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 (OLTL) has developed 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. The Bureau of Coordinated and Integrated Services (BCIS) is responsible for oversight of the Incident Management process.

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

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

1. Death (other than by natural causes) – a death that is suspicious or of unexplained causes is a critical incident. A death due to natural causes is not a critical incident;
2. Serious Injury – an injury that results in emergency room visits, hospitalizations, or death;
3. Hospitalization – for a non-routine medical condition that was not scheduled or planned to occur is a critical incident; a routine planned hospital visit for lab work or routine planned treatment of illness of a participant is not a critical incident;
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. The use of restraints and seclusion are both restrictive interventions, which are defined as 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 result in hospitalization, an emergency room visit or other medical intervention.

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 LTSS providers, including CHC-MCO's, Service Coordinators, and individual providers of waiver services, are responsible for reporting critical incidents through the electronic Enterprise Incident Management system (EIM), an electronic data system that collects information regarding critical incidents involving waiver participants. In addition, Direct Service providers are required to notify the participant's Service Coordinator when a critical incident occurs.

In the event administrators, employees of LTSS and waiver service providers, including CHC-MCO's, Service Coordinators, and individual providers of waiver services have reasonable suspicion that a participant age 60 and over is the victim of a crime, including abuse, neglect, exploitation, or abandonment, or that death is suspicious, the provider must also report under the Older Adults Protective Services Act (OAPSA) (35 P.S. §§ 10225.101 – 10225.5102 and Title 6 Pa. Code, Chapter 15) and follow reporting requirements to the local protective service agency under the Department of Aging. In the event Direct Service providers, Service Coordinators or CHC-MCO's, have reasonable suspicion that a participant between the ages of 18 to 59 is the victim of abandonment, abuse, exploitation, intimidation, neglect, serious injury or bodily injury or sexual abuse, the provider must report under the Adult Protective Services Act (Act 70 of 2010) to the Department of Human Services' APS Hotline. For both OAPSA and APS, the provider must also inform the participant's Service Coordinator within 24 hours of knowledge of the incident. For both OAPSA and APS, the Direct Service provider, Service Coordinator and CHC-MCO's, 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 through EIM.

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.

Timeframes within which critical events must be reported and the methods for reporting:
Required reporters must report critical incidents within 48 hours of their occurrence or discovery. OLTL has initiated a mandatory electronic reporting system for reporting all critical incidents. The electronic reporting system, referred to as EIM, allows Direct Service providers to submit critical incidents through a web-based application where they are accessed by Service Coordinators, the CHC-MCOs and OLTL staff.

Reporters are notified through EIM that their incident reports have been received. CHC-MCO staff will review the critical incidents daily to ensure the health and welfare of participants, to check for completeness and to ensure that what has been reported is truly a critical incident. CHC-MCOs will check the EIM dashboard daily for new incidents and 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.

Within five days of enrollment, the CHC-MCO informs participants of the incident management process. This information is provided through the participant information materials developed by the CHC-MCO's, and reviewed and approved 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 the process for reporting these occurrences to the participant's Service Coordinator directly. The Service Coordinator is responsible for reviewing this information at least annually with the participant at time of reassessment or if there is suspicion of abuse, neglect, exploitation or abandonment. Participants are also provided with information on reporting directly to APS and OAPSA.

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.

The CHC-MCOs receive incident reports through EIM, the CHC-MCO's internal Participant Hotline 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 CHC-MCO is responsible for evaluating incident reports to ensure that the Direct Service provider took prompt action to protect the participant's health and welfare. This may include, but is not limited to, calling 911, seeking the assistance of law enforcement, arranging medical care, suspending the alleged perpetrator or referring to a victim's assistance program. The CHC-

MCO also ensures that the provider meets the additional reporting requirements of the Department of Aging's Older Adult Protective Services Act (35 P.S. §§ 10225.101 – 10225.5102 and Title 6 Pa. Code, Chapter 15), the Department of Human Services' Adult Protective Services Act (Act of October 7, 2010, P.L. 484, No. 70) and/or the Department of Health when applicable.

The CHC-MCO reviews each incident as documented by the reporter to ensure that the report is complete. The CHC-MCO is responsible for investigation of incidents. Once all information is gathered, the CHC-MCO reviews the incident, and works with the Service Coordinator and/or Direct Service provider to ensure the health and welfare of the participant. The incident is closed in EIM when all appropriate actions are taken according to the specifics of the incident and when the participant's health and welfare have been ensured.

