



Virginia Department of  
Behavioral Health &  
Developmental Services

# **Risk Management Regulations Regulatory Compliance**

**December 2021**

**Office of Licensing**  
Virginia Department of Behavioral  
Health and Developmental Services

# Goals of the Presentation

- 1. Review Developmental Disabilities (DD) providers' compliance with the following regulations:**
  - Risk Management (12VAC35-105-520.A-E)
- 2. Highlight some issues that were identified when providers were not compliant**
  - Remind providers of available resources



# Goals of the Presentation

## 3. Review what Risk Management documents will be requested as part of the annual inspections in 2022.

### Annual Inspection Checklist



Some of these documents may be requested in advance as the Licensing Specialists have a lot to review while on site.

Providers need to have these documents ready for review when requested.

# Settlement Agreement Indicator

**“On an annual basis, the Commonwealth determines that at least 86% of DBHDS licensed providers of Developmental Disability (DD) services are compliant with the risk management requirements in the Licensing Regulations.”**

**12VAC35-520.A-E**

RISK  
MANAGEMENT



# DD Inspections - 2021

**Percent of licensed DD providers that met  
100% of risk management requirements =  
61%**

**Data for January 1, 2021 – September 30, 2021\***

Quality improvement means looking at the data and identifying issues that can be addressed in order to improve.

\* Data represents compliance of DD providers for January 1, 2021 to September 30, 2021 unless otherwise noted.

# 12VAC35-105.520.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.**

Regulation	Compliance*
520.A	76%

# Identified Issues

Providers were cited:

1. for failure to submit a completed DBHDS Risk Management Attestation
2. for failure to have a job description for the person designated as risk manager (not a resume)
3. for failure to complete the required training (only trainings listed on the Crosswalk are acceptable)
4. for failure to sign the Attestation



# Example – Not Acceptable

Topic Area	Name of Training Completed Write the name of the specific training or trainings completed. Refer to <u>Crosswalk of DBHDS Approved Risk Management Training</u> for list of approved trainings.	Training Completion Date
<b>EXAMPLE: Risk Management</b>	<b>EXAMPLE: CDDER Live Webinar "Risk Management and Quality Improvement Strategies"</b>	<b>EXAMPLE: December 10, 2020</b>
Risk Management	✓	12/10/2020
Understanding of Individual Risk Screening	✓	12/10/2020
Conducting Investigations	✓	12/10/2020





# Example - Acceptable

## Example – Acceptable

Topic Area	Name of Training Completed Write the name of the specific training or trainings completed. Refer to <u>Crosswalk of DBHDS Approved Risk Management Training</u> for list of approved trainings.	Training Completion Date
<b>EXAMPLE:</b> Risk Management	<b>EXAMPLE:</b> CDDER Live Webinar “Risk Management and Quality Improvement Strategies”	<b>EXAMPLE:</b> December 10, 2020
Risk Management	CDDER Recorded Webinar	July 27, 2021
	DBHDS Risk Management-Quality Improvement Tips and Tools (webinar)	June 24, 2021
Understanding of Individual Risk Screening	CDDER Recorded Webinar	July 27, 2021
Conducting Investigations	Office of Human Rights YouTube Video “Abuse & Neglect: An Overview	November 20, 2021



# 2022 Inspections

**Attestation will be requested again.**

Prepare:

- ✓ Ensure the Attestation is completed and signed by the supervisor.
- ✓ Ensure the job description includes all responsibilities.
- ✓ Include the training the risk manager completed (recording or live) and the date completed.

This certificate is to be read, signed and dated by the person designated as responsible for the risk management function for the provider as well as that person's direct supervisor.

