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A. POLICY STATEMENT:

1) Purpose:


The Purpose of this policy directive is to protect the health, safety, and welfare of patients in State-operated psychiatric hospitals by assuring the development, implementation, and ongoing monitoring of clinical risk management programs and to include clinical risk management as an integral component of systems analysis, risk management, quality improvement, and incident prevention.

The goal of a clinical risk management program is to ensure an integrated and comprehensive strategy for:

- identifying, documenting, reporting and investigating individual incidents on a timely basis;
- reviewing individual incidents to identify the facts, circumstances, processes, systems and areas of clinical risk that may have contributed to the situation, as well as opportunities for performance improvement;
- identifying incident patterns and trends through the compilation and analysis of incident data;
- reviewing incident patterns and trends to identify the facts, circumstances, processes, systems, and areas of clinical risk that may have contributed to these incidents and identify opportunities for performance improvement;
- developing and implementing preventive and corrective action plans that address both human and systemic factors that contributed to the incident(s); and
- monitoring clinical risk management practices.

Although it is usually possible and appropriate to identify the variations in individual performance which contributed to a particular incident, the ultimate health and safety of patients in a facility are best served when the facility:

- identifies the clinical and non-clinical systems, processes and areas of risk which precede and contribute to the human factors;
- notes the opportunities for improvement in these systems, processes and clinical risk areas; and
- develops, implements and monitors plans of correction and prevention that reflect those opportunities.

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Therefore, this policy represents a shift in emphasis from the traditional focus on staff behaviors to an approach that places more significance on systems analysis, clinical risk management, quality improvement, and incident prevention.

2) **Applicability:**

This policy directive applies to all programs under the auspices of State-operated psychiatric facilities.

B. RELEVANT STATUTES AND STANDARDS:


Mental Hygiene Law, sections 7.21(b), 29.29 and 45.19
 Civil Service Law, section 75
 Public Health Law Section 230, 230-a, 230-b
 Social Services Law Sections 413-424
 14 NYCRR Parts 37, 524, 540, 541, 587, and 595
 12 NYCRR Section 801.9
 8 NYCRR Part 17
 21 CFR Parts 803, 804
 OMH Official Policy Manual, sections PC-450, QA-515, QA-520, QA-530 and QA-535
Comprehensive Accreditation Manual for Hospitals (CAMH standards L.D.4.3.4, PI.2, PI 3.1.1, PI. 4.3, PI. 4.4)
OMH Manual for Special Investigations: Guidelines for Investigation of Significant Incidents in OMH Facilities
 Union Contracts¹

C. DEFINITIONS: For purposes of this policy directive:

1) **Abuse** means any of the following acts of a staff person:


a) **intentional improper medication administration:** any intentional administration to a patient of a prescription drug or over-the-counter medication which is not in substantial compliance with a physician's, dentist's, physician's assistant's, specialist's assistant's, or nurse practitioner's prescription;

b) **physical abuse:** any non-accidental contact with a patient which causes or has the potential to cause physical pain or harm, including but not limited to hitting, kicking, slapping, shoving, punching or choking; provided however that this shall not include the application of restraint, when such application is necessary and performed in accordance with applicable laws and regulations, and consistent with training provided pursuant to OMH official policy directive PC-701.

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c) **psychological abuse**: any verbal or nonverbal action by a staff person which causes or has the foreseeable potential to cause a patient emotional distress including, but not limited to, teasing, taunting, name calling, threats, misuse of authority or violation of patient rights; or


¹These include, as applicable: Professional, Scientific & Technical Unit, Article 33; Administrative Services Unit, Article 33; Institutional Services Unit, Article 33; Operational Services Unit, Article 33; Security Services Unit, Article 8; and Security supervisors Unit, Article 8.

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d) **sexual abuse**: any sexual contact involving a patient and a staff person; or any sexual contact involving a non-consenting patient which is allowed or encouraged by a staff person. A person less than 17 years of age or a patient in a State-operated Children's Psychiatric Center or a Children and Youth Unit of a State-operated psychiatric center is deemed incapable of consent.

- 2) **Adverse drug reaction** means any response to a medication that is unintended, undesirable, unexpected or excessive, and that occurs at doses normally used in patients for prophylaxis, diagnosis or therapy of disease, or for the modification of physiologic function. Such a response is considered a **Severe Adverse Drug Reaction** if it:
- a) results in transfer to an emergency room, admission to a medical facility, or a longer hospital stay;
 - b) requires intervention to prevent permanent impairment;
 - c) results in permanent disability;
 - d) results in congenital anomaly;
 - e) is life threatening; or
 - f) results in death.
- 3) **Allegation of abuse or neglect** means a statement, by a patient or others, that abuse or neglect as or may have occurred, and such statement is reasonably reliable².
- 4) **Assault** means a physical attack using force or violence in which a patient is either the victim or the aggressor³. For purposes of incident reporting, assaults are not limited to events which may be categorized as crimes.
- 5) **Child missing from staff supervision** means a patient of an outpatient program who is under the age of 18, and whose whereabouts is not accounted for when expected to be present or under the supervision of staff.
- 6) **Clinical Risk Manager** means a staff person designated by the Executive Director to oversee the facility's clinical risk management program. The Clinical Risk Manager shall be experienced in clinical, administrative, information management, and performance

² A statement must be considered "reasonably reliable" unless there are known facts immediately available which render all substantive aspects of the statement inaccurate when the statement first comes to the attention of staff. Reasonable reliability is a judgment about a statement, not about the condition, competency, or credibility of a patient. Essentially, to say a statement is not reasonably reliable is to say that there is no possibility of its being true.


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³An “assault” is to be distinguished from a “fight.” In an assault, there is a clear aggressor or a clear victim, while in a fight, there is no clear aggressor and no clear victim. **Please also note that pursuant to Sections 33.02(5) and 7.21(b) of the Mental Hygiene Law, incidents which are classified as "assaults", where a patient is the victim, and where the degree of harm to, or need for treatment by, the victim is classified as "2" or "3" on the Severity Rating Scale in accordance with this policy directive, must be reported to the Mental Hygiene Legal Service (MHLS) within 3 business days, and the outcome of the facility’s investigation of such incidents should be provided to MHLS.**

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improvement areas and have received formal training in basic and advanced investigation techniques.

