Risk Management – Quality Improvement
Tips and Tools Training
June 24, 2021
Questions and Answers

1. With the regulations for Quality Improvement and Risk Management does this require that we hire a person specifically for risk management and Quality Assurance, or can it be delegated to an administrator already within our company?

12VAC35-105-520.A requires each licensed service to designate a qualified person with responsibility for the risk management function. The provider may assign additional roles related to risk management depending on the size and scope of the provider's services. The job description of the person (responsible for the risk management function) should reflect that all or part of their responsibilities include those of the risk management function. One person can have risk management responsibilities for a provider's multiple services.

2. Have all non-current guidance documents been taken down from the licensing website?

Yes, the Office of Licensing (OL) regularly removes documents from the webpage.

Please refer to the webpage for trainings, samples and guidance documents related to risk management and quality improvement requirements. Providers can find these documents under the blue ribbon titled "Guidance and Technical Assistance" and then "Quality Improvement-Risk Management Resources for Licensed Providers." Office of Licensing

3. Does the person designated as the Risk Manager need to be onsite or could this be a corporate person that assists with reporting in CHRIS and with the organization?

The person designated as the risk manager has training pursuant to 12VAC35-105-520.A so that person may lead the team or ensure that the team completes its work in compliance with the provider's policy. 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.

4. Do all unplanned hospitalizations/ER visits need to be documented as a serious incident?

Pursuant to the regulations, an unplanned psychiatric or unplanned medical hospital admission of an individual receiving services other than licensed emergency services, except that a psychiatric admission in accordance with the individual's Wellness Recovery Action Plan shall not constitute an unplanned admission for the purposes of this chapter.

Emergency room visits by an individual receiving services, other than licensed emergency services, shall be reported as Level II serious incidents if they occur within the provision of the provider's services or on their premises regardless of whether or not the individual is hospitalized. If the individual goes to the ER during the provision of the provider's service that should be reported as a Level II serious incident by the provider regardless of whether the individual comes home that day.

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

5. In a guidance document regarding reporting the following is mentioned. *Please note that Level II incidents include "a significant harm or threat to the health or safety of others caused by an individual." Therefore, if a serious injury was caused by an individual to an employee, contractor, student, volunteer, or visitor during the provision of services or on the provider's premises the serious injury should also be reported into CHRIS within 24 hours of discovery as a Level II serious incident." Does this mean that any threat made towards a staff member or other person and/or injury to a staff or other person needs to be reported into CHRIS?

If a threat to a staff member, by an individual, is considered to be a threat to the health and safety of that staff member that should be reported. If a staff member receives a serious injury as a result of an individual receiving services, this should be reported. These incidents would be reported in CHRIS for the individual served. A serious injury is defined as any injury resulting in bodily hurt, damage, harm, or loss that requires medical attention by a licensed physician, doctor of osteopathic medicine, physician assistant, or nurse practitioner.

6. Is this (risk assessment) done for each individual in program or one risk assessment for everyone?

12VAC35-105-520.C refers to the systemic risk assessment. As noted in the SAMPLE Systemic Risk Assessment, a systemic 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.

Every organization will have different risks depending on the services provided, the location, the building (or buildings). Each provider needs to think about its potential risks. Please note the risk assessment must include the below components which apply to all locations.
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 process shall incorporate uniform risk triggers and thresholds as defined by the department. The Department has defined these as care concerns.

A Risk Awareness Tool (RAT) is designed to increase awareness of the potential for a harmful event for individuals. Information related to the RAT can be found on the Office of Integrated Health webpage: Assuring Health and Safety for Individuals with Developmental Disabilities with a Comprehensive Risk Management Plan

7. Is the systemic risk assessment performed for each provider home (Sponsored residential program) or is it for the agency overseeing the SRP's?

Please note the risk assessment must include the below components which apply to all locations so data collected throughout the year from each location, individuals served would need to be incorporated into the risk assessment:
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.

As noted in the Guidance for Risk Management, environment of care considerations will be different when services are provided at a location that is not under the direct control of the provider, such as the individual's own home. While providers are more limited in their ability to assess some of the factors listed above in these locations, providers should consider any unique risks associated with the provision of services in these locations during its risk assessment review. In such cases the review does not need to consider each location (e.g. each home) individually, but should identify risks that may be common across the different locations or settings.

As also noted in the Guidance for Risk Management, a review of the environment of care should consider the results of the annual safety inspection conducted pursuant to 12VAC35-105-520.E, when applicable, but is broader than a safety inspection.

12VAC35-105-520.D – The systemic risk assessment process shall incorporate uniform risk triggers and thresholds as defined by the department. The Department has defined these as care concerns.

8. Is quality assurance/risk management the same or should it be separated?

12VAC35-105-520 (Risk Management) includes the regulations related to risk management; 12VAC35-105-620 (Monitoring and evaluating service quality) includes the regulations related to quality improvement. Each provider should determine through its policies and procedures how risk management and quality improvement efforts will be coordinated. The Guidance for Risk Management states that 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.

9. Can we add goals to the QI Plan throughout the year, as long as we're still reviewing and updating our QI program/plan annually? If we meet this year's current goal for quality improvement, can we discontinue that, and add an additional goal?

