

STATEMENTS OF POLICY

Title 55—PUBLIC WELFARE

DEPARTMENT OF PUBLIC WELFARE

[55 PA. CODE CH. 6000]

Incident Management

Purpose

The purpose of this subchapter is to establish processes that will protect the health and safety, enhance the dignity and protect the rights of individuals receiving supports and services.

Applications

This subchapter applies to:

(1) Individuals who receive mental retardation supports and services authorized by a County Mental Health/Mental Retardation Program or who receive supports and services from licensed mental retardation facilities.

(2) Individuals who receive funds from the mental retardation system, either directly or indirectly, to provide or secure supports or services for individuals authorized to receive services from a County Mental Retardation Program and employees of facilities licensed by the Department of Public Welfare's (Department) Office of Mental Retardation (OMR) are to report incidents as defined within this subchapter.

(3) The following chapters within 55 Pa. Code:

(a) Chapter 20 (relating to licensure or approval of facilities and agencies)

(b) Chapter 2380 (relating to adult training facilities)

(c) Chapter 2390 (relating to vocational facilities)

(d) Chapter 6400 (relating to community homes for individuals with mental retardation)

(e) Chapter 6500 (relating to family living homes)

(f) Chapter 6600 (relating to intermediate care facilities for persons with mental retardation)

Background

Providers of mental retardation services and supports, including private and State operated Intermediate Care Facilities for Persons with Mental Retardation, County Mental Health and Mental Retardation Programs and the OMR are partners in the effort to assure the health, safety and rights of persons receiving supports and services. Each reports certain incidents, collects information about those incidents and takes action based on those reports. The development and expansion of community-based supports and services and the increasing flexibility people enjoy to choose a wide variety of both traditional and nontraditional supports have increased the need to establish consistent Statewide processes for reporting, investigating, analyzing trends to prevent the risk of recurrence and taking corrective action in response to incidents.

Services and supports provided through the mental retardation service system are designed to enable each individual to determine the individual's own personal goals and to make decisions about the services and supports the individual receives. While respecting individual and family privacy concerns and the right to individual and family decision making in regard to ser-

vices and supports, the public services system must ensure that safeguards are in place to protect the health, safety and rights of anyone receiving these services and supports.

Discussion

The incident management processes described within this subchapter are more than standardized reporting processes. The primary goal of an incident management system is to assure that when an incident occurs the response will be adequate to protect the health, safety and rights of the individual. This subchapter communicates clear and specific methodologies to assure appropriate responses at the provider, county and State levels. The standardization of reporting, the time frames for reporting, investigation and follow-up are key to conducting individual, provider, countywide and Statewide analysis of incidents. The continuous review and analysis of reported incidents at the provider, county and State levels is aimed at uncovering trends and formulating action to prevent recurrence.

Reportable incidents are to be submitted electronically by means of a web-based system developed by the OMR. The methodology for reporting incidents in the web-based system is documented in a user manual that will be available prior to the effective date of the subchapter.

The incident management processes described in this subchapter expect that certified investigators conduct investigations at the provider, county and State levels. This will assure that all incidents, which require investigation, receive a thorough investigation that meets established standards. A training program and certification process will be established by the OMR.

This subchapter is also applicable to individuals or families who are their own providers.

In addition to the OMR reporting processes described in this statement of policy, reporting requirements of other laws, regulations and policies must also be followed.

Effective Date

The amendments are effective March 25, 2002.

Contact Person

Any comments and questions regarding subchapter should be sent to Paul Hindman, Bureau of Quality Improvement and Policy, 401 Health and Welfare Building, Harrisburg, PA 17105, (717) 783-5771, phindman@state.pa.us.

(Editor's Note: The regulations of the Department are amended by amending a statement of policy by deleting §§ 6000.401—6000.404, 6000.411—6000.414, 6000.421—6000.427, 6000.431—6000.435, 6000.441—6000.445, 6000.451 and 6000.452 and by adding §§ 6000.461—6000.474, to read as set forth in Annex A.

FEATHER O. HOUSTOUN,

Secretary

Fiscal Note: 14-BUL-062. (1) General Fund; (2) Implementing Year 2001-02 is \$639,000; (3) 1st Succeeding Year 2002-03 is \$192,000; 2nd Succeeding Year 2003-04 is \$186,000; 3rd Succeeding Year 2004-05 is \$186,000; 4th Succeeding Year 2005-06 is \$186,000; 5th Succeeding Year 2006-07 is \$186,000; (4) 2000-01 Program—\$575,178,000; 1999-00 Program—\$527,401,000; 1998-99 Program—\$497,360,000; (7) Community MR Services; (8) recommends adoption. This statement of policy establishes

procedures for the reporting, investigating and follow-up of incidents in the mental retardation service system. The costs outlined provide for a training program and will be matched with Federal Medical Assistance funds of \$360,000 in 2001-2002, \$108,000 in 2002-2003 and \$105,000 in 2003-2004 and subsequent years.

Annex A

TITLE 55. PUBLIC WELFARE

PART VIII. MENTAL RETARDATION MANUAL

Subpart A. STATEMENTS OF POLICY

CHAPTER 6000. STATEMENTS OF POLICY

Subchapter D. INCIDENT MANAGEMENT

§§ 6000.401—6000.404. (Reserved).

§§ 6000.411—6000.414. (Reserved).

§§ 6000.421—6000.427. (Reserved).

