State of New York OFFICE OF MENTAL HEALTH OMH OFFICIAL POLICY MANUAL	**Date Revised** 1/1/24	**Pages** 1 of 10	**Section #** QA-535
	Section Quality Assurance		
	Directive Sentinel Events		

A. Policy Statement

The purpose of this policy directive is to have a positive impact in improving care, treatment, services and preventing unintended harm of an individual in care. Certain incidents, called Sentinel Events (SE), are investigated and analyzed in a timely manner to understand the factors that contributed to the event. Necessary systemic corrective actions and opportunities for improvement are taken to reduce the probability of such an event in the future.

This policy directive applies to all OMH 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 clinic treatment, day treatment, or crisis services), when a Sentinel Event occurs on the site or grounds of the outpatient program while under the care and/or supervision of the organization.

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

B. Relevant Statutes, Standards and Requirements

Mental Hygiene Law, sections 7.21 (b), 29.29, and 45.19Civil
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 530OMH
Manual for Special Investigations
JCAHO Sentinel Event Policy
The Joint Commission Comprehensive Accreditation Manual
The Joint Commission Behavioral Health Care and Human Services Manual

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 (TJC) 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), timelines, 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) Individual means a patient at a hospital or resident at a facility.

7) Non-Consensual Sexual Contact means Sexual Contact, as defined in this policy directive[1], in any of the following situations:

a) a person is involved who is less than 17 years of age, or an individual 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 a person who is 18 years old or older 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.

c) the Sexual Contact is between an employee and an individual in care or under supervision.

d) the involved individuals are adults, at least one of whom indicates they did not consent to the Sexual Contact.

e) 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; or

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.

[1] For purposes of this policy directive, sexual contact that rises to the level of a Sentinel Event is defined in (D)(3)(a)(i)(3).

9) Patient means an individual in care or being served by a facility or program and for whom a clinical record is maintained by such facility or program.

10) Permanent harm is an event or condition which results in any level of harm that permanently alters or affects an individual's baseline health.

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

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

13) Root Cause Analysis means the process and completion of a comprehensive systematic analysis for identifying the causal and contributory factors. Root Cause Analysis, which focuses on systems and processes, is the most common form of comprehensive systematic analysis used for identifying the factors that underlie a Sentinel Event.

14) Sentinel Event means a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that results in death, severe harm (regardless of duration of harm), or permanent harm (regardless of severity of harm), or intervention required to sustain life. Also considered a Sentinel Event is the suicide of any individual receiving care, treatment, and service in a setting staffed around the clock or within 7 days of discharge from such setting. Sentinel Events are a subcategory of adverse events.

15) Severe harm is an event or condition that results in life-threatening bodily injury (including pain or disfigurement) that interferes with or results in loss of functional ability or quality of life that requires continuous physiological monitoring and/or surgery, invasive procedure, or treatment to resolve the condition.

16) Sexual Abuse/Assault means any nonconsensual sexual contact of any type when the individual lacks the cognitive or legal ability to consent or the individual does not want the contact to occur.

17) Sexual Contact means vaginal, anal, or oral penetration, or intimate touching of any kind that occurs in a setting where the individual receives around-the-clock care or on the premises of an outpatient program.

18) 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.

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

D. Body of the Directive

Careful identification, investigation, and analysis of patient safety events, as well as strong corrective actions that provide effective and sustained system improvement, is essential to reduce risk and prevent patient harm.

Each facility must have a policy detailing how the organization addresses Sentinel Events. The

organization must complete a thorough comprehensive systematic analysis to determine why the event occurred. The organization must then create a corrective action plan to prevent similar events from happening again, implement the plan, and monitor its effectiveness.

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's Executive Director or designee, or a determination may be made in conjunction with, or solely by, the Director of the OMH Office of Quality Improvement or designee. The Director of the OMH Office of Quality Improvement may also consult with the OMH Chief Medical Officer or other OMH Executive staff in making this determination. The facility's Executive Director or designee 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 individual or individuals in care;

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

State-operated facilities shall not independently notify the Joint Commission of a Sentinel Event. This decision must be made in conjunction with the Director of the OMH Office of Quality Improvement.