- 7) **Clinical Risk Management Specialist** means a staff person experienced in clinical, administrative, information management, and performance improvement areas and trained in investigation techniques, who has been designated by the Executive Director to serve in a staff capacity to the Clinical Risk Manager.
- 8) **Contraband** means an item or substance which is forbidden by the facility or program rules and/or has the potential to cause harm to self and/or others and interfere with patient safety and treatment.
- 9) **Crime** means an event which is or appears to be a crime under New York State or Federal law, involves a patient, either as the victim or the perpetrator and, in addition, affects or has the potential to affect the health or safety of one or more persons or has the potential to have a significant adverse impact on the property or operation of the program. For the purposes of this policy directive, crimes shall:
 - a) include acts committed by persons less than 16 years of age which, if committed by an adult, would constitute a crime; and
 - b) not apply to admissions of past criminal acts, or threats of future actions, which are disclosed only in the context of a therapeutic relationship ⁴.
- 10) **Death of a patient** means the death of any patient of a State-operated facility or program who was receiving services from the facility or program at the time of the death or who was discharged within thirty days of the death. Deaths are differentiated into the following types:
 - a) death due to known medical causes following the expected course of illness or disease, while under treatment consistent with standard medical practices (natural death);
 - b) death due to unexpected natural causes;
 - c) death resulting from an apparent homicide, suicide, or unexplained or accidental cause;
 - d) death which is related to the lack of treatment provided in accordance with generally accepted medical standards; or
 - e) death associated with the use or attempted use of restraint or seclusion.

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⁴Note, however, that this shall not preclude appropriate follow-up for general risk management or Tarasoff related purposes; contact Counsel's Office for further guidance.

- 11) **Director for Quality Management** means a staff person designated by the Executive Director to oversee and direct the facility's quality management program.
- 12) **Fight** means a physical altercation between two or more patients⁵.
- 13) **Fire setting** means a patient action resulting in fire, either deliberate or accidental.
- 14) **Homicide** means the death of a person apparently caused by an act of another individual, when either the victim or the aggressor is a patient.
- 15) **Homicide attempt** means an act by an individual which was apparently intended to kill another person, when either the victim or the aggressor is a patient.
- 16) **Inappropriate sexual behavior** means inappropriate sexual language or behaviors not defined elsewhere engaged in by inpatients of State-operated Children's Psychiatric Centers or Children and Youth Units of State-operated Psychiatric Centers. This includes harassing behavior, including sexually oriented taunting, verbally aggressive threatening or intimidating language and any sexually oriented behavior or language that has a negative impact, or the potential for a negative impact, on the well being of another patient.
- 17) **Incident** means an event involving a patient who receives services provided by a State-operated facility or program which has or may have an adverse effect on the life, health or welfare of the patient and/or another person.
- 18) **Injury** means bodily harm, pain or impairment not resulting from the natural course of illness or disease, which requires medical or dental attention.
 - a) **Injury of accidental origin** means an injury to a patient that is not deliberately caused by the patient or another person.
 - b) **Injury of unknown origin** means an injury to a patient for which a cause cannot be immediately determined.
- 19) **Interrogation** means the questioning of a staff person who appears to be an actual subject for disciplinary action about an incident.
- 20) **Interview** means the questioning of an individual who does not appear to be an actual subject for disciplinary action, about an incident.


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- 21) **Investigation** means the systematic collection and examination of the information and circumstances surrounding an incident.

5 A “fight” is to be distinguished from an “assault;” in a fight, there is no clear aggressor and no clear victim, while in an assault, there is a clear aggressor or a clear victim.

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- 22) **Medication error** means an error in prescribing, transcribing a prescription or, dispensing, or administering a drug, or an error in self-administering a drug or in supervising a patient in the self-administration of a drug.
- 23) **Missing patient** means a patient of an inpatient or residential State-operated psychiatric facility or program, who has not been accounted for when expected to be present and who has not been found on the facility grounds or other expected location. Such term shall also include a patient in an inpatient or residential program who is known to have left the facility grounds without the permission of a staff person, when such permission is otherwise required.
- 24) **Missing subject of Assisted Outpatient Treatment (AOT) court order** means a person who is subject to an Assisted Outpatient Treatment (AOT) court order who fails to keep a scheduled appointment and/or who cannot be located or accounted for within any 24 hour period.
- 25) **Neglect** means any action or failure to act by a staff person which impairs, or creates a substantial risk of impairing, the physical, mental or emotional condition of a patient.
- 26) **Root cause analysis**, a term developed by the Joint Commission on Accreditation of Healthcare Organizations, means a process for identifying the basic or causal factor(s) that underlie variations in performance, including the occurrence or possible occurrence of a sentinel event.
- 27) **Self-abuse** means self-inflicted harm by a patient not intended to result in death.
- 28) **Sentinel event**, a term developed by the Joint Commission on Accreditation of Healthcare Organizations, means an unexpected occurrence involving death or serious physical or psychological injury, or risk thereof.
- 29) **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 and 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.
- 30) **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.
- a) **Sexual contact between children** means any sexual contact that does not meet the criteria for sexual assault that occurs between patients of State-operated Children's Psychiatric Centers or Children and Youth Units of State-operated Psychiatric Centers.

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- b) ***Non-consensual sexual contact between adults*** means any non-consensual sexual contact involving an adult patient that does not meet the criteria for sexual assault. For purposes of this policy directive, any sexual contact that involves a patient who is deemed incapable of consent is defined as non-consensual.
- 31) ***Special investigation*** means a type of investigation which is conducted under the direction of the Executive Director by a Clinical Risk Manager or Clinical Risk Management Specialist and is completed pursuant to a specifically identified incident.
- 32) ***Staff or Staff person*** means an administrator, employee, consultant, volunteer or student affiliated with a program under the auspices of a State-operated psychiatric facility, or a person employed by an entity which has a contract with such a program.
- 33) ***Suicide*** means the death of a patient caused by deliberate self-inflicted injury.
- 34) ***Suicide attempt*** means an act committed by a patient in an effort to cause his or her own death.