OLTL is responsible for reviewing and investigating all allegations of abuse, neglect, or exploitation that identify the CHC-MCO and/or their staff as the alleged perpetrator. OLTL retains the right to review any incident reports, conduct its own investigations and require further corrective actions by the CHC-MCO.

The entity that is responsible for conducting investigations and how investigations are conducted.

The CHC-MCO is responsible for conducting an investigation of incidents. An investigation includes taking the steps necessary to determine if a critical incident has occurred, determining if suspected abuse, neglect, abandonment or exploitation requiring the involvement of protective services is involved, what actions are needed to protect the health and welfare of participants and what actions are needed to mitigate future incidents. The Service Coordinator has two (2) days to enter initial information into EIM in cases involving sexual abuse, serious injury, serious bodily injury or suspicious death, and thirty (30) days from the initial report to enter all the information regarding the incident into EIM.

If the incident meets the standards of 35 P.S. §§ 10225.101 – 10225.5102, Title 6 Pa. Code, Chapter 15) 6 PA Code Chapter 15 or the Act of Oct. 7, 2010, P.L. 484, No. 70, reporting to the appropriate protective services helpline must be done within required timeframes.

Investigations that are performed by the CHC-MCOs include, but are not limited to:

- 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 are 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.

CHC-MCOs 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 EIM 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 thirty (30) business days of the occurrence. When the CHC-MCO is unable to conclude initial investigation within thirty (30) days, request an extension from OLTL through EIM.

In cases investigated involving protective services, the CHC-MCO 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 participant's 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, the CHC-MCO will conduct an on-site review of the incident which may include an audit of the MCO's Service Coordination Entity or Service Coordinator and/or direct service provider. In these cases, the CHC-MCO will audit agency procedures and make corrective recommendations resulting in a Statement of Findings. The provider must submit a Corrective Action Plan to the CHC-MCO within 30 days of the issuance of the Statement of Findings.

If OLTL determines that the CHC-MCO failed to effectively safeguard the participant or violated regulatory requirements, OLTL will conduct an on-site review to audit the CHC-MCO policy and procedures. OLTL will issue a Statement of Findings to the CHC-MCO, requiring a corrective action plan be submitted and completed within 30 days from the issuance of the Statement of Findings.

The timeframes for conducting an investigation and completing an investigation.

The investigation of all critical incidents must be completed within thirty (30) days of receiving the incident report. If the timeframe is not met, the details regarding the delay will be documented in EIM. The MCO will monitor 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.

The CHC-MCOs are responsible for providing oversight of Critical Incidents and events. OLTL staff from Bureau of Coordinated and Integrated Services (BCIS), review reports generated in EIM and reports generated by MCOs to track and trend critical incidents. BCIS staff work with the CHC-MCOs to assure that participant health and welfare is protected. Together, these bureaus discuss trends to identify systemic weaknesses or problems with individual and aggregate MCOs and providers.

The findings and quality improvement recommendations are shared with OLTL's Executive and Management staff at the monthly Quality Management Meetings (QM2) as well as the quarterly meetings with the CHC-MCOs.

Additional agencies have responsibilities for oversight on reports of abuse. The Department of Aging is responsible for administering protective services for the over 60 population; the Department of Human Services' Adult Protective Services Office handles protective services for the 18-60 disability population. The Department of Health has licensure requirements regarding reporting of incidents, and conducts annual licensure of all Home Health and Home Care entities.

