

Notice of Proposed Rulemaking

Amendment of 14 NYCRR Part 836

Incident Reporting in OASAS Certified, Licensed, Funded, or Operated Services

Amendment of 14 NYCRR Part 800.4

OASAS Services: General Provisions

Section:

- 836.1 Background and intent
- 836.2 Legal base
- 836.3 Applicability
- 836.4 Definitions
- 836.5 Incident management plan and incident review committee
- 836.6 Incident reporting, notice, and investigations in facilities and provider agencies certified, licensed or operated by the Office
- 836.7 Incident reporting, notice, and investigations in programs funded, but not certified or licensed, by the Office
- 836.8 Additional notice and reporting requirements for reportable incidents
- 836.9 Recordkeeping and release of records to qualified persons
- 836.10 Duty to cooperate and inspection of facilities
- 836.11 Severability

§836.1 Background and intent

(a) The intent of this Part is to establish minimum standards for incident management programs of any addiction service provider certified, licensed, funded or operated by the Office. Incident management programs are intended to strengthen and standardize the safety net for vulnerable persons such as those receiving services in the OASAS system, to bolster the ability of service providers and the Office to respond more effectively to abuse and neglect allegations and other significant incidents, to ensure that individuals with regular contact with patients are aware of their statutory obligations to adhere to a code of conduct including mandated reporting of certain incidents, and to prevent the recurrence of types of incidents in order to enhance the quality of care and provide every individual receiving services with humane treatment and a safe environment.

(b) The purpose of an incident management program is to ensure a comprehensive strategy for:

(1) identifying, documenting, reporting, and investigating incidents on a timely basis;

(2) identifying incident patterns from the compilation and analysis of incident data;

(3) reviewing incidents and/or patterns to identify preventive or corrective action;

(4) implementing preventive and corrective action plans;

(5) monitoring incident management practices; and

(6) coordinating reporting, investigation, and responding to significant incidents and allegations of abuse and neglect with the Office, the Justice Center for the Protection of People with Special Needs (“Justice Center”), and the Vulnerable Persons’ Central Register (hereinafter, [“Vulnerable Persons’ Register” or] “VPCR”).

§836.2 Legal base

(a) Section 19.07(c) of the Mental Hygiene Law (MHL) charges the Office with the responsibility for seeing that persons in need of treatment for addiction services receive high quality care and treatment, and that the personal and civil rights of persons receiving care, treatment and rehabilitation are adequately protected.

- (b) Section 19.07(e) of the [Mental Hygiene Law] MHL authorizes the Commissioner (“Commissioner”) of the Office to adopt standards including necessary rules and regulations pertaining to addiction services.
- (c) Section 19.09(b) of the [Mental Hygiene Law] MHL authorizes the Commissioner to adopt regulations necessary and proper to implement any matter under their jurisdiction.
- (d) Section 19.20 of the [Mental Hygiene Law] MHL (Protection of People with Special Needs Act, added by Chapter 501 of the Laws of 2012) authorizes the Office to receive and review criminal history information related to certain prospective employees and volunteers.
- (e) Section 19.20-a of the [Mental Hygiene Law] MHL (Protection of People with Special Needs Act, added by Chapter 501 of the Laws of 2012) authorizes the Office to receive and review criminal history information related to persons seeking to be credentialed or applicants for an operating certificate issued by the Office.
- (f) Section 19.21(b) of the [Mental Hygiene Law] MHL requires the Commissioner to establish and enforce certification, inspection, licensing and treatment standards for addiction services facilities and staff.
- (g) Section 19.40 of the [Mental Hygiene Law] MHL authorizes the Commissioner to issue operating certificates for the provision of addiction services.
- (h) Section 22.07(c) of the [Mental Hygiene Law] MHL authorizes the Commissioner to promulgate rules and regulations to ensure that the rights of individuals who have received, and are receiving, addiction services are protected.
- (i) Section 32.01 of the [Mental Hygiene Law] MHL authorizes the Commissioner to adopt any regulation reasonably necessary to implement and effectively exercise the powers and perform the duties conferred by Article 32 of the Mental Hygiene Law.
- (j) Section 32.02 of the [Mental Hygiene Law] MHL authorizes the Commissioner to adopt regulations necessary to ensure quality services to those suffering from compulsive gambling.
- (k) Section 32.07(a) of the [Mental Hygiene Law] MHL authorizes the Commissioner to adopt regulations to effectuate the provisions and purposes of Article 32 of the Mental Hygiene Law.
- (l) Sections 33.16(a)(6) and 33.16(b)(4) of the [Mental Hygiene Law] MHL define a “qualified person” as an individual receiving services, their legal guardian, or a parent, spouse or adult child who has authority to provide consent for care and treatment.

- (m) Section 33.23 of the [Mental Hygiene Law] MHL requires directors of facilities certified by OASAS to provide telephone notification to a “qualified person” of an incident involving a client within twenty-four (24) hours of the initial report.
- (n) Section 33.25 of the [Mental Hygiene Law] MHL requires facilities to release records to “qualified persons”, upon request, relating to allegations and investigations of client abuse or mistreatment.
- (o) Section 491 of the Executive Law requires mandated reporters to immediately report allegations of reportable incidents to the Vulnerable Persons’ Central Register upon discovery.
- (p) Section 492 of the Social Services Law establishes the Vulnerable Persons’ Central Register to which reports of allegations of reportable incidents must be submitted in a manner and on forms approved by the executive director of the Justice Center.
- (q) Article 6, Title 6 of the Social Services Law requires the reporting of suspected abuse or maltreatment of persons under 18 years of age to the New York Statewide Central Register of Child Abuse and Maltreatment (hereinafter, “Statewide Central Register”).
- (r) Section 413 of the Social Services Law identifies persons required to report cases of suspected child abuse or maltreatment to the Statewide Central Register.
- (s) Section 415 of the Social Services Law requires suspected child abuse or maltreatment to be reported immediately by telephone and to be followed by a written report on a form supplied by the commissioner of the Office of Children and Family Services, and further describes procedures for reporting.
- (t) Section 495 of the Executive Law establishes the “Register of Substantiated Category One Cases of Abuse and Neglect” as a statewide register maintained by the Justice Center.
- (u) Chapter 501 of the Laws of 2012 establishes the Justice Center.

