

Attachment B – Appendix G Current Language

Appendix G: Participant Safeguards

Appendix G-1: Response to Critical Events or Incidents

- a. **State Critical Event or Incident Reporting Requirements.** Specify the types of critical events or incidents (including alleged abuse, neglect and exploitation) that the State requires to be reported for review and follow-up action by an appropriate authority, the individuals and/or entities that are required to report such events and incidents and the timelines for reporting. State laws, regulations, and policies that are referenced are available to CMS upon request through the Medicaid agency or the operating agency (if applicable).

Entities required to report critical events have been identified in ODP Bulletins and Regulations. The entities required to report critical events (or “incidents” as defined by ODP in Pennsylvania) are defined in ODP Incident Management Bulletin 6000-04-01 as:

§6000.901. Scope.

- (a) Individuals who are registered with a county mental retardation program or who receive supports and services from facilities licensed by the ODP are afforded the protections detailed in this subchapter.
- (b) Providers 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 providers licensed by ODP are reporters and are to file incident reports as specified in this subchapter.
- (c) County Mental Retardation Programs and Support Coordination entities are reporters and are to file incident reports as specified in this subchapter.

ENTITIES RESPONSIBLE FOR REPORTING

§ 6000.911. Providers.

Employees, contracted agents and volunteers of providers covered within the scope of this subchapter are to respond to events that are defined as an incident in this subchapter. When an incident is recognized or discovered by a provider, prompt action is to be taken to protect the individual’s health, safety and rights. The responsibility for this protective action is assigned to the provider initial reporter and point person. The protection may include, dialing 911, escorting to medical care, separating the perpetrator, calling ChildLine, arranging for counseling and referring to a victim assistance program. Unless otherwise indicated in the individual support plan, the provider point person or designee is to inform the individual’s family within 24 hours, or within 72 hours for medication error and restraint, of the occurrence of an incident and to also inform the family of the outcome of any investigation.

§ 6000.912. Individuals and families.

(a) Individuals and families are to notify the provider, when they feel it is appropriate, or their supports coordinator regarding any health and safety concerns they may have related to a service or support that they are receiving. If an individual or family member observes or suspects abuse, neglect or any inappropriate conduct, whether occurring in the home or out of the home, they should contact the provider or their supports coordinator, or both and they may also contact the Office of Developmental Programs directly at 1-888-565-9435. As specified in this subchapter, the supports coordinator will either inform the involved provider of the incident or file an incident report. Once informed by the supports coordinator, the provider is subsequently responsible to take prompt action to protect the individual, complete an investigation as necessary and file an incident report. In the event of the death of an individual, the family is requested to notify the supports coordinator.

§ 6000.913. County mental health/mental retardation programs.

- (a) When an individual or family informs their supports coordinator that an event has occurred that can be defined as an incident and there is a relationship as specified in § 6000.911(b) (1) - (3), (relating to providers) the supports coordinator is to immediately notify the provider rendering the support or service. The provider is responsible for taking prompt action to protect the individual, completing an investigation as necessary and filing an incident report in HCSIS.
- (b) When an individual or a family member informs the supports coordinator of an event that can be categorized as abuse or

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neglect as defined in this subchapter and there is no relationship as specified in § 6000.911(b) (1) - (3), the supports coordinator will take prompt action to protect the individual. Once the individual's health and safety are assured the supports coordinator will ensure a certified investigator is assigned as necessary and file an incident report in HCSIS.

(c) When a family member of an individual informs the individual's supports coordinator of the death of the individual, the supports coordinator will determine if a report has been filed by a provider. If a provider is not required to file the report, the supports coordinator will file an incident report in HCSIS.

(d) In some circumstances, county mental retardation program staff may be required to report incidents. County staff are to report deaths and incidents of alleged abuse or neglect when a provider or supports coordinator relationship does not currently exist, or in circumstances when the process for reporting or investigating incidents, described in this subchapter, for providers or support coordination entities compromises objectivity.

(e) If a county incident manager or designee is informed that a provider's certified investigator suspects that abuse or neglect is occurring beyond the authority of the provider to investigate, the county is to take all available action to protect the health and safety of the individual. The county may need to employ the resources of law enforcement, ChildLine, area agency on aging, counselors or other protective service agencies to protect the individual.

METHODS OF REPORTING INCIDENTS

There are two methods an entity can use to report a critical incident. These methods include an electronic and a non-electronic means. The primary method used to report incidents is HCSIS. HCSIS allows for the consistent reporting of incidents throughout the Pennsylvania mental retardation system, and allows the user to communicate an incident quickly and efficiently. HCSIS also allows the entity user to relay incident information to the appropriate AE and to ODP in a few steps.

An additional means of reporting is the use of the ODP Customer Service Line. ODP Customer Service team members record information received from the caller and communicate the information to the appropriate ODP regional office. This method of reporting allows the individual to remain anonymous.

INCIDENT CATEGORIES

The following are categories of incidents to be reported using a standardized incident report that is comprised of two components, the first section and the final section. For these incident categories, the first section must be submitted within 24 hours of the occurrence or discovery of the incident. The first section of the incident report includes individual and provider demographics, incident categorization, actions taken to protect the health and safety of the individual, and a description of the incident. The final section of the incident report must be submitted through HCSIS within 30 days of the incident's recognition or discovery, and must contain all of the information from the first section as well as additional specific information relevant to the incident. If the provider agency determines they will not be able to meet the 30-day reporting timeframes for completion of the final section, notification of an extension is to be made to the AE and the ODP regional office by means of HCSIS prior to the expiration of the 30-day period.

Abuse. - The allegation or actual occurrence of the infliction of injury, unreasonable confinement, intimidation, punishment, mental anguish, sexual abuse or exploitation. Abuse is reported on from the victim's perspective, not on the person committing the abuse
Physical abuse – An intentional physical act by staff or other person which causes or may cause physical injury to an individual, such as striking or kicking, applying noxious or potentially harmful substances or conditions to an individual.

