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, case managers, integrated health home care coordinators, and MCO CBCMs, 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, case managers, integrated health home care coordinators, and MCO CBCMs 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.

Per Chapter 441 Iowa Administrative Code 77.30(18),"major incidents" are defined as an occurrence that involves a member who is enrolled in an HCBS waiver, targeted case management, or habilitation services and that: (1) results in a physical injury to or by the consumer that requires a physician's treatment or admission to a hospital; (2) results in the death of any person; (3) requires emergency mental health treatment for the consumer; (4) requires the intervention of law enforcement; (5) requires 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; (6) constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in paragraph "1," "2," or "3"; or (7) involves a member's location being unknown by provider staff who are assigned protective oversight.

All major incidents must be reported by the end of the next calendar day after the incident has occurred using the Iowa Medicaid Portal Access (IMPA) System. Suspected abuse or neglect may be reported to the statewide abuse reporting hotline operated by HHS.

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.
- 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 manufacturing of a dangerous substance in the presence of a child.

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.
- 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.

When a major incident occurs, provider staff must notify the member or the member 's legal guardian within 24 hours of the incident and distribute a complete incident report form as follows:
- Forward a copy to the supervisor with 24 hours of the incident.
- Send a copy of the report to the member's case manager, health home coordinator, or community-based case manager (when applicable) and the BLTC within 24 hours of the incident.
- File a copy of the report in a centralized location and make a notation in the member's file.

Per Chapter 441 Iowa Administrative Code 77.25(1), "minor incidents" are defined as an occurrence involves a member who is enrolled in an HCBS waiver, targeted case management, or habilitation services that is not a major incident and that: (1) results in the application of basic first aid; (2) results in bruising; (3) results in seizure activity; (4) results in injury to self, to others, or to property; or (5) constitutes a prescription medication error. Providers are not required to report minor incidents to the BMLTSS, and reports may be reported internally within a provider's system, in any format designated by the provider (i.e., phone, fax, email, web based reporting, or paper submission). 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 member's file.

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 is provided to applicants and members at the time of application and at the time-of-service plan development. 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, the case manager, health home coordinator, or community-based case manager is responsible for assessing a member's risk factors annually during the reevaluation process, as well as during the quality assurance interview process and the annual IPES interview. HHS recognizes the need to provide training to members using on a more formal process. The state has developed training to ensure that case managers, health home coordinators, and community-based 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.

Reporting of suspected child or adult abuse to HHS Protective Services is mandatory for all Iowa Medicaid HCBS staff, case managers, MCO CBCMs, health home care coordinators, and HCBS providers. HHS Protective Services (PS) receives all mandatory reports of child and dependent adult abuse. HHS PS act in accordance with their rules for investigation of suspected adult or child abuse located at 441 IAC 175 and 441 IAC 176. 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, health home coordinator, or community-based 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.

Iowa Medicaid reviews critical incident reports quarterly to identify trends and patterns as well as identification of root cause and to ensure that remediation has occurred at both the individual and systemic level. HHS QIO reviews and if needed, requests additional information regarding the resolution of critical incidents. Requests for information are forwarded to the case manager, health home coordinator or community-based case manager to verify and provide needed information 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, health home coordinator, community-based 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 uses a web-based critical incident reporting system, that enhances the State's ability to track and trend the discovery, remediation, and improvement of the critical incident reporting process. When needed, revisions are 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, health home coordinator or community-based 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 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 and case manager, health home coordinator, community-based 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 77.30(18)c., 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 in the format defined by the managed care organization. If the member is not enrolled with a managed care organization, the staff member shall report the information to the department's bureau of long-term care either:
a. By direct data entry into the Iowa Medicaid Provider Access System, or
b. By faxing or mailing Form 470-4698, Critical Incident Report, according to the directions on the form.
(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 waiver-eligible or non-waiver-eligible consumers 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.

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 has oversight for monitoring incidents that affect all waiver members. The HCBS QIO reviews all critical incident reports as soon as they are reported to HHS. All critical incidents are tracked in a critical incident database that tracks the date of the event, the specific waiver the member is enrolled in, the provider (if applicable), and the nature of the event, and follow up provided. 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 has been removed from immediate jeopardy, the review is initiated with in twenty working days of receipt of report. For other non-jeopardy incidents, a review is initiated within twenty days. The HCBS QIO meets biweekly to review data tracked in the critical incident database and to decide if policy changes or additional training are needed. Data is compiled and analyzed in attempt to prevent future incidents through identification of system and provider specific training needs, and individual service plan revisions.

