Medicaid agency or the operating agency (if applicable).

Appendix G: Participant Safeguards

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.

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

02/03/2021

ODP uses an electronic web-based reporting solution for incident reporting and management known as the Enterprise Incident Management (EIM) system. All provider entities and Supports Coordination Organizations (SCOs) are considered reporting entities and use EIM to report incidents to ODP. The incident lifecycle contains an incident notification process (known as the first section submission), a formalized investigation if warranted, a final notification process (known as the final section submission), and an approval process (known as the closure of the incident). When an event occurs, or is alleged to have occurred, that is considered an incident per policy, the initial notification is made by the reporting entity (provider or SCO) by submitting the first section of the incident report to ODP within 24 hours of discovery or recognition. Supports Coordinators receive an alert that an incident was filed for a participant receiving Supports Coordination services through the SCO. This first section of the incident report includes a description of the event, incident categorization, as well as the action taken to ensure the health and safety of the participant. Once the first section is submitted, ODP will review the first section of the incident report to ensure that prompt action was taken to protect the participant's health, safety, and rights. If the actions taken are insufficient, ODP will contact the reporting entity and direct additional actions.

All incidents are investigated to rule out or identify instances of abuse, neglect, or exploitation. In addition, certain categories of incidents are required to be investigated by an ODP certified investigator.

Abuse is defined as a deliberate or careless act by a person, including another individual receiving services, which may result in mental or physical harm. Abuse includes misapplication or unauthorized use of restraint with or without injury, physical and psychological acts. Abuse is reported on from the victim's perspective, not the person committing the abuse.

Neglect is defined as the failure to obtain or provide the needed services and supports defined as necessary or otherwise required by law, regulation, policy, or plan (service plan, Behavioral Support Plan, safety plan, etc.). This includes acts that are intentional or unintentional regardless of the obvious occurrence of harm. Examples of neglect include failure to provide medication management, needed services and supports, needed supervision, or protection from hazards, and staff/volunteer receiving a moving violation during the provision of services.

Exploitation is defined as an act or course of conduct by a person against an individual or an individual's resources without informed consent or with consent obtained through misrepresentation, coercion, or threats of force, which results in monetary, personal, or other benefit, gain, or profit for the target, or monetary or personal loss to the individual. Exploitation should be reported regardless of the actual or perceived value of the loss. Exploitation includes failure to obtain informed consent, illegal or improper act of using the material resources or possessions of an individual, requiring an individual to pay for medical care or items covered by insurance or other means, missing/theft of medications, misuses/theft of funds, requiring an individual to pay for items covered by room and board or charging more than allowable rates for room and board, and using an individual to perform unpaid labor.

Rights violation is defined as an unauthorized act which improperly restricts or denies the human or civil rights of an individual, including those rights which are specifically mandated under applicable law, regulation, policy, or plan. Rights violations include any violation of civil or legal rights afforded by law, failure to support an individual to communicate at all times, failure to support choice and opportunity related to health care, violation of privacy, violation of an individual's right to control services received, and any unauthorized use of a restrictive procedure.

Sexual Abuse is defined as any attempted or completed nonconsensual sexual act. The act may be physical or non-physical and achieved by force, threats, bribes, manipulation, pressure, tricks, violence or against an individual who is unable to consent or refuse. Sexual abuse includes any act or attempted act that is sexual in nature between a paid service provider staff and an individual regardless of consent on the part of the individual.

As part of the investigation, an investigator must take his or her first witness statement within 24 hours of being assigned an investigation. The investigator must also complete all witness interviews within 10 days of being assigned the investigation. The investigation and a final investigation determination (either confirmed or not confirmed) must be completed within 30 days.

An incident report is considered finalized when the reporting entity submits the final section of the incident report to ODP. Where appropriate, the final section of the incident report will include the investigation determination as well as the corrective actions that were carried out or planned in order to mitigate and prevent the reoccurrence of the incident. All incident reports must be finalized within 30 days from the date of discovery or recognition or the incident report is not

considered timely. If the reporting entity is unable to finalize the incident report within 30 days due to circumstances beyond its control, the reporting entity shall notify ODP that an extension is necessary and provide the reason for the extension. When the need for an extension is submitted, the reporting entity is obligated to adhere to the extension deadline otherwise the finalization of the incident report is not considered timely.

After the reporting entity finalizes an incident report, ODP performs a review of the incident report within 30 days from the date of finalization. This review ensures that the incident was managed effectively and according to policy and that the investigation determination is supported by evidence, corrective actions are appropriate, planned, and prevent reoccurrence, and other pertinent information is included as necessary.

In addition to reporting incidents to ODP, Pennsylvania also has protective service laws in place for adults with disabilities (ages 18-59) and older adults (ages 60 and over). All provider entities are mandated by law to report incidents of abuse, neglect, exploitation, and suspicious death to the appropriate protective services agencies.

