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*:

X	**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).

Overview of DDA's Policy on Reportable Incidents and Investigations (PORII)

The DDA has established a Policy on Reportable Incidents and Investigations (PORII), which requires that all providers under Self-Directed Services and Traditional Services Delivery Models

to report critical events or incidents to the DDA. The PORII is incorporated into DDA's regulations governing requirements for licensure for providers.

If a critical event or incident is governed by PORII, then the provider, who is providing services at the time of the incident, must report the event or incident in the DDA's software database called the "Provider Consumer Information System" (PCIS2). As further detailed in PORII, either the DDA or the Office of Health Care Quality (OHCQ) review each reported event or incident, depending on the classification. The OHCQ is the DDA's designee within the Maryland Department of Health, responsible for conducting survey and investigative activities to monitor regulatory compliance, on the DDA's behalf, pertaining to provider licensure. The DDA, the OHCQ, and the Office of Long-Term Services and Supports (OLTSS) all have direct access to review reported events or incidents in PCIS2.

PORII also requires that certain events or incidents be reported to external entities such as the State's Protection and Advocacy organization (Disability Rights Maryland), Adult Protective Services, Child Protective Services (as applicable), law enforcement, and any applicable Health Occupations licensing boards (e.g., Maryland Board of Nursing).

Classification of Events or Incidents

Type 1 Incidents include: abuse, neglect, death, hospital admissions or emergency room visits, injury, medication error, and choking. Abuse includes: physical abuse,~~;~~ verbal abuse,~~;~~ mental abuse,~~;~~ sexual abuse~~;~~, ~~involuntary~~ seclusion, and any action or inaction that deprives an individual in DDA funded services of the ability to exercise their legal rights, as articulated in State or federal law including seclusion.

All providers to whom PORII applies must report all Type 1 incidents to DDA immediately upon discovery. The completed Incident Report must be received by the OHCQ, the State Protection and Advocacy agency, CCS, and the DDA regional office within one (1) working day of discovery. In addition, DDA providers must also complete an Agency Investigation Report (AIR) that includes updated information based on the provider's investigation of the incidents, remediation and preventive strategies, and additional services and supports that may be needed. The AIR must be received within ten (10) working days of discovery.

Type 2 Incidents include: law enforcement, fire department, or emergency medical services involvement; theft of an individual's property or funds; unexpected or risky absence; restraints; and any other incident not otherwise defined in the policy that impacts or may impact the health or safety of an individual person. Restraints includes: any physical, chemical, or mechanical intervention used to impede an individual's physical mobility or limit free access to the environment and /or to control acute, episodic behavior including those that are approved as part of the Person-Centered Plan or those used on an emergency basis.

All providers to whom PORII applies must submit an initial report of Type 2 incidents within one (1) working day to the DDA Regional Office, the participant's family/legal guardian/advocate(s), and the participant's Coordinator of Community Service (CCS).

Internally Investigated Incidents are outlined in the PORII and include events such as physical aggression, planned hospital admissions, and minor injuries that require minor routine treatment. A listing of all internally investigated incidents which occurred during the prior quarterly period for all DDA service providers is accessible through the DDA Provider Consumer Information System (PCIS2).

All provider staff to whom PORII applies must report "Internally Investigated Incidents" within one (1) working day of discovery to the provider's director or designee.

Incidents involving Participants in Home Environment

When a participant who resides with their family experiences a critical incident that jeopardizes the participant's health and safety, the CCS will seek the assistance of law enforcement, Child Protective Services, or Adult Protective Services, each of which having the authority to remove the alleged perpetrator or the victim from the home to ensure safety.

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.

The Coordinator of Community Service (CCS) provides and reviews with the participant, and their legal representative and family, the participant's Rights and Responsibilities, annually. The participant's Rights and Responsibilities are generally set forth in the Maryland Annotated Code, Health-General Article Title 7, Subtitle 10 and include the participant's right to be free from abuse, neglect, and exploitation. The Rights and Responsibilities form also explains how the participant can notify proper authorities when problems arise or the participant has complaints or concerns, including law enforcement, Adult Protective Services, Child Protective Services, the CCS, the DDA, and OHCQ. After review with the CCS, the participant, or their legal representative signs the form acknowledging receipt.

The DDA Director of Family Supports and Regional Office Advocacy Specialists also provide information, training, and webinars related to protections and how to report.

DDA providers must ensure a copy of the PORII and the provider's internal protocol on incident management is available to participants receiving services, their parents or guardians, and advocates.

The PORII and all necessary forms are also available on the DDA website.

In addition, COMAR 10.01.18 requires that DDA-licensed vocational and day services programs adopt Sexual Abuse Awareness and Prevention Training, including mandatory reporting requirement, for both its staff and participants.

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.