*By completing the above chart, I am indicating that I have participated in live/recorded trainings and/or reviewed the training power point presentations posted on the Office of Licensing webpage.*

*TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL INFORMATION CONTAINED HEREIN IS CORRECT AND COMPLETE.*

# 12VAC35-105.520.B

**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.**

Regulation	Compliance*
520.B	88%

# Good Risk Management Plans

**Providers were compliant if the plan included:**

- **how the provider would identify risks**
- **how the provider would monitor risks and**
- **how the provider would reduce and minimize**



# SAMPLE

## How the provider will Identify

- Systemic risk assessment
- Safety inspections

## How the provider will monitor

- Review of Serious Incident Reporting
- Committee/leadership review trends (convergence of data)
- Care Concerns

## How the provider will reduce and minimize

- Conduct a root cause analysis
- Propose an initiative to minimize risk related to findings of systemic risk assessment
- Implement a new training

# Risk Management Plan

## Personal Injury

- Incident reporting
- Employee injuries

## Infectious Disease

- Hand hygiene
- Infection control measures

## Property damage or loss

- Financial risks
- Property damage due to weather related event



# 2022 Inspections



**If using templates issued by DBHDS prior to implementation of the regulations effective August 2020, review the document closely to make sure it is compliant with the current regulations and agency requirements.**

**New SAMPLE risk management plan was posted to the Office of Licensing webpage in June 2021.**

# EXAMPLE

The example below is from a template issued prior to 2020.

DBHDS has defined risk triggers and thresholds as care concerns so the highlighted items below are not consistent with current agency requirements.

Table 1

Risk Areas	Measure
Clinical Assessments	Timely completion of all annual assessments
	Actions taken in response to newly identified problems
Individual Services Plans	Plans are complete, signed and dated by all that involved.
	Services are delivered per plan, documentation of services.
Environmental Safety	Building Safety – Doors and Locks, Security System Bathroom hot water temperatures do not exceed 110°F
Medication Events (DBHDS defined triggers/thresholds)	Medication administration errors without injury
	Medication administration error with injury
Accidents (DBHDS defined triggers/thresholds)	Choking with no medical attention required
	Choking resulting in the need for medical attention
Medical (DBHDS defined triggers/thresholds)	Constipation/bowel obstruction requiring medical attention





# 2022 Inspections

**Risk management plan will be requested.**

Prepare -

- ✓ Make sure the risk management plan includes all the components outlined in 520.B.
- ✓ It is a “plan” not a policy.
- ✓ Pursuant to Guidance for a Quality Improvement Program, the risk management plan can be part of the Quality Improvement Plan (make sure it is so designated – identify with a header).



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:

1. The environment of care;
2. Clinical assessment or reassessment processes;
3. Staff competence and adequacy of staffing;
4. Use of high risk procedures, including seclusion and restraint;  
and
5. A review of serious incidents

# 12VAC35-520.C.1 – Environment of Care

Regulation	Compliance*
12VAC35-520.C.1	85%

## Identified Issues:

Some providers did not have a completed systemic risk assessment.

Some provider presented the safety inspection. Environmental risk assessment should include the results of the annual safety inspection, where applicable, but it is much broader than a safety inspection. (12VAC35-105-520.E)



# 12VAC35-520.C.1 –5

## SAMPLE 1 – Non-Residential Provider Risk Assessment

Date completed \_\_\_\_\_ (12VAC35-105-520.C requires at least annually) Completed by \_\_\_\_\_

This sample document does not include all risks that an organization may review. This specific assessment is not required. It is presented as a sample template that may be expanded or otherwise adapted to the needs of an organization. The **green** highlights signify the categories as required in regulation 12VAC35-105-520.C.1-5 and 12VAC35-105-520.D. The risks listed under each category are examples. Each organization should include risks specific to their size, individuals served, location and business model.

As noted in the [Guidance for Risk Management](#) the annual risk assessment review is a necessary component of a provider's risk management plan. Upon completion of the risk assessment, the provider would consider next steps:

- Assign recommendations to appropriate staff members, departments and/or committees
- Determine what recommendations to include in the risk management plan
- Determine how to monitor risk reduction strategies for effectiveness
- Continue to conduct systemic risk assessment reviews as needed

Environment of Care	Findings	Recommendation(s)	Add to Risk Management (RM) Plan (Yes/No/NA)	Comments
Emergency egress	Building exits had boxes/trash	Staff training recommended	No	Assigned to Human Resources
Condition of electrical cords, outlets and electrical equipment	No issues identified	None at this time	NA	
Environmental design, structure, furnishing and lighting appropriate for population and services	Lobby looks dated; seating arrangements could present risks; some areas not ADA compliant	Further study on how environment could be more welcoming to clients and distance seating arranged in the lobby	Yes	Risk manager to add to risk management plan
Ventilation	Age of building presents risks	Contract with consultant to evaluate	Yes	Assigned to building manager to request bids

# 12VAC35-520.C.2 – Clinical Assessment or Reassessment Processes

Regulation	Compliance*
12VAC35-520.C.2	80%

## Identified Issues

Some providers did not have a completed systemic risk assessment.

