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 Medicaid agency or the operating agency (if applicable).

The Office of Long-Term Living has initiated a comprehensive incident reporting and management process. Critical events are referred to as critical incidents and defined as an event that jeopardizes the participant's health and welfare.

Definitions of the types of critical events or incidents that must be reported:

As defined in 55 Pa. Code, Chapter 52, the following are considered critical incidents:

1. Death (other than by natural causes);
2. Serious Injury - that results in emergency room visits, hospitalizations, and death;
3. Hospitalization - except in certain cases, for example hospital stays that were planned in advance*;
4. Provider and staff misconduct – deliberate, willful, unlawful, or dishonest activities;
5. Abuse – the infliction of injury, unreasonable confinement, intimidation, punishment, mental anguish, or sexual abuse of a participant. Types of abuse are, but not necessarily limited to:
   - Physical abuse – defined as a physical act by an individual that may cause physical injury to a participant;
   - Psychological abuse – an act, other than verbal, that may inflict emotional harm, invoke fear, and/or humiliate, intimidate, degrade or demean a participant;
   - Sexual abuse – an act or attempted act, such as rape, incest, sexual molestation,

sexual exploitation, or sexual harassment and/or inappropriate or unwanted touching of a participant; and

- Verbal abuse – using words to threaten, coerce, intimidate, degrade, demean, harass, or humiliate a participant.

6. Neglect – the failure to provide a participant the reasonable care that he, or she requires, including, but not limited to food, clothing, shelter, medical care, personal hygiene, and protection from harm. Seclusion, which is the involuntary confinement of an individual alone in a room or an area from which the individual is physically prevented from having contact with others or leaving, is a form of neglect.
7. Exploitation – the act of depriving, defrauding, or otherwise obtaining the personal property from a participant in an unjust, or cruel manner, against one's will, or without one's consent, or knowledge for the benefit of self, or others;
8. Restraint – Any physical, chemical or mechanical intervention that is used to control acute, episodic behavior that restricts the movement or function of the individual or a portion of the individual's body. Use of restraints and seclusion are both restrictive interventions, which are actions or procedures that limit an individual's movement, a person's access to other individuals, locations or activities, or restricts participant rights.
9. Service Interruption – Any event that results in the participant's inability to receive services that places his, or her health, and or safety at risk. This includes involuntary termination by the provider agency, and failure of the participant's back-up plan. If these events occur, the provider agency must have a plan for temporary stabilization.
10. Medication errors that require medical intervention, for example, hospitalization, or emergency room visits

    * Being admitted for a non-routine medical condition that was not scheduled or planned to occur is a critical incident; a routine hospital visit for lab work or routine treatment of illness of a participant is not a critical incident. A death that is suspicious or of unexplained causes is a critical incident. A death due to natural causes is not a critical incident.

Individuals/entities that are required to report critical events:

Per 55 PA Code Chapter 52 and OLTL's Critical Incident Management Bulletin, administrators and employees of waiver service providers, including Service Coordination Entities and individual providers of waiver services, are responsible for reporting critical incidents, as defined above, to OLTL. In addition, Direct service providers are required to notify the participant's Service Coordinator when a critical incident occurs.

In addition to reporting an incident to OLTL, in the event a direct service provider/Service Coordination Entity has reasonable suspicion that a participant over age 60 is the victim of a crime, including abuse, neglect or exploitation, or that death is suspicious, the provider must also report under the Older Adults Protective Services Agency Act (35 P.S. §§ 10225.101 – 10225.5102 and Title 6 Pa. Code, Chapter 15) and to the local OAPSA agency/the Department of Aging. Providers must also inform the participant's Service Coordination Entity within 24 hours of knowledge of the incident. In addition, the direct service provider/Service Coordination Entity must also immediately contact the appropriate law enforcement official to file a report when incidents involve sexual abuse,

serious injury, serious bodily injury or suspicious death. These additional reporting requirements do not supplant a provider's reporting responsibilities to OLTL.

Reporting applies to:

- Critical incidents that occur during the time the provider is providing services, and
- Critical incidents that occur during the time the provider is contracted to provide services, but fails to do so, and
- Critical incidents that occur at times other than when the provider is providing, or is contracted to provide services if the administrators, or employees become aware of such incidents.

