# Appendix G: Participant Safeguards

## Appendix G-1: Response to Critical Events or Incidents

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

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

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

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

The provider shall document major and minor incidents and make the incident reports and related documentation available to the department upon request. The provider shall ensure cooperation in providing pertinent information regarding incidents as requested by the Department.

Major incident means an occurrence involving a member of services that results in physical injury (including medication error) to or by the member that requires a physician's treatments or admission; results in someone's death; requires emergency mental health treatment for the member; requires the intervention of law enforcements; requires a report of child abuse or dependent adult abuse pursuant to Iowa Code; or, documents unknown whereabouts of a member during service provision. Enrolled waiver service providers, provider staff, and case managers are required to submit incident reports as they are witnessed or discovered. All major incidents must be reported by a member's case manager or provider within 48 hours of witnessing or discovering that an incident has occurred. Incidents are required to be reported within the IME's Iowa Medicaid Portal Access (IMPA) System.

Child abuse and dependent adult abuse is an inclusive definition that includes physical and sexual abuse, neglect and exploitation.
Child abuse is defined in the Code of Iowa 232.68, and may include any of the following types of acts of willful or negligent acts or omissions:
a. Any non-accidental physical injury
b. Any mental injury to a child's intellectual or psychological capacity
c. The commission of a sexual offense with or to a child pursuant as defined in the Code of Iowa
d. The failure on the part of a person responsible for the care of a child to provide for the adequate food, shelter, clothing or other care necessary for the child's health and welfare
e. An illegal drug is present in a child's body as a direct acts or omissions of the person responsible for the child or manufactured a dangerous substance in the presence of the child

Dependent adult abuse is defined in Code of Iowa 235B.2, and may include any of the following types of acts of willful or negligent acts or omissions:
a. Physical injury or unreasonable confinement, unreasonable punishment, or assault of a dependent adult
b. The commission of a sexual offense or sexual exploitation as defined in the Code of Iowa
c. Exploitation of a dependent adult
d. The 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.

A minor incident means occurrence involving a member of services that is not a major incident and that results in the application of basic first aid; results in a bruise, results in seizure activity, results injury to self or others or property, or constitutes a prescription medication error. Because these reports are not forwarded to the IME, minor incidents may be reported internally within a provider's system in any format designated by the provider; these formats can include 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 shall submit the completed incident report to the staff member's supervisor within 72 hours of the incident. The completed report shall be maintained in a centralized file with a notation in the member's file. Providers are not required to report minor incidents to the Bureau of Long Term Care.

When a major incident occurs, provider staff shall notify the member or the member's legal guardian within 24 hours of the incident and shall 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 (when applicable) and the department's Bureau of Long Term Care 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.

As part of the quality assurance policies and procedures for HCBS Waivers, all incidents will be a monitored and remediated by the HCBS Incident Reporting Specialist and HCBS specialists. On 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.

The case manager may report incidents at any time to the IME Bureau of Long Term Care via IMPA. Suspected abuse or neglect is reported to the statewide abuse reporting hotline operated by the Department of Human Services.

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 participants' protections is provided to members at the time of their application. The Department case manager also shares information at the time of service plan development. In addition, this information is shared with members during the quality assurance interview process and during the IPES interview. Informatiion can also be found on the Iowa Department of Human Services Website. The Department of Human Services recognizes the need to provide this training on a more formal process to participants. The state had developed training to ensure that case managers provide this information to members at a minimum on a yearly basis. This information on how to notify authorities of abuse and neglect and exploitation is alo included on each member's service plan as part of their individual safety plan.

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.

For Child and Dependent Adult Abuse, the Department of Human Services (DHS) protective services receives the reports and if immediate threat of physical safety is believed to exist, the Department will make every effort to examine that child or dependent adult within one hour of receipt and/or take any lawful action necessary. If the dependent adult or child is not in danger, the Department will make every effort to examine the dependent adult or child within 24 hours. The DHS protective service unit will notify the member's case manager when an investigation has been opened up to ensure that the case manager is aware of the alleged abuse situation and to ensure that additional services can be added or changes made to the member's plan of care if needed. The DHS protective services unit will provide an evaluation report within 20 days of receipt of the report, which will include necessary actions, and/or an assessment of services needed. The Central Registry of Abuse shall receive the reports as well as the county attorney office. For both child and adult abuse cases, the member and/or the family are notified the results in writing by the department as soon as the investigation has concluded.

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 the Iowa Department of Human Services protective services agency has completed or is in the process of conducting an investigation, the HCBS specialist will coordinate activities with the protective services unit to ensure the safety of the member is addressed. If the protective services agency is not investigating, and immediate jeopardy remains, the member's case manager will be notified immediately to coordinate services and the HCBS specialist will begin a review within two working days of receipt of the report. If it is determined that immediate jeopardy has been removed or not present, the review by the HCBS Specialist will be initiated within twenty working days of receipt of report. A report of findings will be completed by the HCBS Specialist within 30 days of the completion of the investigation and presented to the Bureau of Long Term Care, the provider, and interested stakeholders (members, guardians, case managers, etc.).

The Bureau of Long Term Care meets biweekly to review critical incident reports of child and dependent adult abuse

and member deaths that have been reported through the critical incident reporting process. The Department reviews, and if needed, requests information for follow through and resolution of the abuse allegation and member deaths from the case manager or HCBS Specialist. Request for information is forwarded to the case manager to verify any needed changes and follow-up has occurred with the member. Follow though may include changes to a plan of care or the safety or risk plan. If additional information or actions are required of a provider, the HCBS Specialist will work with the provider to assure any performance issues that are identified in the incident report is addressed. The Specialist will use 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 will generate a report of findings within 30 days of the completion of any review requiring corrective actions.

