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 Waiver Agency or DHCS will act on and document all reported or observed critical events or issues that may affect the health, safety, and/or welfare of waiver participants or their service/care providers as they are discovered. Critical events or incidents are incidents of participant abuse, (verbal, sexual, physical, or mental) or neglect, incidents posing an imminent danger to the participant or service/care providers, fraud or exploitation (including misuse of participant's funds and/or property), or a dangerous physical environment. The Waiver Agency or DHCS provides instruction to the participant, legal representative/legally responsible adult(s), and members of the circle of support annually on how to report events or issues that affect or can affect the health, safety, and welfare of the waiver participant.

The Waiver Agency or DHCS will use the Event/Issue Report form to document concerns or problems expressed by the participant, legal representative/legally responsible adult(s), service/care providers, and/or circle of support. If an event/issue is observed by a waiver provider it must be reported to the Waiver Agency or DHCS within 48 hours. The report will be documented in the participant's case record and an Event/Issue Report will be completed.

The Event/Issue Report form includes:

- A description of the event or issue (the who, what, when, and where);
- Who reported the event or issue;
- All of the State and local agencies, the participant's current primary care physician, and law enforcement agencies that were notified and when;
- The plan of action to address/resolve the event or issue (who, what, when); and
- The resolution, and the date the issue was resolved.

The Event/Issue Report form will be updated to document the resolution of the event/issue.

Incidents of possible abuse, neglect, or exploitation require the Waiver Agency to report the incident immediately to the appropriate local or State agencies and to DHCS within 48 hours. The Waiver Agency and DHCS will adhere to the Health Insurance Portability and Accountably Act of 1996 to protect the participant's Personal Health Information is protected. The Waiver Agency or DHCS is responsible for documenting the referral in the participant's case record, including the agency and the name of the person(s) who received the referral and the person(s) responsible for conducting the investigation. Referrals are made to the following agencies:

- · APS;
- · CPS;
- · Local law enforcement; and
- · Appropriate licensing agencies.

The Event/Issue Report form is used to communicate with the CDPH, L&C on events/issues affecting participants that are related to HHAs, pediatric day health care (PDHC) providers, CLHFs, ICF/DD-CNs and CHHAs. L&C will determine if the provider is in compliance with the California Health and Safety Code §1736-1736.7 (CHHA), 1760-1761.8 (PDHC), 1250(i) (CLHF) and 1250(m) (ICF/DD-CN). After the Waiver Agency consults with DHCS, DHCS forwards the completed confidential Event/Issue Report to L&C with a request that L&C investigate when there has been:

- Failure by the waiver provider to report abuse or neglect of a waiver participant. L&C will also notify the appropriate local or State agencies.
- Failure to notify the participant's current primary care physician of a change in the participant's condition, if the participant is harmed by the failure of this action.
- Failure to inform the participant and legal representative/legally responsible adult(s) of the participant's "Patient Rights";
- Failure to comply with the participant's "Patient Rights";
- Failure to complete the appropriate documentation and/or notify the participant's current primary care physician of an incident:
- Failure to provide services or supplies included in the POT, ordered by the participant's current primary care physician, and that the provider agreed to provide;
- Inadequate or inappropriate evaluation of the participant's needs (e.g., weight loss not assessed);
- Inadequate notification to the participant when services or supplies are changed or terminated; and,
- Failure to act within a professional's scope of practice.

The participant's case record is updated to document the event/issue resolution and closure, along with L&C actions and/or recommendations. During L&C's investigation, the Waiver Agency or DHCS will continue to work with the waiver providers, the participant's current primary care physician, the participant, the participant's legal representative/legally responsible adult(s), and/or circle of support, to confirm that the participant receives needed services and can continue to reside safely in the home.

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.

The Waiver Agency or DHCS is responsible for informing and discussing how to identify and report issues of abuse, neglect or exploitation that impact the health, safety, and welfare of the participant, with the participant, legal representative/legally responsible adult(s), and/or members of the circle of support. The Waiver Agency or DHCS discusses the different types of abuse, neglect, or exploitation with the participant, as well as and how to recognize if any of these occur and whom to contact to report such events/issues.

Each waiver participant, their current primary care physician, and all waiver service providers receive the "Informing Notice" that includes a description of the roles and responsibilities of the participant, caregivers, the participant's current primary care physician, and the waiver service provider(s). It also includes information on how to notify the Waiver Agency or DHCS if there are any issues or concerns that may impact the safety, health, and welfare of the participant.