Entities Receiving Notification of Incident Report

The DDA, the OLTSS, the OHCQ, and CCS receive notification of all Type I incidents submitted in the PCIS2 system. The DDA and CCS also receive notification of all Type II incidents submitted.

PORII also requires that certain events or incidents be reported to external entities such as the State's Protection and Advocacy organization (Disability Rights Maryland), Adult Protective Services, Child Protective Services (as applicable), law enforcement, and any applicable Health Occupations licensing boards (e.g., Maryland Board of Nursing). All allegations of abuse or neglect must be reported to the State's Protection and Advocacy organization, Child or Adult Protective Services, and local law enforcement.

The provider is required to notify the participant's authorized representative(s) (e.g. family, legal guardian, etc.) that an incident report has been submitted. The authorized representative(s) of the participant may request a copy of the incident report in accordance with the State's Public Information Act.

Initial Screening

OHCQ's triage staff reviews all reported Type 1 incidents and DDA staff reviews all reported Type 2 incidents. Dependent on the classification, either the DDA's or the OHCQ's staff performs an initial screening of each reported incident, within one (1) working day of receipt, to determine if that incident poses immediate jeopardy to a participant and, therefore, warrants immediate investigation.

The staff reviews each report and notifies its respective supervisor – the OHCQ's DD Investigation's Unit Manager or DDA's Regional Quality Enhancement Director – of the need to evaluate the report for appropriate assignment based upon the severity and scope of the incident.

If, during the initial screening or evaluation, the DDA reviews a Type 2 incident and reasonably believes that the incident should be classified as a Type 1 incident, then the DDA will refer the incident to OHCQ for further review and possible investigation.

In addition, the content of the written report is evaluated to ensure the following information is included:

1. The participant is not in immediate danger;

2. When applicable, law enforcement and/or adult/child protective services have been contacted;

3. Staff suspected of abuse or neglect have been suspended from duty;

4. The participant has received needed intervention and health care; and

5. Systemic and/or environmental issues have been identified and emergently handled.

If this information is not included in the initial report, the staff will contact the provider to ascertain the status of the participant and ensure the participant's health and safety. If the agency does not provide the information within a reasonable time frame (no later than 48 hours after initial review of the report by triage staff), then the provider's lack of response will influence the decision to begin an on-site investigation or activity more quickly.

Evaluation of Reports

TYPE 1 INCDENTS - OHCQ

Evaluation

The OHCQ ~~utilizes a triage committee to~~ reviews all Type 1 incidents, including those that may have been assigned on an emergency basis. The ~~committee~~ OHCQ staff performs a comprehensive review of the reported incidents. In its evaluation, the ~~committee~~ OHCQ staff takes into consideration the number and frequency of reportable incidents or complaints attributed to the provider and the quality of the provider's internal investigations. The ~~committee~~ OHCQ staff also reviews submitted Agency Incident Reports (AIR), to ensure appropriate actions were taken by the provider in response to an incident. Incidents which may have been previously determined to not require investigation may be re-categorized based on information received in an AIR.

Investigation

The OHCQ has the authority to investigate any DDA providers on behalf of the DDA. The OHCQ does not have the authority to investigate a participant's non-licensed home environment. However, in those circumstances, the OHCQ will refer the matter to

appropriate authorities such as law enforcement, Child Protective Services, or Adult Protective Services.

If the incident warrants further investigation, the OHCQ conducts investigations through on-site inspections, interviews, or reviews of relevant records and documents. The OHCQ initiates investigations based on the priority classification of the incident (as defined in PORII).

During the investigation of an incident, an OHCQ ~~investigator~~ staff reviews the AIR and related documentation. The investigator(s) will make their best effort to interview all persons with knowledge of the incident, including, but not limited to: the participant receiving services, her/his guardian or family member(s), the provider's direct care and administrative staff who were involved in the incident, etc. The investigator also makes direct observations of the participant in her/his environment. When possible, evidence is corroborated between interviews, record reviews, and observations. Deficiencies are, to the extent practicable, cited at an exit conference held upon completion of the on-site investigation. Investigations are completed, whenever possible, within 45 working days of initiation.

The authorized representative(s) of the participant may request investigation results, documented in OHCQ's Statement of Deficiencies, in accordance with the State's Public Information Act.

TYPE 2 INCIDENTS – DDA

Evaluation

~~The~~ DDA Quality Enhancement (QE) staff review each report for completeness and for evidence of the provider's actions to safeguard the health and safety of the participant or others. In its evaluation, the DDA determines if intake information is sufficient to determine dangerous conditions are not present and ongoing. If, based on review of the report, including the AIR, the DDA QE staff is unable to determine that action has been taken by the provider to protect the participant from harm, then the DDA QE staff will

intervene. Depending on the circumstances, the DDA may intervene by contacting the DDA provider or conducting an on-site visit.