Information requests to the case manager or HCBS Specialist for follow up are tracked by the HCBS Unit on a weekly basis until the situation has been resolved.

The waiver program implemented a web-based critical incident reporting system September 1, 2009 that significantly enhanced the ability to track and trend the discovery, remediation and improvement processes of the critical incident reporting system. Revisions have been made to the system based on data collection and feedback from users, further enhancing the incident reporting process.

Incidents are reviewed and forwarded to the case manager as needed to coordinate any follow-up and communication with the Medicaid member, provider and/or family/legal guardian.

e. **Responsibility for Oversight of Critical Incidents and Events.** Identify the State agency (or agencies) responsible for overseeing the reporting of and response to critical incidents or events that affect waiver participants, how this oversight is conducted, and how frequently.

The Department of Human Services has oversight for monitoring incidents that affect waiver participants. There is a HCBS quality assurance team that reviews all critical incident reports as soon as they are reported to the Department. All critical incidents are tracked in a critical incident database. This database tracks the date of the event, the specific waiver the member participates in, the provider (if applicable), and the nature of the event and follow up that was provided. 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 the Iowa Department of Human Services protective services agency has completed or is in the process of conducting an investigation, the HCBS Specialist will coordinate with the other agency. If the protective services agency 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 immediate jeopardy has been removed or not present, the review will be initiated with in twenty working days of receipt of report. For other non-jeopardy incidents, a review will be initiated within twenty days.

The HCBS quality assurance committee meets biweekly to review the data tracked in the critical incident data base and decide if policy changes are needed or if additional training needs to be provided. Data is compiled and analyzed in attempt to prevent future instances through identification of system and provider specific training needs and individual treatment planning 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).

The following is the DHS policy in regards to restraints and use of seclusion. It applies to any and all types of restraints and seclusion that may be used by providers during the provision of waiver services. Restraints may include personal, chemical (medication or drugs) and mechanical restraints used for the purpose of restraining the free movement of an individual's body. Pharmaceutical restraints (medication) are most commonly used to calm an individual down in moments of escalation. Other examples of restraints/seclusion may include, but are not limited to, holding a person down with one's hands, tying an individual down to a bed, the use a straightjacket, a demobilizing wrap, locking an individual in a room, locking an individual out of an area of their residence, or limiting community time. All incidents of restraints and the use of seclusion must be documented in the member's service record and reported to the IME as an critical incident.

In order to ensure that restraint and seclusion procedures are consistent among providers, all providers are reviewed by the HCBS QA Oversight Unit for quality of sevices and the service plans and service documentation are evaluated for acceptable planning and delivery. If deficiencies or red-flags are found, a corrective action may be required or the worker may report to protective services. Rules surrounding the expectations of restraint and seclusion procedure are currently with the state's Assistant Attorney General for review.

"Restraint, restriction, and behavioral intervention. The provider 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 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 (maximum one year) and shall be reviewed at least quarterly.
e. Corporal punishment and verbal or physical abuse are prohibited."

There must be a system for the review, approval and implementation of ethical, safe, humane and efficient behavioral intervention procedures. The system must inform the individual and his/her legal guardian of the restraints and behavioral intervention policy and procedures at the time of entry and as changes occur. These safeguards are the same regardless of what restraints are used including chemical restraints (psychotropic drugs used on a PRN basis). All restraints must be consistent with the Children's Health Act of 2000 & other applicable Federal laws.

All individuals served under a Home & Community Based Waiver service shall be afforded the protections imposed by these rules. Any provider contracting with the department to provide these services shall conduct its activities in accordance with these rules. Restraints and behavioral intervention procedures may be designed and implemented only for the benefit of the person 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, including the use of seclusion, may be allowed depending on the 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 they are reviewed by the interdisciplinary team 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 the Department of Human Services on the supervision and monitoring of members placed in a closed room such as monitoring on a 15 minute basis for example to assure the health and welfare of the member.

Restraint and behavioral intervention procedures may only be used for reducing or eliminating maladaptive target behaviors that are identified in the individual's Restraints and Behavioral Intervention Program.

Corporal punishment and verbal or physical abuse are prohibited.

For the purposes of decelerating maladaptive target behaviors a Restraints and Behavioral Intervention Program includes at least the following components:

1. A clear objective description of the maladaptive target behavior to be reduced or eliminated.

2. A clear objective description of the incompatible or alternative appropriate response, which will be reinforced.

3. 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. Restratinst and behavioral interventions may only be utilized to teach replacement behaviors when non-aversive methods of positive suport have been ineffective.

4. 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:

1. 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.

2. Supervisory personnel from the provider may provide documentation of employees' ability to implement a procedure if the following conditions are met:

- The supervisor's ability to implement the procedure has been documented by a program staff person.
- The supervisor observes each employee in a role play situation and documents the employee's ability to implement the procedure; and
- 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.

3. 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 person's right to be free from aversive, intrusive procedures is balanced against the person'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 individual's behavior must be made by the interdisciplinary team and the program must be described fully as a Restraints and Behavioral Intervention Program incorporated into the individual's service plan and the case manager's plan of care. In general, the Restraints and 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; and
-Be evaluated and approved by the interdisciplinary team through quarterly reviews of specific data on the progress and effectiveness of the procedures.