The CMT evaluates the participant for issues of abuse, neglect, and exploitation during the initial face-to-face visit, or telehealth session conducted in accordance with DHCS' telehealth policies for Medicaid State Plan services, and at each reevaluation visit, or telehealth session. The CMT is required to provide the participant, legal representative/legally responsible adult(s), primary caregiver, and/or members of the participant's circle of support with information on what constitutes abuse (physical, mental and emotional), neglect, and exploitation, and how to report these issues. The CMT documents these steps in the participant's CMR as well as any actions taken.

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.

When an event/issue is observed by, or reported to, the waiver provider, the provider has the responsibility to notify the Waiver Agency or DHCS, and if applicable, other agencies (CPS, APS, or law enforcement). When an event/issue is identified by, or reported to, the Waiver Agency or DHCS, the Waiver Agency or DHCS will complete an Event/Issue Report form. The report is designed to document:

- Who the report is from, the type of event or issue;
- The date and time of the event/issue, if applicable;
- The location of the incident (participant's home, etc.);
- Details of the event;
- · Involved parties;
- The source of the information;
- Individuals who have first-hand knowledge of the event;
- · Whether the participant's current primary care physician was notified; and
- The name, address and phone number of the participant's current primary care physician and any other agencies or individuals that were notified.

The specific nature of an event or issue will determine if notification of others is warranted, e.g., CPS, APS, California Children's Services, Regional Center, law enforcement, and/or CDPH, L&C. Any contact made with other agencies or individuals will be kept confidential as required by law.

The Waiver Agency will discuss the issues with DHCS and develop a plan of resolution. All plans developed to resolve identified problems are thoroughly evaluated by DHCS to verify they are appropriate, will result in a resolution amenable to the participant and/or legal representative/legally responsible adult(s), and will protect the participant's health, safety, and welfare. All contact made by the Waiver Agency or DHCS with a waiver provider, the participant's current primary care physician, the participant and/or the legal representative/legally responsible adult(s) related to the identified event/issue are confidential and clearly summarized and documented in the participant's case record by the Waiver Agency or DHCS. The Waiver Agency or DHCS will continue to follow-up with the waiver provider(s), the participant's current primary care physician, the participant, and, if appropriate, the legal representative/legally responsible adult(s), and other agencies, for resolution. The Waiver Agency or DHCS will keep the participant and/or legal representative/legally responsible adult(s) informed of the progress of the investigation and will continue to follow-up until the issue is resolved. If the issue is not resolved within 30 days, the Waiver Agency will discuss the issue(s) with DHCS and develop an alternative plan for resolution.

In the event a significant incident occurs, jeopardizing the health, safety, and/or welfare of the participant while under the care of a waiver provider, the waiver provider shall submit written documentation to the Waiver Agency or DHCS for review. The waiver provider and the Waiver Agency or DHCS will act immediately on any report of incidents placing the waiver participant or the provider in immediate or imminent danger, including contacting local law enforcement (when the event/issue is abuse, neglect, and/or exploitation), and/or APS or CPS, as applicable, and as required by law. Upon learning of or observing such events, the Waiver Agency will immediately fill out an Event/Issue Report and notify DHCS within 48 hours. When a determination has been made that other agencies or entities need to be involved in the response to, and resolution of, the event/issue, the Waiver Agency or DHCS will immediately contact the appropriate agency and provide the necessary information and documentation to assist in the investigation. The Waiver Agency will continue to follow-up with the appropriate agency, continue to update the Event/Issue Report and the participant of the situation and notify DHCS. When a waiver participant is in eminent threat of abuse or neglect, the CMT will talk to family members and arrange to remove the waiver provider immediately.

If it is proven that a waiver participant suffered an instance of abuse at the hands of a community-based facility, the facility will receive a notice of temporary suspension. DHCS will coordinate the temporary suspension and removing the waiver participant from the facility with A&I as DHCS will continue to pay the facility to care for the participant up to one month after the initiation of the temporary suspension. The CMT will identify an alternate placement location and will work in coordination with DHCS to move the Waiver participant within 30 days. During this 30-day period, the CMT will continue to work with the Waiver providers, the participant's current primary care physician, the participant and her/his legal representative, and circle of support to verify that the participant receives their medically necessary services. Immediate removal can be actuated if there is imminent danger to the participant. DHCS can effect immediate removal by working in coordination with the Waiver Agency, APS/CPS and the local Ombudsman to identify a safe placement. This placement may be temporary until an alternative permanent safe residence is identified. The CMT will continue to visit the participant in the facility to monitor their safety throughout the transition process.

