

SUMMARY: This chapter sets forth the policy of the Maine Department of Health and Human Services (Department) regarding the Reportable Events System including, (1) reporting requirements when a Reportable Event has occurred involving an Individual Receiving Services (any adult with Developmental Disabilities, including Intellectual Disabilities or Autism Spectrum Disorder, determined eligible for and receiving services from a provider of services licensed, funded, or regulated in whole or in part by the Department, and adults with Acquired Brain Injury determined eligible for and receiving waiver services from a provider of services licensed, funded, or regulated in whole or in part by the Department), and (2) the steps involved in review of Reportable Events to identify preventive and corrective action, as appropriate.

The goals of the Reportable Events System and this rule are to: (1) identify events that warrant the attention of key people involved in the support of an Individual Receiving Services; (2) ensure that key people involved in the support of an Individual Receiving Services are made aware of such Reportable Events; (3) initiate a response to ensure the ongoing health and safety of an Individual Receiving Services when a Reportable Event has occurred; and (4) ensure that the Department and Provider Agencies recognize and analyze patterns and trends to improve service delivery. The Department recognizes that some events that meet the definition of a Reportable Event may also qualify as an allegation of Abuse, Neglect, or Exploitation, which requires a separate report in accordance with Department rule and the *Adult Protective Services Act*. See 22 M.R.S. §3477; 10-149 C.M.R. ch. 1.

The Department will preserve the confidentiality and limit the disclosure of records of reportable events pursuant to 34-B M.R.S. §1207.

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Section 1. DEFINITIONS

1. **Abuse:** the infliction of injury, unreasonable confinement, intimidation or cruel punishment that causes or is likely to cause physical harm or pain or mental anguish; sexual abuse or sexual exploitation; financial exploitation; or the intentional, knowing or reckless deprivation of essential needs, through acts or omissions.
2. **Adult Protective Services (APS):** the unit within the Department responsible for carrying out the requirements of 22 M.R.S. §3473, including receiving, promptly investigating, and determining the validity of reports of alleged Abuse, Neglect, and Exploitation of incapacitated and dependent adults and reports of the substantial risk of Abuse, Neglect, and Exploitation of incapacitated and dependent adults.
3. **Adult Protective Services (APS) Central Intake:** the Department APS unit's 24/7 telephone line through which any individual may and all Mandated Reporters shall report allegations of Abuse, Neglect, or Exploitation of a dependent or incapacitated adult.
4. **Care Coordinator:** a staff person who is responsible for the development and ongoing support of the implementation of the care plan of an Individual Receiving Services including monitoring the health, welfare, and safety of the Individual Receiving Services.
5. **Case Manager:** an individual responsible for assuring the timely convening of the personal planning team, developing the personal plan, monitoring the planned services received, and ensuring that those services meet the requirements set forth in the plan for an Individual Receiving Services.
6. **Emergency Medical Services:** acute medical care services provided by a paramedic in an out-of-hospital setting.
7. **Emergency Restraint:** an unplanned physical action that limits or controls the voluntary movement of an Individual Receiving Services against his or her will and that deprives an Individual Receiving Services of the use of all or part of his or her body or maintains an Individual Receiving Services in an area through physical presence, physical limitation, or coercion.
8. **Exploitation:** the illegal or improper use of an incapacitated or dependent adult or that adult's resources for another's profit or advantage.
9. **Follow-Up Report:** a required written account submitted by Provider staff through the Reportable Event Database following any Reportable Event explaining the known cause or likely cause of a Reportable Event and any Remediation Action Steps taken or to be taken in response to the Reportable Event.

