Appendix G: Participant Safeguards

Appendix G-1: Response to Critical Events or Incidents

a. Critical Event or Incident Reporting and Management Process. Indicate whether the state operates Critical Event or Incident Reporting and Management Process that enables the state to collect information on sentinel events occurring in the waiver program.*Select one:*

- (●) **Yes. The state operates a Critical Event or Incident Reporting and Management Process** *(complete Items b through e)*
- ( ) **No. This Appendix does not apply** *(do not complete Items b through e)*

If the state does not operate a Critical Event or Incident Reporting and Management Process, describe the process that the state uses to elicit information on the health and welfare of individuals served through the program.

b. State Critical Event or Incident Reporting Requirements. Specify the types of critical events or incidents (including alleged abuse, neglect and exploitation) that the state requires to be reported for review and follow-up action by an appropriate authority, the individuals and/or entities that are required to report such events and incidents and the timelines for reporting. State laws, regulations, and policies that are referenced are available to CMS upon request through the Medicaid agency or the operating agency (if applicable).

All waiver service providers, and case managers regardless of delivery system (i.e., FFS or managed care) are required to document major and minor incidents and make the incident reports and related documentation available to HHS upon request. Providers and case managers must also ensure cooperation in providing pertinent information regarding incidents as requested by HHS. MCOs must require that all internal staff and network providers report, respond to, and document critical incidents, as well as cooperate with any investigation conducted by the MCO or outside agency, all in accordance with State requirements for reporting incidents for 1915(c) HCBS Waivers, 1915(i) Habilitation Program, PMICs, and all other incidents required for licensure of programs through the Department of Inspections and Appeals.

Major incident is defined as an occurrence that involves a member who is enrolled in an HCBS waiver, targeted case management, or habilitation services and that:
• results in a physical injury to or by the member that requires a physician's treatment or admission to a hospital,
• results in the death of the member, including those resulting from known and unknown medical conditions,
• results in emergency mental health treatment for the member, (EMS, Crisis Response, ER visit, Hospitalization)
• results in medical treatment for the member, (EMS, ER Visit, Hospitalization)
• results in the intervention of law enforcement, including contacts, arrests, and incarcerations,
• results in a report of child abuse pursuant to Iowa Code section 232.69 or a report of dependent adult abuse pursuant to Iowa Code section 235B.3,
• constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in bullets 1, 2, 3, 4, 5, and 6 above
• involves a member's provider staff, who are assigned protective oversight, being unable to locate the member or
• involves a member leaving the program against court orders, or professional advice
• involves the use of physical or chemical restraint or seclusion of the member

Child and dependent adult abuse is an inclusive definition that includes physical and sexual abuse, neglect and exploitation. Child abuse is defined in Iowa Code 232.68, and may include any of the following types of acts of willful or negligent acts or omissions:
- Any non-accidental physical injury.
- Any mental injury to a child's intellectual or psychological capacity.
- Commission of a sexual offense with or to a child.
- Failure on the part of a person responsible for the care of a child to provide adequate food, shelter, clothing or other care necessary for the child's health and welfare.
-The acts or omissions of a person responsible for the care of a child which allow, permit, or encourage the child to engage in prostitution.
- Presence of an illegal drug in a child's body as a direct act or omission of the person responsible for the care of a child or is using, manufacturing, cultivating, or distributing a dangerous substance in the presence of a child.
-The commission of bestiality in the presence of a minor.
-A person who is responsible for the care of a child knowingly allowing another person custody of, control over, or unsupervised access to a child under the age of fourteen or a child with a physical or mental disability, after knowing the other person is required to register or is on the sex offender registry. -The person responsible for the care of the child has knowingly allowed the child access to obscene material or has knowingly disseminated or exhibited such material to the child.
-The recruitment, harboring, transportation, provision, obtaining, patronizing, or soliciting of a child for the purpose of commercial sexual activity. Dependent adult abuse is defined in Iowa Code 235B.2, and may include any of the following types of acts of willful or negligent acts or omissions:
- Physical injury or unreasonable confinement, unreasonable punishment, or assault of a dependent adult. - Commission of a sexual offense or sexual exploitation.
- Exploitation of a dependent adult which means the act or process of taking unfair advantage of a dependent adult or the adult's physical or financial resources, without the informed consent of the dependent adult, including theft, by the use of undue influence, harassment, duress, deception, false representation, or false pretenses.
- Deprivation of the minimum food, shelter, clothing, supervision, physical or mental health care or other care necessary to maintain a dependent adult's life or health.
-Personal degradation of a dependent adult by a caretaker. "Personal degradation" means a willful act or statement by a caretaker intended to shame, degrade, humiliate, or otherwise harm the personal dignity of a dependent adult, or where the caretaker knew or reasonably should have known the act or statement would cause shame, degradation, humiliation or harm to the personal dignity of a reasonable person.

Consistent with 441 Iowa Administrative Code 77, the following process is followed when a major incident occurs or a

staff member becomes aware of a major incident:
(1) The staff member involved shall notify the following persons of the incident by the end of the next calendar day after the incident:
a. The staff member's supervisor.
b. The member or the member's legal guardian. EXCEPTION: Notification to the member is required only if the incident took place outside of the provider's service provision. Notification to a guardian, if any, is always required.
c. The member's case manager.

(2) By the end of the next calendar day after the incident, the staff member who observed or first became aware of the incident shall also report as much information as is known about the incident by direct data entry into the Iowa Medicaid Provider Access (IMPA) System: https://hhs.iowa.gov/medicaid/provider-services/using-provider-portal

(3) The following information shall be reported:
a. The name of the member involved.
b. The date and time the incident occurred.
c. The date and time the incident discovered.
d. The date the report is made and the handwritten or electronic signature of the person making the report.
e. Incident type.
f. A description of the incident.
g. Root cause of the incident.
h. Immediate resolution of the incident.
i. Long term remediation of the incident of needed.
j. Date remediation was completed.

If the critical incident involves the report of child or dependent adult abuse, it is mandatory that this type of critical incident is reported to HHS Protective Services. If the critical incident does not involve child or dependent adult abuse, it will be reviewed by the MCO or HCBS QIO. The MCO will notify the member and/or the family of the results upon conclusion of the investigation, on or within 30 days. If the member is not with an MCO, the FFS case manager will notify the member, guardian, and or legal representative, verbally or in writing, of the results upon conclusion of the investigation, on or within 30 days.

As part of the quality assurance policies and procedures for HCBS Waivers, all incidents will be monitored and remediated by the HCBS Incident Reporting Specialist and HCBS specialists. On a quarterly basis, a QA committee will review data collected on incidents and will analyze data to determine trends, problems and issues in service delivery and make recommendations of any policy changes.

MCOs are also required to develop and implement a critical incident management system in accordance with HHS requirements, in addition to maintaining policies and procedures that address and respond to incidents, remediate the incidents to the individual level, report incidents to the appropriate entities per required timeframes, and track and analyze incidents. MCOs must adhere to the State's quality improvement strategy described in each HCBS waiver and waiver-specific methods for discovery and remediation.

MCOs must utilize system information to identify both case-specific and systemic trends and patterns, identify opportunities for improvement and develop and implement appropriate strategies to reduce the occurrence of incidents and improve the quality of care. All MCO staff and network providers are required to:
- Report critical incidents.
- Respond to critical incidents.
- Document critical incidents.
- Cooperate with any investigation conducted by the HCBS QIO staff, MCO, or outside agency.
- Receive and provide training on critical incident policies and procedures.
- Be subject to corrective action as needed to ensure provider compliance with critical incident requirements.

Finally, MCOs must identify and track critical incidents, and review and analyze critical incidents, to identify and address quality of care and/or health and safety issues, including a regular review of the number and types of incidents and findings from investigations. This data should be used to develop strategies to reduce the occurrence of critical incidents and improve the quality of care delivered to members.

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.

Information concerning protections from abuse, neglect and exploitation, including how to notify the appropriate authorities is provided to applicants and members at the time of application and at the time-of service plan development and annual review. During enrollment, and when any updates are made, HHS also provides to members a Medicaid Members Handbook, which contains information regarding filing a complaint or grievance. MCO written member enrollment materials also contain information and procedures on how to report suspected abuse and neglect, including the phone numbers to call to report suspected abuse and neglect.

In addition, information can also be found on HHS and MCO websites. The HHS website contains a “Report Abuse and Fraud” section, which describes how to report dependent adult child abuse. The same information is also available in written format in all of the local HHS offices, and members may also call Iowa Medicaid Member Services call center with any questions regarding filing a complaint or grievance.

Finally, each member’s risk factors will be assessed annually during the reevaluation process, as well as during the development of the person-centered service plan. HHS has developed training to ensure that case managers provide this information to members at a minimum on a yearly basis.

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.

HHS Protective Services (PS) receives all mandatory reports of child and dependent adult abuse. If an immediate threat of physical safety is believed to exist, PS makes every effort to examine that child or dependent adult within one hour of receipt and take any lawful action necessary. If the child or dependent adult is not in danger, PS makes every effort to examine the child or dependent adult within 24 hours. PS notifies the member's case manager when an investigation has been initiated to ensure they are aware of the alleged abuse, and to ensure that additional services can be added or that changes can be made to the member's plan of care if needed. PS provides an evaluation report within twenty days of receipt of the report, which includes necessary actions, and/or an assessment of services needed. The Central Registry of Abuse and County Attorney also receives PS reports. For both child and dependent adult abuse cases, the member and/or the family are notified of the results in writing by HHS as soon as the investigation has concluded. This applies to both individuals enrolled in fee-for-service or managed care.