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. Specify the State agency (or agencies) responsible for detecting the unauthorized use of restraints and how this oversight is conducted and its frequency:
	Title 55 PA. Code Chapter 52 prohibits the restraint of a participant. OLTL may impose sanctions for non-compliance. OLTL is the unit of the State Medicaid Agency that is responsible for detecting the unauthorized use of restrictive interventions. OLTL approves the CHC-MCO Participant Handbook, which includes prohibition of the use of restraints, including chemical restraint, seclusion and other forms of restrictive interventions. At time of enrollment, participants receive a copy of the CHC-MCO Participant Handbook from the CHC-MCO and participants and their families are encouraged to call their Service Coordinator to report the unauthorized use of restraints. The Service Coordinator is responsible for reviewing this information with the participant annually. The CHC-MCO investigates and addresses unauthorized use of restrictive interventions. OLTL is notified about unauthorized use of restraints through the CHC-MCOs in EIM. OLTL staff from the Bureau of Coordinated and Integrated Services will review reports generated in EIM weekly to track and trend critical incidents on restraints to identify systemic weaknesses or problems that will result in reports to the CHC-MCOs, corrective action plans and additional training to address the problem if indicated. To assist in the detection of the unauthorized use of restraints, OLTL requires all CHC-MCOs to provide annual staff training as reviewed and approved by OLTL staff on detection and prevention of abuse and neglect including the use of restraints. All CHC-MCOs and their 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.
○	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 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 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:
	Title 55 PA. Code Chapter 52.16 prohibits providers from using restraint as part of the provision of wavier services. Sanctions are available to the OLTL for non-compliance. OLTL is the unit of the State Medicaid Agency that is responsible for detecting the unauthorized use of restrictive interventions. OLTL approves the CHC-MCO Participant Handbook, which includes prohibition of the use of restraints, including chemical restraint, seclusion and other forms of restrictive interventions. At time of enrollment, participants receive a copy of the CHC-MCO Participant Handbook from the CHC-MCO and participants and their families are encouraged to call their Service Coordinator to report the unauthorized use of restrictive interventions. The Service Coordinator is responsible for reviewing this information with the participant annually. The CHC-MCO investigates and addresses unauthorized use of restrictive interventions. OLTL is notified about unauthorized use of restrictive interventions through the CHC-MCOs in EIM. OLTL staff from the Bureau of Coordinated and Integrated Services will review reports generated in EIM weekly to track and trend critical incidents on restrictive interventions to identify systemic weaknesses or problems that will result in reports to the CHC-MCOs, corrective action plans and additional training to address the problem if indicated. To assist in the detection of the unauthorized use of restrictive interventions, OLTL requires all CHC-MCOs to provide annual staff training as reviewed and approved by OLTL staff 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.
○	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:
	OLTL is the unit within the State Medicaid Agency that is responsible for detecting the unauthorized use of seclusion. OLTL approves the CHC-MCO Participant Handbook, which includes prohibition of the use of restraints, including chemical restraint, seclusion and other forms of restrictive interventions. At time of enrollment, participants receive a copy of the CHC-MCO Participant Handbook from the CHC-MCO and participants and their families are encouraged to call their Service Coordinator to report the unauthorized use of seclusion. The Service Coordinator is responsible for reviewing this information with the participant annually. The CHC-MCO investigates and addresses unauthorized use of seclusion and other restrictive interventions. OLTL is notified about unauthorized use of seclusion through the CHC-MCOs in EIM. OLTL staff from the Bureau of Coordinated and Integrated Services will review reports generated in EIM weekly, to track and trend critical incidents on restrictive interventions and seclusion to identify systemic weaknesses or problems that will result in reports to the CHC-MCOs, corrective action plans and additional training to address the problem if indicated. To assist in the detection of the unauthorized use of seclusion, OLTL requires all CHC-MCOs to provide annual staff training as reviewed and approved by the OLTL staff 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.
○	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.

CHC-MCO Network providers are the primary entity that has ongoing responsibility for monitoring participant medication regimens. As the professionals who prescribe the medications, they ensure that the medication regimen meets the participant's diagnosed condition, that none of the medications conflict and that the doses are prescribed correctly.

Medication monitoring also occurs through the development of the participant's PCSP and Service Coordinator review of the participant's services and during each face-to-face monitoring visit. As part of the annual reassessment, Service Coordinators collect complete information about the participant's medications, including what each medication is for, the frequency and dosage. Service Coordinators will have access to nurses and physicians employed by the CHC-MCOs to assist with questions about medications. Service Coordinators also review medication regimens for individuals during face-to-face monitoring visits and review EIM for reported medication errors. Incidents are reviewed by the CHC-MCOs which follow up with Service Coordinators to advise appropriate action.

Second-line monitoring is completed by Service Coordinators as outlined above and verified by the Department of Human Services, Bureau of Human Services Licensing (BHSL) annually for participants who live in licensed residential habilitation settings. Medications in licensed settings are governed under the following authority: 55 PA Code, Chapter 2600, §2600.181 through §2600.191. The CHC-MCOs monitor unlicensed Residential Habilitation provider's recorded and reportable medication errors to determine what medication administration and management problems are occurring for Residential Habilitation Service providers. Providers who have a high number of medication errors will be retrained.

When participants are receiving respite services in a nursing facility, the nursing facility regulations apply. The PA Department of Health (DOH) Bureau of Facility Licensure and Certification licenses and inspects Nursing Facilities, which 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.