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; and 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.

It is the provider's decision as to when the quality improvement plan is updated to include additional goals and/or to revise goals. The quality improvement plan should be dated and signed to indicate when it is implemented and when any updates occur.

10. If a provider decides that their QI Plan does not need to be updated in response to a citation, where should they document this decision?

The provider's policies and procedures for a quality improvement program should be followed in terms of where to document this decision. The Guidance for a Quality Improvement Program states that providers should have a clear written plan for how they will evaluate their current quality improvement plan to determine if it is sufficient to address the concerns identified in the licensing report and to monitor their pledged CAPs. The written plan shall include the person responsible for the reviews as well as how each review will be documented and stored, so that compliance may be determined by the licensing specialist during reviews.

11. In terms of the Triggers and Thresholds for the Systemic Risk Assessment, are the Care Concerns only applied to an individual or are they also applied to the provider as a whole? For example, if a provider (as a whole) reports 3 or more serious incidents of any kind within 90 days, would this meet a Care Concern threshold? In CHRIS, the Care Concerns are divided into Individual and Provider Care Concerns with different criteria.

Care Concerns are specific to individuals. Initially, the OL was monitoring both Individual and Provider Care Concerns. After assessing the data, the Department has determined that monitoring individual care concern thresholds offers the most useful information for providers to assess if there may be a 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 on a provider level.

12. If our licensing specialist has already reviewed and approved our QIP and Risk Management Plan/Program (approved Oct 2020) do we need to make modifications to meet newly revised/ clarified regulations or are we okay to review October 2021 with new goals/objectives for the agency?

The quality improvement and risk management regulations were effective November 2020. Each provider should review the regulations, as well as Guidance documents, quality improvement and risk management sample documents and training (all posted on the Office of Licensing webpage) to determine whether changes are necessary to ensure compliance. Quality improvement and risk management plans are often reviewed as part of investigations.

13. Risk Management has become a primary focus when licensing specialists review annually. Can we receive review and follow-up on the progress of plan and whether the plan is meeting regulations prior to annual licensing review?

If the provider received a citation related to risk management and their pledged Corrective Action Plan (CAP) was approved, the provider should be implementing the CAP and ensuring it is effective (refer to Guidance for a Quality Improvement Program and Guidance on Corrective Action Plans for more information on implementing a CAP).

If a provider reviews the Guidance for Risk Management, the sample documents: SAMPLE Provider Risk Management Plan, SAMPLE Provider Systemic Risk Assessment, and other information posted to the OL webpage, this will assist providers in being compliant.

14. Can you provide us with the website or link to DMAS that gives samples of Goal setting/measurable goals and objectives you discussed earlier?

The goal setting worksheet mentioned in the training is from the Centers for Medicare and Medicaid Services (CMS). CMS Goal Setting Worksheet

15. On the licensing website under Guidance and Technical Assistance for Quality Improvement Risk Management Training (updated 3/21) when you open the document it is dated November 2020. Is that the correct one?

Based on a review of data, the Office of Licensing determined that it is more beneficial to individuals and providers to focus only on individual care concerns. It should be noted that providers are required to develop a Root Cause Analysis policy in accordance with the regulations (12VAC35-105-160.E.2) and with their own internal determinations which allows providers to independently track and trend provider care concerns they think may be important.

The training provided in November 2020 was updated to reflect this decision to focus on only individual care concerns.

16. Are all ER visits reported in CHRIS system regardless of the reason? We have submitted CHRIS reports that falls within the LEVELS guidelines and received a response that it is not reportable. Please clarify.

Emergency room visits by an individual receiving services, other than licensed emergency services, shall be reported as Level II serious incidents if they occur within the provision of the provider's services or on their premises regardless of whether or not the individual is hospitalized.

17. You mentioned who to contact at the department with questions on what should be reported in the system as level 2 incident, when in doubt, but I did not capture the name. Could you please repeat it?

Providers should contact their Incident Management Unit (IMU) regional specialist. All contact information for the Incident Management Unit is located on the Office of Licensing homepage under Incident Management Unit Regional Contact. The IMU has also established regional mailboxes as another means for providers to contact their IMU regional specialist if they have questions or need to provide information to them. The mailboxes' email addresses are below:

rr-imu_Region1@dbhds.virginia.gov
rr-imu_Region2@dbhds.virginia.gov
rr-imu_Region3@dbhds.virginia.gov
rr-imu_Region4@dbhds.virginia.gov
rr-imu_Region5@dbhds.virginia.gov

When reporting issues about CHRIS please email incident_management@dbhds.virginia.gov. Please provide a screen shot of the issue you are reporting. If you are locked out of your account please email DELTAprod@dbhds.virginia.gov. Please remember per the Memo-CHRIS Updates "All providers are required to have a back-up person to enter incidents into CHRIS. When one individual is locked out of CHRIS the back-up individual will be able to submit the incident within the 24 hour time frame."

18. Will another attestation letter be provided for this training or are we allowed to add this training on the current form?

The Office of Licensing will update the Crosswalk of Approved Risk Management Training and will post on the webpage.