



Virginia Department of
Behavioral Health &
Developmental Services

Office of Licensing Webinar December 16, 2021

DBHDS Vision: A life of possibilities for all Virginians



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

DBHDS Vision: A life of possibilities for all Virginians

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.

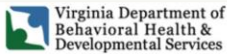
Providers need to have these documents ready for review when requested.

For the third year, the Office of Licensing will be issuing an annual inspection checklist. The licensing specialists (LS) will be evaluating compliance with a number of regulations during annual unannounced inspections. A list of the minimum regulations that will be reviewed as well as criteria for achieving compliance will be shared over the next few weeks. In addition, your LS will review corrective action plans that have been submitted since the last inspection to determine if they have been implemented as approved.

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



Slide 5

DBHDS' efforts to achieve compliance with the Commonwealth's Settlement Agreement with the U.S. Department of Justice includes agreed upon indicators. This slide includes one of those indicators. The Office of Licensing collects critical information related to DD providers' compliance with risk management regulations.

This indicator is one of DBHDS' measurable goals so just like providers, we are collecting data, reviewing data and responding to those areas where we are not meeting the goal.

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.

Throughout this presentation, you will see highlighted in red or green the percentage of compliance. The data included in this presentation is for January 1, 2021 to September 30, 2021.

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%

In early 2021, DBHDS issued the Crosswalk of approved risk management training and the DBHDS Risk Management Attestation. The Crosswalk included approved training/courses which met the requirement for each topic area.

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



The compliance results were related to several issues. Providers failed to complete the Attestation; others did not submit the job description for the person designated for the risk management function; others did not complete training that was on the Crosswalk and others failed to sign the Attestation.

By signing the Attestation, providers attest that the risk manager participated in the live webinar or reviewed the training presentation online. The document is to be signed and dated by the person designated as the risk manager and the person's supervisor.

If the provider has a change in staff (resignation or changes in responsibilities), the person assigned the risk management function (as evidenced 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.

This Crosswalk was updated in August 2021 and was posted to the OL webpage. The document includes the hyperlink to Office of Human Rights training on conducting investigations.

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
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

In this example, the provider did not accurately complete the Attestation. All "topic areas" should be completed as well as the date the training was completed. It is important to read the instructions on how to accurately complete the Attestation. In this example, it is not clear what training was taken for each topic area.

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
EXAMPLE: Risk Management	EXAMPLE: CDDER Live Webinar "Risk Management and Quality Improvement Strategies"	EXAMPLE: 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

In this example, the staff member responsible for risk management watched the CDDER recorded webinar and attended the live training in June. Then later they watched the Office of Human Rights YouTube video on conducting investigations. The Office of Human Rights has also issued a training calendar for 2022 if a provider wants to participate in a live webinar rather than watching the YouTube video.

All hyperlinks to training are included on the Crosswalk of Approved Training posted on the Office of Licensing webpage.

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.

For unannounced inspections in 2022, the risk manager should have their completed Attestation. It is important to read the instructions on how to accurately complete the Attestation.

The language in the Blue Box on this slide is from the Attestation. By signing the document, the risk manager and supervisor are attesting to the fact that the training has been completed.

If the person responsible for risk management function is the owner and does not have a supervisor, this should be included on the document.