10. **Hospital:** a licensed acute health care facility that provides diagnosis and treatment for injuries and illnesses. As used in this rule, Hospital includes licensed psychiatric hospitals and licensed psychiatric units.
11. **Individual Receiving Services:** an adult with a developmental disability, such as an intellectual Disability or Autism Spectrum Disorder, determined eligible for and receiving services from a provider of services licensed, funded, or regulated in whole or in part by the Department, or an adult with an acquired brain injury determined eligible for and receiving waiver services from a provider of services licensed, funded, or regulated in whole or in part by the Department.
12. **Internal Review:** required analysis performed by a Provider following a Reportable Event to determine the cause of the Reportable Event .
13. **Law Enforcement Intervention:** Individual Receiving Services is charged with a crime or is the subject of a police investigation, which may lead to criminal charges; an individual is a victim of a crime; crisis intervention involving police or law enforcement personnel.
14. **Mandated Reporter:** as defined in 22 M.R.S. §3477, a person required to report to the Department when the person knows or has reasonable cause to suspect that an incapacitated or dependent adult has been or is likely to be abused, neglected, or exploited.
15. **Medication Error:** an event relating to a medication taken by an Individual Receiving Services that leads to a health or safety concern of a serious and immediate nature based on inappropriate prescription, packaging, dispensing, administration, monitoring, or an individual's refusal to take a medication where serious health or safety implications result.
16. **Mortality Review Committee:** the committee made up of Department staff tasked with analyzing aggregate data related to the deaths of Individuals Receiving Services to identify patterns and trends and make recommendations to improve care based on trend analysis.
17. **Mortality Review Form:** the Reportable Event Database form completed by the Case Manager or Care Coordinator of an Individual Receiving Services following the death of the Individual Receiving Services.
18. **Neglect:** a threat to an adult's health or welfare by physical or mental injury or impairment, deprivation of essential needs or lack of protection from these.
19. **Physical Plant:** a home, program site, or facility where an Individual Receiving Services resides and the property where the residence is located.
20. **Protection and Advocacy Agency:** the Governor-designated agency pursuant to 5 M.R.S. §19502.

21. **Provider:** an agency licensed, funded, or regulated in whole or in part by the Department that provides support services to an Individual(s) Receiving Services.
22. **Remediation Action Step:** a measure intended to make a Reportable Event less likely to occur again in the future, including changes to a physical environment, changes in Provider or individual staff practices, and other preventative measures.
23. **Reportable Event:** any incident involving an Individual Receiving Services that falls into any of the categories listed in Section 2(2)(A)(1)-(16).
24. **Reportable Event Database:** the electronic system designated by the Department through which Reportable Events and follow-up documentation are submitted.
25. **Required Reporter:** any individual involved in the support of an Individual Receiving Services, including, but not limited to Mandated Reporters.
26. **Rights Violation:** any action or inaction that deprives an Individual Receiving Services with an intellectual disability or autism of any of the rights or basic protections described in 34-B M.R.S. §5605.
27. **Serious Injury:** an injury where an Individual Receiving Services requires treatment beyond first aid.
28. **Suicide Attempt:** an intentional attempt to end one's life. This definition does not include self-injurious behavior where the individual does not intend to end his or her own life.
29. **Suicide Threat:** a verbal or written statement, action, or gesture of an Individual Receiving Services that indicates a present intention to end his or her life and a plan to end his or her life.

Section 2. REPORTING REPORTABLE EVENTS TO THE DEPARTMENT

1. Who Must Report

- A. Any Required Reporter shall report a Reportable Event through the Reportable Event Database when he or she becomes aware of any incident that meets the criteria of Section 2(2)(A).
- B. A Required Reporter need not have witnessed the incident in order to report that a Reportable Event has occurred. Second-hand information received by a Required Reporter triggers the duty to report a Reportable Event .
- C. Where multiple Required Reporters witness or become aware of a Reportable Event, only one Reportable Event report is required to be submitted. Where a Required Reporter is not submitting a Reportable Event report on the basis that a Reportable Event report has

already been submitted by another individual, the Required Reporter has the affirmative duty to ensure that a Reportable Event report has in fact been submitted and that it contains all information known or readily available to the Required Reporters related to the Reportable Event , including the names of all witnesses to the Reportable Event.