Below is a listing of the types of incidents that require reporting within 24 hours of occurrence or discovery:

- (1) Death.
- (2) An intentional and voluntary act to take one's own life
- (3) Inpatient admission to a hospital.
- (4) Abuse, including abuse to an individual by another individual.
- (5) Neglect, including passive and self-neglect.
- (6) Exploitation.
- (7) An individual who is missing for more than 24 hours without prior arrangement or who could be in jeopardy if missing for any period of time.
- (8) Law enforcement activity that occurred during the provision of a service or for which an individual is the subject of a law enforcement investigation that may lead to criminal charges against the individual.
- (9) Injury requiring treatment beyond first aid.
- (10) Fire requiring the services of the fire department or other safety personnel not including responses to false alarms.
- (11) Site closure.
- (12) A violation of individual rights.
- (13) Theft or misuse of individual funds.
- (14) Public Health Emergency

The following types of incidents require reporting within 72 hours of occurrence or discovery:

- (1) Physical restraint.
- (2) A medication error as specified in § 6100.466 (relating to medication errors), if the medication was ordered by a health care practitioner.

The following types of incidents require a formalized investigation to be completed by a Department-certified incident investigator:

- (1) Death that occurs during the provision of a service.
- (2) Inpatient admission to a hospital as a result of an accidental or unexplained injury or an injury caused by a staff person, another individual or during the use of a restraint.
- (3) Abuse, including abuse to an individual by another individual.
- (4) Neglect, with the exception of passive or self-neglect.
- (5) Exploitation.
- (6) An injury requiring treatment beyond first aid as a result of an accidental or unexplained injury or an injury caused by a staff person, another individual or during the use of a restraint.
- (7) Theft or misuse of individual funds.
- (8) A violation of individual rights.
- 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 that includes contact information for Supports Coordinators, local authorities, family members, and advocacy organizations. Waiver participants, families, and/or legal representatives can use this information as needed to report concerns regarding abuse, neglect, and exploitation. This information is discussed at least annually or more frequently as determined necessary by the Supports Coordinator and at the request of a participant or caregiver. ODP has a series of webinars and webcasts that are available to participants and families on the topic of recognition and reporting of incidents, including abuse, neglect and exploitation.

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.

ODP receives initial notification within the EIM system when the first section of the incident report is submitted by a provider or SCO. Notification is also received when the final section of the incident report is submitted by a provider or SCO. ODP evaluates all incident reports within 24 hours of their submission 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 contacting emergency services such as 911, arranging medical care, separating the perpetrator and victim, arranging counseling or referring to a victim assistance program.
- When applicable, the provider met the mandatory reporting requirements by contacting the appropriate protective services agency for adults with a disability or older adults.
- The provider notified the family or guardian of the incident within 24 hours (unless otherwise indicated in the service plan).
- When applicable, the provider initiated an investigation by assigning the case to an ODP Certified Investigator (CI).

ODP requires separation of the victim from the alleged perpetrator (also known as the "target" of the investigation) when an allegation of abuse, neglect, or exploitation is made, and the individual's health and safety are jeopardized. Targets may not have contact with any participants registered to receive services until the investigation is concluded. This separation may include suspending or terminating the alleged target. ODP also complies with Pennsylvania's ACT 28/26, which requires reporting the abuse or neglect of care-dependent persons to the State Attorney General's office and/or the local District Attorney's offices.

When a participant who is residing with his or her family experiences an incident that jeopardizes the victim's health and safety, the provider, Supports Coordinator or ODP will seek the assistance of law enforcement or Protective Service Agencies, who have the authority to remove the alleged perpetrator or the victim from the home or environment to ensure safety.

Incidents of abuse, neglect, exploitation, rights violation and death are investigated by persons that have completed the Department's approved certification course. CIs follow protocols established by ODP as part of the investigatory process. CIs 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). The provider then completes and finalizes the report, including the investigation summary, within 30 days of the incident.

ODP evaluates all finalized reports within 30 days of their notification and approve the report if:

- The appropriate action to protect the participant's health, safety and rights occurred;
- The incident was correctly categorized;
- Timely completion of the certified investigation occurred;
- The investigation summary supports the conclusion;
- Safeguards to prevent reoccurrence are in place;
- Corrective actions have occurred, or are planned to occur, in response to the incident to prevent reoccurrence. When corrective actions are planned the anticipated date of completion must be indicated;
- Changes were made in the participant's service plan necessitated by or in response to the incident;
- The participant or participant's family received notification of the findings by the reporting entity prior to the finalization of the incident report, unless otherwise indicated in the service plan; and
- Incidents of abuse, neglect and exploitation were reported to the appropriate authority as required by Pennsylvania law.

ODP disapproves reports that fail to meet the criteria described above. Disapproved reports revert to the reporting entity, who corrects any deficiencies and resubmits the report for re-evaluation. ODP will continue to work with and monitor the reporting entity to ensure appropriate adherence to the established policies. If the report is satisfactory, ODP closes the incident report.

If additional time is needed to finalize the report, the provider can have the deadline extended. Situations that may warrant an extension of time may include but are not limited to: discharge from hospital has not occurred, investigation is not complete due to law enforcement involvement or criminal justice activities, or witnesses are not able to be interviewed timely due to extenuating circumstances.

Supports Coordinators identify unreported incidents as they conduct monitoring of services and supports including documentation reviews. ODP identifies unreported incidents as part of the waiver participant record review sample. When an unreported incident is identified, the reviewer communicates this finding immediately to the provider who is required to ensure that an incident report is filed and appropriate action is taken to mitigate the incident and ensure action is taken to prevent reoccurrence.

Prior to each of their monthly contacts with participants, Supports Coordinators review EIM for the status of the participants' incident reports and to identify the need for any ISP changes to prevent re-occurrence of any incidents.

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. ODP evaluates all finalized reports, and completes a management review within 30 days after the provider submits the incident report. This oversight occurs on an ongoing basis.

