Risk Management Regulations
Tips and Tools
June 2021

Office of Licensing

Virginia Department of Behavioral
Health and Developmental Services

DBHDS Vision: A life of possibilities for all Virginians

- Systemic Risk Assessment
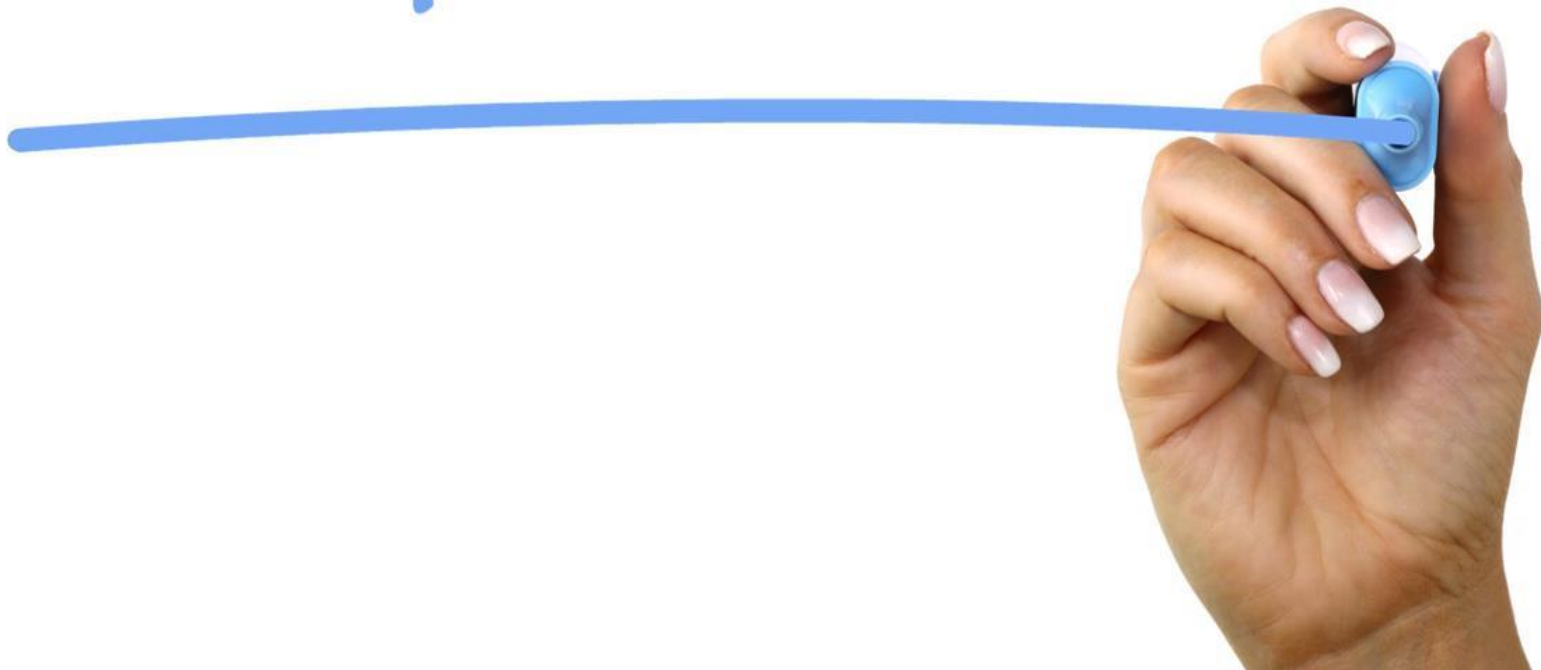- Risk Management Plan

