Virginia Department of Behavioral Health & Developmental Services

DBHDS Office of Licensing
Guidance for Serious Incident Reporting

Effective: November 29, 2018

Purpose: This document contains guidance to providers regarding the definition of "serious incident" and the corresponding reporting requirements as provided in the emergency text containing amendments to the Rules and Regulations for Licensing Providers by the Department of Behavioral Health and Developmental Services, 12VAC35-105, effective September 1, 2018, through February 29, 2020, or until the permanent regulation takes effect.

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 as part of their quality improvement program.
- "[D]uring the provision of a 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, although this information may be pertinent to the case manager's responsibilities under 12VAC35-105-1245. The DBHDS-licensed group home provider, however, is required to collect, maintain, and review this information as part of its quality improvement program.

"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.

- For Level II serious incidents as with Level I serious incidents, “during the provision of a service” means that the incident occurs when the provider is actively providing a service to the individual. If the provider is notified of a Level II incident that occurred or originated when the provider was not actively providing a service, 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.
- Providers licensed to provide a “residential service” as defined by 12VAC35-105-20 provide 24-hour support to individuals. However, if an individual receiving residential services experiences a Level II serious incident while actively receiving services from another licensed provider, the residential service provider is not required to report the incident if they verify that the other provider reported the incident.
    - For example, if an individual who receives group home services sustains a serious injury at their day support program, the group home provider is not required to report the serious injury as long as they verify that the day support provider reported the incident.
    - However, if an individual receiving services from a residential service provider sustains a serious injury during an independent trip to the grocery store, the residential service provider must report the serious injury as a Level II serious incident.
- Level II serious incident also includes a significant harm or threat to the health or safety of others caused by an individual.
    - Peer to peer incidents which result in significant harm or threat to the health or safety of an individual by an another individual should be reported to the Office of Licensing as two separate Level II serious incidents in the CHRIS reporting system.
        - For example, if Individual #1 punches Individual #2 and Individual #2 sustains a broken nose, this Level II serious incident should be reported into CHRIS as a Level II serious incident for Individual #1 because they caused significant harm to another individual and should be reported as a Level II serious incident for Individual #2 because they sustained a serious injury. The provider is also required to report the incident for Individual #2 to the Office of Human Rights and investigate as required by *Human Rights Regulation* 12VAC35-115-50.
    - Peer to peer incidents which do not result in significant harm or threat to the health of the safety of an individual by another individual do not need to be reported to the Office of Licensing as a Level II serious incident.

"Level II serious incidents" include:

Please note that per Code of Virginia § 1-218 the term “includes” means “*includes, but not limited to*.” Therefore, Level II serious incidents are not limited to the incidents enumerated below.

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."*
- Providers are not expected to report missed appointments.
    - For example, if an individual admitted for outpatient or case management services misses an appointment, they are not considered to be missing.

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

- The provider is not required to report if they have to take an individual to an urgent care facility or emergency room for an issue typically treated by a primary care physician because the individual's primary care physician is not accessible at the time treatment is required.
    - For example, if an individual is taken to an urgent care facility over the weekend because the provider believes the individual has a urinary tract infection and the individual's primary care physician is closed over the weekend, this incident is being used in lieu of a primary care physician visit and does not need to be reported. However, if this same individual is taken over the weekend for a urinary tract infection and is admitted to the hospital, the provider must report the incident as an unplanned medical hospital admission (*please see guidance under #4 below*).

4. An unplanned psychiatric or unplanned medical hospital admission;

- DBHDS regulation 12VAC35-105-20 defines "Emergency service" 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 is only receiving licensed emergency services and no other licensed service at the time the individual is admitted to a facility pursuant to a temporary detention order ("TDO") issued by a magistrate, the emergency service provider is not required to report the admission.
- If an individual is receiving services from a provider other than an emergency service provider (*e.g.*, residential service, day support, mental health community support) and is admitted to a facility pursuant to a TDO while the provider is actively providing a service to the individual, this provider is required to report the unplanned admission.
    - For example, an individual living in a group home experiences a psychiatric crisis while in the group home which leads to the issuance of a TDO and a hospital admission. The group home provider would report the incident.
    - During a treatment session, an outpatient service provider is concerned about an individual's suicidal intent; the provider arranges to have the individual evaluated, and the individual is then admitted to the hospital. The outpatient provider would report the incident.
    - An individual who receives outpatient services experiences suicidal thoughts at a time when they are not in a therapy session with their outpatient service provider and contacts emergency services because they are feeling suicidal. The emergency service provider evaluates the individual, and the individual is then admitted to the hospital. Neither the outpatient service provider nor the emergency service provider

would report the incident.

