Virginia Department of Behavioral Health & Developmental Services

Office of Licensing Webinar
December 16, 2021

Updated with Q&A (February 2022)
(Slide 76)

DBHDS Vision: A life of possibilities for all Virginians

Virginia Department of Behavioral Health & Developmental Services

Quality Improvement/Risk Management and Root Cause Analysis

1) A review of data from 2021; and
2) What to expect for Unannounced Inspections in 2022

Goals of the Presentation

1. **Review Developmental Disabilities (DD) providers' compliance with the following regulations:**
   - **Risk Management (12VAC35-105-520.A-E)**
   - **Quality Improvement (12VAC35-105-620.A-D)**
   - **Root Cause Analysis (12VAC35-160.E.2)**

2. Review some issues that were identified when providers were not compliant

- Remind providers of available resources

Goals of the Presentation

3. Review what QI-RM-RCA 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

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 Crosswalk of DBHDS Approved Risk Management Training for list of approved trainings.	Training Completion Date
***EXAMPLE**: Risk Management*	***EXAMPLE**: CDDER Live Webinar "Risk Management and Quality Improvement Strategies"*	***EXAMPLE**: December 10, 2020*
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 Crosswalk of DBHDS Approved Risk Management Training for list of approved trainings.	Training Completion Date
***EXAMPLE**: Risk Management*	***EXAMPLE**: CDDER Live Webinar "Risk Management and Quality Improvement Strategies"*	***EXAMPLE**: December 10, 2020*
Risk Management	CDDER Recorded Webinar DBHDS Risk Management-Quality Improvement Tips and Tools (webinar)	July 27, 2021 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).

12VAC35-105.520.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:

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.

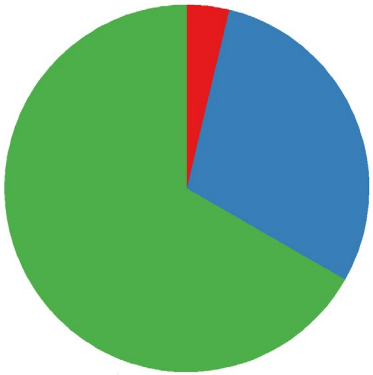
EXAMPLE

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	
ly	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 as 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.

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

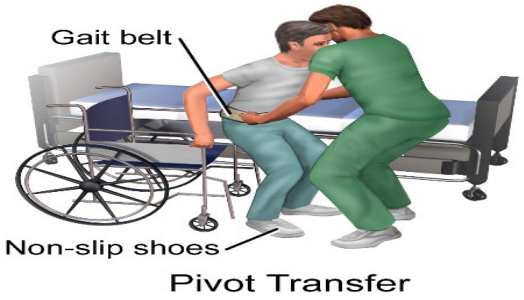
Each provider should consider what high risk procedures, including seclusion and restraint, are being used:

- 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%

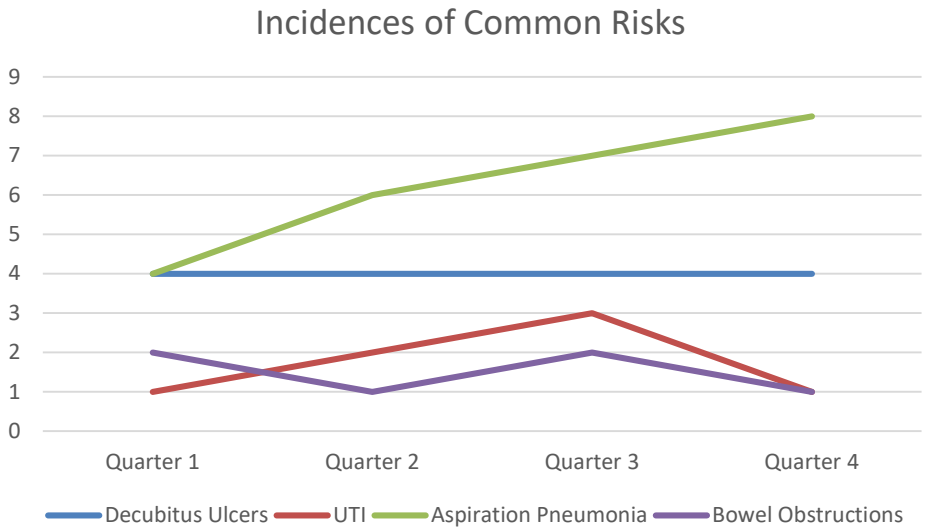
Identified Issue:

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 tends, 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%

12VAC35-520.D – Risk Triggers and Thresholds

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.