The Waiver Agency or DHCS tracks events/issues referred to CDPH, L&C follows up with the participant and/or legal representative/legally responsible adult(s) to make sure the issue has been resolved and there is no longer any risk to the participant's health, safety, and welfare.

If a Waiver Agency is notified of the critical incident that occurred in a facility the Waiver Agency has contracted with, it is Waiver Agency's responsibility to complete an Event/Issue Report form, report immediately to the appropriate local agency, and report to DHCS by email or in writing within two business days or as soon as possible. The Waiver Agency will include the critical incident in the quarterly report sent to DHCS. If DHCS was notified of the critical incident in a place where there was no Waiver Agency, then DHCS will document the incident and report to pertinent department as warranted, such as CPS, law enforcement, L&C, etc.

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.

DHCS is the single state agency responsible for overseeing critical incidents. DHCS utilizes a process for tracking the reporting, documentation, remediation, and outcome of critical incidents. DHCS is responsible for the oversight of critical incidents where there is no Waiver Agency. In places where there is a Waiver Agency, it is the responsibility of the Waiver Agency to oversee, report, and respond to critical incidents.

In areas where there is no Waiver Agency, DHCS is responsible for the oversight of critical incidents. Critical incidents and events are reported to DHCS by the HCBA Case Manager or other HCBA Waiver provider. DHCS logs all critical incidents/events into the MedCompass database along with all follow up that is conducted until a resolution is met. DHCS is able to track the performance and outcomes through this database for reporting purposes.

In areas where there is a Waiver Agency, the Waiver Agency will report to DHCS within 24 hours and will include the incident in the QPR. During the annual audit, DHCS conducts case record reviews to determine: 1) if the case manager staff are completing and submitting the event report for all events that may or are affecting the participant's health and safety; 2) if an appropriate action plan was developed and the outcome of the action plan; 3) if systemic program issues exist that require remediation.

The Waiver Agency shall identify any reported incidents of abuse or neglect since the initial assessment or last reassessment. The Waiver Agency will complete the Event/Issue Report form and document it in the waiver participant's case file. Documentation must include a description of the event, who reported the event, who was notified, the action plan to address the event or issue, the resolution plan and the date of the resolution. The data will be used to identify trends or reoccurring issues, document the number of issues experienced by participants enrolled in the Waiver, document actions taken by DHCS and other involved entities, and document the outcomes of the actions. Waiver Agencies will have a program to track waiver participants and incident reports. DHCS will follow up with the Waiver Agency to monitor remediation and prevention of further similar events. Waiver Agencies will report critical incidents and issues in the Quarterly Utilization Report.

California's CPS and APS programs have primary responsibility to resolve reported events/incidents of abuse, neglect and/or exploitation. In the event that CPS or APS does not take timely and appropriate action, Waiver Agencies will notify local law enforcement if the issue continues. APS and CPS conduct investigations independently from DHCS and according to their own timeline. Their timeframe and processes for informing necessary parties of the results of any investigations, including the Medicaid agency are on an as requested basis. When CPS, APS, and/or local law enforcement are involved, the Waiver Agency is required to continue to monitor the Waiver Participant's health and safety to confirm the issues have been resolved.

Annual reviews along with quarterly reports are used to document reported critical incidents or events, the follow-up and the outcomes. The Waiver Agency or DHCS will keep the participant and the legal representative/legally responsible adult(s) informed of the progress of the investigation and will continue to follow-up until the issue is resolved. If the issue is not resolved within 30 days, the Waiver Agency will discuss the issue(s) with DHCS and develop an alternative plan for resolution. DHCS tracks and analyzes data submitted which includes; who the report is from, the type of event or issue, the date and time of the event/issue, the location of the incident, details of the event, involved parties, the source of information, individuals who have first-hand knowledge of the event, if the participants current primary care physician was notified and the name, address and phone number of the participant's current primary care physician and any other agencies or individuals that were also notified, to verify that the monitoring of remediation activities of all critical incidents and events are resolved.

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.)

O 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:

and G-2-a-ii.