Putting it All Together

Systemic Risk Assessment → Care Concerns → Risk Management Plan → Root Cause Analysis → Quality Improvement Plan → (cycle back to Systemic Risk Assessment)
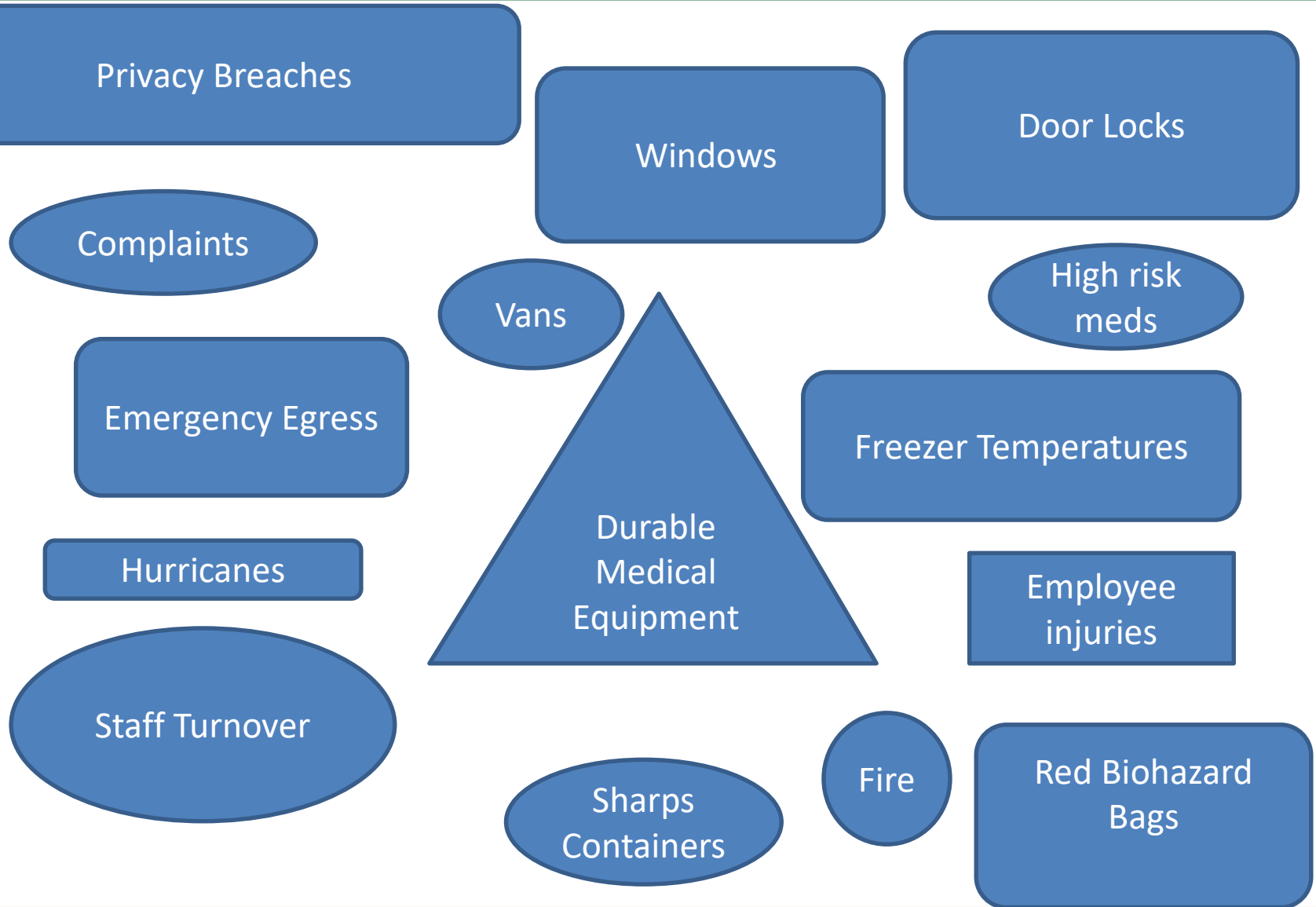
" The provider shall conduct systemic risk assessment reviews at least annually to identify and respond to practices, situations and policies that could result in the risk of harm to individuals receiving services. The risk assessment review shall address at least the following:"

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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**

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Risks – Where to Begin

Privacy Breaches

Windows

Door Locks

Complaints

High risk meds

Vans

Emergency Egress

Durable Medical Equipment

Freezer Temperatures

Hurricanes

Employee injuries

Staff Turnover

Fire

Red Biohazard Bags

Sharps Containers

Identifying risks and potential risks helps to prevent harm to the individuals served, staff and the organization.