The EIM system supports incident management for ODP by allowing for the documentation and analysis of incident data. Data from EIM is used to support implementing quality improvement, risk management and incident management processes for all levels of the support and service system. Through a review of the data, ODP identifies factors that put participants at risk and facilitates the development of interventions and improvement activities to mitigate future risk or reoccurrence. Key data elements of the incident management system include:

- Evidence of prompt and appropriate action in response to incidents.
- Timely reporting of incidents.
- Investigation of incidents.
- Corrective action in response to incidents.

ODP staff meet quarterly to review aggregated incident report data, discuss trends, identify possible causes of trends, and specify next steps for reducing participants' risk of abuse, neglect, or exploitation.

Appendix G: Participant Safeguards

Appendix G-2: Safeguards Concerning Restraints and Restrictive Interventions (1 of 3)

a. Use of Restraints. (Select one): (For waiver actions submitted before March 2014, responses in Appendix G-2-a will display information for both restraints and seclusion. For most waiver actions submitted after March 2014, responses regarding seclusion appear in Appendix G-2-c.)

The state does not permit or prohibits the use of restraints

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

The use of restraints 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. 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). State laws, regulations, and policies that are referenced are available to CMS upon request through the Medicaid agency or the operating agency (if applicable).

ODP only permits physical restraints, defined as a manual method that restricts, immobilizes or reduces a participant's ability to move his arms, legs, head or other body parts freely. Physical restraints may only be used in the case of an emergency to prevent a participant from immediate physical harm to himself or others. A physical restraint may not be used for more than 30 cumulative minutes within a 2-hour period.

Physical restraints may be used only as a last resort safety measure when the participant is in immediate danger of harming him or herself and/or others and less restrictive techniques and resources have been tried but failed. A physical restraint may not be used as a behavioral intervention, consequence, retribution, punishment, for the convenience of staff persons or as a substitution for staffing or individual support.

The following restraints are prohibited:

- Prone position physical restraints and any physical restraint that inhibits digestion or respiration, inflicts pain, causes embarrassment or humiliation, causes hyperextension of joints, applies pressure on the chest or joints or allows for a free fall to the floor.
- Aversive conditioning, defined as the application of startling, painful or noxious stimuli.
- Pressure point techniques, defined as the application of pain for the purpose of achieving compliance. A clinically accepted bite release technique that is applied only as long as necessary to release the bite is not considered a pressure point technique.
- A chemical restraint, defined as a drug used for the specific and exclusive purpose of controlling acute, episodic behavior. A chemical restraint does not include a drug ordered by a health care practitioner or dentist for the following use or event:
- (i) Treatment of the symptoms of a specific mental, emotional or behavioral condition.
- (ii) Pretreatment prior to a medical or dental examination or treatment.
- (iii) An ongoing program of medication.
- (iv) A specific, time-limited stressful event or situation to assist the participant to control the participant's own behavior.
- A mechanical restraint, defined as a device used to control acute, episodic behavior that restricts the movement or function of a participant or portion of a participant's body, including a geriatric chair, bedrail that restricts the movement or function of the participant, helmet with fasteners, waist strap, head strap, restraint vest, camisole, restraint sheet, restraint board, handcuffs, anklets, wristlets, muffs and mitts with fasteners, chest restraint, and other similar devices. A mechanical restraint does not include the use of a seat belt during movement or transportation. A mechanical restraint does not include a device prescribed by a health care practitioner for the following use or event:
- (i) Post-surgical or wound care.
- (ii) Balance or support to achieve functional body position, if the participant can easily remove the device or if the device is removed by a staff person immediately upon the request or indication by the participant, and if the service plan includes periodic relief of the device to allow freedom of movement.
- (iii) Protection from injury during a seizure or other medical condition, if the participant can easily remove the device or if the device is removed by a staff person immediately upon the request or indication by the participant, and if the service plan includes periodic relief of the device to allow freedom of movement.

Physical restraints must be included in the service plan and must be approved by a human rights team prior to implementation. The service plan must be reviewed, and revised, if necessary, according to the time frame established by the human rights team, not to exceed 6 months.

The service plan with restrictive interventions, including physical restraints, must include:

- (1) The specific behavior to be addressed.
- (2) An assessment of the behavior including the suspected reason for the behavior.
- (3) The outcome desired.
- (4) Methods for facilitating positive behaviors such as changes in the individual's physical and social environment, changes in the individual's routine, improving communications, recognizing and treating physical and behavior health conditions, voluntary physical exercise, redirection, praise, modeling, conflict

resolution, de-escalation and teaching skills.

- (5) Types of restrictive procedures that may be used and the circumstances under which the procedures may be used.
- (6) A target date to achieve the outcome.
- (7) The amount of time the restrictive procedure may be applied.
- (8) The name of the staff person responsible for monitoring and documenting progress with the individual plan.

Through review of the incident report and service plan, ODP monitors both the use of approved physical restraints and the procedures used when or if such methods were employed. This process is also used to ensure that no providers have utilized the prohibited practices of seclusion or prone position restraint.

The use of a 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 physical restraint as soon as it is determined that the participant is no longer a risk to himself/herself or others. Additionally, regulations specifically state, "Every attempt shall be made to anticipate and de-escalate the behavior using techniques less intrusive than a restrictive procedure." Service plans identify strategies to avoid the need for restraints. These plans identify the antecedents, thereby enhancing opportunity to intercede before the use of restraint is needed. A restrictive procedure may not be used unless less restrictive techniques and resources appropriate to the behavior have been tried but have failed.