• • • • • • • • • • • • • • • • •	The use of restraints is permitted during the course of the delivery of waiver services	Complete Items G-2-2-i

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 Waiver Agency or DHCS is responsible for monitoring and ensuring the health, safety, and welfare of waiver participants. This is accomplished through initial, scheduled, or unscheduled home visits by the CMT and/or via synchronous video conferencing contact with the participant, the participant's legal representative/legally responsible adult(s), waiver providers, and participant's current primary care physician. If the CMT observes or learns that restraints are being used, an Event/Issue Report form must be completed.

The Waiver Agency or DHCS must determine:

- 1. Whether the use of restraints is ordered by the participant's current primary care physician;
- 2. If a plan with criteria for the use and monitoring of restraints is documented in the participant's POT; and
- 3. If the plan is being followed by the caregivers and/or providers.

The use of physical restraints must be supported by a specific assessed need and justified in the person-centered service plan. The following requirements must be documented in the person-centered service plan:

- A. Identify a specific and individualized assessed need.
- B. Document the positive interventions and supports used prior to any modifications to the person-centered service plan.
- C. Document less intrusive methods of meeting the need that have been tried but did not work.
- D. Include a clear description of the condition that is directly proportionate to the specific assessed need.
- E. Include a regular collection and review of data to measure the ongoing effectiveness of the modification.
- F. Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.
- G. Include informed consent of the individual.
- H. Include an assurance that interventions and supports will cause no harm to the individual.

The Waiver Agency or Case Manager will be trained on the above requirements and must document when the training was done in a format acceptable to DHCS. Training should be reviewed annually and documented in a participant's case file.

Physical restraints may be used when they are "immediately necessary to prevent a resident from injuring themselves or others and/or to prevent the resident from interfering with life-sustaining treatment, and no other less restrictive or less risky interventions exist." CMS Memorandum S&C-07-22, June 22, 2007

Practices to protect the participant's health and safety during the use of physical restraints in the home include the use of alternative interventions prior to the use of restraints and strict adherence to the restraint protocol defined in the POT.

Waiver Agencies shall maintain policies and procedures regarding provider use of restraints that reflect regulatory compliance and include provider training requirements.

The CMT is responsible for adequately training the providers/caregivers in the home about the application and monitoring of physical restraints. The adequacy of the training may be verified through home visits to observe the participant, evaluate caregiver competency and review the POT. In areas not covered by a Waiver Agency, the waiver case management provider will perform the role of the CMT.

The CLHF, ICF/DD-CN, or PDHC may use physical restraints only in compliance with State and Federal regulations and statutes. The Waiver Agency or DHCS will confirm that the CLHF, ICF/DD-CN, or PDHC facility maintain internal policies and procedures that include staff education and training in the administration and monitoring of restraints. If a facility does not meet this requirement, the CLHF, ICF/DD-CN, or PDHC facility will not be permitted to serve as Waiver providers.

If the Waiver Agency or DHCS has determined that physical restraints used for a participant living in their home is appropriately authorized, but the POT does not address preventative interventions, the Waiver Agency or DHCS will assist the participant/legal representative and/or caregiver to identify alternative methods specific to the participant for inclusion in the POT and as ordered by the physician. The Waiver Agency shall maintain policies and procedures regarding provider use of restraints that reflect regulatory compliance.

Unauthorized use of restraints by an HHA, PDHC, CLHF or ICF/DD-CN is reported to and sanctions are imposed by the appropriate authorities to include CDPH, APS, CPS, and law enforcement. Sanctions regarding the use of unauthorized restraints in licensed facilities are imposed by CDPH per investigative findings and may include deficiencies, fines, or termination from Medicare and Medical programs. In the event unauthorized restraints in a facility has been identified, the Waiver Agency or DHCS will assist waiver participants and/or authorized representative to arrange for appropriate alternative placement. If there are additional Waiver participants remaining at the facility, DHCS shall take action to make certain that the remaining participants are not subject to the unauthorized use of restraints. Actions taken by DHCS could include but are not limited to; unannounced site visits, requiring the facility to submit a CAP, suspension of new enrollments, and suspension of the provider and transitioning all remaining waiver participants to other appropriate settings.

The unauthorized use of restraints in the home are reported to APS, CPS, and/or law enforcement.

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:

If the Waiver Agency or DHCS determines that the participant's current primary care physician has not authorized the use of restraints, or the use of the restraints is not in compliance with the POT, the appropriate law enforcement agency, and/or APS or CPS be will contacted to report the incident.