Regulations

Quality Improvement – 12VAC35-105-620.A

A. The provider shall develop and implement written policies and procedures for a quality improvement program sufficient to identify, monitor, and evaluate clinical and service quality and effectiveness on a systematic and ongoing basis.

Regulation	Compliance
12VAC35-105-620.A	**90%**

Reminder

Program

- Structure and/or foundation
- Policies and procedures - 620.D:
  - Criteria for establishing goals and objectives
  - Criteria for updating the QI Plan
  - Criteria for submitting revised corrective action plans
- Standard quality improvement tools

Versus

Plan

- Work plan
- Goals for the year

Quality Improvement – 12VAC35-105-620.B

B. The quality improvement program shall utilize standard quality improvement tools, including root cause analysis, and shall include a quality improvement plan.

Regulation	Compliance*
12VAC35-105-620.B	88%

12VAC35-105-620.C.1

The quality improvement plan shall:

1. Be reviewed and updated at least annually

Regulation	Compliance*
12VAC35-105-620.C.1	80%

Identified Issues

- Providers did not date the plan. This is necessary to demonstrate that the plan was reviewed and updated at least annually.
- A policy is not a plan.
- Copying the regulatory language is not a plan.

12VAC35-105-620.C.2

The quality improvement plan shall:

2. Define measurable goals and objectives

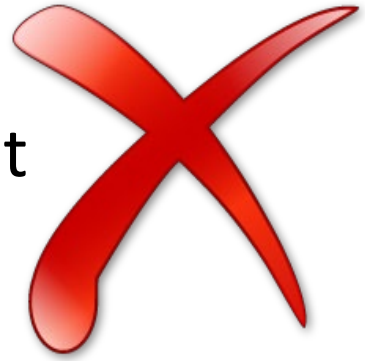
Regulation	Compliance*
12VAC35-105-620.C.2	77%

Identified Issues

Goals and objectives were not measurable

Examples:

Provide a safe environment



Reduce the rate of Level II serious injuries by X% by December 31, 2022

12VAC35-105-620.C.3

The quality improvement plan shall:

3. Include and report on statewide performance measures, as applicable, as required by DBHDS.

Currently the statewide performance measures only apply to providers of developmental disability services. DBHDS is operationally collecting through WaMS and CHRIS.

As this changes, DBHDS will provide additional information.

12VAC35-105-620.C.4

The quality improvement plan shall:

4. Monitor implementation and effectiveness of approved corrective action plans

Regulation	Compliance*
12VAC35-105-620.C.4	74%

Identified Issues

Providers who had approved corrective action plans had not reviewed their QI plan and determined whether it was sufficient to address the concerns identified in the licensing report and to monitor compliance with the provider's pledge CAP.

Or

If the provider decided not to update their QI plan documentation was not included in meeting minutes or as an addendum to the QI plan.

EXAMPLE to Update Plan

Licensing Report	Corrective Action Plan	Quality Improvement Plan
Provider is cited for failure to conduct fire and evacuation drills at least monthly (12VAC35-105-530.A.9)	Provider's pledged CAP includes a revised process to ensure 100% of fire drills will be completed monthly	Provider reviews their QI plan and decides to update the plan to include this goal and monitor it on a monthly basis to ensure revised process is effective and compliance is sustained

EXAMPLE - Decision Not to Update Plan

Licensing Report	Corrective Action Plan	Quality Improvement Plan
Provider is cited for failure to have a Root Cause Analysis Policy (12VAC35-105-160.E.2)	Provider's pledged CAP includes the development of a RCA policy with thresholds appropriate to their organization	Provider reviews their QI plan and decides they already have a goal related to SIR reporting and RCA so they decide not to update the QI Plan. They document this decision in meeting minutes.

12VAC35-105-620.C.5

The quality improvement plan shall:

5. Include ongoing monitoring and progress toward meeting established goals and objectives

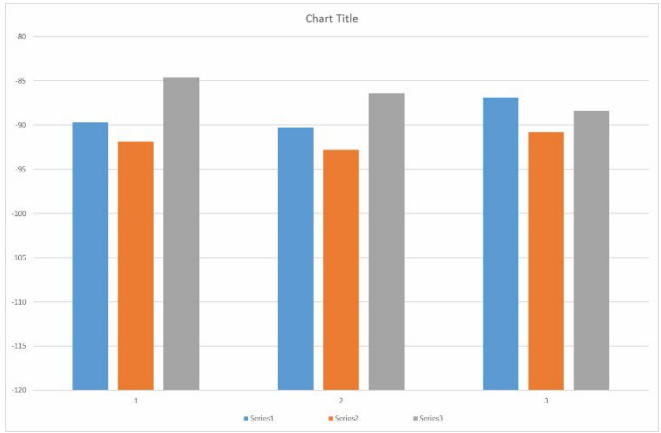
Regulation	Compliance*
12VAC35-105-620.C.5	78%

Identified Issues

Providers did not have measurable goals/objectives so there was no data to monitor/show progress.

