Quality Improvement/Risk Management Training
Root Cause Analysis Training
November 5, 2020 and November 12, 2020

The questions from the training have been consolidated and grouped according to subject matter.

Statewide Performance Measures

1. **What are the statewide performance measures?**
   Please refer to the slides 12-15 of the Quality Improvement-Risk Management training (November 2020) Quality Improvement-Risk Management Training. For further questions regarding the statewide performance measures for provider of Developmental Disability (DD) services, please contact the Office of Developmental Services.

2. **So the statewide performance measures requirement does NOT involve the specific requirements for Community Services Boards (CSBs)?**
   The statewide performance measures currently only apply to providers of developmental disability services. Providers, both private and CSBs, are already reporting to DBHDS as the measures are being operationally collected through WaMS (relative to service planning and implementation) and CHRIS (relative to serious incident reporting).

Corrective Action Plans (CAPs)

3. **Is there a timeframe for how long Corrective Action Plans (CAPs) should be monitored?**
   A corrective action plan shall include a date of completion of each corrective action. When writing a CAP, the frequency for monitoring the plan, including how it will be monitored should be considered. Refer to Guidance on Corrective Action Plans

   A provider's quality improvement plan should include the process by which the provider will monitor implementation and effectiveness of approved CAPs. The provider's policies and procedures shall include the criteria the provider will use to submit revised CAPs, including criteria for when a CAP will no longer be subject to monitoring. The nature of the citation and the corresponding CAP would affect the timeframe for monitoring. For example, if the provider's pledged corrective action plan includes a one-time, permanent fix such as amending language within a form template, the provider will only need to verify completion of the planned activity once as part of its quality improvement activities. A CAP related to failure to review medication errors on a quarterly basis would require several quarters of reviews to demonstrate compliance and the effectiveness of the CAP.

   Whenever a corrective action is implemented, the provider would want to monitor to ensure that the issue identified did not reoccur and/or that the implemented action had the intended effect.

4. **How long is a CAP considered to be "active" where we will be expected to submit updates to the CAP to DBHDS following the planned completion dates that are documented on the CAP? Are we submitting CAP updates ongoing or what is the timeframe? Who are the updates submitted to--Licensing specialist, IMU specialist who originally issued the CAP, etc.**
   Updates on the completion of planned activities should be made based on the planned completion dates contained in the CAP. If a provider determines that they need to submit a revised corrective action plan to the department for approval in accordance with 12VAC35-105-170.H, the revised CAP should be

submitted directly to the licensing staff who issued the licensing report (e.g. Incident Management Unit (IMU), Licensing Specialist (LS) or Investigator).

Serious Incident Reporting

5. **What if you are sending patients to the Emergency Room from inpatient Behavioral Health because that is the process for medical care that otherwise could be seen by a PCP but one is not available at that time?**
   Per regulation, any ER visit is, by definition, a Level II serious incident.

6. **Do we need to complete a CHRIS report for urgent care visits for a Level II serious incident?**
   Providers are no longer required to report an urgent care facility visit as a Level II Serious Incident.

7. **When an individual seriously injures a staff member, with no injury to the individual, does this is require a CHRIS report?**

   Yes, significant harm caused to staff by an individual receiving services should be entered into CHRIS as a Level II serious incident. Please note that per the regulatory definition, Level II serious incidents include a significant harm or threat to the health or safety of others caused by an individual.

8. **Request for clear definition of incident levels.**
   Level I, Level II and Level III serious incidents are defined in 12VAC35-105-20. Additional information related to the incident levels can be found within the **Guidance on Serious Incident Reporting**

Quality Improvement

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.)? Many requirements are already in place as required by previous regulation. Seems like having all related elements presented in one policy would make it easy for specialists to identify compliance.**
   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 we 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. It would be helpful to have a sample policy to ensure providers cover everything.
The Office of Licensing will provide some sample documents on the website for providers to access as resources for developing quality improvement and risk management plans.

12. 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.