Psychological abuse– An act, other than verbal, which may inflict emotional harm, invoke fear and/or humiliate, intimidate, degrade or demean an individual.

Sexual abuse– An act or attempted acts such as rape, incest, sexual molestation, sexual exploitation or sexual harassment and inappropriate or unwanted touching of an individual by another. Any sexual contact between a staff person and an individual is abuse.

Verbal abuse. – Verbalizations that inflict or may inflict emotional harm, invoke fear and/or humiliate, intimidate, degrade or demean an individual.

Improper or unauthorized use of restraint. – A restraint not approved in the individual support plan or one that is not a part of an agency's emergency restraint procedure is considered unauthorized. A restraint that is intentionally applied incorrectly is considered an improper use of restraint.

Death. – All deaths are reportable.

Disease Reportable to the Department of Health – An occurrence of a disease on The Pennsylvania Department of Health List of

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Reportable Diseases. The current list can be found at the Department of Health’s website, www.health.state.pa.us. An incident report is required only when the reportable disease is initially diagnosed.

Emergency closure. – An unplanned situation that results in the closure of a home or program facility for 1 or more days. This category does not apply to individuals who reside in their own home or the home of a family member. (This may be reported as a site report.)

Emergency room visit.– The use of a hospital emergency room. 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. The use of an emergency room by an individual’s PCP, in place of the physician's office, is not reportable.

Fire. – A situation that requires the active involvement of fire personnel, i.e. extinguishing a fire, clearing smoke from the premises, responding to a false alarm, and the like. Situations which require the evacuation of a facility in response to suspected or actual gas leaks and/or carbon monoxide alarms, or both, are reportable. Situations in which staff extinguish small fires without the involvement of fire personnel are reportable. This (may be reported as a site report.

Hospitalization. – An inpatient admission to an acute care facility for purposes of treatment. Scheduled treatment of medical conditions on an outpatient basis is not reportable.

Individual-to-individual abuse. – An interaction between one individual receiving services and another individual receiving services resulting in an allegation or actual occurrence of the infliction of injury, unreasonable confinement, intimidation, punishment, mental anguish, sexual abuse or exploitation. Individual-to-individual abuse. Individual Abuse is reported on from the victim’s perspective, not on the person committing the abuse.

Injury requiring treatment beyond first aid.– Any injury that requires the provision of medical treatment beyond that traditionally considered first aid. First aid includes assessing a condition, cleaning an injury, applying topical medications, applying a Band-Aid, and the like. Treatment beyond first aid includes but is not limited to lifesaving interventions such as CPR or use of the Heimlich maneuver, wound closure by a medical professional, casting or otherwise immobilizing a limb. 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.

Law enforcement activity.– 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 that may lead to criminal charges.
- (ii) An individual is the victim of a crime, including crimes against the person or their property.
- (iii) A crime such as vandalism , or break-in that occurs at a provider site. This may be reported as a site report.
- (iv) 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 while on duty or volunteering. This is reported as a site report.
- (v) 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. This is reported as a site report.
- (vi) A crisis intervention involving police/law enforcement personnel.
- (vii) A citation given to an agency staff person for a moving violation while operating an agency vehicle, or while transporting individuals in a private vehicle, is reported as a site report.

Missing person.– A person is considered missing when they are out of contact with staff for more than 24 hours without prior arrangement or if they are in immediate jeopardy when missing for any period of time. A person may be considered in “immediate jeopardy” based on the person’s personal history and may be considered “missing” before 24 hours elapse. Additionally, it is considered a reportable incident whenever the police are contacted about an individual and/or the police independently find and return the individual, or both, regardless of the amount of time the person was missing.

Misuse of funds– An intentional act or course of conduct, which results in the loss or misuse of an individual’s money or personal property. Requiring an individual to pay for an item or service that is normally provided as part of the individual support plan is considered financial exploitation and is reportable as a misuse of funds. Requiring an individual to pay for items that are intended for use by several individuals is also considered financial exploitation. Individuals may voluntarily make joint purchases with other individuals of items that benefit the household.

Neglect. – The failure to obtain or provide the needed services and supports defined as necessary or otherwise required by law

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or regulation. This includes the failure to provide needed care such as shelter, food, clothing, personal hygiene, medical care, protection from health and safety hazards, attention and supervision, including leaving individuals unattended and other basic treatment and necessities needed for development of physical, intellectual and emotional capacity and well being. This includes acts that are intentional or unintentional regardless of the obvious occurrence of harm.

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 and/or treatment, or both, whether voluntary or involuntary. This includes admissions for “23 hour” observation and those for the review and/or adjustment, or both, of medications prescribed for the treatment of psychiatric symptoms or for the control of challenging behaviors.

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. Examples include but are not limited to, the unauthorized removal of personal property, refusal of access to the telephone, privacy violations, and breach of confidentiality. This does not include restrictions that are imposed by court order or consistent with a waiver of licensing regulations.

Suicide attempt. – The intentional and voluntary attempt to take one’s own life. A suicide attempt is limited to the actual occurrence of an act and does not include suicidal threats.

The following incident categories are reported using a standardized abbreviated HCSIS incident management data entry screens, designed to gather relevant data about these incidents. Data must be input within 72 hours of the recognition or discovery of the event:

Medication error - Any nonconforming practice with the “Rights of Medication Administration” as described in the ODP Medication Administration Training Course. This includes omission, wrong dose, wrong time, wrong person, wrong medication, wrong route, wrong position, wrong technique/method and wrong form.

Restraints - Any 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 support plan or those used on an emergency basis. Improper or unauthorized use of restraint is considered abuse and is to be reported under the abuse category.