Ongoing monitoring/progress means:

- Data as an attachment to the QI plan
- Meeting minutes where data is presented and reviewed



EXAMPLE

Goal – new employees receive required orientation

Objective – By December 31, 2021, 100% of new employees, contractors, volunteers and students shall be oriented in all required policies, procedures and practices within 15 business days of hire.

SAMPLE

Month	Training	# of New Employees	Percent of new employees who complete training in 15 business days
January	Human Rights	5	100%
	Infection Control	5	100%
	Emergency preparedness	5	100%
	Person-centeredness	5	100%

EXAMPLE

Month	Training	# of New Employees	Percent Trained in 15 days
March	Human Rights	8	100%
	Infection Control	8	50%
	Emergency preparedness	8	100%
	Person-centeredness	8	50%

Review data and ask questions:

1. Are new staff completing training but the documentation is missing?
2. Is the training schedule not working?

Take action and continue to monitor:

1. Address deficiencies
2. Demonstrate that you are monitoring progress

12VAC35-105-620.D

The provider's policies and procedures shall include the criteria the provider will use to:

1. Establish measurable goals and objectives

2. Update the provider's quality improvement plan;

3. Submit revised corrective action plans to the department for approval or continue implementing the corrective action plan and put into place additional measures to prevent the recurrence of the cited violation and address identified systemic deficiencies when reviews determine that a corrective action was fully implemented but did not prevent the recurrence of the cited regulatory violation or correct a systemic deficiency pursuant to 12VAC35-105-170.

12VAC35-105-620.D-1.3

Regulation	Compliance*
12VAC35-105-620.D.1	74%
12VAC35-105-620.D.2	74%
12VAC35-105-620.D.3	65%

Identified Issues

Providers did not outline criteria in the policy.

Some providers copied regulatory language but that does not establish the provider's criteria.

12VAC35-105-620.D.1

The provider's policies and procedures shall include the criteria the provider will use to

1. Establish measurable goals and objectives

Criteria examples:

- ❑ The provider will establish measurable goals and objectives that are based on identified areas of non-compliance.
- ❑ The provider will establish measurable goals and objectives that will result in improved outcomes for individuals served.
- ❑ The provider will establish measurable goals and objectives for which valid data is accessible.
- ❑ The provider will establish measurable goals and objectives based on areas of high risk.
- ❑ The provider will establish measurable goals and objectives based in part on what is identified through customer satisfaction results.
- ❑ The provider will establish measurable goals and objectives using the SMART approach (specific, measurable, attainable, relevant and time bound).

12VAC35-105-620.D.2

The provider's policies and procedures shall include the criteria the provider will use to

2. Update the provider's quality improvement plan;

Criteria examples:

- ❑ The provider will update the quality improvement plan at least annually.
- ❑ The provider will update the quality improvement plan whenever there is a change in service.
- ❑ The provider will update the quality improvement plan when a new goal is developed.

12VAC35-105-620.D.3

The provider's policies and procedures shall include the criteria the provider will use to:

3. Submit revised corrective action plans to the department for approval or continue implementing the corrective action plan and put into place additional measures to prevent the recurrence of the cited violation and address identified systemic deficiencies when reviews determine that a corrective action was fully implemented but did not prevent the recurrence of the cited regulatory violation or correct a systemic deficiency pursuant to 12VAC35-105-170.

12VAC35-105-620.D.3

Criteria examples:

- ❑ The provider will submit revised CAPs if progress is not being made to correct the deficiency of the cited violation after X number of months.
- ❑ The provider will conduct a root cause analysis to determine why the CAP is not effective in addressing the identified deficiency.
- ❑ The provider will continue to monitor and then identify additional measures to address the deficiency.

Example – CAP implemented but no improvement in compliance.

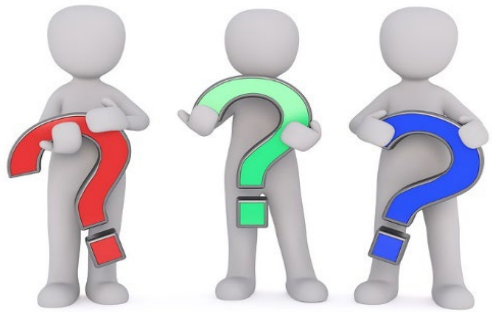
Are you following your policy for when you submit a revised CAP?