ODP detects unauthorized or misapplied physical restraints through the various oversight and monitoring processes. Physical restraints that do not follow ODP standards are reported as abuse.

Regulations require provider staff that administers physical restraints to have specific training regarding the appropriate use and safe implementation, as well as de-escalation techniques/alternatives. This training must be completed within the past 12 months and focus on the proper procedures and specific techniques to follow, ethics of using physical restraints and alternative positive approaches.

ODP utilizes a person-centered planning model for all activities associated with provider training for authorized physical restraints. Training and education for administering a physical restraint is based on the unique needs of the participant as outlined in the service plan. ODP requires that staff associated with waiver services that may need to employ a physical restraint be trained to meet the unique needs of the participant which includes but is not limited to communication, mobility and behavioral needs.

Training curricula and frequency is directly related to the person-centered plan that includes the use of physical restraints. According to regulation, frequency of staff training must occur prior to rendering services to a participant.

Examples of the types of education and trainings include multiple nationally recognized intervention programs that focus on the use of least restrictive interventions such as Safe Crisis Management Certification Training Program and Crisis Prevention Institute's techniques of Nonviolent Crisis Management.

According to ODP policy, a participant's physical condition must be evaluated throughout the physical restraint in order to minimize the potential of harm or injury to the participant. A participant is immediately released from a physical restraint when he or she no longer presents a danger to self or others. Support staff monitors the participant for signs of distress throughout the restraint process and for a period of time (up to 2 hours) following the application of a physical restraint.

All anticipated physical restraint usage must be reviewed with the participant's Primary Care Physician (PCP) to ensure that there are no potential negative health and safety impacts. For example, a PCP may not agree to allow a physical restraint to be used for a participant with osteoporosis due to the risk of a broken bone.

ii. State Oversight Responsibility. Specify the state agency (or agencies) responsible for overseeing the use of restraints and ensuring that state safeguards concerning their use are followed and how such oversight is

conducted and its frequency:

ODP is responsible for oversight of the use of restraints. ODP reviews and approves all service plans, which allows ODP to identify for which participants restraints have been approved. The Department has the authority require revisions or the removal of any restrictive intervention from a service plan. When restraints are used, they are reported as incidents in the EIM system by the entity that employed the restraint. These entities must conduct a monthly analysis of restraint usage to identify trends and patterns and to support strategies to reduce restraint usage at the organization. ODP verifies during oversight monitoring that these activities are being conducted. Physical restraints that are employed and do not follow ODP guidelines are reported as an incident of abuse and investigated. As a result of the investigation and the incident management process, strategies are developed to prevent reoccurrence. In addition, through the personcentered planning process, teams regularly meet to review and discuss progress, lack of progress, and any overuse or misuse of restraints.

As part of the Department's annual licensing inspection process for licensed settings, licensing staff reviews incidents to identify participants who have been restrained and to verify regulations have been met. Providers that frequently use restraints are provided technical assistance, training and other resources needed to decrease the use of restraints.

ODP staff meet quarterly to review aggregated data, discuss trends, identify possible causes of trends and specify next steps for eliminating inappropriate use of restraints.

Appendix G: Participant Safeguards

Appendix G-2: Safeguards Concerning Restraints and Restrictive Interventions (2 of 3)

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.

Service plans with restrictive procedures must be developed and approved by a human rights team prior to implementation. The service plan with restrictive procedures must be reviewed, and revised, if necessary, according to the time frame established by the human rights team, not to exceed 6 months.

The service plan with restrictive interventions, including physical restraints, must include:

- (1) The specific behavior to be addressed.
- (2) An assessment of the behavior including the suspected reason for the behavior.
- (3) The outcome desired.
- (4) Methods for facilitating positive behaviors such as changes in the participant's physical and social environment, changes in the participant's routine, improving communications, recognizing and treating physical and behavior health conditions, voluntary physical exercise, redirection, praise, modeling, conflict resolution, de-escalation and teaching skills.
- (5) Types of restrictive procedures that may be used and the circumstances under which the procedures may be used.
- (6) A target date to achieve the outcome.
- (7) The amount of time the restrictive procedure may be applied.
- (8) The name of the staff person responsible for monitoring and documenting progress with the plan.

Permitted restrictive interventions include:

- Token economies or other reward and/or level systems as part of programming.
- Environmental restrictions.
- Limiting access to objects or items, such as limiting access to food for participants diagnosed with Prader Willi.
- Any requirement that a person is legally mandated to follow as part of probation or a court restriction that supersedes regulation or other ODP policy.

Prohibited restrictive interventions include:

- The use of aversive conditioning; defined as the application, contingent upon the exhibition of maladaptive behavior, of startling, painful or noxious stimuli.
- Access to or the use of a participant's personal funds or property may not be used as reward or punishment. 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.

A restrictive intervention may not be used as retribution, for the convenience of the staff persons or family, as a substitute for the program or in a way that interferes with the participant's developmental program. For each incident requiring restrictive interventions, every attempt shall be made to anticipate and de-escalate the behavior using methods of intervention less intrusive than restrictive interventions. A restrictive intervention may not be used unless less restrictive techniques and resources appropriate to the behavior have been tried but have failed.