§836.3 Applicability

This Part applies to facilities and provider agencies certified, licensed, funded, or operated by the Office, and custodians thereof in the following manner:

- (a) Facilities and provider agencies certified, licensed or operated by the Office are subject to the jurisdiction of the Justice Center and shall follow provisions consistent with Justice Center law and regulations; and
- (b) Providers funded, but not certified or licensed, by the Office are subject to the provisions of this Part solely applicable to such providers as indicated herein.
- (c) To the extent that federal requirements conflict with any of the provisions in this Part, the federal requirements shall supersede the conflicting provisions in this Part with respect to any such facility or provider agency.

§836.4 Definitions

As used in this Part, unless otherwise indicated, the terms listed below shall have the following meanings:

(a) (1) "Incident" means an event or happening, accident or injury during the conduct of any program activity which involves a client, a custodian, or damage to the facility in which the program operates and which has, or may have, an adverse or endangering effect on the life, health or welfare of clients or custodians and is required to be reported, investigated and recorded to designated parties according to Article eleven of the social services law and procedures approved by the Office, reviewed by an Incident Review Committee, and acted upon in an appropriate manner to safeguard the well-being of clients and custodians and to bring the matter to closure.

(2) Incidents are either "reportable" to the Justice Center or "non-reportable."

(3) "Non-reportable" incidents need not be reported to the Justice Center, or if they are reported may be determined as not within the jurisdiction of the Justice Center; nevertheless, these incidents may require documentation in a patient's clinical record or as an incident related to the program or facility which must be maintained by the service provider for review by the provider's Incident Review Committee, or by the Office or the Justice Center, upon request.

~~[(b) "Reportable incident" means an incident of "abuse or neglect" or a "significant incident" as defined in subdivision (c) or (d) of this section; or the death of service recipient as defined in subdivision (c) of section 836.8 of this Part which must be reported in accordance with the requirements of that subsection.]~~

(b) "Reportable incident" means an incident of "abuse or neglect," ~~[or a]~~ "significant incident," or "reportable death" as defined in subdivision (c) or (d) or (e) of this section. ~~[-; or the death of service recipient as defined in subdivision (c) of section 836.8 of this Part which must be reported in accordance with the requirements of that subsection.]~~

(c) "Abuse or neglect" means a reportable incident described by the following conduct that a mandated reporter is required to report to the [Vulnerable Persons' Central Register ("VPCR")] VPCR via a toll-free hotline or reporting online:

(1) "Physical abuse" means conduct by a custodian intentionally or recklessly causing, by physical contact, physical injury or serious or protracted impairment of the physical, mental or emotional condition of a service recipient or causing the likelihood of such injury or impairment. Such conduct may include but shall not be limited to: slapping, hitting, kicking, biting, choking, smothering, shoving, dragging, throwing, punching, shaking, burning, cutting or the use of corporal punishment. Physical abuse shall not include reasonable emergency interventions necessary to protect the safety of any person. In addition, a hotline call shall be made immediately when an injury cannot be explained, and investigation is needed because of the:

- (i) Extent and/or location of the injury;
- (ii) Number of injuries at one time; or
- (iii) Frequency of injuries over time.

(2) "Sexual abuse" means any conduct by a custodian that subjects a person receiving services to any offense defined in article one hundred thirty or section 255.25, 255.26 or 255.27 of the penal law; or any conduct or communication by such custodian that allows, permits, uses or encourages a service recipient to engage in any act described in articles two hundred thirty or two hundred sixty-three of the penal law.

(3) "Psychological abuse" means conduct by a custodian intentionally or recklessly causing, by verbal or

non-verbal conduct, a substantial diminution of a service recipient's emotional, social or behavioral development or condition, supported by a clinical assessment performed by a physician, psychologist, psychiatric nurse practitioner, licensed clinical or master social worker or licensed mental health counselor, or causing the likelihood of such diminution. Such conduct may include but shall not be limited to intimidation, threats, the display of a weapon or other object that could reasonably be perceived by a service recipient as a

means for infliction of pain or injury, in a manner that constitutes a threat of physical pain or injury, taunts, derogatory comments or ridicule. Such conduct shall be reported to the Justice Center when a mandated reporter has reasonable cause to suspect that it occurred, even though no clinical assessment has been undertaken to determine its impact on the service recipient.

(4) "Deliberate inappropriate use of restraints" means the use of a restraint when the technique, the amount of force or the situation in which the restraint is used is deliberately inconsistent with a service recipient's individual treatment/recovery plan, generally accepted treatment practices and/or applicable federal or state laws, regulations or policies, except when the restraint is used as a reasonable emergency intervention to prevent imminent risk of harm to a person receiving services or to any other person. For purposes of this Part a "restraint" shall include the use of any manual, pharmacological or mechanical measure or device to immobilize or limit the ability of a person receiving services to freely move their arms, legs or body. A deliberate inappropriate restraint may include, among other things, a finding that a restraint was used as a punishment or for the convenience of staff.

(5) "Use of aversive conditioning" means the application of a physical stimulus intended to induce pain or discomfort in order to modify or change the behavior of a person receiving services in the absence of a person-specific authorization by the Office pursuant to law, regulations and clinical guidance. Aversive conditioning may include but is not limited to, the use of physical stimuli such as noxious odors, noxious tastes, blindfolds, the withholding of meals and the provision of substitute foods in an unpalatable form and movement limitations used as punishment, including but not limited to helmets and mechanical restraint devices.