D. BODY OF THE DIRECTIVE:


This policy directive consists of 6 sections:

1. Care and Safety of a Patient Involved in an Incident
2. Clinical Risk Management Program
3. Organization and Administration of the Clinical Risk Management Team
4. Identification, Documentation, Reporting and Investigation of Individual Incidents
5. Incident Review Committee
6. Monitoring Roles, Responsibilities, and Requirements

1) Care and Safety of a Patient Involved in an Incident: ANY STAFF PERSON WHO OBSERVES OR IS INFORMED THAT AN INCIDENT HAS OCCURRED MUST IMMEDIATELY PROVIDE ASSISTANCE AND SECURE APPROPRIATE CARE FOR THE PATIENT ⁶.

- a) Inpatient facilities: For every incident, a nurse must assess the patient and notify the physician that the incident has occurred. The physician shall examine the patient before the end of his/her shift, with time of examination based on the acuity of the event.
- b) Outpatient and residential facilities: For every incident, a nurse or other appropriate clinician must assess the patient and notify the physician or nurse that the incident has occurred. If so notified, the physician or nurse shall examine the patient before the end of his/her shift, with time of examination based on the acuity of the event.

2) Clinical Risk Management Program


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- a) Consistent with the requirements of Part 524 of 14 NYCRR, all State-operated

⁶If an allegation of abuse or assault has been made, “appropriate care” shall include separating the alleged perpetrator from the alleged victim, in accordance with *Guideline for Investigation of Significant Incidents in OMH Facilities*.

facilities and programs shall develop, implement and monitor the effectiveness of a clinical risk management program, with the intent of protecting the health and safety of clients and enhancing their quality of care.

- b) At a minimum, clinical risk management programs shall consist of the following components:
- i) Organization and administration. Each facility shall identify staff responsible for the overall operation of the clinical management program, and shall train staff regarding their related roles and responsibilities.
 - ii) Incident management plan. Each facility shall develop and implement a written incident management plan, subject to the approval of the Commissioner or his or her designee, which shall include the following:
 - (1) the goals and objectives of the clinical risk management program; and
 - (2) the policies and procedures for the operation of the clinical risk management program which address, at a minimum, the following:
 - (A) identification, documentation, reporting and investigation of individual incidents;
 - (B) review of individual incidents to identify the facts, circumstances, processes, systems, and areas of risk that contributed to the situation, as well as opportunities for performance improvement;
 - (C) identification of incident patterns and trends;
 - (D) review of incident patterns and trends to identify the facts, circumstances, processes, systems, and areas of risk that may be contributing to these incidents, as well as opportunities for performance improvement;

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(E) development and implementation of preventive and corrective action plans that address both human and systemic factors contributing to the incident(s); and

(F) monitoring of clinical risk management practices.

- iii) Monitoring. Each facility shall ensure that appropriate mechanisms exist for monitoring the overall effectiveness of the clinical risk management program.

3) Organization and Administration of the Clinical Risk Management Team


- a) Each facility operated by the New York State Office of Mental Health is required to establish a Clinical Risk Management Team. The Team shall:
- i) be headed by a Clinical Risk Manager who reports to the Director for Quality Management or, if no such Director has been designated, to the Executive Director; and
 - ii) include at least one Clinical Risk Management Specialist in order to provide backup coverage, provide for multiple investigations, provide mutual support, and perform other Quality Assurance/Risk Management tasks⁷.
- b) Under the direction of the Executive Director, the Clinical Risk Manager and the Clinical Risk Management Specialist(s) shall have overall responsibility for the facility's incident management function, as well as the related clinical risk management tasks.
- c) Staff of the Clinical Risk Management Team are to be engaged full time in clinical risk management and quality improvement functions with no other clinical or line responsibilities⁸.
- d) Clinical Risk Management staff must:
- i) be experienced in clinical, administrative and information management areas;
 - ii) have demonstrated an ability to analyze systems and processes, identify opportunities for improvements in the delivery of care, and provide consultation in the design of workable plans of improvement;

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- iii) have received formal training in the conduct of special investigations through a program approved by Central Office Bureau of Quality Management; and

⁷The number of Clinical Risk Management Specialists will vary from facility to facility, depending upon the size of the facility and the volume of incidents reported. Optimally, however, no facility should have fewer than one Clinical Risk Manager and one Clinical Risk Management Specialist.


⁸In limited instances, this requirement may be modified or waived for certain facilities if written justification is provided which sufficiently demonstrates that: (1) meeting the requirement would impose an unreasonable hardship; (2) the clinical risk management program of the facility would not be diminished; and (3) there are no feasible alternatives to a waiver of the requirement. Requests for waivers must be submitted to both the Bureau of Quality Management and the Division of State Psychiatric Center Management for approval, and determinations regarding such requests shall be provided in writing.

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- iv) be cross-trained in all clinical risk management tasks and activities to ensure uninterrupted surveillance of events of significance to clinical risk management and quality improvement.


- e) The Executive Director shall:
 - i) support continuous review by the Director for Quality Management of the full range of clinical risk management functions and quality improvement opportunities throughout the facility;
 - ii) assess the facility's capability and structures for fulfilling these responsibilities; and
 - iii) identify the variety of tasks in which Clinical Risk Management staff should participate, and provide a staffing pattern that will equip the facility to accomplish these tasks.

- f) In accordance with the following, the Clinical Risk Management Team shall participate in clinical risk management, identification and monitoring of high risk or high need patients, technical assistance, and other functions:
 - i) Clinical Risk Management: The Clinical Risk Management Team shall:
 - (1) coordinate all aspects of the clinical risk management program;
 - (2) review all incoming incident reports to determine the level of follow-up required;
 - (3) examine safety reports, morning rounds reports, and change of shift reports and take other proactive measures to assure events are followed up through incident reporting;
 - (4) assume responsibility for all levels of incident investigation;
 - (5) conduct all special investigations in a timely, objective and thorough manner;
 - (6) track implementation of preventive measures and plans of corrective action;
 - (7) ensure that all incidents receive accurate classification and severity ratings and that significant developments and trends receive appropriate attention; and

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(8) prepare monthly reports on all incident types, to identify and analyze trends as well as deviations related to incidents occurring at the hospital.

