







U.S. Department of Health and Human Services Office of Inspector General, Administration for Community Living, and Office for Civil Rights

Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight

January 2018



The Department of Health and Human Services (HHS), Office of Inspector General (OIG), provides independent and objective oversight that promotes economy, efficiency, and effectiveness in HHS programs and operations. OIG's program integrity and oversight activities are shaped by legislative and budgetary requirements and adhere to professional standards established by the Government Accountability Office (GAO), the Department of Justice (DOJ), and the Inspectors General community. OIG carries out its mission to protect the integrity of HHS programs and the health and welfare of the people served by those programs through a nation-wide network of audits, investigations, and evaluations.



The Administration for Community Living (ACL) serves as the Federal agency responsible for increasing access to community supports while focusing attention and resources on the unique needs of older Americans and people with disabilities across the lifespan. ACL's mission is to maximize the independence, well-being, and health of older adults, people with disabilities across the lifespan, and their families and caregivers. By funding services and supports provided by networks of community-based organizations and with investments in research and innovation, ACL helps make this principle a reality for millions of Americans.



The HHS Office for Civil Rights (OCR) is the Department's civil rights, conscience and religious freedom, and health privacy rights law enforcement agency. OCR's disability nondiscrimination enforcement authorities include Section 504 of the Rehabilitation Act, Title II of the Americans with Disabilities Act, and Section 1557 of the Affordable Care Act.

Joint Report









Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight

Group Home Beneficiaries Are at Risk of Serious Harm



- OIG found that health and safety policies and procedures were not being followed. Failure to comply with these policies and procedures left group home beneficiaries at risk of serious harm.
- These are not isolated incidents but a systemic problem 49 States had media reports of health and safety problems in group homes.

A Roadmap for States - Compliance Oversight Model Practices

A toolbox for better health and safety outcomes in group homes



Model Practices for State Incident Management and Investigation

- Reporting and notification
- Incident review
- ➤ Investigation
- > Corrective action and implementation
- > Trend analysis



Model Practices for State Mortality Reviews

- Identify cause and circumstances of beneficiary death
- ➤ Where warranted, take corrective action
- Identify mortality trends
- Systemic responses and evaluation of their efficacy
- Reporting



Model Practices for State Incident Management Audits

- > Assess incident reporting
- Assess response and review of incidents
- Assess investigations
- Assess corrective actions
- Assess identification and response to incident trends



Model Practices for State Quality Assurance

- Oversight of service planning and delivery
- Periodic assessment of performance
- Review network capacity and accessibility
- Compliance monitoring of requirements and outcomes

Examples

OIG Group Home Health and Safety Work

- ➤ **Objective:** To determine if group homes complied with Federal and State requirements Critical Incidents Not Reported to Investigators for reporting, recording, and detecting critical incidents in group homes
- ➤ Where we did the work: Connecticut, Massachusetts, and Maine
- Finding: OIG found serious lapses in basic health and safety practices in group homes.
- ➤ **Recommendations:** Connecticut, Massachusetts, and Maine should provide additional training, update policies and procedures, and provide access to Medicaid claims data.
- ➤ **Referrals**: OIG made multiple referrals to local law enforcement to address specific incidents of harm.



Connecticut did not report to investigators three separate critical incidents. A resident suffered from repeated head injuries that required treatment at a local hospital's emergency room. An immediate protective service order was issued for the beneficiary based on information OIG provided.

Massachusetts did not report to investigators two separate critical incidents. A resident suffered head lacerations while being restrained by the group home's aides. The resident required treatment at a local hospital's emergency room. Investigations were opened for both incidents based on information OIG provided.

OIG Reports on Group Home Health and Safety

- ➤ Connecticut Did Not Comply With Federal and State Requirements for Critical Incidents Involving Developmentally Disabled Medicaid Beneficiaries (May 2016 A-01-14-00002)
- Massachusetts Did Not Comply With Federal and State Requirements for Critical Incidents Involving Developmentally Disabled Medicaid Beneficiaries (July 2016 – A-01-14-00008)
- ➤ Maine Did Not Comply With Federal and State Requirements for Critical Incidents Involving Medicaid Beneficiaries With Developmental Disabilities (August 2017 A-01-16-00001)

Government Partnership - OIG, ACL, and OCR

- > Depth of expertise and multiple perspectives
- Developing a set of Model Practices that provide States with a roadmap for how to implement better health and safety practices, many of which are already required
- > Coordination with: DOJ, CMS, State stakeholders

Joint Report Suggestions to CMS:

CMS Guidance

Encourage States to implement compliance oversight programs for group homes, such as the Model Practices, and regularly report to CMS

CMS "SWAT" Team

Form a "SWAT" team to address systemic problems in State implementation and compliance with health and safety oversight

CMS Take Action

Take immediate action in response to serious health and safety findings in group homes, using authorities under 42 CFR § 441.304(g)

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I. EXECUTIVE SUMMARY

This joint report is issued by the U.S. Department of Health and Human Services, Office of Inspector General (OIG); Administration for Community Living (ACL); and Office for Civil Rights (OCR) to help improve the health, safety, and respect for the civil rights of individuals living in group homes. The joint report provides suggested model practices to the Centers for Medicare & Medicaid Services (CMS) and States for comprehensive compliance oversight of group homes to help ensure better health and safety outcomes. In addition, the Joint Report provides suggestions for how CMS can assist States when serious health and safety issues arise that require immediate attention.

In recent decades, the United States has seen a shift from institutional care settings to more community-based services and supports. This change is attributable to multiple factors, including a growing desire of individuals, including individuals with disabilities, to live and participate in typical communities; the increased flexibility and use of Medicaid funding for community-based, long-term services and supports; and the implementation of the Supreme Court's *Olmstead* decision. In addition, community-based settings, such as group homes, provide many individuals with greater independence, the choice to live in the community, and access to other opportunities.

Access to services that support community living is a key part of this transformation. Group homes and other residential settings that meet the requirements for home and community-based service provision as defined by the U.S. Department of Health and Human Services (HHS), CMS, are part of the spectrum of integrated options. However, individuals with developmental disabilities are at higher risk of abuse and neglect, particularly where they live (irrespective of

residential setting type), and may have little or no access to police, support services, or external advocates.²

In response to a congressional request concerning the number of deaths and cases of abuse of individuals with developmental disabilities residing in group homes, OIG performed reviews in four States. The congressional request arose in part because of a 2012

82 of the 1,361 deaths of individuals with developmental disabilities in Connecticut involved suspected abuse or neglect.

- CT OPA Report (2012)

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¹ In *Olmstead* v. *L.C.*, 527 U.S. 581 (1999), the U.S. Supreme Court established that unjustified isolation is a form of discrimination under the Americans with Disabilities Act.

² Christy J. Carroll, Efthalia Esser, and Tracey L. Abbott. *State of the States on Abuse and Neglect of Individuals with Developmental Disabilities*. North Dakota Center for Persons with Disabilities, Minot State University, 2010. Available at http://www.ndcpd.org/assets/abuse--neglect-state-of-the-state-paper.pdf. Accessed on October 18, 2017. See also OIG, *Early Alert: The Centers for Medicare & Medicaid Services Has Inadequate Procedures To Ensure That Incidents of Potential Abuse or Neglect at Skilled Nursing Facilities Are Identified and Reported in Accordance With Applicable Requirements* (A-01-17-00504). Available at https://oig.hhs.gov/newsroom/mediamaterials/2017/2017-snf.asp. Accessed on November 8, 2017. OIG identified 134 Medicare beneficiaries whose injuries may have been the result of potential abuse or neglect that occurred from January 1, 2015, through December 31, 2016. OIG also found that a significant percentage of these incidents may not have been reported to law enforcement.

report issued by the Connecticut Office of Protection and Advocacy for Persons with Disabilities (OPA) that found that 82 of the 1,361 deaths state-wide of individuals with developmental disabilities from January 2004 through December 2010 involved suspected abuse or neglect. OPA investigated 81 of those deaths. The deaths involved individuals with injuries such as broken bones; safety issues such as choking incidents and burns associated with scalding; car accidents involving unlicensed drivers; and inadequate medical services at private and public group homes, State training schools, regional centers, skilled nursing facilities, and hospitals. Investigators cited abuse, neglect, and medical errors as contributing factors in these deaths.

OIG's objective in its reviews was to identify instances in which the State agencies that administer the State Medicaid program did not comply with Federal waiver and State requirements for reporting and monitoring critical incidents involving Medicaid beneficiaries with developmental disabilities who reside in group homes.

In OIG's audits of Connecticut, Massachusetts, and Maine, the State agencies did not comply with Federal

waiver and State requirements for reporting and monitoring critical incidents involving Medicaid beneficiaries with developmental disabilities. These audits found that these State agencies:

- failed to ensure that group homes reported all critical incidents,
- failed to ensure that all critical incidents reported by group homes were properly recorded,
- failed to ensure that group homes always reported incidents at the correct severity level.
- failed to ensure that all data on critical incidents were collected and reviewed, and
- failed to ensure that reasonable suspicions of abuse or neglect were properly reported.

As a result of these and similar findings, OIG began meeting regularly with colleagues in the Administration for Community Living and the HHS Office for Civil Rights. The goal was to combine these Federal stakeholders' knowledge and resources to develop comprehensive suggestions for CMS and States that would improve the health and safety of group home beneficiaries while helping maintain their independence.³ In addition, the Department of

An Example of a Group Home's Unreported Critical Incident

A group home did not report a critical incident involving a resident with developmental disabilities. This resident suffered a second-degree burn on his right shoulder that required treatment at a local hospital's emergency room. The group home's aide, while assisting the resident in taking a shower, noticed the injury. The resident's medical records noted the aide stated that the cause of the injury was unknown and the resident could not describe how he received the injury. Because the injury met the definition of a "critical incident," the group home should have reported it.

³ See Appendix E for related HHS reports and activities.

Justice (DOJ), Civil Rights Division, provided technical assistance based on its experience with incident management and quality assurance processes that help qualified individuals with disabilities live successfully in community-based settings. We also sought input from CMS and State stakeholders when developing these comprehensive compliance oversight suggested practices.

OIG, ACL, and OCR recognize there are limitations on the ability of a broad set of compliance oversight practices to fully encompass the varying and diverse legal, cultural, and regional differences of every State in the country. Accordingly, we seek to assist CMS in empowering State government partners to bring about the highest level of health and safety possible for group home beneficiaries. Our suggestions for CMS are focused on State compliance oversight practices, as well as, actions CMS can take to support States and beneficiaries when systemic and serious health and safety issues arise.

Our suggestions for ensuring group-home beneficiary health and safety involve four key compliance oversight components:

- 1. reliable incident management and investigation processes;
- 2. audit protocols that ensure compliance with reporting, review, and response requirements;
- 3. effective mortality reviews of unexpected deaths; and
- 4. quality assurance mechanisms that ensure the delivery and fiscal integrity of appropriate community-based services.

Accordingly, we developed four sets of Model Practices that address each of these key components and align with the requirements currently contained in the CMS Home and Community-Based Services (HCBS) Waiver (see HCBS waiver, Appendix G-1, Participant Safeguards: Response to Critical Events or Incidents⁴). The four Model Practices are:



Model Practices for State Incident Management and Investigation (Appendix A)

Model Practices for Incident Management Audits (Appendix B)

Model Practices for State Mortality Reviews (Appendix C)

Model Practices for State Quality Assurance (Appendix D)

⁴ Available at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/waivers/downloads/hcbs-waivers-application.pdf. Accessed on November 8, 2017.

Collectively implementing these four suggested compliance oversight components should help substantially to ensure the protection of beneficiaries' health, safety, and civil rights; the accountability of provider and service agencies; and the delivery of public services compatible with funding expectations and commitments. These elements are explained more fully in the appendices. We believe that these Model Practices provide a roadmap for States that will help them to ensure the health and safety of group home beneficiaries. States may adopt these Model Practices in whole or in part, depending on the needs of their particular State and population. Although these Model Practices focus specifically on the group home setting, many elements may apply to other noninstitutional care settings as well.

