Appendix G: Participant Safeguards

Brief Overview

Appendix G addresses the following safeguards to assure the health and welfare of waiver participants:

- Response to Critical Events or Incidents (Appendix G-1)
- Safeguards Concerning Restraints and Restrictive Interventions (Appendix G-2)
- Medication Management and Administration (Appendix G-3)

Appendix G-1 and Appendix G-2 Item C-2-c-ii apply to all waivers. Appendices G-2 (except for Item C-2-c-ii) and G-3 may not apply to some waivers. See the instructions for these Appendices for a discussion of their applicability.

Appendix G-1: Response to Critical Events or Incidents

Overview

This appendix applies to all waiver programs. It focuses on the identification and follow-up to critical events or incidents (e.g., abuse, neglect and exploitation) that bring harm, or create the potential for harm, to a waiver participant. ***Effective incident management is essential to assuring the health and welfare of waiver participants***. In this appendix, the state describes the operational features of managing incidents at the individual and provider level as well as its activities to assure that reports are filed and incidents investigated in a timely fashion and to analyze incident data (e.g., about specific types of incidents, providers, participant characteristics, results of investigations, the timeliness of reports and investigations) in order to develop strategies to reduce the risk and likelihood of the occurrence of incidents in the future.

Detailed Instructions for Completing Appendix G-1

Item G-1-a: Critical Event or Incident Reporting and Management Process.

Instructions

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

Item G-1-b: State Critical Event or Incident Reporting Requirements

Instructions

List and briefly define 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 (e.g., a follow-up investigation) by an appropriate authority (e.g., child or adult protective services). Also identify the individuals and/or entities (e.g., waiver providers) that must report such events and incidents and the reporting method or methods that are employed. Specify the time-frames for reporting critical events and incidents. The response to this item may include citations of relevant state laws, regulations, and other published policies. Referenced documents must be

available through the Medicaid agency or the operating agency (if applicable) upon request by CMS.

Technical Guidance

This item focuses on critical events or incidents that the state itself deems as sufficiently serious to warrant near-term review and follow-up by an appropriate authority. Such incidents may include but are not limited to: (a) abuse and neglect as defined by the state; (b) the unauthorized use of restraint, seclusion or restrictive interventions; (c) serious injuries that require medical intervention and/or result in hospitalization; (d) criminal victimization; (e) death; (f) financial exploitation; (g) medication errors; and, (h) other incidents or events that involve harm or risk of harm to a participant. In general, the types of critical events and incidents that must be reported to and monitored by an appropriate authority are specified in state law, regulations or policies. When the waiver serves both children and adults, specify whether different reporting requirements apply to children and adults, including who has responsibility to report critical events or incidents.

CMS Review Criteria

- The state provides for the reporting and investigation of major and serious incidents (abuse, neglect, and exploitation at a minimum).
- The description includes:
  - Definitions of the types of critical events or incidents that must be reported;
  - Identification of the individuals/entities that must report critical events and incidents; and,
  - The timeframes within which critical events or incidents must be reported; and,
  - The method of reporting (e.g., phone, written form, web-based reporting system)

Item G-1-c: Participant Training and Education

Instructions

Describe how training and/or information is provided to participants (and involved family or other unpaid caregivers, as appropriate) concerning the state's protections from abuse, neglect, and exploitation, including how participants (or their informal caregivers) can notify appropriate authorities or entities when the participant may have experienced abuse, neglect or exploitation. Identify the entity or entities that are responsible for providing this training and/or information and how frequently training and education are furnished.

Technical Guidance

This item focuses on how participants (and involved family or other unpaid caregivers, as appropriate) are informed about abuse, neglect and exploitation protections. This might involve formal training concerning whom to contact when the participant believes that s/he has experienced abuse, neglect or exploitation. Alternatively, information about reporting might be furnished verbally and/or in written form to the participant and other involved individuals. The scope of the item does not include training/education that might be furnished to providers or direct support workers about identifying and reporting abuse, neglect, and exploitation.

CMS Review Criteria

The waiver describes:

- How training and/or information are furnished to participants or their informal caregivers concerning protections from abuse, neglect and exploitation, including how to notify the appropriate authorities.
- The entities responsible for providing training and/or information are specified.
- The frequency of providing training and/or information is specified.

Item G-1-d: Responsibility for Review of and Response to Critical Events or Incidents

Instructions

Identify the entity (or entities) to which reports are made of each type of critical event or incident specified in Item G-1-a above. Describe the methods employed to evaluate critical incident reports (e.g., determine that follow-up action is required), and the processes and time frames for responding to critical events or incidents, including conducting investigations.