Methods for detecting unauthorized and/or inappropriate use of physical restraints include observation and inquiry regarding the use of restraints during initial, scheduled, or unscheduled home visits by the CMT and/or via synchronous video conferencing contact with participants, legal representative/legally responsible adult(s), waiver providers and participant's current primary care physician. The CMT verifies that all requirements are followed through observation and interaction with the participant, if possible, review of the POT and evaluation of caregiver competency. In areas not covered by a Waiver Agency the waiver case management provider will perform the role of the CMT.

Methods for detecting unauthorized and/or inappropriate use of physical restraints in a CLHF, ICF/DD-CN, or PDHC facility and ensuring that all state requirements are followed include scheduled or unscheduled facility visits, observation of participant, discussions with assigned staff, medical record and policy and procedure review.

All serious incidents are reported to DHCS where they are reviewed and logged. DHCS has developed an internal tracking system in which incidents are recorded, along with information about the participant and the provider. By tracking this information DHCS is able to identify trends of incidents at all levels and prevent re-occurrences. During the annual audit, DHCS compares what is received in incident reports to what is on file with the providers to verify the State was informed of all incidents. If there is a discrepancy, DHCS may issue a letter of finding to the provider.

Data is collected during the yearly audit of participant and provider files. It is then aggregated in a spreadsheet, which allows for DHCS to identify trends and patterns among providers and participants based on performance measures. The trend/pattern analysis will enable DHCS to identify deficiencies for correction and to identify and take the necessary action(s) to prevent re-occurrences and create improvement strategies. MedCompass will include capacity to establish an audit schedule for incident reporting which will include a flag for completing trend analysis on reports received.

The Waiver Agency or DHCS shall report the unauthorized use of restraints by an HHA, PDHC, CLHF or ICF/DD-CN will also be reported to CDPH, L&C to investigate and follow up on their findings. The Waiver Agency and DHCS are responsible for monitoring CDPH, L&C's investigation and findings.

- 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 Waiver Agency, or DHCS where there is no Waiver Agency, is responsible for monitoring the health, safety, and welfare of Waiver participants. This is accomplished through initial, scheduled, or unscheduled home visits by the CMT and/or via synchronous video conferencing with the participant, their legal representative/legally responsible adult(s), service providers, and the participant's current primary care physician. If the Waiver Agency or DHCS observes or learns that restrictive interventions are being used without authorization, an Event/Issue Report form must be completed, and APS, CPA, and/or the appropriate law enforcement agency will be contacted to report the event. Unauthorized use of restrictive interventions by an HHA, PDHC, CLHF, or ICR/DD-CN will also be reported to CDPH, L&C for investigation and follow-up The Waiver Agency and DHCS are responsible for tracking CDPH, L&C's investigation and findings.

- O 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.
 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:

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 Waiver Agency, or DHCS in areas of the state without a Waiver Agency, is responsible for monitoring the health, safety, and welfare of Waiver participants. This is accomplished through initial, scheduled, or unscheduled home visits by the CMT or HCBA Case Management Provider, and/or via synchronous video conference sessions with participants, their representative/legally responsible adult(s), waiver providers, and the participant's current primary care physician. If the waiver provider, the Waiver Agency, or DHCS observes or learns that seclusion is being used, the Waiver Agency or DHCS shall complete an Event/Issue Report form and notify APS, CPS, and/or the appropriate law enforcement agencies. The Waiver Agency or DHCS shall also report the unauthorized use of seclusion by an HHA, PDHC, CLHF or ICR/DD-CN, to CDPH, L&C for investigation and follow-up. The Waiver Agency and DHCS are responsible for tracking the outcomes of CDPH, L&C's investigation and findings.

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

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).
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:

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.

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

- a. Applicability. Select one:
 - O 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.

CLHF and ICF/DD-CN are responsible for managing the medication for Waiver participants residing in their community-based facility, unless the participant's current primary care physician has submitted an order for the participant to self-manage their medications.

A RN employed by the CLHF or ICF/DD-CN is required to complete an initial assessment of the participant that includes a review of the participant's prescribed medications to develop a medication management plan, which must re-evaluated/updated, as necessary, based on the participant's changing medication needs and the participant's current primary care physician orders. The RN documents the start date, stop date, dosage, and scheduled times of each medication to be provided.

Waiver participants residing in a CLHF or ICF/DD-CN may keep and take their own medications when authorized to do so by their current primary care physician. For those who need help with self-administration the CLHF or ICF/DD-CN staff will assist participants with self-administration or administer medications in accordance with their license, and as necessary.