Documentation requirements.
Documentation regarding the behavior program must include:
A Restraint and Behavioral Intervention Program which is a part of the written individual service plan developed by the individual's case manager and in the provider plan of care developed for the individual.
Approval by the individual's interdisciplinary team, with the written consent of the person's parent if the person is under 18 years of age, or the person's legal guardian, if one has been appointed by the court.
A written endorsement from a physician for any procedure that might affect the person's health.
A functional analysis that is defined as and includes the following components:
A clear, measurable description of the behavior to include frequency, duration, intensity and severity of the behavior;
A 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.
A description of the conditions that precede the behavior in question;
A description of what appears to reinforce and maintain the behavior; and a clear and measurable procedure, which will be used to alter the behavior and develop the functional alternative behavior.
Documentation that the individual, 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, and
Restraints and 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 individual 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; through review of critical incident reports by the Department and member's case manager on a daily basis; Department and case manager review of written documentation authored by provider staff; through the annual review activities associated with the provider Self-Assessment process; and by reports from any interested party (complaints). 100% of waiver providers are reveiwed at least once every five years to ensure that the DHS policy for each type of agency identified restraint and restriction is observed and member rights are safeguarded. If it is found that a waiver provider is not observing DHS policy or ensuring a member's rights, adverse action is taken by the the IME which may include sanction, termination, required corrective action, etc.

The member's case manager is responsible to monitor individual plans of care including the use of restraints, restrictions 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 case manager working with the individual member. The use of restraints must be assessed as needed and identified in the individual member's service plan created by the case manager. 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 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 contracts with the HCBS Provider Quality Oversight Unit to oversee the appropriateness, provider policies and procedures, and service plan components associated with restraints and seclusion. The HCBS Provider Quality Oversight Unit conducts periodic reviews of 100% of enrolled HCBS providers to ensure that policies and procedures are consistent with state and federal rule,

regulations, and best practices. Further, the HCBS Provider Quality Oversight Unit examines enrolled member files to ascertain whether restraints and seclusions are appropriately incorporated into the service plan such that restraints and seclusion are only implemented as designated in the plan (who, what, when, where, why, and how). If the HCBS Provider Quality Oversight Unit reviewer discovers that the provider is less than compliant in these areas, 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 of a more serious nature, recommendations are made to protective services and possible sanctioning (suspension, probation, termination, etc.) may be applied to the provider.

The HCBS Provider Quality Oversight Unit also conducts targeted reviews based on complaints. Complaints may include the inappropriate use of restraints and seclusion. All complaints of this nature are taken seriously and examined to the fullest extent possible. If the HCBS Provider Quality Oversight Unit reviewer discovers that the provider is less than compliant in areas surrounding the use of restraints and/or 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 of a more serious nature, recommendations are made to protective services and possible sanctioning (suspension, probation, termination, etc.) may be applied to the provider.

All providers and service workers are required to submit major incident reports. Categories within the incident report include inappropriate use of restraints and seclusion. These reports, entered into IMPA, trigger milestones in ISIS alerting the service worker 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 on to an HCBS Provider Quality Oversight Unit Specialist for a targeted review. If the HCBS Provider Quality Oversight Unit reviewer discovers that the provider is less than compliant in areas surrounding the use of restraints and/or 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 of a more serious nature, recommendations are made to protective services and possible sanctioning (suspension, probation, termination, etc.) may be applied to the provider.

The HCBS Provider Quality Oversight Unit Incident Reporting Specialist compiles all data related to incidents reported in IMPA associated with the inappropriate use of restraints and seclusion. This data is analyzed to identify trends and patterns and reported on a monthly and quarterly basis to the state. Further data from periodic and targeted provider reviews conducted by the HCBS Provider Quality Oversight Unit Specialists is gathered and analyzed for trends and patterns and reported to the state on a quarterly basis. Trends found in these monthly and quarterly reports, as well as those established in the monthly state QA Committee, guide the dissemination of Informational Letters and revisions to state rules and regulations.

## Appendix G: Participant Safeguards

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

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

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

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

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

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

A restrictive intervention is an action or procedure that 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 Elderly 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.

The Iowa Administrative Code for case management services plans states:
90.5(5) Member rights. Member rights may be limited or restricted only with the consent of the member or the member's legally authorized representative, and only if:
a. The limited right is explained; and
b. A service activity to address the limitation is developed and documented in the service plan with an explanation that describes how the member will work toward having the restriction removed; and
c. Periodic evaluations of the limit are conducted to determine continued need.

Acceptable planning and delivery of restrictive interventions is a joint responsibiltiy of the case manager and the service provider. The 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 the restrictive intervention, and assess and reassess need for continued use. The case manager's plan of care authorizes the services to be delivered to the member and identifies how the services are to be provided. Without the authorization, services cannot be provided to a member. Providers are required to use the case manager's plan of care as the basis for the development and implementation of the providers' treatment plan with the member. 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. Providers are responsbile for training all staff who will be administering interventions, such that the interventions are individualized and in accordance with the previously devised plan. Providers and case managers are responsible for documenting all behavioral interventions, including restrictive interventions, in the the service documentation as well as the participant's response to the intervention. Providers and case managers are also required to submit critical incident reports to the Bureau of Long Term care, via the IMPA tool, any time that a restrictive intervention is utilized.

There must be a system for the review, approval and implementation of ethical, safe, humane and efficient behavioral intervention procedures. The system must inform the individual and his/her legal guardian of the behavioral intervention policy and procedures at the time of entry 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 person and may never be used merely as punishment or for the convenience of the staff or as a substitute for a non-aversive program.

Behavioral intervention procedures may only be used for reducing or eliminating maladaptive target behaviors that are identified in the individual's Behavioral Intervention Program.

