Virginia Department of Behavioral Health & Developmental Services

DBHDS Office of Licensing
Guidance for Serious Incident Reporting

Effective:

Purpose: This document contains clarifications for providers as to the definition of a serious incident and the corresponding reporting requirements to the Office of Licensing per 12VAC35-105 in accordance with emergency amendments effective September 1, 2018.

12VAC35-105-20. Definitions.

"Serious incident" means any event or circumstance that causes or could cause harm to the health, safety, or well-being of an individual. The term serious incident includes death and serious injury. "Level I serious incident" means a serious incident that occurs or originates during the provision of a service or on the premises of the provider and does not meet the definition of a Level II or Level III serious incident. "Level I serious incidents" do not result in significant harm to individuals, but may include events that result in minor injuries that do not require medical attention, or events that have the potential to cause serious injury, even when no injury occurs.

- Providers are not required to report Level I serious incidents via CHRIS to the Office of Licensing.
- Providers shall collect, maintain, and review at least quarterly all Level I serious incidents occurring within the provision of their service or on the premises of the provider as part of their quality improvement program.
- "Provision of service" means that the incident occurs when the provider is actively providing a service to the individual.
    - For example, if an individual reports to their case manager that the individual fell off of their bicycle at their group home and sustained minor injuries, the case manager is not required to collect, maintain, and review this information as part of their quality improvement program. However, this information may be pertinent to the case manager's responsibilities under 12VAC35-105-1245. The incident would be documented as a Level I incident by the DBHDS Licensed Group Home provider.

"Level II serious incident" means a serious incident that occurs or originates during the provision of a service or on the premises of the provider that results in a significant harm or threat to the health and safety of an individual that does not meet the definition of a Level III serious incident. "Level II serious incident" also includes a significant harm or threat to the health or safety of others caused by an individual.

- Providers are only required to report Level II serious incidents that occurred, originated, or happened during the provision of a service or on the premises of the provider.
- Providers of community-based services should only report Level II incidents that happen when the provider is actively providing the service to the individual or when the individual is on the premises of the provider. If the provider is notified of a Level II incident that occurred

when the provider was not actively providing services, then the provider is not required to report the incident.
    - For example, an individual receiving case management services reports to their case manager that last week they went to the emergency room because they were in a car accident, the case manager is not required to report the incident.
- Please note that residential providers are responsible for individuals 24 hours a day and therefore, are required to report all incidents once notified.
    - For example, an individual who receives group home services went home on a home visit over the weekend. When the individual returned to the group home from the home visit, the authorized representative reports that the individual went to the emergency room because the individual was not feeling well. The residential provider is required to report this information within 24 hours from the time the provider was notified of the incident.

"Level II serious incidents" include:

1. A serious injury;

- DBHDS regulation 12VAC35-105-20 defines a serious injury as '*any injury resulting in bodily hurt, damage, harm, or loss that requires medical attention by a licensed physician, doctor of osteopathic medicine, physician assistant, or nurse practitioner.'*

2. An individual who is missing;

- DBHDS regulation 12VAC35-105-20 defines missing as *'a circumstance in which an individual is not physically present when and where he should be and his absence cannot be accounted for or explained by his supervision needs or pattern of behavior.'*

3. An emergency room or urgent care facility visit when not used in lieu of a primary care physician visit;

- If an individual is unexpectedly taken to the emergency room or an urgent care facility it is assumed that the provider believed the incident was serious enough to require emergency or urgent care. Therefore, the incident is required to be reported.
- If an individual has an expected visit to an emergency room or urgent care for something that is not considered a Level II or Level III serious incident (i.e., a cold, etc.), then the provider is not required to report the incident. However, the provider should evaluate how to use the emergency room or urgent care center. Emergency rooms and urgent care centers should not be routinely used in lieu of a primary care physician.

4. An unplanned psychiatric or unplanned medical hospital admission;

- If an individual is only receiving licensed emergency services and no other licensed service at the time of the TDO or ECO, the provider is not required to report the admission.
    - DBHDS regulation 12VAC35-105-20 defines emergency services as "*unscheduled and sometimes scheduled crisis intervention, stabilization, and referral assistance provided over the telephone or face-to-face, if indicated, available 24 hours a day and seven days per week. Emergency services also may include walk-ins, home visits, jail interventions, and preadmission screening activities associated with the judicial process*."