CDPH makes, at a minimum, annual visits to the CLHF and ICF/DD-CN facilities. The Waiver Agency or DHCS also make annual visits. Regional Center staff visit the ICF/DD-CN facilities every 6 months. During these visits, each of these entities has both the authority and responsibility to monitor medication regimens and verify that the participants are receiving the correct, therapeutic medications as ordered and scheduled. This is achieved by reviewing the participant's current primary care physician's orders and the medication records. DHCS and the Waiver Agency document and address findings of potentially harmful practices with the CLHF or ICF/DD-CN and verify if appropriate corrective action was taken during a follow-up visit and/or subsequent program compliance review.

Medication management and administration monitoring is designed to detect potentially harmful practices through ongoing onsite review and evaluation of medication related policies, procedures, documentation and clinical practices. Monitoring is conducted by CDPH, Regional Centers, DHCS, and the Waiver Agency.

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.

State oversight is provided by CDPH at annual provider visits.

The Waiver Agency or DHCS performs extensive client chart reviews at annual provider visits and situations that include potentially harmful practices receive the appropriate follow-up. The Waiver Agency or DHCS, as well as licensed nursing staff of the CLHF or ICF/DD-CN residence, are trained to identify the concurrent use of contraindicated medications. If appropriate follow-up has not occurred, the Waiver Agency or DHCS provides education and training on corrective actions to handle such situations in the future. At subsequent program compliance reviews, the Waiver Agency or DHCS will follow-up regarding previous findings to verify that necessary changes have occurred and continue to be applied, and that corrective actions protect the participant's health and welfare. Through these reviews, the Waiver Agency or DHCS assesses and evaluates the regular management of participant medications by qualified nursing staff at the CLHF or ICF/DD-CN.

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:
 - O 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).

Only a licensed nurse (RN or LVN) may administer a medication.

Unlicensed CLHF or ICF/DD-CN staff have the ability to assist Waiver participants by passing medications or opening syringes, and handing them to the participant; however, the participant must have the ability to self-administer the medication, or the services of an LVN or RN are required. This requirement is enforced by CDPH and DHCS.

Under the HCBA Waiver, the CLHF and ICF/DD-CN are required to have skilled nursing staff sufficient to meet the skilled nursing needs of all waiver participants. If the participant is unable to take medication without assistance, the CLHF or ICF/DD-CN is responsible for providing the licensed nurse, as needed.

The Waiver Agency or DHCS works with the CLHF or ICF/DD-CN nursing staff to confirm that persons responsible for the administration of medications are trained to provide appropriate medication management and client education. The Waiver Agency or DHCS documents any findings of harmful and/or noncompliant practices which are found and follows up with DHCS with their plan for resolution and tracks remediation efforts to improve program performance. The Waiver Agency, DHCS, and CDPH reviews the following:

- · Medication storage;
- · Self-administered medications;
- Medication procedures;
- Medication documentation;
- · Scheduled and controlled drugs, usage, and storage; and
- PRN medications, usage, and disposal.

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:

DHCS and CDPH make, at a minimum, annual visits to the CLHF and ICF/DD-CN. During these visits, DHCS and CDPH have the authority and responsibility to monitor medication regimens and confirm that the participants are receiving the correct, therapeutic medications as ordered and scheduled. This is achieved by reviewing the participant's current primary care physician orders and the medication records.

CLHF and ICF/DD-CN waiver providers must have skilled nursing staff (RN or LVN) in the residence at any time a participant is present. The skilled nursing staff is responsible for medication administration.

CLHF and ICF/DD-CN providers are required to document all medication errors and report the errors that constitute a risk to participant health and safety to the Waiver Agency or DHCS. The report must include information regarding the medication, the error, and the outcome to the extent that it is known at the time of the report.

In the event a participant self-administers medication in error, the CLHF or ICF/DD-CN RN will follow facility policies and procedures for clinical assessment and physician reporting.

Recordable medication errors include but are not limited to, errors in administration of a controlled substance, administration of a drug to which the participant has a known allergy, omission of a prescribed drug, accidental administration of a drug without a physician's order, drugs administered in the wrong dosage, at the wrong time or by the wrong route of administration.

Reportable medication errors include but are not limited to, errors in administration of a controlled substance, administration of a drug to which the participant has a known allergy, omission of a prescribed drug, and accidental administration of a drug without a physician's order and drugs administered in the wrong dosage. Medications administered at the wrong time or by the wrong route of administration may or may not be reported depending upon the risk of harm to the participant.