§§ 6000.431—6000.435. (Reserved).

§§ 6000.441—6000.445. (Reserved).

§ 6000.451. (Reserved).

§ 6000.452. (Reserved).

§ 6000.461. **Applicability.**

This subchapter provides a consistent system for protecting the health and safety, enhancing the dignity, and protecting the rights of individuals receiving supports and services. These procedures apply to licensed facilities, and nonlicensed county mental retardation funded programs serving persons with mental retardation.

§ 6000.462. **Optional applicability.**

Facilities are obligated to comply with Chapters 2380, 2390, 6400, 6500 and 6600. To the extent that this subchapter exceeds the requirements of Chapters 2380, 2390, 6400, 6500 and 6600, the use of this subchapter is optional for facilities until regulations are published. Because this subchapter meets or exceeds the regulatory requirements in Chapters 2380, 2390, 6400, 6500 and 6600, compliance with the reporting procedures in this subchapter will be accepted by the Department as meeting the regulatory requirements of §§ 2380.17, 2390.18, 6400.15, 6500.20 and 42 CFR 483.420(d)(2) (relating to condition of participation: Client procedures).

§ 6000.463. **Incident management process.**

(a) Providers are to:

(1) Promote the health, safety, rights and dignity of individuals receiving services.

(2) Develop provider-specific policy/procedures for incident management.

(3) Ensure that staff and others associated with the individual have proper orientation and training to respond to, document and prevent incidents.

(4) Provide ongoing training to individuals and families on the recognition of abuse and neglect.

(5) Assure when incidents occur that affect a person's health, safety or rights, that the people who are present:

(i) Take prompt action to protect the person's health, safety and rights. This includes separation of the target when the individual's health or safety, or both, is jeopardized. This separation shall continue until an investigation is completed. In addition, the target may not be permitted to work directly with any other service recipient during the investigation process. When the target is

another individual receiving supports or services, and complete separation is not possible, the provider shall institute additional protections.

(ii) Notify the responsible person, designated in provider policy.

(6) Assign trained individuals "point persons" to whom incidents are reported when they occur and who will make certain that all immediate steps to assure health and safety have been implemented and follow the incident through closure.

(7) Input data.

(8) Contact appropriate law enforcement agencies when there is suspicion that a crime has occurred.

(9) Comply with applicable laws, regulations and policies.

(10) Conduct certified investigations.

(11) Analyze the quality of investigations.

(12) Respond to concerns from individuals/family about the reporting and investigation processes.

(13) Inform the family of the incident.

(14) Notify the family of the findings of any investigation.

(15) Maintain an investigation file within the agency.

(16) Create an incident management process which:

(i) Designates an individual with overall responsibility for incident management.

(ii) Considers possible immediate and long-term effects to the individual resulting from an incident or multiple incidents.

(iii) Relies on trend analyses to identify systemic issues.

(iv) Analyzes and shares information with relevant staff, including direct care staff.

(v) Analyzes the quality of investigations.

(vi) Periodically assesses the effectiveness of the incident management process.

(vii) Monitors quality and responsiveness of all ancillary services (such as health, therapies, and the like) and acts to change vendors or subcontractors, or assists the individual to file available grievances or appeals procedures to secure appropriate services.

(b) Counties are to:

(1) Promote the health, safety, rights and dignity of individuals receiving services.

(2) Develop county policies and procedures necessary to implement this subchapter and submit them to the Office of Mental Retardation (OMR) for approval by March 25, 2002.

(3) Have an administrative structure sufficient to meet the mandates of this subchapter:

(i) Designate an individual with overall responsibility for incident management.

(ii) Train staff in incident management procedures.

(iii) Assure that supports coordinators are notified of all incidents.

(iv) Assure that supports coordinators have proper orientation and training to respond to, document and prevent incidents.

(v) Support providers with appropriate training and resources to meet the mandates of this subchapter.

(4) Provide ongoing training to individuals, families, guardians and advocates regarding their rights, roles and responsibilities that are outlined in this subchapter.

(5) Provide training to individuals and families on the recognition of abuse and neglect.

(6) Have the incident management processes in this subchapter referenced in county/provider contracts.

(7) Maintain an investigation file within the county.

(8) Create an incident management process which:

(i) Assures accuracy of incident reports.

(ii) Reviews and closes all provider generated incidents.

(iii) Reviews and analyzes data.

(iv) Identifies and implements individual and systemic changes based on data analysis.

(v) Analyzes and shares information with relevant staff.

(vi) Regularly reviews trend and occurrence data compiled by providers.

(vii) Assesses provider's incident management and investigative processes.

(viii) Assures provider compliance with plans of correction resulting from incidents and investigations.

(9) Conduct certified investigations.

(10) Analyze the quality of investigations.

(11) Respond to concerns from individuals/family about the reporting and investigation processes.

(12) In collaboration with the individual's planning team, revise the individual's plan as needed in response to issues surfaced through the incident management process.

(13) Comply with applicable laws, regulations and policies.

(14) Coordinate with other agencies as necessary.

(15) Input data.

(16) When the county is the initial reporter of the incident, the county will assume the responsibility of the point person.

(c) The OMR is to:

(1) Promote the health, safety, rights and dignity of individuals receiving services.

(2) Develop a web-based electronic data management system.

(3) Create an incident management review process which:

(i) Maintains the Statewide data system.