- ii) Identification and Monitoring of High Risk or High Need Patients: Closely related to clinical risk management functions is the monitoring of high risk and high need patients. Clinical Risk Management staff shall develop rosters of such patients, based on review of incident, restraint and seclusion, case review and other risk management data bases, to facilitate review of patient care, noting interventions already utilized, and projecting options for the future.
- iii) Technical Assistance: Clinical Risk Management staff shall:
 - (1) develop materials and provide training for staff and patients in clinical risk management areas including but not limited to patients' rights as distinguished from privileges, and incident prevention; and
 - (2) serve as a technical resource for staff regarding a variety of clinical risk management related issues, such as a Clinical Risk Management Question Line.
- iv) Other Functions: The Clinical Risk Management Team shall:
 - (1) coordinate the facility-wide Patient Safety Program;
 - (2) oversee, participate, and/or coordinate, as appropriate, in other clinical risk management related functions deemed helpful/supportive by staff, including but not limited to:
 - (A) the facility's Traumatic Events Response Team;
 - (B) the facility's response to Sentinel Events, including overseeing the teams assembled to conduct root cause analysis;
 - (C) performance improvement teams and projects, including the implementation process; and
 - (D) facility responses to inquiries by the Commission on Quality of Care for the Mentally Disabled and Mental Hygiene Legal Services.
 - (3) if so charged by the Executive Director, assume clinical risk management related functions that currently may be handled by others,

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thereby improving the clinical risk management function and freeing other staff for other duties. These activities may include, but are not limited to:


- (A) serving as primary facility liaison with law enforcement agencies on incidents which may be reportable as crimes;
- (B) fact finding and conducting investigations;
- (C) managing confidentiality issues;
- (D) handling information management and data analysis;
- (E) coordinating case review functions;
- (F) conducting medical record reviews; and
- (G) coordinating and monitoring the facility's patient grievance/suggestion system.

4) Identification, Documentation, Reporting and Investigation of Individual Incidents

a) Identification of Incidents.

i) The following shall be regarded and reported as incidents when they involve:

- (1) patients of **INPATIENT** and **RESIDENTIAL PROGRAMS**, **whenever and wherever** the events occur; or
- (2) patients of State operated **OUTPATIENT** programs when the events occur **on program property** or **under the actual or intended supervision of** program staff:
 - (A) abuse or neglect, allegation of;
 - (B) adverse drug reaction, severe;
 - (C) assault;
 - (D) child missing from staff supervision (outpatient only);
 - (E) contraband, possession of;
 - (F) crime ⁹;

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(G) death of a patient;

⁹ The following types of events which may be reportable as crimes have been defined as separate incident categories and should be identified as such for incident management purposes: Allegations of Abuse, Assault, Fire Setting, Possession of Contraband, and Sexual Assault. In addition, the New York State Incident Management and Reporting System (NIMRS) ^{TMSM} provides for reporting the following as Crimes not Listed Elsewhere: Homicide Attempt, Homicide by Patient, Narcotics (Sale or Possession), Robbery, Possession of a Deadly Weapon, and Other Crime. Death **of** a patient by Homicide is to be identified as “Death of a Patient.” A homicide committed **by** a patient is to be identified as a “Crime Not Listed Elsewhere/Homicide by Patient.”

(H) fight;

(I) fire setting;

(J) injury of accidental origin;

(K) injury of unknown origin;

(L) medication error;

(M) missing patient of inpatient¹⁰ or residential facility;

(N) missing subject of Assisted Outpatient Treatment (AOT) court order;

(O) self abuse;


(P) sexual assault;

(Q) sexual behavior , inappropriate¹¹;

(R) sexual contact between adults¹², nonconsensual;

(S) sexual contact between children¹³;

(T) suicide attempt; and

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(U) any other event identified as an incident by the facility or program.

- ii) The following shall be regarded and reported as incidents, when they come to facility attention, when they involve:

¹⁰ OMH Policy QA-520 delineates 3 categories of inpatients who are missing from State-operated psychiatric hospitals, which should be so identified: (1) *Absent person*; (2) *Endangered person*; or *Escaped person*.

¹¹ For the purposes of incident reporting, inappropriate sexual behavior does not apply to obscene language or the use of expletives which would not otherwise constitute an incident. As with all incident types, this category is to be used to identify an event which meets the defining criterion of an incident, i.e., it "has or may have an adverse effect on the life, health or welfare of the client and/or another person." This incident category applies to actions of children and adolescents only. When similar behaviors are performed by adults, they may be identified for incident reporting purposes as Other Reportable Incidents or, if applicable, Crimes.

¹² If a sexual contact meets the criteria for a sexual assault, it should be reported as such.

¹³ If a sexual contact meets the criteria for a sexual assault, it should be reported as such.

(1) patients of State operated **OUTPATIENT** programs **when the events do not occur on program property or under the actual or intended supervision of program staff**; or


(2) patients of State-operated **CASE MANAGEMENT** or **ASSERTIVE CASE TREATMENT** programs, **wherever** or **whenever** the events occur; or

(3) patients whose care is not provided at or by a facility or program operated by the Office of Mental Health but whose care is provided or coordinated by Office of Mental Health staff or otherwise under the auspices of the Office of Mental Health **wherever** or **whenever** the events occur:

(A) abuse or neglect, allegation of;

(B) adverse drug reaction, severe;

(C) assault;


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- (D) crime ¹⁴;
- (E) death of a patient;
- (F) fight;
- (G) fire setting;
- (H) injury, if life-threatening and of accidental or unknown origin;
- (I) medication error;
- (J) missing subject of Assisted Outpatient Treatment (AOT) court order;
- (K) self abuse;
- (L) sexual assault;
- (M) suicide attempt; and
- (N) any other event identified as an incident by the facility or program.