Corporal punishment and verbal or physical abuse are prohibited.

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 state contracts with the HCBS Provider Quality Oversight Unit to oversee the appropriateness, provider policies and procedures, and service plan components associated with restrictions. The HCBS Provider Quality Oversight Unit conducts periodic reviews of 100% of enrolled HCBS providers to ensure that policies and procedures are consistent with state and federal rule, regulations, and best practices. Further, the HCBS Provider Quality Oversight Unit examines enrolled member files to ascertain whether restrictions are appropriately incorporated into the service plan such that restrictions are only implemented as designated in the plan (who, what, when, where, why, and how). If the HCBS Provider Quality Oversight Unit reviewer discovers that the provider is less than compliant in these areas, 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 of a more serious nature, recommendations are made to protective services and possible sanctioning (suspension, probation, termination, etc.) may be applied to the provider.

The HCBS Provider Quality Oversight Unit also conducts targeted reviews based on complaints. Complaints may include the inappropriate use of restrictions. All complaints of this nature

are taken seriously and examined to the fullest extent possible. If the HCBS Provider Quality Oversight Unit reviewer discovers that the provider is less than compliant in areas surrounding the use of restrictive interventions, 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 of a more serious nature, recommendations are made to protective services and possible sanctioning (suspension, probation, termination, etc.) may be applied to the provider.

All providers and case managers are required to submit major incident reports. Categories within the incident report include inappropriate use of restrictions. These reports, entered into IMPA, trigger milestones in ISIS alerting the case manager 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 on to an HCBS Provider Quality Oversight Unit Specialist for a targeted review. If the HCBS Provider Quality Oversight Unit reviewer discovers that the provider is less than compliant in areas surrounding the use of restraints and/or 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 of a more serious nature, recommendations are made to protective services and possible sanctioning (suspension, probation, termination, etc.) may be applied to the provider.

The HCBS Provider Quality Oversight Unit Incident Reporting Specialist compiles all data related to incidents reported in IMPA associated with the inappropriate use of restrictions. This data is analyzed to identify trends and patterns and reported on a monthly and quarterly basis to the state. Further data from periodic and targeted provider reviews conducted by the HCBS Provider Quality Oversight Unit Specialists is gathered and analyzed for trends and patterns and reported to the state on a quarterly basis. Trends found in these monthly and quarterly reports, as well as those established in the biweekly state QA Committee, guide the dissemination of Informational Letters and revisions to state rules and regulations.

# 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).

The following is the DHS policy in regards to restraints and use of seclusion. It applies to any and all types of restraints and seclusion that may be used by providers during the provision of waiver services. Restraints may include personal, chemical (medication or drugs) and mechanical restraints used for the purpose of restraining the free movement of an individual's body. Pharmaceutical restraints (medication) are most commonly used to calm an individual down in moments of escalation. Other examples of restraints/seclusion may include, but are not limited to, holding a person down with one's hands, tying an individual down to a bed, the use a straightjacket, a demobilizing wrap, locking an individual in a room, locking an individual out of an area of their residence, or limiting community time. All incidents of restraints and the use of seclusion must be documented in the member's service record and reported to the IME as an critical incident.

In order to ensure that restraint and seclusion procedures are consistent among providers, all providers are reviewed by the HCBS QA Oversight Unit for quality of services and the service plans and service documentation are evaluated for acceptable planning and delivery. If deficiencies or red-flags are found, a corrective action may be required or the worker may report to protective services. Rules surrounding the expectations of restraint and seclusion procedure are currently with the state's Assistant Attorney General for review.

"Restraint, restriction, and behavioral intervention. The provider 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 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 (maximum one year) and shall be reviewed at least quarterly.
e. Corporal punishment and verbal or physical abuse are prohibited."

There must be a system for the review, approval and implementation of ethical, safe, humane and efficient behavioral intervention procedures. The system must inform the individual and his/her legal guardian of the restraints and behavioral intervention policy and procedures at the time of entry and as changes occur. These safeguards are the same regardless of what restraints are used including chemical restraints (psychotropic drugs used on a PRN basis). All restraints must be consistent with the Children's Health Act of 2000 & other applicable Federal laws.

All individuals served under a Home & Community Based Waiver service shall be afforded the protections imposed by these rules. Any provider contracting with the department to provide these services shall conduct its activities in accordance with these rules. Restraints and behavioral intervention procedures may be designed and implemented only for the benefit of the person 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, including the use of seclusion, may be allowed depending on the 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 they are reviewed by the interdisciplinary team 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 the Department of Human Services on the supervision and monitoring of members placed in a closed room such as monitoring on a 15 minute basis for example to assure the health and welfare of the member.

Restraint and behavioral intervention procedures may only be used for reducing or eliminating maladaptive target behaviors that are identified in the individual's Restraints and Behavioral Intervention Program. Corporal punishment and verbal or physical abuse are prohibited.

For the purposes of decelerating maladaptive target behaviors a Restraints and Behavioral Intervention Program includes at least the following components:
1. A clear objective description of the maladaptive target behavior to be reduced or eliminated.
2. A clear objective description of the incompatible or alternative appropriate response, which will be reinforced.
3. 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.
4. 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:
1. 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.
2. Supervisory personnel from the provider may provide documentation of employees' ability to implement a procedure if the following conditions are met:
• The supervisor's ability to implement the procedure has been documented by a program staff person.
• The supervisor observes each employee in a role play situation and documents the employee's ability to implement the procedure; and
• 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.
3. 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 person's right to be free from aversive, intrusive procedures is balanced against the person'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 individual's behavior must be made by the interdisciplinary team and the program must be described fully as a Restraints and Behavioral Intervention Program incorporated into the individual's service plan and the case manager's plan of care. In general, the Restraints and 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; and
-Be evaluated and approved by the interdisciplinary team through quarterly reviews of specific data on the progress and effectiveness of the procedures.