II. BACKGROUND

HHS OIG performed reviews in four States in response to a congressional request concerning the number of deaths and cases of abuse of individuals with developmental disabilities residing in group homes. The congressional request arose in part because of a 2012 report issued by the Connecticut OPA, which found that 82 of the 1,361 deaths state-wide of people with developmental disabilities, from January 2004 through December 2010, involved suspected abuse or neglect. OPA investigated 81 of those deaths. The deaths involved individuals with injuries such as broken bones; safety issues such as choking incidents and burns associated with scalding; car accidents involving unlicensed drivers; and inadequate medical services at private and public group homes, State training schools, regional centers, skilled nursing facilities, and hospitals. Investigators cited abuse, neglect, and medical errors as contributing factors in these deaths.

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Medicaid Program

The Medicaid program provides medical assistance to low-income individuals and individuals with disabilities. The Federal and State Governments jointly fund and administer the Medicaid program. At the Federal level, CMS administers the program. Each State administers its Medicaid program in accordance with a CMS-approved State plan. Although the State has

considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements.

Medicaid Home and Community-Based Services Waiver

The Social Security Act (the Act) authorizes the Medicaid Home and Community-Based Services Waiver (HCBS waiver) program (the Act § 1915(c)). The program permits a State to furnish home and community-based services that assist Medicaid beneficiaries and make it possible for them to live in the community and avoid institutionalization. There are a number of community-based residential options through which individuals with developmental disabilities can receive Medicaid-funded HCBS, depending on what is offered in a particular State's waiver. Waiver services complement or supplement the services that are available to participants through the Medicaid State plan and other Federal, State, and local public programs and the support that families and communities provide.

Medicaid permits a State to furnish an array of home and community-based services that assist Medicaid beneficiaries and make it possible for them to live in the community and avoid institutionalization.

Each State has broad discretion to design its waiver program to address the needs of specific populations targeted by the State under its HCBS waiver authority.

State agencies may administer the HCBS waivers and implement portions of the waivers through interdepartmental service agreements with other units of State government. The HCBS waiver program supports individuals who require comprehensive support services. These individuals reside either in an out-of-home setting, such as a group home, with 24-hour support or in their family or own home with additional in-home support and supervision.

States must provide certain assurances to CMS to receive approval for HCBS waivers, including that necessary safeguards have been taken to protect the health and welfare of the beneficiaries receiving services (42 CFR § 441.302). A State must provide specific information regarding its plan or process related to beneficiary safeguards, which includes whether the State operates a critical event or incident reporting system (see HCBS waiver, Appendix G-1, Participant Safeguards: Response to Critical Events or Incidents). In its waiver, a State agency generally reports that it has a critical event or incident reporting system that relies on the policies and procedures of the State Department of Developmental Services (DDS) (or a similar State agency).

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⁵ Medicaid beneficiaries eligible for waiver services can receive HCBS in group homes, host homes or adult foster care arrangements, supported living options in apartments or homes with roommates of their choosing, family homes, or privately owned individual homes owned or rented by the beneficiary. The audit conducted by OIG was confined solely to a review of reporting and monitoring actions involving individuals with developmental disabilities living in group homes.

Critical Incident Reporting for Group Homes

The classification of critical incidents in HCBS waivers varies across States and the specific population served by the waiver. The HCBS waiver may classify critical incidents as requiring either a minor or major level of review. Critical incidents requiring a major level of review generally include deaths, physical and sexual assaults, suicide attempts, unplanned hospitalizations, near drowning, missing persons, and serious injuries. Critical incidents requiring a minor level of review generally include suspected verbal or emotional abuse, theft, and property damage. For critical incidents that involve suspected abuse or neglect, the HCBS waiver and State regulations also require mandated reporting.

Critical Incidents

- Deaths
- Physical/sexual assault
- Suicide attempts
- Unplanned hospitalizations
- Near drowning
- Missing persons
- Serious Injuries

How OIG Conducted Its Reviews

OIG reviewed Federal waiver and State requirements for reporting and monitoring critical incidents involving Medicaid beneficiaries with developmental disabilities residing in group homes at selected State agencies. OIG conducted these reviews in Connecticut, Massachusetts, New York, and Maine using Medicaid claims data. OIG's audit period for this series of reviews was from 2012 to 2015. OIG's audit reports on these reviews made recommendations to the State agencies regarding improving policies and procedures.

OIG conducted these performance audits in accordance with generally accepted government auditing standards. Those standards require that audits be planned and performed to obtain sufficient, appropriate evidence to provide a reasonable basis for findings and conclusions based on audit objectives. OIG believes that the evidence obtained provides a reasonable basis for its findings and conclusions based on its audit objectives. OIG's work in this area is continuing in additional States and settings such as skilled nursing facilities. OIG will be issuing a report to CMS that consolidates findings from the individual States. The report will contain specific recommendations to CMS to help improve the program.

OIG's Findings

In OIG's audits of Connecticut, Massachusetts, and Maine, the State agencies did not comply with Federal waiver and State requirements for reporting and monitoring critical incidents involving Medicaid beneficiaries with developmental disabilities. Summaries of five of OIG's findings follow.



1. State Agencies Did Not Ensure That Group Homes Reported All Critical Incidents

Group homes in Connecticut and Massachusetts and community-based providers in Maine are required to report critical incidents to the State DDS (for Connecticut and Massachusetts) or to the State agency for Maine. OIG found that group homes and community-based providers did not report all critical incidents involving Medicaid beneficiaries with developmental disabilities. In Connecticut, of the 310 emergency room visits by 245 of these Medicaid beneficiaries, 176 visits met DDS's definition at the time of a critical incident because they included a severe injury. However, group homes did not report 24 (14 percent) of the critical incidents to DDS. In Massachusetts, group homes reported 499 (85 percent) of the 587 critical incidents treated in hospital emergency rooms. However, group homes did not report to DDS 88 (15 percent) of the critical incidents. In Maine, community-based providers reported 1,474 (66 percent) of the 2,243 critical incidents treated in hospital emergency rooms. However, community-based providers did not report to the State agency 769 (34 percent) of the critical incidents.

An Example of a Group Home's Unreported Critical Incident

A group home did not report to DDS a critical incident involving a resident with Down syndrome and dementia. The resident was encouraged to wear a helmet for protection during seizures and a gait belt when he transferred positions. The resident required one-on-one supervision while walking during a number of specified activities within the group home. The resident had an unwitnessed fall in the group home's kitchen, which was followed by a period of unconsciousness. Hospital emergency room staff evaluated the resident for a trauma to the right side of his head and face with computerized axial tomography. Because these injuries met the DDS definitions of a "critical incident" and a "severe injury," the group home should have reported the incident immediately.

An Example of a Group Home's Unreported Critical Incident

A group home did not report to DDS a critical incident involving a resident with developmental disabilities. This resident suffered a second-degree burn on his right shoulder that required treatment at a local hospital's emergency room. The injury was noticed by one of the group home's aides who was helping the resident take a shower. The aide stated that the cause of the injury was unknown and that the resident could not describe how he received the injury. Because the injury met the DDS definition of a "critical incident," the group home should have reported the incident.

An Example of a Critical Incident Not Reported by the Community-Based Provider

A community-based provider did not report to the State agency a critical incident involving a beneficiary with developmental disabilities. This beneficiary suffered a laceration of unknown origin to her left ear that required treatment at a local hospital's emergency room. The injury was a jagged laceration that required suturing to close the wound. The community-based provider's staff stated the cause of the injury was unknown and that the beneficiary could not

provide a history of the injury. Because the injury met the State agency's definition of a "critical incident," the community-based provider should have reported the incident.



2. State Agencies Did Not Ensure That All Critical Incidents Reported by Group Homes Were Properly Recorded

In Connecticut, OIG found that DDS did not record all critical incidents reported by group homes. Specifically, group homes reported 152 critical incidents to DDS, but DDS did not record 34 (22 percent) of these incidents into its incident reporting system. Because DDS did not record these incidents, the DDS Division of Investigations and OPA never received notice that these incidents occurred and, therefore, could not determine whether abuse or neglect contributed to these injuries. DDS did not enter all critical incidents into its incident reporting system because it did not always follow procedures. Furthermore, these unrecorded critical incidents were not detected because DDS did not have a way to coordinate with the State agency to detect unrecorded and unreported critical incidents.

An Example of a Critical Incident Not Recorded by DDS

A group home reported to DDS a critical incident involving a resident with developmental disabilities who used a wheelchair and had cerebral palsy and pulmonary disease. The group home's staff reported the resident was dropped while being transferred. This resident suffered a displaced fractured clavicle that required treatment at a local hospital's emergency room. Hospital staff used x-rays in their evaluation of him. Because the group home reported this incident to DDS, DDS should have entered the incident into its incident reporting system within 5 days. DDS, however, did not record the incident.



3. State Agencies Did Not Ensure That Group Homes Always Reported Incidents at the Correct Severity Level

In Connecticut, OIG found that group homes did not always correctly report to DDS emergency room visits related to severe injuries, which DDS would have treated as critical incidents. Instead, the group homes frequently reported to DDS emergency room visits as involving either minor or moderate injuries. Even though emergency room visits involving minor and moderate injuries are reportable, DDS did not treat them as critical incidents. DDS reviewed the 176 emergency room records supplied by OIG and determined that 86 (49 percent) emergency room visits originally classified by the group homes as involving either minor or moderate injuries actually involved severe injuries and would have therefore met Connecticut's definition of critical incidents. Accordingly, State agencies could not investigate these 86 critical incidents for potential abuse or neglect.

An Example of a Group Home Reporting the Incorrect Severity Level of an Injury

A group home reported injuries involving a resident with developmental disabilities, scoliosis, and spastic paralysis of all four limbs at an incorrect severity level. This resident suffered a lacerated upper lip, facial contusions, an acute cervical strain, and a fractured tooth; these injuries required treatment at a local hospital's emergency room. During the resident's

treatment, hospital staff evaluated him for additional spine and skull injuries using computerized axial tomography. The group home's staff reported that the resident was injured when he fell from a shower chair, but they also reported that they did not witness his fall. The group home reported these injuries to DDS, but it reported the severity level of the injuries as only "moderate" instead of "severe." As a result, this critical incident was not investigated by either DDS or OPA for potential abuse or neglect.



4. State Agencies Did Not Ensure That All Data on Critical Incidents Were Collected and Reviewed

In Connecticut and Massachusetts, OIG found that DDS did not review and analyze all data on critical incidents. In Connecticut, DDS reviewed medication errors quarterly, but it reviewed internal critical incident data only annually. DDS did not have a way to obtain all data regarding critical events and incidents from the State agency. Accordingly, DDS could not review relevant Medicaid claims data for injuries that required emergency room treatment or hospital admission—key elements in determining whether beneficiaries were involved with critical incidents and whether those incidents were reported and investigated within required timeframes. If DDS had access to relevant Medicaid claims data as contained in the Connecticut Medicaid Management Information System (MMIS), it could have performed a data match similar to the one OIG performed. Because it could not, DDS was unable to detect the 24 critical incidents that group homes did not report or the 34 critical incidents that group homes reported but DDS did not enter into its incident reporting system.

In Massachusetts, DDS reviewed and analyzed only the incidents that were reported by the group homes. DDS did not have a way to obtain and analyze all data regarding critical incidents from the State agency. Accordingly, DDS could not analyze relevant Medicaid claims data for injuries that required emergency room visits or hospital admissions—key elements in determining whether beneficiaries were involved with critical incidents and whether those incidents were reported and investigated within required timeframes. If DDS had access to the relevant Medicaid claims data as contained in the Massachusetts MMIS, it could have performed a data match similar to the one OIG performed. Because it could not, DDS was unable to detect the 88 critical incidents that group homes did not report.



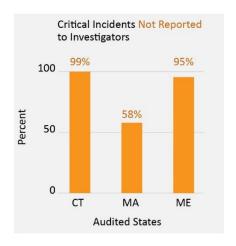
5. State Agencies Did Not Ensure That Reasonable Suspicions of Abuse or Neglect Were Properly Reported

In Connecticut, Massachusetts, and Maine, OIG found that they did not always report reasonable suspicions of abuse or neglect.