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).

Waiver policy regarding the use of restraints 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 44.301(c)(1) and (c)(2).

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 77.25(4), 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.

- 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 the Children's Health Act of 2000 and other 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 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 non-aversive 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 time lines. 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 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 be

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 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. 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, integrated health home coordinator, or community-based 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, integrated health home coordinator, or community-based 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 time lines. 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, integrated health home coordinator, or community-based case manager;
- through review of critical incident reports by HHS and member's case manager, integrated health home coordinator, or community-based case manager on a daily basis;
- HHS and case manager, integrated health home coordinator, or community-based 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 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, integrated health home coordinator, or community-based 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, integrated health home coordinator, or community-based case manager. The use of restraints must be assessed as needed and identified in the individual member's 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 service plan. The case manager, integrated health home coordinator, or community-based 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 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 Unit 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 Unit 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 Unit 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 PS 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 restraints. For fee-for-service members these reports are entered into IMPA, triggering milestones in IoWANS that alert case managers and integrated health home coordinators, and prompting 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 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 PS and possible sanctions (suspension, probation, termination, etc.) may apply.

The HCBS QIO and the MCOs are responsible for conducting Iowa Member Experience Survey (IPES) interviews with waiver members. The IPES tool has been expanded based on the federal Member Experience Survey (PES) tool and thought to capture a more comprehensive view of Iowa's waiver population needs and issues. The IPES tool incorporates the seven principles of the Quality Framework and is able to adjust based on the member interviewed and service enrollment. HCBS Specialists conduct interviews either face-to-face or via telephone, at the discretion of the waiver member. All waiver members have the right to decline interview. The results of these interviews are presented to the state on a quarterly basis.

Finally, the Unit 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 Unit. 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.

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 restraints 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 77.30(18) 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.

Waiver policy regarding the use of restrictive interventions 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 44.301(c)(1) and (c)(2).

FFS and MCO
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 77.25(4) 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 83.67(4)).

Per 441 Iowa Administrative Code Chapter 77.25(4), "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."

These safeguards are the same regardless of what restrictions are used. All restrictions must also be consistent with the Children's Health Act of 2000 and other 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 non-aversive program.

The case manager, health home coordinator, 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, health home coordinator, or community-based 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, health home coordinator, or community-based case manager are also required to submit critical incident reports to the BLTC care, via the 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 an 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, health home coordinator, or community-based 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, health home coordinator, or community-based case manager; through review of critical incident reports by HHS and member's case manager, health home coordinator, or community-based case manager on a daily basis; HHS and case manager, health home coordinator, or community-based 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 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 HCBS QIO is also responsible for conducting IPES interviews with waiver members. The IPES tool has been expanded based on the federal PES tool and thought to capture a more comprehensive view of Iowa's waiver population needs and issues. The IPES tool incorporates the seven principles of the Quality Framework and is able to adjust based on the member interviewed and service enrollment. HCBS Specialists conduct interviews either face-to-face or via telephone, to the discretion of the waiver 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 member's case manager, health home coordinator, or community-based 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:

The first line of responsibility for overseeing the use of restrictive interventions and ensuring safeguards are in place is the member's case manager, integrated health home care coordinator, or community-based 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 member's service plan. The member's case manager, integrated health home care coordinator, or community-based 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 Unit 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 Unit 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 Unit 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 PS 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.

FFS
For FFS members, provider reports of restrictive interventions are entered into IMPA, which trigger milestones in IoWANS for fee-for-service members. These triggers alert case managers and integrated health home care coordinators and prompt the 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 Unit for a targeted review. If the Unit 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.

MCO
For MCO members, provider reports are entered into the designated MCO critical incident reporting system. 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.

IPES INTERVIEWS
The HCBS QIO Unit is also responsible for conducting IPES interviews for FFS members. The MCOs conducts the same IPES interviews for MCO members. The IPES tool has been expanded based on the federal PES tool and thought to capture a more comprehensive view of Iowa's waiver population needs and issues. The IPES tool incorporates the seven principles of the Quality Framework and is able to adjust based on the individual interviewed and service enrollment. IPES interviews are conducted either face-to-face or via telephone at the discretion of the waiver member. All waiver members have the right to decline an interview. The results of these interviews are presented to the state on a quarterly basis.

Finally, the HCBS Unit 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 77.30(18) 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 (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 44.301(c)(1) and (c)(2).