Documentation requirements.
Documentation regarding the behavior program must include:
-A Restraint and Behavioral Intervention Program which is a part of the written individual service plan developed by the individual's case manager and in the provider plan of care developed for the individual.
-Approval by the individual's interdisciplinary team, with the written consent of the person's parent if the person is under 18 years of age, or the person's legal guardian, if one has been appointed by the court.
-A written endorsement from a physician for any procedure that might affect the person's health.
-A functional analysis that is defined as and includes the following components:
-A clear, measurable description of the behavior to include frequency, duration, intensity and severity of the behavior;
-A 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.
-A description of the conditions that precede the behavior in question;
-A description of what appears to reinforce and maintain the behavior; and a clear and measurable procedure, which will be used to alter the behavior and develop the functional alternative behavior.
-Documentation that the individual, 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, and
-Restraints and 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 individual 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; through review of critical incident reports by the Department and member's case manager on a daily basis; Department and case manager review of written documentation authored by provider staff; through the annual review activities associated with the provider Self-Assessment process; and by reports from any interested party (complaints). 100% of waiver providers are reviewed at least once every five years to ensure that the DHS policy for each type of agency identified restraint and restriction is observed and member rights are safeguarded. If it is found that a waiver provider is not observing DHS policy or ensuring a member's rights, adverse action is taken by the IME which may include sanction, termination, required corrective action, etc.

The member's case manager is responsible to monitor individual plans of care including the use of restraints, restrictions 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 case manager working with the individual member. The use of seclusion must be assessed as needed and identified in the individual member's service plan created by the case manager. 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 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 Provider Quality Oversight Unit to oversee the appropriateness, provider policies and procedures, and service plan components associated with restraints and seclusion. The HCBS Provider Quality Oversight Unit conducts periodic reviews of 100% of enrolled HCBS providers to ensure that policies and procedures are consistent with state and federal rule, regulations, and best practices. Further, the HCBS Provider Quality Oversight Unit examines enrolled member files to ascertain whether restraints and seclusions are appropriately incorporated into the service plan such that restraints and seclusion are only implemented as designated in the plan (who, what, when, where, why, and how). If the HCBS Provider Quality Oversight Unit reviewer discovers that the provider is less than compliant in these areas, 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 of a more serious nature, recommendations are made to protective services and possible sanctioning (suspension, probation, termination, etc.) may be applied to the provider.

The HCBS Provider Quality Oversight Unit also conducts targeted reviews based on complaints. Complaints may include the inappropriate use of restraints and seclusion. All complaints of this nature are taken seriously and examined to the fullest extent possible. If the HCBS Provider Quality Oversight Unit reviewer discovers that the provider is less than compliant in areas surrounding the use of restraints and/or 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 of a more serious nature, recommendations are made to protective services and possible sanctioning (suspension, probation, termination, etc.) may be applied to the provider.

All providers and case managers are required to submit major incident reports. Categories within the incident report include inappropriate use of restraints and seclusion. These reports, entered into IMPA, trigger milestones in ISIS alerting the case manager 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 on to an HCBS Provider Quality Oversight Unit Specialist for a targeted review. If the HCBS Provider Quality Oversight Unit reviewer discovers that the provider is less than compliant in areas surrounding the use of restraints and/or 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 of a more serious nature, recommendations are made to protective services and possible sanctioning (suspension, probation, termination, etc.) may be applied to the provider.

The HCBS Provider Quality Oversight Unit Incident Reporting Specialist compiles all data related to incidents reported in IMPA associated with the inappropriate use of restraints and seclusion. This data is analyzed to identify trends and patterns and reported on a monthly and quarterly basis to the state. Further data from periodic and targeted provider reviews conducted by the HCBS Provider Quality Oversight Unit Specialists is gathered and analyzed for trends and patterns and reported to the state on a quarterly basis. Trends found in these monthly and quarterly reports, as well as those established in the monthly state QA Committee, guide the dissemination of Informational Letters and revisions to state rules and regulations.

## 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.

This requirement is only applicable in those situations where the member is receiving respite services outside the family home. Per IAC 77.46(5) respite providers must meet the following requirements as a condition of providing respite care under the children's mental health waiver:
1) Training on provision of medication according to agency policy and procedure
2) The staff member shall not provide any direct service without the oversight of supervisory staff until training is completed.

The case manager and respite agency both will monitor the documentation of medication administration to ensure adherence with the service plan and provider policies and procedure. The provider agency must monitor on a frequent and routine basis as outlined in their own policies and procedures and quality improvement plan. Provider agencies are expected to review medication administration on a daily basis to ensure health and welfare of participant as well as perform quality assurance on a timeframe identified by the agency (most often monthly). The case manager will monitor during the annual service plan development. Monitoring will include 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.1.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 shall be required to complete a corrective action plan and may face sanctions depending on severity and negligence of the circumstance.

Other -
Medication Management: (Oversight activities utilizing the Preferred Drug List)
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 the IME Medical Services Unit 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.

Medication Management: The 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 Medicaid 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 the Department of Human Services on a monthly or quarterly basis.

Medication Management: 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 recipients 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 300 individual patient profiles six times per year by a qualified professional group of Iowa physicians and pharmacists. These professionals have 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. Member 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 to this, a second line of oversight is done through a pharmacy review and through IME Medical Services that reviews statistically valid number of members each year. IME Medical Services reviews member records to assure that the member had a diagnosis or rational documented for each medication taken.