13. 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.
CDDER Training

14. Are goals and objectives after a 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.

Risk Management (RM)

15. **Is the Center for Developmental Disabilities Evaluation and Research (CDDER) the only approved training for the person responsible for risk management?**
    The Office of Licensing has a Crosswalk of DBHDS Approved Risk Management Training required pursuant to 12VAC35-105-520.A and the approved trainings. The crosswalk is posted on the Office of Licensing webpage.

16. **Is there a cost to providers to take the CDDER training?**
    The two hour webinar provided by CDDER Providers was offered free of charge and the recording and PowerPoint presentation are posted to the Office of Licensing webpage.

    In addition, licensed providers of developmental disability services will receive one free enrollment per course provided by CDDER.

17. **Will the CDDER training be offered routinely on an ongoing basis? Person responsible for the risk management function may change within the organization so future training opportunities will be needed.**
    The CDDER training has been recorded and posted to the DBHDS website. If the person responsible for risk management changes within the organization, the recorded training and PowerPoint presentation will be available to access online.

18. **Will DBHDS provide the attestation form for risk management training or can the provider create their own attestation?**
    DBHDS has created an attestation form for providers to complete and maintain as evidence that training has been completed.

19. **Is this training meeting the requirements for 12VAC35-105-520.A?**
    Please refer to the Crosswalk of DBHDS Approved Risk Management Training.

20. **Does having a CPHRM credential meet training requirements? How about VA Risk Control Institute completion?**
    The person designated for the risk management function must complete department approved training in individual risk screening, conducting investigations, root cause analysis, and the use of data to identify risk patterns and trends. These are minimum qualifications. There are certainly many excellent certification programs and additional training opportunities that a provider may encourage the person responsible for the risk management function to avail themselves of but this training is currently not on the list of approved trainings that meet the requirements of 520.A. Providers are encouraged to refer to the Crosswalk of DBHDS Approved Risk Management Training.

21. **What will the risk assessment process look like for In-Home Support providers?**
    An assessment of the environment of care for community based services should include an analysis of the risks associated with the provision of services in the community, and any risks unique to the community locations where services are expected to be provided. While providers may not have direct control over these risks, analysis of such risks will help the provider develop a plan to mitigate those risks.

22. **How does environmental safety in a risk management plan apply for community engagement providers that do not own, rent, or lease the community volunteer location?**
    An assessment of the environment of care for community based services should include an analysis of the risks associated with the provision of services in the community, and any risks unique to the

community locations where services are expected to be provided. While providers may not have direct control over these risks, analysis of them will help the provider develop a plan to mitigate those risks.

23. Does the risk management function have to be handled by ONE person or can there be two people within an agency that handles this function together they satisfy the training requirements and accomplish this tasks necessary?

The regulatory requirement is that the provider must have "a person" designated by the provider to be responsible for the risk management function. This person may oversee other persons who carry out risk management activities, but it is the designated person who is ultimately responsible for the function. Only the designated person is required by the regulation to complete the required training.

24. Somewhere in the regulations it says that RCAs should be done by someone with investigation training. Does everyone involved in the RCA team have to have investigation training as well? What are the specific requirements for the staff in charge of RCA?

The regulations do not require that the RCA should be done by someone with investigation training. 12VAC35-105-520.A states that 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. The person responsible for risk management function has training in RCA so that person may lead the team or give guidance and an overview of the RCA process to the team.

25. Is that one risk manager per company office or company; for those companies with multiple offices?

Each licensed service is required 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 services of the provider.

26. How does environment of care apply to community based services? Are we completing a risk analysis for the physical office or to address risks in the community (many of which are outside of our control)?

An assessment of the environment of care for community based services should include an analysis of the risks associated with the provision of services in the community, and any risks unique to the community locations where services are expected to be provided. While providers may not have direct control over these risks, analysis of them will help the provider develop a plan to mitigate those risks.

27. Liability insurance carrier and Worker's Comp insurance carrier annually conducts risk assessments. Can we use those results to satisfy the risk assessment?

Risk assessments conducted for the purposes of liability insurance and worker's comp insurance can certainly be used to inform quality improvement/risk management planning activities. However, the regulations requirements are that the provider conduct a risk assessment which includes: 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.