(6) "Obstruction of reports of reportable incidents" means conduct by a custodian that impedes the discovery, reporting or investigation of the treatment of a service recipient by falsifying records related to the safety, treatment or supervision of a service recipient, actively persuading a mandated reporter from making a report of a reportable incident to the Vulnerable Persons' Central Register with the intent to suppress the reporting or the investigation of such incident, intentionally making a false statement or intentionally withholding material information during an investigation into such a report; intentional failure of a supervisor or manager to act upon such a report in accordance with Office regulations, policies or procedures; or, for a mandated reporter who is a custodian as defined in subdivision (d) of this section, failing to report a reportable incident upon discovery.

(7) "Unlawful use or administration of a controlled substance" means any administration by a custodian to a service recipient of: a controlled substance as defined by article thirty-three of the public health law, without a prescription; or other medication not approved for any use by the federal food and drug administration. It also shall include a custodian unlawfully using or distributing a controlled substance as defined by article thirty-three of the public health law, at the workplace or while on duty.

(8) "Neglect" means any action, inaction or lack of attention that breaches a custodian's duty and that results in or is likely to result in physical injury or serious or protracted impairment of the physical, mental or emotional condition of a service recipient. Neglect shall include, but is not limited to:

(i) failure to provide proper supervision, including a lack of proper supervision that results in conduct between persons receiving services that would constitute abuse as described in paragraphs (1) through (7) of this subdivision if committed by a custodian; or

(ii) failure to provide adequate food, clothing, shelter, medical, dental, optometric or surgical care, consistent with the rules or regulations promulgated by the Office, provided that the facility or provider agency has reasonable access to the provision of such services and that necessary consents to any such medical, dental, optometric or surgical treatment have been sought and obtained from the appropriate individuals; or

(iii) failure to provide access to educational instruction, by a custodian with a duty to ensure that an individual receives access to such instruction in accordance with the provisions of part one of article sixty-five of the education law and/or the individual's individualized education program.

(d) "Significant incident" means a reportable incident, other than an incident of abuse or neglect as defined in subdivision (c) of this section, which because of its severity or the sensitivity of the situation, may result in, or has the reasonably foreseeable potential to result in, harm to the health, safety or welfare of a person receiving services and shall include but is not limited to:

(1) conduct between persons receiving services that would constitute abuse as described in paragraphs (1) through (7) of subdivision (c) of this section, if committed by a custodian; and

(2) conduct on the part of a custodian, inconsistent with a service recipient's individual treatment/recovery plan, generally accepted treatment practices and/or applicable federal or state laws, regulations or policies and which impairs or creates a reasonably foreseeable potential to impair the health, safety or welfare of a person receiving services, including but not limited to:

(i) unauthorized seclusion, which shall mean the placement of a person receiving services in a room or area from which they cannot, or perceives that they cannot, leave at will;

(ii) unauthorized use of time-out, which shall mean the use of a procedure in which a person receiving services is removed from regular programming and isolated in a room or area for the convenience of a custodian, or as a substitute for programming but shall not include the use of a time-out as an emergency intervention to protect the health or safety of the individual or other persons;

(iii) except as provided for in paragraph (7) of subdivision (c) of this section, the administration of a prescribed or over-the-counter medication, which is inconsistent with a prescription or order issued for a service recipient by a licensed, qualified health care practitioner, and which has an adverse effect on a service recipient. For purposes of this subparagraph, "adverse effect" shall mean the unanticipated and undesirable side effect from the administration of a particular medication which unfavorably affects the well-being of a service recipient;

(iv) inappropriate use of restraints, which shall mean the use of a restraint when the technique, the amount of force or the situation in which the restraint is used are inconsistent with a service recipient's individual treatment/recovery plan, generally accepted treatment practices and/or applicable federal or state laws, regulations or policies; or

(3) Other significant incidents, including but not limited to:

(i) An event that is, or appears to be, a crime under New York state or federal law involving custodians, clients, or others, including children of service recipients in a residential program, as victims or perpetrators;

(ii) Body cavity search; which is explicitly prohibited pursuant to Part 815 of this Title;

(iii) Any violation of a client's rights to confidentiality pursuant to 42 CFR Part 2 or the Health Insurance Portability and Accountability Act (HIPAA).

[(iii)] (iv) Missing client as defined in subdivision (u) of this section;

[(iv)] (v) Suicide attempt whether or not preceded by statements of intent; statement of intent alone is not a suicide attempt; statements of intent should be recorded in a patient's clinical record;

[(v)] (vi) Death of a custodian or mandated reporter during the course of his/her job duties related to the provider facility; shall also be reported to any other appropriate entity;

(vii) Death of an outpatient client if death occurs on program premises or during the course of program activities.

(e) “Reportable Death” or “Administrative Reportable Death” means a reportable incident of a client’s death in an inpatient or residential program under any circumstances or within 30 days if such client’s discharge. Immediate notification must be made to both the VPCR and the Justice Center’s Mortality Review Unit (subject to the provisions of 42 CFR Part 2), the process for which can be found on the Justice Center’s website, the local coroner or medical examiner, or any other state or local agency identified under state laws requiring the collection of health or other vital statistics.

[(e)] (f) "Custodian" means a director, operator, employee or volunteer of a facility or provider agency; or a consultant or an employee or volunteer of a corporation, partnership, organization or governmental entity which provides goods or services to a facility or provider agency pursuant to contract or other arrangement that permits such person to have regular and substantial contact with individuals who are cared for by the facility or provider agency.