- D. No individual may impede or inhibit a Required Reporter's reporting of a Reportable Event. No employer, supervisor, manager, or associate of a Required Reporter may require that permission be granted to report a Reportable Event, and a person making a report may not be subject to any sanction for making a report.
- E. This rule does not require an individual acting in a professional capacity to report if reporting would violate a legal duty of confidentiality.

2. What Must Be Reported

- A. Report of a Reportable Event shall be made to the Department for any event or incident involving an Individual Receiving Services that meets any of the following criteria:
 - i. Death, including but not limited to an unexpected death not attributed to a current medical diagnosis or chronic condition and a natural or expected death caused by a long-term illness, diagnosed chronic medical condition, or age;
 - ii. A Suicide Attempt;
 - iii. A Suicide Threat made by an Individual Receiving Services, which indicates a present intention to end his or her life and a plan to end his or her life;
 - iv. Emergency Department visit;
 - v. Planned or unplanned Hospital admission, including observation status;
 - vi. Medication Error that leads to a health or safety concern of a serious and immediate nature due to any of the following:
 - (a) Refusal to take a prescribed medication;
 - (b) Taking medication in an incorrect dosage, form, or route of administration;
 - (c) Taking medication on an incorrect schedule;
 - (d) Taking medication which was not prescribed;
 - (e) An allergic reaction to a medication; or
 - (f) Incorrect procedure followed for assisting an Individual Receiving Services with self-medication.
 - vii. Medical treatment outside of a Hospital setting provided by Emergency Medical Services beyond first aid;
 - viii. Serious Injury, defined as an injury where an Individual Receiving Services requires treatment beyond first aid;
 - ix. Lost or missing Individual Receiving Services;
 - x. A Physical Plant disaster including, fire, natural disaster, or other incident causing displacement due to the condition of the Physical Plant
 - xi. Law Enforcement Intervention involving any of the following:

- (a) An Individual Receiving Services is charged with a crime or is the subject of a police investigation;
 - (b) An Individual Receiving Services is a victim of a crime and law enforcement has been contacted regarding the crime; or
 - (c) Law enforcement personnel have been contacted as a result of planned strategy or unplanned crisis situation.
 - xii. Transportation accident involving any of the following:
 - (a) An Individual Receiving Services is a pedestrian or cyclist involved in a traffic accident;
 - (b) An Individual Receiving Services is a passenger in a motorized vehicle or on a watercraft involved in an accident; or
 - (c) An Individual Receiving Services is involved in any accident involving a motorized vehicle.
 - xiii. Physical assault or altercation involving any of the following:
 - (a) An Individual Receiving Services initiates a physical altercation with another individual(s) (including staff, another Individual Receiving Services, or any other member of the community);
 - (b) An Individual Receiving Services is physically assaulted by another Individual Receiving Services.
 - xiv. Use of an Emergency Restraint (not as part of an approved behavior plan pursuant to 14-197 C.M.R. ch. 5) on an Individual Receiving Services;
 - xv. Rights Violation involving any action or inaction that deprives an Individual Receiving Services with an intellectual disability or autism of any of the rights or basic protections described in 34-B M.R.S. §5605;
 - xvi. Individual Receiving Services is in a dangerous situation posing an imminent risk of harm to self or others that is not included in any of the categories listed in Section 2(2)(A)(1)-(15).
- B. Reporting a Reportable Event through the Reportable Event Database to the Department does not relieve any individual or Provider of any other duties under statute or regulation, including duties to report known or reasonably suspected Abuse, Neglect, or Exploitation of an incapacitated or dependent adult through Adult Protective Services (APS) Central Intake or duties to report to law enforcement.
- C. Reporting Reportable Events through the Reportable Event Database does not relieve any individual or Provider of any other duties related to ensuring the health, safety, and welfare of individuals receiving services. This rule does not preclude any Provider from monitoring or tracking incidents that are not included in any of the categories listed in Section 2(2)(A)(1)-(15).