- b. Participant Training and Education.** Describe how training and/or information is provided to participants (and/or families or legal representatives, as appropriate) concerning protections from abuse, neglect, and exploitation, including how participants (and/or families or legal representatives, as appropriate) can notify appropriate authorities or entities when the participant may have experienced abuse, neglect or exploitation.

ODP has purchased the license for the College of Direct Support for the use by AE’s, supports coordination entities, providers, families and individuals. This is a web based interactive curriculum that is grounded in a Code of Ethics for Direct Support Professionals and developed by national experts. Pennsylvania currently has over 21,000 learners. Several courses are directly relevant to protection from abuse, neglect and exploitation for the individuals we support, including:

- o Maltreatment of Vulnerable Adults and Children
- o Individuals Rights and Choice
- o Positive Behavior Support
- o Safety at Home and in the Community
- o Cultural Competence
- o Communication (to be added within the next several months)

Individuals and families without access to a personal computer may access the courses at AE and Supports Coordination Entity offices, as well as libraries and other computer labs. Face-to-face training on sexual abuse awareness is available for individuals through ODP’s Training Partnership.

Additionally, ODP has issued an Incident Management statement of policy which establishes processes that will ensure the health and safety, enhance dignity and protect the rights of individuals who receive supports and services.

- Anyone can call to report an abuse/neglect allegation by calling the widely published ODP toll free number. This action prompts an investigation of the allegations by the AE or the Regional ODP Office, depending on the nature of the allegation. The Regional Office is responsible to verify that the investigation was fully completed and that appropriate action has been taken. Appropriate actions often include plans of corrections that address training needs.
- In addition, to support this approach, ODP has in place a Certified Investigation course for Providers, AE’s and ODP

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staff. The course is both value and competency based.

- Each ODP Regional Office has assigned a Community Advocate who is employed by Pennsylvania Disability Rights Network. The advocates serve as a local resource to individuals and families as well as an external source for the Regional Offices.
- ODP analyzes reported incidents individually and in aggregate. Based on this review, targeted initiatives are developed. An example of an initiative is the use of restraint data to identify the unique individuals being restrained and target interventions to those specific initiative individuals. This work improved DPW's current endeavor to address restraint elimination. ODP is working to build capacity in the regional and local level to support positive practices.
- Another contracted specialist is available to work with local teams to address sexuality issues.
- ODP is a member of cross system State advocacy group whose mission is to provide support for individuals who have been victimized. This group's focus is on providing information and training to community services such as rape crisis centers to ensure that the individuals with disabilities that they may serve have proper support and that the centers know the additional community resources that can be made available to individuals.

- c. **Responsibility for Review of and Response to Critical Events or Incidents.** Specify the entity (or entities) that receives reports of critical events or incidents specified in item G-1-a, the methods that are employed to evaluate such reports, and the processes and time-frames for responding to critical events or incidents, including conducting investigations.

Reports

Providers and AE's enter reportable incidents into HCSIS. Each reportable incident is accessible by the ODP regional office for review and approval. AE's review the first section of the incident report within 24 hours of submission and complete the management approval within 30 days of the submission of the final section. The same process occurs at the ODP regional level. ODP Regional approval of incidents must meet criteria within the Incident Management Closure Protocol. Incidents are reviewed at the ODP regional level in aggregate minimally once a month or as needed through ODP Regional Risk Management meetings. The ODP regional office identifies patterns and trends and develops improvement strategies. If improvement strategies have been implemented the ODP regional office monitors the data to evaluate the effectiveness of the interventions. Statewide analytical reports of incident and licensing data will be compiled and presented to the ODP Leadership Board and Central Office Waiver Assurance Oversight Group for review and to make recommendations for action.

Providers

- Employees, contracted agents and volunteers of providers covered within the scope of the Incident Management policy are to respond to events that are defined as an incident in the policy. When an incident is recognized or discovered by a provider, prompt action is to be taken to protect the individual's health, safety and rights. The responsibility for this protective action is assigned to the provider initial reporter and point person. The protection may include dialing 911, escorting to medical care, separating the perpetrator, calling ChildLine, arranging for counseling and referring to a victim assistance program. Unless otherwise indicated in the ISP, the provider point person or designee is to inform the individual's family within 24 hours, or within 72 hours for medication error and restraint, of the occurrence of an incident and to also inform the family of the outcome of any investigation.
- After taking all appropriate actions following an incident to protect the individual, the provider is to report all categories of incidents and complete an investigation as necessary whenever services or supports are:
 - a. Rendered at the provider's site.
 - b. Provided in a community environment, other than an individual's home, while the individual is the responsibility of an employee, contracted agent or volunteer.
 - c. Provided in an individual's own home or the home of his family, while an employee, contracted agent or volunteer is providing services in the home.
- In situations when multiple providers learn of an incident, the provider responsible for the individual at the time the incident occurred is to report the incident and conduct any required investigation. If it cannot reasonably be determined which provider had responsibility at the time of the incident, all providers who are aware of the incident are to report the incident and investigate.
- If, during an investigation, the certified investigator assigned by the provider determines that an alleged perpetrator is not an employee, a volunteer or an individual receiving services from the provider, the certified investigator is to complete the investigation summary in HCSIS incident management application stating the reason why the investigation could not be concluded. The certified investigator is to review the protective action taken by the agency and ensure communication with county staff occurs, outside HCSIS, to alert the county that appropriate interventions may be needed to protect the individual.
- In addition, employees, contracted agents or volunteers of provider agencies are to report deaths, alleged abuse or neglect when they become aware of such incidents regardless of where or when these incidents occur. If the death, alleged abuse or neglect

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occurred beyond the provider's responsibility as specified in § 6000.911(b)(1)-(3), (relating to providers) the provider is not to report the incident in HCSIS, but instead should give notice of the incident, outside of HCSIS, to the individual's supports coordinator.

