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)

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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 certain enumerated 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 the DDA's designee within the Maryland Department of Health, responsible for conducting survey and investigative activities to monitor regulatory compliance, on 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, (including exploitation and financial exploitation), 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 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

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preventive strategies, and additional services and supports that may be needed. The AIR must be received within 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

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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.

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Entities Receiving Notification of Incident Report

The DDA, <u>the OLTSS</u>, <u>the OHCQ</u>, 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 DDA's or 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 – <u>the OHCQ</u>'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, <u>the DDA</u> 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 - OHCO

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 OHCQ staff committee performs a comprehensive review of the reported incidents. In its evaluation, the OHCQ staff committee 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 OHCQ staff committee also reviews submitted Agency Incident

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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.

Participants and representatives are informed within 10 business days of the issuing of the investigation results by the provider.

TYPE 2 INCIDENTS – DDA

Evaluation

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, DDA 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 QE 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.

Participants and representatives are informed within 10 business days of the issuing of the investigation results by the provider.

INCIDENTS OUTSIDE OF A SITE OR SERVICE LICENSED BY MDH

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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.

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The DDA's Director of Nursing and Regional Office Nurses Quality Enhancement (QE) ("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 OfficeQE Nurse may do an on-site survey to review the provider's notes related to the provision of nursing services. The DDA's QERegional Office Nurse's review of incidents allows for trend identification and provider specific action that may lead to remediation. The DDA's Regional OfficeQE 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:

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- 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:

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- 4. 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.
- 5. The CCS conducts quality monitoring and follow up activities on a quarterly basis, during which unauthorized restraints can be detected.
- 6. 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.
- 7. As specified further in Appendix G-1, the PORII requires providers to report certain incidents, including unauthorized use of restraints to the DDA.
- 8. 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.

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DDA's regulations specify that DDA providers must ensure that a Behavior <u>Support</u> Plan (B<u>S</u>P) 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
 - 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;
- 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;
- 8. Identify the person or persons responsible for monitoring the BSP;

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- 9. Specify the data to be collected to assess progress towards meeting the BSP's objectives; and
- 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
- 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.
- 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 Support Plan (BSP). The licensed provider shall:

- 13. Ensure staff are trained on the specific restrictive techniques and strategies;
- 14. 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;
- 15. Report unauthorized restraints;

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- 16. Convene the team within 5 calendar days after an emergency use of a restrictive technique to review the situation and action taken;
- 17. Determine subsequent action, including whether the development or modification of a Behavior Support Plan is necessary; and
- 18. Document that applicable regulatory requirements have been met.

DDA providers shall ensure that its staff do not use:

- 19. Any method or technique prohibited by law, including aversive techniques;
- 20. 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;
- 21. Seclusion;
- 22. A room from which egress is prevented; or
- 23. 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.

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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 <u>the DDA</u> providers and ensure that services, including Behavioral Support Services, are delivered in accordance with the Person-Centered Plan (PCP) and, if applicable, the Behavior <u>Support Plan (BSP)</u>.
 - 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

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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

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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 <u>Behavior Support Plan plan</u> or those used on an emergency basis."

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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.

<u>The</u> 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.

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

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Person-Centered Plan (PCP) and, if applicable, the Behavior <u>Support</u> Plan (B<u>S</u>P).

- 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. 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, <u>as indicated in</u> the PCP_, <u>SFP</u>, 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

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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

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- 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.
 - (a) 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

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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.

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

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.

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- 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

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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.

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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 RegionalQuality 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

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imposition of deficiencies, requiring completion of a plan of correction (POC), and/or sanctions on a DDA provider.

On a systems level, 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.

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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	HW PM1 Number and percent of confirmed incidents of abuse, neglect,		
Measure:	exploitation, and unexplained death for which correction actions executed		
	or planned by appropri	ate entity in required time	frame. Numerator =
	number of confirmed incidents of abuse, neglect, exploitation, and		
		vhich corrective actions ex	-
		quired time frame. Denom	
	incidents reviewed.	qui ou uma grumar z enem	e c. ej
Data Couvea (Sal		listed in the on line appli	action): Other
	ect one) (Several options are		
If 'Other' is selec	ted, specify: Record Review,	Quality Improvement Org	anization (QIO)
	Responsible Party for	Frequency of data	Sampling Approach
	data	collection/generation:	(check each that
	collection/generation	(check each that	applies)
	(check each that	applies)	
	applies)		
	☐ State Medicaid	☐ Weekly	□100% <i>Review</i>
	Agency		
	X Operating Agency	\square Monthly	■ Less than 100%
	A operating figurey		Review
	Cal Charles Endite	V.O. sutsulv	
	☐ Sub-State Entity	X Quarterly	☑ Representative
			Sample; Confidence
			Interval =
	<u>X</u> ⊟ Other	□Annually	Interval = 95% +/-5%