2022 Inspections

Quality improvement policies/procedures (to include criteria) will be requested.

Prepare -

- ✓ Make sure criteria are outlined; appropriate for your organization
- ✓ Avoid copying and pasting regulatory language



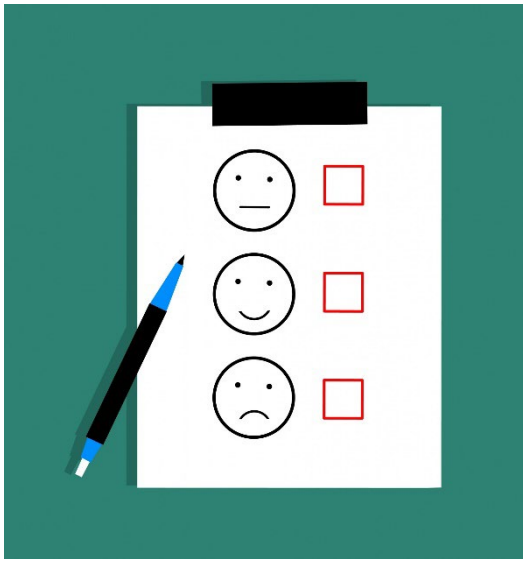
12VAC35-105-620.E

Input from individuals receiving services and their authorized representatives, if applicable, about services used and satisfaction level of participation in the direction of service planning shall be part of the provider's quality improvement plan. The provider shall implement improvements, when indicated.

Regulation	Compliance*
12VAC35-105-620.E	80%

Identified Issues

Providers included in their policy/program that they would obtain customer satisfaction but there was no proof. If the provider did not use a survey, there should be documentation of how customer satisfaction was obtained.



2022 Inspections

Proof that input was requested from individuals and their Authorized Representatives, if applicable, will be requested.

Prepare:

✓ Document how you are obtaining input

✓ Provide example of what is being done with results/findings

Licensing Specialist will be asking:

- How is the provider obtaining this input?
- How is this documented?
- What is being done with results/findings?

(Example – the majority of feedback related to a specific concern: Is the provider addressing through a quality improvement initiative or a goal/objective added to the quality improvement plan?)

12VAC35-105.160.E.2.a-d

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;

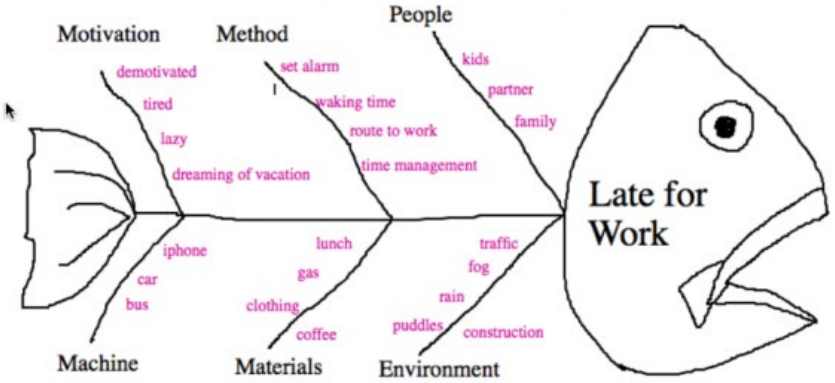
b. Two or more of the same Level III serious incidents occur to the same individual or at the same location within a six-month period;

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.

Root Cause Analysis Policy

Regulation	Compliance*
160.E.2	80%
160.E.2.a	65%
160.E.2.b	72%
160.E.2.c	65%
160.E.2.d	74%



Identified Issues

Providers did not have a root cause analysis policy to include when a more detailed RCA would be conducted.

Providers copied and pasted the regulatory language.

"a threshold number" needs to be determined by the organization.

2022 Inspections

Root cause analysis policy will be requested.

Prepare:

- ✓ Update the RCA policy in accordance with the Final DOJ Regulations (effective August 2020)

- ✓ Determine the "threshold number" for more detailed RCAs

2022 Inspections - Reminder

Regulation	Documents
12VAC35-105-520	DBHDS Risk Management Attestation Job Description for employee responsible for RM function Risk Management Plan Systemic Risk Assessment
12VAC35-105-620	Policies/procedures for a Quality Improvement Program
	Quality Improvement Plan
	Proof of provider obtaining input from individuals receiving services and Authorized Representatives, if applicable
12VAC35-105-160.E.2	Root Cause Analysis Policy

Other documents relating to other regulations as outlined in the Annual Inspection Checklist.