(ii) Analyzes data for Statewide trends and issues.

(iii) Identifies issues and initiates systemic changes and provides periodic feedback.

(iv) Evaluates county and provider reports and analysis of trends.

(4) Monitor implementation of this subchapter.

(5) Approve provider and county policies and procedures relative to incident management.

(6) Support providers and counties with appropriate training to meet the mandate of this subchapter.

(7) Certify investigators.

(8) Provide support and technical assistance to counties to implement the incident reporting system.

(9) Conduct certified investigations.

(10) Analyze the quality of investigations.

(11) Respond to concerns from individuals/families about the reporting and investigation processes.

(12) Review and revise this subchapter as needed.

(13) Assure compliance with applicable laws, regulations and policies.

(14) Coordinate with other agencies as necessary.

§ 6000.464. Reporting.

(a) Anyone who receives funds from the mental retardation system, either directly or indirectly, to provide or secure supports or services for individuals authorized to receive services from the county mental retardation program and employees, subcontractors and volunteers of facilities licensed by the Department of Public Welfare, Office of Mental Retardation (OMR) are to report incidents as defined within this subchapter to the county and the OMR.

(b) When providing services in the home of an individual or his family, providers, their employees or contracted agents are to report incidents that occur when they are present in the home. Additionally, providers, their employees or contracted agents are to report suspected or alleged abuse of which they become aware, regardless of whether they were providing services at the time the alleged abuse occurred. They also are to report the death of any individual to whom they are providing services. When an individual receives only case management services, the supports coordinator is to report incidents of suspected abuse and death whenever the coordinator learns of them.

(c) Reportable incidents shall be submitted electronically by means of a web-based system approved by the OMR. If an agency is not able to submit an electronic report due to system failure, the initial notification should be made to the appropriate regional office. Once the system is again available the incident shall also be entered into the web-based system.

§ 6000.465. Reportable incidents.

(a) *Abuse.* Abuse is the infliction of injury, unreasonable confinement, intimidation, punishment, mental anguish, sexual abuse or exploitation which includes the following:

(1) *Neglect.* The failure to obtain or provide, or both, the needed services and supports defined as necessary in the individual's plan or otherwise required by law or regulation.

(i) Neglect includes the failure to provide needed care such as shelter, food, clothing, attention and supervision, including leaving individuals unattended, personal hygiene, medical care, protection from health and safety hazards, and other basic treatment and necessities needed for development of physical, intellectual and emotional capacity and well being.

(ii) Neglect includes acts that are intentional or unintentional regardless of the obvious occurrence of harm.

(2) *Physical abuse.* An intentional physical act by an individual, staff or other person, which causes or may cause physical injury to an individual, such as striking or kicking, applying noxious or potentially harmful sub-

stances or conditions to an individual. Physical abuse also includes the improper or unauthorized use of restraint.

(3) *Psychological abuse.* Acts, other than verbal, which may inflict emotional harm, invoke fear or humiliate, intimidate, degrade or demean an individual.

(4) *Sexual abuse.* Acts or attempted acts such as rape, incest, sexual molestation, sexual exploitation or sexual harassment and inappropriate or unwanted touching of an individual by another.

(i) Sexual contact between a staff person and an individual is abuse.

(ii) Any sexual exposure of a staff person to an individual is also considered abusive.

(5) *Verbal abuse.* Verbalizations that inflict or may inflict emotional harm, invoke fear or humiliate, intimidate, degrade or demean an individual.

(b) *Accident or injury requiring treatment beyond first aid.*

(1) Any accident or injury that requires the provision of medical treatment beyond that traditionally considered first aid is reportable:

(i) First aid includes assessing a condition, cleaning an injury, applying topical medications, applying a Band-Aid, and the like.

(ii) Treatment beyond first aid includes lifesaving interventions such as CPR or use of the Heimlich maneuver, wound closure by a medical professional, casting or otherwise immobilizing a limb, and the like.

(2) Treatment of an acute or chronic illness, or the assessment of a condition without treatment, by a medical or health professional is not reportable unless otherwise covered (that is, the treatment is provided in an emergency room) except in those instances when the acute illness being treated is one of those contained on the list of reportable diseases published by the Department of Health.

(i) An incident report is required only when the reportable disease is initially diagnosed. Incident reports are not required when an individual receives follow-up treatment of this illness unless the event is otherwise covered (that is, the treatment is provided on an in-patient basis in a hospital).

(ii) Evaluation/assessment of an injury by emergency personnel in response to a "911" call is reportable even if the individual is not transported to an emergency room.

(c) *Death.* Deaths are reportable.

(d) *Emergency closure.* An unplanned situation, which forces the closure of a home or program facility for 1 or more days, is reportable. This category does not apply to individuals who reside in the home of a family member.

(e) *Emergency room visit.* Any use of a hospital emergency room is reportable. This includes situations that are clearly emergencies as well as those when an individual is directed to an emergency room in lieu of a visit to the primary care physician (PCP) or as the result of a visit to the PCP.

(f) *Fire.* A fire or other situation that requires the active involvement of fire personnel, that is, extinguishing a fire, clearing smoke from the premises, responding to a false alarm, and the like, is reportable. Situations which require the evacuation of a facility in response to suspected or actual gas leaks or carbon monoxide alarms,

or both, are reportable. Situations in which staff extinguish small fires without the involvement of fire personnel are reportable.