The DDA will also evaluate the Incident report AIR, and any subsequent correspondence and determine appropriate DDA follow-up which may include: (1) investigation; (2) referring the matter to the OHCQ, law enforcement, or protective services; (3) generalized training; (4) provider specific training; and (5) technical assistance.

An incident report that is incomplete or contains errors will result in a communication from the DDA QE staff to the DDA provider requesting revision to the incident report and resubmission of a complete and correct report.

When a provider reports three (3) or more incidents that involve the same participant within a four-week period, the DDA will determine, based upon the provider's compliance history and nature of the incidents, whether an on-site visit is warranted.

INCIDENTS OUTSIDE OF A SITE OR SERVICE LICENSED BY MDH

When an incident is alleged to have occurred outside of a site or service licensed by MDH, the CCS and service providers will seek the assistance of appropriate authorities for review and investigation such as local law enforcement, Child Protective Services, or Adult Protective Services. The OHCQ, DDA, or OLTSS may also refer the incident to the appropriate entities or jurisdictions for their review and investigation.

When indicated, incidents are referred to the Maryland Office of the Attorney General's Medicaid Fraud Control Unit for consideration of filing criminal charges. When an incident involves legal issues for the participant, it may be referred to the State's Protection and Advocacy organization.

DEATHS

The OHCQ refers all reported deaths to the OHCQ's Mortality Investigation Unit for review and investigation. The OHCQ Mortality Investigation Unit evaluates death reports, determines priority for investigations, and conducts investigations using its own policies and procedures. The OHCQ Mortality Investigation Unit submits its findings to the

Department of Health's Mortality and Quality Review Committee (MQRC). The MQRC is independent of the OHCQ and DDA and reviews the investigations of all deaths of participants that occur in DDA-licensed settings and services.

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 DDA and OLTSS are responsible for oversight of the incident reporting system.

On a quarterly basis, the DDA reviews and analyzes various information including: (1) the types of incidents; (2) participant characteristics; (3) type of providers; and (4) timeliness of reporting and investigations. This information is collected via the DDA incident reporting data system and tracking reports. The DDA also uses national experts, surveys, mortality reports, and research institutes to assist with its analysis, trending, and development of system improvement strategies.

The DDA's ~~Director of Nursing and~~ Regional Office Quality Enhancement (QE) Nurses ~~("DDA's Nursing Staff")~~ review statewide and region-specific incidents related to health and safety, including all deaths. The DDA's QE Nursing Staff then recommends training or educational alerts to address any concerns or trends identified.

In some instances, the DDA's ~~Regional Office~~ QE Nurse may do an on-site survey to review the provider's notes related to the provision of nursing services. The DDA's ~~Regional Office~~ QE Nurse's review of incidents allows for trend identification and provider specific action that may lead to remediation. The DDA's ~~Regional Office~~ QE Nurses provide ongoing technical and follow-up assistance to community nurses, providers, CCSs, participants, and their families.

The OLTSS has the authority to investigate or review any event or issue of a serious nature that does or has the potential to negatively impact on the health, welfare, and safety of waiver participants. The OLTSS also uses its oversight of DDA's execution of delegated functions to ensure that the established procedures are being implemented as intended.

Appendix G-2: Safeguards Concerning Restraints and Restrictive Interventions

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:
X	**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).

USE OF ALTERNATIVE METHODS TO AVOID THE USE OF RESTRAINTS

DDA is committed to the use of positive behavioral interventions and supports for all participants. This includes an emphasis upon the use of non-restrictive behavioral procedures and the reduction of ~~physical~~ restraints.

Positive behavior interventions are based on a tiered system that always begins with positive interactions before moving to formalized restrictive techniques.

1. Tier 1 includes providing positive interactions, choice making, and predictable and proactive settings or environments.

2. Tier 2 focuses on: (i) social, communication, emotional, and physiological intervention or therapies; (ii) mobile crisis teams; and (iii) behavioral respite based on trauma informed care.

3. Tier 3 is the use of restrictive techniques based on a functional assessment and approved strategies developed and approved in the Behavior Support Plan.

METHOD OF DETECTING UNAUTHORIZED USE OF RESTRAINTS

The following strategies are used to detect unauthorized use of restraints:

1. The Coordinator of Community Service (CCS) provides each participant and their legal representative and family members with information about how to report incidents to DDA. This information is also available on the DDA's website as a reference.

2. The CCS conducts quality monitoring and follow up activities on a quarterly basis, during which unauthorized restraints can be detected.

3. DDA's regulations require all DDA providers to take appropriate and reasonable steps to assure participants' health and safety – including overseeing their staff. Providers conduct staff performance evaluations and monitoring activities to ensure each staff member is knowledgeable of applicable policies, person specific strategies, and reporting requirements.

As specified further in Appendix G-1, the PORII requires providers to report certain incidents, including unauthorized use of restraints to the DDA.