- If an individual requires an Emergency Custody Order (ECO) or Temporary Detention Order (TDO) **during the provision** of a licensed service, the provider is required to report the unplanned admission. If an individual is receiving case management services at the time of the unplanned hospital admission, the case manager is only required to report the incident if the admission occurred during the provision of the case manager's services or on the premises of the provider.
- Any time that an individual is admitted to the hospital due to an unplanned medical issue (i.e., appendix, broken bone, burn, the flu, sepsis, etc.) shall be reported.
- If an individual is taken to the hospital after a qualifying event in accordance with their medical protocol, and is not admitted following evaluation, then the provider does not have to report the incident. If it is determined that the individual should be admitted, then the incident shall be reported.

5. Choking incidents that require direct physical intervention by another person;

- If an individual experiences a choking incident that requires abdominal thrusts, formerly known as the Heimlich Maneuver, or other emergency services, the provider shall report the incident.
- If an individual chokes on food but is able to cough up the food by themselves, then the provider is not required to report the incident as a Level II serious incident. However, the choking incident should be recorded by the provider as a Level I serious incident as it is an event that has potential to cause serious injury.
- Providers should review the DBHDS safety alert for "dysphasia/aspiration."

6. Ingestion of any hazardous material

- If any individual drinks, swallows, or absorbs a material that is hazardous to their health (batteries, bleach, chemicals, or any material not meant to be ingested) it shall be reported.
- Provider should review DBHDS safety alert for "hazards of household products."

7. A diagnosis of:

a. A decubitus ulcer or an increase in severity of level of previously diagnosed decubitus ulcer;

- Providers should review the DBHDS safety alert for "pressure ulcers" for the definition and description of levels regarding decubitus ulcer.
- A diagnosis is required by a licensed or certified medical professional.
- This will generally be reported by a provider of residential services as medical diagnoses typically occur within the provision of their services.

b. A bowel obstruction; or

- Providers should review the DBHDS safety alert for "constipation."
- A diagnosis is required by a licensed or certified medical professional.
- This will generally be reported by a provider of residential services as medical diagnoses typically occur within the provision of their services.

c. Aspiration pneumonia.

- Providers should review the DBHDS safety alert for "dysphasia/aspiration."
- A diagnosis is required by a licensed or certified medical professional.
- This will generally be reported by a provider of residential services as medical diagnoses typically occur within the provision of their services.

"Level III serious incident" means a serious incident whether or not the incident occurs while in the provision of a service or on the provider's premises and results in:

- Providers shall report all Level III serious incidents even if the incident did not occur on the provider's premises or within the provision of services.
- All providers that are made aware of a level III serious incident are required to report even if this results in duplicative reporting.

1) Any death of an individual;

- All providers, including case managers, shall report the death of any individual receiving services at the time of death.
  - For example, if an in-home supports provider receives notification that an individual who receives services died over the weekend, the provider is required to report this incident.

2) A sexual assault of an individual;

- Providers shall report to the department and other relevant authorities as required by law that an individual alleges they were sexually assaulted, whether or not the alleged assault occurred within the provision of the provider's services or on their property.

3) A serious injury of an individual that results in or likely will result in permanent physical or psychological impairment;

  - For example, providers shall report if an individual had to have a leg amputated as a result of a car accident whether or not the car accident occurred within the provision of the provider's services or on their property.

4) A suicide attempt by an individual admitted for services that results in a hospital admission.

- Providers shall report a suicide attempt by an individual if the individual is receiving any licensed service at the time of the attempt whether or not the attempt occurred within the provision of the provider's services or on their property.
- If an individual is only receiving licensed emergency services, and no other licensed service at the time of the suicide attempt, it is not required to be reported.

12VAC35-105-160. Reviews by the department; requests for information; required reporting.