Safeguards Concerning the Use of Seclusion

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 an 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 77.25(4), 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 the Children's Health Act of 2000 and other 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 non-aversive 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 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 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, health home coordinator, or community-based 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 time lines. 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, health home coordinator, or community-based case manager; through review of critical incident reports by HHS and member's case manager, health home coordinator, or community-based case manager on a daily basis; HHS and case manager, health home coordinator, or community-based 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 case manager, health home coordinator, or community-based case 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, health home coordinator, or community-based case manager. The use of seclusion must be assessed as needed and identified in the individual member's 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 service plan. The case manager, health home coordinator, or community-based 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 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 Unit 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 Unit 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 Unit 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 PS 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, health home coordinators 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 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 PS and possible sanctions (suspension, probation, termination, etc.) may apply.

The HCBS QIO is also responsible for conducting IPES interviews with waiver members. The IPES tool has been expanded based on the federal PES tool and thought to capture a more comprehensive view of Iowa's waiver population needs and issues. The IPES tool incorporates the seven principles of the Quality Framework and is able to adjust based on the member interviewed and service enrollment. HCBS Specialists conduct interviews either face-to-face or via telephone, to the discretion of the waiver member. All waiver members have the right to decline interview. The results of these interviews are presented to the state on a quarterly basis.

Finally, the Unit 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 Unit. 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)*

b. Medication Management and Follow-Up

i. Responsibility. Specify the entity (or entities) that have ongoing responsibility for monitoring participant medication regimens, the methods for conducting monitoring, and the frequency of monitoring.

Per 441 Iowa Administrative Code 77.30(5)b.(2), respite providers shall meet the following condition: Procedures shall be developed for the dispensing, storage, authorization, and recording of all prescription and nonprescription medications administered. Home health agencies must follow Medicare regulations for medication dispensing. All medications shall 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 consumers and the public. Nonprescription medications shall be labeled with the consumer'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.

The case manager, health home coordinator, or community-based 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, health home coordinator, or community-based case manager also monitor during the annual service plan development. MCO community-based 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 Preferred Drug List (PDL) 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 prior authorization department of Iowa Medicaid QIO utilizes the PDL to review medication management. First line responsibility lies with the prescriber who is contacted by fax or telephone regarding a prescription. Pharmacists review patient profiles for proper diagnosis, dosage strength and length of therapy.

The HHS Member Services Unit has established procedures to monitor Medicaid members' prescribing physicians and pharmacies. Analysis has established risk thresholds for these factors to mitigate possible abuse, harmful drug reactions, and to improve the outcomes of medication regimes for Medicaid members. When it is identified that members exceed the established risk thresholds, the member is placed in lock-in. Lock-in establishes one prescribing physician and one filling pharmacy for each member. The Member Services Unit also conducts statistical analysis of the use of certain drugs and usage patterns. Identification of trends for prescriptions and usage patterns of high risk or addictive medications is presented to HHS on a monthly or quarterly basis.

Second-line monitoring is conducted concerning the use of behavior modifying medications through a variety of mechanisms. First, member education is designed to ensure appropriate utilization (correcting overutilization and underutilization), at a minimum, and to improve adherence. Second, restriction programs, including policies, procedures, and criteria for establishing the need for the lock-in, may also be implemented. Finally, medication therapy management programs are developed to identify and target members who would most benefit, and include coordination between the member, the pharmacist and the prescriber using various means of communication and education.

The Drug Utilization Review (DUR) Commission is a quality assurance body, which seeks to improve the quality of pharmacy services and ensure rational, cost-effective medication therapy for Medicaid members in Iowa. The commission reviews policy issues and provides suggestions on prospective DUR criteria, prior authorization guidelines, OTC coverage, and plan design issues. The DUR system provides for the evaluation of individual member profiles by a qualified professional group of physicians and pharmacists, with expertise in the clinically appropriate prescribing of covered outpatient drugs, the clinically appropriate dispensing and monitoring of

outpatient drugs, drug use review, evaluations and intervention, and medical quality assurance. Members of this group also have the knowledge, ability, and expertise to target and analyze therapeutic appropriateness, inappropriate long-term use of medication, overuse/underuse/abuse/polypharmacy, lack of generic use, drug-drug interactions, drug-disease contraindications, therapeutic duplications, therapeutic benefit issues, and cost-effective drug strengths and dosage forms. In addition, the Iowa Medicaid MSU reviews Medicaid member records to ensure that the member had a diagnosis or rational documented for each medication taken.

The Department of Inspections and Appeals (DIA) is responsible for Medicaid member's medication regimes for waiver members served in an 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 Department of Inspections 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 DIA 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.

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.