OLTL uses the DHS Medication Administration Program to teach unlicensed staff to give medication to participants using a standard curriculum. Many of the provider agencies have nurses who become trainers and monitor medication through the course, while others provide oversight within the agency for medication administration and health issues. The course requires periodic reviews of staff performance to maintain certification. These include reviews of Medication Administration Records or logs for each staff member administering medications. The review of medication administration logs for errors in documentation includes matching the participant's prescribed medications on the log to those available to be given. Maintenance of certification requires review of four (4) Medication Administration Records and two (2) observations of passing medication and documentation. Providers are to use Medication Administration Records from different participants when completing the reviews so that each of the participants' medication regimens is reviewed across the year. The course also 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 checks includes looking at medication allergies for the possibility of a contraindicated drug. CHC-MCOs may choose to train unlicensed staff to give medications in lieu of utilizing the DHS Medication Administration Program.

Providers administering medications are required to have a Medication Protocol in place that details the staff that have been trained and/or are licensed to administer medication, and ensures that providers have trained or licensed staff on duty when individuals need medication administered. The Medication Management Protocol will also detail how the provider monitors medication administration on a daily basis.

Despite the Department's extensive medications administration course, medication errors do sometimes occur. Providers are required to immediately report medication errors to the participant, the participant's designated party, when applicable, and the prescriber. Medication errors that require medical intervention, i.e. hospitalization or emergency room visits, must be reported to the CHC-MCO via EIM within 24 hours of occurrence or discovery as outlined in Appendix G-1-b. If the 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, which is then subject to CHC-MCO investigation and review.

Documentation of medication errors and the prescriber's response must be kept in the participant's record. Providers are required to have a system in place to identify and document medication errors and the pattern of error. Providers must also document follow-up actions that have been taken to prevent future medication errors. Finally, providers are also required to educate participants of their right to question or refuse medication if the participant believes there may be a medication error. Documentation of this individual education must be kept in the participant's file.

If a participant experiences a suspected adverse reaction to a medication, the provider is required to immediately consult a physician or seek emergency medical treatment. Adverse reactions, the prescriber's response and any actions taken are documented in the participant's record.

The Department of Human Services, Bureau of Human Services Licensing (BHSL), monitors licensed Residential Habilitation providers' compliance with 55 PA Code, Chapter 2600, §2600.181 – §2600.191 on an annual basis, and is responsible for oversight and follow-up when licensed providers exhibit noncompliance.

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)).

The CHC-MCOs monitor unlicensed Residential Habilitation provider's recorded and reportable medication errors to determine what medication administration and management problems are occurring for Residential Habilitation Service providers. Providers who have a high number of medication errors will be retrained

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).

Medication Administration by Licensed Residential Habilitation Providers:

Personal Care Home regulations, 55 PA Code, Chapter 2600, apply when participants receive Residential Habilitation Services in licensed settings. These regulations allow for the administration of medication by unlicensed staff when trained using the DHS-approved medications administration course. The current medications administration course requires the review of medication administration logs for errors in documentation including matching the person's prescribed medications on the log to those available to be given. Observations of medication passes are required on an annual basis. Clinical nursing staff is 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 also appear in the regulations, and setting up and monitoring self-administration programs are taught as part of the medication administration program. Personal Care Homes are licensed by the DHS, Bureau of Human Services Licensing, on an annual basis. These requirements do not apply to non-licensed providers.

Medication Administration by Unlicensed Residential Habilitation Providers:

Unlicensed Residential Habilitation providers are required to follow- OLTL's "Medication Management Policy for Unlicensed Providers Bulletin", which clarifies when a participant is expected to self-administer, receive assistance with medication administration, and the training required for provider staff to administer medication.

Self-Administration.

(a) A provider shall assist individuals, as needed, with medication prescribed for the individual's self-administration. This assistance includes helping the individual to

remember the schedule for taking the medication, storing the medication in a secure place and offering the individual the medication at the prescribed times.

(b) If assistance includes helping the individual to remember the schedule for taking the medication, the individual shall be reminded of the prescribed schedule.

(c) The individual's service plan shall identify if the individual is able to self-administer medications. An individual who desires to self-administer medications shall be assessed by a physician, physician's assistant or certified registered nurse practitioner regarding the ability to self-administer and the need for medication reminders.

(d) If the individual does not need assistance with medication, medication may be stored in an individual's room for self-administration. Medications stored in the individual's room shall be kept locked in a safe and secure location to protect against contamination, spillage and theft.