If the incident is a situation that has caused, or is likely to cause a serious injury, impairment, or abuse to the member, and if PS has completed, or is in the process of conducting, an investigation the HCBS specialist coordinates activities with PS to ensure the safety of the member is addressed. If PS is not investigating, and immediate jeopardy remains, the member's case manager is notified immediately to coordinate services, and the HCBS Specialist initiates a review within two working days of receipt of the report. If it is determined that immediate jeopardy has been removed or not present, review by the HCBS Specialist is initiated within twenty working days of receipt of report. The HCBS Specialist prepares a report of findings within thirty days of the investigation being completed. These timelines apply to both individuals enrolled in fee-for-service or managed care.

The HCBS incident and complaint specialists refers any untimely, incomplete, or inaccurate CIR or CIR missing root cause, immediate resolution or long-term remediation to the reporter or the reporter's supervisor as applicable. A pattern or trend of issues, inappropriate or ineffective root causes, immediate resolutions, or long-term remediations may require follow-up technical assistance with the reporter or reporter's supervisor, as applicable. Patterns to look for include but are not limited to:
• Patterns in the timing of incidents (i.e., at transition times, evenings, mornings, when the member is unsupervised, mealtimes.)
• Patterns in root cause- events leading up to the incident or that may have caused the incident.
• Patterns in the type of incident or issue.
• Patterns in staff or others involved.

Technical assistance may be provided by the HCBS incident and complaint specialist or a regional HCBS specialist.

HHS meets monthly to review critical incident reports of child and dependent adult abuse and member deaths that have been reported through the critical incident reporting process. HHS reviews, and if needed, requests information for follow through and resolution of the abuse allegation and member deaths from the case manager or HCBS Specialist. Requests for information are forwarded to the case manager to verify any needed changes and confirm that follow-up has occurred with the member (i.e., changes to a plan of care or the safety or risk plan as necessary). If additional information or actions are required of a provider, the HCBS Specialist works directly with the provider to ensure that performance issues identified in the incident report are addressed. The HCBS Specialist uses the provider's Self-Assessment as the foundation of the review to assure that accuracy in the Self-Assessment and to identify any corrective actions that may be required. The HCBS Specialist generates a report of findings within thirty days of the completion of any review requiring corrective actions.

Information requests to the case manager or HCBS Specialist for follow up are tracked by the HCBS Unit on a weekly basis until the situation has been resolved. HHS utilizes a web-based critical incident reporting system to track and trend the discovery, remediation, and improvement of the critical incident reporting process. Revisions have been made to the system based on data collection and feedback from users, further enhancing the process. Incidents are reviewed by the HCBS QIO within one business day of report and forwarded to the case manager as needed to coordinate any follow-up and communication with the member, provider, and/or family/legal guardian. Incidents that lead to targeted review will initiate investigation by the HCBS QIO Unit within one business day. Findings reports are submitted to the QIO Manager within 15 days of investigation completion. Once the finding report is approved by the Quality Assurance Manager, the findings report is sent to the provider, case manager, or HCBS Specialist.

MCOs are responsible for developing and implementing critical incident management systems in accordance with the HHS requirements. Specifically, MCOs must maintain policies and procedures, subject to HHS review and approval, that: (1) address and respond to incidents; (2) report incidents to the appropriate entities per required timeframes; and (3)

track and analyze incidents. This information is utilized to identify both case-specific and systemic trends and patterns, identify opportunities for improvement and develop and implement appropriate strategies to reduce the occurrence of incidents and improve the quality of care. Training must be provided to all internal staff and network providers regarding the appropriate procedures for reporting, responding to, and documenting critical incidents. Network providers must provide training to direct care staff regarding the appropriate procedures for reporting, responding to, and documenting critical incidents.

Finally, MCOs must identify and track, review and analyze critical incidents to identify and address quality of care and/or health and safety issues. MCOs must also regularly review the number and types of incidents and findings from investigations, in order to identify trends, patterns, and areas for improvement. Based on these findings, the MCO must develop and implement strategies to reduce the occurrence of critical incidents and improve the quality of care delivered to members. Consistent with 441 Iowa Administrative Code 77, the following process is followed when a major incident occurs or a staff member becomes aware of a major incident:
(1) The staff member involved shall notify the following persons of the incident by the end of the next calendar day after the incident:
a. The staff member's supervisor.
b. The member or the member's legal guardian. EXCEPTION: Notification to the member is required only if the incident took place outside of the provider's service provision. Notification to a guardian, if any, is always required.
c. The member's case manager.

(2) By the end of the next calendar day after the incident, the staff member who observed or first became aware of the incident shall also report as much information as is known about the incident to the member's managed care organization and by completing the critical incident report form by direct data entry into the Iowa Medicaid Provider Access (IMPA) System.

(3) The following information shall be reported:
a. The name of the member involved.
b. The date and time the incident occurred.
c. A description of the incident.
d. The names of all provider staff and others who were present at the time of the incident or who responded after becoming aware of the incident. The confidentiality of other members or nonmembers who were present must be maintained by the use of initials or other means.
e. The action that the provider staff took to manage the incident.
f. The resolution of or follow-up to the incident.
g. The date the report is made and the handwritten or electronic signature of the person making the report.

If the critical incident involves the report of child or dependent adult abuse, it is mandatory that this type of critical incident is reported to HHS Protective Services. If the critical incident does not involve child or dependent adult abuse, it will be reviewed by the MCO. The MCO will notify the member and/or the family of the results upon conclusion of the investigation, on or within 30 days. If the member is not with an MCO, the FFS case manager will notify the member, guardian, and or legal representative, verbally or in writing, of the results upon conclusion of the investigation, on or within 30 days.

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.

HHS is responsible for overseeing the operation of the incident management system. The HCBS QIO reviews all critical incident reports as soon as they are reported to HHS. All critical incidents are tracked in the incident management system that tracks the elements as described above in G-1.d. If the incident has caused or is likely to cause a serious injury, impairment, or abuse to the member, and if PS has completed or is in the process of conducting an investigation, the HCBS Specialist will coordinate with PS. If PS is not investigating, the HCBS Specialist will begin an on-site review within two working days of receipt of the report. If it is determined that the member is not in immediate jeopardy, the review is initiated within twenty working days of receipt of report. For all other incidents, a review is initiated within twenty days. Critical incident data is compiled and analyzed aggregately to identify individual, provider and systemic remediation including the provision of training and technical assistance to prevent re-occurrences.

Appendix G: Participant Safeguards

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

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

○ **The state does not permit or prohibits the use of restraints**

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

◉ **The use of restraints is permitted during the course of the delivery of waiver services**. Complete Items G-2-a-i and G-2-a-ii.

i. Safeguards Concerning the Use of Restraints. Specify the safeguards that the state has established concerning the use of each type of restraint (i.e., personal restraints, drugs used as restraints, mechanical restraints). State laws, regulations, and policies that are referenced are available to CMS upon request through the Medicaid agency or the operating agency (if applicable).

The HHS policy regarding restraints is as follows and applies to all types of restraints that may be used by waiver providers. The policy described in this section applies regardless of delivery system (i.e., FFS or MCO), and MCOs are contractually obligated to adhere.

Restraints include, but are not limited to, personal, chemical, and mechanical methods used for the purpose of controlling the free movement of an individual's body. Chemical restraints are most commonly used to calm an individual down in moments of escalation. Other examples of restraints include, but are not limited to, holding a person down with one's hands, tying an individual to a bed, using a straight jacket or demobilizing wrap. As a rights limitation, the restraint procedures must be agreed to by the interdisciplinary team and identified in the member's plan of care (441 Iowa Administrative Code Chapter 83). All incidents of restraints must be documented in a member's file and reported as a critical incident.

Per 441 Iowa Administrative Code Chapter 77, providers "shall have in place a system for the review, approval, and implementation of ethical, safe, humane, and efficient behavioral intervention procedures. All members receiving HCBS shall be afforded the protections imposed by these rules when any restraint, restriction, or behavioral intervention is implemented.

- The system shall include procedures to inform the member and the member's legal guardian of the restraint, restriction, and behavioral intervention policy and procedures at the time of service approval and as changes occur.
- Restraint, restriction, and behavioral intervention shall be used only for reducing or eliminating maladaptive target behaviors that are identified in the member's restraint, restriction, or behavioral intervention program.
- Restraint, restriction, and behavioral intervention procedures shall be designed and implemented only for the benefit of the member and shall never be used as punishment, for the convenience of the staff, or as a substitute for a nonaversive program.
- Restraint, restriction, and behavioral intervention programs shall be time-limited and shall be reviewed at least quarterly.
- Corporal punishment and verbal or physical abuse are prohibited.

These safeguards are the same regardless of what restraints are used. All restraints must also be consistent with applicable Federal laws. All members served under an HCBS waiver service shall be afforded the protections imposed by these requirements. Any provider contracting with HHS to provide waiver services must conduct its activities in accordance with these requirements. Restraint procedures may be designed and implemented only for the safety of the member and may never be used merely as punishment or for the convenience of the staff or as a substitute for a nonaversive program.