[(f)] (g) "Facility" or "provider agency" shall mean a facility or program in which services are provided and which is operated, licensed or certified by the Office. Such facilities and provider agencies are within the jurisdiction of the Justice Center for purposes of reporting reportable incidents to the Justice Center’s [Vulnerable Persons’ Central Register] VPCR.

[(g)] (h) "Mandated reporter" means a custodian or a human services professional but shall not include a service recipient.

[(h)] (i) "Human services professional" means any: physician; registered physician assistant; surgeon; medical examiner; coroner; dentist; dental hygienist; osteopath; optometrist; chiropractor; podiatrist; resident; intern; psychologist; registered nurse; licensed practical nurse; nurse practitioner; social worker; emergency medical technician; licensed creative arts therapist; licensed marriage and family therapist; licensed mental health counselor; licensed psychoanalyst; licensed behavior analyst; certified behavior analyst assistant; licensed speech/language pathologist or audiologist; licensed physical therapist; licensed occupational therapist; hospital personnel engaged in the admission, examination, care or treatment of persons; Christian

Science practitioner; school official, which includes but is not limited to school teacher, school guidance counselor, school psychologist, school social worker, school nurse, school administrator or other school personnel required to hold a teaching or administrative license or certificate; full or part-time compensated school employee required to hold a temporary coaching license or professional coaching certificate; social services worker; any other child care or foster care worker; mental health professional; person credentialed by the Office; peace officer; police officer; district attorney or assistant district attorney; investigator employed in the office of a district attorney; or other law enforcement official.

[(i)] (j) "Physical injury" and "impairment of physical condition" means any confirmed harm, hurt or damage resulting in a significant worsening or diminution of an individual's physical condition.

[(j)] (k) "Delegate investigatory entity" means a facility or provider agency, or any other entity authorized by regulations of the Office or the Justice Center to conduct an investigation of a reportable incident.

[(k)] (l) "Justice Center" means the Justice Center for the Protection of People with Special Needs established pursuant to Chapter 501 of the Laws of 2012.

[(l)] (m) "Person receiving services," or "service recipient" means a client who receives or has received services from a facility or provider agency.

[(m)] (n) "Personal representative" means a person authorized under state, tribal, military or other applicable law to act on behalf of a vulnerable person in making health care decisions, or a service recipient's parent, guardian or other person legally responsible for the service recipient.

[(n)] (o) "Subject of the report" means a custodian, as defined in subdivision (e) of this section, who is reported to the [vulnerable persons' central register] Vulnerable Persons' Central Register for the alleged abuse or neglect of a vulnerable person as defined in subdivision (q) of this section.

[(o)] (p) "Other persons named in the report" means and is limited to the following persons who are named in a report to the Vulnerable Persons' Central Register other than the subject of the report: the service recipient whose care and treatment is the concern of a report to the Vulnerable Persons' Central Register, and the personal representative, if any, as defined in subdivision (m) of this section.

[(p)] (q) "Vulnerable Persons' Central Register" means the statewide central register of reportable incidents involving vulnerable persons, which shall operate in accordance with section four hundred ninety-two of Article 11 of the social services law.

[(q)] (r) "Vulnerable person" means a person who, due to physical or cognitive disabilities, or the need for services or placement, is receiving services from a facility or provider agency.

[(r)] (s) "Intentionally" and "recklessly" shall have the same meanings as provided in subdivisions one and three of section 15.05 of the penal law.

[(s)] (t) "Clinical records" means information concerning or related to the examination or treatment of a person receiving services from a provider agency.

[(t)] (u) "Incident management program" means a plan developed and maintained by service providers pursuant to section 836.5 of this Part including specifications for the identification, investigation, reporting and appropriate response to any incident and review by the provider's Incident Review Committee.

[(u)] (v) "Missing client" means a client (1) over the age of eighteen in a residential facility who has not been accounted for when and where such client is expected to be present and, after forty-eight (48) hours, whose location has not been determined by means of immediate and appropriate diligent efforts (a client is accounted for and not missing if staff has received information regarding the patient's intention to leave treatment against medical advice or to remove themselves to a specific location outside of the facility with or without an approved pass); or

(2) under the age of eighteen in a residential facility who has not been accounted for when and where such client is expected to be present and, after twenty-four (24) hours, whose location has not been determined by means of immediate and appropriate diligent efforts (a client is accounted for and not missing if staff has received information regarding the patient's intention to leave treatment against medical advice or to remove themselves to a specific location outside of the facility with or without an approved pass, or is known to be in the custody of a parent or guardian).

[(v)] (w) "Qualified person" means an individual receiving services or their personal representative as defined in subdivision (l) of this section.

[(w)] (x) “Staff” means custodians identified as an administrator, licensed clinician, contractor, employee, consultant, volunteer, intern, peer advocate, agent, or counselor trainee affiliated with a program certified, licensed, funded, or operated by the Office.

[(x)] (y) “Incident Review Committee” means a committee required by a facility Incident management program and established pursuant to section 836.5 of this Title.

§836.5 Incident management plan and incident review committee

(a) The governing authority of every facility or provider agency certified, licensed, funded, or operated by the Office must establish and maintain written policies and procedures constituting an incident management program for responding to, reporting, investigating and evaluating incidents. All incident management programs are subject to review by the Office and must be consistent with patient rights provisions of Part 815 of this Title and with the requirements of the Justice Center.

(b) At a minimum, an incident management program must be consistent with Justice Center Incident Reporting regulations and incorporate the following:

- (1) identification of staff responsible for administration of the incident management program;
- (2) provisions for annual review by the governing authority;
- (3) specific internal recording and reporting procedures applicable to all incidents observed, discovered or alleged;
- (4) procedures for monitoring overall effectiveness of the incident management program;
- (5) minimum standards for investigation of incidents observed, discovered or alleged, including, but not limited to:
 - (i) physical or medical examination, as indicated by circumstances; name of examiner; written findings;
 - (ii) identification and interviews with any witnesses (interviews conducted separately by qualified, objective persons); written documentation of such interviews;

(iii) review of pertinent physical evidence; documentation (photos, expert assessments) and retention by facility Incident Review Committee, facility executive or other appropriate person;

(iv) documentation of investigative steps taken.