Technical Guidance

The purpose of this item is to describe how reports of critical events or incidents are reviewed and how follow-up of reports is performed when warranted. The response must:

- For each type of critical incident or event identified in Item G-1-a, specify the entity or entities to which reports are submitted. Such entities might include the state's adult protective services agency, the child protective services agency, a licensing authority and/or a program authority (e.g., the state developmental disabilities agency);
- Identify the entity that is responsible for evaluating reports (e.g., making a determination that follow-up is necessary) and how reports are evaluated (e.g., the criteria that are applied in deciding whether follow-up action is warranted);
- Identify the entity that is responsible for follow-up investigations and how investigations are conducted (e.g., whether methods are determined based on severity according to a prescribed protocol, accommodations that are made for participant interviews);
- The timeframe for conducting and completing an investigation (i.e., how promptly an investigation is initiated) and the time-frame for completing an investigation (e.g., within 48-hours, 7-days, 30-days depending on severity and criticality); and,
- The process and time frames for informing the participant (or the participant's family or legal representative as appropriate) and other relevant parties (e.g., the waiver provider, licensing and regulatory authorities, the operating agency) of the investigation results.

The description may be structured in any appropriate manner so long as it addresses each of the elements listed above.

CMS Review Criteria

The waiver specifies:

- The entity (or entities) that receives reports of each type of critical event or incident.
- The entity that is responsible for evaluating reports and how reports are evaluated.
- The entity that is responsible for conducting investigations and how investigations are conducted.
- The timeframes for conducting an investigation and completing an investigation.

- The process and timeframes for informing the participant including the participant (or the participant's family or legal representative as appropriate) and other relevant parties (e.g., the waiver providers, licensing and regulatory authorities, the waiver operating agency) of the investigation results.

Item G-1-e. Responsibility for Oversight of Critical Incidents and Events

Instructions

In the text field, identify the state agency (or agencies) responsible for overseeing the reporting of and response to critical incidents or events, how this oversight is conducted and how frequently.

Technical Guidance

An effective incident management system entails conducting oversight to make sure that applicable policies and procedures are being followed for the reporting of critical incidents or events and that necessary follow-up is being conducted on a timely basis. A critical element of effective oversight is the operation of data systems that support the identification of trends and patterns in the occurrence of critical incidents or events in order to identify opportunities for improvement and thus support the development of strategies to reduce the occurrence of incidents in the future.

The response to this item must specify the following:

- **The state agency or agencies responsible for overseeing the operation of the incident management system.** When this responsibility is not carried out directly by the Medicaid agency and/or the operating agency (if applicable), indicate how the information and findings from oversight activities are communicated to the Medicaid agency and/or the operating agency by the state agency (or agencies) responsible for oversight. Since addressing critical incidents or events is an integral component of assuring the health and welfare of waiver participants, it is critical that the Medicaid agency and/or the operating agency (if applicable) play an active role in the oversight of the operation of the incident management system. For example, if the state's adult protective services (APS) agency has primary oversight responsibility for incident management, there should be processes whereby the APS agency regularly furnishes the Medicaid agency and/or operating agency with information about critical incidents that involve waiver participants and that the agencies work together to identify strategies to reduce the occurrence of critical incidents.
- **How oversight is conducted.** System-wide oversight methods should include gathering information about types of incidents, participant characteristics, providers, how quickly reports are reviewed and investigated, how promptly follow-up takes place, the results of investigations, and whether participants are informed of the investigation results. Oversight includes using information to reduce the occurrence of incidents in the future. The response should describe
    1) How information about critical incidents and events is collected and compiled so that it can be analyzed to enable the identification of trends/patterns and the development of quality improvement strategies to reduce future occurrence of critical incidents or events. For example, reports may be filed by phone, in written form, or through the use of information technology, each of which requires specific practices to collect, compile and analyze the information.

2) How information from critical incident reports is used to identify issues within the waiver population, specific providers at a system-wide level, and how that information is used to develop strategies to reduce occurrences in the future.

3) The frequency of oversight activities.

CMS Review Criteria

The waiver specifies:

- The state entity or entities responsible for overseeing the operation of the incident management system.
- When oversight is not performed by the Medicaid agency or the operating agency (if applicable), the process for the oversight agency to communicate information and findings to the Medicaid agency and/or operating agency.
- The methods for overseeing the operation of the incident management system, including how data are collected, compiled, and used to prevent re-occurrence.
- The frequency of oversight activities.