3. **When Must a Report Be Made**

- A. All of the Reportable Events listed in Section 2(2)(A)(1)-(16) shall be reported through the Reportable Event Database as soon as possible within one (1) business day of the Reportable Event.
 - i. In the event that a Required Reporter does not have access to the Reportable Event Database and can reasonably anticipate that the Reportable Event Database will not be accessible within one (1) business day from the time of the Reportable Event, a report shall be faxed to the Department.

4. **How to Report**

- A. Reportable Events shall be reported through the Reportable Event Database except under the circumstances described in Section 2(3)(A)(1).
- B. A Required Reporter shall provide information in all of the required fields to the extent that such information is known or readily available to the Required Reporter, including information on the immediate response(s) employed to protect the health and safety of the Individual Receiving Services, if applicable.
- C. Within the Reportable Event Database, Required Reporters shall specify all categories identified in Section 2(2)(A) that apply to the Reportable Event being reported within the Reportable Event Database.

Section 3. REPORTABLE EVENT REVIEW AND FOLLOW-UP

1. **Provider Reportable Event Internal Review and Remediation**

- A. When a Provider becomes aware that a Reportable Event has been reported involving an Individual Receiving Services under the Provider's care (whether through the Reportable Event Database or otherwise), the Provider shall conduct an Internal Review into the circumstances surrounding the Reportable Event.
 - i. The Internal Review may involve, but is not limited to, the following:
 - 1. Communication with the Individual Receiving Services, if appropriate;
 - 2. Communication with any witnesses to the Reportable Event, if appropriate;
 - 3. Survey of the area where the Reportable Event occurred, if appropriate.
- B. The Provider and the Individual Receiving Services' Case Manager or Care Coordinator shall communicate as part of the Internal Review process and work cooperatively to determine the cause of the Reportable Event and to identify potential Remediation Action Steps.

- C. Following the Internal Review, the Provider shall determine what, if any, Remediation Action Steps would decrease the likelihood that such an incident will reoccur.
- D. Reporting Reportable Event and conducting Internal Review and remediation of Reportable Event does not preclude Providers from conducting reviews and identifying Remediation Action Steps related to other events, incidents, or observations that are not identified within the categories of Reportable Event listed in Section 2(2)(A)(1)-(16).

2. Provider Reportable Event Follow-Up

A. Provider Follow-Up Report

- i. Following the Provider Internal Review, the Provider shall submit a Follow-Up Report to the Department through the Reportable Event Database outlining the following:
 - 1. The date and time of the Reportable Event and, if the Reportable Event is reported in the Reportable Event Database more than one business day from the time of the Reportable Event, an explanation for the delay in reporting;
 - 2. A summary of the circumstances that resulted in the Reportable Event ;
 - 3. An outline of any Remediation Action Steps that were taken following the Reportable Event to decrease the likelihood that the same or a similar incident will reoccur, including the date(s) of implementation and the party or parties responsible for implementing each Remediation Action Step;
 - 4. An outline of any future Remediation Action Steps that will be taken to decrease the likelihood that such an incident will reoccur, including the planned dates of implementation, if applicable, and the party or parties responsible for implementing each Remediation Action Step;
 - 5. If no Remediation Action Steps have been or will be taken in response to the incident, an explanation as to why Remediation Action Steps are not necessary.
- ii. The Provider Follow-Up Report on a Reportable Event shall be submitted into the Reportable Event Database no later than thirty (30) calendar days from the date of the Reportable Event.

3. Case Manager and Care Coordinator Reportable Event Follow-Up

- A. The Case Manager or Care Coordinator shall review the Reportable Event Database to determine whether Provider Reportable Event Follow-Up has taken place and ensure that Remediation Action Steps are reflected in the person-centered plan of the Individual Receiving Services, as necessary.