The Waiver Agency or DHCS documents any findings of harmful and/or noncompliant practices, follows up with the CLHF or ICF/DD-CN to obtain a plan for resolution, and tracks remediation efforts to improve program performance. Immediate actions taken by DHCS to remediate the issue could include but are not limited to: having the facility submit a CAP, suspending new enrollments, requiring the updating of internal policies and procedures, requiring additional staff training, conducting additional onsite visits, etc.

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

Medication errors that occur when a participant is under a provider's care, including those where the provider is assisting the participant to self-administer.

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

Medication errors that constitute a risk to the participant's health and safety and occur when a participant is under a provider's care, including those where the provider is assisting the participant to self-administer.

O 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:

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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.

Medication errors are reported to the Waiver Agency, DHCS and CDPH for follow-up at least quarterly.

During the annual audit, DHCS reviews the Medication Administration Record (MAR) along with the physicians orders associated with all waiver participants. If there is a discrepancy or an error, the State notates it in their findings and issues a letter of findings with a request for a CAP. Once a CAP is received from the provider and is approved by DHCS, a follow up visit is conducted by DHCS to verify that remediation of the issue has occurred. Upon DHCS' verification of remediation, the CAP is lifted.

All medication errors that are reported to DHCS are logged and reviewed. DHCS has developed an internal tracking system to record the incident along with information about the participant and the provider. By tracking this information DHCS is able to identify trends of incidents at all levels and prevent re-occurrences.

Information that is required when submitting this information to DHCS includes information regarding the medication, the error, and the outcome of the incident, to the extent that it is known at the time of the report. DHCS is able to review and aggregate this data for reporting purposes. Medication errors are reported to the Waiver Agency, DHCS and CDPH for follow-up at least quarterly. Overall performance is aggregated on a yearly basis for purposes of reporting in the 372 Report.

Appendix G: Participant Safeguards

Quality Improvement: Health and Welfare

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

a. Methods for Discovery: Health and Welfare

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

i. Sub-Assurances:

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

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:

and % of HCBA Waiver Event/Issue Reports that are appropriately documented in the event/issue tracking system. Numerator: Number of Event/Issue Reports that are appropriately documented in the event/issue tracking system / Denominator: Total number of cases reviewed.

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

Responsible Party for

collection/generation (check each that applies):	(check each that applies):		
State Medicaid Agency	☐ Weekly		⊠ 100% Review
Operating Agency	☐ Monthl	y	Less than 100%
□ Sub-State Entity	□ Quarterly		Representative Sample Confidence Interval =
Other Specify: Waiver Agency	X Annual	ly	Stratified Describe Group:
	Continuously and Ongoing		Other Specify:
	Other Specify:		
Data Aggregation and Ana	lysis:		
Responsible Party for data aggregation and analysis (check each that applies):			f data aggregation and k each that applies):
X State Medicaid Agency		□ Weekly	
Operating Agency		☐ Monthly	7
Sub-State Entity		Quarter	ly
Other Specify:		Annuall	у

Frequency of data

collection/generation

Sampling Approach

(check each that applies):

Responsible Party for data aggregation and analysis (that applies):		Frequency of data aggregation and analysis(check each that applies):		
		☐ Continu	ously and Ongoing	
		Other Specify:		
Performance Measure: # and % of case records documenting that the CMT has discussed recognizing instances of abuse, neglect, or exploitation with the participant, family, and/or cir of support. Numerator: Number of case records documenting the participant/family/circle of support have been informed to recognize instances of abuse, neglect or exploitation / Denominator: Number of case records reviewed.				
Data Source (Select one): Record reviews, on-site If 'Other' is selected, specify	;			
Responsible Party for data collection/generation (check each that applies):	Frequency o collection/ge (check each t	neration	Sampling Approach (check each that applies):	
State Medicaid Agency	□ Weekly		☐ 100% Review	
Operating Agency	☐ Monthl	у	∠ Less than 100% Review	
☐ Sub-State Entity	□ Quarter	rly	Representative Sample Confidence Interval =	
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▼ Other Specify: Waiver Agency	Annual Annual	ly	☐ Stratified Describe Group:	
5	☐ Continu	ously and	Other	
	Ongoin	g	Specify:	

	Other Specify:			
Data Aggregation and Analysis: Responsible Party for data aggregation and analysis (check each that applies):		Frequency of analysis(chec		
State Medicaid Agence	у	□ Weekly		
Operating Agency		☐ Monthly		
Sub-State Entity	☐ Sub-State Entity		ly	
Other Specify:		⊠ Annuall	y	
		☐ Continu	ously and	Ongoing
		Other Specify:		

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

Performance Measures

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

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

Performance Measure:

and % of events/issues reported to DHCS within the required timeframes identified

in the Waiver Agency Contract. Numerator: Number of of events/issues reported to DHCS within the required timeframes identified in the Waiver Agency Contract / Denominator: Number of event/incidents reported.