Appendix G-2: Safeguards Concerning Restraints and Restrictive Interventions

Overview

This Appendix concerns the use of restraints and/or restrictive interventions during provision of waiver services. When either is permitted, the state must specify the safeguards that it has established concerning their use and how the state ensures that such safeguards are followed. Providing effective safeguards in the use of restraints and/or restrictive interventions is integral to assuring the health and welfare of waiver participants. When restraints and/or restrictive interventions are not permitted, the state must have a means to detect unauthorized use. The terms used in this Appendix are defined in the Glossary. .

Detailed Instructions for Completion of Appendix G-2

Item G-2-a: Use of Restraints

Instructions

Select one of the two main choices. If the state does not permit the use of restraints as part of the provision of waiver services and/or their use is prohibited under state policy, select the first choice. Also, identify the state agency or agencies that are responsible for detecting the unauthorized use of restraints and how oversight is performed to ensure that unauthorized use does not take place. If the use of restraints by a paid caregiver is permitted during the course of providing waiver services, including in the participant's private residence, select the second choice and complete the next two items. Use of restraints must comport with the home and community-based setting requirements at Section 42 CFR 441.301(c)(4)(iii) and (vi)(F), and person-centered service planning and plan requirements at 42 CFR 44.301(c)(1) and (c)(2).

Technical Guidance

For the purposes of this item, restraints include personal restraints (e.g., holds), drugs used as restraints, and mechanical restraints. When a state prohibits the use of restraints during the

delivery of waiver services, it still must have processes that are designed to detect their unauthorized use. Such processes may include regular monitoring of participant health and welfare, the performance of periodic provider quality reviews, and an incident management system in which unauthorized restraint is a reportable incident.

CMS Review Criteria

- When the first choice is selected, the response is consistent with the remainder of the waiver application.
- When the first choice is selected, the state provides specific methods to detect unauthorized use of restraints, and specifies the state agency (or agencies) responsible for conducting this oversight.
- Use of restraints must comport with the home and community-based setting requirements at Section 42 CFR 441.301(c)(4)(iii) and (vi)(F), and person-centered service planning and plan requirements at 42 CFR 44.301(c)(1) and (c)(2).

Item G-2-a-i: Safeguards Concerning the Use of Restraints

Instructions

Specify the safeguards that have been established concerning the use of each type of restraint (i.e., personal restraints, drugs used as restraints, mechanical restraints). If state laws, regulations, and policies are referenced in the response to this item, they must available upon request to CMS through the Medicaid agency or the operating agency (if applicable).

Technical Guidance

When the use of restraints is permitted, identify the types of restraints (i.e., personal restraints, drugs used as restraints, mechanical restraints) that are allowed and describe in detail the safeguards that the state has established concerning the use of each type of restraint that is permitted. If the use of specific types of restraint is explicitly prohibited in policy, identify the restraints that are not allowed. For example, personal restraints may be permitted but the use of mechanical restraints prohibited.

For each type of restraint that is allowed, the safeguards should address:

1) Requirements concerning the use of alternative strategies to avoid the use of restraints;
2) Methods for detecting the unauthorized use of or misapplication of restraints;
3) The protocols that must be followed when restraints are employed (including the circumstances when their use is permitted and when they are not) and how their use is authorized;
4) The practices that must be employed in the administration of a restraint to ensure the health and safety of individuals;
5) Required documentation (record keeping) concerning the use of restraints; and,
6) The education and training requirements that provider agency personnel must meet who are involved in the administration of a restraint.

CMS Review Criteria

For each type of restraint permitted, the State has identified safeguards that address:

- The use of alternative methods to avoid the use of restraints;
- Methods for detecting the unauthorized use of restraints;
- The protocols that must be followed when restraints are employed (including the circumstances when their use is permitted) and how their use is authorized;
- The practices that must be employed to ensure the health and safety of individuals;
- Required documentation concerning the use of restraints; and
- Education and training requirements that personnel who are involved in the administration of restraints must meet.

Item G-2-a-ii: State Oversight Responsibility

Instructions

Specify the State agency (or agencies) responsible for overseeing the use of restraints and ensuring that State safeguards concerning their use are followed. Describe how this oversight is conducted and its frequency

Technical Guidance

- **Identify the state agency (or agencies) responsible for overseeing the use of restraints and ensuring that state safeguards concerning their use are followed.** When the Medicaid agency or the operating agency (if applicable) does not conduct this oversight, describe how the results of monitoring the use of restraints are regularly communicated to the agency that operates the waiver. Since the use of restraints has potential implications for the health and welfare of waiver participants, it is important that the agency that administers the waiver be informed and aware of potential violations of state policies concerning the use of restraints in order for them to undertake appropriate remedial and system improvement activities.
- **How oversight is conducted.** Oversight methods include monitoring the use of restraints to ensure that all applicable state requirements are followed and to detect unauthorized, inappropriate/ineffective use or over use. Oversight methods should include gathering information about frequency, length of time of each use and the duration of use over time as well as the impact of restraints on the individual. Oversight also includes using information to assure proper use and to reduce the use of restraints in the future. The response should include