Although Connecticut group homes reported 152 critical incidents to DDS during the period of our audit, DDS did not report 151 of the 152 to OPA as potential incidents of abuse or neglect involving Medicaid beneficiaries who had developmental disabilities. OIG reported to OPA the 176 critical incidents it identified during its audit (the 152 critical incidents that DDS did not

report and 24 critical incidents that group homes failed to report). OPA stated that DDS should have reported all 176 as incidents with a reasonable suspicion of abuse or neglect. OPA then opened 24 new investigations and updated 9 ongoing investigations—33 critical incidents involving potential abuse or neglect. OPA also issued 8 immediate protective service orders involving 14 critical incidents to protect group home residents with developmental disabilities from potential harm.

In Massachusetts, of the 587 critical incidents involving Medicaid beneficiaries with developmental disabilities that occurred during the period of our review, 73 (12 percent) were reported to the Disabled Persons Protection Commission (DPPC) as potential



incidents of abuse or neglect. However, the remaining 514 (88 percent) were not reported to DPPC. OIG reported to DPPC the 514 unreported critical incidents it identified. DPPC officials stated that they believed that 102 of the unreported incidents (20 percent) should have been reported as incidents with reasonable suspicion of abuse or neglect. DPPC officials stated that 240 incidents (47 percent) did not have to be reported and that they did not have enough information to determine whether the remaining 172 incidents (33 percent) should have been reported. Therefore, OIG determined that staff of DDS and group homes did not report as required 58 percent of the 175 incidents (73 critical incidents reported to DPPC plus 102 additional critical incidents that should have been reported) that met the State's "reasonable cause to believe" threshold regarding whether a suspicion of abuse or neglect exists.

In Maine, the State agency must also immediately report the suspected abuse, neglect, or exploitation of an incapacitated or dependent adult to the appropriate district attorney's office. The State agency did not report all suspected incidents of abuse, neglect, or exploitation to the appropriate district attorney's office. During the audit period, the State agency received 15,939 critical incident reports for 15,897 individual critical incidents related to potential abuse or neglect involving 1,886 beneficiaries from community-based providers. There were no records demonstrating that the State agency reported 15,130 (95 percent) of the 15,897 critical incidents.⁶

An Example of DDS Not Reporting a Critical Incident That Had Reasonable Suspicion of Abuse or Neglect

Connecticut DDS did not report to OPA any of the three separate critical incidents that occurred in 2012 and 2013 involving a nonverbal group home resident with cerebral palsy and a history of self-injury. This resident suffered from repeated head injuries that required treatment at a local

⁶ Maine State agency staff review critical incident reports submitted to the State agency and determine if the reports should be sent to an Adult Protective Services Unit supervisor for further assessment. A State agency supervisor reviews the reports and decides whether or not the State agency will accept the reports for investigation. The "Not Accepted for Investigation" category includes critical incidents for which the State agency (1) completed an assessment but did not accept for investigation and (2) did not complete an assessment for investigation. We did not determine how many critical incidents were not assessed for investigation.

hospital's emergency room. These injuries included contusions with bruising and swelling of the head and face. This resident was evaluated with x-rays and computerized axial tomography. Because these injuries met the DDS definition of a "critical incident" and there was reasonable evidence to suspect abuse or neglect, DDS should have reported the incidents immediately to OPA. On the basis of the information OIG provided, OPA issued an immediate protective service order for this beneficiary.

An Example of DDS Not Reporting a Critical Incident That Had Reasonable Suspicion of Abuse or Neglect

Staff of the Massachusetts DDS and the group home did not report to DPPC either of two separate critical incidents that occurred in December 2013 and April 2014 involving a resident with oppositional defiance disorder and seizures. This resident suffered head lacerations that required treatment at a local hospital's emergency room. The medical records noted that the resident was injured while being restrained by the group home's aides. The resident cut her head on a bed headboard during the first incident and on a chair during the second incident. In each case, the group home submitted an incident report to DDS, but neither DDS staff nor group home staff filed a report with DPPC. Because these injuries met the DDS definition of a "critical incident" and DPPC officials stated that there was reasonable evidence to suspect abuse or neglect, DDS should have reported the incidents immediately to DPPC. On the basis of the information OIG provided, DPPC opened investigations of both incidents.

The Formation of an Interagency Group To Examine Group Home Health and Safety

As a result of these and similar findings, OIG contacted stakeholders across Government that shared our interest and concerns in the area of group-home health and safety. OIG's Federal partners shared a concern about the systemic failures identified in critical incident reporting and monitoring of incident management within group homes. The group also realized that strong incident reporting and management systems constitute a critical element of enhanced quality assurance for community-based settings. OIG began meeting regularly with its colleagues in the Administration for Community Living and the HHS Office for Civil Rights. We hoped to combine our

While this approach is unusual, we believe the magnitude of the danger for beneficiaries has warranted this effort and the joint report that has come from it.

knowledge and resources to develop comprehensive suggestions for CMS and States that would improve the health and safety of group home beneficiaries across the country. In addition, we received technical assistance from DOJ, Civil Rights Division, and sought input from CMS and State stakeholders. While this approach is unusual, we believe the magnitude of the danger for beneficiaries has warranted this effort and the joint report that has come from it.

This interagency group began meeting in August 2016 to discuss and examine how to ensure the systemic health and safety of group home beneficiaries. The group developed three suggestions for CMS. First, we developed a model for comprehensive compliance oversight through four Model Practices that address the key components of ensuring beneficiary health and safety and that align with the requirements currently contained in the 1915(c) HCBS waiver (Appendix G-1, Participant Safeguards: Response to Critical Events or Incidents). The four Model Practices are:



Model Practices for State Incident Management and Investigation (Appendix A)

Model Practices for Incident Management Audits (Appendix B)

Model Practices for State Mortality Reviews (Appendix C)

Model Practices for State Quality Assurance (Appendix D)

We believe that these Model Practices provide a roadmap for States that will empower them to ensure the health and safety of group home beneficiaries. States may adopt these Model Practices in whole or in part depending on the needs of their particular State and population. Although these Model Practices are specifically focused on the group home setting, many elements may apply to other noninstitutional care settings as well.

Second and third, we developed suggestions for actions CMS can take to support States and beneficiaries when systemic and serious health and safety problems arise in group homes. Where there is evidence of a systemic failure to implement compliance oversight for group homes, CMS should form a "SWAT" team to assist the State in addressing the problem effectively. Where there are serious health and safety findings, CMS should take immediate action, using its authorities under 42 CFR § 441.304(g) for group homes, to ensure that beneficiaries are safe.

III. KEY COMPONENTS OF HEALTH AND SAFETY COMPLIANCE OVERSIGHT

Generally, assurance of program beneficiary health and safety involves four critical components:

- 1. reliable incident management and investigation processes;
- 2. audit protocols that ensure compliance with reporting, review, and response requirements;
- 3. effective mortality reviews of unexpected deaths; and
- 4. quality assurance mechanisms that ensure the delivery and fiscal integrity of appropriate community-based services.

In turn, each of these four components of health and safety assurances must embody certain critical elements to be effective and reliable. These elements are delineated in the Model Practices presented in Appendices A through D. As noted, these practices align with existing requirements contained in the HCBS waiver (Appendix G-1, Participant Safeguards: Response to Critical Events or Incidents).

1. Reliable Incident Management and Investigation Processes

Collectively, these four compliance oversight components help ensure that beneficiary health, safety, and civil rights are adequately protected, that provider and service agencies operate under appropriate accountability mechanisms, and that public services are delivered consistent with funding expectations.

Incident management involves providing immediate and effective responses to serious incidents to protect the involved beneficiary's safety and well-being and to mitigate reoccurrence. It also involves ensuring that the facts and circumstances of serious incidents are reviewed quickly and effectively and, as warranted, investigated. It includes ensuring that trends and patterns regarding serious incidents are identified and addressed through timely implementation of effective corrective actions (e.g., additional provider and staff training focused on both quality assurance and improvement, necessary changes and reforms to specific protocols in service delivery, and enhancements to standard operating policies). It involves ensuring that appropriate governmental entities and provider and support coordination agencies receive timely notification of serious incidents, and it includes public reporting regarding the overall safety and well-being of Medicaid beneficiaries.

2. Audit Protocols That Ensure Compliance With Reporting, Review, and Response Requirements

An effective audit system of public agency and provider incident management activities involves processes to assess for timely and appropriate incident reporting, investigation, and response and for implementation of timely and appropriate corrective actions to minimize reoccurrence. It also involves assessments to determine if public agencies and providers are undertaking systemic reviews to identify and appropriately address incident trends or patterns.

3. Effective Mortality Reviews of Unexpected Deaths

An effective mortality review protocol involves timely reporting of all beneficiary deaths, including identification of the cause of death and the circumstances contributing to or associated with the death. It includes, where warranted, identification and implementation of corrective actions likely to minimize the reoccurrence of the immediate factors contributing to the death. It also includes identification of mortality trends and patterns that warrant systemic responses to reduce avoidable risks of death and other adverse outcomes. It includes the timely implementation of systemic responses and ongoing evaluation of their efficacy. And it includes periodic reporting of mortality trends and responses to ensure public reporting regarding the health, welfare, and safety of program beneficiaries.

4. Quality Assurance Mechanisms That Ensure the Delivery and Fiscal Integrity of Appropriate Community-Based Services

A comprehensive quality assurance system of community-based services includes the incident management, audit, and mortality review components discussed above and certain other elements of quality assurance. The quality assurance system includes the oversight of individualized service planning and delivery; the enhanced oversight of, and support for, high-risk beneficiaries; the assessment of the inclusion of service beneficiaries into their community; initial certification reviews of all new service providers and support coordination agencies; periodic assessments of the performance of service providers and support coordination agencies; audits of provider workforce assurances and background checks; reviews of the provider network's capacity, stability, and accessibility; assessments of the fiscal integrity of service billing and reimbursement; and compliance monitoring related to Federal fiscal and programmatic requirements.

Collectively, these four compliance oversight components help ensure that beneficiary health, safety, and civil rights are adequately protected, that provider and service agencies operate under appropriate accountability mechanisms, and that public services are delivered consistent with funding expectations and commitments. Additionally, we hope adoption and implementation of the suggested Model Practices across the four critical element areas will ultimately inform larger quality improvement efforts related to delivery of home and community-based services and the experience of beneficiaries receiving these supports to realize community-living goals.

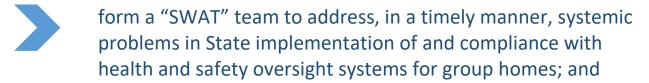
IV. CONCLUSION

OIG's audit work in this area is continuing in additional States. Media coverage and disturbing trends identified by advocacy organizations and protection and advocacy entities throughout the country continue to uncover terrible examples of abuse and neglect of Medicaid beneficiaries in group homes, nursing facilities, and hospitals.

OIG, ACL, and OCR make the following suggestions to help maintain independence, human dignity, choice, and self-determination for Medicaid beneficiaries; improve compliance with *Olmstead*; and ensure safety and a high quality of care for beneficiaries.

Based on OIG's audit work and work with the interagency group, OIG, ACL, and OCR suggest that CMS:







APPENDIX A

Model Practices for State Incident Management and Investigation

This appendix sets forth the Model Practices for State Incident Management and Investigation. As detailed below, incident management and investigation involve providing immediate and effective responses to serious incidents to protect the involved beneficiary's safety and wellbeing and to mitigate reoccurrence.