(g) *Hospitalization.* An inpatient admission, excluding a psychiatric admission, to an acute care facility for purposes of treatment is reportable. Scheduled treatment of medical conditions on an outpatient basis is not reportable.

(h) *Law enforcement activity.*

(1) The involvement of law enforcement personnel is reportable in the following situations:

(i) An individual is charged with a crime or is the subject of a police investigation, which may lead to criminal charges.

(ii) An individual is the victim of a crime, including crimes against the person or their property (such as, vandalism, break-ins, harassment, and the like).

(iii) An on-duty employee or an employee who is volunteering during off duty time, who is charged with an offense, a crime or is the subject of an investigation.

(iv) A volunteer who is charged with an offense, a crime or is the subject of an investigation resulting from actions or behaviors that occurred while volunteering.

(v) Crisis intervention involving police/law enforcement personnel.

(vi) Agency staff cited for a moving violation while operating an agency vehicle, or while transporting individuals in a private vehicle.

(2) Minor traffic accidents that result in no injury are not reportable unless otherwise covered.

(i) *Medication error.* Reportable medication errors include the following:

(1) *Wrong medication.* When an individual receives and takes medication that is not the individual's medication. This includes medication intended for another person, discontinued medication and inappropriately labeled medication.

(2) *Wrong dose.* When an individual receives the wrong dosage of medication.

(3) *Omission.* When an individual does not receive a prescribed dose of medication. Omission includes medication that is not available because a prescription has not been filled or if the medication is not available for any other reason. Omission does not include an individual refusing to take the medication.

(j) *Missing person.* A person is considered missing and reportable when the person is out of contact with staff for more than 24 hours without prior arrangement or if the person is in immediate jeopardy, when missing for any period of time.

(1) A person with good survival skills may be considered in "immediate jeopardy" based on the person's personal history and may be considered "missing" before 24 hours elapse.

(2) It is considered a reportable incident whenever the police are contacted about an individual or the police independently find and return the individual, or both, regardless of the amount of time the person was missing.

(k) *Misuse of funds.*

(1) An intentional act or course of conduct, which results in the loss or misuse of an individual's money or personal property is reportable including the following:

(i) Requiring an individual to pay for an item or service that is normally provided as part of the individual's plan of support is considered financial exploitation and is reportable.

(ii) Requiring an individual to pay for items that are intended for use by several individuals is also considered financial exploitation.

(2) Individuals may voluntarily make joint purchases with other individuals of items that benefit the household.

(l) *Psychiatric hospitalization.* An inpatient admission to a psychiatric facility, including crisis facilities and the psychiatric departments of acute care hospitals, for the purpose of evaluation or treatment, or both, whether voluntary or involuntary is reportable as follows:

(1) Includes admissions for 23-hour observation.

(2) Includes those for the review or adjustment, or both, of medications prescribed for the treatment of psychiatric symptoms or for the control of challenging behaviors.

(m) *Restraints.*

(1) Restraint consists of physical, chemical or mechanical intervention used to control acute, episodic behavior that restricts the movement or function of the individual or portion of the individual's body, including those that are approved as part of an individual's plan or those used on an emergency basis. Improper or unauthorized use of restraint is considered abuse and shall be reported under the abuse category.

(i) *Physical.* A physical, or manual restraint is a physical hands-on technique that last more than 30 seconds, used to control acute, episodic behavior that restricts the movement or function of an individual or portion of an individual's body such as a basket hold and prone or supine containment.

(ii) *Mechanical.* A mechanical restraint is a device used to control acute, episodic behavior that restricts the movement or function of an individual or portion of an individual's body. Examples of mechanical restraints include anklets, wristlets, camisoles, helmets with fasteners, muffs and mitts with fasteners, poseys, waist straps, head straps, restraining sheets and similar devices. A device used to provide support for functional body position or proper balance and a device used for medical treatment, such as a wheelchair belt or helmet for prevention of injury during seizure activity are not considered mechanical restraints.

(iii) *Chemical.* A chemical restraint is a drug used to control acute, episodic behavior that restricts the movement or function of an individual. A drug ordered by a licensed physician as part of an ongoing treatment program is not a chemical restraint. A drug ordered by a licensed physician for a specific, time-limited stressful event or situation to assist the individual to control the individual's own behavior, is not a chemical restraint. A drug ordered by a licensed physician as pretreatment prior to medical or dental examination or treatment is not a chemical restraint.

(2) The documentation of restraint usage does not include:

(i) The use of a protective device as defined within applicable regulations.

(ii) The use of a safety or support device designed to assure proper body positioning or balance, and the like.

(iii) The use of restraints authorized/ordered by a physician or dentist during the provision of medical/dental treatment by the medical practitioner, while an individual is hospitalized, or to prevent aggravation while an injury is healing.

(n) *Rights violation.* An act, which is intended to improperly restrict or deny the human or civil rights of an individual, including those rights which are specifically mandated under applicable regulations is reportable. Examples would include the unauthorized removal of personal property, refusal of access to the telephone, privacy violations, breach of confidentiality, and the like. Restrictions that are imposed by court order or consistent with a waiver of licensing regulations are not included.

(o) *Suicide attempt.* The intentional and voluntary attempt to take one's own life is reportable. A suicide attempt is limited to the actual occurrence of an act and does not include suicidal threats.

§ 6000.466. Sequence of reporting.