Physical and chemical restraints may be allowed depending on the provider's agency policy to ensure that there is an accompanying behavioral intervention plan, documentation of each instance, and monitoring of its use. These types of restraints must be considered on an individual basis after the interdisciplinary team reviews them, and entered into the written plan of care with specific timelines. If a member were placed in a closed room the timeframe would need to be determined on an individual basis and spelled out in the service plan. The provider would need to document the use of this restraint in the member's service file each time it was utilized by staff. The provider would be required to have a written policy approved by HHS on the supervision and monitoring of members placed in a closed room, for example monitoring on a fifteen-minute basis to assure the health and welfare of the member.

Restraint procedures may only be used for reducing or eliminating maladaptive target behaviors that are identified in the member's Behavioral Intervention Program. For the purposes of decelerating maladaptive target behaviors, a Behavioral Intervention Program includes at least the following components:
- A clear objective description of the maladaptive target behavior to be reduced or eliminated.
- A clear objective description of the incompatible or alternative appropriate response, which will reinforced.

- A list of restraints and behavioral interventions utilized to teach replacement behaviors that serve the same behavioral function identified through a functional analysis or review of the maladaptive target behaviors. Restraints and behavioral interventions may only be utilized to teach replacement behaviors when nonaversive methods of positive support have been ineffective.

- A baseline measurement of the level of the target behavior before intervention.

Any provider employee who implements an aversive procedure must be able to carry out the procedure as it is written. Staff must be trained and exhibit proficiency as described below before administering restraints. An employee's ability to implement a procedure must be documented in one of the following ways:
- A program staff person may observe each employee in a role-play situation in order to document his or her ability to implement the procedure as written.
- Supervisory personnel from the provider may provide documentation of employees' ability to implement a procedure if the following conditions are met: (i) the supervisor's ability to implement the procedure has been documented by a program staff person; (ii) the supervisor observes each employee in a role play situation and documents the employee's ability to implement the procedure; and (iii) the provider maintains a list of those employees who have been observed and are considered capable of implementing the procedure. The list should specify the dates that an employee demonstrated competency and the name of staff that certified the employee.
- Implementation of a program to alter an individual's behaviors.

Restraints and behavioral intervention procedures must be implemented by systematic program review. It must ensure that a member's right to be free from aversive, intrusive procedures is balanced against the member's interests in receiving services and treatment whenever a decision regarding the use of aversive procedures is made. Any decision to implement a program to alter a member's behavior must be made by the interdisciplinary team and the program must be described fully as a Behavioral Intervention Program incorporated into the member's service plan and the case manager's plan of care. In general, the Behavioral Intervention Program must meet the following minimum requirements:
- Show that previous attempts to modify the maladaptive target behavior using less restrictive procedures have not proven to be effective, or the situation is so serious that a restrictive procedure is immediately warranted.
- The proposed procedure is a reasonable response to the member's maladaptive target behavior.
- Emphasize the development of the functional alternative behavior and positive approaches and positive behavior intervention.
- Use the least restrictive intervention possible.
- Ensure the health and safety of the individual and that abusive or demeaning intervention is expressly prohibited.
- Be evaluated and approved by the interdisciplinary team through quarterly reviews of specific data on the progress and effectiveness of the procedures.

Documentation regarding the behavior program must include:
- A Restraint and Behavioral Intervention Program that is a part of the written individual service plan developed by the member's case manager and in the provider plan of care developed for the member.
- Approval by the member's interdisciplinary team, with the written consent of the member's parent if the member is under eighteen years of age, or the member's legal guardian if one has been appointed by the court.
- A written endorsement from a physician for any procedure that might affect the member's health.
- A functional analysis that is defined as, and includes, the following components: (i) clear, measurable description of the behavior to include frequency, duration, intensity and severity of the behavior; (ii) clear description of the need to alter the behavior; an assessment of the meaning of the behavior, which includes the possibility that the behavior is an effort to communicate, the result of medical conditions or environmental causes; or the result of other factors; (iii) description of the conditions that precede the behavior in question; (iv) description of what appears to reinforce and maintain the behavior; and (v) a clear and measurable procedure, which will be used to alter the behavior and develop the functional alternative behavior.
- Documentation that the member, the guardian, and interdisciplinary team are fully aware of and consent to the program in accordance with the interdisciplinary process.
- Documentation of all prior programs used to eliminate a maladaptive target behavior.
- Documentation of staff training.

Behavioral Intervention Programs shall be time limited and reviewed at least quarterly. Restraints must be considered on an individual basis after they are reviewed by the interdisciplinary team and entered into the

written plan of care with specific timelines. All restraints are explained to the member and their legal representative and agreed upon ahead of time.

Unauthorized use of restraints would be detected via:
- interviews with the member, their family and staff and case manager;
- review of critical incident reports by HHS and member's case manager;
- review of written documentation authored by provider staff;
- annual review activities associated with the provider quality oversight processes;
- the complaints and grievance processes.

Reviews may include desk reviews where the department requests member's records to be reviewed or onsite where the department or department designee goes onsite to review documentation. One hundred percent of waiver providers are reviewed at least once every five years to ensure that the HHS policy for each type of agency identified restraint is observed and member rights are safeguarded. If it is found that a waiver provider is not observing HHS policy or ensuring a member's rights, adverse action is taken by Iowa Medicaid, which may include sanction, termination, required corrective action, etc.

The member's case manager is responsible to monitor individual plans of care including the use of restraints and behavioral interventions.

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 first line of responsibility for overseeing the use of restraints and ensuring safeguards are in place is the member's case manager. The use of restraints must be assessed as needed and identified in the individual member's person-centered service plan. The use of restraints would also require the development and implementation of a behavior plan, and the plan would be included in the member's person-centered service plan. The case manager is responsible for monitoring to assure that supports and services in the service plan are being implemented as identified. Any issues with the use of restraints would be addressed with the provider of service and corrected as needed.

The State also contracts with the HCBS QIO to oversee the appropriateness, provider policies and procedures, and service plan components associated with restraints. The HCBS QIO conducts periodic reviews of 100% of enrolled waiver service providers to ensure that policies and procedures are consistent with State and federal rule, regulations, and best practices. Further, the HCBS QIO examines member files, and conducts targeted reviews based on complaints, to ascertain whether restraints are appropriately incorporated into the service plan, such that restraints are only implemented as designated in the plan (who, what, when, where, why, and how). If the HCBS QIO discovers that the provider is less than compliant, the provider is required to complete a corrective action plan (CAP) and implement the CAP to 100% compliance. If it is found that the circumstances are more serious, recommendations are made to PI and possible sanctions (suspension, probation, termination, etc.) may apply.

All waiver service providers are required to submit critical incident reports. Categories within the incident report include inappropriate use of restraints. These reports are entered into IMPA. If it is found that the incident demands further investigation, the issue is passed to the HCBS QIO for a targeted review. If the HCBS QIO discovers that the provider is less than compliant in areas surrounding the use of restraints, the provider is required to complete a corrective action plan (CAP) and implement the CAP to 100% compliance. If it is found that the circumstances are more serious, recommendations are made to PI and possible sanctions (suspension, probation, termination, etc.) may apply.

The HCBS QIO compiles all data related to incidents reported in IMPA associated with the inappropriate use of restraints, as well as data from periodic and targeted provider reviews conducted by the HCBS QIO. Data is analyzed to identify trends and patterns and reported on a monthly and quarterly basis to HHS. Trends are used, along with those established in the monthly HCBS QA Committee, to guide the dissemination of Informational Letters and revisions to State Administrative Rules.

In addition, MCOs must identify and track critical (major) incidents, regularly review the number and types of incidents and findings from investigations and develop and implement strategies to reduce the occurrence of critical incidents and improve the quality of care delivered to members. MCOs are required to follow the process outlined at 441 Iowa Administrative Code 77 for reporting major incidents. The State maintains ultimate oversight through the mechanisms identified in the submitted amendment (i.e., HCBS QIO, critical incident review, etc.)

Appendix G: Participant Safeguards

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

b. Use of Restrictive Interventions. *(Select one)*:

○ **The state does not permit or prohibits the use of restrictive interventions**

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

◉ **The use of restrictive interventions is permitted during the course of the delivery of waiver services** Complete Items G-2-b-i and G-2-b-ii.

i. Safeguards Concerning the Use of Restrictive Interventions. Specify the safeguards that the state has in effect concerning the use of interventions that restrict participant movement, participant access to other individuals, locations or activities, restrict participant rights or employ aversive methods (not including restraints or seclusion) to modify behavior. State laws, regulations, and policies referenced in the specification are available to CMS upon request through the Medicaid agency or the operating agency.

A restrictive intervention is an action or procedure that imposes a restriction of movement, that limits a member's movement, access to other individuals, locations or activities, or restricts a member's rights. 441-IAC Chapter 77 describes restrictive interventions as restraints, restrictions and behavioral intervention.

The HHS policy regarding restrictive interventions is as follows and applies to all types of restrictions that may be used by waiver providers. A restrictive intervention is an action or procedure that limits a member's movement, access to other individuals, locations or activities, or restricts a member's rights. The use of any restrictive interventions as part of the waiver program is treated as rights limitations of the member receiving services. As a rights limitation, the restrictive interventions must be agreed to by the interdisciplinary team and identified in the member's plan of care (441 Iowa Administrative Code 83.).