- I. Intended Outcomes of Incident Management and Investigation
- II. Participants in State Incident Management and Investigation
- III. Essential Components of State Incident Management and Investigation
- IV. Detailed Elements of the Essential Components
 - A. Reporting and Notifications
 - B. Incident Reviews
 - C. Investigations
 - D. Corrective Action Recommendations and Implementation
 - E. Trend Analysis

Attachment A: Suggested Data Elements for Incident and Investigation Database Systems

I. Intended Outcomes of Incident Management and Investigation

- A. To ensure responses to serious incidents in community-based service systems that timely and effectively resolve the immediate event/situation (i.e., protecting the safety and well-being of the individuals involved and preventing a reoccurrence);
- B. To ensure that the facts and circumstances of serious incidents are timely and effectively reviewed and investigated as required;
- C. To ensure that trends and patterns regarding serious incidents are identified and addressed with appropriate recommendations for corrective actions (including but not limited to additional provider and staff training focused on both quality assurance and improvement, necessary changes and reforms to specific protocols in service delivery, and enhancements to standard operating policies);
- D. To ensure that recommendations for corrective actions associated with serious incidents are timely and effectively implemented;
- E. To ensure that implemented corrective actions are effective in preventing or reducing the occurrence of serious incidents;

- F. To ensure that Government officials (Federal and State), provider and support coordination agencies, and designated protection and advocacy entities receive timely and effective notification of serious incidents; and
- G. To ensure public reporting related to the overall safety and well-being of individuals supported by community-based service systems and support for the quality assurance of community-living options for individuals.

II. Participants in State Incident Management and Investigation

- A. This model for State Incident Management and Investigation focuses on two main participants: service provider agencies and State officials.
- B. Other primary reporters of incidents include service recipients, family members, and friends of service recipients, as well as support coordinators and advocates. Support coordinators and support coordination agencies also have primary roles in the immediate review of reported incidents and timely responses to health and safety issues for involved service recipients. On occasion, service providers may invite these participants to contribute to discussions of particular incidents at meetings of the provider's Incident Management Review Committee. These participants can provide valuable information in many incident investigations.
- C. The Federal Government also has statutory roles of ensuring that States' incident management and investigation programs actually work as designed to ensure the accountable reporting, investigation, resolution, and prevention of serious events and situations that do or could jeopardize the health and welfare of service recipients. Additionally, the Federal Government should have the capacity to undertake independent incident investigations and audits of States' Incident Management and Investigation processes in response to State quality assurance reports, citizen complaints, and concerns that may surface in Medicaid or Medicare data. The Federal Government also has the unique capacity to identify and respond to trends in incidents and incident investigation findings across States and to use its observations to frame ongoing, needed quality improvements in the Federal regulatory framework for States' community-based service systems.

III. Essential Components of State Incident Management and Investigation

- A. Reporting and Notification
- B. Incident Review
- C. Investigation
- D. Corrective Action Recommendations and Implementation
- E. Trend Analysis

IV. Detailed Elements of the Essential Components

A. REPORTING AND NOTIFICATIONS

- 1. Service Providers
 - i. Service providers should ensure that all incidents are reported as soon as possible after discovery.
- 2. Support Coordinators and Support Coordination Agencies
 - Support coordinators and support coordination agencies should be required to report to designated State officials any instances of failed incident reporting or failed external notifications of incidents.
- 3. Service Providers and the State
 - i. Service providers and the State should ensure that individuals (including service recipients, staff, and family members) are free from retaliation or adverse consequences because they reported incidents or allegations of abuse, neglect, exploitation, or other staff misconduct or errors.
 - Service providers should ensure that failed incident reporting and delays in incident reporting result in appropriate employee discipline, including employee suspension or termination.
 - ii. The State should take assertive steps to identify patterns of failed incident reporting and delays in incident reporting by service providers. The steps should include reviews of incident reporting by service providers and support coordination agencies. These reviews should rely on cross-reference assessments of a variety of data sources (e.g., hospitalization and emergency room billing records, licensure or certification findings, grievance and complaint reports, and daily note documentation).

The State should also ensure that it imposes appropriate sanctions against such providers, including fines, suspension of permission to enroll new participants, waiver contract termination, and decertification.

- 4. Service Providers, Support Coordination Agencies, and the State
 - i. The State, service providers, and support coordination agencies should ensure safeguards are in place to protect the confidentiality

of incident reports and any databases containing incident report information.

5. The State

- The State should disseminate and ensure appropriate training of service providers and support coordinators regarding what events, situations, and circumstances constitute reportable incidents.
 Reportable incidents should include:
 - a. deaths;
 - b. allegations of physical, psychological, or financial exploitation;
 - c. allegations of physical or psychological neglect;
 - d. allegations of physical or psychological abuse;
 - e. allegations of sexual abuse;
 - f. incidents involving the inappropriate restraint or seclusion of service recipients;
 - g. events that lead to adverse consequences or outcomes to service recipients because of staff misconduct or error;
 - h. events that result in injury or illness to a service recipient requiring medical treatment beyond first aid;
 - i. choking incidents;
 - j. hospital emergency room visits where the injury or the medical condition could indicate abuse or neglect, as well as unplanned hospitalizations of service recipients;
 - k. service recipient elopements whereby the individual is removed from staff supervision or the individual is placed at risk of serious harm:
 - 1. behavioral incidents of a service recipient that result in
 (a) employee physical intervention with the service
 recipient including restraint, (b) serious risk of harm to the
 individual, other service recipients, employees, or
 community citizens, or (c) property damage valued at more
 than \$150;

- m. emergency situations, including fires, flooding, and serious property damage, that result in harm or risk of harm to service recipients;
- n. financial exploitation or theft of a service recipient's property or funds of \$25 or greater;
- o. incidents that may involve criminal conduct by service recipients or employees; and
- p. incidents involving law enforcement personnel.
- ii. The State should identify criteria for ranking incidents by seriousness of harm or potential harm to service recipients.
- iii. The State should implement policies requiring service providers to inform families or guardians and support coordinators about reported incidents as soon as possible after discovery and in all cases within 72 hours.
- iv. The State should ensure that clarification is sent to service providers of any required external incident report notifications to other State officials or agencies (including law enforcement as applicable) for certain serious incidents, including deaths, allegations of abuse and neglect, and possible criminal acts.
- v. The State should take assertive steps to identify patterns of failed or delayed external notifications of incidents by service providers and to ensure that it takes appropriate actions against such providers, including fines, suspension of permission to enroll new participants, waiver contract termination, and decertification.

6. Federal Government

i. In the context of its overall role in protecting waiver service recipients from harm, the Federal Government should ensure reviews of accountable incident reporting by States. Such reviews include Federal oversight to ensure that States are conducting credible assessments of accountable incident reporting, as well as periodic federally directed assessments of incident reporting by service providers.

B. INCIDENT REVIEWS

- 1. States should set objective criteria to ensure that for those incidents that result in significant injury, service providers ensure a preliminary review by senior management and an immediate response to all incidents within 24 hours of their discovery.
- 2. Service providers should establish Incident Management Review Committees to ensure a comprehensive review of incidents and investigation findings. Every Incident Management Review Committee should:
 - i. identify the facts surrounding incidents, including any contributing factors;
 - ii. review investigations of reported incidents;
 - iii. identify needed corrective actions or remedies to prevent or reduce the likelihood of future similar incidents:
 - iv. review and either accept or reject the recommended corrective actions from investigations and mortality reviews of incidents;
 - v. document in its official minutes all accepted recommendations and rationales for any rejected recommendations;
 - vi. ensure that recommended corrective actions or remedies are implemented in a timely and appropriate manner; and
 - vii. evaluate the outcomes of instituted corrective actions or remedies.
- 3. Service providers' Incident Management Review Committees should meet on a regularly scheduled basis (e.g., biweekly), except when none of the above-listed review activities are pending.
- 4. The State should establish a State Incident Management Review Committee, which should:
 - i. reach out to adult protective services, protection and advocacy entities, and other partners that can provide data on the number and types of incidences reported in group homes and technical assistance and subject matter expertise to the committee's deliberations:
 - ii. review particularly serious incidents (including substantiated reports of abuse and neglect and apparently preventable deaths);

- iii. review the adequacy of State and provider investigations of serious incidents in accordance with the standards specific in Section C, Investigations, below;
- iv. identify and review trends and patterns in reported incidents and the findings, conclusions, and recommendations in State investigations;
- v. review annual reports of the trends and patterns in reported incidents and State investigations;
- vi. identify and respond to State, regional, and other identified trends and patterns in incidents and State investigations; and
- vii. discuss potential systems-wide corrective actions for improving quality assurance (including but not limited to additional training of providers and State personnel; necessary changes and reforms to specific protocols in service delivery, incidence reporting, and management; and enhancements to specific policies and provider requirements).
- 5. The State Incident Management Review Committee should meet regularly to ensure its review responsibilities are carried out in timely manner. Service providers and State Incident Management Review Committees should maintain appropriate minutes of their meetings, meeting attendees, their deliberations regarding incidents, and recommendations for corrective actions.
- 6. The State should ensure comprehensive oversight of the operation of the State's Incident Management and Investigation Program, including but not limited to periodic State-conducted reviews of the incident management and investigation activities of provider and support coordination agencies, State investigators, and the State's Incident Management Review Committee.

C. INVESTIGATIONS

- 1. The State should ensure independent State investigations of:
 - i. allegations of physical or emotional abuse and neglect that result in serious or repeated harm to service recipients;
 - ii. allegations of sexual abuse;
 - iii. allegations of financial exploitation in which the goods stolen are valued at more than \$250 or thefts of lesser value occurring repeatedly;

- iv. deaths that occurred unexpectedly or that appear or are alleged to be due to provider or support coordinator misconduct, abuse, or neglect;
- v. incidents that result in potentially life-threatening or serious injury or illness that appear or are alleged to be due to provider or support coordinator misconduct, abuse, or neglect or that occurred under suspicious circumstances (e.g., repetitive ER visits, multiple uses of physical restraints per day);
- vi. incidents that result in potentially life-threatening or serious injury that were due to environmental hazards (e.g., fires, drownings, serious automobile accidents, weather emergencies); and
- vii. incidents that result in criminal charges or incarceration of service recipients or employees.
- 2. For serious incidents not described above, the State may (at its discretion) delegate the conduct of the investigations to provider or support coordination agencies or another authorized entity.
- 3. Regardless of whether incident investigations are conducted by State investigators or a delegated agency or entity, incident investigations involving allegations of physical abuse and neglect that result in death or potentially life-threatening or serious injury or illness should be completed within 14 days. When the 14-day timeframe cannot be met, the State should ensure that a designated senior State official reviews and approves timeframe extensions.

All other incident investigations should be completed within 30 days. When the 30-day timeframe cannot be met, the State should ensure that a designated senior State official reviews and approves timeframe extensions.

- 4. Regardless of whether incident investigations are conducted by State investigators or a delegated agency or entity, the State should ensure that all investigators have successfully completed a competency-based training program that meets generally accepted professional standards.
- 5. Regardless of whether incident investigations are conducted by State investigators or a delegated agency or entity, the State should develop and ensure compliance with performance standards for conducting incident investigations. Such standards should include:
 - i. a review of the person-centered service plan of the service recipient and other reported incidents in the past year;

- ii. a review of the circumstances leading up to and following the incident;
- iii. interviews with all witnesses to the incident (employees, service recipients, and community citizens);
- iv. interviews with family members or guardians of the service recipient;
- v. interviews with other relevant parties, including provider agency supervisory, management, and health care personnel and the assigned support coordinator for the service recipient;
- vi. reports of the State protection and advocacy entity related to investigations of incidences that have occurred in group home settings;
- vii. reviews of relevant documents and medical records maintained by the service provider, support coordinator, or external health care entities, including hospitals and outpatient medical providers; and
- viii. reviews of law enforcement reports, death certificates, and autopsy reports (as available).
- 6. Regardless of whether incident investigations are conducted by State investigators or a delegated agency or entity, the State should develop a standard template for incident investigation reports that includes sections related to:
 - i. findings and observations associated with all completed investigative activities,
 - ii. the investigation's conclusions, and
 - iii. the investigation's recommended corrective actions.
- 7. Regardless of whether incident investigations are conducted by State investigators or a delegated agency or entity, the State should ensure appropriate reviews and approval of completed investigations by trained State personnel. Such reviews should include:
 - i. the investigation's compliance with the above investigation performance and format requirements and
 - ii. the appropriateness of the investigation's findings, conclusions, and recommendations.