Many real life occurrences may result in events that may be classified under multiple types of incidents. In an attempt to assist the point person in identifying an appropriate order for reporting incidents that may be classified under multiple categories, the following sequence is suggested. This sequence may not be appropriate in all situations but should be used as a guide in selecting the most appropriate category.

- (1) Death.
- (2) Suicide attempt.
- (3) Hospitalization or psychiatric hospitalization.
- (4) Emergency room visit.
- (5) Neglect, physical abuse, psychological abuse, sexual abuse or verbal abuse.
- (6) Missing person.
- (7) Accident or injury requiring treatment beyond first aid.
- (8) Physical restraint, mechanical restraint or chemical restraint.
- (9) Fire.
- (10) Misuse of funds.
- (11) Rights violation.
- (12) Law enforcement activity.
- (13) Medication error.
- (14) Emergency closure.

§ 6000.467. Reporting roles.

(a) *Initial reporter.*

(1) The initial reporter is the person on the scene who witnesses the incident or is the first to discover or be made aware of the signs of an incident.

(i) The initial reporter first responds to the situation by securing the safety of the individuals involved.

(ii) As soon as the immediate needs of the persons have been met, the reporter notifies the provider point person of the incident.

(iii) The initial reporter receives instructions on next steps to take.

(iv) The initial reporter then documents observations.

(2) In cases of alleged abuse or neglect, the initial reporter shall comply with all applicable laws and regulations.

(b) *Point person.*

(1) This role is pivotal in the incident management process.

(2) A point person is a person authorized in policy to:

(i) Receive verbal reports of incidents.

(ii) Ensure that web-based reports are submitted.

(iii) Communicate with others involved in the investigation.

(iv) Follow-up and review of the incident.

(3) When an incident is reported, the point person shall:

(i) First confirm that appropriate actions have been taken or order additional actions to secure the safety of the individuals involved in the incident.

(ii) Assure notification requirements of the Older Adults Protective Services Act (35 P. S. §§ 10211—10224) and 23 Pa.C.S. §§ 6301—6384 (relating to Child Protective Services Law) are met.

(iii) Determine whether an investigation or other follow-up is needed.

(iv) Secure the scene when an investigation is needed.

(v) Determine if an incident should be a site report or multiple individual reports.

(vi) Assure that, when needed, an investigator is promptly assigned.

(vii) Notify appropriate supervisory/management personnel within 24 hours of the incident, as specified in provider or county internal policies.

(viii) Initiate the web-based initial notification within 24 hours.

(ix) Notify the family within 24 hours unless otherwise indicated by the individual.

(4) As a general rule, the person who begins as point person should be the person who follows an incident through closure. However, there may be more than one point person identified by an agency.

§ 6000.468. Standardized incident report time frames.

Incident reports are to be submitted electronically through a web-based system approved by the Office of Mental Retardation (OMR). This electronic system will conform to the three time frames for submission specified in this subchapter. The three-time frame sections are:

(1) *Initial notification.* Due within 24 hours of the incident or within 24 hours of when the provider learns of the incident.

(2) *Incident report.* Due within 5 days of the incident or of the date when the provider learns of the incident.

(3) *Final report.* Due when the incident is finalized by the provider, with an outside limit of 30 days from the date of the incident or of the date the provider learns of the incident unless notification of an extension has been generated. If the provider agency determines that he will not be able to meet the reporting time frames of the final report, notification of the extension shall be made to the county and the regional office of OMR prior to the expiration of the 30-day period.

§ 6000.469. Standardized incident reports.

(a) *Initial notification.* The initial notification shall include the following:

(1) The name of the individual involved/affected by the incident. If the incident involves several individuals, all names and other identifying information may be submitted as part of a single "site" report.

(2) The primary and secondary nature of the incident, based on the "reportable incidents" definitions in § 6000.465 (relating to reportable incidents).

(3) The actions taken to address the incident.

(4) The current status of the individual.

(5) The date and time when the incident occurred or was recognized/discovered.

(6) The location where the incident occurred.

(7) The name and address of the provider agency or other person/entity submitting the initial notification.

(8) The name of the person making the initial report.

(9) The name of the point person who has assumed responsibility for follow-up of the incident.

(10) A determination of whether or not an investigation is needed.

(11) The home address of the individual.

(12) The individual's date of birth.

(13) The individual's base service unit number. If the incident involves several individuals, all names and other identifying information may be submitted as part of a single site report.

(14) The date and time of the initial notification.

(15) A description of the immediate and subsequent steps taken by the point person or other representatives of the provider to assure the individual's health, safety and response to the incident, including date, time and by whom those steps were taken.

(16) An identification of all persons to whom the initial notification has been (or will be) submitted (that is, family, law enforcement agency, and the like).

(i) The date and time of the notifications.

(ii) The method (phone, fax, electronic, and the like) by which the notification was made.

(iii) The person who has/will notify the necessary parties.

(b) *Incident report.* The incident report will contain all of the information included on the initial notification and add:

(1) An indication if the incident report will be the final report.

(2) A current update on the individual's status.

(3) A change of classification or additional information on the nature of the incident, if applicable.

(4) Narrative description of the incident completed by staff or other persons who were present when the incident occurred or who discovered that an incident had occurred. The narrative description may be summarized by the provider but the written statements of the persons directly involved shall be available for review, if needed.

(5) An identification of other persons who may have witnessed or been directly involved in the incident.