    1) How information about restraints is collected and compiled so that it can be analyzed to enable the identification of trends/patterns and the development of quality improvement strategies. For example, reports may be filed by phone, in written form, or through the use of information technology, each of which requires specific practices to collect and then compile and analyze the information
    2) How information about the use of restraints is used to identify issues related to the waiver populations, providers at the system-wide level and how that information is used to develop strategies to ensure the proper use and achieve a reduction in the use of restraints.
    3) The frequency of oversight activities.

CMS Review Criteria

The response specifies:

- The state agency (or agencies) responsible for overseeing the use of restraints and

ensuring that the state's safeguards are followed.

- When oversight is not performed by the Medicaid agency or the operating agency (if applicable), the process for the oversight agency to communicate information and findings to the Medicaid agency and/or operating agency.
- Methods for detecting unauthorized use, over use or inappropriate/ineffective use of restraints and ensuring that all applicable state requirements are followed.
- How data are analyzed to identify trends and patterns and support improvement strategies.
- The methods for overseeing the operation of the incident management system including how data are collected, compiled, and used to prevent re-occurrence.
- The frequency of the oversight activities.

Item G-2-b: Use of Restrictive Interventions

Instructions

Select one of the two main choices. If the state does not permit the use of restrictive interventions during the provision of waiver services and/or their use is prohibited under state policy, select the first choice. Also, identify the state agency or agencies that are responsible for detecting the unauthorized use of restrictive interventions and how oversight is performed to ensure that unauthorized use does not take place. If the use of restrictive interventions by a paid provider is permitted during the course of providing waiver services, including in the participant's private residence, select the second choice and complete the next two items. Use of restrictive interventions must comport with the home and community-based setting requirements at Section 42 CFR 441.301(c)(4)(iii) and (vi)(F), and person-centered service planning and plan requirements at 42 CFR 44.301(c)(1) and (c)(2).

Technical Guidance

Restrictive interventions limit an individual's movement; a person's access to other individuals, locations or activities, or restrict participant rights. Restrictive interventions also include the use of other aversive techniques (not including restraint or seclusion) that are designed to modify a person's behavior.

When a state prohibits the use of restrictive interventions during the delivery of waiver services, it still must have specific processes that are designed to detect their unauthorized use.

CMS Review Criteria

- The response is consistent with the remainder of the waiver application.
- When the first choice is selected, the state specifies methods to detect unauthorized use of restrictive intervention, and the state agency (or agencies) responsible for conducting this oversight.
- Use of restrictive interventions must comport with the home and community-based setting requirements at Section 42 CFR 441.301(c)(4)(iii) and (vi)(F), and person-centered service planning and plan requirements at 42 CFR 44.301(c)(1) and (c)(2).

Item G-2-b-i: Safeguards Concerning the Use of Restrictive Interventions

Instructions

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 must be available to CMS upon request through the Medicaid agency or the operating agency.

Technical Guidance

The use of restrictive interventions has potential adverse ramifications for the health and welfare of waiver participants. Consequently, when their use is permitted during the course of the provision of waiver services, it is important that there be effective safeguards in place to ensure that such interventions are only used when necessary and are carried out in a manner that avoids harm to the waiver participant.

When the use of restrictive interventions is permitted during the course of the provision of waiver services, identify the types of interventions that are allowed (including the circumstances under which they are allowed) and the types of restrictive interventions that are specifically prohibited. For example, a state may prohibit the use of aversive methods altogether. Do not include here restraints or seclusion that already have been addressed in Item G-2-a and G-2-c.

Describe in detail the safeguards that have been established for each type of permitted restrictive intervention. These safeguards should address:

1) First use of non-aversive methods (i.e., a requirement that aversive methods may only be employed as a last resort);
2) Methods to detect the unauthorized use of restrictive interventions;
3) Protocols for authorizing the use of restrictive interventions, including treatment planning requirements and review/reauthorization procedures (including, as applicable the use of Human Rights Committees);
4) Required documentation (record keeping) when restrictive interventions are used; and,
5) Required education and training of personnel involved in the authorization and administration of restrictive interventions.