- Any person, including the victim, shall be free from intimidation, discriminatory, retaliatory or disciplinary actions exclusively for the reporting or cooperating with a certified investigation. These individuals have specific rights as defined by the Whistleblower Law (43 P.S. §§ 1421-1428) and the Older Adults Protective Services Act (35 P.S. § 10225.5102). The provider, AE, and ODP are responsible to ensure these rights are guaranteed. Violations of the Law and Act, as well as the Incident Management policy, by the provider can result in licensing citations, suspension or disqualification, and other legal ramifications.
- If, during an investigation, the certified investigator assigned by the provider determines that an alleged perpetrator is not an employee, a volunteer or an individual receiving services from the provider, the certified investigator is to complete the investigation summary in the HCSIS incident management application stating the reason why the investigation could not be concluded. The certified investigator is to review the protective action taken by the agency and ensure communication with county staff occurs, outside HCSIS, to alert the county that appropriate interventions may be needed to protect the individual

Supports Coordinators.

- When an individual or family informs their supports coordinator that an event has occurred that can be defined as an incident and there is a relationship to the provider as specified in §6000.911(b)(1)-(3) of the Incident Management Bulletin the supports coordinator is to immediately notify the provider rendering the support or service. The provider is responsible for taking prompt action to protect the individual, completing an investigation as necessary and filing an incident report in HCSIS.
- When an individual or a family member informs the supports coordinator of an event that can be categorized as abuse or neglect as defined in this subchapter and there is no relationship to the provider as specified in §6000.911(b)(1)-(3) of the Incident Management bulletin, the supports coordinator will take prompt action to protect the individual. Once the individual's health and safety are assured the supports coordinator will ensure a certified investigator is assigned as necessary and file an incident report in HCSIS.
- When a family member of an individual informs the individual's supports coordinator of the death of the individual, the supports coordinator will determine if a report has been filed by a provider. If a provider is not required to file the report, the supports coordinator will file an incident report in HCSIS.

County Mental Health/Mental Retardation Programs.

- In some circumstances, county mental retardation program staff may be required to report incidents. County staff are to report deaths and incidents of alleged abuse or neglect when a provider or supports coordinator relationship does not currently exist, or in circumstances when the process for reporting or investigating incidents, described in this subchapter, for providers or support coordination entities compromises objectivity.
- If a county incident manager or designee is informed that a provider's Certified Investigator suspects that abuse or neglect is occurring beyond the authority of the provider to investigate, the county is to take all available action to protect the health and safety of the individual. The county may need to employ the resources of law enforcement, ChildLine, area agency Area Agency on Aging, counselors or other protective service agencies to protect the individual.

Review of Incidents:

The process and procedures of reviewing of incidents on the statewide and regional level is defined in Bulletin number 00-06-11, entitled "Provider and County Incident Management Analysis Report" (issued June 23, 2006). The purpose of this Bulletin is to describe the delivery of Incident Management (IM) Trend and Quality Performance Reports (aggregate data), components of the IM Analysis Report templates, and submission dates for the Provider and County IM Analysis Reports.

Upon review of the provided Trend and Quality Performance Reports, Providers and Counties are to complete and submit a single qualitative IM Analysis Report semi-Annually. Provider reports should be submitted via e-mail to each AE with whom a person is registered. Counties are to forward their report to the appropriate ODP regional office.

The counties review all submitted provider reports and provide feedback to the providers. This feedback may include recommendations for improving risk management/quality management processes or offers of technical assistance. The ODP regional office's Risk Management Committees review all submitted county reports and provide feedback to the counties and the Statewide Risk Management Workgroup.

The formal process for the Statewide Risk Management Workgroup to complete a statewide Incident Management (IM) Analysis Report that will provide completed aggregate IM data analysis and recommendations on statewide system improvements is currently being finalized within ODP.

Currently, ODP Regional offices are reporting IM data and developing regional action plans to address the steps and

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recommendations regarding the statewide initiative to eliminate the use of restraint. The Statewide Positive Practices Committee is also charged with this data analysis, operational recommendations, and program support.

The Incident Management Trend and Quality Performance Reports data delivery process is aimed at providing standard aggregate data to providers and counties. The IM Trend and Quality Performance Reports are sources of relevant data for Incident Management/Risk Management/Quality Management Committee meetings at provider, county, and statewide levels.

Delivery of the IM Data:

The delivery process of IM Trend and Quality Performance Reports for providers and counties are outlined in the referenced bulletin. Providers can access the reports via HCSIS and counties can access their reports via the Data Warehouse. The IM Trend and Quality Performance Reports will be delivered on a quarterly basis (based on calendar year). The Reports will encompass the last five quarters of data from the date the reports are received. These reports include the following:

Five Data Summary Reports:

1. Incident Management Data Summary
2. Incident Management Data Summary for Provider Compared to Statewide Data
3. Incident Management Investigation Data Summary
4. Incident Management Investigation Data Summary Compared to Statewide Data
5. Incident Management Milestone Data Summary

Two QM Core Performance Reports:

1. Reduction in Incidents for Providers (Restraints)
2. Reduction in Repeat Occurrences of Incidents for Unique Individuals for Providers

Template:

Also, a template has been developed that creates a standardized format for the completion of the Provider and County IM Analysis Report. The template is used to assist in:

- Converting incident and investigation data into information.
- Analyzing aggregate data.
- Identifying systemic issues derived from the aggregate analysis.
- Identifying preventative initiatives to reduce risk of recurrence.
- Identifying quality recommendations and strategies to promote the continued effort to ensure the health, welfare, and rights of people receiving supports and services.

The IM Analysis Report template has a list of “Questions for Consideration.” These questions are to be used as guidelines in the development of the IM Analysis Report. In addition, the IM Analysis Report template describes the systemic quality improvement and prevention activities implemented to improve and enhance the health and safety of individuals being served.