(6) A specific description of any injury received by the individual, including the cause, effect and the body part involved.

(7) Specific sign and symptoms of any illness (acute or chronic), which may be contributory to the incident.

(8) If the incident involves an illness or injury:

(i) The name of the practitioner/facility by whom the individual was treated initially.

(ii) The date and time of the initial contact with a health-care/medical practitioner.

(iii) The nature/content of the initial treatment/evaluation.

(iv) The nature of, date of, time of, and practitioner involved in subsequent treatments, evaluations, and the like.

(9) If the individual has been hospitalized, the name and address of the hospital, the admitting diagnoses, the estimated (or actual) date of discharge and the discharge diagnoses.

(10) Background information on the individual, including level of mental retardation, pertinent medical history, diagnoses, and the like.

(11) The name of the certified investigator assigned, if the incident requires investigation and the date on which the investigation began.

(12) If the incident involves an allegation of abuse, current status of the target of the investigation, if one has been identified.

(13) If the nature of the incident requires contact with local law enforcement:

(i) The name and department/office of the persons contacted.

(ii) The date and time of the contact.

(iii) The name of the person who initiated the contact.

(iv) A description of any steps taken by law enforcement officials.

(c) *Final report.* The final report will be completed by the provider and will retain the information from the initial notification and incident report and will add the following:

(1) Present status of the individual in reference to the incident.

(2) Summary of the investigator's findings and conclusions.

(3) If the incident involves an allegation of some type of abuse/neglect, the conclusion reached on the basis of the investigation (that is, the allegation is confirmed, not confirmed, inconclusive, and the like) and the status of the target.

(4) Description of the steps taken by the provider in response to the conclusions reached as a result of the investigation.

(5) Verification by the provider that all necessary corrective actions have been identified.

(6) If any corrective action cannot/has not been completed by the time the final report is submitted, the expected date of completion shall be provided along with the identity of the person responsible for carrying the extended action through to completion.

(7) If the incident involves an injury of unknown origin, confirmation of the cause if one has been identified and steps taken to prevent recurrence.

(8) Description of changes in the individual's plan of support necessitated by or in response to the incident.

(9) If the individual was hospitalized, the final report shall include an indication that the hospital discharge summary was provided, a summary of its contents and a description of any plans for subsequent medical follow-up.

(10) Documents, which are not immediately available, shall be forwarded to the appropriate county, the appropriate regional office and other appropriate parties as they become available. If, after attempting to acquire the document it is determined to be unobtainable the expecting party will be notified. If the individual is deceased, the final report shall be supplemented by a hardcopy of the information included as information included as follows:

(i) A lifetime medical history.

(ii) A copy of the death certificate.

(iii) An autopsy report if one has been completed.

(iv) A discharge summary from the final hospitalization if the individual died while hospitalized.

(v) The results of the most recent physical examination.

(vi) The most recent health and medical assessments.

(11) The name and address of the family member notified of the results of the investigation.

(12) A date on which the incident was considered "finalized" by the provider and the name and title of the provider representative who made the finalization determination.

(i) An incident is "finalized" when the report is complete, investigation is complete, and all required follow-up has been identified. This should normally happen within 30 days of the incident or first knowledge of the incident by the provider, unless an extension has been generated.

(ii) After final submission by the provider, the county or Office of Mental Retardation will perform a management review and close the incident.

§ 6000.470. Investigation process.

(a) A reportable incident may be investigated by the provider, county or the Office of Mental Retardation (OMR).

(b) Certain designated incidents are to be investigated, either jointly or independently, by the provider, the county or OMR.

(c) All of these designated investigations are to be conducted by certified investigators.

(d) The involvement of the county or OMR, or both, may not hinder the prompt investigation by the provider.

(e) Investigations are to be completed on a standardized investigation format and according to standard investigation procedures. The standard format is included in the *Pennsylvania Certified Investigation Manual* that can be found at www.omrinvestigators.com.

(f) Criteria will be developed by OMR regarding the scope and nature of death investigations.

(g) The training and certification of personnel to conduct investigations will be provided for by OMR.

(h) When an incident requires investigation, the provider point person shall assure that a certified investigator is designated to conduct the investigation.

(i) The county/OMR may determine a need to conduct its own investigation following review of the provider investigation or based upon an analysis of incidents and trends.

(j) The following indicates what incidents require investigation by the provider:

- (1) Accidental injury requiring hospitalization.
- (2) Unexplained injury requiring hospitalization or emergency room treatment.
- (3) Staff to individual injury requiring hospitalization or emergency room treatment or treatment beyond first aid.
- (4) Allegation or finding of abuse.
- (5) Rights violation.
- (6) Misuse of funds.

(k) The following indicates what incidents require investigation by the provider and the county:

(1) An injury resulting from restraint requiring hospitalization or emergency room treatment or treatment beyond first aid.

(2) An allegation or finding of abuse involving improper or unauthorized use of restraint.

(l) The following indicates what incidents require investigation by the provider and DPW/OMR or Department of Health (with county participation as requested by OMR): deaths of individuals who reside in provider-operated settings.

(m) The following indicates what incidents require investigation by the county or OMR: any reportable incident, in which the CEO or board of directors of an organization is the target of the investigation, requires outside investigation.

§ 6000.471. Certified investigators.

(a) Certified investigators are people who:

(1) Have been trained according to Office of Mental Retardation (OMR) specifications.