Lock-In: Trending and analysis has been conducted by the MSU and "lock-in" strategies have been implemented for members who have, historically, multiple prescribers and pharmacies. Identification of these members allows the Medicaid payment of only one prescribing physician and one pharmacy. This allows for increased monitoring of appropriate medication management and mitigates the risk associated with pharmacological abuses and negative contraindications.

Drug Utilization Review (DUR) Commission: The 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 (DIA): This DIA is responsible for oversight of licensed facilities. DIA communicates all findings to HHS and any issues identified during the RCF/ID licensure process, or critical incidents as they arise. The DIA tracks information and provides training as necessary to improve quality. This information is also shared with HHS. Both the DIA 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: DHHS contracts with the Unit to oversee the appropriateness, provider policies and procedures, and service plan components associated with medication management. The Unit 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 Unit examines member files, and conducts targeted reviews based on complaints, to ascertain whether medications are appropriately incorporated into the service plan. If the Unit 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 PS 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 77.30(18) 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 health home coordinators 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 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 PS and possible sanctions (suspension, probation, termination, etc.) may apply.

The Unit 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 Unit. 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)*

ii. State Policy. Summarize the state policies that apply to the administration of medications by waiver providers or waiver provider responsibilities when participants self-administer medications, including (if applicable) policies concerning medication administration by non-medical waiver provider personnel. State laws, regulations, and policies referenced in the specification are available to CMS upon request through the Medicaid agency or the operating agency (if applicable).

Respite Service providers must have policies and procedures developed for dispensing, storage, and recording all prescription and nonprescription medication administered. 441 Iowa Administrative Code Chapters 77.30(3)(b)(2), 77.33(6) (b)(2), 77.34(5) (b)(2), 77.37(15) (b)(2), 77.39(14) (b)(2), and 77.46(5)(e) state:

Providers must have a policy and procedure for the storage, handling, prescribing, dispensing and administration of prescription medications. For Schedule II medications the procedure must demonstrate compliance with 481-63.16(135C) Drugs

Home health agencies must follow Medicare regulations for medication dispensing. All medications shall 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 members for whom the medications are not prescribed and the public. Nonprescription medications shall be labeled with the 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."

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 Self-Assessment quality improvement process requires providers to have a policy and procedure for the storage and provision of medication. This process requires a more uniform approach for the provider in the requirements for medication management. The Provider Self-Assessment review checklist used by the HCBS 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 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. Currently the self-assessment process is not set forth in the Iowa Administrative Code.

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 Medicaid members and the public. 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 Specialists through Iowa Medicaid would oversee this policy upon 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.

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

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

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

a. 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 BMLTSS 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, Medicaid 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, health home coordinator, or community-based case manager when they occur. The case manager, health home coordinator, 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 Self-Assessment quality improvement process requires providers to have a policy and procedure regarding medication administration and medication management. The Provider 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 Self-Assessment process conducted by the HCBS 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. HHS is in the process of promulgating rules to establish the Provider Self-Assessment quality improvement process in the Administrative Code.

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 must track and trend all major and minor incident reports. Per Chapter 441 Iowa Administrative Code 77.30(18), "major incidents" are defined as an occurrence involving a member during service provision that: (1) results in a physical injury to or by the member that requires a physician's treatment or admission to a hospital; (2) results in the death of any person; (3) requires emergency mental health treatment for the member; (4) requires the intervention of law enforcement; (5) requires 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; (6) constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in paragraph "1," "2," or "3"; or (7) involves a member's location being unknown by provider staff who are assigned protective oversight.

Service providers, provider staff, HHS TCM, MCO CBCM, health home coordinators, and community-based case managers are required to submit incident reports as they are witnessed or discovered. All major incidents must be reported within 48 hours of witnessing or discovering an incident has occurred, using Iowa Medicaid's Iowa Medicaid Portal Access (IMPA) System. Suspected abuse may be reported to the statewide abuse reporting hotline operated by HHS.

Per Chapter 441 Iowa Administrative Code 77.30(18), "minor incidents" are defined as an occurrence involving a member during service provision that is not a major incident and that: (1) results in the application of basic first aid; (2) results in bruising; (3) results in seizure activity; (4) results in injury to self, to others, or to property; or (5) constitutes a prescription medication error.

Providers are not required to report minor incidents to the BMLTSS, and reports may be reported internally within a provider's system, in any format designated by the provider (i.e., phone, fax, email, web based reporting, or paper submission). 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 member's file.

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 Self-Assessment process conducted by the HCBS Specialists.