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Reporting Culture

Promote a culture that balances safety and accountability in an environment where events or near misses can be used as an opportunity for improvement to mitigate further incidences.

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Reporting Culture

The 4 Es

Establish trust

Encourage reporting

Eliminate fear of punishment

Examine errors, close call and hazardous conditions

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Slide 10

What is a Risk Assessment?

Is it a list of tasks for the risk manager?

Is it copying the regulations into your policy and then filing it?

What is a Systemic Risk Assessment?

A tool for proactively identifying systemic risks <u>before</u> adverse events occur

Where to begin:

1. Determine a format

2. Determine who will conduct the risk assessment (leadership, risk manager, committee)

Various Formats

Risk Area	Findings	Recommendation	Add to Risk Management Plan	Assigned To	Follow-up Date
Environment of Care – shingles need replacing	Latest rainfall resulted in some water damage	Obtain contractor bid	Yes	Safety officer	Report due August 2021

Checklist Format - Example

Yes	No	NA	Risk	Action	Follow-up
X			Debris and boxes in stairwell?	None	
X			The stairwells are free from debris to ensure safe emergency exits.	None needed at this time; continue to monitor	

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Requirements

The reason providers <u>can</u> use their own format, is that every provider's risks will vary, but the risk assessment shall:

- Be conducted at least annually (date)

- Inform the risk management plan

- Incorporate uniform risk triggers and thresholds

Environment of Care

Guidance for Risk Management (August 2020)

Physical environment where services are provided, such as the building and physical premises

Examples:

- Any site where individuals are served
- How the area where services are provided is arranged
- Any special protective features that may be present
- Location, amount and condition of safety equipment, including
  - Fire extinguishers
  - First Aid kits
  - Flashlights
  - And much more..........

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How is the environment of care risk assessment different than the annual safety inspection?

Guidance:

"A review of the environment of care should consider the results of the annual safety inspection (12VAC35-105-520.E), when applicable, but is broader than a safety inspection."
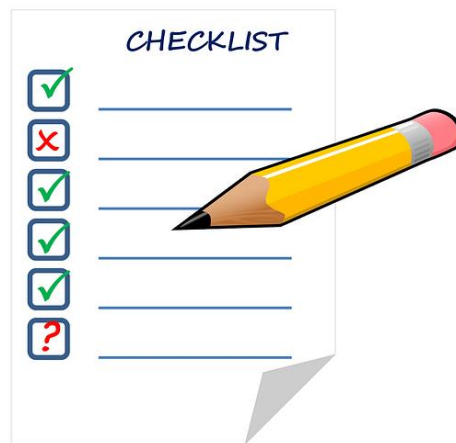
Safety Inspection

Annual safety inspection are also to be completed at least annually and are to be completed for each service location.

Safety Inspection

- ✓ Expiration dates
- ✓ Fire extinguishers
- ✓ Tripping hazards
- ✓ Water temperatures
- ✓ Flashlights

Monthly	Quarterly	Annually

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The regulations specify a systemic risk assessment which includes the environment of care <u>and</u> a safety inspection (12VAC35-105-520.E)

Licensing specialists conducting an annual inspection would be asking for both of these documents.