- If an individual is receiving case management services at the time of an unplanned psychiatric or unplanned medical hospital admission, the case manager is only required to report the incident if the admission occurred while the case manager was actively providing case management service to the individual.
- If an individual is admitted to a hospital due to an unplanned medical issue (*e.g.*, appendix, broken bone, burn, the flu, sepsis, etc.), this incident must be reported by the provider that was providing services at the time of admission. If the incident requiring admission did not occur during the provision of services then it would not need to be reported.

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

- If an individual experiences a choking incident that requires physical aid by another person, such as abdominal thrusts (Heimlich maneuver), back blows, clearing the airway, or CPR, the provider must report the incident.
- If an individual chokes on food but is able to cough up the food on their own without the physical aid of another person, then the provider is not required to report the incident as a Level II serious incident. The choking incident should, however, be recorded by the provider as a Level I serious incident, as choking is an event that has the potential to cause serious injury.

6. Ingestion of any hazardous material

- If an individual drinks, swallows, or absorbs a material that causes significant harm to the individual or is a threat to their health and safety, the provider should report this as a Level II serious incident.
- The DBHDS safety alert "Hazards of Household Products" provides additional guidance about hazardous materials.

7. A diagnosis of:

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

- A diagnosis of decubitus ulcer or an increase in severity of level of a previously diagnosed decubitus ulcer should be reported as a Level II serious incident once the provider has sought and obtained a diagnosis from a medical professional.
- It is recommended providers review the DBHDS safety alert for "pressure ulcers" for the definition and description of levels regarding decubitus ulcer.

b. A bowel obstruction; or

- A diagnosis of a bowel obstruction should be reported as a Level II serious incident once the provider has sought and obtained a diagnosis from a medical professional.
- It is recommended providers review the DBHDS safety alert for "constipation."

c. Aspiration pneumonia.

- A diagnosis of aspiration pneumonia should be reported as a Level II serious incident once the provider has sought and obtained a diagnosis from a medical professional.
- It is recommended providers review the DBHDS safety alert for "dysphasia/aspiration."

"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:

- "[W]hile in the provision of a service" means that an incident occurs when the provider is actively providing a service to the individual.
- Providers must report all Level III serious incidents even if the incident did not occur on the provider's premises or while the provider was actively providing a service to the individual.
- All providers that are aware of a Level III serious incident affecting an individual they serve are required to report the incident even though it may result in duplicative reporting.

1) Any death of an individual;

- All providers, including case managers, must report the death of any individual receiving services from the provider at the time of death.
  - For example, if an in-home supports provider and case manager receive notification that an individual receiving services died over the weekend, both the in-home supports provider and the case manager are required to report the death.

2) A sexual assault of an individual;

- Any sexual assault required by other applicable laws to be reported to other relevant authorities shall be reported to those authorities in accordance with law.
- The department recognizes that reporting an allegation of sexual assault could impact the therapeutic relationship of the individual with the provider; therefore, reporting should be trauma-informed and respect the therapeutic relationship.
- The provider should report any sexual assault of an individual receiving services alleged to have resulted from any act or failure to act by the provider's employee or other person responsible for the care of an individual in the provider's program.
- The provider must report to DBHDS any alleged sexual assault of a minor or of an adult who is determined to lack capacity pursuant to 12VAC35-115-145.
- For alleged sexual assault of an individual who is an adult with capacity:
  - If the alleged sexual assault occurs in the provision of a service or on the provider's premises, the provider must report the alleged sexual assault to DBHDS.
  - If the alleged sexual assault does not occur in the provision of a service or on the provider's premises, reporting of the alleged sexual assault to DBHDS is required only if the adult with capacity gives consent for the report to be made.

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

- For example, all providers must report if an individual had to have a leg amputated as a result of a car accident whether or not the car accident occurred on the provider's premises or within the provision of their services.
- Whether or not a serious injury will likely result in permanent impairment is a judgment that

providers must make based upon the information available to them at the time. Documentation in progress notes regarding this determination can be used to support a decision to report, or not report.