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

Only major incidents of medication errors that affect the health and safety of the member, as defined by the major incident criteria, are required to be reported to the State. All medication errors, both major and minor, are required to be reported to the member's guardian, case manager, health home coordinator, or community-based case manager.

○ **Providers responsible for medication administration are required to record medication errors but make information about medication errors available only when requested by the state.**

Specify the types of medication errors that providers are required to record:

iv. State Oversight Responsibility. Specify the state agency (or agencies) responsible for monitoring the performance of waiver providers in the administration of medications to waiver participants and how monitoring is performed and its frequency.

The BMLTSS is responsible for the oversight of waiver provider's implementation of policies and procedures related to the administration of medications to waiver members. Oversight monitoring is completed by the QIO through service documentation review, CIR reviews, the provider Self-Assessment process, and monitoring of the waiver member by the member's case manager, health home coordinator, 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 77.30(18) for reporting major incidents. The State maintains ultimate oversight through the mechanisms identified in the submitted renewal application.

All medication errors are considered either major or minor incidents, as noted in Subsection "iii.b" above. The 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 the appropriateness, provider policies and procedures, and service plan components associated with medication management. The Unit 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 Unit examines member files, and conducts targeted reviews based on complaints, to ascertain whether medications are appropriately incorporated into the service plan. If the Unit 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 PS 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 medication administration. These reports are entered into IMPA, trigger milestones in IoWANS for fee-for-service members that alert case managers and health home coordinators 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 PS and possible sanctions (suspension, probation, termination, etc.) may apply.

The Unit 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 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

Quality Improvement: Health and Welfare

As a distinct component of the States quality improvement strategy, provide information in the following fields to detail the States 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-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 member 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:
person-centered service plan

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:	☐ **Annually**	☒ **Stratified** Describe Group:

contracted entity including MCOs		IA.0299 - BI (6%) IA.0213-AIDS/HIV (.05%) IA.0242 - ID (47%) IA.0345 - PD (4%) IA.0819 - CMH (4%) IA.4111 - HD (9%) IA.4155 - Elderly (30%)
	☐ **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**
	☐ **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):*

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

Data Source (Select one):
Critical events and incident reports
If 'Other' is selected, specify:
Data collected in the FFS and MCO CIR databases.

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 MCOs	☐ **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**
	☐ **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:
FFS and MCO CIR databases

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 MCOs	☐ **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**
	☐ **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-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:
FFS and HCBS unit and MCO data obtained from CIR databases

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 entities including MCOs	☐ **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**
	☐ **Continuously and Ongoing**
	☐ **Other** Specify:

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

Data Source (Select one):
Critical events and incident reports
If 'Other' is selected, specify:
FFS/HCBS Unit and MCO data obtained from CIR databases.

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 MCOs	☐ **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**
	☐ **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):*

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 and MCOs	☐ **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**
	☐ **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 percentage of providers reviewed that met the requirements for the use of restraint, restriction, or behavioral intervention programs with restrictive procedures. Numerator: number providers reviewed 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:

Provider's policies and procedures. All certified and periodic reviews are conducted on a 5 year cycle; at the end of the cycle all providers are reviewed.

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	☐ **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**

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

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

Performance 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 percentage 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** Specify: Contracted Entity	☐ **Annually**	☒ **Stratified** Describe Group: IA.0299 - BI (6%) IA.0213-AIDS/HIV (.05%) IA.0242 - ID (47%) IA.0345 - PD (4%) IA.0819 - CMH (4%) IA.4111 - HD (9%) IA.4155 - Elderly (30%)
	☐ **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**

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

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

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.

The HCBS QIO, and each MCO, is responsible for conducting IPES interviews with waiver members. The IPES tool has been expanded based on the federal PES tool and thought to capture a more comprehensive view of Iowa's waiver population needs and issues. The IPES tool incorporates the seven principles of the Quality Framework and is able to adjust based on the member interviewed and service enrollment. HCBS Specialists conduct interviews either face-to-face or via telephone, to the discretion of the waiver member. All waiver members have the right to decline interview. The results of these interviews are presented to the state on a quarterly basis.

b. Methods for Remediation/Fixing Individual Problems

i. Describe the States 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 Incident Reporting Specialist and each MCO analyzes data for individual and systemic issues. Individual issues require communication with the case manager to document all efforts to remediate risk or concern. If these efforts are not successful, staff continues efforts to communicate with the case manager, the case manager's supervisor, and protective services when necessary. All remediation efforts of this type are documented in the monthly and quarterly reports.

The HCBS Specialists conducting 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 and MCOs	☒ **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.