Medication Management: DIA -The department of Inspections and Appeals is responsible for member's medication regimes for waiver members served in a residential care facility. 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 Residential care facilities are licensed facilities and must meet all Department of Inspections Rules and Regulations to obtain a license that is renewed on an annual basis. Medical records are reviewed during the licensure renewal. Persons administrating medication shall be a licensed nurse or physician or have successfully completed a department approved medication aide course. For respite services, if the provider stores handles prescribes dispenses or administers prescription or over the counter medications the provider shall develop procedures for the storage handling prescribing dispensing or administration of medication. For controlled substances procedures shall be in accordance with department of inspections and appeals. If the provider has a physician on staff or under contract the physician shall review and document the provider's prescribed medication regime at least annually in accordance with current medical practice. Policies and procedures shall be developed in written form by the provider for the dispensing, storage, and recording of all prescription and nonprescription medications administered. This would include the monitoring medications requiring close supervision because of fluctuating physical or psychological conditions, including antihypertensive, digitalis preparations, mood-altering or psychotropic drugs, or narcotics. These policies and procedures shall be 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. 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.

Activities utilizing the Preferred Drug List
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 DHS-IME 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 Member Services Unit and Lock-in strategies implemented for individuals who have, historically, multiple prescribers and pharmacies. Identification of these individuals 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
This commission is a second line monitoring process with oversight by the DHS. 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 Commission.

The Department of Inspections and Appeals
This agency is responsible for the oversight of licensed facilities. The Department of Inspections and Appeals communicate all findings with the Department of Human Services department and any issues they find with Residential Care Facilities during their licensures process or if any issues or critical incidents arise Monitoring is done at a minimum on an annual basis or as issues or critical incidents arise. The Department of Inspections and Appeals tracks information and provides training as necessary to improve quality. This information is also shared with the Department of Human Services. Both the Department of Inspections and Appeals and the Department of Human Service will follow up with the Residential Care Facility to assure that action steps have been made to ensure potential harmful practices do not happen again.

HCBS Provider Quality Oversight Unit
The Department of Human Services contracts with the HCBS Provider Quality Oversight Unit to oversee the appropriateness, provider policies and procedures, and service plan components associated with medication management. The HCBS Provider Quality Oversight Unit conducts periodic reviews of 100% of enrolled HCBS providers to ensure that policies and procedures are consistent with state and federal rule, regulations, and best practices. Further, the HCBS Provider Quality Oversight Unit examines enrolled member files to ascertain whether medication management are appropriately incorporated into the service plan such that medication management is designated in the plan (who, what, when, where, why, and how). If the HCBS Provider Quality Oversight Unit reviewer discovers that the provider is less than compliant in these areas, 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 of a more serious nature, recommendations are made to protective services and possible sanctioning (suspension, probation, termination, etc.) may be applied to the provider.

The HCBS Provider Quality Oversight Unit also conducts targeted reviews based on complaints. Complaints may include the inappropriate use of medication. All complaints of this nature are taken seriously and examined to the fullest extent possible. If the HCBS QA reviewer 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 of a more serious nature, recommendations are made to protective services and possible sanctioning (suspension, probation, termination, etc.) may be applied to the provider.

All providers and service workers are required to submit major incident reports. Categories within the incident report include inappropriate use of medication. These reports, entered into IMPA, trigger milestones in ISIS alerting the service worker 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 on to an HCBS Provider Quality Oversight Unit Specialist for a targeted review. If the HCBS Provider Quality Oversight Unit reviewer discovers that the provider is less than compliant in areas surrounding the use of restraints and/or 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 of a more serious nature, recommendations are made to protective services and possible sanctioning (suspension, probation, termination, etc.) may be applied to the provider.

The HCBS Provider Quality Oversight Unit Incident Reporting Specialist compiles all data related to incidents reported in IMPA associated with the inappropriate use of medication. This data is analyzed to identify trends and patterns and reported on a monthly and quarterly basis to the state. Further data from periodic and targeted provider reviews conducted by the HCBS Provider Quality Oversight Unit Specialists is gathered and analyzed for trends and patterns and reported to the state on a quarterly basis. Trends found in these monthly and quarterly reports, as well as those established in the monthly state QA Committee, guide the dissemination of Informational Letters and revisions to state rules and regulations.

# 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. The Iowa Administrative Code rules states "Storage and provision of medication. If the provider stores, handles, prescribes, dispenses or administers prescription or over-the-counter medications, the provider shall develop procedures for the storage, handling, prescribing, dispensing or administration of medication. For controlled substances, procedures shall be in accordance with department of inspections and appeals rule 481—63.18(135). If the provider has a physician on staff or under contract, the physician shall review and document the provider's prescribed medication regime at least annually in accordance with current medical practice." For respite providers the rules for medication administration include "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 members 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 Iowa administrative rule for the provision of medication administration or for the self-administration of medications by 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:

1. The provider's role in the management and/or administration of medications
2. If staff administers medications, the policy will identify the:
a. Training provided to staff prior to the administration of medications
b. Method of documenting the administration of medications
c. Storage of medications
d. The assessment process used to determine 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 the Department upon request. Currently the self-assessment process is not codified in Iowa Administrative code.