CMS Review Criteria

The response specifies:

- The types of restrictive interventions that are permitted, the circumstances under which they are allowed, and the types of restrictive interventions that are not allowed.
- For each type of restrictive intervention that is permitted, the state's safeguards address:
  - First use of non-aversive methods;
  - Methods to detect the unauthorized use of restrictive interventions;
  - Protocols for authorizing the use of restrictive interventions, including treatment planning requirements and review/reauthorization procedures;
  - Required documentation when restrictive interventions are used; and
  - Required education and training of personnel involved in authorization and administration of restrictive interventions.

Item G-2-b-ii: State Oversight Responsibility

Instructions

Specify the State agency (or agencies) responsible for monitoring and overseeing the use of

restrictive interventions, how this oversight is conducted, and its frequency. When the state does not permit the use of restrictive interventions, the response to this item should focus on how the state detects the unauthorized use of restrictive interventions.

Technical Guidance

- **Identify the state agency (or agencies) responsible for overseeing the use of restrictive interventions and ensuring that state safeguards concerning their use are followed.** When this oversight is not carried out by the Medicaid agency or the operating agency (if applicable), describe how the results of monitoring the use of restrictive interventions are regularly communicated to the agency that operates the waiver. Since use of restrictive interventions has potential implications for the health and welfare of waiver participants, it is important that the agency that administers the waiver be aware of potential violations of state policies concerning the use of restrictive interventions in order for them to undertake appropriate remedial and system improvement activities..

- **How oversight is conducted.** Oversight methods include monitoring the use of restrictive interventions to ensure that all applicable state requirements are followed and detecting their unauthorized, inappropriate/ineffective use or over use. Oversight methods should include gathering information about frequency, length of time of each use and the duration of use over time as well as the impact of restrictive interventions on the individual. Oversight also includes using information to assure proper use and to reduce the use of restrictive interventions in the future. The response should include;
  1) How information about restrictive interventions is collected and compiled so that it can be analyzed to enable the identification of trends/patterns and the development of quality improvement strategies . For example, reports may be filed by phone, in written form, or through the use of information technology, each of which requires specific practices to collect, compile and analyze the information.
  2) How information about the use of restrictive interventions used to identify issues related to the waiver populations, providers and at the system-wide level and how that information is used to develop strategies to ensure the proper use and achieve a reduction in the use of restrictive interventions in the future.
  3) The frequency of oversight activities.

CMS Review Criteria

The waiver specifies:

- The state agency (or agencies) responsible for overseeing the use of restrictive procedures and ensuring that the state's safeguards are followed.
- When oversight is not performed by the Medicaid agency or the operating agency (if applicable), the process for the oversight agency to communicate information and findings to the Medicaid agency and/or operating agency.
- Methods for detecting unauthorized use, over use or inappropriate/ineffective use of restrictive procedures and ensuring that all applicable state requirements are followed.
- How data are analyzed to identify trends and patterns and support improvement strategies.
- The methods for overseeing the operation of the incident management system including how data are collected, compiled, and used to prevent re-occurrence.
- The frequency of oversight activities.

Item G-2-c: Use of Seclusion

Instructions

Select one of the two main choices. If the state does not permit the use of seclusion as part of the provision of waiver services and/or their use is prohibited under state policy, select the first choice. Also, identify the state agency or agencies that are responsible for detecting the unauthorized use of seclusion and how oversight is performed to ensure that unauthorized use does not take place. If the use of seclusion by a paid caregiver is permitted during the course of providing waiver services, including in the participant's private residence, select the second choice and complete the next two items. Use of seclusion must comport with the home and community-based setting requirements at Section 42 CFR 441.301(c)(4)(iii) and (vi)(F), and person-centered service planning and plan requirements at 42 CFR 44.301(c)(1) and (c)(2).

Technical Guidance

For the purposes of this item, seclusion means involuntarily isolating an individual as a means of controlling the person's behavior. Seclusion is distinguished from "time out" which does not involve preventing a person from leaving an area and which is considered to be a restrictive intervention. Consult the Glossary for the definition of the terms used in this item.

When a state prohibits the use of seclusion during the delivery of waiver services, it still must have processes that are designed to detect their unauthorized use. Such processes may include regular monitoring of participant health and welfare, the performance of periodic provider quality reviews, and an incident management system in which unauthorized seclusion is a reportable incident.

CMS Review Criteria

- When the first choice is selected, the response is consistent with the remainder of the waiver application.
- When the first choice is selected, the state provides specific methods to detect unauthorized use of seclusion, and specifies the state agency (or agencies) responsible for conducting this oversight.
- Use of restrictive interventions must comport with the home and community-based setting requirements at Section 42 CFR 441.301(c)(4)(iii) and (vi)(F), and person-centered service planning and plan requirements at 42 CFR 44.301(c)(1) and (c)(2).