¹⁴ The following types of events which may be reportable as crimes have been defined as separate incident categories and should be identified as such for incident management purposes: Allegations of Abuse, Assault, Fire Setting, Possession of Contraband, Sexual Assault. In addition, the New York State Incident Management and Reporting System (NIMRS) TMSM provides for reporting the following as Crimes not Listed Elsewhere: Homicide Attempt, Homicide by Patient, Narcotics (Sale or Possession), Robbery, Possession of a Deadly Weapon, and Other Crime. Death **of** a patient by Homicide is to be identified as Death of a Patient; a homicide committed **by** a patient is to be identified as a Crime Not Listed Elsewhere/Homicide by Patient.

b) Documentation

- i) Incident management plans shall include procedures for documenting the occurrence of all identified incidents and the results of all related investigations and reviews. Any incident related documentation shall be separate from the patient's case record. However, a description of any clinical impact which an incident may have on a patient shall be recorded in the case record.
- ii) All allegations of abuse shall be documented in the facility's incident management system and, if a decision is made that an allegation is not

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reasonably reliable, the reasons for this decision shall also be documented.

c) Reporting

i) *Internal reporting* (Intra-facility notifications):

(1) Facility incident management policies shall include procedures for notifying appropriate program staff when a staff person observes, discovers or is otherwise informed of the occurrence of any incident. The level and type of staff to be notified shall be consistent with the seriousness of the incident. At a minimum, policies need to provide for notifying the Clinical Risk Management Team of all incidents.

(2) All identified incidents shall be reported through the New York State Incident Management and Reporting System (NIMRS TMSM).

(3) Medication-related events.


(A) Severe adverse drug reactions are to be reported as incidents in accordance with D)4)a)i) of this Policy Directive.

(B) While only severe adverse drug reactions are required to be reported as incidents, any suspected adverse drug reaction should be managed in accordance with facility policy.

(C) If a medication error is identified and documented as an incident, the facility shall elect to review the incident through the incident management system or by routing it to the Pharmacy and Therapeutics Committee for follow-up, and it shall be the facility's decision which course to follow, provided, however, that for all such incidents which are life-threatening, the review findings shall be reported to and reviewed by the Clinical Risk Management Team. Individual facility incident management policies shall specify a given facility's procedures for responding to medication errors.

ii) *Central Office Reporting:*

(1) All incidents, including the ones listed in D)4)a) of this Policy Directive, are to be given a severity rating in accordance with the procedures established in D)4)c)ii)(4). However, the following incidents are required to be reported immediately to the Bureau of Quality management in Central Office whenever they are identified, *regardless of severity level:*


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- (A) severe adverse drug reaction;
- (B) allegation of abuse or neglect;
- (C) child missing from staff supervision (outpatient);
- (D) crime;
- (E) death of a patient;
- (F) missing patient¹⁵;
- (G) missing subject of Assisted Outpatient Treatment (AOT) court order;
- (H) sexual assault;
- (I) sexual contact between children;
- (J) suicide attempt;
- (K) any incident which jeopardizes a patient's life; and
- (L) any event that may attract adverse media attention.

(2) In addition to the incidents identified in subparagraph (1) above, any other incident must be reported immediately to the Bureau of Quality Management in Central Office if it meets one or more of the following criteria:

- (A) the police are called and respond, on site, due to possible criminal activity;
- (B) it appears that the incident may have resulted from serious staff person neglect; or

¹⁵ For adults, only reports of escaped persons and endangered persons are required, but all missing persons under age 18 are to be so reported.

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(C) the incident is given a severity rating of high in accordance with the rating scale set forth in D)4)c)ii)(4), utilizing Table A. (See next page.)

(3) All events shall be given a severity rating, using the rating scale in Table A. Table A provides for rating an incident in consideration of 2 factors¹⁶.

(A) Harm/Need for Treatment - a composite rating intended to measure both the amount of physical and/or psychological harm resulting from the incident and the level of the medical and/or psychotherapeutic intervention required as a result of the incident.

(B) Risk - the potential for serious harm, given the actions taken and the level of motivation of the person(s) engaging in the incident.

(4) Table A shall be used to rate incidents in accordance with the following procedure:

(A) For all incidents, a judgment is to be made regarding the severity of the incident, rating the incident as 1=low, =moderate, or 3=high on each of the severity factors as appropriate. (If only one of the two severity factors applies to a particular incident, only that factor need be rated).

(B) When, for any given incident, there is variability across severity factors, providers shall determine the overall rating by selecting the rating that is highest. (If, for example, harm/need for treatment is low, but risk is high, then the incident should be given a severity rating of high.)

¹⁶The New York State Incident Management Reporting System (NIMRS) TMSM provides for the rating of incidents on Physical and/or Psychological Harm/Need for Treatment and Risk and alerts the user when an incident needs to be reported immediately to Central Office.



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Table A. Incident Severity Rating Scale

Rating Severity Factor	1 LOW	2 MODERATE	3 HIGH
Harm/Need for Treatment	No physical harm, or minor harm, e.g., bruise, minor laceration; medical intervention limited to first aid or less; and/or no or little psychological harm, experienced by person; no treatment beyond reassurance and support	Moderate physical injury which requires medical treatment by a physician, (e.g., significant bleeding necessitating sutures or simple fractures requiring X-ray and/or non-surgical treatment); and/or moderate psychological harm, e.g., negative changes in affect, behavior, or cognition, requiring change in treatment, e.g., medication change or psychotherapeutic intervention	Injuries requiring admission to a hospital; life-threatening injuries requiring emergency life saving procedures (e.g., CPR, intubation, surgery, etc.); and/or life threatening psychiatric conditions as evidenced by suicide or homicide threats or attempts or the need for a major change in treatment.
Risk	No risk or slight risk of complications or Serious harm	Potential for moderate injury or harm	Risk for serious medical or psychiatric complications, life threatening harm

(5) Certain Sentinel Events have been identified as Reviewable Sentinel Events under criteria established by the Office of Mental Health under agreement with the Joint Commission for the Accreditation of Healthcare Organizations and shall be reported as such to the Bureau of Quality Management in Central Office¹⁷. The following events shall be considered

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Reviewable Sentinel Events when they occur in a setting where the patient receives around-the-clock care or on the premises of an outpatient program:

¹⁷ For policy regarding sentinel events, see OMH Official Policy Manual, Section QA-535.

(A) an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or Underlying condition;

(B) suicide of a patient;

(C) rape or sodomy (even if the outcome was not death or major loss of function); or

(D) sexual intercourse, sodomy, or oral sex between a staff person and a patient, regardless of whether the behavior is considered "consensual" or "non-consensual," or whether the patient is considered "competent" or "incompetent."