Anyone can call the DDA, OLTSS, or OHCQ to file a complaint, including the unauthorized use of restraints or seclusion on a participant. In addition, complaints can be filed anonymously via the OHCQ website.

RESTRAINT PROTOCOLS

The DDA providers are required to comply with applicable regulations governing the development of Behavior Support Plans, provision of Behavioral Support Services (BSS), and use of restraints as per the Code of Maryland Regulations (COMAR) 10.22.10 which is further described in this section. The DDA's BSS are designed to assist participants, who exhibit challenging behaviors, in acquiring skills, gaining social acceptance, and becoming full participants in their community.

The emergency use of restraints is permitted in limited circumstances – when the participant presents a danger to the health or safety of himself or herself or serious bodily harm to others. The use of seclusion is prohibited. DDA providers are required to document and report the use of emergency restraints in accordance with PORII.

DDA's regulations specify that DDA providers must ensure that a Behavior Support Plan (BSP) is developed for each participant for whom it is required and must:

1. Represent the least restrictive, effective alternative or the lowest effective dose of a medication;

2. Be implemented only after other methods have been systematically tried, and objectively determined to be ineffective;

3. Be developed, in conjunction with the team, by qualified professionals who have training and experience in applied behavior analysis;

4. Be based on and include:

    a. a functional analysis or assessment of each challenging behavior as identified in the Person-Centered Plan;

b. specify the behavioral objectives for the participant; and

c. a description of the hypothesized function of current behaviors, including their frequency and severity and criteria for determining achievement of the objectives established;

5. Take into account the medical condition of the participant, describing the medical treatment techniques and when the techniques are to be used;

6. Take into account any trauma history of the participant to ensure that any behavioral objectives do not re traumatize the participant;

~~6.~~7.Specify the emergency procedures to be implemented for the participant with a history of exhibiting behaviors that present a danger to self or serious bodily harm to others, including a description of the adaptive skills to be learned by the participant that serve as functional alternatives to the challenging behavior or behaviors to be decreased;

~~7.~~8.Identify the person or persons responsible for monitoring the BSP;

~~8.~~9.Specify the data to be collected to assess progress towards meeting the BSP's objectives; and

~~9.~~10. Ensure that each use of mechanical and physical restraint, the reason for its use, and the length of time used is described and documented, as a part of data collection

~~10.~~11. Before implementation, the licensee shall ensure that each BSP, which includes the use of restrictive techniques:

a. Includes written informed consent of the: (a) participant; (b) participant's legal guardian; or (c) surrogate decision maker as defined in Title 5, Subtitle 6 of the Health-General Article of the Maryland Annotated Code;

b. Is approved by the PCP team; and

c. Is approved by the standing committee as specified in regulations.

~~11.~~12. Before a DDA provider discontinues a Behavior Support Plan, the team and an individual, appropriately licensed under Health Occupations Article with training and experience in applied behavior analysis, shall recommend that the participant no longer needs a Behavior Support Plan.

PRACTICES TO ENSURE THE HEALTH AND SAFETY OF PARTICIPANTS

As required by DDA's regulations, the use of any restrictive technique must be described in an approved ~~Behavior Plan (BP).~~BSP. The licensed provider shall:

1. Ensure staff are trained on the specific restrictive techniques and strategies;
2. Collect and present objective data to the authorizing licensed health care practitioner to indicate whether the restrictive technique being used is effective in reducing the participant's challenging behavior;
3. Report unauthorized restraints;
4. Convene the team within 5 calendar days after an emergency use of a restrictive technique to review the situation and action taken;
5. Determine subsequent action, including whether the development or modification of a Behavior Support Plan is necessary; and
6. Document that applicable regulatory requirements have been met.

DDA providers shall ensure that its staff do not use:

1. Any method or technique prohibited by law, including aversive techniques;
2. Any method or technique that deprives a participant of any basic right specified in Title 7 of the Health-General Article of the Maryland Annotated Code or other applicable law, (e.g., access to a telephone; right to share room with a spouse; visitors; access to clothing and personal effects; vote; receive, hold, or dispose of personal property; and receive services), except as permitted in regulations;

3. Seclusion;

4. A room from which egress is prevented; or

5. A program which results in a nutritionally inadequate diet.

In addition, the DDA Quality Enhancement staff review use of restraints to identify remediation efforts or any preventive measures to reduce or eliminate restraint use. The DDA's Director of Clinical Services will review unauthorized restraints or restrictive interventions on a quarterly basis. The DDA's Director of Clinical Services will coordinate with the DDA's Provider Services staff for any necessary provider specific remediation.

REQUIRED DOCUMENTATION OF USE OF RESTRAINTS

DDA providers must document all use of restraints and restrictive techniques in the participant's record, including the specific technique, reasons for use, and length of time used. Antecedent, behavior, consequence data are reviewed as part of monitoring of the BSP.

In addition, PORII requires that a provider report any unauthorized use of restraints.

