

Attachment C – Appendix G Proposed Language

Appendix G: Participant Safeguards

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Appendix G-1: Response to Critical Events or Incidents

- a. **Critical Event or Incident Reporting and Management Process.** Indicate whether the State operates Critical Event or Incident Reporting and Management Process that enables the State to collect information on sentinel events occurring in the waiver program. *Select one:*

Yes. The State operates a Critical Event or Incident Reporting and Management Process
(complete Items b through e)

No. This Appendix does not apply (do not complete Items b through e)
If the State does not operate a Critical Event or Incident Reporting and Management Process, describe the process that the State uses to elicit information on the health and welfare of individuals served through the program.

N/A

- b. **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 are identified in ODP Bulletins and Regulations. Entities required to report critical events (or “incidents” as defined in Pennsylvania code) are defined in ODP Bulletin and include employees, contracted agents and volunteers of waiver service providers, Administrative Entities (AEs), and ODP staff. 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 they are receiving.

Required reporters must report the following critical incidents within 24 hours of their occurrence or discovery. These critical incidents must be investigated by an ODP-certified investigator and in accordance with ODP’s established timelines and standards. Critical incidents include:

- Abuse Death Emergency room visit resulting from:
 - Unexplained injury
 - Staff to Individual Injury
 - Injury resulting from Individual to Individual abuse
 - Injury Resulting from restraint
- Hospitalization resulting from:

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- Accidental Injury
- Unexplained injury
- Staff to Individual Injury
- Injury resulting from Individual to Individual abuse
- Injury Resulting from restraint
- Individual-to-individual abuse, sexual
- Injury requiring treatment beyond first aid:
 - Staff to individual injury
 - Resulting from individual to individual abuse
 - Resulting from a restraint
- Misuse of funds
- Neglect
- Rights violation

Exploitation may be reported within the categories of abuse, misuse of funds, and rights violation rather than as a discrete category.

Required reporters must also report the following incidents within 24 hours of their occurrence or discovery. Certified investigation is not required.

- Suicide attempt
- Hospitalization that does not involve:
 - Accidental Injury
 - Unexplained injury
 - Staff to Individual Injury
 - Injury resulting from Individual to Individual abuse
 - Injury Resulting from restraint
- Psychiatric Hospitalization
- Emergency room visits that do not involve:
 - Unexplained injury
 - Staff to Individual Injury
 - Injury resulting from Individual to Individual abuse
 - Injury Resulting from restraint
- Individual to Individual Abuse that does not involve sexual abuse
- Missing person

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- Injury requiring treatment beyond first aid that does not involve:
 - Staff to individual injury
 - Resulting from individual to individual abuse
- Disease reportable to the Department of Health
- Fire
- Law enforcement activity
- Emergency closure (of a facility or home)

Required reporters must report the following incidents within 72 hours of their occurrence or discovery. Certified investigation is not required.

- Medication error
- Restraint (unless involving emergency room visit, hospitalization or abuse)

REPORTING INCIDENTS

Providers are required to record incidents in HCSIS. If an incident is reported through ODP's Customer Service Line, ODP Customer Service team members record information received from a caller and communicate the information to the appropriate ODP regional office. ODP regional office staff then ensure an incident report is submitted if appropriate.

- c. 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.

Supports Coordinators deliver and discuss information concerning protections from abuse, neglect, and exploitation, including how to notify appropriate authorities. Each waiver participant receives a document prepared by ODP that includes contact information for Supports Coordinators, authorities, family members, advocacy organizations and others. Waiver participants, families, and/or legal representatives can use this information as needed to report concerns regarding abuse, neglect, and exploitation. The document includes ODP's toll-free Customer Service Line number. This information shall be discussed at least annually and or more frequently as determined necessary by the SC and at the request of a participant or caregiver.

- d. 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.