(6) All Reviewable Sentinel Events shall require development and submission of a Root Cause Analysis¹⁸ to the Bureau of Quality Management in Central Office for these incidents, consistent with OMH/JCAHO guidelines.

iii) *External Reporting:*

(1) The Executive Director or the administrator on duty is responsible for the timely notification of appropriate persons or organizations of certain incidents in accordance with the provisions of this Policy Directive.

(2) Each facility shall have procedures to assure that appropriate notifications occur. Such procedures must generally identify who, within the facility, bears responsibility for making each type of required notification. Copies of all external reports must be concurrently sent to the Bureau of Quality Management in Central Office. The following notifications are required:

(A) Commission on Quality of Care for the Mentally Disabled (CQC).


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1. The CQC and its Mental Hygiene Medical Review Board¹⁹ must be notified of all patient deaths within 3 working days, using form CQC-100.

1. An Adverse Drug Reaction should be reported to the Food and Drug Administration (FDA), following FDA specifications and in accordance with FDA requirements, when the patient outcome is:

¹⁸ For policy regarding root cause analyses, see OMH Official Policy Manual, Section QA-535.

¹⁹ The Mental Hygiene Medical Review Board is a board within the CQC, established in accordance with Mental Hygiene Law §45.15.

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2. The CQC must be notified in writing of all allegations of patient or child abuse or neglect within 72 hours²⁰.

(B) Food and Drug Administration (FDA).

- i. death;
- ii. life-threatening;
- iii. hospitalization (initial or prolonged);
- iv. disability;
- v. congenital anomaly;
- vi. required intervention to prevent permanent impairment; or
- vii. reaction related to the use of a newly marketed drug as part of post-marketing surveillance.

2. Incidents resulting in serious injury or death through the use of medical devices shall be reported to the FDA in accordance with the Safe Medical Devices Act.

(C) Persons Who May Be Endangered. Any person or persons who are known to be potentially endangered by a patient placed on missing patient-escape status must be notified immediately.


(D) Local Law Enforcement Authorities

1. Local law enforcement authorities must be notified in a timely manner of any incident when it appears that a crime may have occurred²¹.
2. Local law enforcement authorities shall also be notified as soon as possible when a patient has been placed on missing patient-escape status²².

(E) Medical Examiner/Coroner. When a patient dies while an inpatient of a State-operated facility, the County Medical Examiner or Coroner must be notified immediately in accordance with applicable OMH Policy²³.

²⁰See OMH Official Policy Manual QA-515 for more information about this requirement as it relates to allegations of child abuse or neglect.

²¹ See OMH Official Policy Manual QA-530 for more detailed information about this requirement.

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²² See OMH Official Policy Manual QA-520 for specific information about this requirement.

²³ See OMH Official Policy Manual PC-450 for specific information about these requirements.

(F) Board of Visitors and the Mental Hygiene Legal Service (MHLS). The Board of Visitors and the Mental Hygiene Legal Service must both be notified within 3 working days of any incident of alleged child or patient abuse or neglect. The Board of Visitors and MHLS must also both be notified of the results of the investigation of such allegations²⁴.


(G) New York Statewide Central Register of Child Abuse and Maltreatment (SCR).

1. The New York Statewide Central Register of Child Abuse and maltreatment (SCR) must be notified immediately, by telephone, of any incident of alleged child abuse or neglect. The Social Services Law mandates the reporting to the SCR of allegations of abuse or neglect as defined in C)3) of this policy directive, as well as all other types of suspected abuse or neglect of children, including suspected abuse or neglect of a child by a parent²⁵.

2. If a family member or visitor harms a child or adolescent on the property of a State operated facility or program, such an event would be identified as an incident using applicable incident terminology and would also be reported to the SCR as abuse.

(H) Next of Kin. Unless the patient involved in an incident is an adult who objects to such notification, the patient's next of kin or guardians shall be notified immediately of allegations of abuse or neglect, incidents involving missing patients or incidents involving patient death or injury. In such cases, next of kin or guardians shall also be notified of the outcomes of the investigation and review process for the most serious incidents.

(I) Contact Persons and Other Mental Health Programs. When an inpatient of a State-operated psychiatric facility is considered missing, any contact person identified in the missing person's case record (e.g., next-of-kin, friend, legal guardian) shall be notified. In addition, any mental health program, including a case management program, which

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²⁴Please also note that pursuant to Sections 33.02(5) and 7.21(b) of the Mental Hygiene Law, incidents which are classified as "assaults", in which a patient is the victim, and where the degree of harm to, or need for treatment by, the victim is classified as "2" or "3" on the Severity Rating Scale are considered "abuse" for purposes of notification of MHLS and must be reported in accordance with this provision.

²⁵ See OMH Official Policy Manual QA-515 for specific information about this requirement.


recently provided services to the person or is likely to encounter the missing person, shall be notified²⁶.

(J) New York State Education Department, New York State Health Department, and National Practitioner Data Bank. In cases where possible misconduct of licensed practitioners or physicians is related to an incident, Counsel's Office must be contacted for advice regarding notification of the New York State Education Department, the New York State Department of Health, and the National Practitioner Data Bank, as applicable.

(K) New York State Department of Labor. In cases where an incident results in the fatality or inpatient hospitalization of an employee of the Office of Mental Health, Counsel's Office and the Bureau of Human Resources must be contacted for advice regarding notification of the New York State Department of Labor, Division of Safety and Health.

d) Investigation

- i) All incidents are to be immediately reported to the Clinical Risk Management team in accordance with D)4)c)i)(1) of this Policy Directive.
- ii) Upon notification of an incident, the Clinical Risk Manager and Clinical Risk Management Specialist(s) shall review each report to assess the circumstances surrounding the incident, conduct a preliminary investigation, if indicated, and determine what level of investigation is appropriate.


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- iii) The Clinical Risk Manager and/or Clinical Risk Management Specialist shall have complete authority to consult with any patients, staff persons, or other individuals on information pertinent to any investigation. He or she may request any resources or staff actions necessary to properly conduct the investigation.
- iv) The Clinical Risk Manager and Clinical Risk Management Specialist must, at a minimum, complete an initial examination of the circumstances surrounding each incident. A determination shall then be made with regard to the need for any further investigation, commensurate with the seriousness and circumstances of the incident.
- v) For outpatient mental health programs, the extent of the investigation of events which do not occur on the property of such program or under the intended supervision of staff of such program shall be determined by

²⁶See OMH Official Policy Manual QA-520 for specific information about this requirement.

both the seriousness of the incident and the accessibility of the information to program staff.