Per 441 Iowa Administrative Code Chapter 77., "shall have in place a system for the review, approval, and implementation of ethical, safe, humane, and efficient behavioral intervention procedures." All members receiving HCBS shall be afforded the protections imposed by these rules when any restraint, restriction, or behavioral intervention is implemented.
a. The system shall include procedures to inform the member and the member's legal guardian of the restraint, restriction, and behavioral intervention policy and procedures at the time-of-service approval and as changes occur.
b. Restraint, restriction, and behavioral intervention shall be used only for reducing or eliminating maladaptive target behaviors that are identified in the member's restraint, restriction, or behavioral intervention program.
c. Restraint, restriction, and behavioral intervention procedures shall be designed and implemented only for the benefit of the member and shall never be used as punishment, for the convenience of the staff, or as a substitute for a nonaversive program.
d. Restraint, restriction, and behavioral intervention programs shall be time-limited and shall be reviewed at least quarterly.
e. Corporal punishment and verbal or physical abuse are prohibited."

These safeguards are the same regardless of what restrictions are used. All restrictions must also be consistent with applicable Federal laws. All members served under an HCBS waiver service shall be afforded the protections imposed by these requirements. Any provider contracting with HHS to provide waiver services must conduct its activities in accordance with these requirements. Restrictions may be designed and implemented only for the benefit of the member and may never be used merely as punishment or for the convenience of the staff or as a substitute for a nonaversive program.

The case manager, or community-based case manager has the responsibility to assess the need for the restrictive interventions, identify the specific restrictive intervention, explain why the intervention is being used, identify an intervention plan, monitor the use of the restrictive intervention, and assess and reassess need for continued use. The service plan authorizes the services to be delivered to the member and identifies how they are to be provided. Without the authorization, services cannot be provided to a member.

Providers are required to use the service plan as the basis for the development and implementation of the providers' treatment plan. The provider is responsible for developing a plan to meet the needs of the member and to train all staff on the implementation strategies of the treatment plan, such that the interventions are individualized and in accordance with the previously devised plan. Providers and the case manager are responsible for documenting all behavioral interventions, including restrictive interventions, in the service plan as well as the member's response to the intervention. Providers and case manager are also required to submit critical incident reports via the critical incident management system in IMPA, any time a restrictive intervention is utilized.

Providers are required to maintain a system for the review, approval and implementation of ethical, safe, humane and efficient behavioral intervention procedures, that inform the member and his/her legal guardian of the behavioral intervention policy and procedures at the time of entry into a facility and as changes occur. Non-aversive methods of intervention must be designed and utilized as the option of first use, prior to design or implementation of any behavioral intervention containing aversive techniques. Behavioral intervention procedures may be designed and implemented only for the benefit of the member and may never be used merely as punishment or for the convenience of the staff or as a substitute for a nonaversive program.

Behavioral intervention procedures may only be used for reducing or eliminating maladaptive target behaviors that are identified in the member's Behavioral Intervention Program. Corporal punishment and verbal or physical abuse are prohibited. Restrictions may only be used for reducing or eliminating maladaptive target behaviors that are identified in the member's Behavioral Intervention Program. For the purposes of decelerating maladaptive target behaviors, a Behavioral Intervention Program includes at least the following components:
- A clear objective description of the maladaptive target behavior to be reduced or eliminated.
- A clear objective description of the incompatible or alternative appropriate response, which will be reinforced.
- A list of restrictions and behavioral interventions utilized to teach replacement behaviors that serve the same behavioral function identified through a functional analysis or review of the maladaptive target behaviors. Restrictions and behavioral interventions may only be utilized to teach replacement behaviors when non-aversive methods of positive support have been ineffective.
- A baseline measurement of the level of the target behavior before intervention.

Any provider employee who implements an aversive procedure must be able to carry out the procedure as it is written. A person's ability to implement a procedure must be documented in one of the following ways:
- A program staff person may observe each person in a role-play situation in order to document his or her ability to implement the procedure as written.
- Supervisory personnel from the provider may provide documentation of employees' ability to implement a procedure if the following conditions are met: (i) the supervisor's ability to implement the procedure has been documented by a program staff person; (ii) the supervisor observes each employee in a role play situation and documents the employee's ability to implement the procedure; and (iii) the provider maintains a list of those employees who have been observed and are considered capable of implementing the procedure. The list should specify the dates that an employee demonstrated competency and the name of staff that certified the employee.
- Implementation of a program to alter a member's behaviors.

Restrictions and behavioral intervention procedures must be implemented by systematic program review. It must ensure that a member's right to be free from aversive, intrusive procedures is balanced against the member's interests in receiving services and treatment whenever a decision regarding the use of aversive procedures is made. Any decision to implement a program to alter a member's behavior must be made by the interdisciplinary team and the program must be described fully as a Behavioral Intervention Program incorporated into the member's service plan and the case manager's plan of care. In general, the Behavioral Intervention Program must meet the following minimum requirements:
- Show that previous attempts to modify the maladaptive target behavior using less restrictive procedures have not proven to be effective, or the situation is so serious that a restrictive procedure is immediately warranted.
- The proposed procedure is a reasonable response to the member's maladaptive target behavior.
- Emphasize the development of the functional alternative behavior and positive approaches and positive behavior intervention.
- Use the least restrictive intervention possible.
- Ensure the health and safety of the member and that abusive or demeaning intervention is expressly prohibited.
- Be evaluated and approved by the interdisciplinary team through quarterly reviews of specific data on the progress and effectiveness of the procedures.

Documentation regarding the Behavioral Intervention Program must include:
- Approval by the member's interdisciplinary team, with the written consent of the member's parent if the member is under eighteen years of age, or the member's legal guardian if one has been appointed by the court.
- A written endorsement from a physician for any procedure that might affect the member's health.
- A functional analysis that is defined as, and includes, the following components:
(i) clear, measurable description of the behavior to include frequency, duration, intensity and severity of the behavior;
(ii) clear description of the need to alter the behavior; an assessment of the meaning of the behavior, which

includes the possibility that the behavior is an effort to communicate, the result of medical conditions or environmental causes; or the result of other factors;
(iii) description of the conditions that precede the behavior in question;
(iv) description of what appears to reinforce and maintain the behavior; and
(v) a clear and measurable procedure, which will be used to alter the behavior and develop the functional alternative behavior.
- Documentation that the member, the guardian, and interdisciplinary team are fully aware of and consent to the program in accordance with the interdisciplinary process.
- Documentation of all prior programs used to eliminate a maladaptive target behavior.
- Documentation of staff training.

Behavioral Intervention Programs shall be time limited and reviewed at least quarterly. Restrictions must be considered on an individual basis after they are reviewed by the interdisciplinary team and entered into the written plan of care with specific timelines. All restrictions are explained to the member and their legal representative and agreed upon ahead of time. Unauthorized use of restrictions would be detected via interviews with the member, their family and staff and case manager; through review of critical incident reports by HHS and member's case manager; HHS and case manager review of written documentation authored by provider staff; through the annual review activities associated with the provider quality oversight processes; and by reports from any interested party (complaints).

Reviews may include desk reviews where the department requests member's records to be reviewed or onsite where the department or department designee goes onsite to review documentation. One hundred percent of waiver providers are reviewed at least once every five years to ensure that the HHS policy for each type of agency identified restriction is observed and member rights are safeguarded. If it is found that a waiver provider is not observing HHS policy or ensuring a member's rights, adverse action is taken by Iowa Medicaid, which may include sanction, termination, required corrective action, etc.

The member's case manager is responsible to monitor individual plans of care including the use of restrictions and behavioral interventions.

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:

A restrictive intervention is an action or procedure that imposes a restriction of movement, that limits a participant's movement, access to other individuals, locations or activities, or restricts a participant's rights. 441-IAC chapter 77 describes restrictive interventions as restraints, restrictions and behavioral intervention. Per the description of restrictive interventions noted in the application (G-2-b-i) above, Iowa will need to review its inclusion of restraint as a restrictive intervention.

The first line of responsibility for overseeing the use of restrictive interventions and ensuring safeguards are in place is the member's case manager. The use of restrictive interventions must be assessed as needed and identified in the individual member's service plan. The use of restrictions would also require the development and implementation of a restrictive intervention plan and the plan would be included in the participant's service plan. The member's case manager is responsible for monitoring the service plan to assure that supports and services in the service plan are being implemented as identified in the service plan. Any issues with the use of restrictive interventions would be addressed with the provider of service and corrected as needed.

The State contracts with the HCBS QIO to oversee the appropriateness, provider policies and procedures, and service plan components associated with restrictions. The HCBS QIO conducts periodic reviews of 100% of enrolled waiver service providers to ensure that policies and procedures are consistent with State and federal rule, regulations, and best practices. Further, the HCBS QIO examines member files, and conducts targeted reviews based on complaints, to ascertain whether restrictions are appropriately incorporated into the service plan, such that restrictions are only implemented as designated in the plan (who, what, when, where, why, and how). If the HCBS QIO discovers that the provider is less than compliant, the provider is required to complete a corrective action plan (CAP) and implement the CAP to 100% compliance. If it is found that the circumstances are more serious, recommendations are made to PI and possible sanctions (suspension, probation, termination, etc.) may apply.

All waiver service providers, regardless of if serving FFS or MCO members, are required to submit major incident reports. Categories within the incident report include inappropriate use of restrictions.

Provider reports of restrictive interventions are entered as a critical incident into IMPA, which trigger milestones in IoWANS for fee-for-service members. These triggers alert case managers and prompt Iowa Medicaid HCBS Incident Reporting Specialist to conduct a review of the restrictive intervention. If it is found that the restrictive intervention demands further investigation, the issue is passed to the HCBS QIO for a targeted review. If the HCBS QIO discovers that the provider is less than compliant in areas surrounding the use of restrictions, the provider is required to complete a corrective action plan (CAP) and implement the CAP to 100% compliance. If it is found that the circumstances are more serious, recommendations are made to the Iowa Medicaid Program Integrity Unit for possible sanctions that may apply.