Critical incident reports are also taken from participants, families or other interested parties through OLTL's toll-free Participant HelpLine. Additional information regarding the HelpLine is contained in Appendix F.

Timeframes within which critical events must be reported and the methods for reporting: Required reporters must report critical incidents to OLTL, and Service Coordination Entities when applicable, within 48 hours of their occurrence or discovery. OLTL has initiated an electronic reporting system for reporting all critical incidents. The electronic reporting system affords OLTL staff quick access to the critical incident through the web. Service Coordinators are required to submit incidents through the SAMs system; Aging Waiver service providers are required to submit incidents utilizing the OLTL incident reporting form which is submitted to OLTL through an email resource account: RA_Incident@pa.gov.

Incidents reported through the OLTL Participant HelpLine are entered into EIM by OLTL staff and the incidents are handled the same way as those reported directly through the web-based application. The following information is collected for each reported incident, regardless of how it is received: reporter information, participant demographics, OLTL program information, event type/details and description of the incident

OLTL reviews the critical incidents daily to ensure for the health and welfare of participants, to check for completeness and to ensure that what has been reported is truly a critical incident. Supervisors in BPO refer cases to their staff for follow-up and action as 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.

At time of enrollment, the IEB informs participants, and their families or legal representatives, of the incident management process and the availability of protective services through the local AAA. This information is provided through the participant information materials developed by OLTL. These materials include how to recognize and report abuse, neglect and exploitation, as well as the prohibition on the use of restraints, seclusion and other restrictive interventions. In addition, the information includes both the AAA's and OLTL's toll free numbers and the process for reporting suspected abuse, neglect and exploitation. The Service Coordinator is responsible for reviewing this information at least annually with the participant, and their family or legal representative, at time of reassessment or if there is suspicion of abuse, neglect, exploitation or abandonment.

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.

The entity (or entities) that receives reports of each type of critical event or incident.

BPO receives reports through SAMS, the RA box, the Participant Helpline and any other source and evaluates all critical incidents as defined in Appendix G-1-b above.

The entity that is responsible for evaluating reports and how reports are evaluated.

The Service Coordinator is responsible for conducting an investigation of incidents The Service Coordination Entity has two (2) days to provide initial information to OLTL in cases involving sexual abuse, serious injury, serious bodily injury or suspicious death, and 30 days from the initial report to provide all the information regarding the incident to OLTL.

If the incident meets the standards of 35 P.S. §§ 10225.101 – 10225.5102, and Title 6 Pa. Code, Chapter 15, reporting to the appropriate protective services helpline must be done within required timeframes.

Investigations that are performed by the Service Coordination Entities include:

- Onsite investigation – An onsite in-person visit is conducted for fact finding. The incident facts, sequence of events, interview of witnesses and observation of the participant and/or environment is required.
- Telephone investigation - Review of the Incident Report (IR) revealed facts are missing or additional information is required and can be obtained through conducting a telephone investigation.

No further action is required when the incident report meets all three of the following conditions:

1) The facts and sequences of events is outlined with sufficient detail; and
2) Preventative action through the service plan is implemented and documented; and
3) The participant is not placed at any additional risk.

Service Coordinators are required to:

- Take necessary actions to ensure the health and welfare of the participant
- Follow up with direct service provider to ensure all appropriate actions have been taken.
- Complete incident report and submit to OLTL via SAMS within the timeframes outlined in the OLTL Incident Management Policy if not already submitted by direct service provider.
- Conduct an investigation of the incident to determine specifics of the incident which include: Fact finding, identify the sequence of events, identify potential causes, and assess service planning to determine any needed changes and documentation.
- Provide a report to OLTL within 30 business days of the occurrence. When unable to conclude initial investigation within 30 days, request an extension from OLTL.

In cases investigated involving protective services, the Service Coordinator works with the protective service worker to ensure the health and welfare of the participant. This may involve revisions to the service plan as necessary, to meet the participants' needs and to mitigate recurrence of the incident.

In cases where regulatory compliance or failure to effectively safeguard the participant is identified in the investigation, OLTL will conduct an on-site review of the Service Coordination Entity or direct service provider to audit agency procedures and make corrective recommendations resulting in a Statement of Findings.

The timeframes for conducting an investigation and completing an investigation.

The investigation of all critical incidents must be completed within 30 days of receiving the incident report. If the timeframe is not met the details regarding the delay will be documented in SAMS. OLTL reviews and approves extension requests and closely monitors any investigative process that is taking beyond the allotted time for completion.