- vi) For each incident for which further investigation is warranted, the investigation shall be sufficiently thorough to identify the fundamental reasons the incident occurred, including both human errors and clinical and non-clinical systems, processes and risk areas that may have contributed to the problem²⁷.
- vii) Investigation process:
 - (1) Recommended components of the investigation process, depending on the type and severity of the incident, include but are not limited to:
 - (A) Preservation of Evidence
 - 1. It may be necessary to secure the scene of an incident to assure that physical evidence is preserved. This is especially necessary for the more serious incidents, including allegations of patient or child abuse or neglect or incidents which may require police involvement. Until an initial investigation is completed, the scene of an incident should be secured by preventing persons from entering the scene and disturbing physical evidence (e.g., furniture,

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broken glass, spills, etc.). However, if it is not possible to secure the scene without endangering patients, action shall be taken to eliminate the hazard.

2. Physical evidence of an incident should be preserved whenever possible. For example, if a patient is seriously injured, bloodied clothing or linens should be saved until such time as any facility or police investigation and any disciplinary action are completed.

3. Any written documents potentially associated with the incident shall be collected and safeguarded as soon as the incident is reported or discovered, to ensure that they are not altered or lost. Such documents may include, but are not limited to, patients' charts, staff assignment logs, incident reports, and shift-to-shift communication books.


²⁷For criteria regarding sentinel events and guidelines for the conduct of root cause analyses, see OMH Official Policy Manual, Section QA-535.

(B) Interviewing Witnesses

1. All potential witnesses to an incident, including patients, shall be interviewed, as appropriate. Interviews should be conducted separately, out of earshot of other witnesses.
2. Each potential witness should be asked appropriate questions in an effort to gather pertinent information about the incident. Interviewers should consult and be familiar with the interview standards and procedures set forth in the *OMH Manual for Special Investigations*, which covers this subject in greater detail.

(C) Interrogation of Staff

1. If a staff person is believed or suspected to have engaged in misconduct which could lead to disciplinary action, s/he shall be questioned or interrogated by a Clinical Risk Manager or Clinical Risk Management Specialist, a personnel officer, or another appropriately trained manager.

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2. If the person conducting the investigation believes that a staff person may have engaged in misconduct, s/he shall review the available information with the administrator on duty, unit chief, or the facility personnel officer for the purpose of determining further action. Interrogations shall be conducted in accordance with standards and procedures set forth in the *OMH Manual for Special Investigations*.

(D) Analysis of Evidence

1. The results of an incident investigation shall be summarized in an investigative report. The purpose of such report is to describe the methods and procedures used in conducting the investigation, summarize the evidence collected, outline the factual theories considered, and explain the findings reached.


2. Witness statements and other supporting documents or evidence shall be appended to the report.

(2) For all incidents except those which by definition require special investigation in accordance with this policy directive (as set forth below in (4)(D) of this subparagraph), the investigation may be upgraded or downgraded at the discretion of the Clinical Risk Manager and/or Clinical Risk Management Specialist, in conjunction with the facility administration, as the findings of the investigation unfold. When an incident classification is downgraded, all evidence pertaining to the change in classification shall be documented.

(3) Other agencies may be required to conduct an investigation into an incident pursuant to other laws or regulations. The initiation of such an investigation shall not alter a facility's or program's responsibility to investigate the incident.

(4) Special Investigations

(A) A "special investigation" is a comprehensive, objective investigation and analysis of patient related incidents. A special investigation is to be conducted for all high risk incidents: incidents involving the serious injury or death of a patient or staff member, (particularly those in which staff person misconduct and/or incompetence is suspected or the circumstances are suspicious or unexplained), and allegations of patient abuse.

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(B) Except by special arrangement, all special investigations will be conducted by the Clinical Risk Manager, or by Clinical Risk Management Specialists designated for this purpose, who have received specialized training in investigative procedures.

(C) Special investigations shall be conducted in a manner consistent with the *OMH Manual for Special Investigations*.

(D) At a minimum, the following types of incidents shall always require a special investigation, provided, however, the Executive Director, the Chief Medical Officer, or the Central Office Director for Quality Management may request that a special investigation be conducted on any incident:

1. homicides;
2. suicides;
3. all other inpatient deaths except natural deaths;
4. homicide and suicide attempts by inpatients;
5. allegations of physical, sexual, or psychological abuse or neglect;
6. serious assaults²⁸ involving inpatients, including sexual assaults;_____

²⁸ "Serious Assaults" are defined here as those that result in admission to a hospital, life threatening injuries requiring emergency life saving procedures (e.g. CPR, intubation, surgery, etc.), life threatening psychiatric conditions as evidenced by suicide or homicide threats or attempts or the need for a major change in treatment, and/or risk for serious medical or psychiatric complications or life threatening harm.

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7. all life threatening injuries;
8. escaped/endangered patients; or
9. other events that jeopardize a patient's life.

viii) Multiple program involvement.

(1) When an incident involves a patient who is also receiving services from other mental health programs, including programs not operated by the Office of Mental Health, the responsibility for compliance with this policy shall be determined as follows:


(A) Each of the facilities/programs should identify, document, and report the incident internally.

(B) All facilities/programs serving the patient should work cooperatively, where appropriate, in the gathering of information and in the review of investigation findings. They should use the incident review process as an opportunity to identify clinical and non-clinical systems, processes and areas of risk which may have contributed to the incident, to identify opportunities for performance improvement, and to develop and implement plans of correction and/or prevention.

(C) Where joint review is not possible, each involved facility/program is required to review, pursuant to Part 524 of 14 NYCRR, its own involvement with the patient as well as its policies and procedures to identify the facts, circumstances, processes, systems, and areas of risk that may have contributed to the incident(s), as well as opportunities for performance improvement.

(D) When an incident occurs on the property of a specific facility or program, or when the patient is under the actual or intended supervision of program staff, such facility/program shall have primary responsibility for addressing the incident in accordance with this policy and/or Part 524 of 14 NYCRR, as applicable.