For MCO members, the MCO receives a nightly report out of the critical incident management system of all critical incident reports for their enrollees. In the MCO system and processes, MCO CBCMs are alerted along with the MCO Critical Incident Reporting Specialist to conduct a review of the restrictive intervention. Processes for targeted review, provider corrective actions and PI referral, if warranted, are followed as discussed in the FFS process.

Finally, the HCBS QIO compiles all data related to incidents associated with the inappropriate use of restrictions, as well as data from periodic and targeted provider reviews. Data is analyzed to identify trends and patterns and reported on a monthly and quarterly basis to HHS. Trends are used, along with those established in the monthly State QA Committee, to guide the dissemination of Informational Letters and revisions to State Administrative Rules. MCO Community based case managers are responsible for monitoring service plans to assure that supports and services in the service plan are being implemented as identified in the service plan. Any issues with the use of restrictive interventions would be addressed with the provider of service and corrected as needed. In addition, MCOs must identify and track critical incidents, regularly review the number and types of incidents and findings from investigations and develop and implement strategies to reduce the occurrence of critical incidents and improve the quality of care delivered to members. MCOs are required to follow the process outlined at 441 Iowa Administrative Code Chapter 77 for reporting major incidents. The State maintains ultimate oversight through the mechanisms identified in the waiver submission (i.e., HCBS QIO, critical incident review, etc.).

Appendix G: Participant Safeguards

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

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

○ **The state does not permit or prohibits the use of seclusion**

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

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

i. Safeguards Concerning the Use of Seclusion. Specify the safeguards that the state has established concerning the use of each type of seclusion. State laws, regulations, and policies that are referenced are available to CMS upon request through the Medicaid agency or the operating agency (if applicable).

Waiver policy regarding the use of seclusion comport with the home and community-based setting requirements at Section 42 CFR 441.301(c)(4)(iii) and (vi)(F), and person-centered service planning and plan requirements at 42 CFR 441.301(c)(1) and (c)(2).

The HHS policy regarding seclusion is as follows and applies to all types of seclusions that may be used by waiver providers, regardless of delivery system (i.e., FFS or MCO). Examples of seclusion include but are not limited to locking a member in a room, locking a member out of an area of their residence, or limiting community time. All incidents of seclusion must be documented in the member's service record and reported to Iowa Medicaid as a critical incident. As a rights limitation, the seclusion procedures must be agreed to by the interdisciplinary team and identified in the member's plan of care (441 Iowa Administrative Code Chapter 83). All incidents of seclusion must be documented in a member's file and reported as a critical incident.

Per 441 Iowa Administrative Code Chapter 77, providers "shall have in place a system for the review, approval, and implementation of ethical, safe, humane, and efficient behavioral intervention procedures." All members receiving home- and community-based habilitation services shall be afforded the protections imposed by these rules when any restraint, restriction, or behavioral intervention is implemented.
a. The system shall include procedures to inform the member and the member's legal guardian of the restraint, restriction, and behavioral intervention policy and procedures at the time of service approval and as changes occur.
b. Restraint, restriction, and behavioral intervention shall be used only for reducing or eliminating maladaptive target behaviors that are identified in the member's restraint, restriction, or behavioral intervention program.
c. Restraint, restriction, and behavioral intervention procedures shall be designed and implemented only for the benefit of the member and shall never be used as punishment, for the convenience of the staff, or as a substitute for a nonaversive program.
d. Restraint, restriction, and behavioral intervention programs shall be time-limited and shall be reviewed at least quarterly.
e. Corporal punishment and verbal or physical abuse are prohibited.

The same standard is used for seclusion as a restrictive intervention. All seclusions must also be consistent with applicable Federal laws. All members served under an HCBS waiver service shall be afforded the protections imposed by these requirements. Any provider contracting with HHS to provide waiver services must conduct its activities in accordance with these requirements.

Seclusion procedures may be designed and implemented only for the benefit of the member and may never be used merely as punishment or for the convenience of the staff or as a substitute for a nonaversive program. Seclusion may be allowed depending on the provider's agency policy to ensure that there is an accompanying behavioral intervention plan, documentation of each instance, and monitoring of its use. Seclusion can be considered on an individual basis after the interdisciplinary team reviews them and are entered into the written plan of care with specific timelines. If a member were placed in a closed room, the time frame would need to be determined on an individual basis and spelled out in the service plan. The provider would need to document the use of this seclusion in the member's service file each time it was utilized by staff. The provider would be required to have a written policy approved by HHS on the supervision and monitoring of members placed in a closed room, such as monitoring on a fifteen-minute basis to assure the health and welfare of the member.

Seclusion procedures may only be used for reducing or eliminating maladaptive target behaviors that are identified in the member's Behavioral Intervention Program. For the purposes of decelerating maladaptive target behaviors, a Behavioral Intervention Program includes at least the following components:
- A clear objective description of the maladaptive target behavior to be reduced or eliminated. - A clear objective description of the incompatible or alternative appropriate response, which will be reinforced.
- A list of seclusions and behavioral interventions utilized to teach replacement behaviors that serve the same behavioral function identified through a functional analysis or review of the maladaptive target behaviors. Seclusions and behavioral interventions may only be utilized to teach replacement behaviors when nonaversive methods of positive support have been ineffective.
- A baseline measurement of the level of the target behavior before intervention.

Any provider employee who implements an aversive procedure must be able to carry out the procedure as it is written. A person's ability to implement a procedure must be documented in one of the following ways:
- A program staff person may observe each person in a role-play situation in order to document his or her ability to implement the procedure as written.
- Supervisory personnel from the provider may provide documentation of employees' ability to implement a procedure if the following conditions are met:
(i) the supervisor's ability to implement the procedure has been documented by a program staff person.
(ii) the supervisor observes each employee in a role play situation and documents the employee's ability to implement the procedure; and
(iii) the provider maintains a list of those employees who have been observed and are considered capable of implementing the procedure. The list should specify the dates that an employee demonstrated competency and the name of staff that certified the employee.
- Implementation of a program to alter an individual's behaviors.

Seclusion and behavioral intervention procedures must be implemented by systematic program review. It must ensure that a member's right to be free from aversive, intrusive procedures is balanced against the member's interests in receiving services and treatment whenever a decision regarding the use of aversive procedures is made. Any decision to implement a program to alter an member's behavior must be made by the interdisciplinary team and the program must be described fully as a Behavioral Intervention Program incorporated into the member service plan and the case manager's plan of care. In general, the Behavioral Intervention Program must meet the following minimum requirements.
- Show that previous attempts to modify the maladaptive target behavior using less restrictive procedures have not proven to be effective, or the situation is so serious that a restrictive procedure is immediately warranted.
- The proposed procedure is a reasonable response to the person's maladaptive target behavior. - Emphasize the development of the functional alternative behavior and positive approaches and positive behavior intervention.
- Use the least restrictive intervention possible.
- Ensure the health and safety of the individual and that abusive or demeaning intervention is expressly prohibited.
- Be evaluated and approved by the interdisciplinary team through quarterly reviews of specific data on the progress and effectiveness of the procedures.

Documentation regarding the behavior program must include:
- Approval by the member's interdisciplinary team, with the written consent of the member's parent if the member is under eighteen years of age, or the member's legal guardian if one has been appointed by the court.
- A written endorsement from a physician for any procedure that might affect the member's health.
- A functional analysis that is defined as and includes the following components:
(i) clear, measurable description of the behavior to include frequency, duration, intensity and severity of the behavior;
(ii) clear description of the need to alter the behavior; an assessment of the meaning of the behavior, which includes the possibility that the behavior is an effort to communicate, the result of medical conditions or environmental causes; or the result of other factors;
(iii) description of the conditions that precede the behavior in question;
(iv) description of what appears to reinforce and maintain the behavior; and
(v) a clear and measurable procedure, which will be used to alter the behavior and develop the functional alternative behavior.
- Documentation that the member, the guardian, and interdisciplinary team are fully aware of and consent to the program in accordance with the interdisciplinary process.
- Documentation of all prior programs used to eliminate a maladaptive target behavior.
- Documentation of staff training.

Behavioral Intervention Programs shall be time limited and reviewed at least quarterly. Seclusions must be considered on an individual basis after they are reviewed by the interdisciplinary team and entered into the written plan of care with specific timelines. All seclusions are explained to the member and their legal

representative and agreed upon ahead of time.

Unauthorized use of seclusion would be detected via interviews with the member, their family and staff and case manager; through review of critical incident reports by HHS and member's manager on a daily basis; HHS and case manager review of written documentation authored by provider staff; through the annual review activities associated with the provider Self-Assessment process; and by reports from any interested party (complaints). Reviews may include desk reviews where the department requests member's records to be reviewed or onsite where the department or department designee goes onsite to review documentation. One hundred percent of waiver providers are reviewed at least once every five years to ensure that the HHS policy for each type of agency identified seclusion is observed and member rights are safeguarded. If it is found that a waiver provider is not observing HHS policy or ensuring a member's rights, adverse action is taken by Iowa Medicaid, which may include sanction, termination, required corrective action, etc.

The member's manager is responsible to monitor individual plans of care including the use of seclusion and behavioral interventions.