Home Health agencies that provide waiver services must follow Medicare regulations for medication

administration and dispensing. All medications shall be stored in their original containers with the accompanying physician's or pharmacists directions and label intact. Medications shall be stored so they are inaccessible to members 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. 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 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 IME 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:

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 the department upon request. Major incidents must be reported to the Department of Human Service's IME-Bureau of Long Term Care (via IMPA). Providers shall ensure cooperation in providing pertinent information regarding incidents as requested by the Department.

As part of the major incident reporting process described in Appendix G-1, Critical Incident management, the Department 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 service worker when they occur. The case manager monitors the errors and makes changes to the member's plan of care 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 providers to 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 the Department 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. Currently the self-assessment process is not codified in Iowa Administrative Code.

Other professionals or family members may report medication error incidents at any time as a complaint. The Department or HCBS Specialist will take complaints via e-mail, fax or phone. Suspected abuse or neglect is reported to the reporting hotline operated by the Department of Human Services.

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

The providers must track and trend all major and minor incident reports.
Major incidents include any medication error that results in:
1. Physical injury that requires physician's treatment or admission to the hospital
2. Results in death
3. Requires emergency mental health treatment
4. Intervention of law enforcement
5. Requires a report of child abuse
6. A prescription medication error or pattern of medication errors

Minor includes any incidents and medication errors that do not fit the above.

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 the Department upon request and will be reviewed as part of the ongoing Self-Assessment process conducted by the HCBS Provider Quality Oversight Specialists.

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

Only major incidents of medication errors which the health and safety of the member has been jeopardized, as defined in the major incident criteria, are required to reported to the state. All medication errors, both major and minor, are required to be reported to the member's 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 Department of Human Services, IME - Bureau of Long Term Care, is responsible for the oversight of waiver providers in the administration of medications to waiver members. Oversight monitoring is completed through IMPA, the provider Self-Assessment process and monitoring of the member by the member's case manager. All of these processes have been described in detail in this Appendix.

All medication errors are considered either major or minor incidents. Major medication errors are medication errors that require the member to be seen by a physician, results in a hospitalization, or result in a member's death. These major incidents are reported to the department and follow the incident reporting follow up protocol of the department.

The Department of Human Services contracts with the HCBS Provider Quality Oversight Unit to oversee the appropriateness, provider policies and procedures, and service plan components associated with medication management. The HCBS Provider Quality Oversight Unit conducts periodic reviews of 100% of enrolled HCBS providers to ensure that policies and procedures are consistent with state and federal rule, regulations, and best practices. Further, the HCBS Provider Quality Oversight Unit examines enrolled member files to ascertain whether medication management are appropriately incorporated into the service plan such that medication management is designated in the plan (who, what, when, where, why, and how). If the HCBS Provider Quality Oversight Unit reviewer discovers that the provider is less than compliant in these areas, 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 of a more serious nature, recommendations are made to protective services and possible sanctioning (suspension, probation, termination, etc.) may be applied to the provider.

The HCBS Provider Quality Oversight Unit also conducts targeted reviews based on complaints. Complaints

may include the inappropriate use of medication. All complaints of this nature are taken seriously and examined to the fullest extent possible. If the HCBS QA reviewer 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 of a more serious nature, recommendations are made to protective services and possible sanctioning (suspension, probation, termination, etc.) may be applied to the provider.

All providers and case managers are required to submit major incident reports. Categories within the incident report include inappropriate use of medication. These reports, entered into IMPA, trigger milestones in ISIS alerting the case manager the incident demands further investigation, the issue is passed on to an HCBS Provider Quality Oversight Unit Specialist for a targeted review. If the HCBS QA reviewer discovers that the provider is less than compliant in areas surrounding the use of medication, 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 of a more serious nature, recommendations are made to protective services and possible sanctioning (suspension, probation, termination, etc.) may be applied to the provider.

The HCBS Provider Quality Oversight Unit Incident Reporting Specialist compiles all data related to incidents reported in IMPA associated with the inappropriate use of medication. This data is analyzed to identify trends and patterns and reported on a monthly and quarterly basis to the state. Further data from periodic and targeted provider reviews conducted by the HCBS Provider Quality Oversight Unit Specialists is gathered and analyzed for trends and patterns and reported to the state on a quarterly basis. Trends found in these monthly and quarterly reports, as well as those established in the biweekly state QA Committee, guide the dissemination of Informational Letters, provider training, and revisions to state rules and regulations.

## Appendix G: Participant Safeguards

### Quality Improvement: Health and Welfare

*As a distinct component of the State's quality improvement strategy, provide information in the following fields to detail the State's methods for discovery and remediation.*

**a. Methods for Discovery: Health and Welfare**
***The state demonstrates it has designed and implemented an effective system for assuring waiver participant health and welfare.*** *(For waiver actions submitted before June 1, 2014, this assurance read "The State, on an ongoing basis, identifies, addresses, and seeks to prevent the occurrence of abuse, neglect and exploitation.")*

**i. Sub-Assurances:**

**a.** ***Sub-assurance: The state demonstrates on an ongoing basis that it identifies, addresses and seeks to prevent instancesof abuse, neglect, exploitation and unexplained death.*** *(Performance measures in this sub-assurance include all Appendix G performance measures for waiver actions submitted before June 1, 2014.)*

**Performance Measures**

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

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

**Performance Measure:**
**HW-1a: Number, percent and frequency of major incidents, by type. Numerator = # of each type of major incident reported; Denominator = # of major incidents reported**