(6) procedures for the implementation of corrective action plans if required;

(7) establishment of an Incident Review Committee pursuant to subdivision (f) of this section;

(8) required periodic training in mandated reporting obligations of custodians and the Justice Center code of conduct, in addition to any other training as may be required by the Office and consistent with Justice Center regulations;

(9) provision for retention of records, review and release pursuant to Justice center regulations and section 33.25 of the mental hygiene law.

(c) Any provider of services dually certified, licensed, funded, or operated by the Office and another New York State agency may substitute the other agency's required incident reporting program for the requirements of this section provided such program meets or exceeds the scope and requirements of this Part and such substitution has been previously approved by the Office and is consistent with Justice Center regulations. As a condition of such approval, a provider must comply with any other provisions relevant to incidents as required by the Office and have a current operating certificate that is not subject to any limitations.

(d) Upon admission to a program, clients, and others when appropriate and subject to applicable confidentiality laws, must be informed that a program maintains an incident management program.

(e) Upon clearance for employment any custodian must be informed of the service provider's incident management program, custodian obligations as a mandated reporter, and an original signed attestation by such custodian that they have received and understand such obligations. Custodian attestation to receiving and understanding the Code of Conduct must be renewed annually.

(f) Incident Review Committee. Each provider's incident management program must provide for the establishment of an Incident Review Committee. Such committee may also perform other review functions for the facility or service provider, including but not limited to, quality improvement and/or utilization review, however minimum requirements include, but are not limited to:

(1) Each Incident Review Committee must include members of the governing body of the provider agency and other persons identified by the director, including some members from the following: direct support staff, licensed health care practitioners, service recipients and representatives of family, consumer and other advocacy organizations subject to the provisions of 42 CFR Part 2 (if appropriate, based on the size of the facility or provider agency, the Office may authorize an exemption from this requirement or portions of this requirement upon review of a written request). The executive director of a provider may not serve as an incident review committee member.

(2) Services not requiring medical staff may substitute a Qualified Health Professional for the medical staff.

(3) In a service co-located within a general hospital or a certified hospital for mental illness, or a service that is part of a larger human services agency, the functions of the Incident Review Committee may be performed by a hospital-wide committee or an agency-wide committee, provided a representative from the addiction services unit serves on the committee and confidentiality is maintained pursuant to 42 CFR Part 2, and the functions of the committee meet or exceed the requirements of this Part.

(4) Members of the committee shall be trained in confidentiality laws and regulations and shall comply with section 74 of the Public Officers Law (code of ethics).

(5) Committee functions and responsibilities. At a minimum, each Incident Review Committee must:

(i) review and evaluate all incidents;

(ii) determine the facts, review and evaluate ongoing practices and procedures in relation to such incidents, and recommend any indicated changes in practices and procedures to improve the provider's response to all incidents;

(iii) determine whether there are patterns, trends, or common causes of incidents and make recommendations for changes to prevent recurrence;

(iv) meet as often as necessary to properly execute its functions, but in no event less than quarterly;

(v) keep written minutes of its deliberations and submit bi-annual reports to the governing authority;

(vi) prepare a summary of incidents reviewed and recommendations made, if any, at each meeting;

and

(vii) take any action necessary to follow up on recommendations made.

(6) Incident Review Committees are responsible for reviewing individual incidents and incident patterns to determine the timeliness, thoroughness and appropriateness of the program's response. The committee may make recommendations to the governing body regarding the implementation of any preventive or corrective action.

(7) Incident Review Committees are responsible for monitoring the compliance of the program's incident management practices and the implementation of any corrective action taken by the provider. Any corrective action required must be endorsed, in writing, by the facility director or their designee, identify a monitoring date and person responsible for assessing the efficacy of the corrective action.

~~[(8) The Incident Review Committee must quarterly compile a collective report of the total number of incidents by type, its findings and recommendation; such reports shall be maintained by the governing authority to be available for inspection or review by the Office for purposes of recertification or by the Justice Center for such purposes as it may designate.]~~

§836.6 Incident reporting, notice, and investigations in facilities and provider agencies certified, licensed or operated by the Office

(a) Unless otherwise indicated herein, all reportable incidents as defined in this Part shall be reported to the Vulnerable Persons' Central Register.

(b) A custodian of any service provider who personally observes, is advised of, or otherwise becomes aware of an incident must take immediate and appropriate action to intervene and attempt to prevent or limit injury or potential injury to any person to the greatest extent possible.

(c) In accordance with a provider's incident management program, a written incident report must be initiated or a call made by a mandated reporter as defined in this Part to the Vulnerable Persons' Central Register toll-free hotline immediately after a reportable incident is discovered.

(1) Every mandated reporter who has direct knowledge of an incident and has reasonable cause to suspect that a person receiving services has been subjected to a reportable incident is required to make a report to the VPCR unless:

- (i) they have actual knowledge that the reportable incident has been reported to the VPCR; and
- (ii) that they have been named as a person with knowledge of the incident in such prior report.

(2) For purposes of this reporting obligation, “discovery” occurs when a mandated reporter has “reasonable cause to suspect” that a service recipient has been subjected to a reportable incident. This may occur either:

(i) when a mandated reporter witnesses a suspected reportable incident; or

(ii) when another person, including a service recipient, comes before the mandated reporter, in the mandated reporter’s professional or official capacity, and provides the mandated reporter with reasonable cause to suspect that a service recipient has been subjected to a reportable incident.