The systemic risk assessment did not include clinical assessment or reassessment processes.

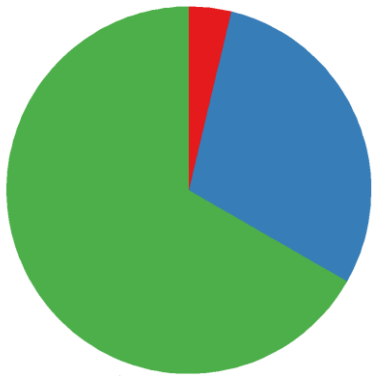
# EXAMPLE

When the annual systemic risk assessment is conducted, a provider identifies that there have been an increase in falls and so they review whether reassessments were being completed identifying risks unique to the individuals served.

Upon further review, the manager noted that the policy was not being implemented consistently.

The provider identifies this as a risk on the systemic risk assessment. The risk management plan could then be revised to include how this will be addressed (policy revision, increased chart audits).

# EXAMPLE



Potential Severity Rating			
Minor	Moderate	Significant	C
Moderate	High	Extreme	
Low	Moderate	High	
Very Low	Low	Moderate	
Very Low	Very Low	Low	



## SIRs Level I

- Reviewing quarterly
- Increase in falls

## Systemic Risk Assessment

- Is the reassessment process identifying individual risks?

## Risk Management Plan

- Review policy
- Implement more audits of reassessments

# 12VAC35-520.C.3 – Staff Competence and Adequacy of Staffing

Regulation	Compliance*
12VAC35-520.C.3	80%

Many risks related to staffing

- Employees meet minimum qualifications to perform their duties
- Employees complete orientation before being assigned to direct care work
- Background checks
- Up to date CPR certifications
- Staffing schedules are consistent with the provider's staffing plan





## Identified Issues:

Some providers did not have a completed systemic risk assessment.

Systemic risk assessment did not include staff competence and adequacy of staffing.

Example – As part of the annual systemic risk assessment, the provider might ask such questions:

- What was the staff turnover rate?
- What issues impacted the staffing plan over the past year?
- What are the provider's risks?
- How does the provider attempt to reduce/mitigate those risks?

# 12VAC35-520.C.4 – Use of High Risk Procedures

Regulation	Compliance*
12VAC35-520.C.4	79%

## Identified Issues:

Some providers did not have a completed systemic risk assessment.

Some providers did not include high risk procedures.

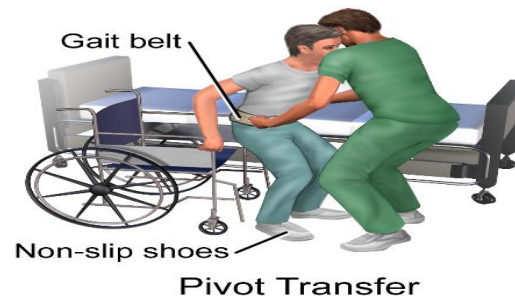
**Each provider should consider what high risk procedures, including seclusion and restraint, are being used:**

- Administration of high risk medications
- High risk methods of medication administration
- Transfer of individuals
- Much more .....

# 12VAC35-520.C.4 – Use of High Risk Procedures

Based on the provider's high risk procedures, then you consider:

- Are we following applicable laws and regulations that govern their use?
- Are we reviewing procedures to determine whether still appropriate?
- Are staff who are implementing high risk procedures qualified to do so?