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	Quality Improvement	☐ Continuously and	☐ Stratified:			
	Organization (QIO)	Ongoing	Describe Group:			
		□Other				
		Specify:				
			☐ Other Specify:			
			_			
Performance	HW PM2 Number and	percent of participants wh	no received information			
Measure:	about how to identify ar	nd report abuse, neglect, a	and exploitation.			
	Numerator = number of	f participants who receive	d information about			
	reporting abuse, neglec	t, and exploitation. Denon	ninator = number of			
	participants reviewed.	participants reviewed.				
Data Source (Selec	ct one) (Several options are	listed in the on-line applic	cation): Other			
If 'Other' is selecte	ed, specify: Participant Reco	ord Review, <i>Quality Impro</i>	vement Organization			
(QIO)						
(QIO)						
(QIO)	Responsible Party for	Frequency of data	Sampling Approach			
(OIO)	Responsible Party for data	Frequency of data collection/generation:	Sampling Approach (check each that			
(OIO)						
(QIO)	data	collection/generation:	(check each that			
(OIO)	data collection/generation (check each that	collection/generation: (check each that	(check each that			
(QIO)	data collection/generation	collection/generation: (check each that	(check each that			
(OIO)	data collection/generation (check each that	collection/generation: (check each that	(check each that			
(OIO)	data collection/generation (check each that applies)	collection/generation: (check each that applies)	(check each that applies)			
(OIO)	data collection/generation (check each that applies) □ State Medicaid	collection/generation: (check each that applies)	(check each that applies)			
(QIO)	data collection/generation (check each that applies) □ State Medicaid Agency	collection/generation: (check each that applies) Weekly	(check each that applies) □100% Review			
(OIO)	data collection/generation (check each that applies) □ State Medicaid Agency	collection/generation: (check each that applies) Weekly	(check each that applies) □100% Review X Less than 100%			
(OIO)	data collection/generation (check each that applies) □ State Medicaid Agency X Operating Agency	collection/generation: (check each that applies) Weekly Monthly	(check each that applies) □100% Review X Less than 100% Review			

 \square Annually

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<u>X</u>⊟ Other

95% +/-5%

Specify:		
Quality Improvement	\square Continuously and	☐ Stratified:
Organization (QIO)	Ongoing	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	HW - PM3 Number and percent of incidents with investigation initiated		
Measure:	within the required timeframe. Numerator = number of incidents with		
	investigation initiated wi	ithin the required timefra	me. Denominator =
	number of records reviewed.		
Data Source (Select o	one) (Several options are l	isted in the on-line applic	cation): Other
If 'Other' is selected,	specify: OHCQ Record Re	eview, <i>Quality Improvem</i>	ent Organization (QIO)
	Responsible Party for	Frequency of data	Sampling Approach
	data	collection/generation:	(check each that
	collection/generation	(check each that	applies)
	(check each that	applies)	
	applies)		
	☐ State Medicaid	□Weekly	□ 100% Review
	Agency		
	X Operating Agency	□Monthly	X Less than 100%
			Review

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	☐ Sub-State Entity	X Quarterly	X Representative
			Sample; Confidence
			Interval =95
	XOther	\square Annually	95% +/-5%
	Specify:		
	OHCQ <u>, Quality</u>	☐ Continuously and	□ Stratified:
	<u>Improvement</u>	Ongoing	Describe Group:
	Organization (QIO)		
		□Other	
		Specify:	
			☐ Other Specify:
Performance	HW - PM 4 Number and	l percent of incidents with i	investigation completed
Measure:	within the required time	within the required timeframe. Numerator = number of incidents with	
	investigation completed	within the required timefro	ame. 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, 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

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☐ Sub-State Entity	X Quarterly	X Representative
		Sample; Confidence
		Interval =95
XOther	\square Annually	95% +/-5%
Specify:		
OHCQ <u>, Quality</u>	☐ Continuously and	□ Stratified:
<u>Improvement</u>	Ongoing	Describe Group:
Organization (QIO)		
	□ Other	
	Specify:	
		☐ Other Specify:

[
Performance	HW - PM 5 Number and percent of critical incidents systemic		
Measure:	interventions implemented. Numerator = number of critical incidents		
	systemic interventions in	nplemented. Denominato	r = number of critical
	incidents systemic interventions.		
Data Source (Select o	one) (Several options are	listed in the on-line appl	ication): Other
If 'Other' is selected,	specify: Systemic Interve	ntion Review	
	Responsible Party for	Frequency of data	Sampling Approach
	data	collection/generation:	(check each that
	collection/generation	(check each that	applies)
	(check each that	applies)	
	applies)		
	11 /		
	☐ State Medicaid	☐ Weekly	X 100% Review
	Agency		
	X Operating Agency	□Monthly	□Less than 100%
			Review

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☐ Sub-State Entity	□ Quarterly	X Representative
		Sample; Confidence
		Interval =95
□ Other	X Annually	
Specify:		
	☐ Continuously and	□ Stratified:
	Ongoing	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	HW - PM 6_Number and percent of incidents of restraint where proper			
Measure:	procedures were followed. Numerator = number of incidents of restraint			
	where proper procedure	where proper procedures were followed. Denominator = number of		
	incidents of restraint reviewed.			
Data Source (Select of	one) (Several options are l	isted in the on-line applic	eation): Other	
If 'Other' is selected,	specify: Restraint Record	Review <u>, PCIS2 and Qual</u>	ity Improvement	
Organization (QIO)				
	Responsible Party for	Frequency of data	Sampling Approach	
	data	collection/generation:	(check each that	
	collection/generation	(check each that	applies)	
	(check each that	applies)		
	applies)			
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☐ State Medicaid	☐ Weekly	□100% Review
Agency		
X Operating Agency	\square Monthly	☑ Less than 100%
		Review
☐ Sub-State Entity	X Quarterly	☑ Representative
		Sample;
		Confidence Interval
		=
<u>X</u> □ Other	\square Annually	95
Specify:		
Quality Improvement	☐ Continuously and	☐ Stratified:
Organization(QIO)	Ongoing	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	Per guidance received at	2017 HCBS Conference	, this is not applicable to
Measure:	Community Supports Wa	iver as there are no resio	lential services.
Data Source (Select one) (Several options are listed in the on-line application): Other			
If 'Other' is selected, specify: N/A			
	Responsible Party for	Frequency of data	Sampling Approach
	data	collection/generation:	(check each that
	collection/generation		applies)

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	(check each that	(check each that	
	applies)	applies)	
	☐ State Medicaid	□Weekly	□ 100% Review
	Agency		
	X Operating Agency	□Monthly	X Less than 100%
			Review
	☐ Sub-State Entity	□Quarterly	\square Representative
			Sample;
			Confidence Interval
			=
	Ø Other	\square Annually	
	Specify:		
	N/A	☐ Continuously and	□ Stratified:
		Ongoing	Describe Group:
		ØOther	
		Specify:	
<u> </u>		N/A	☑ Other Specify:
			N/A
If applicable, i	n the textbox below provi	de any necessary addition	al information on the
strategies emp	loyed by the State to disco	over/identify problems/iss	ues within the waiver
program, inclu	ding frequency and partie	s 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

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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 ensure DDA providers' compliance with applicable reporting requirements set forth in PORII. The DDA's QE staff will provide technical assistance and support on an on-going basis to 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 additional communications with andconference call, letter, in person meeting, and training to providers. 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):

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

The DDA's Provider Relations Services staff provide technical assistance and support on an ongoing basis to 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 additional communications with andeonference call, letter, in person meeting, and training to providers. DDA will document its remediation efforts in the provider's file and share with the OHCO Executive Director.

Remediation with CCS Providers:

<u>The DDA</u>'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, and additional communications with and training to providers. The DDA will document its remediation efforts in the provider's file.

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ii. Remediation Data Aggregation

Responsible Party (check	Frequency of data
each that applies):	aggregation and
	analysis
	(check each that
	applies)
☐ State Medicaid Agency	☐ Weekly
X Operating Agency	☐ Monthly
☐ Sub-State Entity	X Quarterly
□ -XOther	☐ Annually
Specify:	
Quality Improvement	☐ Continuously and
Organization(QIO)	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
0	Yes

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