Waiver service providers are to pursue alternative strategies to the use of restrictive interventions. If the participant receives Specialized Skill Development services, the participant's Behavioral Support Plan (BSP) and Crisis Intervention Plan (CIP) identify specific interventions tailored to the participant that anticipate and de-escalate challenging behaviors before restrictive interventions are considered necessary.

ODP requires documentation of restrictive intervention usage as part of the progress notes completed by provider staff. ODP utilizes a person-centered planning model for all activities associated with provider training for authorized restrictive interventions. Training and education surrounding restrictive interventions are based on the unique needs of the participant as outlined in the service plan with restrictive procedures. The curriculum is based on the specific techniques outlined in the behavior support plans with restrictive procedures. ODP requires that staff associated with waiver services that may need to employ a restrictive intervention be trained to meet the unique needs of the participant which includes but is not limited to communication, mobility and behavioral needs (these education and training requirements are outlined in Appendix C: Participant Services C-1/C-3: Service Specification).

Training curricula and frequency is directly related to the person-centered plan that includes the use of restrictive interventions. According to regulation, frequency of staff training must occur prior to rendering

services to a participant.

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 oversees the use of restrictive interventions through oversight monitoring activities. Service plans with restrictive procedures are approved by a human rights team prior to the use of any restrictive intervention. The only exception to using a restrictive intervention without an approved plan is when the intervention is used for the first time during an emergency situation in order to protect the health and safety of a participant. Restrictive interventions that do not follow ODP guidelines are reported as an incident of a rights violation and investigated. As a result of the investigation and incident management process, strategies are developed to prevent reoccurrence. In addition, through the person-centered planning process, the team regularly meets to review and discuss progress, lack of progress, and any overuse of restrictive interventions.

As part of the Department's annual licensing inspection process for licensed settings, licensing staff review service plans to identify participants who have restrictive interventions in place and to verify that restrictive intervention procedure plan regulations have been met. Providers that frequently use restrictive interventions are provided technical assistance, training and other resources needed to decrease restrictive intervention usage.

Appendix G: Participant Safeguards

Appendix G-2: Safeguards Concerning Restraints and Restrictive Interventions (3 of 3)

c. Use of Seclusion. (Select one): (This section will be blank for waivers submitted before Appendix G-2-c was added to WMS in March 2014, and responses for seclusion will display in Appendix G-2-a combined with information on restraints.)

The state does not permit or prohibits the use of seclusion

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

ODP prohibits seclusion as a type of restrictive intervention. ODP is the state agency responsible for monitoring and overseeing the use of restrictive interventions to ensure that seclusion is not a method being used. When alleged seclusion has been identified, the usage is reported as an incident of abuse and investigated. As a result of the investigation and incident management process, strategies are developed to prevent reoccurrence.

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

i. Safeguards Concerning the Use of Seclusion. Specify the safeguards that the state has established

concerning the use of each type of 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).

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

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.

First-line responsibility for monitoring participant medication regimens resides with the medical professionals who prescribe and the pharmacists who dispense medications.

Medication regimens are recorded in the participant's ISP, and Supports Coordinators review medication records, including for behavior modifying medications, to assess that the medications specified in the ISP are current. For participants taking any type of medication, the Supports Coordinators review the medication regimen during each face-to-face monitoring visit using the service plan monitoring tool which lists: the medication that the participant takes; the reason for the medication; the total daily dose; whether or not blood levels are necessary; 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. Supports Coordinators also document allergies. The service plan monitoring tool is used to monitor medication given at home, including a licensed residential setting, and at a day program. Monitoring of medication occurs three times a quarter in different locations. Participants that are prescribed behavior modifying medications are required to have their medication reviewed by the prescribing psychiatrist at least every 3 months. Supports Coordinators ensure these reviews are occurring during each faceto-face monitoring visit. Monitoring is designed to detect potentially harmful practices and ensure follow up to address such practices. If concerns or issues related to medication administration are discovered at a face-to-face monitoring visit, the Supports Coordinator communicates this information directly with the participant's team.

In addition, medication errors are a reportable incident. As part of annual provider monitoring, ODP reviews a sample of participant records, including medications. ODP also reviews incident reports related to medication errors, along with other incidents data as specified in Appendix G- 1. ODP has nurses who help with questions about medications. ODP requires corrective action if necessary.

Department licensing also monitors medication and medication administration. Providers with licensed sites are monitored using a sampling strategy. Licensing personnel review medication administrator certification as well as medication regimens on Medication Administration Records 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. Regional nurses meet regularly with the ODP Medical Director and are able to review medication related concerns.

ODP uses the DHS Medication Administration Program (MAP) to teach unlicensed staff to give medication to participants using a standard curriculum. The MAP course requires periodic reviews of staff performance to maintain certification. Record of completion of these reviews is maintained at the provider level and must be available for licensing review. The MAP course teaches staff to review medication when it is received from the pharmacy and compare it to the Medication Administration Records, thus providing a regular review of medications by provider staff. Part of the documentation and safety measures include looking at medication allergies for the possibility of a contraindicated drug.

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.

As part of annual provider monitoring, ODP reviews a sample of participant records, including medications. ODP also reviews incident reports related to medication errors, along with other incidents data as specified in Appendix G-1. ODP has nurses who help with questions about medications. ODP requires corrective action if necessary.