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

**IMPA reports are generated by the HCBS Incident Reporting Specialist. This data on incidents is inductively analyzed on a monthly, quarterly and annual basis.**

| **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** |
| ☐ **Other** Specify: | ☐ **Annually** |
| | ☐ **Continuously and Ongoing** |
| | ☐ **Other** Specify: |

| | |
|---|---|
| | |

**Performance Measure:**
**HW-2a: Number and percent of major incidents that were reported within required timeframes as specified in the approved waiver. Numerator = # of major incidents reported timely (within 48 hours); Denominator = # of major incidents reported**

**Data Source** (Select one):
**Critical events and incident reports**
If 'Other' is selected, specify:
**IMPA reports are generated by the HCBS Incident Reporting Specialist. This data on timeliness is inductively analyzed on a monthly, quarterly and annual basis.**

| **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** |
| ☐ **Other**<br>Specify: | ☐ **Annually** |
| | ☐ **Continuously and Ongoing** |
| | ☐ **Other**<br>Specify: |

**Performance Measure:**
**HW-3a: Number and percent of medication errors that resulted in a waiver participant requiring medical treatment. Numerator = # of medication errors resulting in medical treatment; Denominator = # of medication errors**

**Data Source** (Select one):
**Critical events and incident reports**
If 'Other' is selected, specify:
**IMPA reports are generated by the HCBS Incident Reporting Specialist. This data on reported med errors is inductively analyzed on a monthly, quarterly and annual basis.**

| **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**<br>Confidence Interval = |
| ☑ **Other**<br>Specify:<br>Contracted Entity | ☑ **Annually** | ☐ **Stratified**<br>Describe Group: |
| | ☐ **Continuously and Ongoing** | ☐ **Other**<br>Specify: |
| | ☐ **Other**<br>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**<br>Specify: | ☐ **Annually** |
| | ☐ **Continuously and Ongoing** |
| | ☐ **Other**<br>Specify: |

**Performance Measure:**
**HW-4a: Number and percent of unexplained, suspicious or untimely deaths compared to the total number of deaths. Numerator = # of unexplained, suspicious or untimely deaths; Denominator = # of deaths**

**Data Source** (Select one):
**Critical events and incident reports**
If 'Other' is selected, specify:
**IMPA reports are generated by the HCBS Incident Reporting Specialist. This data on suspicious or untimely deaths is inductively analyzed on a monthly, quarterly and annual basis.**

| **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**<br>Confidence Interval = |
| ☑ **Other**<br>Specify:<br>Contracted Entity | ☑ **Annually** | ☐ **Stratified**<br>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-5a: Number and percent of member survey respondents who reported they feel safe in their living environment. Numerator = # of suveys reporting member feels safe in living environment; Denominator = # of suveys**

**Data Source** (Select one):
**Analyzed collected data (including surveys, focus group, interviews, etc)**
If 'Other' is selected, specify:
**The IPES survey is conducted at a 95% confidence level and responses recorded in a database. Data is pulled and inductively analyzed.**

| 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 = 5% |
| ☑ **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** |
| ☐ **Other** Specify: | ☐ **Annually** |
| | ☐ **Continuously and Ongoing** |
| | ☐ **Other** Specify: |

**Performance Measure:**
**HW-6a: Number and percent of experience/satisfaction survey respondents who reported that someone hit or hurt them physically. Numerator = # of survey respondents reporting that someone hit or hurt them physically Denominator = # of survey respondents**

**Data Source** (Select one):
**Analyzed collected data (including surveys, focus group, interviews, etc)**
If 'Other' is selected, specify:
**The IPES survey is conducted at a 95% confidence level and responses recorded in a database. Data is pulled and inductively analyzed.**

| **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<br>Confidence Interval = 5% |
| ☑ Other<br>Specify:<br>Contracted Entity | ☐ Annually | ☐ Stratified<br>Describe Group: |
| | ☐ Continuously and Ongoing | ☐ Other<br>Specify: |
| | ☐ Other<br>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<br>Specify: | ☐ Annually |
| | ☐ Continuously and Ongoing |
| | ☐ Other<br>Specify: |

**Performance Measure:**
**HW-7a: Number and percent of experience/satisfaction survey respondents who reported they do not feel safe with the people they live with. Numerator = # of survey respondents reporting member does not feel safe with the people they live with; Denominator = # of survey respondents**

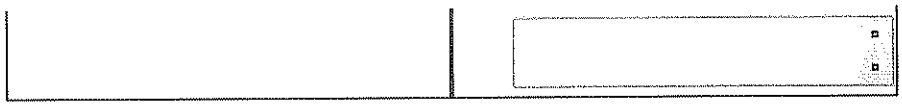
**Data Source** (Select one):

**Analyzed collected data (including surveys, focus group, interviews, etc)**
If 'Other' is selected, specify:
**The IPES survey is conducted at a 95% confidence level and responses recorded in a database. Data is pulled and inductively analyzed.**

| **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 = 5% |
| ☑ **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** |
| ☐ **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.*

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.*

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.*

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 Quality Assurance unit is responsible for monitoring and analyzing data associated with the major incidents reported to the state, via IMPA, for members on waivers. Data is pulled from the data warehouse 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 on a monthly basis. The analysis of this data is presented to the state on a monthly and quarterly basis.
The HCBS provider oversight unit 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 individual 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 State's method for addressing individual problems as they are discovered. Include information regarding responsible parties and GENERAL methods for problem correction. In addition, provide information on the methods used by the State to document these items.

The HCBS Incident Reporting Specialist 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 a these efforts are not successful, the IR Specialist 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.

General methods for problem correction at a systemic level include informational letters, provider trainings, collaboration with stakeholders and changes in 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**<br>Specify: | ☑ **Annually** |
| | ☐ **Continuously and Ongoing** |
| | ☐ **Other**<br>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.