A. The provider shall permit representatives from the department to conduct reviews to:

1. Verify application information;

2. Assure compliance with this chapter; and

3. Investigate complaints.

B. The provider shall cooperate fully with inspections and investigations, and shall provide all information requested by the department.

- Representatives of DBHDS will request documentation from a provider, including documents relating to an individual's death, to determine if the provider has complied with DBHDS regulations. The provider is required to submit this documentation and any requested information to the department within 10 business days per 12VAC35-105-160.H.

Examples of Non-Compliance:
- Any withholding of information or documentation from the department.
- Not submitting the information to the department within 10 business days of the request, unless the department granted the provider an extension.

C. The provider shall collect, maintain, and review at least quarterly all Level I serious incidents as part of the quality improvement program in accordance with 12VAC35-105-620 to include an analysis of trends, potential systemic issues or causes, indicated remediation, and documentation of steps taken to mitigate the potential for future incidents.

- Level I serious incidents are not required to be reported into the department's web-based reporting application (CHRIS).
- The reason for monitoring Level I serious incidents is to minimize the risk of the occurrence of additional Level I, II, or III incidents in the future.
- The provider's quality improvement plan should address how the provider will identify trends and systemic issues and indicate remediation and the steps taken to mitigate (reduce or alleviate) the potential for future incidents.
  Example:
  - A provider's quarterly review of Level I incidents identified several falls without serious injury to individuals.

1. Analysis of trends – The provider reviews all falls, falls per individual, environment in which the falls occurred, time of day when the falls occurred, etc., to determine any trends and look at any patterns, e.g., same individual, same location, like locations (bathrooms). The provider can determine if the issue is systemic and how best to address it.

2. Potential systemic issues or causes – The provider reviews policies, procedures, or protocols related to fall prevention.

3. Indicated remediation – The provider makes recommendations to prevent a reoccurrence. Depending on the trend analysis, this remediation could be related to falls sustained for one

individual or all individuals.

4. Documentation of steps taken to mitigate the potential for future incidents – The provider documents specific steps or actions taken to reduce or manage the likelihood or severity of an adverse outcome.
   Example:
   - If falls had occurred from a bed, the provider may mitigate future incidents by placing a fall mat near a bed to prevent more serious injuries.

For additional information, please see the DBHDS Office of Licensing, Guidance for a Quality Improvement Program.

D. The provider shall collect, maintain, and report or make available to the department the following information:

1. Each allegation of abuse or neglect shall be reported to the department as provided in 12VAC35-115-230 A.

- Providers shall report each allegation of abuse or neglect via the department's web-based reporting application (CHRIS) within 24 hours of receipt of the allegation. [NOTE: This is not a change]

2. Level II and Level III serious incidents shall be reported using the department's web-based reporting application and by phone to anyone designated by the individual to receive such notice and to the individuals authorized within 24 hours of discovery. Reported information shall include the information specified by the department as required in its web-based reporting application but at least the following: the date, place, and circumstances of the serious incident. For serious injuries and deaths, the reported information shall also include the nature of the individual's injuries or circumstances of the death and any treatment received; and the circumstances of the death or serious injury. For all other Level II and Level III serious incidents, the reported information shall also include the consequences or risk of harm that resulted from the serious incident. Deaths that occur in a hospital as a result of illness or injury occurring when the individual was in a licensed service shall be reported.

- Providers shall report Level II and Level III serious incidents to an individual's guardian or authorized representative within 24 hours of discovering the incident.
- Providers shall report deaths if the individual was not yet discharged from the service at the time of death.

3. Instances of seclusion or restraint shall be reported to the department as provided in 12VAC35-115-230 C 4.

- Providers shall report any instance of seclusion or restraint that does not comply with 12VAC35-115 (the "Human Rights Regulations") or approved variances, or that results in injury to an individual, to the department via the department's web-based reporting application (CHRIS) within 24 hours. The individual's authorized representative, if

applicable, should also be notified by the provider within 24 hours. [NOTE: This is not a change.]

E. A root cause analysis shall be conducted by the provider within 30 days of discovery of Level II and Level III serious incidents. The root cause analysis shall include at least the following information: (i) a detailed description of what happened; (ii) an analysis of why it happened, including identification of all identifiable underlying causes of the incident that were under the control of the provider; and (iii) identified solutions to mitigate its reoccurrence.