- 8. The State should make reasonable efforts to ensure that State investigators and State investigation reviewers (including members of the State Incident Management Review Committee) have access to death certificates, autopsy reports, and medical and hospital records pertinent to the investigation of unusual, suspicious, sudden, or apparently preventable deaths.
- 9. The State should assure that administrative or legislative efforts, or both, will be made to ensure that autopsies are requested and conducted for deaths in which abuse or neglect is suspected or alleged or the circumstances of the death are unusual, suspicious, sudden, or apparently preventable.
- 10. The State should ensure the dissemination of appropriate summaries⁷ of investigation findings, conclusions, and recommendations for corrective action to:
 - i. relevant service provider personnel including employees directly associated with the incident,
 - ii. the service recipient's support coordinator and support coordination agency, and
 - iii. the service recipient and his or her family or friends (with consent of the individual service recipient or their legal guardian or legal representative if the service recipient is unable to provide consent).

D. CORRECTIVE ACTION RECOMMENDATIONS AND IMPLEMENTATION

- 1. The State should conduct a trend analysis of incidents and identify the specific incident types that would benefit from a systemic intervention.
- 2. The State should inform providers, support coordinators, and other stakeholders of recommendations for corrective actions, including any systemic interventions required as the result of trend analysis, and their responsibility to address such recommendations in a timely manner by implementing them or substantiating that they are unnecessary.
- 3. Providers and the State should maintain accountable tracking systems for all recommendations for corrective actions emanating from incident reviews and investigations. Such tracking systems should include accepted and rejected recommended corrective actions and ongoing status

⁷ Summaries should be informative but protect the confidentiality of service recipients and individuals interviewed in the course of the investigation.

- reporting of the implementation and date of accepted recommended corrective actions.
- 4. Providers, support coordination agencies, and the State should ensure that accepted recommended corrective actions are implemented within the required timeframes, and they should provide written documentation to the State justifying any implementation delay of more than 30 days.
- 5. The State should ensure ongoing monitoring of the implementation of accepted recommended corrective actions (via its tracking system) by service providers and the State.
- 6. Service providers identified as having recurring deficiencies in the timely implementation of accepted recommended corrected actions should be subject to State actions, including fines, suspension of permission to enroll new participants, waiver contract termination, and decertification.
- 7. Service providers and the State should periodically, at least annually, review their corrective action tracking systems to evaluate:
 - i. the systems' overall performance in ensuring the timely implementation of accepted recommended corrective actions and
 - ii. the effectiveness of implemented corrective actions to achieve the intended outcomes.

E. TREND ANALYSIS

- 1. Service providers and the State should ensure timely entry of data into the Incident and Investigation Database Systems. Those data should include:
 - i. incident reports;
 - ii. findings and recommendations of their Incident Management Review Committees:
 - iii. findings and recommendations of State incident investigations; and
 - iv. the status of corrective actions. (See Attachment A for specific recommended data elements to be included in Incident and Investigation Database Systems.)
- 2. Using their Incident and Investigation Database Systems, service providers are responsible for identifying trends and patterns in filed incidents and the findings and recommendations of their Incident Management Review Committees and State investigations involving their service recipients.

- 3. Service providers should ensure on a quarterly basis that identified trends and patterns are shared with their Incident Management Review Committees. Service providers should provide to the State an annual report of identified trends and patterns in their incidents, incident review findings and recommendations, and State incident investigations.
- 4. Using their ongoing and annual trend analysis activities, service providers are responsible for identifying needed additional corrective actions (including systemic actions) and for ensuring that they are implemented in a timely manner.
- 5. The State is responsible for ensuring that service providers comply with the above trend analysis requirements, including their obligation to identify and implement needed additional corrective actions to address adverse trends and patterns in service recipient protection and safety.
- 6. Using the State Incident and Investigation Database System, as well as providers' annual trend analysis reports, the State should at least biennially conduct its own trend analysis of reported incidents, the findings and recommendations of the State's Incident Management Review Committee, and the findings and recommendations of State investigations. Reports of these analyses, after the deletion of any personally identifiable information, should be available to the public to ensure the transparency of the State's Incident Management and Investigation program. Based on this analysis, the State should identify and implement any additional corrective actions that are needed. Such additional recommendations may address:
 - i. needed state-wide remedies.
 - ii. needed regional remedies, and
 - iii. needed remedies for select groups of service recipients and providers.

Attachment A

Suggested Data Elements for Incident and Investigation Database Systems

- Name (or identification number) of individual involved
- Incident report identification number
- Date the incident occurred
- Provider agency
- Region (administrative waiver region)
- Location of incident (e.g., residential home, own home with family, day program site, community location)
- Age of the individual involved
- Sex of the individual involved
- Race or ethnicity of the individual involved
- Type of disability
- Type of incident (use a standardized list with definitions)
- Level of harm or injury to the individual: (i) none, (ii) injury or harm requiring treatment up to and including first aid, (iii) injury or harm requiring medical treatment beyond first aid, injury or harm requiring hospitalization, and (iv) injury or harm resulting in death
- Narrative description of the incident (fairly detailed narrative description of up to 150 words)
- Service provider or service provider's Incident Management Review Committee investigative findings and recommendations
- Incident referred for State investigation (yes/no)
- Date of the State Incident Management Review (if applicable)
- Findings and recommendation of the State Incident Management Review Committee (narrative field of up to 150 words) (if applicable)
- Date of State investigation (if applicable)

- State investigation substantiated physical abuse (yes/no)
- State investigation substantiated neglect (yes/no)
- State investigation substantiated sexual abuse (yes/no)
- State investigation substantiated exploitation (yes/no)
- State investigation substantiated psychological or verbal abuse, or both (yes/no)
- State investigation substantiated other form of staff misconduct not associated with abuse, neglect, or exploitation (yes/no)
- Incident is identified in trending analysis (yes/no)
- Narrative description of State investigation findings, recommendations, and corrective actions (narrative field of up to 150 words) (if applicable)
- Narrative fields that track recommendation implementation and corrective action relevant to State Incident Management Review Committee and State investigation recommendations and corrective actions (optional)

APPENDIX B

Model Practices for Incident Management Audits

This appendix sets forth the Model Practices for Incident Management Audits. As detailed below, effective incident management auditing involves processes to assess timely and appropriate incident reporting, investigation, and response and for implementation of timely and appropriate corrective actions to minimize reoccurrence.

- I. Major Components
- II. Audit Expectations
- III. Audit Performance Measures
 - A. Incident Reporting and External Notifications
 - B. Individual Incident Review
 - C. Incident Investigations
 - D. Implementation and Effectiveness of Corrective Actions
 - E. Systemic Incident Review for Trends and Patterns
- IV. Incident Documentation Audits
 - A. Audit Sample
 - B. Audit Reporting, Compliance Scoring, and Corrective Actions
 - C. Audit Methods
- V. Medicaid Data Correlation Audits
 - A. Sample Requirements
 - B. Audit Reporting, Compliance Scoring, and Corrective Actions
 - C. Audit Methods

I. Major Components

The Incident Management Audit process has two components designed to assess, each from different perspectives, the basic expectations and performance measures of a State's Incident Management and Investigation activities.

- A. The Incident Documentation Audit is an audit of a sample of incident reports, incident investigations, and other documents (i.e., protection and advocacy complaint data) and documentation associated with incidents for all service recipients in currently approved and operational CMS-funded community programs. The Incident Documentation Audit can be conducted at the Federal or State levels as part of waiver applications or renewals. In response to complaints or other concerns, CMS or States can conduct selected elements of an Incident Documentation Audit. This type of audit focuses on the State's actions to incidents that were reported.
- B. The Medicaid Data Correlation Audit is an audit of Medicaid service claim data to determine if (as appropriate) incident reports were filed, incident investigations and reviews were conducted, and appropriate corrective actions were recommended and implemented in a timely manner in response to serious

incidents requiring health care services at a hospital emergency room or in other areas of the hospital. This audit evaluates whether serious incidents associated with hospital emergency room visits and unplanned hospitalizations were reported.

II. Audit Expectations

Incident Management Audits address five major expectations of a State's Incident Management and Investigation activities:

- 1. Accountable incident reporting and external notifications of serious incidents
- 2. Timely and appropriate response and review of individual incidents
- 3. Timely, comprehensive, and nonpartial investigations of individual incidents
- 4. Timely implementation of appropriate corrective actions in response to individual incidents
- 5. Informative systemic review of incidents to identify, address, and respond to trends and patterns in incidents

III. Audit Performance Measures

A. ACCOUNTABLE INCIDENT REPORTING AND EXTERNAL NOTIFICATIONS OF SERIOUS INCIDENTS

- 1. Documentation shows that service providers and support coordination agencies have an appropriate understanding of what events and situations should be reported as incidents.
- 2. Incident reports for incidents resulting in significant injuries are filed as soon as possible, but in all cases within 24 hours.
- 3. Incident reports provide a clear, complete, and legible description of the incidents.
- 4. Incident reports (or associated documentation) provide a description of the provider's immediate response to the incidents.
- 5. The documented providers' immediate responses to incidents ensure service recipients' safety and well-being.
- 6. Incident reports (or associated documentation) show that law enforcement was notified of incidents that may be associated with possible criminal acts as soon as possible.

- 7. Incident reports (or associated documentation) show that in accordance with State rules and regulations other external parties (including but not limited to family, conservators, guardians, the State's Medicaid agency, and the State's protection and advocacy entity) or other appropriate parties were notified of incidents in a timely manner.
- 8. Documentation shows that the State identifies and imposes appropriate sanctions against service providers, support coordination agencies, and others that are identified as having a pattern of *not* complying with the above performance measures related to incident reporting and notifications.

B. INDIVIDUAL INCIDENT REVIEW

- 1. Incident reports (or associated documentation) show that providers ensure a timely review of all incidents by senior management or the provider's Incident Management Committee or both.
- 2. The meeting minutes from a service provider's Incident Management Committee show that the committee reviews all incidents in accordance with CMS expectations as described in the State's approved HCBS waiver application and the State's regulatory and policy requirements.
- 3. The meeting minutes from a service provider's Incident Management Committee show that the committee meets as frequently as needed to ensure the timely review of incidents.
- 4. The meeting minutes from a service provider's Incident Management Committee show that the Committee is composed of appropriate members consistent with CMS expectations as described in the State's approved HCBS waiver application and the State's regulatory and policy requirements.
- 5. The meeting minutes from a service provider's Incident Management Committee show that the committee thoroughly reviews incidents and associated investigations such that the committee:
 - i. identifies the facts surrounding incidents as well as the contributing factors associated with incidents;
 - ii. reviews incident investigation reports and discusses their findings and recommendations;
 - iii. considers additionally needed corrective actions and remedies to prevent or reduce the likelihood of future similar incidents;
 - iv. explicitly accepts or rejects the recommended corrective actions in investigations; and

- v. tracks accepted recommended corrective actions to ensure that they are carried out in a timely manner.
- 6. The meeting minutes from a service provider's Incident Management Committee provide a listing of all incidents reviewed and an adequate summary of the committee's findings and recommendations and other activities of the committee.
- 7. Documentation shows that the State identifies and imposes appropriate sanctions against service providers that are identified as having a pattern of *not* complying with the above performance measures related to incident reviews and Incident Management Committees.