Resources – Refer to OL Webpage

QUALITY IMPROVEMENT-RISK MANAGEMENT RESOURCES FOR LICENSED PROVIDERS

- Crosswalk of Approved Risk Management Training and DBHDS Risk Management Attestation (August 2021)
- Q&A from Risk Management – Quality Improvement Tips and Tools Training (August 2021)
- Risk Management – Quality Improvement Tips and Tools Training (June 2021)
- SAMPLE Provider Quality Improvement Plan (June 2021)
- SAMPLE Provider Risk Management Plan (June 2021)
- SAMPLE Provider Systemic Risk Assessment (June 2021)
- Quality Improvement – Risk Management Training (Updated March 2021)
- Q&A from November 2020 QI-RM-RCA Training (Updated March 2021)
- Risk Management & Quality Improvement Strategies Training by the Center for Developmental Disabilities Evaluation & Research – Recorded Webinar (December 2020)
- Risk Management & Quality Improvement Strategies Training by the Center for Developmental Disabilities Evaluation and Research – Handout (December 2020)
- Quality Improvement – Risk Management Training (November 2020)
- Root Cause Analysis Training (November 2020)
- Q&A from November 2020 QI-RM-RCA Training (January 2021)

Resources – Refer to OL Webpage

Guidance

- LIC 16: Guidance for A Quality Improvement Program (November 2020)
- LIC 17: Guidance for Serious Incident Reporting (November 2020)
- LIC 18: Individuals with Developmental Disabilities with High Risk Health Conditions (June 2020)
- LIC 19: Corrective Action Plans (CAPs) (August 2020)
- LIC 20: Guidance on Incident Reporting Requirements (August 2020)
- LIC 21: Guidance for Risk Management (August 2020)

Resources – Coming Soon!

The Office of Licensing will be issuing the following SAMPLE documents:

Root Cause Analysis Policy

Quality Improvement Program - Policy

Other Resources

Centers for Medicare and Medicaid Services

CMS QAPI Framework

Institute for Healthcare Improvement (IHI) Toolkit

IHI Toolkit

Q&A

1. Is this training only for developmental disability services?

While the data shared within the training is pulled from inspections conducted of developmental service providers, the information/tips for how to achieve/maintain compliance with the Licensing Regulations applies to all providers.

2. We only have to do that training once? Or is it yearly? Do we need to sign the updated attestation form since it was signed prior to August 2021?

The training required for the person designated as the risk manager only needs to be completed once, unless a provider is found to be non-compliant with risk management or Root Cause Analysis (RCA) requirements for reasons that are related to a lack of knowledge. In that case, the provider may be required to demonstrate that they have completed additional training offered by the Commonwealth as part of their corrective action plan (CAP).

By signing the Attestation, providers attest that the risk manager participated in live/recorded trainings and/or reviewed the training power point presentations posted on the Office of Licensing webpage. The document is to be signed and dated by the person designated as the risk manager and their supervisor.

If the provider has a change in staff (resignation or changes in responsibilities), the person assigned the risk management function (as evidence by their job description) would need to complete the training and complete the Attestation. The completed Attestation should be kept on file and available upon request by the Licensing Specialist. Example – the risk manager resigns and the organization delegates another staff member to be the risk manager or hires a new person. That staff member would need to complete the training and complete the Attestation. That person's job description should reflect this responsibility.

The Crosswalk was updated in August 2021 to include the Office of Human Rights YouTube video on conducting investigations as well as the June 2021 Office of Licensing webinar.

Q&A

3. Are we supposed to complete the new updated attestation if we completed the original version? When in 2022 should the updated attestation be completed? Is the Attestation updated annually?

If the provider's current attestation includes proof that all required trainings were completed, and your Risk Manager remains the same as last year, the attestation does not need to be updated.

If you did not include documentation of the Human Rights Training on your attestation form last year, then your attestation should be updated to include proof that ALL trainings were completed as required. This should occur as soon as possible. The Crosswalk was updated August 2021 and was posted to the OL webpage (includes link to Office of Human Rights training on conducting investigations).

4. Can the risk attestation be written or must it be typed?

The attestation form can be typed or handwritten.

5. How long after hire is a risk manager supposed to have the trainings completed? The regulations do not specify.

12VAC35-105-440 states that new employees, contractors, volunteers, and students shall be oriented commensurate with their function or job-specific responsibilities within 15 business days. The provider shall document that the orientation covers each of the following policies, procedures, and practices. If the provider has an employee that transitions to the Risk Management position, that employee they must be oriented commensurate with their job-specific responsibilities within 15 business days.

