risk of such events occurring in the future.

a) **Sentinel Events for which a Root Cause Analysis is Required:**

i) A Root Cause Analysis shall be required for any of the following Sentinel Events which occurs in a setting where a patient receives around-the-clock (i.e. continuous twenty-four hour) care or supervision (including, but not limited to, a hospital or community residence), or which occurs on the premises of an outpatient program:

14) unanticipated death or major permanent loss of function, not related to the natural course of the patient’s illness or underlying condition;

15) suicide, including suicide within 72 hours of discharge from an inpatient or residential setting;

16) Sexual Assault or non-consensual skin to skin Sexual Contact when one or more of the following are present: investigatory evidence, (such as staff and/or patient witness statements, corroborating the Sexual Contact); sufficient clinical evidence obtained by the organization to support allegations of the non-consensual Sexual Contact; admission by the involved individuals that the non-consensual Sexual Contact occurred on the premises; and/or evidence secured through a rape kit or a police investigation; or

17) abduction of a patient.

ii) In addition to the events identified in this paragraph, if a “near miss” has occurred or an area of serious risk has been identified, the facility must conduct a Root Cause Analysis or apply a different performance improvement tool.

iii) In determining whether or not a Root Cause Analysis is indicated for a particular Sentinel Event, a distinction must be made between an
adverse outcome that is primarily related to the natural course of a patient’s illness or underlying condition (for which a Root Cause Analysis is not required), and a death or major permanent loss of function that is associated with the treatment or lack of treatment of that condition, or otherwise is not clearly and primarily related to the natural course of the patient’s illness (for which a Root Cause Analysis is required). In indeterminate cases, the event will be presumed to require a Root Cause Analysis, without delay for additional information, such as autopsy results.

b) The Root Cause Analysis should be thorough and at a minimum should include:

   i) a determination of the human and other factors most directly associated with the sentinel event, and the process(es) and systems related to its occurrence;

   ii) an analysis of the underlying systems and processes through a series of “Why?” questions to determine where redesign might reduce risk;

   iii) an inquiry into all areas appropriate to the specific type of event as described in the current edition of “Minimum Scope of Root Cause Analysis for Specific Types of Sentinel Events” (see

   iv) identification of risk points and their potential contributions to this type of event;

   v) a determination of areas in which improvement could be made in processes or systems in order to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist.

c) A root cause must be credible and should:

   i) include participation by the leadership of the organization and by the individuals most closely involved in the processes and systems under review;

   ii) be internally consistent, i.e., not contradict itself or leave obvious questions unanswered;

   iii) provide an explanation for all findings of “not applicable” or “no problem”; and

   iv) include consideration of any relevant literature.

d) The Root Cause Analysis must be accepted by OMH’s Office of Quality Management.
4) **Action Plan**

Pursuant to the findings of the Root Cause Analysis, an Action Plan shall be developed to identify and correct any systemic problems which may have contributed to the sentinel event. The Action Plan must be accepted by OMH’s Office of Quality Management. The plan will be accepted by such Office if it:

a) identifies changes that can be implemented to reduce risk, or formulates a rationale for not undertaking such changes; and

b) identifies, where improvement actions are planned, who is responsible for implementation, when the action will be implemented, including any pilot testing, and how the effectiveness of the actions will be evaluated and monitored.

5) **Preparing Materials for Possible Submission to JCAHO**

All materials prepared in response to a Sentinel Event (e.g. root cause analysis) shall be stamped “DRAFT” and shall NOT contain any specific patient or staff names. Only “C” number(s) or staff title(s) should be used in preparing these materials. Incident report(s) and special investigation(s) shall continue to require names.

The Root Cause Analysis and the Action Plan should be prepared and summarized using the “Framework for Conducting a Root Cause Analysis” grid and the “Framework for an Action Plan in Response to a Sentinel Event” *(See [link](http://jcaho.org/accredited+organizations/sentinel+event/se_forms+and+tools.htm))*. The Root Cause Analysis should be a separate, stand-alone document apart from any Special Investigation which is completed. If the facility wishes to use an alternate tool for reporting the Root Cause Analysis, prior approval shall be requested of the Director of the OMH Office of Quality Management.