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ODP receives and evaluates reports on each type of critical incident (identified in Item G-1-a). When a critical incident is recognized or discovered, prompt action must be taken to protect the participant and file an incident report in the web based Home and Community Services Information System (HCSIS) Incident Management System within 24 hours.

In accordance with the current Bulletin, within 24 hours of an incident report being submitted, designated staff from both the AE and ODP Regional Office evaluates the report to ensure that:

- The provider took prompt action to protect the participant's health, safety and rights. This may include, but is not limited to dialing 911, arranging medical care, separating the perpetrator, calling ChildLine, arranging counseling or referring to a victim assistance program;
- The provider separated the participant from the target when the participant's health and safety was jeopardized;
- If applicable, the provider met the notification requirements of 35 P.S. §§ 10225.101 - 10225.5102 and 23Pa. C.S. §§6301-6384 (relating to The Older Adults Protective Services Act and Child Protective Services Law);
- The provider notified the family of the incident within 24 hours (unless otherwise indicated in the individual support plan); and,
- The provider initiated an investigation by assigning the case to a Certified Investigator (CI).

ODP requires CIs to participate in four (4) days of training in investigatory procedures. ODP only certifies participants who successfully complete the training and pass a final examination. ODP requires recertification every three (3) years.

CIs follow the protocol established in the Certified Investigator's manual.

Investigators accommodate the witness's communication needs as appropriate and conduct interviews individually, and in a private place, if possible. If the witness requires the presence of a third party, the CI must arrange for third party representation (i.e. a staff person or family member).

When the CI completes the investigation, he or she enters the summary into HCSIS. The provider then completes and finalizes the report within 30 days. HCSIS sends an electronic alert notifying ODP and the AE of the finalized report.

The AE evaluates all finalized reports within 30 days and approves the report if it indicates:

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- The appropriate action to protect the participant’s health, safety and rights occurred;
- The incident is correctly categorized;
- Timely completion of the certified investigation;
- Ensures the investigation summary supports the conclusion;
- Placement of proper safeguards;
- Corrective action in response to the incident has taken, or will take place;
- The steps taken by the provider in response to the investigation’s conclusions;
- Changes in the participant’s plan of support necessitated by or in response to the incident;
- The anticipated date of completion of any corrective action that cannot/has not been completed before finalization; and,
- The participant or participant’s family received notification of the findings, unless otherwise indicated in the individual plan.
- Incidents of abuse, neglect and exploitation were reported to the appropriate authority as required by Pennsylvania Law

The AE disapproves reports that fail evaluation. Disapproved reports revert to the provider, who corrects any deficiencies and resubmits the report for re-evaluation. ODP Regional Office staff evaluates approved reports within 30 days and, if satisfactory, closes the investigation.

Methods for Detecting Unreported Incidents

ODP reviews waiver participant records through the AE Oversight and Monitoring Process (AEOMP) and identifies if a critical incident has been unreported. If an unreported incident is discovered, the AEOMP reviewer communicates this finding immediately to the AE who is required to ensure that an incident report is filed and appropriate action is taken.

- e. **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 responsible for the oversight of and response to critical incidents. Within 24 hours of the submission of an incident report, both the designated AE and ODP Regional office staff review the incident to determine that appropriate actions to protect the participant occurred. After the final section of the incident report is submitted in HCSIS, the AE completes a management review within 30 days. The management review process determines that:

- The appropriate action to protect the participant occurred,
- The incident categorization is correct,
- Certified investigation occurred,
- Proper safeguards are in place,
- Corrective action in response to the incident has, or will, take place.

After the AE approves the incident report, ODP regional office staff complete a management review within 30 days. The management review validates all of the above including the AE’s response to the incident.

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Each regional office also reviews significant events during monthly Risk Management Workgroup meetings. The Risk Management Workgroup provides the AE or provider technical assistance when a need is identified.

ODP completes an analysis of aggregate incident data to identify patterns and trends statewide and regionally as described in Appendix H. ODP identifies factors that put people at risk and recommends appropriate interventions and improvement activities.

