



DBHDS Office of Licensing
Guidance for Risk Management

Effective: August 22, 2020

Purpose: This document contains guidance to providers regarding the requirements for risk management adopted to address compliance with the 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").

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.

12VAC35-105-520. Risk management.

Settlement Agreement [indicators](#) addressed:

V.C.1.1, V.C.1.4, V.C.1.5, V.C.4.1, V.C.4.3, and V.C.4.4

Guidance:

12VAC35-105-20. Definitions.

The following definitions (pending final approval) are relevant to this guidance document:

"Risk management" means an integrated system-wide program to ensure the safety of individuals, employees, visitors, and others through identification, mitigation, early detection, monitoring, evaluation, and control of risks.

"Root cause analysis" means 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

"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.

12VAC35-105-520. Risk management.

- A. *The provider shall designate a person responsible for the risk management function who has completed department approved training, which shall include training related to risk management, understanding of individual risk screening, conducting investigations, root cause analysis, and the use of data to identify risk patterns and trends.*

Guidance:

All providers are required to designate a qualified person with responsibility for the risk management function.

Qualifications for this position shall be obtained through the completion of department approved training in these enumerated areas of risk management responsibility:

1. Individual risk screening;
2. Conducting investigations;
3. Root cause analysis; and
4. The use of data to identify risk patterns and trends.

Note that these are minimum qualifications. Providers may also provide training in additional areas relevant to the risk management function, which may include topics such as emergency preparedness, use of universal precautions to prevent infections, prevention of inadvertent release of protected health information (PHI), and other areas of potential risk to providers.

DBHDS will post information about approved training on its website. Providers that the Office of Licensing determines are non-compliant with risk management requirements for reasons that are related to a lack of knowledge will be required to demonstrate that they complete training offered by the Commonwealth or other training determined by the Commonwealth to be acceptable, as part of their corrective action plan (CAP).

- B. *The provider shall implement a written plan to identify, monitor, reduce, and minimize harms and risk of harm, including personal injury, infectious disease, property damage or loss, and other sources of potential liability.*

Guidance:

Providers must have a written risk management plan focused on identifying, monitoring, reducing, and minimizing harms and risk of harm through a continuous, comprehensive approach. This plan should include identifying year-over-trends and patterns and the use of baseline data to assess the effectiveness of risk management systems.

The written risk management plan should be reviewed and updated at least annually, or any time that the provider identifies a need to review and update the plan based on ongoing quality review and risk management activities, such as during its quarterly reviews of all serious incidents.

As required by 12VAC35-105-620, a provider's risk management plan may be a standalone risk management plan or it may be integrated into the provider's overall quality improvement plan. Risk management plans and overall risk management programs should reflect the size of the organization, the population served, and any unique risks associated with the provider's business model.

In developing a risk management plan, the provider should consider how the following characteristics affect the provider's level and types of risks:

- How many individuals does the provider serve?
- What are the needs and characteristics of those served?
- What are typical risks associated with this population?
- What services does the provider offer; what risks are involved with these services?
- What is the location(s) where services are provided?
- What is the provider's business model?

The risk assessment process is focused on identifying both existing and potential harms and risks of harm. The harms and risk of harm that a risk management plan must focus on identifying, monitoring, reducing, and minimizing, include at least:

- Personal injury;
- Infection disease;
- Property damage or loss; and
- Any other identified source of potential liability.

C. *The provider shall conduct systemic risk assessment reviews at least annually to identify and respond to practices, situations, and policies that could result in the risk of harm to individuals receiving services. The risk assessment review shall address at least the following:*

Guidance:

An annual risk assessment review is a necessary component of a provider's risk management plan.

This review should include consideration of harms and risks identified and lessons learned from the provider's quarterly reviews of all serious incidents conducted pursuant to 12VAC35-105-160.C., including an analysis of trends, potential systemic issues or causes, indicated remediation, and documentation of steps taken to mitigate the potential for future incidents.

The risks enumerated in the regulation are not an exhaustive list. Other risks that providers should consider include:

- Financial risks including whether the provider has sufficient capital to support the business if revenue decreases or is delayed, per 12VAC-35-105-210; and whether the provider has instituted the appropriate checks and balances over financial transactions;
- Business risks; and
- Workforce related risks.

1. *The environment of care;*

Guidance:

The "environment of care" means the physical environment where services are provided, such as the building and physical premises. A review of the environment of care should consider the results of the annual safety inspection conducted pursuant to 12VAC35-105-520.E, when applicable, but is broader than a safety inspection.

Examples of environmental considerations include such things as:

- The location where services are provided (e.g. in individual's own home, at a correctional facility, or at a location under the provider's control);
- How the area where services are provided is arranged;
- Any special protective features that may be present;
- The location, amount, and condition of safety equipment, including:
 - Fire extinguishers;
 - First aid kits;

- Flash lights;
- Emergency egress routes and exit signs; and
- Any other safety equipment that is or should be present.
- The condition and temperature regulation of refrigerators that store food or medications;
- Security of medication storage;
- Condition of electrical cords, outlets, and electrical equipment;
- The adequacy, suitability, and condition of lighting; and
- Any other physical features that could present safety risks if not properly arranged, secured, maintained, or otherwise addressed.