6. Where do you find the attestation?

The attestation is part of the document titled Crosswalk of DBHDS Approved Risk Management Training on the Office of Licensing webpage and can be found at the following link:

Crosswalk of DBHDS Approved Risk Management Training and Attestation

Q&A

7. If a new person is hired as the Risk Manager and completed these trainings while working at a previous job, will it be acceptable to have a copy of that form in the personnel file at the new place of employment?

A provider may accept a completed/signed attestation from another provider, if their Risk Manager completed the training/attestation while working for another provider. However, the current supervisor should sign/date the attestation indicating review and approval of the already completed attestation which should be maintained within the risk manager's personnel file.

8. When is the portion of the training focusing on MHSS providers; is this also a part of the training?

This training includes data specific to providers of developmental disability services as it relates to the DOJ Settlement Agreement; however, providers of Mental Health, Substance Abuse and Brain Injury services are responsible for being compliant with the regulations reviewed during this training. The guidance documents are located on the Office of Licensing's web-page and can be applied to all services.

9. Often multiple unplanned hospital visits occur because the hospitals prematurely discharge despite our advocacy and when the individual continues to need medical attention and we take them back to appropriately seek care, it seems we are dinged for doing exactly what we should be doing. We are often 'answering for' the hospital's lack of appropriate care. Are there conversations happening about how to better join providers in advocacy for appropriate medical care rather than always approaching this from a 'care concern' perspective?

Thank you for bringing your concern to our attention. When care concern thresholds are met, it may be an indication that a provider needs to re-evaluate an individual's needs and supports, review the results of their root cause analysis or even consider making more systemic changes.

However, the OL realizes that providers who take individuals with higher needs may have a higher number of incidents.

Therefore, just because an incident meets a care concern threshold does not mean that a provider is not doing what they are supposed to be doing or that the OL has concerns. As we have stated before, serious incident reports are not punitive.

Please feel free to contact our office directly with additional systemic concerns.

Q&A

10. Can the systemic assessment be added to the QIP or should it be separate?

A systemic risk assessment is a tool for proactively identifying systemic risks and should inform the Risk Management plan. The assessment may be a part/addendum to the RM plan but should be clearly delineated as such and include all components as required in the regulations (12VAC35-105-520-C.1-5 and 12VAC35-105-520.D). The risk assessment process is focused on identifying both existing and potential harms and risks of harm.

However, 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.

11. It would be helpful to get the slides before the training is conducted. Is that possible?

Thank you for your feedback. We will consider this for our next webinar.

12. What date will the 2022 Attestation Training be offered?

The Office of Licensing is not offering a 2022 Attestation Training. However, the hyperlink to the pre-recorded trainings required by the person responsible for the Risk Management function are included within the Crosswalk of DBHDS Approved Risk Management Training. The Office of Licensing will utilize Constant Contact to notify providers when live trainings are being offered.

Q&A

13. Clients are asked on a quarterly basis regarding satisfaction of services. Is it enough to have a policy that this is reviewed and addressed on a quarterly basis with established criteria and thresholds for further investigation?12VAC35-105-620.E states that input from individual receiving services and their authorized representations, if applicable, about services used and satisfaction level of participation in the direction of service planning shall be part of the provider's quality improvement plan. The provider shall implement improvements, when indicated.

The provider should have documentation that this inquiry regarding satisfaction of services occurs, and that action is taken to address identified issues, when indicated.

14. How often does the systemic risk assessment need to be completed?

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:

- The environment of care;
- Clinical assessment or reassessment processes;
- Staff competence and adequacy of staffing;
- Use of high risk procedures, including seclusion and restraint; and
- A review of serious incidents

15. The company completes risk assessments at least quarterly. Are there any samples or guidance for the annual risk report?

Yes, a sample risk management plan can be found on our website: SAMPLE Risk Management Plan

Q&A

16. Because we all try to work together why are we currently doing a round 3 for DBHDS when everyone is trying to complete and get ready to annual inspections, it seems to be a duplication of the same work.

Thank you for expressing your concerns. We understand there are other offices and/or agencies completing inspections as well in response to expectations outlined in the Settlement Agreement. The Department continues to work on ways to reduce the burden to providers and your concern will be communicated to those working on this project.

Shauna Hooker is the contact for Quality Service Reviews (QSR) and can be reached at shauna.hooker@dbhds.virginia.gov.

17. Are the care concerns measured on a per individual basis or across the entire company? Are the two (2) care concern thresholds referring to an individual or the whole provider?