(2) Have received a certificate in investigation from OMR.

(b) Providers, counties and OMR shall have certified investigators available to conduct investigations.

(c) To be a certified investigator a person shall:

- (1) Be a high school graduate.
- (2) Be 21 years of age or older.

(3) Meet the criminal background requirements of the Older Adults Protective Services Act (35 P. S. §§ 10211—10224) and 23 Pa.C.S. §§ 6301—6385 (relating to Child Protective Services Law).

(4) Successfully complete the training.

(d) Training and testing requirements are as follows:

(1) Training and testing will be required for certification as an investigator.

(2) Persons who have taken the course "Conducting Serious Incident Investigation" after October 1, 1998, offered by Labor Relations Alternatives, Inc, may apply to take a test to be certified without needing to retake the course.

(3) Only those who pass the test will be certified.

(e) The following apply to certification:

(1) Certification is good for 3 years.

(2) At least once every 3 years certified investigators shall participate in a refresher class to be certified.

(3) Investigators shall have conducted a minimum of three investigations since being certified.

(4) Certification may be withdrawn by OMR for cause.

§ 6000.472. Investigation protocol.

(a) The Office of Mental Retardation (OMR) will establish a protocol for the conduct of investigations.

(b) At a minimum, the investigation protocol will include:

- (1) A process for addressing conflict of interest.
- (2) Establishing the purpose of the investigation.
- (3) Interviewing.
- (4) Gathering evidence.
- (5) Weighing credibility.
- (6) Reporting findings.
- (7) Conclusions.

(c) The investigation record shall include:

- (1) The incident report.
- (2) Evidence.
- (3) Witness statements.
- (4) The certified investigator's report.

(i) The investigation record shall be secured and separate from the individual's record.

(ii) A summary of the investigator's report shall be entered into the standardized web-based incident report.

(iii) Families and individuals shall be notified of the outcome of all investigations.

§ 6000.473. Data and information analysis.

(a) *Provider role.* Trend analysis is one of the critical uses of the data, which accumulate when incidents are reported and documented in a database. Trend analyses provide the agency, the county and the Office of Mental Retardation (OMR) with insights into specific issues that cannot be gained from the review of individual reports. As part of an ongoing risk management/quality improvement process, the provider may choose to examine different questions or analyze a specific trend, or both, at regular intervals.

(1) Some suggested areas for trend analysis are as follows which is not an all-inclusive list:

(i) The same things happening to the same individuals over a period of time.

(ii) Different things happening to the same person over time.

(iii) The same things happening across groups over time.

(iv) Involvement of the same staff.

(v) A cluster of incidents that are outside the norm.

(vi) Variations from the norm over time.

(vii) Variables that impact on incidents.

(viii) Impact of place, time, and the like.

(ix) The nature of injury.

(x) High occurrence by type (locked in vehicles, left at site unattended by para transit, and the like).

- (xi) Low or no reporting.
 - (xii) A typical risk or atypical risk.
 - (xiii) Process analysis/time needed to bring closure.
 - (xiv) The causes of hospitalization (including psychiatric diagnoses).
 - (xv) The causes of death (especially those that are sudden and unexpected).
 - (xvi) Positive findings after allegations.
 - (xvii) The impact of changes on subsequent rate of events.
 - (xviii) A comparison of staff vacancy rate with rate/type of incidents.
 - (xix) A comparison of variables (turnover rate, use of overtime).
 - (xx) The average number of incidents per person supported (changes over time, locales).
 - (xxi) The changes in rate of incidents as models of support change.
 - (xxii) Agency issues (increase in medication errors since, and the like).
- (2) The provider review process shall include review of all incident reports and investigation.
- (i) Incident reports shall be reviewed individually to determine if provider action has been appropriate and sufficient.
 - (ii) Incident reports to be reviewed in aggregate to determine if trends may be developing that warrant further intervention for the individual or systemic intervention, beyond what may have been taken in response to the individual incident.
- (3) The provider's administrative responses may include the following:
- (i) Referral to the Health Care Quality Unit (HCQU).
 - (ii) Revision of an individual plan.
 - (iii) Other action necessary to promote the health, safety and rights of individuals served by the provider.
- (4) Using system generated data, the provider shall complete and file quarterly reports with the county within 30 days of the end of the calendar quarter that include:
- (i) Incidents per month by individual and site.
 - (ii) Summary comparisons to prior 4 quarters.
 - (iii) Incidents requiring investigation by individual and site.
 - (iv) Results of investigations (confirmed, unconfirmed and inconclusive).
 - (v) Actions to be taken in response to the conclusion/determination.
 - (vi) Analysis of increases/decreases in numbers and types of incidents from previous quarter and previous year by individual, by location.
 - (vii) Analysis of individuals with three or more incidents during the reporting period to detect patterns or connections.
 - (viii) Analysis of significant factors that may influence the data.
 - (ix) Qualitative analysis of investigations conducted.

(x) Analysis of the implementation of corrective actions during the reporting period.

(xi) Discussion of special areas of concerns identified in the review process.

(b) *County role.*

(1) The county shall have procedures for the review and analysis of system generated data on all reported incidents. The procedures shall include at least quarterly reviews to determine what trends may be developing.

(2) The county shall report an incident data to OMR at least semiannually on June 1st and December 1st of each year. The report to OMR shall include at a minimum:

(i) Incidents by provider by quarter for the reporting period.