28. What are the differences required per provider? For instance, an in-home provider versus a group home. It would be helpful if the department could break it down so the different providers understand more specifically what applies to their setting (specifically referring to risk assessment).

All regulations apply to all licensed services unless specifically stated otherwise. For suggestions on what to include in the systemic risk assessment (520.C and 520.D) please review the Guidance for Risk Management and the trainings related to Quality Improvement-Risk Management on the Office of Licensing webpage.

29. What is considered a high risk medication in terms of an example used in the systemic risk assessment?

A high risk medication is a medication that carries a greater than typical risk of serious side effects or other complications. When conducting a risk assessment, a provider shall consider the use of high risk procedures. More information on systemic risk assessment can be found in Guidance for Risk Management

Risk triggers and thresholds

The identification of uniform risk triggers and thresholds sets a standard for what a provider must "incorporate" into the provider's systemic risk assessment process. Providers have significant discretion to determine how to incorporate these risk triggers and thresholds, and the department fully expects providers to take into account the size of the provider, the number of individuals served, the type(s) of services that the provider offers, and other unique factors that affect the provider's risk and risk assessment process when determining how to do so. Please reference - Assuring Health and Safety for Individuals with Developmental Disabilities with a Comprehensive Risk Management Plan

It is important to note that the risk triggers and thresholds are different from the criteria a provider establishes for conducting a more detailed Root Cause Analysis. While at times there may be overlap with a provider's criteria for conducting a more detailed RCA; the risk triggers and thresholds are defined as care concerns through review of serious incident reporting conducted by the Incident Management Unit (IMU).

30. Are the care concerns for each individual or overall for the practice? If Individual A had one visit for hospitalization; Individual B had one hospitalization and Individual C had one hospitalization or Individual A have 3 hospitalizations within a 30 day period.

The IMU reviews serious incidents not only on an individual level but systematically as well to identify possible patterns/trends by individual, a provider's licensed service as well as 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. At times, a review of a serious incident raises a concern about a provider's ability to ensure the adequacy of supports to one or more individuals receiving their licensed service or may be an indication a provider may need to re-evaluate an individual's needs and supports, review the results of root cause analysis and make systemic changes or updates to their risk management or quality improvement plan. The IMU has identified these situations as Care Concerns. Incidents of individuals or providers who meet the following Care Concern criteria will trigger follow-up by the IMU or other offices as specified below:

Individual Care Concerns Criteria:

- Three (3) or more unplanned medical hospitalizations, ER visits or psychiatric hospitalizations within a ninety (90) day time-frame for any reason.
- Multiple (2 or more) unplanned medical hospitalizations or ER visits for the same condition or reason that occur within a thirty (30) day time-frame.

- Any combination of 3 or more incidents of any type within a thirty (30) day time-frame.
- Multiple (2 or more) unplanned hospital visits for: falls, choking, urinary tract infection, aspiration pneumonia, or dehydration within a ninety (90) day time-frame for any reason.
- Any incidents of decubitus ulcers or medically verified cases of bowel obstruction

In addition, this information is shared with the Office of Integrated Health and the Office of Human Rights who may follow-up to provide technical assistance as appropriate

31. Are the risk triggers and thresholds only CHRIS reportable events or are they for any individual being served?

DBHDS has developed event-based triggers and thresholds (outlined above). The Incident Management Unit (IMU) of the Office of Licensing utilizes CHRIS to complete trend analysis in order to alert providers when such criteria has been met. When the IMU identifies that thresholds for these triggers have been met, they will be flagged in CHRIS so the provider can review these events for determination of needed changes to services. Individual Care Concern Reports are available in CHRIS.

32. Do the risk triggers and thresholds apply to all licensed services? An outpatient clinic may send individuals to a behavioral health unit of a hospital 3 times in 30 days.

The risk triggers and thresholds apply to all services. An outpatient clinic would want to review to determine if there is a need to re-evaluate an individual's needs and potentially update the individual's service plan.