- d. Responsibility for Oversight of Critical Incidents and Events.** Identify the State agency (or agencies) responsible for overseeing the reporting of and response to critical incidents or events that affect waiver participants, how this oversight is conducted, and how frequently.

ODP is the state agency responsible for the oversight of and response to critical incidents.

Within 24 hours of the submission of the first section of the incident report, both the designated AE and ODP Regional office staff review the incident to determine that appropriate actions to protect the individual occurred. After the provider submits the final

section of the HCSIS incident report, the AE is to complete a management review within 30 days. The management review process will include a determination that:

- The appropriate action to protect the individual occurred,
- The incident categorization is correct,
- Certified investigation occurred if needed,
- Proper safeguards are in place,
- Corrective action in response to the incident has, or will, take place. After the administrative entity approves the incident report,
- ODP regional office staff complete a management review within 30 days of the AE’s approval. The management review will include all of the above including the AE’s response to the incident.

Each regional office also reviews significant events during the Risk Management committee meetings which are held

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at least monthly. When identified technical assistance is provided to the AE or provider.

During the annual ISP meetings and quarterly review of waiver participants, in licensed settings, the incidents of waiver participants are reviewed by the ISP team.

Annually, ODP will complete an analysis of aggregate incident data and licensing data to identify patterns and trends statewide and regionally. Factors that put people at risk are identified and recommendations made to implement appropriate interventions and improvement activities. Information from these reports is shared with stakeholders, and ODP staff are responsible for follow through.

Appendix G: Participant Safeguards

Appendix G-2: Safeguards Concerning Restraints and Restrictive Interventions (1 of 2)

a. Use of Restraints or Seclusion.

(Select one):

The State does not permit or prohibits the use of restraints or seclusion

Specify the State agency (or agencies) responsible for detecting the unauthorized use of restraints or seclusion and how this oversight is conducted and its frequency:

The use of restraints or seclusion is permitted during the course of the delivery of waiver services. Complete Items G-2-a-i and G-2-a-ii.

- i. Safeguards Concerning the Use of Restraints or Seclusion.** Specify the safeguards that the State has established concerning the use of each type of restraint (i.e., personal restraints, drugs used as restraints, mechanical restraints or seclusion). State laws, regulations, and policies that are referenced are available to CMS upon request through the Medicaid agency or the operating agency (if applicable).

The Department is clear on its mission to eliminate restraints as a response to challenging behaviors. Through multiple bulletins and regulations, ODP carries out this mission and has demonstrated its commitment to the Positive Practices Paradigm and Everyday Lives.

Use of Alternative Methods before Instituting Restraints/Seclusion.

ODP Bulletin 00-06-09, Elimination of Restraints through Positive Practice, asks providers “to pursue alternative strategies to the use of restraint”. For example, physical restraints are the only type of restraint permitted, but may only be used as a last resort safety measure when there is a threat to the health and safety of the individual or others, and only when less intrusive measures such as redirection, reflective listening, and other positive practices are ineffective in each situation. A physical restraint is a hands-on technique that lasts thirty seconds or more used to control acute, episodic behavior that restricts the movement or function of an individual or portion of the individual's body. Physical restraint is always a last resort emergency response to protect the individual's safety. Consequently, it is never used as a punishment, therapeutic technique or for staff convenience. The individual is immediately to be released from the restraint as soon as it is determined that the individual is no longer a risk to him/herself or others.

Additionally, regulations specifically state “every attempt shall be made to anticipate and de-escalate the behavior using methods of intervention less intrusive than restrictive procedures”. Seclusion is prohibited by regulation and in Bulletin 00-06-09. Seclusion is placing an individual in a locked room. A locked room includes a room with any type of engaged locking device, such as a key lock, spring lock, bolt lock, foot pressure lock, or physically holding the door shut.

Mechanical and chemical restraints are also prohibited by Bulletin 00-06-09. 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. A chemical restraint is a drug used to control acute, episodic behavior that restricts the movement or function of an individual and is not a standard treatment for the individual's medical or psychiatric diagnosis.

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Additionally, after any type of restraint has been used, two means of review are pursued so the provider and Commonwealth can determine if the use of a restraint was unauthorized. The first is through the Positive Practices Approach of Debriefing. ODP Bulletin 00-06-09 describes how this process could identify if a restraint was unauthorized. Second, regulation requires a Restrictive Procedure Committee review and update of restraint procedure plans.

ODP Bulletin 00-06-09 states that “Individual and team involvement in a post-restraint debriefing is critical to determine how future situations can be prevented. It is important, as part of the ongoing planning process to review each occurrence of restraint. Information from the debriefing sessions should, at minimum, be included in the Supports Coordinator monitoring update. These discussions can be separate and distinct with the intended purpose of determining what could have been done differently to avoid the restraint. Any changes to the individual’s plan shall be documented in the ISP.”

Licensing regulations for licensed residential services and adult training facilities spell out requirements related to restrictive procedures. These regulations require that these licensed providers establish a restrictive procedure review committee, generally as per the regulatory requirements outlined below:

Restrictive procedure review committee

- (a) If a restrictive procedure is used, there shall be a restrictive procedure review committee.
- (b) The restrictive procedure review committee shall include a majority of persons who do not provide direct services to the individual.
- (c) The restrictive procedure review committee shall establish a time frame for review and revision of the restrictive procedure plan, not to exceed 6 months between reviews.
- (d) A written record of the meetings and activities of the restrictive procedure review committee shall be kept.