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:

The first line of responsibility for overseeing the use of seclusion and ensuring safeguards are in place is the member's case manager. The use of seclusion must be assessed as needed and identified in the individual member's person-centered service plan. The use of seclusion would also require the development and implementation of a behavior plan and the plan would be included in the member's person-centered service plan. The case manager is responsible for monitoring to assure that supports and services in the service plan are being implemented as identified. Any issues with the use of seclusion would be addressed with the provider of service and corrected as needed.

The State contracts with the HCBS QIO to oversee the appropriateness, provider policies and procedures, and service plan components associated with seclusion. The HCBS QIO conducts periodic reviews of 100% of enrolled waiver service providers to ensure that policies and procedures are consistent with State and federal rule, regulations, and best practices. Further, the HCBS QIO examines member files, and conducts targeted reviews based on complaints, to ascertain whether seclusion is appropriately incorporated into the service plan, such that seclusion is only implemented as designated in the plan (who, what, when, where, why, and how). If the HCBS QIO discovers that the provider is less than compliant, the provider is required to complete a corrective action plan (CAP) and implement the CAP to 100% compliance. If it is found that the circumstances are more serious, recommendations are made to PI and possible sanctions (suspension, probation, termination, etc.) may apply.

All waiver service providers are required to submit major incident reports. Categories within the incident report include inappropriate use of seclusion. These reports are entered into IMPA, trigger milestones in IoWANS for fee-for-service members that alert case managers and prompt the HCBS Incident Reporting Specialist to conduct a review of the incident. If it is found that the incident demands further investigation, the issue is passed to the HCBS QIO for a targeted review. If the HCBS QIO discovers that the provider is less than compliant in areas surrounding the use of seclusion, the provider is required to complete a corrective action plan (CAP) and implement the CAP to 100% compliance. If it is found that the circumstances are more serious, recommendations are made to PI and possible sanctions (suspension, probation, termination, etc.) may apply.

Finally, HCBS QIO compiles all data related to incidents reported in IMPA associated with the inappropriate use of seclusion, as well as data from periodic and targeted provider reviews conducted by the HCBS QIO. Data is analyzed to identify trends and patterns and reported on a monthly and quarterly basis to HHS. Trends are used, along with those established in the monthly State QA Committee, to guide the dissemination of Informational Letters and revisions to State Administrative Rules.

Appendix G: Participant Safeguards

Appendix G-3: Medication Management and Administration (1 of 2)

This Appendix must be completed when waiver services are furnished to participants who are served in licensed or unlicensed living arrangements where a provider has round-the-clock responsibility for the health and welfare of residents. The Appendix does not need to be completed when waiver participants are served exclusively in their own personal residences or in the home of a family member.

a. Applicability. Select one:

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

- **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.

The case manager, and any provider responsible for medication administration must monitor the documentation of medication administration to ensure adherence to the service plan and provider policies and procedure. The provider agency frequently and routinely monitors as outlined in their policies and procedures, and quality improvement plans. Provider agencies are expected to review medication administration on a daily basis to ensure health and welfare of member as well as perform quality assurance on a timeframe identified by the agency (most often monthly). The case manager also monitors during the annual service plan development. Case managers monitor the documentation of medication administration to ensure adherence to the service plan and provider policies and procedures.

Monitoring includes review of the service documentation to ensure that medications have been administered at the designated times and by designated individuals. Further monitoring occurs through the report of major incidents whenever a medication error results in physicians' treatment, mental health intervention, law enforcement intervention, death, or elopement. When a major incident has occurred, follow-up, investigation, and remediation occurs as identified in G.l.d. All medication errors resulting in a major incident report or discovered via complaint are fully investigated. If it is determined that a harmful practice has been detected, the provider agency completes a corrective action plan and may face sanctions depending on severity and negligence of the circumstance.

The Iowa Medicaid program has actively managed Medicaid pharmacy benefits through a uniform Preferred Drug List (PDL) and uniform prior authorization guidelines since 2005. A governor appointed medical assistance pharmaceutical and therapeutics (P&T) committee was established for the purpose of developing and providing ongoing review of the PDL. The pharmacy prior authorization departments of Iowa Medicaid FFS and MCOs utilizes the PDL and prior authorization guidelines to review medication management.

The Department of Inspections and Appeals and Licensing (DIAL) is responsible for Medicaid member's medication regimes for waiver members served in a Residential Care Facility (RCF). All medical regimes are included in the member's record. Medications administered by the facility are recorded on a medical record by the individual who administers medication. All RCFs are licensed facilities and must meet all DIAL's Administrative Rules to obtain an annually renewable license. Medical records are reviewed during licensure renewal. Persons administrating medication must be a licensed nurse or physician or have successfully completed a department approved medication aide course. If the provider stores, handles, prescribes, dispenses, or administers prescription or over the counter medications the provider is required to develop procedures for the storage, handling, prescribing, dispensing, or administration of medication. For controlled substances, providers must maintain DIAL procedures. If the provider has a physician on staff or under contract, the physician must review and document the provider's prescribed medication regime at least annually in accordance with current medical practice. Policies and procedures must be developed in written form by the provider for the dispensing, storage, and recording of all prescription and nonprescription medications administered, monitoring medications requiring close supervision because of fluctuating physical or psychological conditions, including antihypertensive, digitalis preparations, mood-altering or psychotropic drugs, or narcotics. Policies and procedures are reviewed by the HCBS Specialists for compliance with state and federal regulations. If deficiencies are found, the provider is required to submit a corrective action, and follow-up surveys may be conducted based on the severity of the deficiency.

Per 441 Iowa Administrative Code Chapter 77, respite providers must meet the following requirements as a condition of providing respite care under the waiver: (1) training on provision of medication according to agency policy and procedure; and (2) the staff member shall not provide any direct service without the oversight of supervisory staff until training is completed.

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.

Second line responsibility is utilized when issues are more complex. Occurrences of high dosage use for certain medications or prescribing drugs for an age group where the drug is not FDA indicated are sent to Iowa Medicaid for review. In some cases, edits have been placed in the computer system so the prescriber could not prescribe for age groups not indicated.

Drug Utilization Review (DUR) Commission: DUR is a second line monitoring process with oversight by HHS. The DUR system includes a process of provider intervention that promotes quality assurance of care, patient safety, provider education, cost effectiveness and positive provider relations. Letters to providers generated as a result of the professional evaluation process identify concerns about medication regimens and specific patients. At least one Iowa licensed pharmacist is available to reply in writing to questions submitted by providers regarding provider correspondence, to communicate by telephone with providers as necessary and to coordinate face-to-face interventions as determined by the DUR.

The Department of Inspections and Appeals and Licensing (DIAL): DIAL is responsible for oversight of licensed facilities. DIAL communicates all findings to HHS and any issues identified during the RCF/ID licensure process, or critical incidents as they arise. DIAL tracks information and provides training as necessary to improve quality. This information is also shared with HHS. Both DIAL and HHS follow-up with identified RCF/IDs to assure that action steps have been made to ensure potential harmful practices do not reoccur.

HCBS QIO Unit: HHS contracts with the HCBS QIO to oversee provider policies and procedures and service plan components associated with medication management. The HCBS QIO conducts periodic reviews of 100% of enrolled waiver service providers to ensure that policies and procedures are consistent with State and federal rule, regulations, and best practices. The HCBS QIO examines member files and conducts targeted reviews based on complaints to ascertain whether medications are appropriately incorporated into the service plan. If the HCBS QIO discovers that the provider is less than compliant, the provider is required to complete a corrective action plan (CAP) and implement the CAP to 100% compliance. If it is found that the circumstances are more serious, recommendations are made to PI and possible sanctions (suspension, probation, termination, etc.) may apply.

With respect to MCO members, community-based case managers are responsible for monitoring service plans to assure that supports and services in the service plan are being implemented as identified in the service plan. Any issues with the use of medication would be addressed with the provider of service and corrected as needed. In addition, MCOs must maintain documentation of the member’s medication management done by the MCOs clinical staff; monitor the prescribing patterns of network prescribers to improve the quality of care coordination services provided to members through strategies such as: (a) identifying medication utilization that deviates from current clinical practice guidelines; (b) identifying members whose utilization of controlled substances warrants intervention; (c) providing education, support and technical assistance to providers; and (d) monitor the prescribing patterns of psychotropic medication to children, including children in foster care. Finally, MCOs must identify and track critical incidents, regularly review the number and types of incidents and findings from investigations and develop and implement strategies to reduce the occurrence of critical incidents and improve the quality of care delivered to members. MCOs are required to follow the process outlined at 441 Iowa Administrative Code Chapter 77 for reporting major incidents. The State maintains ultimate oversight through the mechanisms identified in the submitted amendment (i.e., HCBS QIO, critical incident review, etc.).

All waiver service providers are required to submit major incident reports. Categories within the incident report include medication errors. These reports are entered into IMPA, trigger milestones in IoWANS for fee-for-service members that alert case managers and prompt the HCBS Incident Reporting Specialist to conduct a review of the incident. If it is found that the incident demands further investigation, the issue is passed to the HCBS QIO for a targeted review. If the HCBS QIO discovers that the provider is less than compliant in areas surrounding medication management, the provider is required to complete a corrective action plan (CAP) and implement the CAP to 100% compliance. If it is found that the circumstances are more serious, recommendations are made to PI and possible sanctions (suspension, probation, termination, etc.) may apply.