(3) For purposes of this reporting obligation, “reasonable cause to suspect” does not require conclusive evidence that the incident occurred; a rational or sensible suspicion is sufficient and may be based on the mandated reporter’s observations, training and experience, and the mandated reporter’s disbelief of an explanation provided for an injury.

(d) In addition to those reports of reportable incidents that must be made to the Justice Center, an initial incident report must be forwarded to the director or designee ~~[for investigation]~~ immediately after an incident is discovered. Such an initial incident report shall, at a minimum, contain the following information:

(1) The exact date and time of the incident if known; and

(2) a description of the incident, including location, and actions taken in response to it; and

(3) the name(s), address(es), and telephone number(s) of the victim(s), witness(es), and any other persons involved; and

(4) the presence of injuries, if any, and first aid provided to address such injuries.

(e) The Justice Center shall determine whether a reportable incident shall be investigated by the Justice Center or delegated to the Office for investigation. If an incident is delegated to the Office by the Justice

Center, the Office may investigate such reportable incident itself or may delegate such an investigation to the facility or provider agency. ~~[For any investigation of a reportable incident of abuse or neglect that is not conducted by the Justice Center, the final report of such investigation of abuse or neglect must be provided to the Justice Center no later than fifty (50) days after the Justice Center accepts the initial report of the incident, unless an extension of time is granted for documented good cause. Any final report of a delegated significant incident must be provided to the Justice Center within sixty (60) days after the Justice Center accepts the initial report of the incident, unless an extension of time is granted for documented good cause.]~~ After the Justice Center accepts the initial report of the incident, any final report of a delegated significant incident must be provided to the Justice Center within 60 days, unless an extension of time is granted for documented good cause.

(f) All incidents must be recorded by the service provider and all incident reports and other relevant records made available for inspection by the Office and the Justice Center, when appropriate.

(g) Upon notice to the Office, service providers may delay reporting for no more than twenty-four (24) hours in order to conduct a preliminary review of an allegation of abuse or neglect, where a service provider does not have reasonable cause to suspect that the allegation has occurred because:

(1) the person making the allegation of abuse or neglect has a documented history of making false reports of abuse or neglect and no other person has come forward as a witness to such allegation; or

(2) the person making the allegation of abuse or neglect has a documented behavioral or psychological condition that would tend to cause such person to make a false report of abuse or neglect and no other person has come forward as a witness to such allegation.

(h) Any delayed discovery of an allegation pursuant to subdivision (g) of this section must be documented, such documentation including:

(1) the reasons identified above for such delay in any subsequent report to the Justice Center; or

(2) the basis for a determination not to report; such documentation shall be available to the Justice Center or the Office upon request.

§836.7 Incident reporting, notice, and investigations in programs funded but not certified or licensed by the Office

(a) Prevention programs and other services funded, but not certified or licensed by the Office, shall report incidents to the Office, and not the Justice Center. Reports shall be made to the OASAS bureau of Patient Advocacy. The initial report of such an incident, in such a program, must, at a minimum, contain:

(1) The exact date and time of the incident if known; and

(2) a description of the incident, including location, and actions taken in response to it; and

(3) the name(s), address(es), and telephone number(s) of the victim(s), witness(es), and any other persons involved; and

(4) the presence of injuries, if any, and first aid provided to address such injuries.

(b) All other provisions of this Part are applicable to prevention programs and other services funded but not certified or licensed by the Office.

§836.8 Additional notice and reporting requirements for reportable incidents

(a) Subject to the provisions of 42 CFR Part 2, in addition to any other notice provisions required in this Part, notification of reportable incidents involving a client must be made pursuant to section 33.23 of the Mental Hygiene Law by the director or designee to the client's family or significant other, designated emergency contact, or other qualified person. Such notification must be made by telephone or secure electronic method immediately after an incident is discovered.

(b) If it appears that a crime may have been committed against any custodian or service recipient, the provider must immediately make such reports as are necessary to provide notification to the appropriate law enforcement agency of the incident. A provider may disclose client-identifying information to the appropriate law enforcement agency only when such disclosure:

(1) is directly related to a client's commission of a crime on the premises of the program or a threat to commit such a crime; and

(2) is limited to the circumstances of the incident, including the status of the individual committing or threatening to commit the crime, and such individual's name and address.

(c) In the event of a [client's death in an inpatient or residential program under any circumstances or within 30 days of such client's discharge,] reportable death, immediate notification must be made to both the VPCR and the Justice Center's Mortality Review Unit (subject to the provisions of 42 CFR Part 2), the process for which can be found on the Justice Center's website, the local coroner or medical examiner, or any other state or local agency identified under state laws requiring the collection of health or other vital statistics.

(d) In addition to reporting requirements of subdivision (a) of this section, in the case of a missing client the provider's policies and procedures and missing client reports must indicate that the appropriate supervisory staff member was notified immediately. If such supervisor deemed it necessary, a diligent search must be made by staff of the physical plant, grounds and surroundings. Telephone inquiries may be made to the person's home or any other appropriate location, provided such calls are made in such manner so as not to violate confidentiality requirements of 42 CFR Part 2. Incident reports of a missing client must state the efforts made to locate the client as well as the outcome of such efforts.

(e) Nothing herein shall require staff to submit a report to a provider's director or designee if such director or designee is alleged to have committed the reportable or significant incident or to be directly involved in the alleged reportable or significant incident. If the director or director's designee is alleged to have committed the reportable or significant incident or to be directly involved in the alleged reportable or significant incident, staff members as mandated reporters as defined in section 836.4 of this Part must report such allegations only to the VPCR and the Office.

§836.9 Recordkeeping and release of records to qualified persons

(a) A copy of each incident report including identifying information must be kept on file at the program for a minimum of [six (6)] ten (10) years and must be subject to inspection and review by the Office or the Justice Center.