(e) To be considered capable to self-administer medications, an individual shall:

(1) Be able to recognize and distinguish his medication.

(2) Know how much medication is to be taken.

(3) Know when medication is to be taken.

(f) The individual's record kept by the provider shall include a current list of prescriptions, Complementary and Alternative Medications (CAM) and Over the Counter (OTC) medications for each individual who is self-administering medication.

Medication Administration:
(a) A provider may provide medication administration services for an individual who is assessed to need medication administration services and for an individual who chooses not to self-administer medications in accordance with an assessment done by a physician and documented on the individual's service plan.

(b) Prescription medication that is not self-administered shall be administered by one of the following:

(1) A physician, licensed dentist, licensed physician's assistant, registered nurse, certified registered nurse practitioner, licensed practical nurse or licensed paramedic.

(2) A graduate of an approved nursing program functioning under the direct supervision of a professional nurse who is present in the setting in which the medication is administered.

(3) A student nurse of an approved nursing program functioning under the direct supervision of a member of the nursing school faculty who is present in the setting the medication is administered.

(4) A staff person who has completed the DHS-approved medication administration training for the administration of oral; topical; eye, nose and ear drop prescription

medications; insulin injections and epinephrine injections for insect bites or other allergies.

Medication Administration Training

(a) Pursuant to 55 Pa. Code § 52.14(t) (relating to ongoing responsibilities of providers), providers are required to participate in Department-mandated trainings. A provider who chooses to provide medication administration services for an individual who is assessed to need medication administration services in accordance with an assessment referenced above must participate in either the OLTL-approved medications administration course or have staff trained by the CHC-MCO.

(b) The OLTL-approved medications administration course refers to the Department of Human Services Office of Developmental Program's training program. Information on this training program is found by calling 1-800-438-1958 or by going to: https://medsadmin.tiu11.org/cms/

(c) A staff person who has successfully completed the OLTL-approved medications administration course that includes the passing of the OLTL-approved performance-based competency test within the past 2 years may administer oral; topical; eye, nose and ear drop prescription medications and epinephrine injections for insect bites or other allergies.

(d) A staff person is permitted to administer insulin injections following successful completion of an OLTL-approved medications administration course that includes the passing of a written performance-based competency test within the past 2 years, as well as successful completion of an OLTL-approved diabetes patient education program within the past 12 months.

(e) A record of the training shall be kept including the staff person trained, the date, source, name of trainer and documentation that the course was successfully completed.

Medication Administration by Nursing Facilities:
When participants are receiving respite services in a nursing facility, the nursing facility regulations apply. The PA Department of Health (DOH) Bureau of Facility Licensure and Certification licenses and inspects Nursing Facilities, which are subject to the Nursing Home Regulations of Title 28 and 55 of the PA Code and 42 CFR 483.1-483.75.

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:
	Providers are required to immediately report medication errors to the participant, the participant's designated party, when applicable, the MCO and the prescriber. Medication errors that require medical intervention, i.e. hospitalization or emergency room visits, must be reported to the CHC-MCO via EIM within 24 hours of occurrence or discovery as specified in OLTL Critical Incident Management Bulletin. EIM is accessible to providers, Service Coordinators and the CHC-MCOs.
	(b) Specify the types of medication errors that providers are required to *record:*
	Providers record medication errors which include: failure to administer a medication, administration of the wrong medication, administration of the wrong amount of

■	medication, failure to administer a medication at the prescribed time, administration to the wrong person, and administration through the wrong route.
■	(c) Specify the types of medication errors that providers must *report* to the State:
■	Medication errors that require medical intervention, i.e. hospitalization or emergency room visits, must be reported to the CHC-MCO via EIM within 24 hours of occurrence or discovery as specified in OLTL Critical Incident Management Bulletin.
○	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.

OLTL monitors performance of providers in the administration of medication to waiver participants both directly and indirectly. CHC-MCOs and OLTL will review incident reporting trends to identify and address any issues that arise with specific providers and/or participants. As described in section G-3-b-i, direct monitoring occurs through annual DHS licensing reviews of licensed Residential Habilitation providers and the CHC-MCOs monitoring reviews of unlicensed Residential Habilitation providers. In addition, direct monitoring occurs as part of the Service Coordinator's face-to-face monitoring visits with participants. If the SC identifies issues with medication management during their monitoring visits, the PCSP will be reviewed to determine what additional supports may be necessary.