# 12VAC35-520.C.5 – Review of Serious Incidents

Regulation	Compliance*
12VAC35-520.C.5	84%

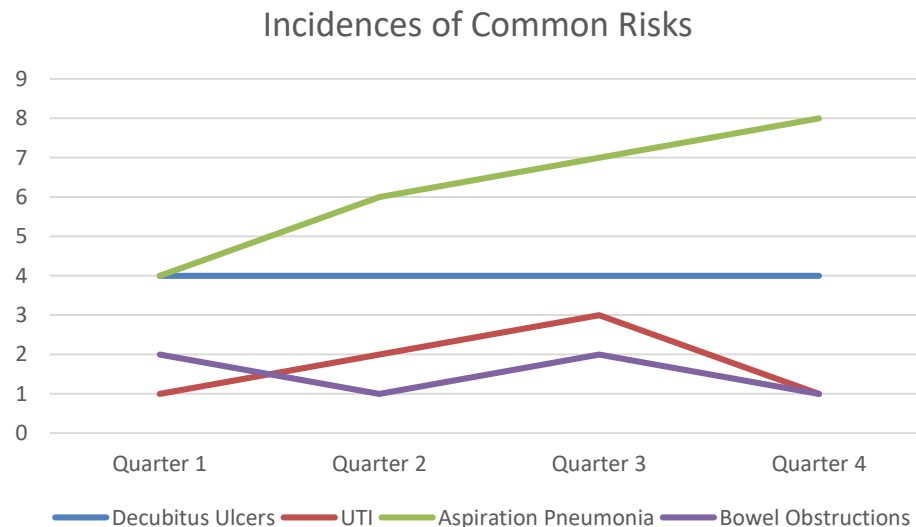
## Identified Issue:

Providers failed to review serious incidents for patterns and trends as part of their systemic risk assessment

# Serious Incidents

**12VAC35-105-160.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.**

Provider's systemic risk assessment should identify the incidences of common risks and conditions that occurred. DD providers would focus on incidences of common risks for individuals served.



# Serious Incidents

**Real time - review incidents as they occur**

**At least Quarterly** – review all incidents (Level I, II and III) and identify patterns and trends

**Annually** – conduct the systemic risk assessment and include all data from SIRs

Risk Management plan and/or Quality Improvement plan includes documentation of steps to mitigate the potential for future incidents.

## **Example:**

A provider reviews all SIRs quarterly. The provider identifies an increase in choking incidents. While some of the incidents did not result in a Level II incident (direct physical intervention by another person), the provider identified this as a potential risk and decides to prevent and/or mitigate future incidents. The provider reviews their risk management plan and conducts a root cause analysis to determine why the increase in choking incidents. Based on the results of the RCA, the provider revises dietary protocols.

# 12VAC35-520.D – Risk Triggers and Thresholds

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

Regulation	Compliance*
12VAC35-520.D	78%



## Care Concerns **(Revised as of 10-4-2021)**

- Multiple (two or more) unplanned hospital visits for a serious incident including: falls, choking, urinary tract infection, aspiration pneumonia, dehydration, or seizures within a ninety (90) day time-frame for any reason; and
- Any incidents of a decubitus ulcer diagnosed by a medical professional, an increase in the severity level of a previously diagnosed decubitus ulcer, or a diagnosis of a bowel obstruction diagnosed by a medical professional.

# Identified Issues

**Providers who had care concerns were cited if there was nothing in their systemic risk assessment regarding how they address such care concerns in their risk management process.**

**Some providers did not identify risk triggers and thresholds as care concerns.**

# Care Concern Thresholds – IMU's Role

## Reviews serious incidents

- Individual level
- Systematically
- Identify possible patterns/trends by individual, a provider's licensed service as well as across providers.

Also to identify areas where there is potential risk for more serious future outcomes.

May be an indication a provider may need to:

- Re-evaluate
- Review root cause analysis
- Consider making systemic changes

# 2022 Inspections

## **Systemic Risk Assessment will be requested.**

Prepare:

- ✓ Review SAMPLE systemic risk assessment on OL webpage
- ✓ Determine the best format for your organization
- ✓ Think about risks to your organization
- ✓ Include all of 12VAC35-105-520.C.1-4 and 520.D

### Reminders:

It is not a blank checklist; not a policy that states a systemic risk assessment will be completed.

This is not a risk assessment for individuals but for the provider's systemic risks.

## 12VAC35-520.E – Annual Safety Inspection

**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.**

Regulation	Compliance*
12VAC35-520.E	90%

Providers were compliant with conducting safety inspections at each service location.