The IMU reviews and tracks serious incidents on an individual level by licensed service. For example, if a group home serves four individuals and each person was admitted to the hospital within a (ninety) 90 day timeframe, this would not constitute a care concern. However, if one individual was taken to the hospital 2 times within 90 days, then the care concern threshold for "Multiple (2 or more) unplanned hospital visits for a serious incident: falls, choking, urinary tract infection, aspiration pneumonia, dehydration, or seizures within a ninety (90) day timeframe for any reason" would have been met.

Providers will be able to view IMU action as soon as the incident has been triaged. The actions will be captured in the “License Specialist Action” tab of CHRIS.

Providers will be able to generate CHRIS reports on incidents that have been identified as Care Concern Thresholds.

Providers may access the *Provider Excel Individual Care Concern Threshold LSA notification* in CHRIS to see a list of individuals who have met the Care Concern Thresholds.

Case Managers can run the *Excel-CM report Care Concern Threshold LSA notification* in CHRIS to see a report of any individual served by them regardless of provider.

The report is found in CHRIS under DSI-13- Individual Care Concern.

Q&A

Question #17 (continued)

Below is the list of Care Concern Thresholds the IMU will track through the incident management process.

- Multiple (2 or more) unplanned hospital visits for a serious incident: falls, choking, urinary tract infection, aspiration pneumonia, dehydration, or seizures within a ninety (90) day time-frame for any reason.
- 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.

18. Is the Root Cause Analysis (RCA) supposed to be done monthly, every quarter, or yearly?

RCA related to serious incidents 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. The provider shall also develop and implement a root cause analysis policy for determining when a more detailed root cause analysis should be conducted (12VAC35-105-160.E.2).

RCAs can also be conducted as part of a provider's quality improvement or risk management program as RCA is considered a standard quality improvement tool 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.

19. When we have questions regarding some of the topics presented today, who is a good contact person? Many times, I have called to try and get questions answered and not been able to get ahold of any one to assist me.

Providers are encouraged to contact their licensing specialist for questions related to regulatory compliance. The list of the staff and their supervisors are posted on our website under Office of Licensing Contact Information.

Office of Licensing Contact Information

Q&A

20. If providers have already updated QIP's and completed risk assessment before this training is the expectation providers update it if before their annual assessment.

The provider only needs to update their QI plan and RM assessment if:

1. The provider was non-compliant during last year's inspection; or

2. After completion of this webinar, the provider determines themselves that they are not in compliance with the regulations.

21. Can you post the direct link to the resources page?

Quality Improvement-Risk Management Resources can be found on the Office of Licensing Website under the "Training and Technical Assistance Tab"

TRAINING AND TECHNICAL ASSISTANCE

BEHAVIORAL HEALTH ENHANCEMENT AND ASAM

- Aligning the Licensing Regulations with ASAM Criteria Training (April 2021)
- Memo Behavioral Health Enhancement and American Society of Addiction Medicine (March 2021)
- ICT/ACT Licensing Requirements Crosswalk (March 2021)

QUALITY IMPROVEMENT-RISK MANAGEMENT RESOURCES FOR LICENSED PROVIDERS

- Risk Management – Quality Improvement Tips and Tools Training June 2021 (Updated January 2022
- QI-RM-RCA Webinar (December 2021)
- Crosswalk of Approved Risk Management Training and DBHDS Risk Management Attestation (August 2021)
- SAMPLE Provider Quality Improvement Plan (June 2021)
- SAMPLE Provider Risk Management Plan (June 2021)
- SAMPLE Provider Systemic Risk Assessment (June 2021)
- Quality Improvement – Risk Management Training (Updated March 2021)
- Q&A from November 2020 QI-RM-RCA Training (Updated March 2021)

22. What's an example of a more detailed RCA?

12VAC35-160.E.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.

Q&A

23. Can you briefly explain key differences between risk management plan vs quality improvement plan?

A quality improvement (QI) plan is a detailed work plan developed by a provider that defines steps the provider will take to review the quality of services it provides and to manage initiatives to improve quality. A quality improvement plan consists of systematic and continuous actions that lead to measurable improvement in the services, supports, and health status of the individuals receiving services. A QI plan includes measurable goals and objectives as well as progress toward meeting those goals.

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

24. Does this training provide a certificate?

No

25. How do providers receive feedback regarding the identified issues noted? The reason for the question is it may be helpful if providers knew especially what their identified issues are as it applies to the regulations.

Providers may reach out to their Licensing Specialist to ask questions and seek regulatory technical assistance. In addition, an exit interview should occur as part of the annual inspection and this provides an opportunity to discuss areas of non-compliance as well as recommendations for coming into compliance with the regulations.