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%

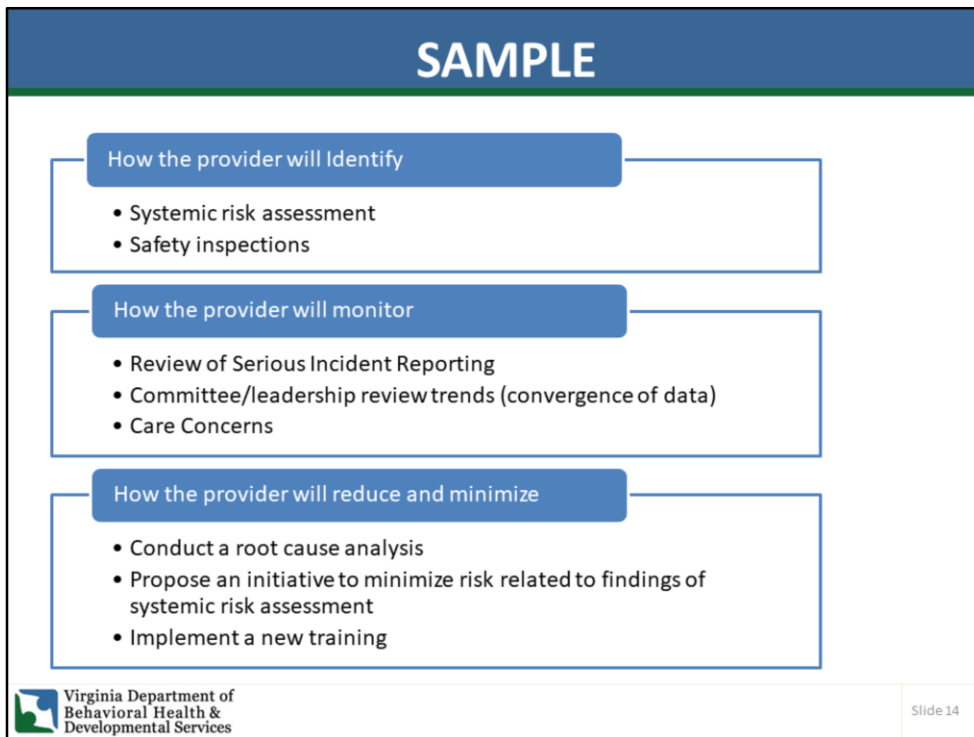
The 86% compliance goal was met. Please note that a risk management plan is not a policy and should include all of the elements.

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**





Reminder – there is a SAMPLE risk management plan posted to the Office of Licensing webpage. The SAMPLE includes how the provider might identify, monitor, reduce and minimize risks. There could be many more ways.

Identification – systemic risk assessment, safety inspection, etc.

How does a provider monitor? There may be a committee, a work group, a team that regularly reviews data and looks for trends. The convergence of data is when a provider identifies that there has been an increase in serious incidents when there has been staff turnover.

Reducing and minimizing – look at root causes, propose a quality improvement initiative or 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

 Virginia Department of Behavioral Health & Developmental Services

Slide 15

Referencing the regulations again 12VAC35-105-520.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.

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)



Environment of Care – what does that mean? Again, every organization will have different risks associated with its environment of care. It will depend on the location, the building (or buildings). Each provider needs to think about its environment of care and the potential risks.

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

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A SAMPLE systemic risk assessment was posted to the OL webpage and training was conducted in June 2021 (power point posted to the OL webpage). This slide is just part of that 12 page document which provided several different ways to complete a systemic risk assessment.

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.

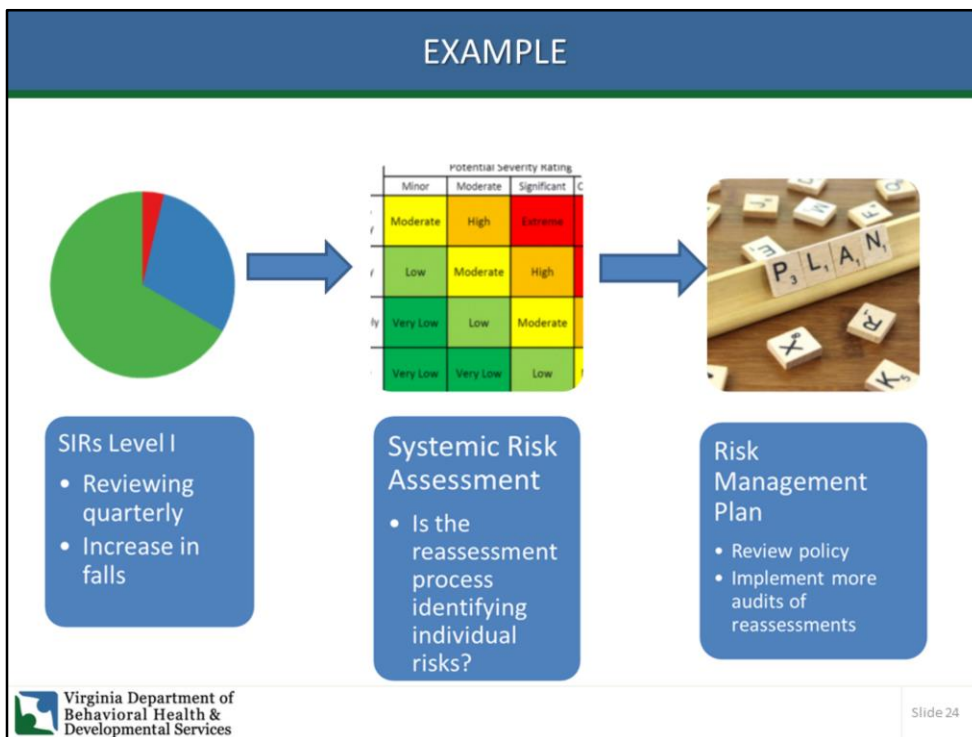
The systemic risk assessment did not include clinical assessment or reassessment processes.