ODP will work with ODP licensing staff when providing oversight of medication management to providers licensed by ODP: Community Homes, Family Living Homes, and Adult Training Facilities. ODP's licensing staff review medication information when conducting standard annual licensing reviews. This includes looking at medication practices, logs, storage, etc. 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. ODP will review licensing reviews as part of annual provider monitoring.

Through the Office of Medical Assistance Programs (OMAP) oversight, Fee for Service (FFS) and Managed Care Organizations (MCO) complete Drug Utilization Reviews (DURs). Each participant's medications are reviewed at the time of refill or with the addition of a new medication. The DUR reviews the medications both prospectively and retrospectively. Findings are communicated to healthcare practitioners either collectively thru Continued Medical Education 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. 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.

ODP oversees the Medication Administration Program, which is designed to teach proper medication administration to unlicensed staff. Lessons covered in the Program are intended to increase safety, minimize potentially harmful practices and include: Observations, Reporting Changes, Communication and Healthcare Practitioner Visit, Recording and Storage of Medication, Handwashing and Gloving, Administration, Documentation, Medication Errors, and Self-administration of Medication.

The ODP risk manager provides ongoing monitoring of reported medications errors. ODP regional risk managers collaborate with ODP regional nurses, the medical director, and Health Care Quality Unit (HCQU) staff to assure reporting occurs while working to prevent known causes of medication errors. ODP regional nurses may also monitor the provider activities around medication administration, usually in response to either a problem related to licensing surveys or a request from the provider because of issues at the agency. 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. In addition, the HCQUs have developed guidance for providers regarding medication administration policies and procedures to supplement what is in the MAP course. HCQUs also provide technical assistance regarding medication administration and implementing changes to prevent errors.

Despite ODP's extensive medication administration course, medication errors sometimes occur. ODP requires providers to report medication errors via EIM within 72 hours of occurrence or discovery. The EIM medication error report utilizes a root cause analysis approach, requiring the reporter to answer a series of questions aimed at identifying what happened as well as the contributing factors that can then be addressed and minimized. The questions include: "Why did the error occur?", "What was the response to the error?" and "What was or will be the agency system response to prevent this type of error from occurring in the future?" This approach also informs the curriculum offered in the medication management course and allows for process improvement.

If a medication error is the result of a critical incident, such as neglect or results in a critical incident, such as death, then it is not reported as a medication error but rather as the higher-level critical incident. The incident is then subject to investigation and ODP review. Medication error reporting data is reviewed and analyzed during quarterly risk management meetings.

Appendix G: Participant Safeguards

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

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 allow for the administration of medication by unlicensed staff when trained using a standard Medication Administration course.

The current medication administration course for providers requires the review of medication administration logs for errors in documentation including matching the persons prescribed medications on the log to those medications available to be given. Observations 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.

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:

Medication errors are reported to ODP via an electronic database (EIM), which is accessible by the Supports Coordinator and providers.

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

All medication errors that providers are required to record are also required to be reported.

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

Providers report medication errors in EIM, 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.

As part of annual provider monitoring, ODP reviews a sample of participant records, including medications. ODP also reviews incident reports related to medication errors, along with other incidents data as specified in Appendix G-1. ODP has nurses who help with questions about medications. Supports Coordinators monitor medication administration and practices in the manner described in G-3--2. ODP monitors the performance of Supports Coordinators and reviews medication errors through the 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.

For licensed Community Homes, Family Living Homes, and Community Participation Support facilities, ODP's licensing staff review medication information when conducting standard annual licensing reviews. This includes looking at medication practices, logs, storage, etc. 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.

Appendix G: Participant Safeguards

Quality Improvement: Health and Welfare

As a distinct component of the States quality improvement strategy, provide information in the following fields to detail the States methods for discovery and remediation.

a. Methods for Discovery: Health and Welfare

The state demonstrates it has designed and implemented an effective system for assuring waiver participant health and welfare. (For waiver actions submitted before June 1, 2014, this assurance read "The State, on an ongoing basis, identifies, addresses, and seeks to prevent the occurrence of abuse, neglect and exploitation.")

i. Sub-Assurances:

a. Sub-assurance: The state demonstrates on an ongoing basis that it identifies, addresses and seeks to prevent instances of abuse, neglect, exploitation and unexplained death. (Performance measures in this sub-assurance include all Appendix G performance measures for waiver actions submitted before June 1, 2014.)

Performance Measures

For each performance measure the State will use to assess compliance with the statutory assurance (or sub-assurance), complete the following. Where possible, include numerator/denominator.

For each performance measure, provide information on the aggregated data that will enable the State to analyze and assess progress toward the performance measure. In this section provide information on the method by which each source of data is analyzed statistically/deductively or inductively, how themes are identified or conclusions drawn, and how recommendations are formulated, where appropriate.

Performance Measure:

Performance Measure HW1: Number and percent of confirmed incidents of abuse, neglect, exploitation and unexplained death for which corrective action was taken. Numerator = Number of confirmed incidents of abuse, neglect, exploitation and unexplained death for which corrective action was taken. Denominator = Number of confirmed incidents of abuse, neglect, exploitation and unexplained death.