Detailed Documentation Regarding the Use of Restraints and Seclusion

All of these licensed providers must have written restraint policies. The regulations also require a restrictive procedure plan be written prior to the use of any restraint and only to ensure the health and safety of an individual. The only exception to using a restraint without a restraint procedure plan is when the restraint is used in an emergency to protect the health and safety of an individual. Compliance with regulations is reviewed as part of annual ODP licensing inspections. Bulletin 00-06-09 supports regulations and provides additional clarification on restraint documentation. Additionally,

Bulletin 00-06-11 Provider and County Incident Management Analysis Report outlines how the Commonwealth tracks incidents, and creates a Performance Report specifically on restraints.

Restraint, as a behavior modification technique or any use other than to protect health and safety, should not be incorporated as part of any ISP or as the method for modifying and/or eliminating behavior in a behavior plan.

It is recommended that all Providers develop agency-wide policies and procedures for the reduction and eventual elimination of restraint. These policies and procedures should outline the specific steps to be taken for the elimination of restraint components in any individual plan as well as general policies and procedures promoting the goal of restraint elimination.

Education and Training Requirements for Personnel who Administer Restraints and Seclusion

Education and training are key components to ODP’s plan to reduce and eliminate restraints across the Commonwealth. Bulletin 00-06-09 outlines recommended curriculum content and training timeframes. It also frames training requirements for targeted staff. Specific sections of the residential and adult training regulations identify mandatory training requirements for personnel regarding restraints. Additionally, ODP has several resources available to providers to educate and train staff regarding the safe use of restraint and reduction and elimination of the necessity to use restraint.

The following training and education resources are available to providers:

- ODP (via web-cast)
- Health Care Quality Units
- ODP Consultants
- The Pennsylvania Training Partnership for People with Disabilities and Families
- In- house Provider Agency and State Center staff curricula
- College of Direct Support (CDS) online training sessions
- Positive Practices Resource Team (PPRT) which is a cross program office initiative between ODP and OMHSAS (Office of Mental Health and Substance Abuse Services) to provide direct technical assistance, training and support to providers who are supporting individuals, including waiver participants, who are experiencing high restraint usage or who

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have significant behavioral challenges.

- ii. **State Oversight Responsibility.** Specify the State agency (or agencies) responsible for overseeing the use of restraints or seclusion and ensuring that State safeguards concerning their use are followed and how such oversight is conducted and its frequency:

ODP is responsible for ongoing oversight of the use of restraints or seclusion. Restraints and seclusion are reviewed during annual inspections of licensed providers, and through ODP Regional Risk Management meetings (at least monthly). ODP also has established a Positive Practices Review Team that is responsible for ongoing review of restraints and restraint elimination on both aggregate and individual levels. Policies are outlined in the Incident Management bulletin and in regulations. ODP's Deputy Secretary must review and sign off on any waiver of restraint regulation. (The allowance for regulatory waivers is included in Department regulations.). Aggregate data analysis of restraint and seclusion information occurs concurrently with the analysis of incident data.

The AE is responsible for the oversight of restraint use at the local level. Aggregate data analysis of restraint and seclusion occurs, at least, on a semi-annual basis. The analysis report is then sent to the appropriate ODP regional office for review and feedback.

Appendix G: Participant Safeguards

Appendix G-2: Safeguards Concerning Restraints and Restrictive Interventions (2 of 2)

b. Use of Restrictive Interventions.

(Select one):

The State does not permit or prohibits the use of restrictive interventions

Specify the State agency (or agencies) responsible for detecting the unauthorized use of restrictive interventions and how this oversight is conducted and its frequency:

The use of restrictive interventions is permitted during the course of the delivery of waiver services Complete Items G-2-b-i and G-2-b-ii.

- i. **Safeguards Concerning the Use of Restrictive Interventions.** Specify the safeguards that the State has in effect concerning the use of interventions that restrict participant movement, participant access to other individuals, locations or activities, restrict participant rights or employ aversive methods (not including restraints or seclusion) to modify behavior. State laws, regulations, and policies referenced in the specification are available to CMS upon request through the Medicaid agency or the operating agency.

The following definitions and regulations are applicable to licensed providers, who are reviewed through annual ODP licensing inspections:

The use of aversive conditioning, defined as the application, contingent upon the exhibition of maladaptive behavior, of startling, painful or noxious stimuli, is prohibited.

Personal Funds and Property: (a) An individual's personal funds or property may not be used as reward or punishment. (b) An individual's personal funds or property may not be used as payment for damages unless the individual consents to make restitution for the damages.

Appropriate use of restrictive procedures.

(a) A restrictive procedure may not be used as retribution, for the convenience of staff persons, as a substitute for the program or in a way that interferes with the individual's developmental program.

(b) For each incident requiring restrictive procedures:

(1) Every attempt shall be made to anticipate and de-escalate the behavior using methods of intervention less intrusive than restrictive procedures.

(2) A restrictive procedure may not be used unless less restrictive techniques and resources appropriate to the behavior have been tried but have failed.

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Restrictive procedure review committee.

- (a) If a restrictive procedure is used, there shall be a restrictive procedure review committee.
- (b) The restrictive procedure review committee shall include a majority of persons who do not provide direct services to the individual.
- (c) The restrictive procedure review committee shall establish a time frame for review and revision of the restrictive procedure plan, not to exceed 6 months between reviews.
- (d) A written record of the meetings and activities of the restrictive procedure review committee shall be kept.

Restrictive procedure plan.