EDUCATION AND TRAINING REQUIREMENTS

In addition to training specific to a participant's BSP, the DDA's regulations require that all individuals providing behavioral supports and implementing a BSP must receive training on the principles of behavioral change and on appropriate methods of preventing or managing challenging behaviors, which ~~–~~ is done through mandatory training of the DDA's approved behavior support curriculum. In addition, family members will receive the necessary support and training to implement these positive behavior interventions as well.

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:

The DDA, OLTSS, and OHCQ are responsible for overseeing the use of restraints and ensuring that State safeguards concerning their use are followed.

METHOD OF DETECTING UNAUTHORIZED USE, OVERUSE OR INAPPROPRIATE OR INEFFECTIVE USE OF RESTRAINTS AND ALL APPLICABLE STATE REQUIREMENTS ARE FOLLOWED

1. The DDA and OHCQ monitor the DDA providers and ensure that services, including Behavioral Support Services, are delivered in accordance with the Person-Centered Plan (PCP) and, if applicable, the Behavior Support Plan (BSP).

    a. The OHCQ conducts regulatory site visits of DDA providers to ensure that providers are providing services in accordance with applicable regulations, the PCP, and BSP.

    b. DDA staff conduct on-site interviews with participants and the DDA provider's staff during visits and ascertain ~~that~~ those services, including Behavioral Support Services, are delivered in accordance with plans and that the participant is satisfied with services being received.

2. The OHCQ, DDA, and OLTSS conduct unannounced visits and observations of DDA providers, including interviewing participants, to gauge quality of services, identify needs and concerns, and follow up on any areas of concern. Interviews of participants may be conducted in a private area, especially when the nature of the conversation involves the present staff.

3. The OLTSS conducts independent reviews and investigations, including reviewing a sample of participants' records to ensure that services were provided in accordance with applicable requirements and assurances and were based on assessed needs, the PCP~~, SFP~~, and BSP.

DATA USE STRATEGIES

1. The DDA and OHCQ meet on a quarterly basis to review data analysis and trends and discuss participant specific and systemic issues identified during their respective investigations and reviews of survey reports.

2. Data ~~collected as part OHCQ's and DDA's monitoring activities of~~on Behavioral Support Services is analyzed and provided to the Statewide Behavioral Supports Committee (SBSC). The SBSC's mission is to promote and monitor the safe, effective, and appropriate use of behavior change techniques and provide recommendations to the DDA. DDA uses recommendations from the SBSC to make systemic improvements in the provision of Behavioral Support Services for participants receiving waiver services.

3. DDA will also share data and trends with the DDA Quality Advisory Council for input on system improvement strategies.

METHOD FOR OVERSEEING THE OPERATION OF THE INCIDENT MANGEMENT SYSTEM AND FREQUENCY

The DDA uses quarterly and annual quality reports, based on performance measure data and system outcomes, to oversee and continuously assess the effectiveness of the incident management system.

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:

X	**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.

RESTRICTIVE INTERVENTIONS

The State defines restraints (restrictive interventions) as "Any physical, chemical or mechanical intervention used to impede an individual's physical mobility or limit free access to the environment and /or to control acute, episodic behavior including those that are approved as part of an individual's Behavior Support Plan~~plan~~ or those used on an emergency basis."

Generally, as further detailed in Appendix G-2-a-i, DDA is committed to providing positive behavioral interventions and supports for all participants. This includes an emphasis upon the use of non-restrictive behavioral procedures and the reduction of physical restraints.

The DDA provides the same safeguards for use of restrictive interventions as it does restrictive techniques, which is set forth in Appendix G-2-a-i.

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:

The DDA, OLTSS, and OHCQ are responsible for overseeing the use of restraints and ensuring that State safeguards concerning their use are followed.

The DDA, OLTSS, and OHCQ perform the same oversight activities regarding use of restrictive interventions as it does restrictive techniques, which is set forth in Appendix G-2-a-ii.

c. Use of Seclusion.

X	**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:
	STATE's METHOD OF DETECTING UNAUTHORIZED USE OF SECLUSION 1. The DDA and OHCQ monitor DDA providers and ensure that services, including Behavioral Support Services, are delivered in accordance with the Person-Centered Plan (PCP) and, if applicable, the Behavior Support Plan (BSP). a. The OHCQ conducts regulatory site visits of licensed providers to ensure that providers are providing services in accordance with applicable regulations, the PCP, and BSP. b. The DDA staff conduct on-site interviews with participants and the DDA provider's staff during visits and ascertain ~~that services~~those services, including Behavioral Support Services, are delivered in accordance with plans and that the participant is satisfied with services being received; 2. The OHCQ, DDA, and OLTSS conduct unannounced visits and observations of DDA providers, including interviewing participants, to gauge quality of

	services, identify needs and concerns, and follow up on any areas of concern. Interviews of participants may be conducted in a private area, especially when the nature of the conversation involves the present staff. **3.** The OLTSS conducts independent reviews and investigations, including reviewing a sample of participants' records to ensure that services were provided in accordance with applicable requirements and assurances and were based on assessed needs, as indicated in the PCP~~, SFP,~~ and BSP.
	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 in the specification are available to CMS upon request through the Medicaid agency or the operating agency (if applicable).