The HCBS QIO compiles all data related to incidents reported in IMPA associated with the inappropriate use of medication, as well as data from periodic and targeted provider reviews conducted by the HCBS QIO. Data is analyzed to identify trends and patterns and reported on a monthly and quarterly basis to HHS. Trends are used, along with those established in the monthly State QA Committee, to guide the dissemination of Informational

Letters and revisions to State Administrative Rules.

Appendix G: Participant Safeguards

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

c. Medication Administration by Waiver Providers

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

- ○ **Not applicable.** *(do not complete the remaining items)*
- ◉ **Waiver providers are responsible for the administration of medications to waiver participants who cannot self-administer and/or have responsibility to oversee participant self-administration of medications.** *(complete the remaining items)*

• **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).

Supported community living, supported employment, and respite service providers must have policies and procedures developed for dispensing, storage, and recording all prescription and nonprescription medication administered. 441 Iowa Administrative Code Chapter 77 requires: Procedures shall be developed for the dispensing, storage, authorization, and recording of all prescription and nonprescription medications administered.

Providers are required to have staff trained on medication administration and provide safe oversight of medication administration. The State does not require specific medication administration curriculum to be used. Providers are responsible to assure that staff has the skills needed to administer medications safely. There are no uniform requirements in the Iowa Administrative Code for the provision of medication administration or for the self-administration of medications by Medicaid members.

The Provider Quality Self-Assessment process requires providers to have a policy and procedure for the storage and administration of medication. This process requires a more uniform approach for the provider in the requirements for medication management. The Provider Quality Self-Assessment review checklist used by the HCBS QIO Specialist to review providers identifies the following minimum standards that the medication policy will identify:
- The provider’s role in the management and/or administration of medications
- If staff administers medications, the policy will identify the: (1) training provided to staff prior to the administration of medications; (2) method of documenting the administration of medications; (3) storage of medications; (4) the assessment process used to determine the Medicaid member’s role in the administration of medications.

The Provider Quality Self-Assessment process also requires providers to have discovery, remediation and improvement processes for medication administration. The information and results of these activities is available to HHS upon request.

Home Health agencies that provide waiver services must follow Medicare regulations for medication administration and dispensing. All medications must be stored in their original containers with the accompanying physician's or pharmacist’s directions and label intact. Medications shall be stored so they are inaccessible to those who do not need access. Nonprescription medications shall be labeled with the Medicaid member's name. In the case of medications that are administered on an ongoing long-term basis, authorization shall be obtained for a period not to exceed the duration of the prescription. All providers of respite must develop policies that assure that personnel that administer medications have the appropriate skills and that there is oversight by medical personnel. Provider non-medical waiver staff that administers medications must have oversight of a licensed nurse. If the medication requires, the staff is required to complete a medication management course through a community college.

The requirements for non-medical waiver providers must have in order to administer medications to Medicaid members who cannot self-administer is that the provider must have a written policy in place on what the requirements are for their staff to do this and how. If the medications are psychiatric medications the person would have to have successfully completed a medication aide class. Oversight for a staff member who administers medications that require oversight such as in the case of psychiatric medications would need to follow the requirements as spelled out through the Board of Nursing such as having oversight by a registered nurse. The HCBS QIO Specialists would oversee this policy during regular reviews of the provider.

State oversight responsibility is described in Appendix H for the monitoring methods that include identification of problems in provider performance and support follow-up remediation actions and quality improvement activities.

- **Medication Error Reporting.** *Select one of the following:*

◉ **Providers that are responsible for medication administration are required to both record and report medication errors to a state agency (or agencies).**
Complete the following three items:

(a) Specify state agency (or agencies) to which errors are reported:

Providers are required to complete incidents reports for all occurrences meeting the criteria for major and minor incidents and make the incident reports and related documentation available to HHS upon request. Major incidents must be reported to the Iowa Medicaid via IMPA. Providers must ensure cooperation in providing pertinent information regarding incidents as requested by HHS.

As part of the major incident reporting process described in Appendix G-1, HHS will review and follow-up on all medication errors that lead to a member hospitalization or death. This can include the wrong dosage, the wrong medication delivered, medication delivered at the wrong time, medication administration delivery not documented, unauthorized administration of medication, or missed dosage. Providers are required to submit all medication errors, whether major or minor, to the member's case manager or community-based case manager when they occur. The case manager or community-based case manager monitors the errors and makes changes to the member’s service plan as needed to assure the health and safety of the member.

The Provider Quality Self-Assessment process requires providers to have a policy and procedure regarding medication administration and medication management. The Provider Quality Self-Assessment process also requires that providers have discovery, remediation, and improvement processes for medication administration and medication errors. Specifically, providers are required to have ongoing review of medication management and administration to ensure that medications are managed and administered appropriately. Providers are also required to track and trend all medication errors to assure all medication errors are reviewed and improvements made based on review of the medication error data. The information and results of these activities is made available to HHS upon request and will be reviewed as part of the ongoing Provider Quality Self-Assessment process conducted by the HCBS QIO Specialists. This will include random sampling of providers, incident specific review (complaint and IR follow up) and on-site provider review held every five years.

Other professionals or family members may report medication error incidents at any time as a complaint. Suspected abuse is reported to the reporting hotline operated by the Department of Health and Human Services.

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

Providers are required to record all medication errors, both major and minor, that occur. Providers are required to track and trend all medication errors and assure all medication errors are reviewed and improvements made based on review of the medication error data. The information and results of these activities is made available to HHS upon request and will be reviewed as part of the ongoing Provider Quality Self-Assessment and certification review processes conducted by the HCBS Specialists.

Major incident is defined as an occurrence that involves a member who is enrolled in an HCBS waiver, targeted case management, or habilitation services and that:
• results in a physical injury to or by the member that requires a physician's treatment or admission to a hospital,
• results in the death of the member, including those resulting from known and unknown medical conditions,
• results in emergency mental health treatment for the member, (EMS, Crisis Response, ER visit, Hospitalization)
• results in medical treatment for the member, (EMS, ER Visit, Hospitalization)
• results in the intervention of law enforcement, including contacts, arrests, and incarcerations,
• results in a report of child abuse pursuant to Iowa Code section 232.69 or a report of dependent adult abuse pursuant to Iowa Code section 235B.3,
• constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in bullets 1, 2, 3, 4, 5, and 6 above
• involves a member's provider staff, who are assigned protective oversight, being unable to locate the member or
• involves a member leaving the program against court orders, or professional advice
• involves the use of physical or chemical restraint or seclusion of the member

All major incidents must be reported by the next calendar day following the incident or discovering an incident has occurred, using Iowa Medicaid's Iowa Medicaid Portal Access (IMPA) System.

Per Chapter 441 Iowa Administrative Code chapter 77 a medication error is included in the definition of "minor incidents" Providers are not required to report minor incidents to HHS. When a minor incident occurs or a staff member becomes aware of a minor incident, the staff member involved must submit the completed incident report to the staff member's supervisor within 72 hours of the incident. The completed report must be maintained in a centralized file with a notation in the participant's file.

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

Only major incidents of medication errors that result in physical injury, death, emergency mental health treatment, medical treatment, law enforcement intervention, or a report of child or dependent adult abuse of the member, as defined by the major incident criteria, are required to be reported to HHS.

○ **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:

- **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.

Iowa Medicaid is responsible for the oversight of waiver providers in the administration of medications to waiver members. Oversight monitoring is completed through IMPA, the Provider Quality Self-Assessment process and monitoring of the participant by the member's case manager or community-based case manager. With respect to MCO members, community-based case managers are responsible for monitoring service plans to assure that supports and services in the service plan are being implemented as identified in the service plan. Any issues with the use of medication would be addressed with the provider of service and corrected as needed. In addition, MCOs must maintain documentation of the member's medication management done by the MCOs clinical staff; monitor the prescribing patterns of network prescribers to improve the quality-of-care coordination services provided to members through strategies such as:
(a) identifying medication utilization that deviates from current clinical practice guidelines;
(b) identifying members whose utilization of controlled substances warrants intervention;
(c) providing education, support and technical assistance to providers; and
(d) monitor the prescribing patterns of psychotropic medication to children, including children in foster care.

Finally, MCOs must identify and track critical incidents, regularly review the number and types of incidents and findings from investigations and develop and implement strategies to reduce the occurrence of critical incidents and improve the quality of care delivered to members. MCOs are required to follow the process outlined at 441 Iowa Administrative Code Chapter 77 for reporting major incidents. HHS maintains ultimate oversight through the mechanisms identified (i.e., HCBS QIO, critical incident review, etc.). All of these processes have been described in detail in this Appendix.

All medication errors are considered either major or minor incidents, as noted in Subsection "iii.b" above. Major incidents are reported to the department and follow the incident reporting follow up protocol of the department.

HHS contracts with the HCBS QIO to oversee provider policies and procedures and service plan components associated with medication management. The HCBS QIO conducts periodic reviews of 100% of enrolled waiver service providers to ensure that policies and procedures are consistent with State and Federal rule, regulations, and best practices. Further, HCBS QIO examines member files, and conducts targeted reviews based on complaints, to ascertain whether medications are appropriately incorporated into the service plan. If the HCBS QIO discovers that the provider is less than compliant, the provider is required to complete a corrective action plan (CAP) and implement the CAP to 100% compliance. If it is found that the circumstances are more serious, recommendations are made to the Program Integrity unit for possible sanctions (suspension, probation, termination, etc.).