Environment of Care

	Findings	Recommendations	Add to Risk Management Plan	Comments – Assigned to Department/Staff	Date completed; status report
Emergency egress	Building exits had boxes/trash	Staff training recommended	No	Assigned to Human Resources; report on status by (insert date)	
Ventilation	Age of building presents risks	Contract with consultant to evaluate	Yes	Assigned to building manager to request bids	Added to RM plan; bids requested (insert date)

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Guidance for Risk Management

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

<u>Reassessments</u> include: (1) reviews of incidents in which the individual was involved, and (2) review of the individual's health risks.

The Independent Reviewer for the Settlement Agreement noted that this (and high risk procedures) were not consistently included in the systemic risk assessments.

12VAC35-520.C.2 – Assessment and Reassessment

	Findings	Recommendations	Add to Risk Management Plan	Comments – Assigned to	Follow-up Date
Assessment Process	Physical exams are being completed prior to admission	Continue to monitor	No	Nursing director to monitor	
Reassessments	Individuals' health risks are not being reviewed	Nursing to develop new policy and monitor for effectiveness	Yes	Nursing	

Are policies and processes effectively identifying and mitigating risks unique to each individual?

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Staff Competency and Adequacy of Staffing
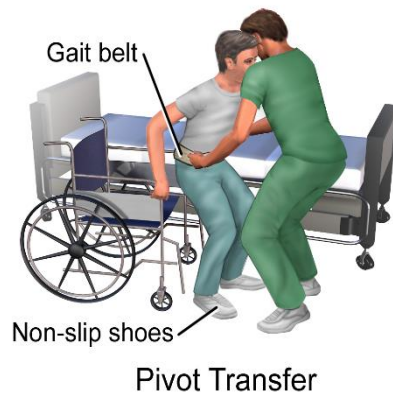
Risks vary according to the licensed provider:

- ✓ Inability to hire staff
- ✓ CPR certifications
- ✓ Background checks
- ✓ Training
- ✓ Evaluations
- ✓ Staff injuries
- ✓ Turnover rates

What are your risks – how will you seek to mitigate?

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Seclusion and restraint

High-Risk Medicines

A Anti-Infectives

P Potassium
and other electrolytes

I Insulin

N Narcotics
and other sedatives

C Chemotherapeutic
agents

H Heparin
and anticoagulants

www.cec.health.nsw.gov.au/programs/high-risk-medicines

MEDICATION SAFETY
AND QUALITY
High-Risk Medicines

CLINICAL
EXCELLENCE
COMMISSION

Gait belt

Non-slip shoes

Pivot Transfer

High risk methods of medication administration

High Risk Procedures

High risk procedures may involve questions such as:

- Is the use of seclusion and restraint, in compliance with Human Rights Regulations?

- Are procedures related to high risk procedures reviewed regularly?

- Are the staff permitted to implement high risk procedures properly trained?

- Are high risk procedures properly authorized and reviewed per policy, regulation, and law?

- Are all Level I serious incidents reviewed at least quarterly?

- What trends are identified?

- What kinds of incidents are reported? Are they related in terms of the type of incident?

- Were there similar incidents that appeared close together in time? Was there anything unique that took place at that time?

- Any patterns (time of day, day of week, location, program, certain types of activities, presence of other people/visitors)?

- Reflect on what has been learned from Root Cause Analyses

- Does the provider have an updated policy that defines who has the authority and responsibility to act when a serious incident or a pattern of serious incidents indicates that an individual is at risk

And much more!

The items highlighted are those <u>required</u> by regulation.

There are so many more risks that may affect your organization

- security breaches

- business risks

- financial risks

- liability risks

SAMPLE

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

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.

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Care Concern Thresholds – IMU's Role

Reviews <u>serious incidents</u>

–individual level

–systematically

–identify possible patterns/trends by individual, a provider's licensed service as well as across providers

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

<u>May</u> be an indication a provider may need to:

• re-evaluate

• review root cause analysis

• consider making more systemic changes.

Care Concern Thresholds – What it is Not

- Doesn't necessarily mean there is a provider concern.