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:

N/A

- 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).

USE OF RESTRAINTS

Prohibited:

ODP prohibits the following types of restraints in 6400, 6500, 2380, 3800 and 5310 licensed settings:

- **Seclusion:** Seclusion is defined as 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.
- **Chemical:** 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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- When a physician orders a medication that is part of the ongoing individualized plan and has documented as such for treating the symptoms of mental illness, the medication is not considered a chemical restraint. The use of Pro Re Nata (PRN) medication will be done in accordance with State prescribed procedures which includes development of a post review protocol by the provider's quality improvement/risk management committee to ensure that use of the medication was consistent with the Bulletin's expectations.
- **Mechanical:** 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, goggles, waist straps, head straps, restraining sheets and similar devices. When a physician orders a mechanical device to protect the individual from possible harm following surgery or an injury, it is not a mechanical restraint. Examples of mechanical devices that are not restraints include a device used to provide support for functional body position or proper balance and a device used for medical treatment, such as sand bags to limit movement after medical treatment, a wheelchair belt that is used for body positioning and support or a helmet for prevention of injury during seizure activity, are not considered mechanical restraints.

All waiver providers must comply with regulations regarding precluded restraints in PA Code 55, Chapter 51, Section 22 . This includes the use of :

- Prone (face down) manual (physical) restraint. No provider, licensed or unlicensed, may use a prone restraint.

Permitted:

ODP permits the following types of restraints when the conditions outlined below are met:

- Manual restraints, commonly referred to as physical restraints, are permitted and used only as a last resort safety measure when the individual is in imminent danger of harming oneself and/or others and other measures are ineffective. 55 PA Code § 6500.172, 6400.202, 2380.161 defines a manual restraint as a hands-on technique that lasts more than 30 seconds. A hands-on technique lasting less than 30 seconds to guide or redirect the individual away from potential harm/injury is not considered a physical restraint. Manual restraint that inhibits the respiratory and/or digestive system, that involves compliance through the infliction of pain, hyperextension of joints, and pressure on the chest or joints, or that involves the use of 'takedown' techniques in which the individual is not supported and/or that allows for free fall as the individual goes to the floor are not permitted.
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- Mechanical restraints are permitted when they include the use of helmets, mitts and muffs to prevent self-injury on an interim basis but only for the first 3 months after admission to a licensed facility under 55 PA Code §2380, 6400 and 6500. If a mechanical restraint is used, the following apply:
 - The use of a mechanical restraint may not exceed 2 hours, unless a licensed physician examines the participant and gives written orders to continue the use of the restraint. Reexamination and new orders by a licensed physician are required for each 2-hour period the restraint is continued. If a restraint is

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removed for a purpose other than for movement and reused within 24 hours after the initial use of the restraint, it is considered continuation of the initial restraint.

- A licensed physician shall be notified immediately after a mechanical restraint is used.
- The restraint shall be checked for proper fit by staff at least every 15 minutes.
- Physical needs of the participant shall be met promptly.
- The restraint shall be removed completely for at least 10 minutes during every 2 hours the restraint is used.
- There shall be training for the participant aimed at eliminating or reducing the need for the restraint in the future.
- Chemical restraints are permitted in a licensed facility under 55 PA Code §2380, 6400 and 6500 if they are ordered by a licensed physician on an emergency basis and the following apply:
 - Prior to each incidence of administering a drug on an emergency basis, a licensed physician shall examine the participant and give a written order to administer the drug.
 - Prior to each re-administration of a drug on an emergency basis, a licensed physician shall examine the participant and order re-administration of the drug.
 - The participant's vital signs shall be monitored at least once each hour.
 - Physical needs of the participant shall be met promptly.

During licensing surveys, the Department validates that restraints, if administered, were applied in accordance with requirements.

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 reducing restraints statewide.

ODP encourages all providers to 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.