26. When will there be a training on changes with MCO'S? A lot of providers are struggling with all the changes.

Thank you for your question. We would recommend that you contact the Department of Medical Assistance Services (DMAS) or your MCO to request training regarding changes that have occurred.

Q&A

27. Do Supportive In-home Providers have to turn in a policy and procedures that's address HBCS rights for the QSR? Does it apply to just group homes?

If a provider is billing in-home residential (meaning a staff coming into the home of the individual/family) a specific HCBS policy is not required. If the provider is billing sponsored residential (meaning an individual lives with a paid sponsor in the sponsor's home) a specific HCBS policy is required.

28. Should the agency have a separate Risk Manager for each service provided? Or one Risk Manager for all services?

Each licensed service is required to designate a qualified person with responsibility for the risk management function. The same person could serve as risk manager for multiple services. The designated person should be familiar with the day-to-day operations of the service as well as familiar with the individuals served. The regulations do not require the person to be onsite. The provider may assign additional roles related to risk management depending on the size and scope of services of the provider.

29. Initially it was stated that previous job experience would be accepted in place of training. Has that changed? How would one document that?

The Crosswalk of DBHDS Approved Risk Management Training should be reviewed and DBHDS Attestation completed (previous training doesn't apply).

30. When the supervisor (of the person responsible for the risk management function) signs the attestation, they are attesting that they have reviewed the document signed by the risk manager or does their signature means they [supervisor] have also attending the various trainings, etc.?

The person responsible for the risk management function (per their job description needs to complete the training). The supervisor attests that the person has completed it.

Q&A

31. We are a group day service. We have an individual in day support who came to program and reported chest pain within 20 minutes of arrival. We called 911 individual was taken to the hospital. This happened again several weeks later. We received a care concern CAP. Should we have received that CAP?

The Office of Licensing does not issue citations for care concerns. If the provider received a citation from the Incident Management Unit, it was due to the incident not being reported within the 24-hour timeframe.

32. If there is an issue identified as needing improvement/plan/monitoring, how long does this issue need to be monitored? At some point if the plan is developed, and implemented, the end goal would be to resolve the issue. How do we document that a concern has been resolved and no longer needs monitoring?

The provider QI program (12VAC35-105-620.A) could outline how this may be addressed. If the goal is met, the provider may wish to incorporate surveillance measures as a way to periodically monitor for sustained performance.

33. Do you need to fill out incident reports on chronic UTI's that are not going to the ER?

A UTI that does not require medical attention likely does not need to be reported as a serious incident however should be tracked as Level I Serious incident. Providers should maintain records of any Level I incident. Only incidents that meet the requirement of a Level II or Level III incident must be reported in CHRIS.

Please refer to our regulations as well as our Serious Incident Reporting guidance documents and trainings. The OL has specific ribbons on the webpage for serious incident documentation as well as CHRIS training documents.

Guidance for Serious Incident Reporting

Guidance on Incident Reporting Requirements

#33 continued

34. Once the attestation is completed, will the provider receive a certificate and how will DBHDS know that the provider participated in the training?

The provider is attesting to the fact that they competed the training. There are no certificates.

35. How do we get credit for attending this training? Do we keep our registration form?

This webinar is being offered to provide feedback related to the 2021 annual inspections of developmental service providers as well as including data related to compliance as it relates to the DOJ Settlement Agreement.

36. Is there a sample survey available for individuals and authorized representative/stakeholders? The provider should create a survey that is meaningful to their organization and the scope of the services offered.

37. Looking at the attestation, I don't see where the information regarding the Office of Human Rights training on conducting investigations is located, please advise.

The Office of Human Rights has a YouTube video related to conducting investigations and the

link is on the Crosswalk.

Crosswalk of DBHDS Approved Risk Management Training and DBHDS Risk Management Attestation

Virginia Department of Behavioral Health & Developmental Services

Office of Licensing (OL)

Crosswalk of DBHDS Approved Risk Management Training

Office of Human Rights "Investigating Abuse & Neglect: An Overview for Community Providers"	Conducting Investigations	The risk manager may register for an Office of Human of Rights webinar or watch the video. The training calendar is posted on the Office of Human Rights webpage and the youtube link for the training is pasted below: https://dbhds.virginia.gov/assets/doc/QMD/human-rights/ohr-2021-statewide-training-calendar_current1.docx https://www.youtube.com/watch?v=4wB4dx-olyk

38. Where do we send the completed attestation?

The provider should keep the completed document in the risk manager's personnel file. The Licensing Specialist will request the attestation during their review.