C. INCIDENT INVESTIGATIONS

- 1. Documentation indicates that independent investigations are ensured for all incidents associated with unexpected deaths; allegations of physical, emotional, and sexual abuse; allegations of neglect; allegations of financial exploitation (> \$250); and other serious incidents as required by State rules and regulations.
- 2. Documentation indicates that investigations are completed within 30 days of the date the incident report was filed, except in instances when supplemental documentation indicates a justifiable rationale for the delay in the completion of the investigation.
 - Examples of a justifiable rationale include delays because of an ongoing law enforcement investigation or the unavailability of an important witness because of serious illness or injury.
- 3. Documentation indicates that investigations are conducted by investigators who have completed a certified investigator training program approved by CMS as described in the State's approved HCBS waiver application, the State, or both.
- 4. Documentation indicates that investigations include basic required investigative activities, including:
 - i. a review of the person-centered service plan of the service recipient and other reported incidents in the past year;
 - ii. a review of the circumstances leading up to and following the incident:
 - iii. interviews with all witnesses to the incident (employees, service recipients, and other individuals in the community);

- iv. interviews with family members or guardians of the service recipient (with the consent of the service recipient or his or her legal guardian or legal representative if the recipient is unable to provide consent)
- v. interviews with other relevant parties, including provider agency supervisory, management, and health care personnel and the assigned support coordinator for the service recipient;
- vi. reviews of relevant documents and medical records maintained by the service provider, support coordinator, protection and advocacy entities, or external health care entities, including hospitals and outpatient medical providers; and
- vii. reviews of law enforcement reports, death certificates, and autopsy reports (as available).
- 5. Investigation reports are prepared using a standard format complying with any standards established by CMS that ensures discrete narratives related to (i) a listing of the investigative activities, (ii) findings and observations associated with all completed investigative activities, and (iii) the investigation's conclusions and recommendations.
- 6. Investigation reports indicate that investigators have access to and review death certificates, autopsy reports, and medical and hospital records pertinent to incidents being investigated.
- 7. Investigation reports indicate that autopsies are requested and conducted for deaths where abuse or neglect is suspected or alleged and other deaths caused by suspected provider or support coordinator misconduct.
- 8. Appropriate summaries of investigation findings, conclusions, and recommendations for corrective action are prepared and made available to:
 - i. relevant service provider personnel, including employees directly associated with the incident;
 - ii. the service recipient's support coordinator and support coordination agency;
 - iii. the service recipient and his or her family and friends (with the consent of the service recipient or his or her legal guardian or legal representative if the service recipient is unable to provide consent); and
 - iv. the State protection and advocacy entity.

- 9. Documentation indicates that the service recipient or their legal guardian or legal representative have had the opportunity to review the investigation findings, conclusions, and recommendations and have had the opportunity to respond to any investigation findings through a predetermined grievance process under the State HCBS waiver authority.
- 10. Documentation indicates that the State identifies and imposes appropriate sanctions against service providers that are identified as having a pattern of *not* complying with the above performance measures related to incident investigations.

D. IMPLEMENTATION AND EFFECTIVENESS OF CORRECTIVE ACTIONS

- 1. Documentation indicates that service providers, support coordination agencies, and other pertinent individuals or entities take timely and effective actions to implement recommendations for corrective actions related to individual incidents.
 - *Timely* is defined as "as soon as possible" and within 30 days in all cases except where a written reasonable justification for the delayed implementation is available.
- 2. Documentation indicates that the State maintains an accountable tracking system to monitor the implementation of recommendations for corrective actions emanating from incident reviews and investigations.
- 3. Documentation indicates that the State ensures appropriate methods to verify (on a sample basis) that the recommendations for corrective actions from the reports of service providers, support coordination agencies, and others were in fact implemented.
- 4. Documentation indicates that the State identifies and imposes appropriate sanctions against service providers, support coordination agencies, and others that are identified as having a pattern of *not* responding to recommended corrective actions in a timely and effective manner.

E. SYSTEMIC INCIDENT REVIEW FOR TRENDS AND PATTERNS

1. Meeting minutes from a service provider's Incident Management Committee or other documentation and reports indicate that the service provider periodically, at least annually, reviews incident data, including investigative findings and recommended corrective actions. The review is to identify trends and patterns in filed incidents as well as noncompliance issues related to the State's regulatory and policy requirements for incident management.

- 2. Meeting minutes from a service provider's Incident Management Committee or other documentation and reports indicate that identified trends and patterns (as referenced above) are addressed in a timely and appropriate manner.
- 3. Meeting minutes from a service provider's Incident Management Committee or other service provider documentation and reports indicate that the service provider periodically evaluates actions taken in response to identified trends and patterns to ensure that they have been effective in addressing identified problems and concerns.
- 4. State documentation or reports indicate that the State regularly reviews trend and pattern analyses reports prepared by service providers and takes appropriate actions to respond to issues and concerns affecting the health and welfare of service recipients.
- 5. State documentation or reports indicate that the State periodically conducts state-wide incident studies to identify trends and patterns in reported incidents and investigation findings and that it takes appropriate actions to respond to identified issues and concerns affecting the health and welfare of service recipients.

IV. Incident Documentation Audits

A. AUDIT SAMPLE

- 1. The Incident Documentation Audit is based on the review of a sample of incident reports filed in the first quarter of the 12-month period before the date of the State's submittal of a new waiver application or a renewal waiver application. These samples include:
 - i. all unexpected deaths;
 - ii. all allegations of physical or sexual abuse;
 - iii. all allegations of financial exploitation for amounts greater than \$250;
 - iv. a statistically significant random sample of allegations of neglect;
 - v. a statistically significant random sample of other "serious" incidents (not included above); and

⁸ Multiple Incident Documentation Audits are not necessary for States that submit multiple new waiver applications or waiver renewal applications within a 3-year period.

vi. a statistically significant random sample of "nonserious" incidents.

B. AUDIT REPORTING, COMPLIANCE SCORING, AND CORRECTIVE ACTIONS

- 1. States should report to CMS Incident Documentation Audit findings in aggregate across all of the above samples as well as separately for each of the above samples.
- 2. States should also report their Incident Documentation Audit findings by Medicaid regional administration units. Additionally, as applicable, findings should identify service providers that demonstrate an increase in incidences or a pattern of noncompliance with incident reporting and other expectations of Incident Management Programs.
- 3. States should report their Incident Documentation Audit findings to CMS at least 90 days before the date it submits its new or renewal waiver application.
- 4. Findings reports should be presented to CMS to provide discrete compliance scores for each of the performance measures of Incident Management processes detailed above.
- 5. For all performance measures (detailed above), an 86-percent compliance score is expected. States should develop and implement plans of correction for all performance measure scores of less than 86 percent before CMS's approval of new or renewal waiver applications.
- 6. Failure to implement appropriate corrective actions for substandard compliance scores may result in CMS sanctions, including but not limited to adverse decisions on new or renewal waiver applications.
- 7. At its discretion, CMS may impose immediate sanctions against States whose Incident Documentation Audits result in poor compliance scores or selected negative results that indicate that its waiver service recipients may be at risk of imminent harm.

C. AUDIT METHODS

1. States should rely on their electronic Incident and Investigation Database to select the required audit samples. The sample selection methods will be explicitly presented in reports of the audit findings.

⁹ The audit protocol assumes that all States have an electronic Incident Database.

2. Once incident samples are selected, the State (with the assistance of service providers and support coordinators) will gather required documents and documentation for the audit.

Such documents and documentation should include:

- i. reports of the incidents and any associated investigations;
- ii. copies of any associated daily service notes or other documentation associated with the incident report;
- iii. any meeting minutes from service providers' Incident Management Committees that are associated with the sample incidents;
- iv. other documentation maintained by service providers associated with the sample incidents, including their responses, reviews, and corrective actions;
- v. documentation and reports of service providers associated with the sample incidents related to their periodic reviews of incidents and investigations to identify trends and patterns;
- vi. documentation of the State verifying its ongoing review of service providers' reports related to the providers' reported trends and patterns in incidents and investigations; and
- vii. State documentation and reports associated with its periodic reviews of incidents state-wide to identify trends and patterns.
- 3. This documentation should be sorted and reviewed in accordance with the performance measures listed earlier, and findings should be documented on a standardized audit tool developed and approved by CMS as described in the State's approved HCBS waiver application.
- 4. In addition to the above documentation, States should collect and review any documentation associated with its ongoing monitoring of the compliance of service providers and support coordination agencies with the major expectations and performance measures for Incident Management processes.
 - Such documentation should include sanctions taken against service providers and support coordination agencies that demonstrate patterns of noncompliance.
- 5. To ensure the integrity of Medicaid Data Correlation Audits, CMS and States should maintain copies (paper or electronic) of all documentation collected and audit tools for at least 5 years.

- 6. States should ensure that the audit team is composed of professionals knowledgeable about incident management systems and their expectations and performance measures. These professionals should also be independent of State personnel charged with the direct implementation or management of the State's Incident Management processes. 10
 - In concert with the above requirements, States should maintain current curriculum vitae of all professionals on their audit teams.
- 7. To preserve nonbiased audit findings and conclusions, States should ensure the explicit tracking of any alterations or substantive edits of draft reports of Incident Documentation Audits.
- 8. To ensure the timeliness and the relevance of their findings and conclusions, Incident Documentation Audits should be completed within 90 days of their initiation.

V. Medicaid Data Correlation Audits

A. SAMPLE REQUIREMENTS

- 1. Medicaid Data Correlation Audits should rely on samples of Medicaid service data related to waiver recipients.
 - The audit team should review these data to identify service reports that would appear to have warranted the filing of an incident report.
- 2. Medicaid Data Correlation Audits may be directed by CMS or States (either voluntarily or as required by CMS).
- 3. Medicaid Data Correlation Audits should focus on waiver service recipients whose care and supports are largely the responsibility of paid service providers, not family members or friends. These recipients should include:
 - i. individuals in residential services,
 - ii. individuals who receive in-home paid staff supports at least 40 hours a week, and
 - iii. individuals who receive day services at least 20 hours a week. 11

¹⁰ States may at their discretion contract out Incident Documentation Audits to independent consultants or consultant organizations that meet the above-listed requirements.

¹¹ This restriction is included because States do not usually require the reporting of incidents involving service recipients while in the care of family or friends.

- 4. Medicaid services data to be screened should include services associated with:
 - i. Allegations of abuse, neglect and/or exploitation;
 - ii. hospital emergency room visits;
 - iii. unplanned hospitalizations;
 - iv. ambulance services; and
 - v. urgent care center visits caused by accidental injuries. 12
- 5. The time period for the data collected may vary based on the size of the applicable waiver service recipient sample population, but at a minimum it should include Medicaid services data for at least one quarter of a calendar year.

B. AUDIT REPORTING, COMPLIANCE SCORING, AND CORRECTIVE ACTIONS

- 1. Findings of Medicaid Data Correlation Audits should include state-wide findings as well as findings by Medicaid regional administration units (within the State).
 - Additionally, as applicable, findings should identify service providers that demonstrate a pattern of noncompliance with incident reporting and other expectations of Incident Management processes.
- 2. Finding reports should provide discrete compliance scores for each of the performance measures of Incident Management processes detailed above.
- 3. For all performance measures, CMS should establish an 86-percent compliance score. CMS should require States to develop and implement plans of correction for all performance measure scores of less than 86 percent before CMS approves any new or renewal waiver applications.
- 4. Failure to implement appropriate corrective actions for substandard compliance scores may result in CMS sanctions, including but not limited to adverse decisions on new or renewal waiver applications.
- 5. At its discretion, CMS may impose immediate sanctions against States whose Medicaid Data Correlation Audits result in poor compliance scores

¹² CMS may also wish to include service reports for individual waiver service recipients who have exceptionally high State Medicaid billings, exclusive of billings for State plan nursing, health aide, and clinical therapy or behavior support services.

or selected negative results that indicate that its waiver service recipients may be at risk of imminent harm.

C. AUDIT METHODS¹³

- 1. CMS and States should rely on States' state-wide Medicaid databases to draw the samples of Medicaid services data. The sample selection methods should be explicitly presented in the report of the audit findings.
- 2. Once the Medicaid services data are retrieved, CMS or the States should organize the data by service recipient and check the state-wide Incident and Investigation Database to determine which services have a corresponding incident report.
- 3. For services data that have a corresponding incident report, CMS or the States should request the provider agencies filing the report to submit documentation related to the incident and the provider(s)'s response to the incident.

Such documentation should include:

- i. a copy of the incident report and any associated investigations;
- a copy of any associated daily service notes or other documentation (including internal provider staff shift communication notes) associated with the incident/Medicaid service report;
- iii. meeting minutes from service providers' Incident Management Review Committee that are associated with the sample incidents;
- iv. other documentation maintained by service providers associated with the sample incidents, including the providers' responses, reviews, and any corrective actions; and
- v. documentation and reports of service providers associated with the sample incidents related to the providers' periodic reviews of incidents and investigations to identify trends and patterns.
- 4. This documentation should be sorted and reviewed in accordance with the above-stated performance measures. The findings should be documented on a standardized audit tool developed and approved by CMS.
- 5. For services data that do not have a corresponding incident report, CMS or the States should request explanations for the lack of a report from the

¹³ As referenced above, CMS may itself conduct Medicaid Data Correlation Audits. Alternately, States may conduct their own Medicaid Data Correlation Audits, either voluntarily or as required by CMS.