  Individuals with higher needs may have a higher number of incidents

- An incident meeting a care concern threshold does not mean that there is a provider concern.

- Doesn't always equate to an investigation.

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Accessing Information about Care Concern Thresholds

- Documented in the Licensing Specialist (LSA) part of CHRIS
- Providers and CSBs are able to run a report in CHRIS

- This is to help provide some trending information for providers to use.
  - another tool providers may use
  - Probably consistent with data collected via provider RCA

- Doesn't always equate to an investigation.

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Role of OHR and OIH

OHR is copied on care concern thresholds when there is a possibility that the concern may indicate the potential for abuse/neglect.

OIH is copied when a care concern threshold indicates a potential for a health and safety concern.

Why?

– Determine if it would be helpful to follow up with provider to offer information, training, resources or technical assistance.

– Does not mean provider has done anything wrong.

– Our way of sharing information and ensuring providers are aware of trends we are seeing at the state level.

Care Concern Threshold

Providers should have an established protocol on how to handle Care Concerns identified by DBHDS.

The protocol could include:

–Complete Root Cause Analyses (RCA)

–Review Previous Incidents

–Review the Individual's Support Plan

–Conduct Team Meeting

–Staff Retraining

–Additional Assessments

Care Concern Threshold

Example of when a Fall Care Concern Threshold has been identified:

• Complete RCA- include physical environment (review lighting, uneven floors, clutter, medications, behavior, medical status, etc)

• Review all incidents (Level I, II, III) involving the individual, identify/analyze patterns and trends or potential systemic issue

• Meet with the team to review/update ISP, identify corrective actions or preventative measures, written protocols, additional assessment, additional supports to mitigate future incidents

• Train or educate staff with new or updated supports

• Designate a person in the organization who will conduct on-going monitor, record or documentation of implementation of corrective actions and ensuring supports written in the plan are in place/performed, monitor effectiveness and reduce incidents (Need to be measurable, i.e. no falls incident within 90 days). DOCUMENT, document, and document.

• Team review of the effectiveness of the plan initially (upon plan implementation) i.e. within 3 and 6 months, then annually if no incidents, or anytime there is need or changes in the individual's status- medical, behavioral, etc.

Risk Triggers and Thresholds

What will licensing specialist be looking for?

That the provider's systemic risk assessment includes a review of risk triggers and thresholds (care concerns) that were met and how they were addressed.

What if the provider didn't have any care concerns?

The provider should include in their risk management plan how they would review/address care concerns if they do arise.

What if no changes were necessary after review of care concerns?

The provider should document why no changes were made to individual or programmatic services.

Systemic Risk Assessment

Risk assessment complete – Is the provider done?

No – the provider has identified risks

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Next Steps

- ✓ Prioritize what risks to address now versus later
- ✓ Add items to the Risk Management Plan
- ✓ Assign it to staff as to how to reduce/mitigate the risk
- ✓ Keep reviewing (not once and done)

Putting it All Together

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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."

Tips:

❖ Refer to the Guidance for Risk Management (August 2020)

❖ Start with outline such as:

❑ Date, signature, title of staff signing the plan

❑ Introduction

❑ Leadership role

❑ Roles and responsibilities

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Risk Management Plan

Policy

- Outline your serious incident reporting procedures
- Include procedures for
  - Hand hygiene
  - Emergency management
  - Reporting employee injuries
  - Reporting visitor injuries

Plan

- Identify
- Monitor
- Reduce and minimize harms and risks of harm including:
  - Personal injury
  - Infectious disease
  - Property damage or loss
  - Other sources of potential liability

Examples

Identify

- Systemic risk assessment
- Safety inspections

Monitor

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

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

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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

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Risk Management Plan

General Tips:

- Get input from frontline staff

- Regularly share updates with staff

- Please don't put it on the shelf --

- Revisit regularly – update/revise/evaluate

Risk Management Plan

SAMPLE Risk Management Plan

Office of Licensing Guidance for Risk Management states "the provider should review and update the plan at least annually or any time the provider identifies a need to review and update the plan based on ongoing quality review and risk management activities."