Data Source (Select one):

Other

If 'Other' is selected, specify:

Enterprise Incident Management (EIM)

Responsible Party for data collection/generation (check each that applies):	Frequency of data collection/generation (check each that applies):	Sampling Approach (check each that applies):
State Medicaid Agency	Weekly	100% Review
Operating Agency	Monthly	Less than 100% Review
Sub-State Entity	Quarterly	Representative Sample Confidence Interval =
Other Specify:	Annually	Stratified Describe Group:
	Continuously and Ongoing	Other Specify:
	Other Specify:	

Data Aggregation and Analysis:

Responsible Party for data aggregation and analysis (check each that applies):	Frequency of data aggregation and analysis(check each that applies):
State Medicaid Agency	Weekly
Operating Agency	Monthly
Sub-State Entity	Quarterly
Other Specify:	Annually

Responsible Party for data aggregation and analysis (check each that applies):	Frequency of data aggregation and analysis(check each that applies):
	Continuously and Ongoing
	Other Specify:

Performance Measure:

Performance Measure HW2: Number and percent of participants who received information about how to identify and report abuse, neglect and exploitation. Numerator = Number of participants who received information about how to identify and report abuse, neglect and exploitation. Denominator = Number of participants reviewed.

Data Source (Select one):

Other

If 'Other' is selected, specify:

Participant Record Review

Responsible Party for data collection/generation (check each that applies):	Frequency of data collection/generation (check each that applies):	Sampling Approach (check each that applies):
State Medicaid Agency	Weekly	100% Review
Operating Agency	Monthly	Less than 100% Review
Sub-State Entity	Quarterly	Representative Sample Confidence Interval = 90%+/-10%
Other Specify:	Annually	Stratified Describe Group:
	Continuously and Ongoing	Other Specify:

Other Specify:	

Data Aggregation and Analysis:

Responsible Party for data aggregation and analysis (check each that applies):	Frequency of data aggregation and analysis(check each that applies):
State Medicaid Agency	Weekly
Operating Agency	Monthly
Sub-State Entity	Quarterly
Other Specify:	Annually
	Continuously and Ongoing
	Other Specify:

b. Sub-assurance: The state demonstrates that an incident management system is in place that effectively resolves those incidents and prevents further similar incidents to the extent possible.

Performance Measures

For each performance measure the State will use to assess compliance with the statutory assurance (or sub-assurance), complete the following. Where possible, include numerator/denominator.

For each performance measure, provide information on the aggregated data that will enable the State to analyze and assess progress toward the performance measure. In this section provide information on the method by which each source of data is analyzed statistically/deductively or inductively, how themes are identified or conclusions drawn, and how recommendations are formulated, where appropriate.

Performance Measure:

Performance Measure HW3: Number and percent of critical incidents finalized,

including strategies to mitigate/prevent future incidents, within the required time frame. Numerator = Number of critical incidents finalized, including strategies to mitigate/prevent future incidents, within the required time frame. Denominator = All critical incidents, by type of incident.

Data Source (Select one):

Other

If 'Other' is selected, specify:

Enterprise Incident Management (EIM)

Responsible Party for data collection/generation (check each that applies):	Frequency of data collection/generation (check each that applies):	Sampling Approach (check each that applies):
State Medicaid Agency	Weekly	100% Review
Operating Agency	Monthly	Less than 100% Review
Sub-State Entity	Quarterly	Representative Sample Confidence Interval =
Other Specify:	Annually	Stratified Describe Group:
	Continuously and Ongoing	Other Specify:
	Other Specify:	

Data Aggregation and Analysis:

Responsible Party for data aggregation and analysis (check each that applies):	Frequency of data aggregation and analysis(check each that applies):
State Medicaid Agency	Weekly
Operating Agency	Monthly
Sub-State Entity	Quarterly
Other Specify:	Annually
	Continuously and Ongoing
	Other Specify:

Performance Measure:

Performance Measure HW4: Number and percent of confirmed incidents reported and reviewed at quarterly risk management meetings to determine any patterns related to participants or providers. Numerator = Number of confirmed incidents reported and reviewed to quarterly risk management meetings. Denominator = All confirmed incidents.

Data Source (Select one):

Other

If 'Other' is selected, specify:

EIM

Responsible Party for data collection/generation (check each that applies):	Frequency of data collection/generation (check each that applies):	Sampling Approach (check each that applies):
State Medicaid Agency	Weekly	100% Review
Operating Agency	Monthly	Less than 100% Review
Sub-State Entity	Quarterly	Representative Sample Confidence Interval =

Other Specify:	Annually	Stratified Describe Group:	
	Continuously and Ongoing	Other Specify:	
	Other Specify:		

Data Aggregation and Analysis:

Responsible Party for data aggregation and analysis (check each that applies):	Frequency of data aggregation and analysis(check each that applies):
State Medicaid Agency	Weekly
Operating Agency	Monthly
Sub-State Entity	Quarterly
Other Specify:	Annually
	Continuously and Ongoing
	Other Specify:

c. Sub-assurance: The state policies and procedures for the use or prohibition of restrictive interventions (including restraints and seclusion) are followed.

Performance Measures

For each performance measure the State will use to assess compliance with the statutory assurance (or

sub-assurance), complete the following. Where possible, include numerator/denominator.

For each performance measure, provide information on the aggregated data that will enable the State to analyze and assess progress toward the performance measure. In this section provide information on the method by which each source of data is analyzed statistically/deductively or inductively, how themes are identified or conclusions drawn, and how recommendations are formulated, where appropriate.

Performance Measure:

Performance Measure HW5: Number and percent of participants with restrictive interventions where proper procedures were followed. Numerator = Number of participants with restrictive interventions where proper procedures were followed. Denominator = Number of participants with a restrictive intervention plan reviewed.

