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SAMPLE 4: Medication Assistance Service Provider Annual Systemic Risk Assessment

Disclaimer- This document is for educational purposes only. This sample was created using the Systemic Risk Assessment Template (April 2023) developed by the Office of Licensing. Providers are encouraged to reference the [Guidance for Risk Management](#) for additional information.

A risk assessment is a careful examination of what the provider identifies as internal and external factors or situations that could cause harm to individuals served or that could negatively impact the organization. The risk assessment should lead to a better understanding of actual or potential risks and how best to minimize those risks. Systemic risk assessments vary depending on numerous factors such as an organization's size, population served, location, or business model.

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.

12VAC35-105-520.D. The systemic risk assessment review process shall incorporate uniform risk triggers and thresholds as defined by the department.

The Department of Behavioral Health and Developmental Services (DBHDS) defined risk triggers and thresholds as care concerns through review of serious incident reporting conducted by the Incident Management Unit.

Below is the list of individual care concern thresholds (Revised as of 1/2023):

- Multiple (Two or more) unplanned medical hospital admissions or ER visits for falls, 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.
- Any choking incident that requires physical aid by another person, such as abdominal thrusts (Heimlich maneuver), back blows, clearing of airway, or CPR.
- Multiple (Two or more) unplanned psychiatric admissions within a ninety (90) day timeframe for any reason.

This sample document does not include all risks that an organization may review. The annual systemic risk assessment presented below is an example that may be expanded or otherwise adapted to the needs of an organization. The **green highlights** signify the categories of the systemic risk assessment as required in regulations 12VAC-35-105-520.C.1-5 and 12VAC35-105-520.D. Each organization should include risks specific to their size, individuals served, location, and business model. Upon completion of the annual systemic risk assessment, the provider would consider the following 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

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Annual Systemic Risk Assessment TEMPLATE

Provider Name:

Policy #:

Regulation: 12VAC35-105-520

Effective:

Revised:

Risk Areas	Findings	Risk Score (N/A if not used)	Recommendation(s)	Comments/Actions	Add to Risk Management (RM) Plan (Yes/No/NA)	Date
Environment of Care						
Chemicals/cleaning supplies	Chemicals were identified without labels and no Material Safety Data Sheets (MSDS) available.	3	Review of all chemicals and update MSDS	Assign to Risk Manager	Yes	
Traffic safety	Concerns regarding traffic flow and impact on neighborhood traffic	2	Leadership to meet with neighborhood representatives; add to Risk Management Plan with steps to mitigate risks	Assign to Executive Officer	Yes	
Outdoor lighting	Employee surveys report concerns about outdoor lighting during early morning	3	Add to safety inspection checklist to ensure regular monitoring	Assign to Risk Manager	No	
Clinical Assessment and Reassessment Processes						

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Risk Areas	Findings	Risk Score (N/A if not used)	Recommendation(s)	Comments/Actions	Add to Risk Management (RM) Plan (Yes/No/NA)	Date
Face to face counseling session at least every two weeks for first year of treatment.	Documentation present	2	Monthly audits to continue	Assign to Program Director	No	
Duplication of opioid medication services	Policy for contacting services within 50 miles radius before admitting has been followed and documentation present.	1	Monthly audits to continue	Assign to Program Director	Yes	
Documentation of individual's level of lifestyle ability prior to dispensing take-home medication	Monthly record reviews were not consistently completed	2	Add to RM plan as goal and report quarterly to Quality Improvement Committee	Assign to Program Director	Yes	
Staff Competence and Adequacy of Staffing						
Background checks on employees	Documentation was not present in employee files	3	Human Resources to review procedures for documentation and implement quality assurance audits	Assign to Human Resources Director	Yes	
Emergency Preparedness Training	Training for employees regarding emergency or natural disasters needs to be reviewed and revised	2	Update training to include lessons learned from pandemic	Assign to Safety Officer and Human Resources	No	
Use of High-Risk Procedures						
Compliance with security for storage of methadone which complies with DEA and Virginia Board of Pharmacy	Written plan has not been reviewed in over a year.	3	Review and revise plan as determined necessary	Assign to Risk Management Committee	Yes	

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Risk Areas	Findings	Risk Score (N/A if not used)	Recommendation(s)	Comments/Actions	Add to Risk Management (RM) Plan (Yes/No/NA)	Date
Security of opioid agonist medication supplies	Turnover in staff has resulted in some security lapses	3	Training refresher for all staff	Assign to Program Director	Yes	
Review of Serious Incidents						
Review of all serious incidents	Review of incidents occurred per policy; trend identified of slight increase over the past two years of incidents involving verbal threats to employees	1	Conduct employee survey regarding employee safety concerns	Assign to Human Resources and Risk Manager	No	
Risk Triggers and Thresholds (Care Concerns)						
Process is in place to monitor for individual care concerns and respond as necessary	No individual care concerns identified	1	Continue to monitor	Assign to Nursing Director	No	
Additional Risks						
Public relations	Concerns from community were shared with leadership	2	Executive leadership to meet with community leaders to address	Assign to Executive Officer	No	
Electronic health records	Clinic has cybersecurity system to protect confidential health information from being compromised and/or manipulated	1	None at this Time	Assign to IT Manager	No	

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Risk Matrix for use when determining a risk score:

Likelihood - it will happen ↑	Very Likely	Acceptable Risk Medium 2	Unacceptable Risk High 3	Unacceptable Risk Extreme 4
	Quite Likely	Acceptable Risk Low 1	Acceptable Risk Medium 2	Unacceptable Risk High 3
	Unlikely	Acceptable Risk Low 1	Acceptable Risk Low 1	Acceptable Risk Medium 2
		Minor	Moderate	Major
		Impact - How serious is the risk? →		

[Provider Designee Signature]

[Date]