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).



Throughout the year, the provider is reviewing Level I serious incidents on a quarterly basis and sees an increase in falls. When the systemic risk assessment is completed, the provider asks is the reassessment process identifying all the individual's risks (are people aging and/or presenting with new risks related to falls?). If the provider considers this to be an area of risk, they include this in their risk management plan – they perhaps review their policy and/or implement more audits of reassessments to make sure they are being done according to policy.

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%

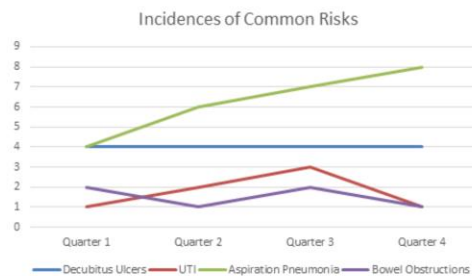
Identified Issue:

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.



Reminder regarding 160.C - all serious incidents are to be reviewed at least quarterly to analyze for trends, potential systemic issues. When completing the annual systemic risk assessment, a provider would look at incidents for trends and patterns. For example, is there an increase in Aspiration Pneumonia. And if so, that is a risk that should be addressed in the provider's risk management plan or as part of the provider's quality improvement program.

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.

DBHDS has defined risk triggers and thresholds as care concerns. Please note that the care concerns were revised as of October 4, 2021. We noticed that those who got care concerns, didn't have anything in their plan.

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

The IMU reviews serious incidents not only on an individual level but systematically as well to identify possible patterns/trends by individuals, a provider's licensed service, and across providers.

Through this review, the IMU is able to identify areas, based on serious incidents, where there is potential risk for more serious future outcomes.

When care concerns thresholds are met it may be an indication a provider may need to re-evaluate an individual's needs and supports, review the results of their root cause analysis or even consider making more 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.