Not 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:

Not applicable

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:

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

As per the Maryland Nursing Practice Act and applicable regulations, Registered Nurses are responsible for supervision and monitoring of participant medication regimens when delegation of medication and treatment to non-nursing staff is occurring. See Code of Maryland Regulations (COMAR) 10.27.11, governing delegation of nursing tasks.

State regulations require that the licensed health care practitioner must review any medication that has been prescribed to modify behavior at a minimum of every 90 days, that PRN orders for medications to modify behavior are prohibited, and that medications to modify behavior may not be used in quantities that interfere with an individual's ability to participate in daily living activities.

Activities of licensed health care practitioners, including registered nurses delegating nursing tasks, are overseen by Maryland's Health Occupations licensing boards (e.g., Board of Physicians, Board of Nursing, etc.) to ensure these licensed health care practitioners practice within the scope of their licensure and in accordance with applicable laws and regulations.

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.

(a) Methods To Ensure Medications are Managed Appropriately

The OHCQ is involved in monitoring the community providers to ensure that medications are managed properly for participants. The OHCQ conducts regulatory site visits to licensed community providers to assure that providers are providing services in accordance with State regulations.

The OHCQ staff review of participant's medical charts, medication administration records, physician orders, nursing assessments and services, and staff medication administration training are part of licensing surveys.

The DDA's staff survey provider practices and provide technical assistance to develop and maintain effective systems (e.g. medication management) for serving individuals. As part of site visits, DDA staff review participant's records, including health records.

Upon OHCQ's or DDA's staff discovery of medication administration issues, the provider must develop a corrective action plan, which is monitored by the DDA staff.

Additionally, the reporting of medication errors is covered by the DDA's Policy on Reportable Incidents and Investigations (PORII). Under the policy, medication errors are classified as a "Type I" incident and defined as "the failure to administer medications as prescribed and/or the administration of medication not prescribed by a licensed physician/nurse practitioner/physician's assistant, e.g. incorrect dosage, time of administration and/or route, and omission of dosages."

OHCQ will:

1. Evaluate Incident Report to determine need for investigation.

2. Refer incident to other agencies when appropriate. 3. Notify the DDA Regional Office if incident is assigned for investigation. 4. Complete the investigation and, if necessary, issue a Statement of Deficiencies. 5. Request Plan of Correction (POC) if needed. 6. Review and approve agency's POC 7. Provide written report with findings and conclusions to involved parties. The DDA will: 1. Assure agency complies with reporting. 2. Assist OHCQ investigation as requested.

c. Medication Administration by Waiver Providers

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

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

The DDA Medication Technician Training Program (MTTP) Chapter 8, establishes the tool to be utilized by the registered nurse to determine an individual's ability to self-medicate. The MTTP also provides recommendations for monitoring by the registered nurse. Code of Maryland Regulations 10.22.02.12 requires that providers- develop and adopt written policies and procedures for ensuring that medications are administered in accordance with the practices established by the curriculum found in the MTTP. All DDA provider nurses and staff who administer medications must receive training following this curriculum.

All nurses must comply with the Maryland Nurse Practice Act, and applicable Maryland regulations, which gives Registered Nurses the ability to delegate the task of administering medication to appropriately trained and certified staff.

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:
■	Under the PORII, medication errors must be reported to the Office of Health Care Quality (OHCQ) and the DDA.
■	(b) Specify the types of medication errors that providers are required to *record:*
■	All medication errors must be recorded.
■	(c) Specify the types of medication errors that providers must *report* to the State:
■	The following medication errors must be reported: 1) Any significant medication error that has the potential to cause harm; 2) Any medication error that results in an individual requiring medical or dental observation or treatment by a physician, physician's assistant, or nurse; and

■	3) Any medication error that results in the admission of an individual to a hospital or 24-hour infirmary for treatment or observation.
	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.

The responsibility of monitoring the performance of DDA providers in the administration of medication is shared by the OHCQ and the DDA. Each DDA Regional Office is staffed by a registered nurse who provides training and technical assistance to nurses from DDA providers. In addition, the DDA QE Nurses review incidents related to medication errors. Both the OHCQ and the DDA conduct site visits of -DDA providers to ensure their compliance with COMAR and the Maryland Board of Nursing (MDON) regulations. ~~the medication administration regulations and conduct reviews of medication administration records.~~The OHCQ, which investigates critical incidents including medication errors, provides investigative reports directly to the DDA and the providers. In addition, applicable reports from the DDA, the OHCQ and the OLTSS are reviewed during the quarterly quality meetings. Trends and untoward events indicated in incident report review are discussed ~~during quarterly meetings~~ between DDA ~~Regional~~ Quality Enhancement Nurses and the provider community nurses as needed. Educational programming and alerts may be developed based on this information.