(b) Copies of the minutes and summaries of the Incident Review Committee must be kept on file at the program for a minimum of [six (6)] ten (10) years and must be subject to inspection and review by the Office or the Justice Center.

(c) Subject to the provisions of 42 CFR Part 2, records and reports released in accordance with this Part shall be released to qualified persons pursuant to subdivision (b) of section 33.23 of the Mental Hygiene Law, section 33.25 of the Mental Hygiene Law, and shall include a statement that such records and reports shall not be further disseminated by the recipient except as provided by law.

(d) Subject to the provisions of 42 CFR Part 2, upon the written request of a qualified person, the director of the program must:

(1) promptly provide to such qualified person a copy of the written incident report, provided the names and other personally identifying information of clients and employees shall not be included unless such clients and employees authorize such disclosure;

(2) offer to hold a meeting with such qualified person to further discuss the incident; and

(3) provide such qualified person with a written report on the actions taken to address the incident within 10 days of discovery of the incident;

(4) release, within 21 days of the conclusion of any investigation, records and documents pertaining to allegations and investigations into client abuse or mistreatment at a program.

(e) Providers are required to cooperate with Justice Center investigations of abuse or neglect and significant incidents by making related records available upon the request of authorized investigators.

(f) Providers are required to cooperate with the Justice Center in making records relating to abuse and neglect available for disclosure pursuant to subdivision (6) of section 490 of the social services law.

§836.10 Duty to cooperate and inspection of facilities

(a) Subject to the provisions of 42 CFR Part 2, as part of an investigation of abuse or neglect, a service provider must cooperate with any investigation or inspection conducted by the Office or the Justice Center, or

any representative thereof to the extent necessary to carry out the functions, power, and duties of the Justice Center. Such cooperation shall include at a minimum to allow the Office and/or the Justice Center to inspect its facility and all relevant books, data and records, including but not limited to, client or resident records, kept by such provider, to submit to the Justice Center any relevant records requested pursuant to Justice Center regulations, and to interview and examine any client or resident at its facility except that no such client or resident shall be examined without their consent. Such data includes:

(i) for the subject of an investigation of abuse or neglect, the alleged subject's name, date of birth, social security number or alien registration number, physical or residential address and, if different, their mailing address;

(ii) for a service recipient alleged to be the victim of an allegation of abuse or neglect, the alleged victim's date of birth and mailing address; whether the alleged victim is a self-advocate or has a personal representative as defined in this Part and the mailing address of any such personal representative.

(b) Failure of a service provider to provide requested data, records or information shall be reported to the Office which may impose a fine, and/or suspend, revoke or limit the provider's operating certificate and/or take any other appropriate action in accordance with applicable law or regulation.

§ 836.11 Severability

If any provision of this Part or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of this Part that can be given effect without the invalid provision or applications, and to this end the provisions of this Part are declared to be severable.

Section 800.4. Definitions

The following terms are defined for purposes of all Parts of Chapter XXI of this Title, unless a term is defined and indicated as applicable only for purposes of a specific Part.

(a) "*Addiction disorder*" means substance use disorder as defined in this Part and/or gambling disorder as defined in this Title and/or problem gambling as defined in this Title.

- (b) “*Addiction services*” means examination, evaluation, diagnosis, care, treatment, or rehabilitation of persons with substance use disorder, gambling disorder, or problem gambling and their families or significant others.
- (c) “*Approved medication*” means any medication approved by state and federal authorities for the treatment of substance use disorder.
- (d) “*Clinical staff*” is staff who provide services directly to patients as prescribed in a treatment/recovery plan; clinical staff includes licensed medical staff, credentialed or licensed staff, non-credentialed staff, and student interns.
- (e) “*Commissioner*” means the Commissioner of the Office of Addiction Services and Supports unless otherwise indicated.
- (f) “*Diagnosis*” for purposes of admission, treatment and level of care transition planning (discharge planning) means the identification criteria contained in the most current editions of both the International Classification of Diseases, and the Diagnostic and Statistical Manual.
- (g) “*Full Opioid agonist*” means methadone.
- (h) “*Medical Director*”.
- (1) Each program must have a physician designated by the program sponsor to be the medical director. The medical director shall be a physician licensed and currently registered as such by the New York State Education Department and shall have at least one year of education, training, and/or experience in substance use disorder services. The medical director is a physician who has overall responsibility for the following (this overall responsibility may not be delegated):
- (i) medical services provided by the program;
 - (ii) oversight of the development and revision of policies, procedures and ongoing training for matters including, but not limited to, routine medical care, specialized services, specialized medications, medical and psychiatric emergency care, screening for, and reporting of, communicable diseases and infection in accordance with law, public health education including prevention and harm reduction;
 - (iii) collaborative supervision with the program director of non-medical staff in the provision of substance use disorder services;
 - (iv) supervision of medical staff in the performance of medical services;
 - (v) assisting in the development of necessary referral and linkage relationships with other institutions and agencies including, but not limited to, general or specialty hospitals and nursing homes, health-related facilities, home health agencies, hospital outpatient departments, diagnostic and treatment facilities, laboratories and related resources;
 - (vi) ensuring program compliance with all federal, state and local laws and regulations.
- (2) All medical directors, whether full-time or part-time, other than medical directors in place as of the effective date of this regulation, must hold a board certification in addiction medicine from a certifying entity appropriate to their primary or specialty board certification. Physicians may be hired as probationary medical directors if not

so certified but must obtain certification within four (4) years of being hired. In addition, the medical director must have a federal DATA 2000 waiver to prescribe buprenorphine.

(3) The medical director may serve as medical director of more than one program certified by the Office.