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

- The United States Centers for Disease Control and Prevention define a suicide attempt as "a non-fatal, self-directed, potentially injurious behavior with an intent to die as a result of the behavior; might not result in injury."
- If an individual admitted for services is admitted to the hospital as a result of self-directed behavior, and it is determined by a licensed professional that the individual intended to die as a result of the behavior, all providers are required to report this incident as a Level III serious incident regardless of whether the incident occurred within the provision of their services or on their property.
- Self-injurious behavior without the intent to die that results in a hospital admission or trip to the emergency room does not need to be reported as a Level III serious incident by all providers. However, the incident should be reported as Level II serious incident by a provider if the incident occurred within the provision of their services or on their property.
- Providers must report a suicide attempt that results in a hospital admission by an individual if the individual is already admitted to, or receiving any licensed service at the time of, the attempt whether or not the attempt occurred on the provider's premises or while the provider was actively providing services to the individual.
    - For example, if an individual receiving outpatient services attempts suicide over the weekend and is admitted to the hospital, the outpatient provider must report this incident even though the individual was not within the provision of the outpatient provider's services at the time of the incident.
- If an individual is only receiving licensed emergency services, and no other licensed service at the time of the suicide attempt, the emergency service provider is not required to report the incident.

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.

  Examples of Non-Compliance:
  - Failure to provide information or documentation requested by the department to determine compliance with regulations.

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 provider monitoring of Level I serious incidents is to minimize the risk of the occurrence of additional Level I, II, or III incidents in the future.
- Provider quality improvement plans, required by 12VAC35-105-620, 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 – Examples of an analysis of trends include: the provider reviews all falls, falls per individual, the 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. For example, systemic causes could include a lack of a protocol for assessing an individual's fall risk, an environment that increases the risk of falls (area rugs that slip, or can be tripped over; furniture placement; etc.), or other causes that can affect multiple individuals.

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 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 individual's authorized representative 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. 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 must report Level II and Level III serious incidents to an individual's guardian or authorized representative within 24 hours of discovering the incident.
- Providers must 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 must 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, must 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), as defined by 12VAC35-105-120, 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*."

An RCA focuses on systems, processes, and outcomes, not people. The goals of an RCA are to find out what happened, why it happened, and determine if action needs to be taken. A root cause analysis, as required in these regulations, should include, at minimum, documentation that the three elements below were considered to the extent that they are known, or could be known by the provider. A more detailed root cause analysis, including convening a team, collecting and analyzing data, mapping processes, etc., may be considered based upon the circumstances of the incident.

(i) a detailed description of what happened –

Documentation of what happened should include the step-by-step sequence of events leading up to the incident and the actions taken immediately following the incident. In the case of a Level III incident that did not occur while the individual was receiving active services from the provider, or on the provider's premises, this documentation should include as much information as was reported to, or is otherwise known by the provider.

(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

Analysis of why an incident occurred should:

1. Compare what happened to what should have happened before, during, and after the incident.
2. Compare the actions taken before, during, and after the incident to the requirements in the provider's policies and procedures, DBHDS licensing and other applicable regulations, accreditation standards, and applicable laws.
3. Clearly identify the underlying causes of the incident that were under the control of the provider.
4. In the case of a Level III serious incident that did not occur while the individual was actively receiving services from the provider or on the provider's premises, only be based on what is reported to or otherwise known by the provider.

(iii) identified solutions to mitigate its reoccurrence -

The RCA should identify solutions, as applicable, to be taken by the provider to keep the situation from occurring again or minimize the likelihood of its reoccurrence. These solutions should be individual-specific and systemic as indicated by the analysis of the

incident. Implementation of these solutions and their efficacy should be monitored as part of the provider's quality improvement program, in accordance with 12VAC35-105-620.

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.

- Throughout the course of inspections and investigations, whether on-site, in-person or via email, phone, letter, or other means of communication, DBHDS will request documentation, including documents relating to an individual's death, to determine the provider's compliance with regulations.

  Examples of Non-Compliance:
  - Failure to provide information or documentation requested by the department to determine compliance with regulations.

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.

- Throughout the course of inspections and investigations, DBHDS will request documentation, including documents relating to an individual's death, to determine the provider's compliance with regulations. In some instances, the department may not be able to determine the provider's compliance based on information already received and will request additional information. The provider must submit this documentation and any requested information to the department within 10 business days of the issuance of the licensing report requesting additional information per 12VAC35-105-160.H.

  Examples of Non-Compliance:
  - Failure to provide information or documentation requested by the department to determine compliance with regulations.
  - Not submitting the information to the department within 10 business days of issuance of a licensing report requesting additional information without having been granted an extension in accordance with subsection H.

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

- DBHDS may take negative action against any provider who submits false or misleading information, documents, or reports, whether written or oral, to the department.