Problematic results from any of the above discovery processes may be addressed in several ways. These include but are not limited to: (1) a citation from the OHCQ set forth in a Statement of Deficiencies (SOD);(2) requirements for further team planning which may necessitate a change to a participant's PCP; (3) consultation with

the individual's prescribing physician; 4) required changes to a provider's policy or procedure; or 5) the imposition of deficiencies, requiring completion of a plan of correction (POC), and/or sanctions on a DDA provider.

On a systems level, the DDA uses data from surveys and critical incident reports to identify trends and develop new or revise policies, procedures, and training related to improved participant health.

Quality Improvement: Health and Welfare

As a distinct component of the State's quality improvement strategy, provide information in the following fields to detail the State's 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.)*

i. **Performance Measures**

For each performance measure the State will use to assess compliance with the statutory 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:	*HW-PM1 Number and percent of confirmed incidents of abuse, neglect, exploitation, and unexplained death for which correction actions executed or planned by appropriate entity in required timeframe. Numerator = number of confirmed incidents of abuse, neglect, exploitation, and unexplained death for which corrective actions executed or planned by appropriate entity in required time frame. Denominator = number of incidents reviewed.*
Data Source *(Select one) (Several options are listed in the on-line application): Other*	
If 'Other' is selected, specify: Record Review, Quality Improvement Organization (QIO)	

	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*
	X Operating Agency	☐ *Monthly*	☑ *Less than 100% Review*
	☐ *Sub-State Entity*	*X Quarterly*	☑ *Representative Sample; Confidence Interval =*
	x☐ *Other* *Specify:*	☐ *Annually*	*95% +/-5%*

	Quality Improvement Organization(QIO)	☐ *Continuously and Ongoing*		☐ *Stratified: Describe Group:*
		☐ *Other* *Specify:*		
				☐ *Other Specify:*

Performance Measure:	*HW-PM2 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 reporting abuse, neglect, and exploitation. Denominator = number of participants reviewed.*
Data Source *(Select one) (Several options are listed in the on-line application): Other*	
If 'Other' is selected, specify: Participant Record Review, Quality Improvement Organization (QIO)	

	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*
	X Operating Agency	☐ *Monthly*	*X Less than 100% Review*
	☐ *Sub-State Entity*	*X Quarterly*	*X Representative Sample; Confidence Interval =*

	x☐ *Other* *Specify:*	☐ *Annually*		*95% +/-5%*
	Quality Improvement Organization (QIO)	☐ *Continuously and Ongoing*		☐ *Stratified: Describe Group:*
		☐ *Other* *Specify:*		
				☐ *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 Measure:	*HW - PM3 Number and percent of incidents with investigation initiated within the required timeframe. Numerator = number of incidents with investigation initiated within the required timeframe. Denominator = number of records reviewed.*		
Data Source *(Select one) (Several options are listed in the on-line application): Other*			
If 'Other' is selected, specify: OHCQ Record Review and Quality Improvement Agency			
	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*
	X Operating Agency	☐ *Monthly*	*X Less than 100% Review*
	☐ *Sub-State Entity*	*X Quarterly*	*X Representative Sample; Confidence Interval =95*
	x Other *Specify:*	☐ *Annually*	*95% +/-5%*
	OHCQ, Quality Improvement Organization (QIO)	☐ *Continuously and Ongoing*	☐ *Stratified: Describe Group:*
		☐ *Other* *Specify:*	
			☐ *Other Specify:*

Performance Measure:	*HW -PM 4 Number and percent of incidents with investigation completed within the required timeframe. Numerator = number of incidents with investigation completed within the required timeframe. Denominator = number of records reviewed.*
Data Source (Select one) (Several options are listed in the on-line application): *Other*	
If 'Other' is selected, specify: *OHCQ Record Review and* Quality Improvement Agency	

	Responsible Party for data collection/generation	***Frequency of data collection/generation:***	***Sampling Approach*** ***(check each that applies)***

	(check each that applies)	***(check each that applies)***	
	☐ *State Medicaid Agency*	☐ *Weekly*	☐ *100% Review*
	X Operating Agency	☐ *Monthly*	*X Less than 100% Review*
	☐ *Sub-State Entity*	*X Quarterly*	*X Representative Sample; Confidence Interval =95*
	*x*Other *Specify:*	☐ *Annually*	*95% +/-5%*
	OHCQ and Quality Improvement Agency	☐ *Continuously and Ongoing*	☐ *Stratified: Describe Group:*
		☐ *Other* *Specify:*	
			☐ *Other Specify:*