Root Cause Analysis

33. Are there specifications on what a "more detailed RCA" entails? What is a basic RCA?
12VAC35-105-160E.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 chart causal factors, should be conducted.

12VAC35-105-160.E.1 – The root cause analysis shall include at least the following information: a) a detailed description of what happened; b) an analysis of why it happened, including identification of all identifiable underlying causes of the incident that were under the control of the provider; and c) identified solutions to mitigate its reoccurrence and future risk of harm when applicable.

34. All of these can be avoided by the provider simply raising the threshold.
The ability of providers to define their own thresholds is in recognition of the vast differences between providers based on their size, the number of individuals that they serve, and the type of services that they offer. While it is true that providers can raise these thresholds, it is anticipated that providers will

adopt thresholds that are reasonable in relation to their unique circumstances and that the provider would recognize the importance of conducting a root cause analysis to understand why an adverse outcome occurred and how it can be prevented from happening in the future.

35. What is a process map?

A process map is a quality improvement tool that graphically shows the inputs, actions and outputs of a process in a clear, step-by-step map of the process. By using a process map it is possible to identify challenges and how to improve processes.

36. Where is a team required for a RCA?

A team is required for conducting a more detailed root cause analysis (12VAC35-160.E.2). Whether or not a team is required is provider/service specific and should be addressed by providers within their RCA policy. There is no requirement for the size of a RCA team.

37. A provider has 30 days to complete a RCA, is there a timeline for when the team needs to convene and complete the analysis?

There is no regulatory requirement for when the team must convene to complete the RCA as long as the RCA is completed within the 30 days. Timeframes should be included within the provider's RCA policy which OL will review to see the provider followed their own policy. Best practice would certainly be to begin interviewing people and collecting information as soon as possible following an event or events that require a more detailed RCA.

38. What is the correct job title for the person in charge of RCA?

The regulations do not require a specific title for the person in charge of conducting RCA. The provider's RCA policy might include specifics related to who conducts a RCA and/or who appoints a RCA team when a more detailed RCA is required pursuant to the provider's policy. The person designated as the risk manager has RCA 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.

39. Would the person conducting these interviews for the RCA also be required to have certification such as needed for persons conducting investigations?

The only required risk management training are the training topics enumerated in 12VAC35-105-520.A. If staff are appointed to a RCA team and are asked to interview people regarding an incident, it is not necessary to have specific training. The person responsible for the risk management function who has training in RCA could help lead the team or provide information on how to ask questions.

Providers should consider whether any additional training or certification would be helpful for their staff members with RM responsibilities.

40. Should we include state system issues in our RCA process?

The RCA process is intended to identify the root cause(s) of specific incidents so that the provider can take appropriate steps to mitigate the risk that such incidents may recur. This process should include consideration of any circumstances/occurrences that the provider believes may have contributed to the incident at issue.

41. Is this level of review expected for every single RCA or only certain ones?

The level of detail involved in a Root Cause Analysis is expected to vary based on, among other things, the specific thresholds specified in the provider's policies and procedures for triggering the requirement to conduct a more detailed RCA.

42. Once a threshold has been met, how long do we have to complete our more detailed RCA?
RCAs shall be conducted within 30 days of the discovery of a Level II serious incident and any Level III serious incident that occurs during the provision of services, or on the provider's premises. When a threshold has been met requiring a more detailed RCA, the 30 day timeline for conducting the RCA remains the same. Therefore, the RCA should be conducted within 30 days of the occurrence of the incident that ultimately met the threshold.

43. Explain the difference between the CHRIS investigations being required to be completed within 10 days of an incident and RCAs having 30 days. Seems investigations should be a part of RCAs.
A root cause analysis is not the same as an investigation. Investigations often focus on what happened and who may have been responsible. Root cause analysis is more about asking "why" and the focus is on systems factors. The Office of Human Rights regulations include timelines related to provider's completion of investigations of abuse/neglect and exploitation allegations. Provider can contact the local Office of Human Rights advocate if there are questions regarding these investigations.