The TJC 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) business 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 Improvement, within five (5) business days as to whether an incident qualifies as a Sentinel Event. If appropriate, notification to TJC will be made by the Director of the OMH Office of Quality Improvement, 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 TJC policy allows for TJC examination of Sentinel Event materials on-site, or the facility may choose to send the materials to TJC. Facilities shall consult with the Director of the OMH Office of Quality Improvement in deciding which option, if any, to pursue when this situation occurs. The Office of Quality Improvement must approve all materials prior to forwarding to TJC.

Notification time frames, regardless of whether an incident has been classified as a Sentinel Event, should also be consistent with the Official OMH Policy Manual,sections QA-510, QA-515, QA-520 and QA-530.

3) Root Cause Analysis

A root cause is the most fundamental reason that an adverse event has occurred. A Root Cause Analysis is a thorough and credible comprehensive analysis that 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[2] which occurs in a setting where an individual receives 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:

1) An event, not primarily related to the natural course of an illness or underlying condition, that results in death, severe harm (regardless of duration of harm), or permanent harm (regardless of severity of harm).

2) Suicide, including suicide within 7 days of discharge from an inpatient or residential setting.

3) Sexual abuse/assault of any individual while receiving care including, but not limited to the following:
   a) unwanted touching of any kind; especially of the breasts, buttocks or perineal area;
   b) all types of sexual assault or battery such as rape, coerced nudity (partial or complete);
   c) forced observation of masturbation or sexually explicit images, including pornography, texts or social media; or
   d) taking sexually explicit photographs or audio/video recordings of an individual and maintaining or distributing them[3]. This would include, but is not limited to nudity, fondling, or intercourse involving an individual.

[2] Sentinel Event Policy and Procedures | The Joint Commission
[3] Such as posting on any social media platform.

4) Sexual abuse/assault of any staff member, licensed independent practitioner, visitor, or vendor while on site at the premises.

5) Abduction of any individual served receiving care, treatment, and services.

6) Fall resulting in any of the following: any fracture; surgery, casting, or traction; required consult/management or comfort care for a neurological (e.g., skull fracture, subdural or intracranial hemorrhage) or internal (e.g., rib fracture, small liver laceration) injury; a patient with coagulopathy who receives blood products as a result of the fall; or death or permanent harm as a result of injuries sustained from the fall (not from physiologic events causing the fall).

6) Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the hospital. To be considered a Sentinel Event, equipment must be in use at the time of the event; staff do not need to be present.

7) Physical assault of any individual (leading to death, permanent harm, or severe harm) while receiving care, treatment, and services while on site at the organization/facility or while under the supervision/care of the organization.

8) Physical assault (leading to death, permanent harm, or severe harm) of a staff member, licensed independent practitioner, visitor, or vendor while on site at the organization/facility or while providing care or supervision to individuals served.

9) Homicide of any individual while receiving care, treatment, and services while on site at the organization/facility or while under the supervision/care of the organization

10) Homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the organization/facility or while providing care/supervision to individuals served.

11) Any elopement (that is, unauthorized departure) of an individual served from a staffed around the clock care setting (including the ED), leading to death, permanent or severe harm.

ii) In addition to the events identified in this paragraph, if an event has been stopped prior to becoming a Sentinel Event (e.g. a “near miss”) or an area of serious risk has been identified, the facility must conduct a Root Cause Analysis or where appropriate, 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:

a) An adverse outcome that is primarily related to the natural course of a individual’s illness or underlying condition (for which a Root Cause Analysis *is not* required), and

b) A death or harm (permanent or severe) 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 individual'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 repeatedly asking a series of "Why" questions until the systemic causal factors associated with each step in the sequence that led to the Sentinel Event are identified;

iii) an inquiry into all areas appropriate to the specific type of event;

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

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 Analysis 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) be clear (understandable information);

iv) be accurate (validated information and data);

v) be precise (objective information and data without internal inconsistencies);

vi) be relevant (focus on issues related or potentially related to Sentinel Event)

vii) provide an explanation for all findings of "not applicable" or "no problem", and

viii) include consideration of any relevant literature.

d) The Root Cause Analysis must be accepted by OMH's Office of Quality Improvement.