Item G-2-c-i: Safeguards Concerning the Use of Seclusion

Instructions

Specify the safeguards that have been established concerning the use of seclusion. If state laws, regulations, and policies are referenced in the response to this item, they must available upon request to CMS through the Medicaid agency or the operating agency (if applicable).

Technical Guidance

When the use of seclusion is permitted, describe in detail the safeguards that the state has established concerning the use of seclusion that is permitted. The safeguards should address:

1) Requirements concerning the use of alternative strategies to avoid the use of seclusion;

2) Methods for detecting the unauthorized use of or misapplication of seclusion;
3) The protocols that must be followed when seclusion is employed (including the circumstances when it is permitted and when it is not) and how its use is authorized;
4) The practices that must be employed in the administration of seclusion to ensure the health and safety of individuals;
5) Required documentation (record keeping) concerning the use of seclusion; and,
6) The education and training requirements that provider agency personnel must meet who are involved in the administration of seclusion.

CMS Review Criteria

For each type of seclusion permitted, the State has identified safeguards that address:

- The use of alternative methods to avoid the use of seclusion;
- Methods for detecting the unauthorized use of seclusion;
- The protocols that must be followed when seclusion is employed (including the circumstances when its use is permitted) and how its use is authorized;
- The practices that must be employed to ensure the health and safety of individuals;
- Required documentation concerning the use of seclusion; and
- Education and training requirements that personnel who are involved in the administration of seclusion must meet.

Item G-2-c-ii: State Oversight Responsibility

Instructions

Specify the State agency (or agencies) responsible for overseeing the use of seclusion and ensuring that State safeguards concerning its use is followed. Describe how this oversight is conducted and its frequency.

Technical Guidance

- **Identify the state agency (or agencies) responsible for overseeing the use of seclusion and ensuring that state safeguards concerning its use is followed.** When the Medicaid agency or the operating agency (if applicable) does not conduct this oversight, describe how the results of monitoring the use of seclusion are regularly communicated to the agency that operates the waiver. Since the use of seclusion has potential implications for the health and welfare of waiver participants, it is important that the agency that administers the waiver be informed and aware of potential violations of state policies concerning the use of seclusion in order for them to undertake appropriate remedial and system improvement activities.
- **How oversight is conducted.** Oversight methods include monitoring the use of seclusion to ensure that all applicable state requirements are followed and to detect unauthorized, inappropriate/ineffective use or over use. Oversight methods should include gathering information about frequency, length of time of each use and the duration of use over time as well as the impact of seclusion on the individual. Oversight also includes using information to assure proper use and to reduce the use of seclusion in the future. The response should include

    1) How information about seclusion is collected and compiled so that it can be analyzed to enable the identification of trends/patterns and the development of quality improvement strategies. For example, reports may be filed by phone, in

written form, or through the use of information technology, each of which requires specific practices to collect and then compile and analyze the information

2) How information about the use of seclusion is used to identify issues related to the waiver populations, providers at the system-wide level and how that information is used to develop strategies to ensure the proper use and achieve a reduction in the use of seclusion.
3) The frequency of oversight activities.

CMS Review Criteria

The response specifies:

- The state agency (or agencies) responsible for overseeing the use of seclusion and ensuring that the state's safeguards are followed.
- When oversight is not performed by the Medicaid agency or the operating agency (if applicable), the process for the oversight agency to communicate information and findings to the Medicaid agency and/or operating agency.
- Methods for detecting unauthorized use, over use or inappropriate/ineffective use of seclusion and ensuring that all applicable state requirements are followed.
- How data are analyzed to identify trends and patterns and support improvement strategies.
- The methods for overseeing the operation of the incident management system including how data are collected, compiled, and used to prevent re-occurrence.
- The frequency of the oversight activities.

Appendix G-3: Medication Management and Administration

Overview

This section addresses two distinct topics: (a) medication management, which means the review of waiver participant medication regimens (e.g., the appropriateness of the medications that a person receives) and (b) medication administration (the administration of medications to participants who are unable to administer their own medications by waiver providers). Both of these topics have potential ramifications for the health and welfare of waiver participants.

Detailed Instructions for Completing Appendix G-3

Item G-3-a: Applicability

Instructions

Select whether this section applies to the waiver. If it applies, then complete the remainder of the section. If not, do not complete the rest of the section.

