Virginia Department of Behavioral Health & Developmental Services

DBHDS Office of Licensing
Guidance for Serious Incident Reporting

Effective: November 28, 2020

Purpose: This document contains guidance to providers regarding the definition of "serious incident" and the corresponding reporting requirements adopted to address compliance with the US Department of Justice's Settlement Agreement with Virginia within the Rules and Regulations for Licensing Providers by the Department of Behavioral Health and Developmental Services [12VAC35-105] ("Licensing Regulations"). For additional information related to the department expectations for serious incident reporting please visit the department's August 22, 2020, Incident Reporting Memo.

Regulations addressed: Note all regulatory language is formatted in *italics* while guidance language is in plain text located within boxes under the label "guidance."

12VAC35-105-20. Definitions.

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

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.

Guidance:

Providers are not required to report Level I serious incidents via DBHDS' web-based reporting application (CHRIS) to the Office of Licensing.

Level I serious incidents, by definition, occur or originate during the provision of services or on the premises of the provider. "[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 his case manager that the individual fell off of his bicycle at the group home and sustained minor injuries, the case manager is not required to collect, maintain, and review this information as part of the 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 (discussed further below).

"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" includes a significant harm or threat to the health or safety of others caused by an individual.

Guidance:

Like Level I serious incidents, Level II serious incidents, by definition, occur or originate during the provision of services or on a provider's premises, where "during the provision of services" 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 serious 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 the provider attempts to verify that the other provider reported the incident. Once a residential provider becomes aware that an individual experienced a Level II serious incident during the provision of another provider's services, the residential provider should reach out directly to the other provider to attempt to verify that the other provider reported the incident. The residential provider should select a consistent manner to document any attempts to verify the submission of an incident report by another provider, as well as the other provider's response. Verification may occur through phone conversations, face-to-face interactions, e-mails, or fax. A simple confirmation from the other provider that they submitted the report is sufficient; the residential provider is not required to receive a copy of the incident report. If the residential provider cannot receive confirmation from the other provider that a serious incident report was submitted, then the residential provider may submit a complaint to the Office of Licensing at olcomplaints@dbhds.virginia.gov.

- For example, if an individual who receives group home services sustains a serious injury at a day support program, the group home provider is not required to report the serious injury as long as the group home provider reaches out to the day support provider to verify that the day support provider reported the incident. The group home provider should document all attempts to reach out to the day support provider and the response received.
- 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.

In addition, if an individual receiving services is temporarily away from a provider's services for a visit or trip with family, and the individual experiences a Level II serious incident, the incident does not need to be reported to the Office of Licensing.

- For example, an individual who receives group home services has a choking incident which requires direct physical intervention while on a family trip to the beach. When the individual returns, their parent informs the provider of the incident. The provider does not need to report the choking incident requiring physical intervention as a Level II serious incident. However, the provider should internally document the report made by the family and based on the specific details surrounding the incident, the provider may need to evaluate individual supports to determine if they are still appropriate.

"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 that 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 that person caused significant harm to another individual. This incident should also be reported as a Level II serious incident for Individual #2 because that person 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 Regulations to Assure the Rights of Individuals Receiving Services from Providers Licensed, Funded, or Operated by the Department of Behavioral Health and Developmental Services [12VAC35-115-50] ("Human Rights Regulations").
- Peer to peer incidents that 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:

Guidance:

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;

Guidance:

"Serious injury" means "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 or was missing;

Guidance:

"Missing" is defined in 12VAC35-105-20 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, the person is not considered missing.

3.An emergency room visit;

Guidance:

Emergency room visits by an individual receiving services, other than licensed emergency services, shall be reported as Level II serious incidents if they occur within the provision of the provider's services or on their premises.

If the provider calls first responders due to an emergency, and an emergency medical technician (EMT) recommends an ER visit but the individual declines to go, this does not need to be reported as there was no "emergency room visit" as listed within the regulations. Please note that if there was another Level II serious incident which led to the call for first responders, then that should be reported as a Level II serious incident.