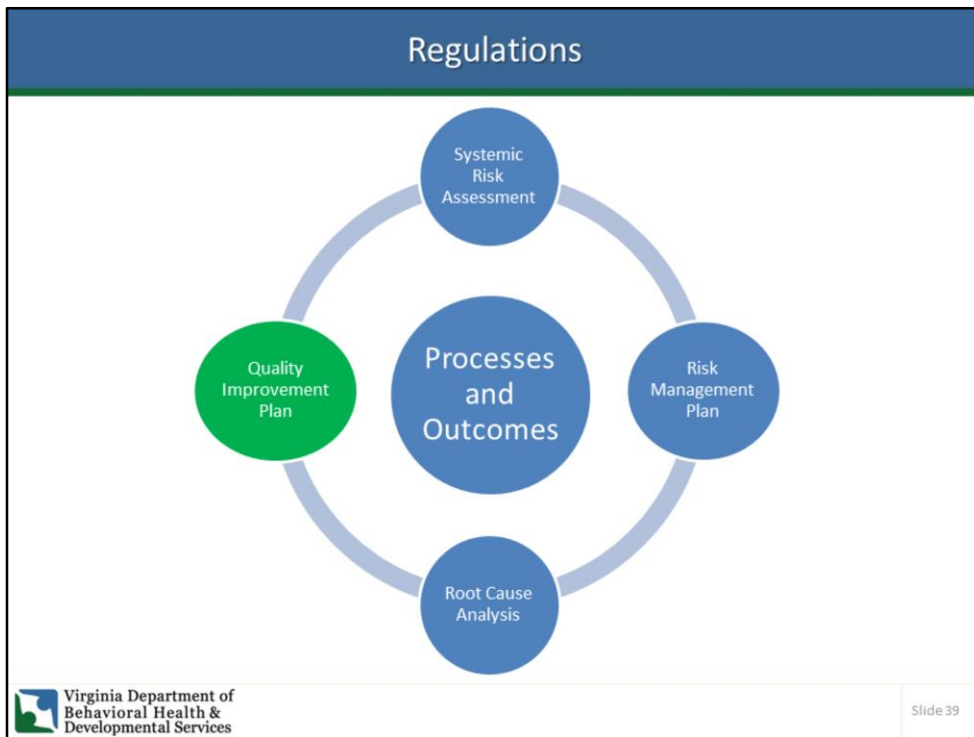
A SAMPLE risk assessment was posted to the Office of Licensing webpage and training was conducted in June 2021. The presentation was also posted to the OL webpage.

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.



This visual is a reminder that there is a relationship to a central idea which is – to improve the provider’s processes and outcomes for individuals served. The ring of circles contributes to the central idea.


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	{	<ul style="list-style-type: none">• Structure and/or foundation• Policies and procedures - 620.D:<ul style="list-style-type: none">• Criteria for establishing goals and objectives• Criteria for updating the QI Plan• Criteria for submitting revised corrective action plans• Standard quality improvement tools
<u>Versus</u>		
Plan	{	<ul style="list-style-type: none">• Work plan• Goals for the year

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Slide 41

The difference between a program and a plan is that the program is outlined in policies and procedures, but the provider's quality improvement plan is the provider's work plan or road map 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%



The organization determines whether the plan is calendar year, fiscal year, or whatever is appropriate to the organization.

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.



The Office of Licensing (OL) provided a SAMPLE quality improvement plan as well as training in June 2021. The SAMPLE is posted to the OL webpage.

12VAC35-105-620.C.2

The quality improvement plan shall:

2. Define measurable goals and objectives

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



Providers involved in writing goals for an Individual Support Plan or a treatment plan should utilize the same concept for writing your organization's quality improvement goals and objectives.

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



While providing a safe environment is a good goal, it is not measurable. It is measurable to reduce the rate of Level II serious injuries by X% by December 31, 2022. This would require that you have baseline data.

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.

This regulation was Non-Determined this year. As this changes, DBHDS will inform providers accordingly.

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%



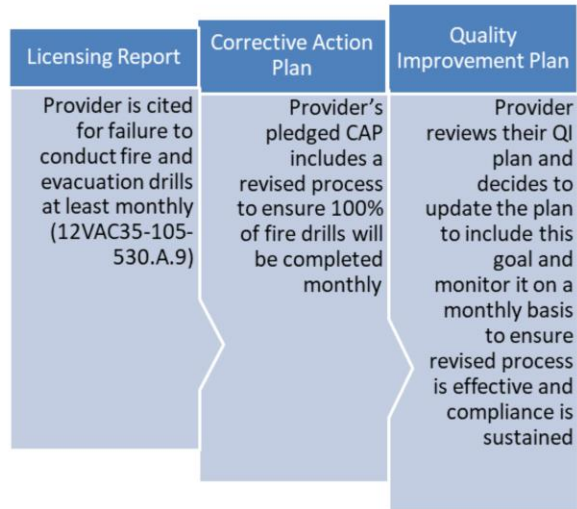
Identified Issues

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.