Once completed, all materials shall be sent to the Director the OMH Office of Quality Management within 45 days of the discovery of the Sentinel Event. These materials will be reviewed and comments will be shared with the facility, asking for amendments as needed.

6) **Written Progress Report**

Four months after completion of the Root Cause Analysis and Action Plan, the facility shall submit a progress report to the Office of Quality Management. This progress report should state whether or not the steps discussed in the original action plan were completed, should indicate any changes that were made and the rationale for such changes, and should provide a short evaluation of the steps taken toward accomplishing the changes which were originally proposed.

7) **Facility Procedures**
a) Executive Director

1. Appoints chairperson of Root Cause Analysis Team\(^2\) from the membership of the Cabinet and appoints at least one member from the Risk Management Committee; other team members should be selected from facility staff (e.g., staff from the treating unit) as appropriate to the event;

2. Identifies and assigns a facilitator/leader who has knowledge of Root Cause Analysis and Performance Improvement tools;

3. Sets expectations and time lines for communication between the Root Cause Analysis Team and executive management;

4. Empowers the Root Cause Analysis Team to conduct its assessment and make changes and/or recommendations reinforcing confidentiality and the openness to critique systems; and

5. Provides resources (including adequate blocks of time) to meet and to complete the tasks.

b) Root Cause Analysis Team

1. Creates a work plan to measure progress;

2. Creates a process to communicate with senior staff;

3. Conducts an in-depth discussion of why the event occurred and performs a comprehensive examination of the event, which may include a review of:

   a. medical records documents;
   b. committee minutes;
   c. investigative reports;
   d. building plans, schematic diagrams; and
   e. documents from sources external to the facility.

4. Utilizes Performance Improvement tools as part of the analysis (possibilities include: fish bone diagram, flow charts, control charts, and other tools as described below)

   a. Explores all possible or potential causes, focusing on processes, not people (e.g. Brainstorm);
   b. Sorts and analyzes cause list (e.g. Cause and Effect diagram);
   c. Determines if causes are special or common (e.g. Flowchart);
   d. Examines priority of causes (e.g. Pareto Chart/Histogram); and
   e. For a special cause in the process, searches for common causes in the system.

\(^2\)A new Root Cause Analysis Team should be convened for each Sentinel Event.
5. Completes a Root Cause Analysis grid to identify special or common cause variations in care processes.

6. Designs and implements an Action Plan which:
   a. identifies systems/process changes;
   b. identifies Performance Improvement initiatives and makes recommendations to minimize future occurrence;
   c. identifies or recommends individuals responsible for completing initiatives or changes; and;
   d. assesses progress and adjusts accordingly.
7. Ensures ongoing communication with Executive leadership.

c) Chair, Root Cause Analysis Team

   Presents the status of the case to the Executive Director and Cabinet.

d) Executive Director and Cabinet

   1. Reviews and approves the Root Cause Analysis and the recommended Action Plan. If there are any changes, sends material back to the Root Cause Analysis Team for additional work;

   2. Submits copies of the Root Cause Analysis and Action Plan to the Director of the Office of Quality Management within 45 days of the Sentinel Event or the discovery of the Sentinel Event, whichever occurs first.

e) Executive Director

   1. Disbands the Root Cause Analysis Team, once the Office of Quality Management approves the Root Cause Analysis and Action Plan;

   2. Assigns responsibility for monitoring and follow-up of the Action Plan to a designee(s).

f) Executive Director’s Designee

   1. Monitors completion of the Action Plan, with a focus on improvements in the larger system and elimination of the root cause(s);

   2. Develops an evaluation plan to determine the effect

   3. Presents to the Cabinet an on-going status report on the implementation of the Action Plan recommendations and initiatives, and evaluation of outcomes, until completed or responsibility is transferred.

g) Executive Director and Cabinet

   1. Submits follow-up report regarding implementation of the Action Plan to the Director of the OMH Office of Quality Management; or hosts follow-up site visit by Central Office Bureau of Quality Management.