- For example, an individual experiences a choking incident, which requires direct physical intervention, and 911 is dialed. By the time the EMTs arrive, provider staff were able to successfully clear the individual's airway. The EMTs suggest that the individual should still be transported to the emergency room for an evaluation, but the individual refuses to go. The provider does not need to report this as an emergency room visit as the individual refused to go to the emergency room. However, the incident should still be reported as a Level II serious incident as it was a choking incident which required direct physical intervention.

If an individual is taken to the emergency room and later refuses care while at the emergency room, this should still be reported as a Level II serious incident as an emergency room visit did occur.

4. An unplanned psychiatric or unplanned medical hospital admission of an individual receiving services other than licensed emergency services, except that a psychiatric admission in accordance with the individual's Wellness Recovery Action Plan (WRAP) shall not constitute an unplanned admission for the purposes of this Chapter;

Guidance:

If an individual is admitted to the hospital for psychiatric services, and the individual's admission is in accordance with the individual's Wellness Recovery Action Plan (WRAP), then the admission is not an unplanned admission and does not need to be reported.

In addition, if an individual is only receiving licensed emergency services and no other licensed service at the time the individual experiences an unplanned psychiatric admission, the emergency service provider is not required to report the admission.

- "Emergency service" is defined 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 receiving services from a provider other than an emergency service provider (*e.g.*, residential service, day support, mental health community support), and the individual experiences an unplanned psychiatric admission while the provider is actively providing a service to the individual, the 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 that leads to the issuance of a TDO and an unplanned hospital admission. The group home provider would be required to 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 then the individual is admitted to the hospital. The outpatient provider would report the incident.
  - If an individual who receives outpatient services experiences suicidal thoughts at a time when the individual is not in a therapy session with the outpatient service provider and the individual contacts emergency services and ultimately experiences an unplanned psychiatric admission, then neither the outpatient service provider nor the emergency service provider would be required to 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.*, appendicitis, a fractured bone, a burn, the flu, sepsis, etc.) that occurred while the individual was receiving services, then the provider that was providing the service would be required to report the incident. But, 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;

Guidance:

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; then the provider must report the incident.

If an individual chokes on food but is able to cough up the food without the physical aid of another person, 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, because choking is an event that has the potential to cause serious injury.

6. Ingestion of any hazardous material;

Guidance:

If an individual drinks, swallows, or absorbs a material that causes significant harm to the individual or is a threat to the individual's health and safety, the provider must 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;

Guidance:

A diagnosis of decubitus ulcer or an increase in level of severity of a previously diagnosed decubitus ulcer must be reported as a Level II serious incident once the provider has sought and obtained a diagnosis from a medical professional.

It is recommended that providers review the DBHDS safety alert for "pressure ulcers" for the definition and description of levels regarding decubitus ulcer.

b. A bowel obstruction; or

Guidance:

A diagnosis of a bowel obstruction must 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.

Guidance:

A diagnosis of aspiration pneumonia must 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 "dysphagia/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 receiving services are required to report the incident even though it may result in duplicative reporting.

1) Any death of an individual;

Guidance:

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 a case manager receive notification that an individual receiving services died over the weekend, both are required to report the death.

2) A sexual assault of an individual;

Guidance:

Any sexual assault required by other applicable laws to be reported to other relevant authorities shall be reported to those authorities in accordance with the law.

The provider must 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.

DBHDS 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.

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 suicide attempt by an individual admitted for services, other than licensed emergency services, that results in a hospital admission.

Guidance:

DBHDS regulation 12VAC35-105-20 defines a "suicide attempt" as "*a nonfatal, self-directed, potentially injurious behavior with an intent to die as a result of the behavior regardless of whether it results 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 emergency room visit does not need to be reported as a Level III serious incident by all providers. However, the incident must be reported as a 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 services 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.

Guidance:

Representatives of DBHDS will request documentation from a provider, including documents relating to an individual's death, to determine if the provider complied with DBHDS regulations.

Examples of Non-Compliance:

- Failure to provide information or documentation requested by DBHDS to determine compliance with regulations.

C. The provider shall collect, maintain, and review at least quarterly all serious incidents, including 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.