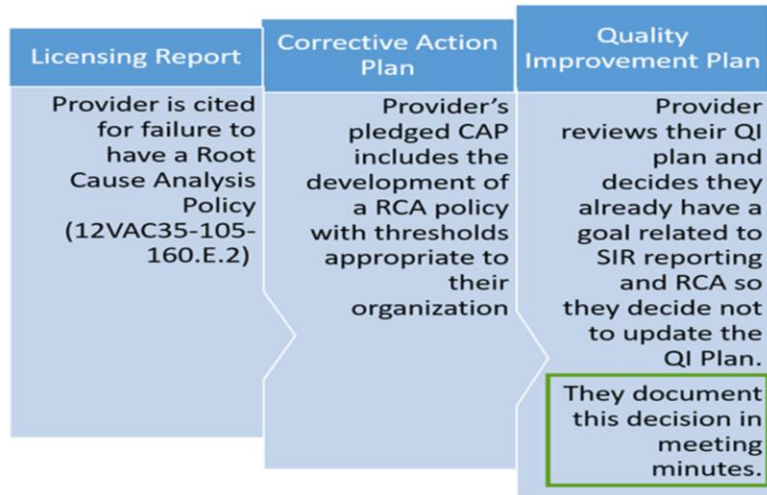
Or

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



EXAMPLE - Decision Not to Update Plan



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%



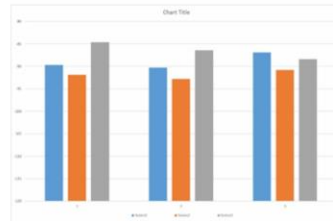
It is important to review and respond to the data and that is why the goals/objectives need to be measurable.

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%

This is just an example to demonstrate how a provider may monitor. For instance, the SAMPLE chart does not include all required training pursuant to regulation 12VAC35-105-440.

EXAMPLE

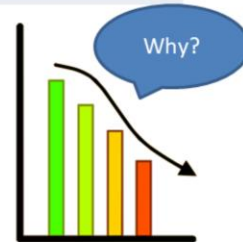
Month	Training	# of New Employees	Percent Trained in 15 days
March	Human Rights	8	100%
	Infection Control	8	50%
	Emergency preparedness	8	100%
	Person-centeredness	8	50%

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



The whole purpose of collecting and reviewing the data is to make sure the provider is making progress toward the established goal/objective. In this example, the provider does well for two or three months, but then there is a dip in compliance. So the provider asks questions to identify problems and then takes action. The provider doesn't wait until November to review data and then identify that there was a problem. Ongoing monitoring needs to be demonstrated.

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.**

Providers need to include in their policies and procedures the criteria they will use.

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.

Criteria could be defined as a **principle or standard by which something may be judged or decided.**

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).

So begin by asking – “what are your criteria for establishing measurable goals and objectives?”

An organization’s leadership may get MANY ideas for goals and objectives and they can’t do everything in one year. So your criteria help you prioritize what the provider will establish as a goal and how to measure it.

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



Providers should really think about what the criteria are for establishing goals, updating their plan, or updating their Corrective Action Plans.

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

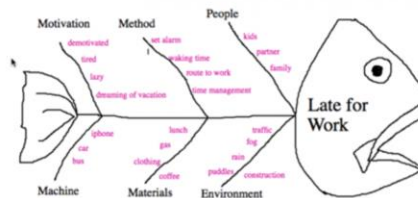
2. The provider shall develop and implement a root cause analysis policy for determining when a more detailed root cause analysis, including convening a team, collecting and analyzing data, mapping processes, and charting causal factors, should be conducted. At a minimum, the policy shall require for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

**official
policy**

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

The RCA policy may be included in the Serious Incident Policy.

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.

So in summary, the following documents will be requested as part of the 2022 inspections. Please note, there are other documents that will be requested relating to other regulations and the Office of Licensing will issue the Inspection Checklist in the coming weeks.

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 \(January 2021\)](#)



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Behavioral Health &
Developmental Services

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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 \(August 2020\)](#)

In addition, the Guidance documents related to Quality Improvement and Risk Management should be referenced as the documents provide additional information.

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](#)

In addition, there are many excellent resources available including the Centers for Medicare and Medicaid Services which has a Quality Assurance/Performance Improvement framework that includes some resources for setting goals. In addition the Institute for Healthcare Improvement offers a Quality Improvement Toolkit.

Questions