- State, provider agencies, or service providers, as well as any other available documentation indicating that the incident received an appropriate response.
- 6. To assure the integrity of Medicaid Data Correlation Audits, CMS and the States should maintain copies of all documentation collected and audit tools for at least 3 years.
- 7. CMS or the States should ensure that the audit team is composed of professionals knowledgeable about incident management systems and their expectations and performance measures.
- 8. When States conduct their own Medicaid Data Correlation Audits, States should ensure that members of the audit team are independent of State personnel charged with the direct implementation or management of the State's Incident Management processes. 14
 - In concert with the above requirements, States should be required to maintain current curriculum vitae of all professionals on the audit teams.
- 9. In addition, if States are conducting their own Medicaid Data Correlation Audits to preserve the nonbiased audit findings and conclusions, States should ensure the explicit tracking of any alterations or substantive edits of initially prepared draft reports of Incident Documentation Audits.
- 10. To ensure the timeliness and relevance of their findings and conclusions, Medicaid Data Correlation Audits should be completed and made publicly available within 120 days of their initiation.

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¹⁴ States may at their discretion contract out Incident Documentation Audits to independent consultants or consultant organizations that meet the above-listed requirements.

Appendix B

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APPENDIX C

Model Practices for State Mortality Reviews

This appendix sets forth the Model Practices for State Mortality Reviews. As detailed below, effective mortality reviews involve timely reporting of all beneficiary deaths, including identification of the cause of death and the circumstances contributing to or associated with the death.

- I. Intended Outcomes of State Mortality Reviews
- II. Essential Participants and Activities for State Mortality Reviews
- III. The State Mortality Review Database

I. Intended Outcomes of State Mortality Reviews

- A. Accountable and timely reporting of all service recipient deaths
- B. Identification of the causes of deaths
- C. Identification of the immediate and longer term (up to 12 months before the death) circumstances and events that contributed to or were associated with deaths
- D. Identification of corrective actions that may eliminate or lessen the likelihood of circumstances and events that contribute to or are associated with the causes related to specific deaths
- E. Identification of trends and patterns in deaths that indicate needed systemic changes or reforms in community-based services that may reduce the risk of death and other adverse outcomes for service recipients
- F. Appropriate and timely implementation of identified corrective actions and systemic changes and reforms to reduce the risk of death and other adverse outcomes for service recipients
- G. Ongoing evaluation to ensure that implemented corrective actions and systemic changes or reforms have been effective in reducing the risk of death and other adverse outcomes for service recipients
- H. Periodic public reporting on the number, causes, and circumstances of deaths to ensure public transparency regarding the health, welfare, and safety of beneficiaries of community-based services

II. Essential Participants and Activities for State Mortality Reviews

A. State Mortality Review processes should ensure the accountable and timely reporting of deaths, including checks on service provider and support coordination agencies' death reporting practices.

Service provider and support coordination agencies identified as having a pattern of delayed or failed death reporting or of filing reports that are misleading or incomplete should be subject to State sanctions, including fines, suspension of permission to enroll new participants, waiver contract termination, and decertification.

B. State Mortality Review processes should ensure a preliminary review of the cause and circumstances of *all* reported deaths and identify the deaths warranting further State investigation and review. Such preliminary death reviews should be completed within 1 week of the date the death was reported.

As necessary, preliminary death reviews will include followup contact with the service provider(s) and support coordinator for additional information. Generally, preliminary death reviews will often occur before the State's receipt of the death certificate. Preliminary death reviews should not be officially closed until the death certificate has been received and reviewed.¹⁵

C. State Mortality Review processes should ensure State investigations of deaths that are determined upon preliminary review to be unusual, suspicious, sudden and unexpected, or apparently preventable, including all deaths alleged or suspected to be associated with neglect, abuse, or criminal acts.

State death investigators should have a professional medical background (e.g., registered nurse, certified nurse practitioner, physician assistant, and physician) and have completed a nationally certified training program for conducting critical incident (including death) investigations.

- D. State Mortality Review processes should include a State Mortality Review Committee that has responsibility for comprehensive review of deaths identified as being unexpected, sudden and unusual or unnatural, caused by suspicious circumstances, associated with suspected or alleged provider misconduct or abuse or neglect, or any combination of these.
- E. State Mortality Review processes should ensure that their comprehensive death reviews include the review of relevant records and documents associated with the death, including:

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¹⁵ Death certificates are often not available from State health departments until 90 days after the death, and autopsy reports are often not available until 120 to 180 days after the death.

- 1. service provider and support coordinator documentation, including (a) the person-centered service plan for the individual who is deceased, (b) notes related to service delivery (by both waiver and nonwaiver providers), and (c) any other service provider or State reviews or investigations of the death;
- 2. incident reports related to the deceased in the 6 to 12 months before death;
- 3. death certificates;
- 4. autopsy and medical examiner or coroner reports;
- 5. emergency medical personnel reports and documentation;
- 6. medical records including physicians, specialists, hospital, and emergency room records related to the individual who is deceased in the 6 to 12 months before death;
- 7. records and documentation of medical professionals who treated the individual who is deceased within 6 months of his or her death; and
- 8. as available, any State or other agency investigation of the death.
- F. State Mortality Review processes should include working with other State and local authorities to establish protocols and procedures (including guardian or family caregiver consent) to ensure that the above-listed documents are made available in a timely manner. ¹⁶
- G. State Mortality Review processes should ensure that autopsies are requested and performed for all deaths deemed to be unusual or suspicious or without a known cause of death, including all deaths whose circumstances suggest possible neglect, abuse, or criminal conduct.¹⁷
- H. State Mortality Review processes should ensure that State Mortality Review Committees establish appropriate procedures and practices to ensure that:

¹⁶ It is typically neither effective nor efficient to require service providers and support coordination agencies to gather death certificates, autopsies, and other medical records essential for the completion of comprehensive death reviews, as most often State officials have (or can obtain more readily) authorization to obtain these documents.

¹⁷ Uniformly ensuring autopsies as referenced above is frequently challenging. Families often do not wish to have autopsies performed. Medical examiners and coroners often refuse to perform autopsies of "natural" deaths regardless of the circumstances or the lack of a clear cause of death. And autopsies are costly and most States do not have a mechanism for reimbursing localities for these costs. Thus, State Mortality Review processes should make extra efforts in working with other State and local authorities to promote the conduct of autopsies of deaths that meet the above criteria.

- 1. the committee's membership includes an interdisciplinary group of medically credentialed and other professionals (including providers and advocates) who are knowledgeable of community-based services;
- 2. the committee relies on explicit criteria to identify deaths that should be afforded comprehensive reviews by the committee;
- 3. the committee meets sufficiently frequently to guarantee the timely and comprehensive reviews of all required deaths; and
- 4. the committee members have timely access to all necessary documents and reports to assure comprehensive review of all required deaths.
- I. State Mortality Review processes should track service provider and support coordination agencies' implementation of recommendations for corrective actions emanating from the State's Mortality Review Committee.
 - Although such tracking systems may rely primarily on service provider and support coordination agencies' written reports of corrective actions taken, State Mortality Review processes should also require periodic onsite reviews to ensure that reported corrective actions have been appropriately implemented.
- J. State Mortality Review processes should ensure that appropriate actions (including fines, suspension of permission to enroll new participants, and waiver contract termination and decertification) are imposed against service providers and support coordination agencies found to have patterns of delayed or failed implementation recommendations issued by the State Mortality Review Committee.
- K. State Mortality Review processes should periodically, but at least biennially, evaluate the effectiveness of implemented recommendations for corrective actions to reduce the death rate (total, by cause, by provider) or to achieve other positive outcomes for service recipients or the service system (e.g., reduced emergency room visits, hospitalizations, and critical incidents).
- L. State Mortality Review processes should periodically, but at least biennially, do a trend analysis of deaths and issue any systemic interventions to ameliorate the conditions that resulted in the trend.
- M. State Mortality Review processes should provide at least biennial public reporting on the number, causes, and circumstances of deaths of individuals receiving community-based services, including the trends and patterns identified by the State Mortality Review process.

III. The State Mortality Review Database

A. State Mortality Review processes should establish a State Mortality Review Database that, at a minimum, includes the following data elements:

- 1. name, age, race or ethnicity, disability type, and sex of the individual who is deceased;
- 2. community-based (waiver) services received by the deceased individual and the name(s) of the service provider(s);
- 3. narrative of the events leading up to the individual's death and the immediate circumstances of the death;
- 4. location of the death (e.g., individual's home, established day program, community setting, hospital emergency room, hospital, and hospice facility);
- 5. immediate and secondary causes of death;
- 6. if the death was . . .
 - i. expected due to a known terminal illness;
 - ii. associated with a known chronic illness;
 - iii. a sudden, unexpected death;
 - iv. due to unknown cause
 - v. due to an accident and, if so, the type of accident;
 - vi. due to self-inflicted injury or illness (e.g., suicide, serious self-injurious behavior);
 - vii. due to suspicious or unusual circumstances; and
 - viii. due to suspected or alleged neglect, abuse, or criminal activity.
- 7. whether an autopsy was conducted and, if so, a narrative of its findings;
- 8. findings of the *preliminary* reviews of all deaths by the State Mortality Review process;
- 9. findings and recommended corrective actions of the *comprehensive* death reviews by the State Mortality Review Committee of selected deaths as defined above; and
- 10. tracking information related to the implementation of recommended corrective actions issued by the State Mortality Review Committee.
- B. State Mortality Review processes should make use of the State Mortality Review Database to identify trends and patterns in:

- 1. the demographics of the deceased individuals, their community (waiver) services, and their providers;
- 2. causes of death;
- 3. total death rates and death rates by cause of death, geographic region, and service provider per total number of service recipients with the same demographics;
- 4. a comparison of death rates with national mortality statistics and available mortality statistics for comparable community-based services in other States;
- 5. circumstances of death;
- 6. findings and recommendations of the State Mortality Review Committee; and
- 7. the appropriate implementation of recommendations issued by State Mortality Review Committees by service providers, support coordination agencies, and the State (as applicable).

APPENDIX D Model Practices for State Quality Assurance

This appendix sets forth the Model Practices for State Quality Assurance. As detailed below, comprehensive quality assurance of community-based services includes the incident management, audit, and mortality review components discussed above and certain other elements of quality assurance.

- I. Essential Components of State Community-Based Services Quality Assurance
- II. Quality Assurance Participants
- III. Basic Operational Tasks of Quality Assurance
- IV. Surveillance Capacities
 - I. Essential Components of State Community-Based Services Quality Assurance
 - A. A critical incident management and investigation process
 - 1. Is ongoing
 - B. Mortality reviews
 - 1. Are ongoing
 - 2. Are conducted by State committees or external contractors
 - C. Oversight of individualized service planning and delivery
 - 1. Emphasizes person-centered planning
 - 2. Emphasizes individualized and relevant goals
 - 3. Emphasizes appropriate service recommendations
 - 4. Emphasizes practical action steps or interventions
 - 5. Includes random onsite service recipient audits annually that cover either 10 percent of waiver enrollees or a statistically significant sample (whichever is larger) of waiver enrollees
 - D. Identification and timely intervention for high-risk service recipients
 - 1. Includes ongoing clinical crisis management and prevention services
 - E. Assessment of community inclusion outcomes for service recipients
 - 1. Periodic onsite audits of community day services and employment services

- F. Initial certification reviews of all new service providers and support coordination agencies
 - 1. Mandated initial reviews that must be passed before the start of waiver service delivery
- G. Assessment of service provider and support coordination agency performance
 - 1. Are consistent with regulatory and professional standards
 - 2. Are periodic, at least biennial, audits of providers of:
 - i. residential services,
 - ii. day services,
 - iii. employment, and
 - iv. personal care, nursing, behavioral support, and support coordination 18
- H. Audits of workforce safeguard assurances by providers
 - 1. Include assessments of pre-employment screening and background checks
 - 2. Include assessments of staff training
 - 3. Include assessments of performance evaluation
 - 4. Are periodic, at least biennial, audits of providers of:
 - i. residential services,
 - ii. day services,
 - iii. employment, and
 - iv. personal care, nursing, behavioral support, and support coordination ¹⁹
- I. Reviews of a provider's network adequacy in terms of capacity, stability, and service accessibility
 - 1. Are annual State assessments, including service gap analyses

¹⁸ Some States allow providers and support coordination agencies that have least 2 years of operation within the waiver program and strong performance records to conduct these audits triannually.