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

Responsible Party for data collection/generation (check each that applies):	Frequency o collection/ge (check each t	neration	Sampling Approach (check each that applies):		
State Medicaid Agency	□ Weekly		X 100% Review		
Operating Agency	☐ Monthly	y	Less than 100%		
□ Sub-State Entity	☐ Quarterly		Representative Sample Confidence Interval =		
Other Specify: Waiver Agency	⊠ Annually		Stratified Describe Group:		
	Continu Ongoin	ously and	Other Specify:		
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Data Aggregation and Ana	Data Aggregation and Analysis				
Responsible Party for data aggregation and analysis (check each that applies):			f data aggregation and k each that applies):		
X State Medicaid Agency		□ Weekly			

Responsible Party for data

aggregation and analysis (check each that applies):		analysis(check each that applies):		
Operating Agency		☐ Monthly		
Sub-State Entity		Quarter	ly	
Other Specify:		⊠ Annuall	y	
		Continu	ously and Ongoing	
		Other Specify:		
obligations. Numerator: Nu	umber of even uthorities, in a Total numbe t reports	its/issues appr accordance wi	ith state mandated reporting	
Responsible Party for data collection/generation (check each that applies):	Frequency o collection/ge (check each t	neration	Sampling Approach (check each that applies):	
State Medicaid Agency	□ Weekly		⊠ 100% Review	
Operating Agency	□ Monthl	y	Less than 100% Review	
□ Sub-State Entity	□ Quartei	rly	Representative Sample Confidence Interval =	
Other Specify:	Annual	ly	Stratified Describe Group:	

Frequency of data aggregation and

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	U Quarter	ly
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	Ongoin Other Specify:	Specify: Specify:

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

Performance Measures

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

For each performance measure, provide information on the aggregated data that will enable the State to

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

Performance Measure:

and % of incidents of restrictive interventions with orders from the participant's current PCP with the supporting documentation required under the waiver.

Numerator: Number of documented incidents of restrictive interventions with orders from the participant's current PCP with the required supporting documentation / Denominator: Number of documented incidences of restrictive interventions

Data Source (Select one): Critical events and incident reports

If 'Other' is selected, specify:

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

Data	Aggr	egation	and	Anal	vsis:

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:

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

Performance Measures

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

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

Performance Measure:

and % of case files documenting that the Waiver participant received an annual physical. Numerator: Number of case files with documentation indicating that the Waiver participant received an annual physical / Denominator: Number of case files reviewed

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

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

State Medicaid Agency	□ Weekly		☐ 100% Review			
Operating Agency	☐ Monthly		Less than 100% Review			
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Other Specify: Waiver Agency	Annually		Stratified Describe Group:			
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Data Aggregation and Anal	Date 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 Agence	y	□ Weekly				
Operating Agency		☐ Monthly				
Sub-State Entity		Quarterly				
Other Specify:		Annually				
		☐ Continuously and Ongoing				
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Γ	aggregation and analysis (check each hat applies):	Frequency of data aggregation and analysis(check each that applies):	
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	mediation/Fixing Individual Problems		1 . 0
	0=	ual problems as they are discovered. Include hods for problem correction. In addition, propertion is a secure of the correction.	
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Responsible Party(check each that applies):	Frequency of data aggregation and analysis (check each that applies):
⊠ State Medicaid Agency	□ Weekly
Operating Agency	☐ Monthly
☐ Sub-State Entity	Quarterly
Other Specify:	⊠ Annually
	☐ Continuously and Ongoing

	Responsible Party(check each that applies):	Frequency of data aggregation and analysis(check each that applies):			
		Other Specify:			
 c. Timelines When the State does not have all elements of the Quality Improvement Strategy in place, provide timelines to design methods for discovery and remediation related to the assurance of Health and Welfare that are currently non-operational. No Yes Please provide a detailed strategy for assuring Health and Welfare, the specific timeline for implementing identified strategies, and the parties responsible for its operation. 					