- B. The Case Manager or Care Coordinator shall consult with the Individual Receiving Services on the Remediation Action Steps taken or to be taken by the Provider in a manner that demonstrates inclusion and informed consent of the Individual Receiving Services and his or her legal guardian as appropriate.
4. **Additional Follow-Up on Reportable Event that involve the Death of an Individual Receiving Services**
- A. **Mortality Review Form**
 - i. Following any Reportable Event that involves the death of an Individual Receiving Services, the Individual Receiving Services' Case Manager or Care Coordinator shall complete the Mortality Review Form within the Reportable Event Database.
 - ii. The Mortality Review Form shall be submitted into the Reportable Event Database no later than ten (10) business days from the date of the Reportable Event involving the death of an Individual Receiving Services.
 - iii. In the event that the Case Manager or Care Coordinator is not available at the time of death, a supervisor of the Case Manager or Care Coordinator shall complete the Mortality Review Form within the required timeframe.
 - B. **Mortality Review Committee**
 - i. The Mortality Review Committee will conduct trend analysis based on completed Mortality Review Form aggregate data.
 - ii. The Mortality Review Committee will meet quarterly to review any identifiable patterns and trends related to the deaths of Individuals Receiving Services.
 - iii. The Mortality Review Committee will produce an annual report to the Commissioner that outlines trend analysis findings and makes recommendations to improve care for Individuals Receiving Services.
5. **Additional Follow-Up on Reportable Events Involving Rights Violations**
- A. The Protection and Advocacy Agency shall have access within the Reportable Event Database to Reportable Events that involve one or more alleged Rights Violations.
 - B. The Protection and Advocacy Agency may investigate any Reportable Event that involves one or more alleged Rights Violations.
 - C. Providers must cooperate fully with the Protection and Advocacy Agency during any investigation of a Reportable Event involving one or more Rights Violations.
 - D. Requirements within this Rule related to Provider Reportable Event Internal Review, Remediation, and Follow-Up Reports are not impacted by whether the Protection and

Advocacy Agency investigates a Reportable Event involving one or more alleged Rights Violations. Provider requirements following a Reportable Event involving one or more alleged Rights Violations are governed by Section 3.

6. Department and Provider Aggregate Reportable Event Review

- A. Providers shall conduct trend analysis of Reportable Event data on an ongoing basis, at least quarterly, in order to identify areas where services may be improved to ensure the health and safety of Individuals Receiving Services.
- B. The Department will meet quarterly with every Provider required to report Reportable Event in accordance with this Rule to discuss Reportable Event data collected during the previous quarter, including, but not limited to:
 - i. The total number of Reportable Event involving Individuals Receiving Services under the Provider's care during the quarter;
 - ii. Any identified trends and patterns associated with Reportable Events;
 - 1. Examples of data sets that may be identified and discussed are:
 - a. Aggregate Reportable Events per quarter per Individual Receiving Services by Reportable Event type;
 - b. Aggregate Reportable Events per quarter by Provider site by Reportable Event type;
 - c. Increases and decreases in the number of Reportable Events reported from the previous quarter or previous year;
 - d. Increases and decreases in the number of Reportable Event types from previous quarters or previous years.
 - iii. The adequacy and effectiveness of the Provider's Reportable Event Reviews, Remediation Action Steps, and Follow-Up Reports and the timeliness of same;
 - iv. Comparison of any trend analysis performed by the Department with trend analysis performed by the Provider.

STATUTORY AUTHORITY: 34-B M.R.S. §5604-A

EFFECTIVE DATE:

July 14, 2007 – filing 2007-296, as “Regulations Regarding Reportable Events, Adult Protective Investigations and Substantiation Hearings Regarding Persons with Mental Retardation or Autism”

REPEALED AND REPLACED:

May 28, 2018 – filing 2018-087, as “Reportable Events System”

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self and MDSOAB

There should be three attachments:
March 20, 2018 written testimony on LD 716
Sundram's 2007 Adult Protective regulation
May 28, 2018 current regulation that repealed and replaced Sundram's