Tip – Best practice is to include the date and applicable signatures at the top or bottom of the document. Revisions could also be noted and dated in this section.

Example - Date _____ Signature _____ Title of Person _____

Review/Revision date: _____

Tip - Best practice is to include an introduction regarding the purpose of the risk management plan and how it is tied to the organization's mission and vision.

Example - Introduction

The provider's risk management plan supports the organization's mission and vision. The risk management plan seeks to continuously improve safety and minimize or prevent errors and events that result in harm through proactive risk management activities. Acknowledging that safety is everyone's responsibility, the organization strives to ensure the safety of individuals, employees, visitors, and others through the identification, mitigation, early detection, monitoring, evaluation, and control of risks.

This section could also reference other policies, procedures, protocols or plans that represent the organization's quality and risk management programs.

Tip – Best practice is to include a section regarding leadership's role in the organization's risk management program. Leadership's commitment to a culture of safety and the importance of identifying and addressing risks could be outlined. Leadership has the responsibility for ensuring adequate resources are available for risk management activities.

Example - Leadership

The leadership of the organization is committed to promoting safety and has the overall responsibility for the effectiveness of the risk management program including managing adverse events occurring with individuals served, staff, visitors, and organizational assets. Leadership supports a non-punitive culture that promotes awareness and empowers staff to identify risk-related issues.

Based on the organization's size and structure, this section could then outline designated committees that are charged with monitoring risks and reviewing the impact of risk reduction strategies.

Tip – Best practice is to include a section outlining the roles and responsibilities related to risk management.
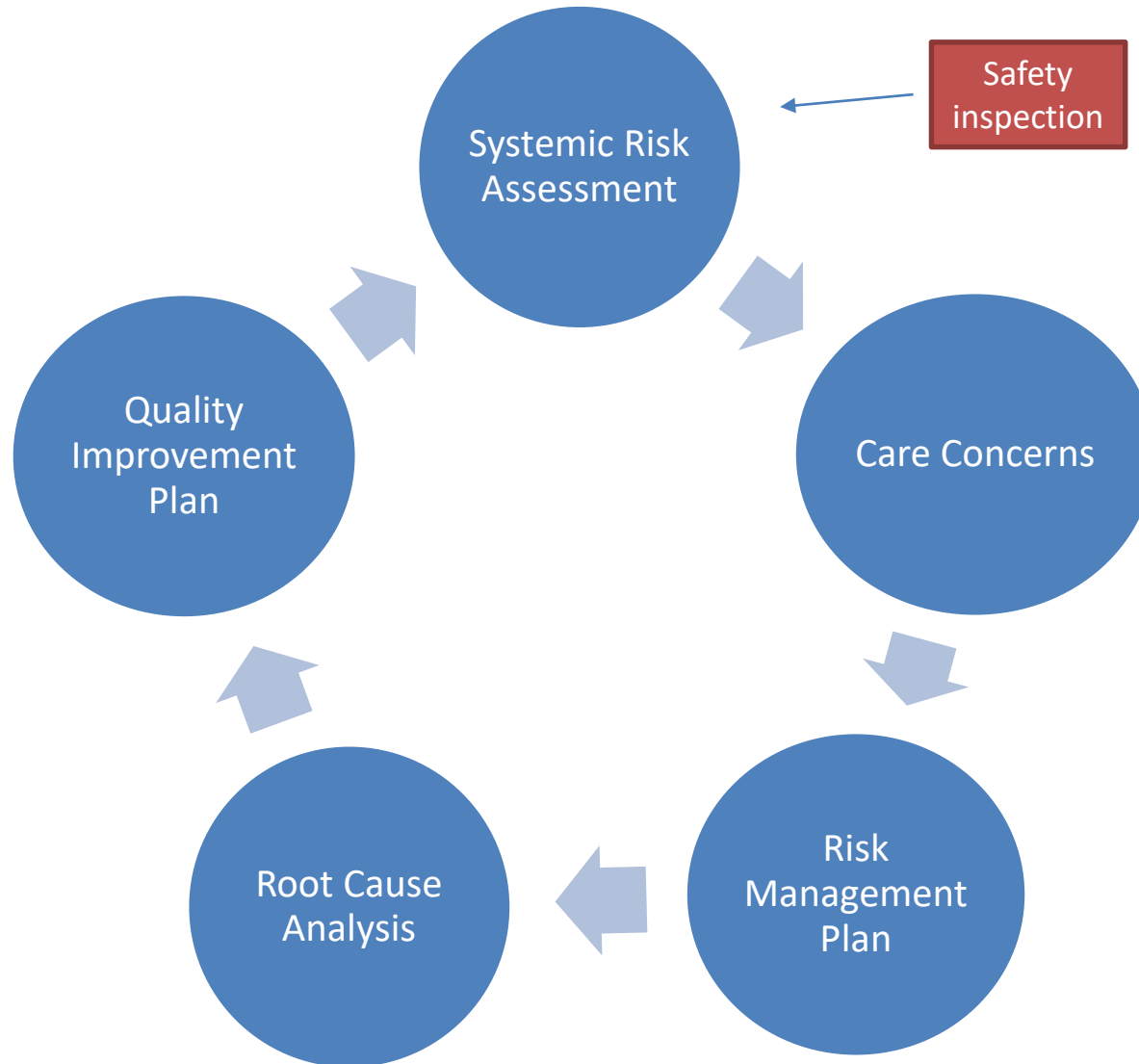
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Reminder