Performance Measure:	*HW - PM 5 Number and percent of critical incidents systemic interventions implemented. Numerator = number of critical incidents systemic interventions implemented. Denominator = number of critical incidents systemic interventions.*
Data Source (Select one) (Several options are listed in the on-line application): *Other*	
If 'Other' is selected, specify*: Systemic Intervention Review and Quality Improvement Agency*	

	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*	*X 100% Review*
	X Operating Agency	☐ *Monthly*	☐ *Less than 100% Review*
	☐ *Sub-State Entity*	☐*Quarterly*	*X Representative Sample; Confidence Interval =95*
	☐ *Other* *Specify:*	*X Annually*	
		☐ *Continuously and Ongoing*	☐ *Stratified: Describe Group:*
		☐ *Other* *Specify:*	
			☐ *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 Measure:	*HW - PM 6 Number and percent of incidents of restraint where proper procedures were followed. Numerator = number of incidents of restraint where proper procedures were followed. Denominator = number of incidents of restraint reviewed.*

Data Source *(Select one) (Several options are listed in the on-line application): Other*			
If 'Other' is selected, specify: Restraint Record Review -PCIS2 and Quality Improvement Agency			
	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*
	X Operating Agency	☐ *Monthly*	☑ *Less than 100% Review*
	☐ *Sub-State Entity*	*X Quarterly*	☑ *Representative Sample; Confidence Interval =*
	x☐ *Other* ~~an~~*Specify: Quality Improvement Organization(QIO)*	☐ *Annually*	*95% +/-5%*
		☐ *Continuously and Ongoing*	☐ *Stratified: Describe Group:*
		☐ *Other* *Specify:*	
			☐ *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 Measure:	*HW - PM 7:Number and percent of participants receiving Community Living – Group Home or Enhanced Supports whose identified health care needs are being addressed. Numerator = number of participants whose identified health care needs are being addressed. Denominator = number of participants reviewed.*
Data Source *(Select one) (Several options are listed in the on-line application): Other*	
If 'Other' is selected, specify: Participant Record Review, Quality Improvement Organization(QIO)	

	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*
	X Operating Agency	☐ *Monthly*	*X Less than 100% Review*
	☐ *Sub-State Entity*	*X Quarterly*	☐ *Representative Sample; Confidence Interval =*
	X Other *Specify:*	☐ *Annually*	*95% +/-5%*
	Community Living – Group Home and Enhanced Supports providers; Quality Improvement Organization(QIO)	*X Continuously and Ongoing*	☐ *Stratified: Describe Group:*
		☐ *Other* *Specify:*	

				☐ *Other Specify:*

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

b. Methods for Remediation/Fixing Individual Problems

i. *Describe the State's 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.*

Incident Reporting and Investigations (Appendix G-1):

The DDA's Quality Enhancement (QE) staff provides oversight and ensures the DDA providers' compliance with applicable reporting requirements set forth in PORII. The DDA~~'s Quality Enhancement~~QE staff will provide technical assistance and support on an on-going basis to the DDA providers and the Office of Health Care Quality (OHCQ) to address specific remediation issues with the provider. Dependent on the identified issues, the DDA may use a variety of remediation strategies including conference call, letter, in person meeting, and training. ~~DDA will document its remediation efforts in the provider's file and share with the OHCQ Executive Director.~~

Use of Unauthorized Restraints or Restrictive Interventions (Appendix G-2):

The DDA's Director of Clinical Services will review unauthorized restraints or restrictive interventions on a quarterly basis. The Director of Clinical Services will coordinate with the DDA Provider ~~Relations~~ Services staff for any necessary provider specific remediation.

DDA's Provider ~~Relations~~ Services staff provide technical assistance and support on an on-going basis to the DDA providers and will address specific remediation issues with the provider. Dependent on the identified issues, the DDA may use a variety of remediation strategies including conference call, letter, in person meeting, and training. ~~DDA will document its remediation efforts in the provider's file and share with the OHCQ Executive Director.~~

Remediation with CCS Providers:

The DDA's Coordination of Community Services staff provide technical assistance and support on an on-going basis to licensed CCS providers and will address specific remediation issues with the provider. Dependent on the identified issues, the DDA may use a variety of remediation strategies including ~~conference call, letter, in person meeting,~~ additional communication with and training to providers. The DDA will document its remediation efforts in the provider's file.

ii. **Remediation Data Aggregation**

	Responsible Party *(check each that applies):*	**Frequency of data aggregation and analysis** *(check each that applies)*
[redacted]	☐ **State Medicaid Agency**	☐ **Weekly**
	X Operating Agency	☐ **Monthly**
	☐ **Sub-State Entity**	**X Quarterly**
	x☐ **Other** Specify:	☐ **Annually**

	Quality Improvement Organization(QIO)	☐ **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.

X	**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.