Within 48 hours of the conclusion of the critical incident investigation, participants must be informed of the outcome of investigations. The Service Coordinator is responsible for conveying this information to the participant.

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.

OLTL is responsible for providing oversight of Critical Incidents and events. OLTL staff from the Bureaus of Quality & Provider Management (BQPM) and Participant Operations (BPO) work together to address critical incidents. BQPM staff reviews reports generated in EIM to track and trend critical incidents. BPO staff work with Service Coordinators and Direct Service providers to assure that participant health and welfare is protected. Together, these two bureaus discuss trends to identify systemic weaknesses or problems with individual providers.

The findings and quality improvement recommendations are shared with OLTL's Executive and Management staff at the monthly Quality Management Meetings (QM2) and the Quality Council Meetings, which are held three times a year. The QM2 and Quality Council make recommendations to the Director of the BQPM who presents them to the OLTL Deputy Secretary.

Additional Agencies responsible for oversight include the Department of Aging and the Department of Health. The Department of Health has licensure requirements regarding reporting of incidents and conduct annual licensure of all Home Health and Home Care entities.

Service Coordinators play an instrumental role in oversight as well and are required to make quarterly monitoring contacts, a minimum of which two must be in-person. If an instance of abuse, neglect or exploitation is found, the Service Coordinators will immediately refer the case to the local protective services unit, in addition to filing a critical incident policy according to waiver policy.

The Department of Aging maintains a statewide database on all participants who were referred to the Protective Service Unit for investigation of allegations of abuse, neglect, exploitation and abandonment and oversees the Older Adult Protective Services program. The Department of Aging also conducts systematic monitoring and evaluation of the quality of protective services provided by the AAAs while providing the administrative and clinical technical assistance needed to maintain program and service quality.

Appendix G-2: Safeguards Concerning Restraints and Restrictive Interventions

a. Use of Restraints *(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:
	At time of enrollment, the IEB informs participants, and their families or legal representatives, of the prohibition on the use of restraints, seclusion and other forms of restrictive interventions. This information is provided through the participant information materials developed by OLTL. The Service Coordinator is responsible for reviewing this information at least annually at time of reassessment and discussing the prohibition of restraints with the participant. As part of the participant informational materials, participants and their families are encouraged to either call their Service Coordinator or the OLTL Participant HelpLine to report the unauthorized use of restraints. The Office of Long Term Living is notified about unauthorized use or restraints through the Service Coordination Entities and participants. Once a complaint has been filed it is recorded by OLTL staff in a central database and appropriate actions are taken, including notification of the local law enforcement agency. To assist in the detection of the unauthorized use of restraints, OLTL requires all Service Coordination providers to annually provide staff training on detection and prevention of abuse and neglect including the use of restraints. All Service Coordinators are instructed to be vigilant for signs of authorized restraints, seclusion or other restrictive interventions through their routine monitoring and engagement with individuals. Title 55 PA. Code Chapter 52 prohibits the restraint of a participant. Sanctions are available to the OLTL for non-compliance. This requirement is monitored during onsite provider monitoring activities by the Quality Management Efficiency Teams.
○	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. 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).

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:

b. Use of Restrictive Interventions

●	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:
	At time of enrollment, the IEB informs participants, and their families or legal representatives, of the prohibition on the use of restraint, seclusion and other forms of restrictive interventions. This information is provided through the participant information materials developed by OLTL. The Service Coordinator is responsible for reviewing this information and discussing the prohibition of restraints and restrictive interventions at least annually with the participant. As part of the participant informational materials, participants and their families are encouraged to either call their Service Coordinator or the OLTL Participant HelpLine to report the unauthorized use restrictive interventions. The Office of Long Term Living is notified about unauthorized use of restrictive interventions through the Service Coordination Entities and participants. Once a complaint has been filed it is recorded by OLTL staff in a central database and appropriate actions are taken, including notification of the local law enforcement agency. To assist in the detection of the use of restrictive interventions, OLTL requires all Service Coordination providers to annually provide staff training on detection and prevention of abuse and neglect including the use of restrictive interventions. All Service Coordinators are instructed to be vigilant for signs of unauthorized restraints, seclusion or other restrictive interventions through their routine monitoring and engagement with individuals. Title 55 PA. Code Chapter 52 prohibits the restraint of a participant. Sanctions are available to the OLTL for non-compliance. OLTL Bureau of Quality & Provider Management (BQPM) is responsible for monitoring and oversight of the use of restrictive interventions during onsite provider monitoring conducted every 2 years.
○	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-a-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.