(ii) Summary comparisons of provider data for the past four quarters.

(iii) Incidents requiring investigation by provider.

(iv) Incidents requiring investigation by the county.

(v) Analysis of increases/decreases in numbers and types of incidents from previous reporting period.

(vi) Analysis of individuals with six or more incidents during the reporting period.

(vii) Analysis of significant factors that may influence the data.

(viii) Analysis of the implementation of corrective actions during the reporting period.

(ix) Discussion of special areas of concerns identified in the review process.

(x) A mechanism to communicate the results of its analyses to the providers.

(xi) Discussion of joint actions between the county and the provider to reduce incidents.

(3) Based on trend analysis, counties and HCQUs jointly determine the need for technical assistance.

(c) *The HCQU role.* The HCQU shall have access to incident data from counties with whom they serve. The HCQU shall review data:

(1) Related to medication errors, emergency room visits, inpatient hospitalizations, suicide attempts deaths and other health related matters.

(2) To determine where trends suggest training, a change in procedures, or where medical supports are needed.

(3) Based on trend analysis, counties and HCQU's jointly determine the need for technical assistance.

(d) *The OMR role is as follows:*

(1) OMR will review data on all reported incidents at least semiannually to determine what trends may be developing Statewide or by county and take appropriate administrative steps to intervene.

(2) The OMR will issue an annual report reviewing Statewide incident trends.

§ 6000.474. Families.

The Office of Mental Retardation (OMR) joins families in concern about the health and safety of their relatives who receive supports and services through its licensed and funded programs. This subchapter specifies the process for providers, counties and the OMR to report and investigate incidents that jeopardize the health and

safety of individuals receiving services. In addition to the requirements placed on those providing and overseeing services, the OMR also relies on families to report incidents that may affect the family member's health and safety.

(1) *Notification to families.* Family members of individuals who receive services outside the family home, have a right to receive timely, accurate and complete information regarding their relative's health and safety. Unless otherwise indicated by family members receiving services outside the family home:

(i) Family members shall be notified of the reportable incidents.

(ii) Family members shall be notified with 24 hours of occurrence or when they are discovered.

(iii) Family members shall be notified of the outcome of any investigation when it is complete.

(2) *Notification of incidents by families.*

(i) If a family member observes or suspects abuse, neglect or inappropriate conduct, whether services are provided out of the home or in the home, the family member should contact the county supports coordinator and may also contact OMR directly at 1-888-565-9435.

(ii) In the event of a death, the family is to notify the supports coordinator. The supports coordinator assumes the role of the point person as described in § 6000.467 (relating to reporting roles).

(3) *When services are provided in the family's home.*

(i) An increasing number of individuals are supported in their own homes or the homes of their families. When services are provided in the home of an individual or his family:

(A) Provider employees or their contract agents shall report incidents involving the individual receiving services that occur when they are present in the home.

(B) Providers or their contract agents shall report possible abuse of which they become aware regardless of whether they are present at the time or whether it involves a paid caregiver.

(C) If the family observes inappropriate conduct, it should contact the supports coordinator to initiate an incident report or they may also contact OMR directly at 1-888-565-9435.

(D) When a family reports questionable conduct that may constitute abuse, an investigation shall be conducted by a certified investigator.

(E) If a provider staff is present when an incident occurs or becomes aware of abuse, the provider shall report the incident in Home and Community Based Services Information System (HCSIS). The provider is responsible for investigating the situations that directly involve its staff or volunteers.

(F) If provider staff observes abuse that does not involve the provider staff, the provider should report the situation to the supports coordinator who will assume the role of point person and file an incident report in HCSIS. The supports coordinator in conjunction with the county Incident Manager will determine if a certified investigator will investigate or a referral to Childline or law enforcement, or both, will be made. The county certified investigator will document in HCSIS either the summary of the investigator's investigation or that of Childline/law enforcement.

(ii) Families are encouraged to cooperate to assure fairness and accuracy of the report.

(4) *When the family is the provider of service.*

(i) When a family member is the provider, that is, is identified in the individual plan as the provider and is receiving remuneration, incidents needing investigation by the provider (see § 6000.465 (relating to reportable incidents)) shall be reported to the supports coordinator who will initiate an incident report.

(ii) If that the family provider is the target of an investigation, the family provider may request that the county assign a certified investigator, unrelated to the target, that is also a family member of a person with mental retardation.

(5) *When individuals and families purchase community services.* Families and individuals may purchase services from community organizations and individual people who are not licensed or otherwise regulated by the OMR, who have no contractual relationship with the county and who are therefore not covered by this subchapter.

(i) Entities such as YM/WCAs, community recreational programs, adult education programs and clubs are included.

(ii) If individuals or family members become aware of abuse or neglect involving these entities or organizations, a report of the incident shall be made to their supports coordinator or OMR at 1-888-565-9435.

(6) *Incidents involving children 18 and under.* Any act of abuse or neglect which constitutes criminal conduct shall be reported under 23 Pa.C.S. §§ 6301—6385 (relating to Child Protective Services Law), if applicable, and to local law enforcement. Families may contact their support coordinator for assistance in making the reports.

(7) *Reporting deaths.* Death of a family member can be an emotionally trying time and the sympathies of the people who are responsible to administer supports and services shall be extended to family members at those times. Family members shall notify the supports coordinator of the death of an individual receiving services as soon as possible.

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