4) <u>Action Plan</u>

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 Improvement. The plan will be accepted by such Office if it:

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

b) Identifies the following:
   i) where improvement actions are planned,

   ii) who is responsible for implementation,

   iii) when the action will be implemented,

   iv) any pilot testing, and

   v) how the effectiveness of the actions will be evaluated, monitored, and sustained.

5) Preparing Materials for Possible Submission to TJC

All materials prepared in response to a Sentinel Event (e.g., Root Cause Analysis) shall be stamped "DRAFT" and shall NOT contain any specific individual or staff names. Only "initials" 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" as provide by TJC currently available at: www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/rca_framework_101017.pdf

The Root Cause Analysis should be a separate, stand-alone document apart from any Special Investigation which is completed.

Once completed, all materials shall be sent to the OMH Office of Quality Improvement within 45 business 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) Status Report

Four months after completion of the Root Cause Analysis and Action Plan, the facility shall submit a status report to the Office of Quality Improvement. This status 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
   i) Appoints chairperson of Root Cause Analysis Committee[4] from the membership of the Cabinet and appoints at least one member from the Risk Management

[4] A new Root Cause Analysis Committee should be convened for each Sentinel Event

Committee; other team members should be selected from facility staff (e.g., staff from the treating unit) as appropriate to the event.

ii) Identifies and assigns a facilitator/leader who has knowledge of Root Cause Analyses and Performance Improvement tools.

iii) Sets expectations and timelines for communication between the Root Cause Analysis Committee and executive management.

iv) Empowers the Root Cause Analysis Committee to conduct its assessment and make changes and/or recommendations reinforcing confidentiality and the openness to critique systems.

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

vi) Makes support systems available for staff who have been involved in the Sentinel Event.

vii) Provides annual written reports to the governing body that include the number and type of Sentinel Event.

b) Root Cause Analysis Committee

i) Creates a work plan to measure progress.

ii) Creates a process to communicate with senior staff.

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

1) medical records documents,
2) committee minutes,
3) investigative reports,
4) building plans, schematic diagrams, and
5) documents from sources external to the facility**.**

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

v) Explores all possible or potential causes, focusing on processes, not people (e.g., Brainstorm) which shall include but is not limited to

1) sorts and analyzes cause list (e.g., Cause and Effect diagram),
2) determines if causes are special or common (e.g.,Flowchart),
3) examines priority of causes (e.g., Pareto Chart /Histogram), and
4) for any special cause identified in the process, searches for common causes in the system.

vi) Completes a Root Cause Analysis report to identify special or common cause

variations in care processes such as TJC framework[5].

vii) Designs and implements an Action Plan which:
   1) identifies systems/process changes,
   2) identifies Performance Improvement initiatives and makes recommendations to minimize future occurrence,
   3) identifies or recommends individuals responsible for completing initiatives or changes, and
   4) assesses progress and adjusts accordingly.

viii) Ensures ongoing communication with Executive leadership.

c) Chair, Root Cause Analysis Committee
   i) Presents the status of the case to the Executive Director and Cabinet

d) Executive Director/Cabinet
   i) 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 Committee for additional work or revision(s),

   ii) Submits copies of the Root Cause Analysis and Action Plan to the Office of Quality Improvement within 45 business days of the Sentinel Event or the discovery of the Sentinel Event, whichever occurs first.

e) Executive Director
   i) Disbands the Root Cause Analysis Committee, once the Office of Quality Improvement approves the Root Cause Analysis and Action Plan.

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

f) Executive Director's Designee
   i) Monitors completion of the Action Plan, with a focus on improvements in the larger system and elimination of the root cause(s)

   ii) Develops an evaluation plan to determine the effectiveness of improvements/changes, and whether the desired outcomes are attained, and

   iii) 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
   i) Submits follow-up report regarding implementation of the Action Plan to OMH Office of Quality Improvement or hosts follow-up site visit by OMH Office of Quality Improvement.

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[5] www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/rca_framework_101017.pdf