¹⁹ Workforce safeguard audits may be incorporated in service provider and support coordination audits. They are listed separately because it is often more efficient to conduct these audits with teams of specialized auditors.

- 2. Have stakeholder participation
- J. Assessment of the fiscal integrity of service billing and reimbursement
 - 1. Includes ongoing State desk audits
 - 2. Includes periodic onsite audits of select service providers and support coordination agencies
- K. Compliance monitoring related to Federal fiscal and programmatic requirements
 - 1. Includes State desk audits of mandated reporting by service providers and support coordination agencies,
 - 2. Includes ongoing onsite audits of select service providers and support coordination agencies
- L. Reports or reviews issued by any local or State protection and advocacy entity related to complaints about abuse and neglect of individuals residing in group homes

II. Quality Assurance Participants

- A. Service recipients, family members, friends, legal conservators, or guardians
- B. Advocates
- C. Protection and advocacy entities
- D. State Councils on Developmental Disabilities
- E. University Centers for Excellence in Developmental Disabilities
- F. Service providers
- G. Case Management or Support coordination providers
- H. State government administrators of the Community-Based Service System
- I. Federal Government administrators of the Community-Based Service System
- J. Typically these participants work together in developing and implementing a State's quality assurance process, but each participant group also has certain primary roles in the process:
 - 1. Service recipients, families, and friends offer primary data regarding their personal experiences and satisfaction with the Community-Based Service System. They may also provide information to other participants in the quality assurance process in structuring and evaluating their quality

assurance activities. They also give information to the State through the grievance and appeal process and satisfaction surveys of how the Community-Based Service System affects the individual (e.g., adequacy of provider network, availability of services, choice of provider and services).

- 2. Advocates, including Disability Rights organizations, local or state-wide advocacy groups, protection and advocacy entities, State councils on developmental disabilities, and consumer advocacy associations, offer independent advice related to their views of emerging and ongoing quality assurance issues in the Community-Based Service System.
- 3. Universities, including University Centers for Excellence in Developmental Disabilities, can be a source for training and technical assistance to providers that will increase their capacity. Universities can also serve as a resource for establishing incident reporting systems and for establishing processes for analyzing information to identify trends.
- 4. Service providers and support coordination providers have an obligation to institute internal quality assurance auditing activities to evaluate their performance (including service recipient and family satisfaction) relative to regulatory and professional standards.

Robust and accountable internal quality assurance auditing programs developed and implemented by providers are the critical and often undervalued foundation of an accountable and effective quality assurance process for State's Community-Based Service System.

- 5. State government administrators have the overall quality assurance oversight obligation for:
 - i. service recipient health, well-being, and safety and
 - ii. the service system's performance in meeting Federal and State regulatory requirements and complying with professional standards for services.

Inherent in these responsibilities is the States' obligations to:

- i. attend to the satisfaction of service recipients, families, and friends with the service system and
- ii. ensure that service providers and support coordination agencies design and implement accountable and responsive internal quality assurance processes.

The State Medicaid agency is ultimately responsible for administration of the waiver, including oversight of the performance of waiver functions by other State and local or regional non-State agencies and contracted entities. State government administrators should ensure that their own quality assurance auditing activities provide a reliable and valid evaluation of the performance of its Community-Based Service System consistent with Federal and State regulatory requirements and professional standards. These State-directed quality assurance auditing activities also provide a validation check for providers' internal quality assurance audit processes.

State-directed quality assurance activities typically include:

- i. initial and recurring licensing or certification evaluations of providers;
- ii. service recipient satisfaction surveys;
- iii. critical incident monitoring and investigations;
- iv. mortality reviews;
- v. overall assessments of the adequacy, accessibility, and nondiscrimination of the service provider and support coordination agency networks; and
- vi. certain administrative audits to ensure that the Community-Based Service System is compliant with State and Federal programmatic and fiscal requirements.

State-directed quality assurance audits and assessments also include assurance related to fundamental principles and values of community-based services waiver programs, including nondiscrimination, community inclusion, individualization of service planning, respect for the rights of individuals with disabilities to make their own decisions, and risk management. These assessments are often incorporated in ongoing, person-centered service assessments and service providers' and support coordinators' service delivery, consistent with the requirements of the State's approved waiver.

In addition, State quality assurance activities should include the capacity to identify and respond to trends in providers' internal quality assurance audits, as well as its own State-directed audits. Responding to these trends allows States to ensure timely corrective actions and, where necessary, regulatory reforms to respond to weaknesses in the Community-Based Service Systems before problems become more serious.

6. The Federal Government's role in quality assurance for States'
Community-Based Service Systems depends substantially on data and reports of the States' own quality assurance activities.

Specifically, the Federal Government first and foremost should ensure that States' quality assurance processes, including mandates for provider-directed internal quality assurance procedures, operate effectively and efficiently to identify concerns and ensure needed remedial actions in response to their observations and conclusions.

Additionally, the Federal Government should have the capacity to undertake independent quality assurance investigations and audits in response to State quality assurance reports, citizen complaints, and concerns that may surface in Medicaid and Medicare data.

The Federal Government also has the unique capacity to identify and respond to trends in the quality assurance data among States and to use these observations to affect ongoing needed quality improvements in the Federal regulatory framework for State Community-Based Service Systems.

III. Basic Operational Tasks of Quality Assurance

- A. Quality assurance processes, whether in industry, education, or health care, have eight basic operational tasks:
 - 1. data collection,
 - 2. data analysis,
 - 3. evaluating the effectiveness of the overall systems,
 - 4. determining findings and conclusions,
 - 5. identifying trends that need to be addressed,
 - 6. identifying corrective actions or remedies (as needed),
 - 7. implementing corrective actions or remedies, and
 - 8. evaluating the effectiveness of implemented corrective actions or remedies.
- B. Historically, State quality assurance processes for their Community-Based Services System have invested most of their time and resources on Task 1, data collection. Less time and fewer resources have been spent on Task 2, data review and analysis, and still less time on Task 4, determining findings and conclusions.

States may find they need to allocate more resources to Tasks 5 through 8, the identification, implementation, and evaluation of needed corrective actions that are essential to ensuring positive outcomes of their quality assurance efforts.

C. This allocation of resources is inevitable in view of the disproportionate resources required to collect and analyze quality assurance data relative to other tasks. However, it is critical that the model for States' Community-Based Services Systems ensures that States allocate sufficient time and resources to ensuring the success of the State's quality system and addressing any intended corrective action outcomes of these programs. Without this allocation, quality assurance systems may generate impressive "processes" and reports but minimal positive outcomes.

Thus, the model should ensure that, for each component of the quality assurance process, States develop effective and practical action steps that address all eight tasks with sufficient attention to checks and balances on appropriate and effective corrective action outcomes.

IV. Surveillance Capacities

Surveillance capacities refer to a quality assurance program's "action" capabilities to ensure that it is able to collect reliable and valid data related to the quality assessments undertaken.

- A. State quality assurance processes rely on a number of different surveillance capacities that can be generally categorized in five types:
 - 1. external reporting by service recipients, peers, families and friends, service providers and support coordinators (voluntary and mandatory), and protection and advocacy entities;
 - 2. desk/paper audits of service planning and service provision documentation;
 - 3. onsite data collection activities, including routine reviews, inspections, and investigations of service locations, service recipients, and allegations of abuse and neglect or other misconduct;
 - 4. reviews of provider and support coordinator reporting related to mandated reporting and service provision; and
 - 5. State-directed systemic reviews of the service system (often done to assess the overall provider network's stability, accessibility, and fiscal integrity of service billing and reimbursement).
- B. Specific data collection activities of quality assurance processes related to these surveillance capacities include (among others):
 - 1. service recipient, peer, family, and friend reporting of concerns and complaints (e.g., informal and formal complaint and grievance systems);
 - 2. satisfaction surveys of service recipients and family and friends;

- 3. mandated reporting of critical incidents, deaths, and abuse and neglect;
- 4. mandated provider reporting on the status of high-risk service recipients;
- 5. mandated provider reporting of weather, fire, and other emergency situations; infection control concerns; involvement of law enforcement; disenrollment of service recipients; and others; and
- 6. desk audits of service provider and support coordinator documentation, including:
 - i. person-centered service plans (PCSPs),
 - ii. service billings,
 - iii. internal quality assurance audit findings, and
 - iv. pre-employment screening and training for staff members.
- C. Person-centered quality reviews to ensure assessment and documentation of the individual's needs and documentation that substantiates services were rendered in the amount, frequency, duration, and scope required:
 - 1. onsite inspections of community homes and other service provision locations (e.g., day programs and crisis and respite homes) to assess performance compliance with regulatory and professional standards (i.e., initial certification reviews and ongoing licensure reviews);
 - 2. onsite investigations of critical incidents and other allegations or concerns of performance deficiencies;
 - 3. mortality reviews (independent or State directed) including or in addition to trend analysis of unexpected or unanticipated deaths and trend analysis of deaths that were the result of abuse or neglect;
 - 4. onsite evaluations of service providers' and support coordinators' reporting of critical incidents, implemented corrective actions, PCSP development, service delivery, and billings; and
 - 5. meetings with advocates to identify emerging issues and trends in complaints and rights violations in conjunction with a review of the State's own complaint and appeal systems.

Appendix E Related HHS Reports and Activities

OIG Office of Audit Services Related Reports

| Report Title | Report Number | Date Issued |
|---|----------------------|----------------|
| Maine Did Not Comply With Federal and State Requirements for Critical Incidents Involving Medicaid Beneficiaries With Developmental Disabilities | <u>A-01-16-00001</u> | August 2017 |
| Early Alert: The Centers for Medicare & Medicaid Services Has Inadequate Procedures To Ensure That Incidents of Potential Abuse or Neglect at Skilled Nursing Facilities Are Identified and Reported in Accordance With Applicable Requirements | <u>A-01-17-00504</u> | August 2017 |
| Massachusetts Did Not Comply With Federal and State Requirements for Critical Incidents Involving Developmentally Disabled Medicaid Beneficiaries | <u>A-01-14-00008</u> | July 2016 |
| Connecticut Did Not Comply With Federal and State Requirements for Critical Incidents Involving Developmentally Disabled Medicaid Beneficiaries | <u>A-01-14-00002</u> | May 2016 |
| Review of Intermediate Care Facilities in New York with High Rates of Emergency Room Visits by Intellectually Disabled Medicaid Beneficiaries | <u>A-02-14-01011</u> | September 2015 |
| Oversight of Quality of Care in Medicaid Home and Community-Based Services Waiver Programs | OEI-02-08- 00170 | June 2012 |

Administration for Community Living Related Activities

| Living Well: Model Approaches for | https://www.grants.gov/web/grants/view- |
|---|---|
| Enhancing the Quality, Effectiveness and | opportunity.html?oppId=292514 |
| Monitoring of Home and Community-Based | |
| Services for Individuals with Developmental | |
| Disabilities | |
| | |

| State Protection & Advocacy Systems | https://www.acl.gov/programs/aging-and-disability-networks/state-protection-advocacy-systems |
|---|--|
| State Councils on Developmental Disabilities | https://www.acl.gov/programs/aging-and-disability-networks/state-councils-developmental-disabilities |
| National Network of University Centers for Excellence in Developmental Disabilities Education, Research & Service | https://www.acl.gov/programs/aging-and-disability-networks/national-network-university |
| Self-Advocacy Resource and Technical Assistance Center (SARTAC) | http://selfadvocacyinfo.org/ |