Environment of care considerations will be different when services are provided at a location that is not under the direct control of the provider, such as at an individual's own home. While providers are more limited in their ability to assess some of the factors listed above in these locations, providers should consider any unique risks associated with the provision of services in these locations during its risk assessment review. In such cases the review does not need to consider each location (e.g. each home) individually, but should identify risks that may be common across the different locations or settings.

2. *Clinical assessment or reassessment processes;*

Guidance:

Examples of assessments include physical exams that are completed prior to admission or any time that there is a change in the individual's physical or mental condition.

Reassessments include: (i) reviews of incidents in which the individual was involved, and (ii) reviews of the individual's health risks.

Persons designated as responsible for the risk management function need not be engaged in the clinical assessment or reassessment process, but should review these processes during the risk assessment review process. For example, are assessment processes effectively identifying and mitigating risks unique to each individual?

3. *Staff competence and adequacy of staffing;*

Guidance:

Examples of factors related to staff competency and adequacy of staffing include whether:

- All employees meet minimum qualifications to perform their duties;
- All employees complete orientation training prior to being assigned to perform direct care work;
- All employees have undergone background checks;
- All employees have completed abuse and neglect training;
- All employees have up to date CPR certification;
- Employees who administer medications have received requisite training;
- Employees have completed additional training applicable to their job functions, such as initial and annual fire safety training;
- Staffing schedules are consistent with the provider's staffing plan; and

- The staffing plan continues to be adequate to meet the needs of the individuals being served. Reviews of serious incidents over the prior year may help to inform this consideration.

4. *Use of high risk procedures, including seclusion and restraint; and*

Guidance:

In addition to seclusion and restraint, examples of high risk procedures may include:

- The administration of high risk medications;
- High risk methods of medication administration;
- Procedures used to transfer individuals who require assistance transferring from one location to another; and
- Any other procedure that may pose a greater than average risk to the health and safety of individuals, staff members, or third parties.

Examples of high risk procedure considerations include the following:

- Whether the use of seclusion and restraint, and other high risk procedures are in compliance with the 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] (“Human Rights Regulations”) and the Licensing Regulations and any other applicable laws and regulations that govern their use;
- Identification and review of procedures that are typically conducted by the provider which are potentially high risk;
- Whether staff who are permitted to implement high risk procedures have the requisite training, experience, and qualifications to do so safely and in accordance with regulation;
- Whether all high risk procedures are properly authorized and reviewed per policy, regulation, and law; and
- The findings from any root cause analysis is conducted when a high risk procedure causes or is otherwise associated with a serious injury.

5. *A review of serious incidents.*

Guidance:

The provider’s systemic risk review shall evaluate serious incidents at least annually. Examples of considerations related to serious incidents include whether:

- All Level I serious incidents were reviewed at least quarterly to identify trends in accordance with 12VAC35-105-160;
- Any patterns or trends that have been identified require additional safeguards or risk mitigation strategies;
- The provider has an updated policy that defines who has the authority and responsibility to act when a serious incident or a pattern of serious incidents indicates that an individual is at risk; and
- Serious incidents and patterns of serious incidents are reviewed and appropriate follow-up is conducted or implemented to address individual or system-level risks.

D. *The systemic risk assessment review process shall incorporate uniform risk triggers and thresholds as defined by the department.*

Guidance:

DBHDS will disseminate information about uniform risk triggers and thresholds in separate guidance when they are developed.

E. *The provider shall conduct and document that a safety inspection has been performed at least annually of each service location owned, rented, or leased by the provider. Recommendations for safety improvement shall be documented and implemented by the provider.*

Guidance:

An annual safety inspection must be completed at each service location. This inspection should evaluate the premises for safety concerns.

Examples of safety concerns include the operability of fire safety equipment, emergency egress routes, any cooking and electrical devices on the premises, and trip hazards or other dangerous items or scenarios.

F. *The provider shall document serious injuries to employees, contractors, students, volunteers, and visitors that occur during the provision of a service or on the provider's property. Documentation shall be kept on file for three years. The provider shall evaluate serious injuries at least annually. Recommendations for improvement shall be documented and implemented by the provider.*

Guidance:

Failure to document serious injuries to employees, contractors, students, volunteers, and visitors will result in the issuance of a licensing report citing 12VAC35-105-520.F.

Documented serious injuries to employees, contractors, students, volunteers, and visitors shall be evaluated at least annually. This evaluation shall include identification of recurring serious injuries, trends, any other indication of systemic safety deficiencies, and planned steps to remedy the same.

The evaluation and planned remediation steps should be incorporated into or aligned with the provider's annual systemic risk assessment review process or both.

*Please note that Level II incidents include "a significant harm or threat to the health or safety of others caused by an individual." Therefore, if a serious injury was caused by an individual to an employee, contractor, student, volunteer, or visitor during the provision of services or on the provider's premises the serious injury should also be reported into CHRIS within 24 hours of discovery as a Level II serious incident.