(E) When an incident occurs in a location or situation which is not under the auspices of any facility or program, the facility/program that is providing psychiatric services to the subject of the incident, when informed of the occurrence of such incident, shall have the primary responsibility of documenting and reporting the incident, internally and externally to the Office of Mental Health and following the procedures of this policy directive and/or Part 524 of 14 NYCRR, as applicable. In cases wherein multiple

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facilities/programs of psychiatric services cannot come to agreement as to who shall assume primary responsibility for reporting and investigation, such facilities/programs must contact the Central Office Bureau of Quality Management to resolve the dispute.

(2) Cooperation of the involved facilities/programs is expected and required pursuant to Mental Hygiene Law and regulations, and may be required pursuant to written agreements. However, unless deemed necessary by the Office of Mental Health, multiple independent investigations of a single incident are not required.


(3) When an incident occurs in a location or situation which is under the auspices of a non-mental health facility/program, such as a residence licensed by another State agency, the mental health facility/program(s) shall be responsible for compliance with the incident management mandates of this policy to the extent practicable, unless otherwise mandated by written agreements between the involved agencies.

- ix) For all investigations, the Executive Director has overall responsibility and oversight, and the final report shall be presented to him or her.
- x) The findings of investigations of patient deaths, incidents which jeopardize a patient's life, and any other events specified by the Office of Mental Health shall be forwarded upon completion to the Central Office Bureau of Quality Management.


5) Incident Review Committee

a) The Executive Director shall appoint an Incident Review Committee to assure that incidents that may adversely affect the care and safety of patients are appropriately addressed and that preventive and corrective measures are identified.

- i) The composition of the Incident Review Committee shall include, but not be limited to the director for Quality Management, the Clinical Director, a physician, nurse, social worker, therapy aide, and appropriate clinical risk management staff. The Incident Review Committee shall include only employees of the Office of Mental Health and persons who are considered officers of the Department of Mental Hygiene for purposes of Section 73 and 74 of the Public Officers Law. The composition of the Incident Review Committee must be such that a free and open exchange of information is ensured, in order to facilitate full and complete investigations.

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- ii) The Director for Quality Management or Clinical Risk Manager shall serve as Chairperson of the committee, provided, however, that the Facility Director may designate another senior staff person as the committee Chairperson, subject to prior approval of the Central Office Director for Quality Management.
- iii) In the review of incidents, the perspective and input of family members and recipients may be helpful in assuring that the Incident Review Committee's analysis is thorough and addresses all relevant issues. In this regard, the Committee may consult with advisory bodies that include family members and recipients to provide such perspective and input. The Incident Review Committee may create a specific advisory body for this purpose or may utilize groups already in existence for this function.
- iv) The Incident Review Committee shall meet no less often than monthly.
- v) The Incident Review Committee is responsible for reviewing individual incidents and incident patterns and trends to determine the timeliness, thoroughness and appropriateness of the facility/program's responses to incidents.
 - (1) The committee shall take an active role in assuring that all incidents receive an appropriate level of review, that investigations are thorough, that opportunities for improvement in clinical and nonclinical systems are identified, when appropriate, and that plans of correction and prevention are developed and implemented.
 - (2) The committee shall review all incidents meeting the criteria for immediate reportability to Central Office, as well as all incidents for which a special investigation or root cause analysis is conducted. In addition, the Incident Review Committee may comprehensively review any incident. The committee may initiate further investigation of any incident or refer any incident back to the Clinical Risk Manager for additional investigation.
 - (3) The committee's review of any incident that meets the criteria for immediate reportability to Central Office shall be completed within 30 days. If, in unusual circumstances, the review cannot be completed within 30 days, an explanation of the delay must be included in the written minutes.

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(4) As necessary, the committee shall make recommendations to the Executive Director regarding the implementation of any preventive or corrective action.

(5) The committee shall also work with the Clinical Risk Manager to monitor the implementation of any preventive or corrective action which has been recommended.

(6) Incident Review Committee members who may bear some responsibility for an incident shall be excluded from the committee's deliberations regarding that incident.

(7) Written minutes of all meetings shall be maintained and reports shall be submitted to the Facility Director, as determined necessary by the committee.

(A) Written minutes shall include documentation of the committee's discussions, findings and recommendations, as well as follow-up actions taken to assure that all recommended preventive and/or corrective measure(s) are implemented.

(B) Minutes shall also indicate when review of a particular incident has been completed. Review shall be deemed complete when all relevant information, including the final investigation report, has been gathered, opportunities for improvement have been identified, and plans of correction/prevention have been developed and implemented.


(8) The Incident Review Committee is responsible for monitoring the general compliance of the facility/program's incident management practices with the requirements of this policy and the facility/program's policies and procedures.

(9) The Incident Review Committee shall prepare quarterly reports as required by Central Office Bureau of Quality Management .

6) Monitoring Roles, Responsibilities, and Requirements

a) Unit/Ward Administrators. Unit/Ward administrators shall:

- i) assure that individual incidents on their units are documented and immediately reported to the Clinical Risk Management Team;

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- ii) assure appropriate follow-up to all patients, especially those that are high need and high risk; and
- iii) be responsible to ensure that post-incident discussion occurs on a daily basis in rounds, with the goal of developing risk reduction strategies.

b) Director for Quality Management and Clinical Risk Manager. The facility Director for Quality Management and Clinical Risk Manager shall monitor the implementation of this Policy Directive.

c) Executive Director.

- i) The Executive Director, by carrying overall responsibility for the health and safety of patients in the facility's care and for promoting improvements in performance and quality of care, plays a critical role in setting the tone of the facility, including the degree of openness to opportunities for improvement. It is imperative that the Executive Director provide solid direction and support for the facility's total risk management program, including the management of incidents, the conduct of major incident investigations and root cause analyses, and the development and implementation of plans of preventive and corrective action.
- ii) The Executive Director shall review the recommendations outlined in the quarterly reports of the Incident Review Committee. If the Executive Director accepts an Incident Review Committee recommendation for corrective or preventive action, s/he shall ensure the prompt initiation of such action.
- iii) The Executive Director shall ensure that the progress in completing corrective or preventive actions taken in response to previous Incident Review Committee recommendations is monitored.