(i) “*Medical staff*” means physicians, nurse practitioners, registered physician assistants, and registered nurses licensed and certified by the State Education Department practicing within the scope of, and in accordance with, the terms and conditions of such licenses and certifications, and working with, or under the supervision of a physician, or other medical professional if required by law.

(j) “*Medication for addiction treatment*” (MAT) means treatment of substance use disorder i.e., substance use disorder and concomitant conditions with medications requiring a prescription or order from an authorized prescribing professional.

(k) “*Multi-disciplinary team*” means a team of health professional staff including, at a minimum, one medical staff member (where applicable) as defined in this section, one credentialed alcoholism and substance abuse counselor (CASAC) and one other staff member who is a qualified health professional as defined in this section in a discipline other than alcohol and substance use disorder counseling. If the treatment service has a gambling designation on their operating certificate, the multi-disciplinary team must include Qualified Problem Gambling Professional (QPGP), consistent with this Chapter.

(l) “*Naloxone emergency overdose prevention kit*” means a kit as prescribed or distributed pursuant to state law and is used to reverse an opioid overdose.

(m) “*Office*” or “*OASAS*” means the New York State Office of Addiction Services and Supports.

(n) “*Opioid agonist*” means methadone or buprenorphine and/or buprenorphine/naloxone, or any other agonist medication that may be approved by the federal or state government for the treatment of opioid use disorder.

(o) “*Opioid antagonist*” for purposes of substance use disorder treatment medication means naltrexone. Opioid antagonist for purposes of overdose prevention medication means naloxone.

(p) “*Partial Opioid agonist*” means buprenorphine and/or buprenorphine/naloxone.

(q) “*Peer advocate*” is a Certified Recovery Peer Advocate (CRPA) who holds a certification from a certifying authority recognized by the Commissioner.

(r) “*Prescribing professional*” is any medical professional appropriately licensed under New York State law and registered under federal law to prescribe approved medications.

(s) “*Program*” means a location wherein a provider is authorized to provide addiction services.

(t) “*Provider*” means an individual, association, partnership, corporation, public or private agency sponsor, as “sponsor” is defined in this Part, other than an agency or department of the state, which provides addiction services via one or more Office certified, funded or otherwise authorized program.

(u) “*Qualified Health Professional*” means any of the professionals listed below, who are in good standing with the appropriate licensing or certifying authority, as applicable, with a minimum of one year of experience or satisfactory completion of a training program in the treatment of addiction:

- (1) a credentialed alcoholism and substance abuse counselor (CASAC) **or credentialed prevention professional** who has a current valid credential issued by the Office, or a comparable credential, certificate or license from another recognized certifying body as determined by the Office;
- (2) a counselor certified by and currently registered as such with the National Board for Certified Counselors;
- (3) a rehabilitation counselor certified by the Commission of Rehabilitation Counselor Certification;
- (4) a therapeutic recreation therapist certified by the National Council on Therapeutic Recreation or the American Therapeutic Recreation Association; or a person who holds a baccalaureate degree in a field allied to therapeutic recreation and, either before or after receiving such degree, has five years of full-time, paid work experience in an activities program in a health care setting;
- (5) a professional licensed and currently registered as such by the New York State Education Department to include:
- (i) a physician who has received a doctor of medicine (M.D.) or doctor of osteopathy (D.O.) degree;
 - (ii) a physician assistant (PA);
 - (iii) a certified nurse practitioner (NP);
 - (iv) a registered nurse (RN);
 - (v) a psychologist;
 - (vi) an occupational therapist;
 - (vii) a social worker (LMSW; LCSW), including an individual with a Limited Permit Licensed Master Social Worker (LP-LMSW) only if such person has a permit which designates the OASAS-certified program as the employer and is under the general supervision of a LMSW or a LCSW; and
 - (viii) a mental health practitioner including: a licensed mental health counselor (LMHC), a marriage and family therapist (LMFT), a creative arts therapist (LCAT), and licensed psychoanalyst; and any mental health practitioner with a Limited Permit.
- (v) “*Quality improvement*” means an ongoing process by which an addiction service systematically assesses the adequacy and appropriateness of the addiction treatment services provided to patients and provides recommendations for improvement.
- (w) “*Significant other*” is an individual who is admitted to treatment and manifests psychological, behavioral and/or emotional effects arising from another person's substance use disorder, regardless of whether the other individual is in treatment. A significant other must be determined to be able to participate actively in and benefit from the treatment process.
- (x) “*Sponsor*” (formerly “*governing authority*”) means the provider of service or an entity that substantially controls or has the ability to control substantially the provider of service. For the purpose of this Part, factors used to determine whether there is substantial control shall include, but are not limited to, the following:
- (1) the right to appoint and remove directors or officers;
 - (2) the right to approve bylaws or articles of incorporation;
 - (3) the right to approve strategic or financial plans for a provider of service; or

(4) the right to approve operating or capital budgets for a provider of service.

(y) "*Student Intern*" means a person enrolled in a formal educational program which could lead to a degree, certification or credential which may qualify that person as a Qualified Health Professional.

(z) "*Substance use disorder*" means a group of cognitive, behavioral, and physiological symptoms indicating that an individual continues using substances despite significant substance-related physical, psychological and social problems as determined through assessment and diagnosis using the most recent version of the DSM. Substance use disorder, or addiction, is a treatable, chronic medical condition. Substance use disorder treatment shall include alcoholism, alcohol abuse, substance abuse, substance dependence, chemical dependence, chemical abuse and/or chemical dependence.

(aa) "*Substance use disorder services*" or "*chemical dependence services*" shall mean and include examination, evaluation, diagnosis, care, treatment, or rehabilitation of persons with substance use disorders and their families or significant others.

(bb) "*Utilization review*" means a process by which a service systematically monitors the appropriateness of admissions, the need for continued stay, and the necessity for an alternative level of care.