Technical Guidance

This question 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 question does not need to be completed when waiver participants are served exclusively in their own private residences or in the home of a family member. However, a state may include this Appendix if it wishes. This

may be the case when supporting waiver participants who live in their own private residences or the home of a family member entails the involvement of waiver providers in the management and/or administration of their medications.

Item G-3-b: Medication Management and Follow-Up

Medication management means the review of a participant's full medication regimen to ensure its appropriateness. When individuals receive medications for the purpose of modifying or controlling behavior, the state is expected to have policies and procedures concerning the effective use and management of such medications. Medication management also is relevant when a participant receives multiple medications in order to guard against over or inappropriate medication.

Item G-3-b-i: Responsibility

Instructions

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

Technical Guidance

First-line responsibility for monitoring participant medication regimens resides with the medical professionals who prescribe medications. The response to this item should identify the entity or entities that conduct second-line monitoring.

This second-line monitoring may or may not be conducted by a state agency. Entities responsible for second-line monitoring may include licensing agencies, case or care managers, or others. Monitoring also might include the review of medication regimens by Medicaid agency utilization review staff or contractors. When behavior modifying medications are employed, second line monitoring responsibility must be specified. It is not expected that in-depth monitoring will be conducted in the case of medications that are prescribed for the short-term treatment of an illness.

The response must describe how second-line monitoring is conducted, by whom and how frequently (e.g., periodic review of medication regimens by a care manager or nurse). Monitoring methods should be designed to detect potentially harmful practices and provide for follow-up to address such practices. Specify whether monitoring has been designed to focus on waiver participants who have especially complex medication regimens or who are prescribed behavior modifying medications as part of their treatment programs. Monitoring may be conducted as part of the periodic monitoring of participant health and welfare.

CMS Review Criteria

The waiver specifies:

- The entity or entities responsible for ongoing monitoring of participant medication regimens.
- The scope of monitoring (i.e., whether monitoring is designed to focus on certain types of medications or medication usage patterns).
- Methods for conducting monitoring.
- Frequency of monitoring.
- How monitoring has been designed to detect potentially harmful practices and follow-up to address such practices.
- How second-line monitoring is conducted on the use of behavior modifying medications.

Item G-3-b-ii: State Oversight and Follow-up

Instructions

Describe how the state oversees or monitors second-line medication management processes 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) responsible for follow-up.

Technical Guidance

Provide an overview of how the state oversees the performance of second-line medication monitoring processes to ensure that potentially harmful practices are identified and addressed. Specify the state agency (or agencies) responsible for this oversight and how frequently oversight is performed. If the Medicaid agency or operating agency (if applicable) does not directly conduct this oversight, describe how oversight results are regularly shared with the agency that administers the waiver program.

If improvements in oversight are planned during the period that the waiver is in effect, such improvements should be briefly identified here and described in more detail in Appendix H.

CMS Review Criteria

The waiver specifies:

- The state agency (or agencies) responsible for oversight
- When oversight is not conducted by the Medicaid agency or the operating agency (if applicable), the process to communicate information and findings from monitoring are regularly communicated to the Medicaid agency and the operating agency (if applicable).
- How state monitoring is performed and how frequently
- How the state monitoring program gathers information concerning potentially harmful practices and employs such information to improve quality.

Item G-3-c: Medication Administration by Waiver Providers

This item concerns the administration of medications by waiver providers to waiver participants who are not able to self-administer their medications or the oversight by waiver providers of participant self-administration of medications.

Item G-3-c.i: Provider Administration of Medications

Instructions

Select the "yes" response when waiver providers administer medications or oversee the self-administration of medications by waiver participants. Complete the remainder of the item. If waiver providers do not administer medications or oversee self administration, select the second response. Do not complete the remainder of the item.

Item G-3-c.ii: State Policy

Instructions

Summarize the state policies that apply to 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 personnel. State laws, regulations, and policies that are referenced in the summary must be available to CMS

upon request through the Medicaid agency or the operating agency (if applicable).

Technical Guidance

When waiver providers administer medications to participants who are unable to self-administer, states typically have adopted formal policies (in law and/or regulation) that govern this practice. The response to this item should summarize the applicable policies, including whether administration is restricted to licensed medical personnel or may be performed by non-medical waiver provider personnel. In the case of the latter, the summary should identify the training/education that such personnel must have in order to administer medications and the extent of oversight by licensed medical professionals that is performed. The summary also should describe the state's policies with respect to waiver providers overseeing the self-administration of medications by waiver participants.