USE OF ALTERNATIVE METHODS BEFORE INSTITUTING RESTRAINTS AND PROTOCOLS

Physical restraint is always a last resort emergency response to protect the participant's safety. Consequently, it is never used as a punishment, therapeutic technique or for staff convenience. The participant is immediately to be released from the restraint as soon as it is determined that the participant 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".

METHODS FOR DETECTING UNAUTHORIZED USE OF RESTRAINTS

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A review of each type of restraint that has been employed is undertaken by ODP so the provider and Commonwealth can determine if the use of the restraint was unauthorized. This review is referred to as a debriefing session. ODP policy describes how this process may identify if a restraint was unauthorized.

Debriefing sessions address the needs directly following a restraint where events and strategies are discussed in greater depth and detail. The debriefing sessions should work to address trauma and minimize the negative effects of the use of restraint while addressing the following components:

- Thorough analysis of the events that occurred before, during and after each incident.
- Strategies to prevent or decrease the time of future restraints
- Skills or methods to prevent a future crisis.
- Appropriate additions, deletions, or modifications to an participant's individual support plan, including recommendations and outcomes.

RESTRAINT AUTHORIZATION

ODP policy requires the report and investigation of any restraint determined to be improper or unauthorized. Any 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 restraints.

Licensing regulations for licensed residential services and adult training facilities outline the requirements related to restraints. When the same participant experiences a restraint twice in a 6-month period, a behavior support plan must be developed, reviewed and approved before any additional restraints are implemented for that person.

Regulations also specify the content of the restrictive procedure plan. It must address:

- The specific behavior addressed;
- Antecedent or reason for behavior;
- Measurable desired outcome;
- Behavior modification methods;
- Alternatives to restrictive behaviors; and,
- What type of procedure, under what circumstances its applied and how.

If a restraint is used in a licensed setting, the restraint application will be reviewed by a restrictive procedure review committee that is convened by the provider. The restrictive procedure review committee contains a majority of persons who do not provide direct services to the participant and is responsible to establish a time frame for review and revision of the restrictive procedure plan, not to exceed 6 months between reviews. Recommendations from the committee must be incorporated or responded to prior to approval of the restrictive procedure plan being approved for implementation.

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During licensing surveys, if there has been a restraint requiring the development of a plan, that plan must be evaluated to ensure review and approval by the chairman of the restrictive procedure review committee and by the provider program specialist prior to the use of restraint.

PRACTICES THAT MUST BE EMPLOYED IN THE ADMINISTRATION OF A RESTRAINT TO ENSURE HEALTH AND SAFETY OF INDIVIDUALS

According to ODP policy, a participant's physical condition must be evaluated throughout the restraint in order to minimize the potential of individual harm or injury. Manual (physical) restraints cannot exceed 30 minutes within a two-hour time period. A participant is immediately released from physical restraint when they no longer present a danger to self or others. Support staff monitor the participant for signs of distress throughout the restraint process and for a period of time (up to two hours) following the application of a restraint.

The restrictive procedure plan includes the specific behavior to be addressed, the suspected antecedent or reason for the behavior, the single behavioral outcome desired stated in measurable terms, and a target date for achieving the outcome. The restrictive procedure plan must also include methods for modifying or eliminating the behavior, such as changes in the participant's physical and social environment, changes in the participant's routine, improving communication, teaching skills and reinforcing appropriate behavior. It must also contain the types of restrictive procedures that may be used and the circumstances under which the procedure may be used, the amount of time the restrictive procedure may be applied and the physical problems that require special attention during the use of the restrictive procedure.