Data Source (Select one):

Other

If 'Other' is selected, specify:

Enterprise Incident Management (EIM)

Responsible Party for data collection/generation (check each that applies):	Frequency of data collection/generation (check each that applies):	(check each that applies):	
State Medicaid Agency	Weekly	100% Review	
Operating Agency	Monthly	Less than 100% Review	
Sub-State Entity Other	Quarterly Annually	Representative Sample Confidence Interval =	
Specify:	·	Describe Group:	
	Continuously and Ongoing	Other Specify:	
	Other Specify:		

Data Aggregation and Analysis:

Responsible Party for data aggregation and analysis (check each that applies):	Frequency of data aggregation and analysis(check each that applies):
State Medicaid Agency	Weekly
Operating Agency	Monthly
Sub-State Entity	Quarterly
Other Specify:	Annually
	Continuously and Ongoing
	Other Specify:

d. Sub-assurance: The state establishes overall health care standards and monitors those standards based on the responsibility of the service provider as stated in the approved waiver.

Performance Measures

For each performance measure the State will use to assess compliance with the statutory assurance (or sub-assurance), complete the following. Where possible, include numerator/denominator.

For each performance measure, provide information on the aggregated data that will enable the State to analyze and assess progress toward the performance measure. In this section provide information on the method by which each source of data is analyzed statistically/deductively or inductively, how themes are identified or conclusions drawn, and how recommendations are formulated, where appropriate.

Performance Measure:

Performance Measure HW6: Number and percent of participants whose identified healthcare needs are being addressed. Numerator = Number of participants whose identified healthcare needs are being addressed. Denominator = Number of participants reviewed.

Data Source (Select one):

Other

If 'Other' is selected, specify:

Participant Record Review

Responsible Party for data collection/generation (check each that applies):	Frequency of data collection/generation (check each that applies):	Sampling Approach (check each that applies):	
State Medicaid Agency	Weekly	100% Review	
Operating Agency Sub-State Entity	Monthly	Less than 100% Review	
	Quarterly	Representative Sample Confidence Interval =	
Other Specify:	Annually	Stratified Describe Group:	
	Continuously and Ongoing	Other Specify:	
	Other Specify:		

Data Aggregation and Analysis:

Responsible Party for data aggregation and analysis (check each that applies):	Frequency of data aggregation and analysis(check each that applies):	
State Medicaid Agency	Weekly	
Operating Agency	Monthly	
Sub-State Entity	Quarterly	
Other Specify:	Annually	

Responsible Party for data aggregation and analysis (check each that applies):	Frequency of data aggregation and analysis(check each that applies):
	Continuously and Ongoing
	Other Specify:

ii. If applicable, in the textbox below provide any necessary additional into	formation on the strategies employed by the
State to discover/identify problems/issues within the waiver program, i	including frequency and parties responsible.

b. Methods for Remediation/Fixing Individual Problems

i. Describe the States method for addressing individual problems as they are discovered. Include information regarding responsible parties and GENERAL methods for problem correction. In addition, provide information on the methods used by the state to document these items.

HW2. Number and percent of participants who received information about reporting abuse, neglect, and exploitation. ODP reviews a sample of participant records to determine if participants/families have been provided information about reporting abuse, neglect, and exploitation. If there was no documentation that the information was provided, ODP will direct the Supports Coordinator to follow-up with the participant and his or her family to provide the necessary information. The Supports Coordinator will use the Supports Coordinator Monitoring tool to document that information about reporting abuse, neglect, and exploitation was offered as well as to document the date follow-up occurred. Documentation of remediation actions is expected to be submitted to ODP by the SCO within 30 days of notification.

HW4. All confirmed incidents of abuse, neglect or exploitation are reported and reviewed at quarterly risk management meetings to identify patterns of recurrence or risk by participants or providers. When such patterns are identified, ODP will contact the SC, the participant, the provider(s) or other individuals as appropriate to determine necessary follow-up actions to reduce the risk of recurrence.

HW6. Number and percent of participants whose identified health care needs are being addressed. Using the sample of waiver participants, ODP reviews monitoring conducted by the participant's SC. The ODP standardized individual monitoring tool includes questions evaluating whether identified health care needs are addressed as specified in the service plan. In any instance where the Supports Coordinator identifies a concern regarding addressing identified health care needs, and the issue remains unresolved, ODP will work with the SCO to resolve the situation. Resolution can include but is not limited to resumption of services at the required frequency, additional assessment by the current service provider, pursuit of a second opinion/consultation from an alternate provider, changes in service provider, team meetings, or changes in service schedule. The SCO will provide documentation of the resolution to ODP. Remediation is expected to occur within 30 days of notification.

ii. Remediation Data Aggregation

Remediation-related Data Aggregation and Analysis (including trend identification)

Responsible Party(check each that applies):	Frequency of data aggregation and analysis(check each that applies):
State Medicaid Agency	Weekly
Operating Agency	Monthly
Sub-State Entity	Quarterly
Other Specify:	Annually
	Continuously and Ongoing
	Other Specify:

c. Timelines

When the State does not have all elements of the Quality Improvement Strategy in place, provide timelines to design methods for discovery and remediation related to the assurance of Health and Welfare that are currently non-operational.

No

Yes

Please provide a detailed strategy for assuring Health and Welfare, the specific timeline for implementing identified strategies, and the parties responsible for its operation.