CMS Review Criteria

The waiver specifies:

- Policies concerning the administration of medications to individuals who are unable to self-administer and the responsibilities of providers for overseeing self-administration.
- If applicable, the training/education that non-medical waiver providers must have in order to administer medications to participants who cannot self-administer and the extent of the oversight of these personnel by licensed medical professionals.

Item G-3-c.iii: Medication Error Reporting

Instructions

Select whether providers who administer medications to waiver participants who are unable to self-administer must both record and report medication errors to a state agency. If this choice is selected, specify the state agency to which errors are reported and the types of medication errors that providers must: (a) record and (b) report. If providers are required to record errors but not report them to a state agency, select the second choice and specify the types of errors that providers must record. If providers are not required to record and/or report errors or waiver providers do not administer medications but only oversee their self-administration by waiver participants, select the "not applicable" choice.

Technical Guidance

Medication error recording and reporting are important medication administration quality assurance/improvement tools. In some states, providers are required to record medication errors and report some or all errors to a state agency. In other states, providers are required to record but not report errors (in this instance, recorded errors may be reviewed during a periodic provider quality review). Medication errors include such errors as wrong dose, wrong time, wrong route, wrong medication or missed medication.

CMS Review Criteria

If applicable, the waiver specifies:

- The types of medication errors that providers must record and/or report.
- When reporting is required; the agency to which errors must be reported is specified.

Item G-3-c.iv: State Oversight Responsibility

Instructions

Specify the state agency (or agencies) responsible for monitoring the performance of waiver providers in the administration of medications to waiver participants who are unable to self-administer, how monitoring is performed and its frequency.

Technical Guidance

Here, describe how the performance of waiver providers in administering medications is monitored. If monitoring is not performed by the Medicaid agency or the operating agency (if applicable), describe how monitoring results are regularly communicated to the agency that is responsible for administering the waiver.

Monitoring may take the form of reviewing provider records or analyzing provider-reported errors. The response should indicate how frequently monitoring of medication administration is conducted. A state also may have linked the reporting of specific types of medication errors to its critical incident management system. Describe how this monitoring is designed to identify problems in provider medication administration, support remediation as appropriate and contribute to quality improvement efforts in this arena.

The response should describe how information about medication monitoring is compiled and explain how the collection of these data supports the identification of trends/patterns and the development of quality improvement strategies.

CMS Review Criteria

The waiver specifies:

- The state agency (or agencies) responsible for the on-going monitoring of waiver provider agencies' performance in administering participant medications.
- When oversight is not conducted by the Medicaid agency or the operating agency (if applicable), the process to communicate information and findings to the Medicaid agency or the operating agency.
- Monitoring methods include the identification of problems in provider performance and support follow-up remediation actions and quality improvement activities.
- How data are acquired to identify trends and patterns and support improvement strategies.

Quality Improvement: Health and Welfare

Health and Welfare

The State demonstrates it has designed and implemented an effective system for assuring waiver participant health and welfare.

The State demonstrates on an ongoing basis that it identifies, addresses and seeks to prevent instances of abuse, neglect, exploitation and unexplained death.

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.

State policies and procedures for the use or prohibition of restrictive interventions (including restraints and seclusion) are followed.

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.

Instructions

The QIS must describe how the state Medicaid Agency will determine that each waiver assurance (and its associated component elements) is met. The waiver assurance is listed above. For each assurance, this description must include:

- Activities or processes that are related to *discovery and remediation*, i.e., review, assessment or monitoring processes; who conducts the discovery or remediation activities and with what frequency. These monitoring activities provide the foundation for quality improvement by generating information regarding compliance, potential problems and individual corrective actions. The information can be aggregated and analyzed to measure the overall system performance in meeting the waiver assurances. The types of information used to measure performance, should include relevant quality measures/indicators.
- The entity or entities responsible for reviewing the results (data and information) of discovery and remediation activities to determine whether the performance of the system reflects compliance with the assurances; and,
- The frequency at which system performance is measured.

Technical Guidance

This QIS element focuses on *discovery* and *remediation* activities, that is, processes to assess, review, evaluate or otherwise analyze a program, process, operation, or outcome. Specifically, the evidence produced as a result of discovery and remediation activities should provide a clear picture of the state's compliance in meeting an assurance.

CMS Review Criteria

- The discovery of compliance with this assurance and the remediation of identified problems must address:
    - How the Medicaid agency assures compliance with the following health and welfare assurance:

      The state, on an on-going basis, identifies, addresses, and seeks to prevent the occurrence of abuse, neglect and exploitation.

    - How frequently oversight is conducted; and
    - The entity (or entities) responsible for the discovery and remediation activities.