Root cause analysis (RCA) is a method of problem solving designed to identify the underlying causes of a problem. The focus of a root cause analysis is on systems, processes and outcomes that require change to reduce the risk of harm – 12VAC35-105-20.

A RCA focuses on systems, processes, and outcomes, not people. The goals of a RCA are to find out what happened, why it happened, and determine if action needs to be taken. If the provider determines that changes need to be implemented, they should implement such changes to keep the situation from occurring again.

The best way to conduct a root cause analysis is by convening a team. It is recommended that the team be made up of staff that were involved in the event and people responsible for the processes or systems. It doesn't have to be a large team. If an organization is very small and it is difficult to convene a team, a single individual in addition to the person who witnessed the incident may conduct the RCA analysis but that additional person should be a manager or supervisor who was not involved in the incident. If a person is the sole owner of a sponsored residential home and is also the sponsored provider, without any oversight or supervision from anyone other than themselves, then they are excluded from the requirement to include an uninvolved supervisor.

(i) a detailed description of what happened –

The convening RCA team should:

1. Look at all records of the incident including incident reports, medical records, service plans, logs, and video tapes.
2. Complete interviews to find out what happened from the perspective of the person or people involved. The number of people interviewed should depend on the nature and the seriousness of the event. The purpose of the interview is not to look to determine if someone is at fault, but to look for the facts in order to solve a potential problem.
3. Document who was interviewed and each person's account of the event.
4. Based on the information collected, document the step by step sequence of events leading up to the critical incident and the actions taken immediately following the incident

(ii) an analysis of why it happened, including identification of all identifiable underlying causes of the incident that were under the control of the provider

The analysis should:

1. Compare what happened to what should have happened before, during, and after the incident.
2. Compare the actions taken to the requirements in the provider's policies and procedures, DBHDS licensing and other applicable regulations, accreditation standards, and applicable laws.
3. State the problem clearly.

4. Explore “why” the Level II or Level III serious incident happened.
5. After completing the root cause analysis there should be a clear statement of cause. The causal statement should focus on systems and processes and what caused this event.

(iii) identified solutions to mitigate its reoccurrence -

Once the provider has concluded the analysis, they should:

1. Take action to mitigate the chance of reoccurrence.
2. Continue to monitor changes to ensure that they are effective.

Further information and resources related to root cause analysis are located at:
http://www.dbhds.virginia.gov/quality-management/facility-quality-and-risk-management

F. The provider shall submit, or make available, reports and information that the department requires to establish compliance with these regulations and applicable statutes.

- DBHDS will request documentation, including documents relating to an individual’s death, to determine if there is compliance with regulations. The provider is required to submit this documentation and any requested information to the department within 10 business days of the issuance of the licensing report per 12VAC35-105-160.H.

  Examples of Non-Compliance:
  - Any withholding of information or documentation from the department.
  - Not submitting the information to the department within 10 business days of the request, unless the department granted the provider an extension.

G. Records that are confidential under federal or state law shall be maintained as confidential by the department and shall not be further disclosed except as required or permitted by law; however, there shall be no right of access to communications that are privileged pursuant to § 8.01-581.17 of the Code of Virginia.

H. Additional information requested by the department if compliance with a regulation cannot be determined shall be submitted within 10 business days of the issuance of the licensing report requesting additional information. Extensions may be granted by the department when requested prior to the due date, but extensions shall not exceed an additional 10 business days.

- DBHDS will request documentation, including documents relating to an individual’s death, to determine if there is compliance with regulations. The provider is required to submit this documentation and any requested information to the department within 10 business days of the issuance of the licensing report per 12VAC35-105-160.H.

  Examples of Non-Compliance:
  - Any withholding of information and/or documentation from the department.
  - Not submitting the information to the department within 10 business days of the request and not being granted an extension.

I. Applicants and providers shall not submit any misleading or false information to the department.

- DBHDS may take negative actions (sanctions, denial, provisional, revocation, summary suspension) against any provider who submits false or misleading information, documents, or reports to the department.