DETAILED DOCUMENTATION REGARDING THE USE OF RESTRAINTS

According to ODP policy, all licensed providers must have written restraint policies. ODP annual licensing inspections review compliance with the following requirements:

- A restrictive procedure plan must be developed and approved prior to the use of any restraint
- A restrictive procedure plan must be developed to ensure the health and safety of a participant when 2 or more emergency restraints are employed within 6 months.
- The restrictive procedure plan, and revisions, must be documented in the ISP.
- 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 participant.
- Copies of the restrictive procedure plan are kept in the participant's record.
- Meeting records of the restrictive procedure committee are also required kept on file.
- Each restraint is reported/documented in HCSIS
- Documentation of the training program must include:
 - Names of staff trained
 - Dates trained
 - Training description
 - Source of training

EDUCATION AND TRAINING REQUIREMENTS FOR PERSONNEL WHO ADMINISTER RESTRAINTS

Regulations require that provider staff that administer restraints have specific training. This training must be completed within the past 12 months and focus on the proper procedures and specific techniques to follow, ethics of using restraints and alternative positive approaches.

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- 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. ODP Regional risk management committees monitor the incidence of restraint applications. Action plans are developed including strategies intended to remediate and/or improve outcomes for consumers.

Appendix G-2: Safeguards Concerning 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 specifications are available to CMS upon request through the Medicaid agency or the operating agency.

APPROPRIATE USE OF RESTRICTIVE INTERVENTIONS

Prohibited

ODP prohibits the following types of restrictive interventions:

- The use of aversive conditioning, defined as the application, contingent upon the exhibition of maladaptive behavior, of startling, painful or noxious stimuli, is prohibited.
- Seclusion, defined as placing a participant in a locked room, is prohibited. A locked room includes a room with any type of door locking device, such as a key lock, spring lock, bolt lock, foot pressure lock or physically holding the door shut.
- Personal Funds and Property:
 - A participant's personal funds or property may not be used as reward or punishment.

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A participant's personal funds or property may not be used as payment for damages unless the participant consents to make restitution for the damages.

Permitted

ODP strongly discourages the use of restrictive interventions. If restrictive interventions are applied they must conform to the following in order to be permitted:

- 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 participant's developmental program and may only be employed as a last resort.
- A restrictive procedure may not be used unless less restrictive techniques and resources appropriate to the behavior have been tried but have failed.
- Restrictive interventions/procedures other than restraints may include:
 - Token economies or other reward and/or level systems as part of programming
 - Environmental restrictions, for example, limiting access to food for individuals diagnosed with Prader Willi.
 - Intensive supervision such as 1:1 or 2:1 staffing levels or higher, for purposes of behavior monitoring/intervention/redirection.
 - Anything that a person is legally mandated to follow as part of probation or a court restriction that is superseded by our regulation and other ODP policy.
 - Exclusions are permitted as follows:
 - Exclusion is the removal of a participant from the participant's immediate environment and restricting the participant alone to a room or area. If a staff person remains with the participant, it is not exclusion.
 - Exclusion shall be used only when necessary to protect the participant from self-injury or injury to others.
 - Exclusion shall be used only when it has been documented that other less restrictive methods have been unsuccessful in protecting the participant from self-injury or injury to others.
 - A participant shall be permitted to return to routine activity within the time specified in the restrictive procedure plan not to exceed 60 minutes within a 2-hour period.
 - Exclusion may not be used for a participant more than 4 times within a 24-hour period.
 - A participant in exclusion shall be monitored continually by a staff person.
 - A room or area used for exclusion shall have at least 40 square feet of indoor floor space, with a minimum ceiling height of 7 feet.
 - A room or area used for exclusion shall have an open door or a window for staff observation of the participant.
 - A room or area used for exclusion shall be well lighted and ventilated.

USE OF NON-RESTRICTIVE METHODS FIRST

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

PROTOCOLS FOR AUTHORIZING THE USE OF RESTRICTIVE INTERVENTIONS, INCLUDING TREATMENT PLANNING AND REVIEW/AUTHORIZING PROCEDURES.