Guidance for Risk Management (August 2020)

A provider's risk management plan may be a standalone risk management plan <u>or</u> it may be integrated into the provider's overall quality improvement plan.
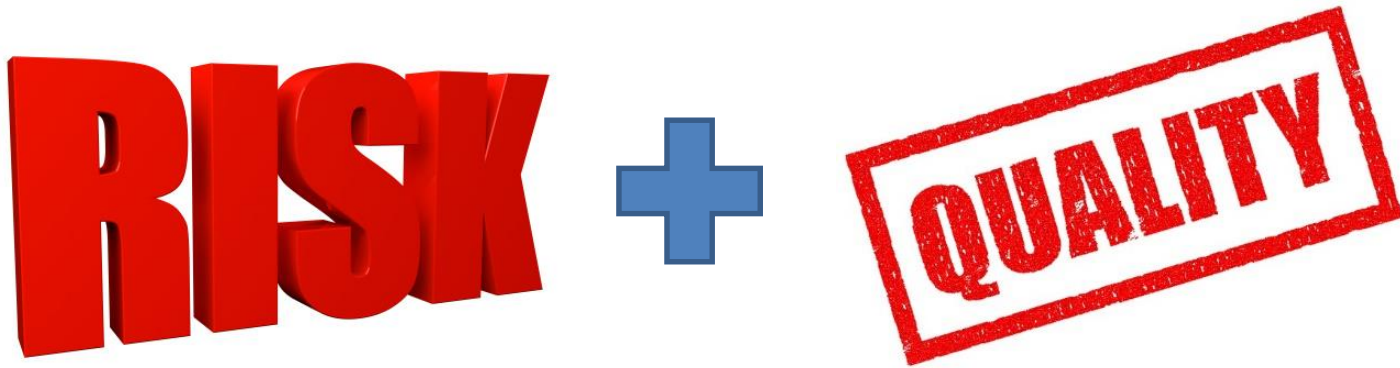
Putting it All Together

Resources – OL Webpage

Guidance for Risk Management

https://townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\GuidanceDocs\720\GDoc_DBHDS_6874_v3.pdf

Centers for Medicare and Medicaid Services

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Downloads/ProcessToolFramework

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