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:

c. Use of Seclusion *(select one):*

●	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:

	At time of enrollment, the IEB informs participants of the prohibition on the use of restraint, seclusion and other forms of restrictive interventions. This information is provided through the participant information materials developed by OLTL. The Service Coordinator is responsible for reviewing this information at least annually at time of reassessment and discussing the prohibition of seclusion with the participant. As part of the participant informational materials, participants and their families are encouraged to either call their Service Coordinator or the OLTL Participant HelpLine to report the unauthorized use of seclusion. The Office of Long-Term Living is notified about unauthorized use of seclusion through the Service Coordination Entities and participants. Once a complaint has been filed, it is recorded by OLTL staff in a central database and appropriate actions are taken, including notification of the local law enforcement agency. To assist in the detection of the use of seclusion, OLTL requires all Service Coordination providers to provide annual staff training on detection and prevention of abuse and neglect including the use of seclusion. All Service Coordinators are instructed to be vigilant for signs of unauthorized restraints, seclusion or other restrictive interventions through their routine monitoring and engagement with individuals. OLTL Bureau of Quality & Provider Management (BQPM) is responsible for monitoring and oversight of the use of restrictive interventions during onsite provider monitoring conducted every 2 years.
○	The use of 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 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-3: Medication Management and Administration

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:

●	**Yes**. This Appendix applies *(complete the remaining items)*.
○	**No**. This Appendix is not applicable *(do not 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.

Only participants who require respite services with a Nursing Facility, the Nursing Facility regulations apply. Nursing Facilities are licensed and inspected by the PA Department of Health (DOH). Bureau of Facility Licensure and Certification and are subject to the Nursing Home Regulations of Title 28 and 55 of the PA Code and 42 CFR 483.1-483.75.

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.

Nursing Facilities are licensed and inspected by the PA DOH Health, Bureau of Facility Licensure and Certification and are subject to the Nursing Home regulations of Title 28 and 55 of the PA Code and 42 CFR 483.1 – 483.75. DOH performs yearly surveys and medication management is part of the survey. Nursing facilities pharmacy management is governed under the following authority 28 pa code § 211.9 amended under section 803 of the Health Care Facilities Act (35 P. S. § 448.803); and section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)).

c. Medication Administration by Waiver Providers

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

●	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)*
○	Not applicable (*do not 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).

Only participants who require respite services within a Nursing Facility, the Nursing Facility regulations apply. Nursing Facilities are licensed and inspected by the PA Department of

Health (DOH), Bureau of Facility Licensure and Certification and are subject to the Nursing Home regulations of Title 28 and 55 of the PA Code and 42 CFR 483.1 – 483.75. Department of Health Regulations for Nursing Facilities can be located at the DOH web site at http://www.dsf.health.state.pa.us/health/site/default.asp: scroll down page and click on Nursing facilities, then click Long term care licensure regulation.

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:
	PA Department of Health Department of Public Welfare
	(b) Specify the types of medication errors that providers are required to *record:*
	All identified medication errors are required to be recorded.
	(c) Specify the types of medication errors that providers must *report* to the State:
	The Aging Waiver provides services to participants in their own personal residences or in the home of a family member. In the event that a participant requires respite services in a Nursing Facility, the Nursing Facility regulations apply. Nursing Facilities are licensed and inspected by the PA Department of Health, Bureau of Facility Licensure and Certification and are subject to the Nursing Home regulations of Title 28 and 55 of the PA Code and 42 CFR 483.1 – 483.75.
○	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.

Only participants who require respite services within a Nursing Facility, the Nursing Facility regulations apply. Nursing Facilities are licensed and inspected by the PA Department of Health (DOH), Bureau of Facility Licensure and Certification and are subject to the Nursing Home regulations of Title 28 and 55 of the PA Code and 42 CFR 483.1 – 483.75. Department of Health Regulations for Nursing Facilities can be located at the DOH web site at http://www.dsf.health.state.pa.us/health/site/default.asp: scroll down page and click on Nursing facilities, then click Long term care licensure regulation.