All waiver service providers are required to submit major incident reports. Categories within the incident report include inappropriate medication administration. These reports are entered into IMPA, trigger milestones in IoWANS for fee-for-service members that alert case managers and prompt the HCBS Incident Reporting Specialist to conduct a review of the incident. If it is found that the incident demands further investigation, the issue is passed to the Unit for a targeted review. If the Unit discovers that the provider is less than compliant in areas surrounding medication administration, the provider is required to complete a CAP and implement the CAP to 100% compliance. Again, if it is found that the circumstances are more serious, recommendations are made to the Program Integrity unit for possible sanctions (suspension, probation, termination, etc.).

The HCBS QIO compiles all data related to incidents reported in IMPA associated with the inappropriate medication administration, as well as data from periodic and targeted provider reviews conducted by the Unit. Data is analyzed to identify trends and patterns and reported on a monthly and quarterly basis to Iowa Medicaid. Trends are used, along with those established in the monthly State QA Committee, to guide the dissemination of information and changes to policy as needed.

Appendix G: Participant Safeguards

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 instancesof abuse, neglect, exploitation and unexplained death.*** *(Performance measures in this sub-assurance include all Appendix G performance measures for waiver actions submitted before June 1, 2014.)*

Performance Measures

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

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

Performance Measure:
HW-a1: Number and percent of IAC-defined major critical incidents requiring follow-up escalation that were investigated as required. Numerator: number IAC-defined major critical incidents requiring follow-up escalation that were investigated as required; Denominator: number of IAC-defined major critical incidents requiring follow-up escalation.

Data Source (Select one):
Critical events and incident reports
If 'Other' is selected, specify:

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

	Ongoing	Specify:
	☐ **Other** Specify:	

Data Aggregation and Analysis:

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

Performance Measure:
HW-a2: Number and percent of Critical Incident Reports (CIRs) including alleged abuse, neglect, exploitation, or unexplained death that were followed up on as required. Numerator: # of CIRs including alleged abuse, neglect, exploitation, or unexplained death that were followed up on as required; Denominator: # of CIRs that included alleged abuse, neglect, exploitation, or unexplained death.

Data Source (Select one):
Critical events and incident reports
If 'Other' is selected, specify:

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

(check each that applies):		
☒ **State Medicaid Agency**	☐ **Weekly**	☒ **100% Review**
☐ **Operating Agency**	☐ **Monthly**	☐ **Less than 100% Review**
☐ **Sub-State Entity**	☒ **Quarterly**	☐ **Representative Sample** Confidence Interval =
☒ **Other** Specify: Contracted Entity including MCO	☐ **Annually**	☐ **Stratified** Describe Group:
	☐ **Continuously and Ongoing**	☐ **Other** Specify:
	☐ **Other** Specify:	

Data Aggregation and Analysis:

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

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

Performance Measure:
HW-a3: Number and percent of member service plans that indicate the member received information on how to identify and report abuse, neglect, exploitation and unexplained deaths. Numerator: #of members service plans that indicate the members received information on how to identify and report abuse, neglect, exploitation and unexplained deaths. Denominator: Total # of member service plans reviewed.

Data Source (Select one):
Record reviews, off-site
If 'Other' is selected, specify:

Responsible Party for data collection/generation *(check each that applies):*	**Frequency of data collection/generation** *(check each that applies):*	**Sampling Approach** *(check each that applies):*
☒ **State Medicaid Agency**	☐ **Weekly**	☐ **100% Review**
☐ **Operating Agency**	☒ **Monthly**	☒ **Less than 100% Review**
☐ **Sub-State Entity**	☒ **Quarterly**	☒ **Representative Sample** Confidence Interval = 95% confidence level with +/- 5% margin of error
☒ **Other** Specify: Contracted entity including MCO	☐ **Annually**	☒ **Stratified** Describe Group:

		IA. Adults with Disabilities Waiver 8% IA. Child and Youth Waiver 8% IA. Elderly Waiver 29% IA. Intellectual Disabilities Waiver 49% IA. Brain Injury Waiver 6%
	☐ **Continuously and Ongoing**	☐ **Other** Specify:
	☐ **Other** Specify:	

Data Aggregation and Analysis:

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

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

Performance Measures

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

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

Performance Measure:
HW-b1: Number and percent of unresolved critical incidents that resulted in a targeted review that were appropriately resolved. Numerator: number of unresolved critical incidents that resulted in a targeted review that were appropriately resolved; Denominator: number of unresolved critical incidents that resulted in a targeted review.

Data Source (Select one):
Critical events and incident reports
If 'Other' is selected, specify:

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

	☐ **Other** Specify:	

Data Aggregation and Analysis:

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

Performance Measure:
HW-b2: Number and percent of critical incidents where root cause was identified.
Numerator: Number of critical incidents where root cause was identified.
Denominator: # of Critical Incident Reports

Data Source (Select one):
Critical events and incident reports
If 'Other' is selected, specify:

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

		Sample Confidence Interval =
☒ **Other** Specify: Contracted Entity including MCO	☐ **Annually**	☐ **Stratified** Describe Group:
	☐ **Continuously and Ongoing**	☐ **Other** Specify:
	☐ **Other** Specify:	

Data Aggregation and Analysis:

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

Performance Measure:

HW-b3: Number and percent of emergency room visits that meet the definition of a CI where a CIR was submitted. Numerator: Number emergency room visits, that meet the definition of a CI, where a CIR was submitted; Denominator: Number of emergency room visits meeting the definition of CI.

Data Source (Select one):
Other
If 'Other' is selected, specify:
MMIS submitted claims and Critical events and incident reports.

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

Data Aggregation and Analysis:

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

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

Performance Measures

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

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

Performance Measure:
HW-c1: Number and percent of providers that met the requirements for the use of restraint, restriction, or behavioral intervention programs with restrictive procedures. Numerator: number providers that met the requirements for use of restraint, restriction, or behavioral intervention programs with restrictive procedure; Denominator: total number of reviewed providers.

Data Source (Select one):
Record reviews, on-site
If 'Other' is selected, specify:

Responsible Party for data collection/generation *(check each that applies):*	**Frequency of data collection/generation** *(check each that applies):*	**Sampling Approach** *(check each that applies):*
☒ **State Medicaid Agency**	☐ **Weekly**	☒ **100% Review**

☐ **Operating Agency**	☐ **Monthly**	☐ **Less than 100% Review**
☐ **Sub-State Entity**	☐ **Quarterly**	☐ **Representative Sample** Confidence Interval =
☒ **Other** Specify: Contracted Entity including MCO	☐ **Annually**	☐ **Stratified** Describe Group:
	☒ **Continuously and Ongoing**	☐ **Other** Specify:
	☐ **Other** Specify:	

Data Aggregation and Analysis:

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

Responsible Party for data aggregation and analysis *(check each that applies):*	**Frequency of data aggregation and analysis***(check each that applies):*

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

Performance Measures

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

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

Performance Measure:
HW-d1: Number and percent of waiver members who received care from a primary care physician in the last 12 months. Numerator: Number of waiver members who received care from a primary care physician in the last 12 months; Denominator: Number of waiver members reviewed.

Data Source (Select one):
Other
If 'Other' is selected, specify:
MMIS Claims Data

Responsible Party for data collection/generation *(check each that applies):*	**Frequency of data collection/generation** *(check each that applies):*	**Sampling Approach** *(check each that applies):*
☒ **State Medicaid Agency**	☐ **Weekly**	☐ **100% Review**
☐ **Operating Agency**	☐ **Monthly**	☒ **Less than 100% Review**
☐ **Sub-State Entity**	☒ **Quarterly**	☒ **Representative Sample** Confidence Interval = 95% confidence level with +/- 5% margin of error
☒ **Other**	☒ **Annually**	☒ **Stratified**

Specify: Contracted Entity		Describe Group: IA. Adults with Disabilities Waiver 8% IA. Child and Youth Waiver 8% IA. Elderly Waiver 29% IA. Intellectual Disabilities Waiver 49% IA. Brain Injury Waiver 6%
	☐ **Continuously and Ongoing**	☐ **Other** Specify:
	☐ **Other** Specify:	

Data Aggregation and Analysis:

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

Responsible Party for data aggregation and analysis *(check each that applies):*	**Frequency of data aggregation and analysis***(check each that applies):*

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.

The HCBS QIO and each MCO are responsible for monitoring and analyzing data associated with the major incidents reported for members on waivers. Data is pulled from the data warehouse and from MCO reporting on a regular basis for programmatic trends, individual issues and operational concerns. Reported incidents of abuse, medication error, death, rights restrictions, and restraints are investigated further by the HCBS Incident Reporting Specialist as each report is received. The analysis of this data is presented to the state on a quarterly basis.

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.

The HCBS Quality Oversight Unit (QIO) and MCOs are also responsible for conducting the HCBS CAHPS survey with waiver participants. The HCBS QIO or MCO conduct interviews either face-to-face or via telephone, to the discretion of the member. All waiver members have the right to decline interview. The results of these interviews are presented to the state on a quarterly basis. The HCBS Specialists conducting CAHPS interviews conduct individual remediation to flagged questions. In the instance that a flagged question/response occurs, the Specialist first seeks further clarification from the member and provides education when necessary. Following the interview, the case manager is notified and information regarding remediation is required within 30 days. This data is stored in a database and reported to the state on a quarterly and annual basis. MCO are responsible for research and follow up to flagged responses. General methods for problem correction at a systemic level include informational letters, provider trainings, collaboration with stakeholders and changes to provider policy.

ii. Remediation Data Aggregation

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

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

c. Timelines

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

- (●) **No**
- ( ) **Yes**

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