- (a) For each individual for whom restrictive procedures may be used, a restrictive procedure plan shall be written prior to use of restrictive procedures.
- (b) The restrictive procedure plan shall be developed and revised with the participation of the program specialist, the individual's direct care staff, the interdisciplinary team as appropriate and other professionals as appropriate.
- (c) The restrictive procedure plan shall be reviewed, and revised, if necessary, according to the time frame established by the restrictive procedure review committee, not to exceed 6 months.
- (d) The restrictive procedure plan shall be reviewed, approved, signed and dated by the chairperson of the restrictive procedure review committee and the program specialist, prior to the use of a restrictive procedure, whenever the restrictive procedure plan is revised and at least every 6 months.
- (e) The restrictive procedure plan shall include:
 - (1) The specific behavior to be addressed and the suspected antecedent or reason for the behavior.
 - (2) The single behavioral outcome desired stated in measurable terms.
 - (3) Methods for modifying or eliminating the behavior, such as changes in the individual's physical and social environment, changes in the individual's routine, improving communications, teaching skills and reinforcing appropriate behavior.
 - (4) Types of restrictive procedures that may be used and the circumstances under which the procedures may be used.
 - (5) A target date for achieving the outcome.
 - (6) The amount of time the restrictive procedure may be applied, not to exceed the maximum time periods specified in this chapter.
 - (7) Physical problems that require special attention during the use of restrictive procedures.
 - (8) The name of the staff person responsible for monitoring and documenting progress with the plan.
- (f) The restrictive procedure plan shall be implemented as written.
- (g) Copies of the restrictive procedure plan shall be kept in the individual's record.

Restrictive procedure records.

A record of each use of a restrictive procedure documenting the specific behavior addressed, methods of intervention used

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to address the behavior, the date and time the restrictive procedure was used, the specific procedures followed, the staff person who used the restrictive procedure, the duration of the restrictive procedure, the staff person who observed the individual if exclusion was used and the individual's condition during and following the removal of the restrictive procedure shall be kept in the individual's record.

Informing and encouraging exercise of rights.

(a) Each individual, or the individual's parent, guardian or advocate, if appropriate, shall be informed of the individual's rights upon admission and annually thereafter.

(b) Statements signed and dated by the individual, or the individual's parent, guardian or advocate, if appropriate, acknowledging receipt of the information on rights upon admission and annually thereafter, shall be kept.

(c) Each individual shall be encouraged to exercise his rights.

Rights.

An individual may not be deprived of rights.

Rights of the individual.

(a) An individual may not be neglected, abused, mistreated or subjected to corporal punishment.

(b) An individual may not be required to participate in research projects.

(c) An individual has the right to manage personal financial affairs.

(d) An individual has the right to participate in program planning that affects the individual.

(e) An individual has the right to privacy in bedrooms, bathrooms and during personal care.

(f) An individual has the right to receive, purchase, have and use personal property.

(g) An individual has the right to receive scheduled and unscheduled visitors, communicate, associate and meet privately with family and persons of the individual's own choice.

(h) An individual has the right to reasonable access to a telephone and the opportunity to receive and make private calls, with assistance when necessary

(i) An individual has the right to unrestricted mailing privileges.

(j) An individual who is of voting age shall be informed of the right to vote and shall be assisted to register and vote in elections.

(k) An individual has the right to practice the religion or faith of the individual's choice.

(l) An individual has the right to be free from excessive medication.

(m) An individual may not be required to work at the home, except for the upkeep of the individual's personal living areas and the upkeep of common living areas and grounds.

Civil rights.

(a) An individual may not be discriminated against because of race, color, religious creed, disability, handicap, ancestry, national origin, age or sex.

(b) The home shall develop and implement civil rights policies and procedures. Civil rights policies and procedures shall include the following:

(1) Nondiscrimination in the provision of services, admissions, placement, use of the home, referrals and communication with non-English speaking and nonverbal individuals.

(2) Physical accessibility and accommodations for individuals with physical disabilities.

(3) The opportunity to lodge civil rights complaints.

(4) Informing individuals of their right to register civil rights complaints

In addition to the laws, regulations and policies to assure safety related to restraint and seclusion, ODP has initiated statewide activities such as Positive Approaches and participates in the Department of Public Welfare's initiative to reduce restraint applications.

- ii. **State Oversight Responsibility.** Specify the State agency (or agencies) responsible for monitoring and overseeing the use of restrictive interventions and how this oversight is conducted and its frequency:

All restrictive interventions are clearly defined and outlined in ODP's regulations. During their annual reviews, licensing staff are responsible for reviewing incidents during which restrictive interventions were used as well as any restrictive procedure plans that may be in place. Additionally, ODP has issued a bulletin which outlines the policies and procedures for Incident Management.

ODP Regional risk management committees meet at least monthly and monitor the incidence of restraint applications and share findings and analysis with the statewide Positive Practices Resource Team (PPRT). The PPRT reviews that appropriate services and supports are in place for individuals experiencing restraint applications.

The Statewide ODP Risk Management Workgroup is charged with completing analysis of statewide incident data. This Workgroup is comprised of ODP Regional Risk Managers, the ODP Central Office Risk Management Director, and the ODP Area Quality Management leads. The Workgroup has completed analysis of fiscal year 2004/2005 incident data, and compiled a statewide Incident Management report based on this review. The report will serve as ODP's baseline for incident analysis. Recommendations from the Statewide Risk Management Workgroup will be proposed to ODP

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Leadership and ultimately implemented statewide. ODP Regional Offices will develop action plans to address the recommendations to promote systems change.

Appendix G: Participant Safeguards

Appendix G-3: Medication Management and Administration (1 of 2)

This Appendix must be completed when waiver services are furnished to participants who are served in licensed or unlicensed living arrangements where a provider has round-the-clock responsibility for the health and welfare of residents. The Appendix does not need to be completed when waiver participants are served exclusively in their own personal residences or in the home of a family member.

a. Applicability. Select one:

No. This Appendix is not applicable (*do not complete the remaining items*)

Yes. This Appendix applies (*complete the remaining items*)

b. Medication Management and Follow-Up

- i. Responsibility.** Specify the entity (or entities) that have ongoing responsibility for monitoring participant medication regimens, the methods for conducting monitoring, and the frequency of monitoring.

Supports Coordinators review medication regimens for individuals during face-to-face monitoring visits using a standard ISP monitoring tool.

