Office of Licensing

Frequently Asked Questions

12VAC35-105-620 – Monitoring and Evaluating Service Quality

1. **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.

2. **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

3. **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).

   A root cause analysis can also be conducted as part of a provider's quality improvement or risk management program as it 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.

4. **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 that they do not comply with the regulations.

5. **What are the 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.

6. **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.

7. **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.

8. **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.

9. **Can a provider choose to have one policy that is the quality improvement policy and procedures, which covers it all (risk management, monitoring and evaluating service quality, etc.)?**
   A provider may have one document that is the quality improvement/risk management plan or two separate plans. In terms of the policies and procedures that make up the provider's quality improvement program and risk management program, there may be several policies involved (e.g. Serious Incident Reporting policy; Root Cause Analysis policy). In addition, 620.D requires that the provider's policies and procedures include the criteria used to establish goals and objectives, update the provider's quality improvement plan, and submit revised corrective action plans. Additional information related to quality improvement can be found within the Guidance for a Quality Improvement Program.

10. **What is the expectation for how providers update quality improvement plans?**
    Providers may exercise discretion in determining the process for developing and updating a quality improvement plan so long as the plan meets the regulatory requirements detailed in 12VAC35-105-620 and is updated at least annually.

    Providers are not required to update their quality improvement plan each time a licensing report is issued. However, anytime a provider is issued a licensing report, the provider should review their quality improvement plan to determine whether their current plan is sufficient to address the concerns identified in the licensing report and to monitor compliance with the provider's pledged CAP. If the current quality improvement plan is not sufficient, then the provider will need to update the plan accordingly. 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. **Can the Plan, Do, Study, Act (PDSA) cycle be used as the criteria to establish goals, update quality improvement plan and submit revised corrective action plans?**
    PDSA is one of many quality improvement tools that could be selected by the provider as part of the provider's quality improvement program. The PDSA model for quality improvement could be used to monitor and evaluate progress toward meeting established goals and objectives and/or determining whether a CAP is effective in addressing identified citations.

    12VAC35-620.D - the provider's policies and procedures include the criteria used 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.

    Providers should include in policy the process they will use to develop, implement and update their plan, and thereby demonstrate an ongoing, iterative process. An example of criteria for establishing measurable goals and objectives could be that the provider has determined what is the most high risk, high volume or problem prone area to focus their goals and objectives. Another criteria could be that when no progress is demonstrated, the provider will implement a quality improvement initiative which could follow the Plan, Do, Study, Act quality improvement model.

12. **Is there a specific training for quality assurance?**
    The regulations do not include a specific training that is required for quality improvement or quality assurance, but the training provided by the Center for Developmental Disabilities Evaluation and Research (CDDER), "Risk Management and Quality Improvement Strategies" included information related to using data for quality improvement.

13. **Are goals and objectives after a Corrective Action Plan (CAP)?**
    A provider's quality improvement plan shall include measurable goals and objectives (12VAC35-105-620.C.2).The goals and objectives may or may not be based on the provider's approved CAPs. A provider may determine through its own review of its program and risks that goals and objectives unrelated to CAPs should be included.

    The provider's goals and objectives should be what is most meaningful to the provider in terms of clinical and service quality and effectiveness. Anytime a provider is issued a licensing report, the provider should review their quality improvement plan to determine whether their current plan is sufficient to address concerns identified in the licensing report and to monitor compliance with the provider's pledged CAP. These reviews should be documented.

14. **Can we add goals to the QI Plan throughout the year, as long as we are 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.

15. **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.