Guidance:

The reason for provider monitoring of Level I, II and III serious incidents is to minimize the risk of any future serious incidents.

Provider quality improvement plans, required by 12VAC35-105-620, must 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, i.e. bathrooms). Through this analysis, 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 by one individual or all individuals. For example, if falls occurred from a bed, the provider may mitigate future incidents by placing a fall mat near a bed to prevent serious injuries.

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.

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.

Guidance:

Providers shall report each allegation of abuse or neglect via the Human Rights side of 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 telephone or email 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 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.

Guidance:

Level II and Level III serious incidents shall be reported via the Licensing side of CHRIS within 24 hours of discovery.

In addition, 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.

Guidance:

Providers must report to DBHDS via the Human Rights side of CHRIS within 24 hours any instance of seclusion or restraint that does not comply with the Human Rights Regulations or approved variances, or that results in injury to an individual. 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 serious incidents and any Level III serious incidents that occur during the provision of a service or on the provider's premises.

Guidance:

"Root cause analysis" (RCA), as defined by 12VAC35-105-20, 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 does not focus on the people involved but focuses on systems, processes, and outcomes. 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 a minimum, documentation that the three elements below were considered to the extent that they are known, or could be known by the provider.

1. The root cause analysis shall include at least the following information:

a. A detailed description of what happened;

Guidance:

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.

b. 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

Guidance:

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.

c. Identified solutions to mitigate its reoccurrence and future risk of harm when applicable*.*

Guidance:
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 and future risk of harm. These solutions should be both individual-specific and systemic as indicated by the analysis of the incident. Implementation of these solutions and their effectiveness 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/assets/doc/QMD/OL/root-cause-analysis-training-(november-2020).pdf*

2. *The provider shall develop and implement a root cause analysis policy for determining when a more detailed root cause analysis, including convening a team, collecting and analyzing data, mapping processes, and charting causal factors, should be conducted. At a minimum, the policy shall require for the provider to conduct a more detailed root cause analysis when:*

    a. *A threshold number, as specified in the provider's policy based on the provider's size, number of locations, service type, number of individuals served, and the unique needs of the individuals served by the provider, of similar Level II serious incidents occur to the same individual or at the same location within a six month period;*
    b. *Two or more of the same Level III serious incidents occur to the same individual or at the same location within a six month period;*
    c. *A threshold number, as specified in the provider's policy based on the provider's size, number of locations, service type, number of individuals served, and the unique needs of the individuals served by the provider, of similar Level II or Level III serious incidents occur across all of the provider's locations within a six month period; or*
    d. *A death occurs as a result of an acute medical event that was not expected in advance or based on a person's known medical condition.*

Guidance:
Providers must include within their RCA policy the criteria that will be used to determine whether a more detailed RCA is warranted. When developing the RCA policy, providers should take into consideration the number of locations, the number of individuals receiving services, the type of services the provider provides, and the unique needs of the individuals.

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

Guidance:

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 DBHDS to determine compliance with regulations.
- Failure to submit information requested by licensing staff.

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.

Guidance:

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, DBHDS 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 DBHDS 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 DBHDS to determine compliance with regulations.
- Not submitting the information to the Office of Licensing within 10 business days of issuance of a licensing report that requested additional information when no extension was granted in accordance with subsection H.

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

Guidance:

DBHDS may take negative action against any provider that submits written or oral false or misleading information, documents, or reports to DBHDS.

J. The provider shall develop and implement a serious incident management policy, which shall be consistent with this section and which shall describe the processes by which the provider will document, analyze, and report to the department information related to serious incidents.

Guidance:

Providers must develop and implement a written policy that describes how the provider will ensure compliance with this section.

The provider's serious incident management policy should address how the provider will:

- Collect, maintain, and review all serious incidents including Level I serious incidents at least quarterly;
- Document persons identified by individuals to receive notification of serious incidents and ensure that individual's authorized representatives, and anyone else identified by the individual receives notification of serious incidents within 24 hours; and
- Ensure that Level II and Level III serious incidents are reported to DBHDS within required timeframes.