They can use Health Care Quality Units (HCQUs) for support with regard to questions about medications. Nurses from the Health Care Quality Units (HCQUs) review medications for a random sample of individuals across the state every year. As part of the Health Risk Profile and individual case reviews, the HCQU will review the records, provide training and answer questions.

ODP licensing reviews medication information when conducting standard annual reviews for licensed providers. This includes review of medication practices, logs, storage, etc.

Through its regional offices, ODP monitors AE's by reviewing a sample of individual records including the medications that people take. The AE's have access to nurses who help with questions about medications and responses.

- ii. Methods of State Oversight and Follow-Up.** Describe: (a) the method(s) that the State uses to ensure that participant medications are managed appropriately, including: (a) the identification of potentially harmful practices (e.g., the concurrent use of contraindicated medications); (b) the method(s) for following up on potentially harmful practices; and, (c) the State agency (or agencies) that is responsible for follow-up and oversight.

Through the Office of Medical Assistance Programs each participant's medications are reviewed at the time of refill or addition of a new medication via a standard pharmacy program to look for problems like therapeutic duplication, prescribed allergic medications, dosages over the recommended level, concurrent use of contraindicated medications, etc. The pharmacist contacts the prescribing practitioner if a potential problem before filling the prescription.

This information is reviewed through a Drug Utilization Review both prospectively and retrospectively and findings are communicated to healthcare practitioners either collectively thru Continued Medical Education (CME) or individually. In addition to the pharmacist contacting the prescribing practitioner, patterns of potentially harmful practices are communicated to the practitioner community via remittance advices and CME addressing the particular issue. In addition, nurses from the Health Care Quality Units (HCQUs) review medications for a random sample of individuals across the state every year. They address issues for individuals directly with the provider and use patterns to develop educational materials and training about those issues. Follow-up occurs in multiple ways including directly from the HCQU, the AE, or ODP. Licensing reviews bring problematic patterns about medication administration practices to a central level and then they are addressed either directly with a provider or incorporated into the medication administration training course. Follow-up of these findings occur through the regional offices of ODP. Information about best practices and potentially harmful new drug information is communicated to the field via Drug Alerts. Direct consultation with a pharmacist with a specialty certification in psychiatric pharmacology occurs on an as needed basis.

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c. Medication Administration by Waiver Providers

i. Provider Administration of Medications. *Select one:*

Not applicable. *(do not complete the remaining items)*

Waiver providers are responsible for the administration of medications to waiver participants who cannot self-administer and/or have responsibility to oversee participant self-administration of medications. *(complete the remaining items)*

ii. State Policy. Summarize the State policies that apply to the administration of medications by waiver providers or waiver provider responsibilities when participants self-administer medications, including (if applicable) policies concerning medication administration by non-medical waiver provider personnel. State laws, regulations, and policies referenced in the specification are available to CMS upon request through the Medicaid agency or the operating agency (if applicable).

State regulations for community homes and day programs allow for the administration of medication by unlicensed staff when trained using a standard Medication Administration course. The current medication administration course requires the review of medication administration logs for errors in documentation including matching the person's prescribed medications on the log to those available to be given. Observation of medication passes are required on an annual basis. Clinical nursing staff are not required to take the administration course as this is part of their clinical scope of practice under the State Nursing

Board. Self administration guidelines appear in the regulations and setting up and monitoring self administration programs are taught as part of the medication administration program. These requirements do not apply to non-licensed providers.

Medications are also monitored by supports coordinators as part of their routine monitoring of licensed and unlicensed waiver services.

The autonomy of individuals who have the capacity to make health care decisions is respected, and decisions made by competent individuals are honored. Competency is determined by the involved physician. If an individual is not competent to make a particular decision, another person must make the decision on the individual's behalf. When necessary, surrogate decision makers should be chosen in the following order:

1. A health care agent.
2. A guardian of the individual.
3. A health care representative.
4. The administrative head of a provider agency.

iii. Medication Error Reporting.

Select one of the following:

Providers that are responsible for medication administration are required to both record and report medication errors to a State agency (or agencies).

Complete the following three items:

(a) Specify State agency (or agencies) to which errors are reported:

The Department of Public Welfare, Office of Developmental Programs via an electronic database, HCSIS which is accessible by the state, AE's and providers.

(b) Specify the types of medication errors that providers are required to *record*:

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See below

(c) Specify the types of medication errors that providers must *report* to the State:

Providers report medication errors as specified in the Incident Management module of HCSIS including wrong person, wrong medication (wrong medication, extra dose, and discontinued medication), wrong dose, wrong route, wrong time, wrong form, wrong technique/method, and wrong position.

Providers responsible for medication administration are required to record medication errors but make information about medication errors available only when requested by the State.

Specify the types of medication errors that providers are required to record:

- iv. State Oversight Responsibility.** Specify the State agency (or agencies) responsible for monitoring the performance of waiver providers in the administration of medications to waiver participants and how monitoring is performed and its frequency.

ODP monitors performance of providers with regard to medication administration through multiple mechanisms. Each AE is monitored by reviewing a sample of people in the waiver including reviewing their medications. Annual licensing inspections monitor medication administration through standardized reviews of licensed services. AE's and supports coordinators monitor medications for individuals. Health Care Quality Units (HCQUs) provide training and technical assistance to providers on an on-going basis to promote the use of best practices around medication administration. They review the medications of a random sample of people over a year's time.

The required medication administration course teaches problem solving and has been modified to address problems identified through data captured in HCSIS. The HCQU's, AE's, and regional risk management committees review medication errors on a regular basis. ODP reviews reports submitted by the AE. The AE review reports submitted by providers. Any medication error leading to hospitalization, emergency room visit, etc. is reviewed in depth with the potential for investigation. ODP reviews lead to changes in the medication administration instrument and additional training. Currently ODP is developing training related to best practices. Health Alerts are issued and distributed widely on specific drugs issues.