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- Prior to a restrictive procedure being employed a restrictive procedure review committee must approve the use. The restrictive procedure review committee shall include a majority of persons who do not provide direct services to the participant and is convened by the provider. The committee establishes time frames for review and revision of the restrictive procedure plan, not to exceed 6 months between reviews. The committee will ensure that the restrictive procedure plan includes the types of restrictive procedures that may be used and the circumstances under which the procedures may be used, the specific behavior to be addressed and the suspected antecedent or reason for the behavior, and outcome desired stated in measurable terms. Methods for modifying or eliminating the behavior, such as changes in the participant's physical and social environment, changes in the participant's routine, improving communications, teaching skills and reinforcing appropriate behavior will also be included in the plan and reviewed by the committee.

METHODS FOR DETECTING UNAUTHORIZED USE OF RESTRICTIVE INTERVENTIONS

ODP has initiated statewide activities such as Positive Approaches and participates in the Department of Public Welfare's initiative to reduce restrictive interventions. 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.

- **Support Coordinator Monitoring**

SCs review incidents reported and meet with the consumer in various settings for a specific number of times per year depending upon the waiver type. During these monitoring visits, they meet the consumer in various settings and observe their interactions with staff and others. If restrictive procedures are observed and there is no restrictive procedure plan in place, the SC must report this as an incident in HCSIS and follow through with the provider to assure that a plan is developed before any additional restrictive procedures can be applied.

REQUIRED DOCUMENTATION (RECORD KEEPING) WHEN RESTRICTIVE INTERVENTIONS ARE USED

- **Restrictive procedure records**

A record of each use of a restrictive procedure documenting the specific behavior addressed, methods of intervention used 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 participant if exclusion was used and the participant's condition during and following the removal of the restrictive procedure shall be kept in the participant's record.

EDUCATION AND TRAINING REQUIREMENTS FOR PERSONNEL WHO AUTHORIZE AND/OR ADMINISTER RESTRICTIVE INTERVENTIONS

Regulations require that provider staff that administer restraints have specific training. This training must be completed within the past 12 months and focus on the proper procedures and specific techniques to follow, ethics of using restraints and alternative positive approaches.

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- 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:

ODP is responsible for overseeing the use of restrictive interventions and ensuring that the state's safeguards are followed.

During annual licensing inspections of providers, 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.

ODP recognizes the importance of data analysis in monitoring and preventing inappropriate use of restrictive interventions. Our current data analysis activities occur on an as needed basis, as issues arise. We are working to develop an ongoing, systematic approach to data analysis in order to better protect the health and welfare of our waiver participants.

Appendix G 3: Medication Management and Administration

- 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.

For participants that take medication their Supports Coordinators review medication regimens during each face-to-face monitoring visit using the ISP monitoring tool which lists the medication that the person takes; the reason for the medication; the total daily dose; whether or not blood levels are necessary to follow; and what the medication is supposed to do. Monitoring to detect potentially harmful practices related to medication occurs for all waiver participants that take medication. The elements of the tool designed to do this include: looking at the completeness and correctness of medication administration documentation; efficacy of medication; knowledge of side effects and strategy to report; changes in medications or presence of side effects; changes in health that might be related to medication; and appropriate and timely communication about health issues between medical practitioners and the participant's team. SCs also document allergies including those to medications in the ISP. The ISP monitoring tool is used to monitor medication given at home including a licensed, residential setting, and in a day program. Monitoring of medication occurs three times a quarter in different locations in the Consolidated waiver and once every six months each in the home and at the day program for the PFDS waiver. The Health Care Quality Units (HCQUs) are available for support with regard to questions about medications and on request will review medications for individuals particularly those with complex medication regimens or behavior modifying medications as part of their treatment program.

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The ODP uses the DPW Medication Administration Program to teach unlicensed staff to give medication to participants using a standard curriculum. Many of the provider agencies have nurses. Some of the nurses become trainers and monitor medication through the course, while others provide oversight within the agency for medication administration and health issues. The course requires periodic reviews of staff performance to maintain certification. These include reviews of Medication Administration Records (MAR) or logs for each staff member administering medications. The review of medication administration logs for errors in documentation includes matching the person's prescribed medications on the log to those available to be given. Maintenance of certification requires review of 4 MARs and two observations of passing medication and documentation. Providers are to use MARs from different participants when completing the reviews so that each of the participants' medication regimens are reviewed across the year. As well the course teaches staff to review medication when it is received from the pharmacy and compare it to the MAR, thus providing a regular review of medications by provider staff. Part of the documentation and checks include looking at medication allergies for the possibility of a contraindicated drug.

ODP licensing also monitors medication and medication administration. Providers with licensed sites are monitored using a sampling strategy. Licensing personnel look at trainer and medication administrator certification as well as medication regimens on MARs as compared to the physician documentation to assure consistency between the two. As well they compare allergies and unusual reactions to medication to the medication list to detect any use of contraindicated medications. ODP nurses may be involved when medication regimens are complex or licensing personnel have questions about the implementation of the medication course to provide clinical input.

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.

ODP nurses not only teach the medication administration course, but also monitor the provider activities around medication administration and the performance of the provider trainers in order to assure safety and maintain the integrity of the program. These reviews occur periodically and usually in response to either a problem related to licensing surveys or a request from the provider because of issues at the agency. A formal checklist is employed for providers where the ODP nurses evaluate their program. The nurses also may provide technical assistance with respect to medication errors and the implementation of the medication program. They, then follow-up on these recommendations and any plans of correction required by licensing related to medication administration to assure that the potentially harmful practices are remedied. Follow-up occurs by visiting the provider site and either observing the medication administration training or reviewing charts to assess the changes in practice. In addition to this the HCQUs have developed standard guidance for providers regarding medication administration policies and procedures to supplement what is in the standard course and provide technical assistance regarding medication administration and implementing changes to prevent errors.

c. Medication Administration by Waiver Providers

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

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

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- **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. Licensed nurses 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.

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, AEs, SCs and providers.

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

There are no types of medication errors that providers are required to record, but not report.

- (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:

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N/A

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 in the administration of medication to waiver participants both directly and indirectly. As described in section G-3bi direct monitoring occurs through annual ODP licensing reviews and periodically by the state nurses that teach the course. In addition the AEOMP directly evaluates individual waiver participant's medication information during monitoring. Each AE is monitored by reviewing a sample of people in the waiver. Indirect monitoring occurs through monitoring by the AEs and supports coordination (SC) monitor medications for individuals. SCs monitor medication administration and practices in the manner described in G-3bii. AEs monitor the performance of SCs and review medication errors through their risk management processes including evaluating the information about how the errors occurred in order to intervene with a provider that shows poor medication administration practices. Health Care Quality Units (HCQUs) also provide indirect monitoring of medication administration through their individual case and provider reviews. These are done on an as needed basis. When HCQUs, SCs, and AEs review medications, the results are communicated to the ODP in a number of ways. Typically the SCs and AEs participate in HCQU reviews and then document any suggestions in service notes. Provider issues related to implementation of the Medication Administration course are referred to the nurses or the Medical Director to be addressed either at the level of the provider or the level of the course if an issue is identified. Licensing documents findings in their licensing reports, but also communicates any issues around the implementation of the course to the nurses and the Medical Director by phone, email or in person.

The reporting strategy for medication errors facilitates a root cause analysis on the part of the provider related to each specific medication error. Problems with specific providers regarding medication administration practices are remediated in a number of ways. The nurses from ODP provide technical assistance to the providers around their medication practices especially those that are identified as being unsafe or problematic. The medication administration course itself includes a set of standard remediations for medication administrators that have made errors in order to assure that they know how to properly administer and document related to that particular situation. The HCQUs provide training and technical assistance to providers on an on-going basis to promote the use of best practices around medication administration.

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.