44. What if the events leading up to the incidents were outside of the control of the provider? If incidents occur that are not determined to not be within the control of the provider, is it acceptable to indicate this in the 5 Whys or indicate what we see as the actual root cause?
There may be situations where the events leading up to the incident were outside of the control of the provider. In completing the RCA, the provider should include all underlying causes that were under the control of the provider. The provider may still be able to identify solutions to mitigate the reoccurrence and future risk of harm, when applicable.

45. Can the root cause analysis policy be part of the risk management policy?
Yes, one policy could cover the requirements of RCA (12VAC35-105-160.E.2) and risk management (12VAC35-105-520.B).

46. Will Level II serious incidents of presumptive positive or lab confirmed diagnoses of COVID-19 be counted towards the DBHDS uniform thresholds for similar Level IIs for an individual, same location, and/or all locations for conducting the more detailed RCAs?

An Office of Licensing correspondence, dated January 14, 2021, addressed revised expectations related to required reporting of individuals diagnosed with COVID-19. The threshold numbers for conducting a more detailed root cause analysis are to be determined by the provider as part of the provider's Root Cause Analysis policy. A root cause analysis would be expected if multiple people in the same location were diagnosed with COVID-19 in order for the provider to determine what could be learned to prevent spread of COVID-19 as well as addressing any systemic issues related to infection control.

47. Can you do the 5 Whys with sending someone with a MH condition to the ER for further assessment in an outpatient environment?

The 5 Whys technique for conducting a RCA can be used any time if that meets the provider's RCA policy. The 5 Whys technique assists in meeting the regulatory requirement of "an analysis of why it

happened, including identification of all identifiable underlying causes of the incident under the control of the provider." (12VAC35-105-160.E.1.b)

Five Whys Example
Why was an individual taken to the emergency room for an assessment?
The individual presented with violent behavior toward himself and others in the outpatient clinic.
Why was the individual presenting violent behavior toward himself and others in the outpatient clinic?
The individual's medications had not been renewed and he was without medications.
Why weren't the medications renewed?
The medication was not renewed because it required lab results which had not been received.
Why had the lab results not been received?
The lab results were delayed because the lab sent the results via email to the individual who did not have access to emails rather than sending directly to the pharmacy

48. Do we have to do a more detailed root cause when we reach a threshold for unrelated, random deaths for Mental Health Case Management clients?

RCAs are required only for level II serious incidents and level III serious incidents that occur during the provision of services or on the provider's property; so a more detailed RCA would be required for a death that occurs as a result of an acute medical event that was not expected in advance or based on the person's known medical condition only if the death occurred during the provision of services or on the provider's premises. If the MH case management service was not being provided, and the individuals were not on the provider's premises, then the RCA would not be required.

49. What is your suggestion when a provider reaches a threshold across all localities and there is literally no root cause? For example, we get dozens of unexpected Emergency Room Visits. There is typically no trend or reason why these are occurring, they just occur frequently based on our population.

As noted in 12VAC35-105-160.E.2, the provider's RCA policy would outline the threshold based on the unique needs of the individuals served. It is necessary to review incidents to attempt to identify possible trends which could lead to a root cause that could be mitigated. Root Cause Analysis and developing potential corrective actions are essential tools for making improvements through the provider's quality management program. RCA is a tool designed to help identify not only what and how an event occurred, but also why it happened. Only once it is determined why an event occurred, or in this situation a threshold number of similar events occur, will a provider be able to identify measures that may prevent or reduce the number of future similar events. It is only through the root cause analysis process that all the contributory factors can be identified.

50. It would be helpful to have examples other than for developmental disability residential services. A lot of the regulation changes and requirements are clear for how they apply to residential settings, but are more challenging to apply to other services (for instance, outpatient clinic).

Disclaimer: The examples provided below are for educational purposes **only**. Each provider's policy should outline provider specific thresholds based on the size, number of locations, number of individuals served and the unique needs of the individuals served. In addition, the thresholds must meet all the minimum requirements included within 12VAC35-105-160.E.2.a-d:

a. “A threshold number, as specified by 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”

   Example – A partial hospitalization program at one (1) location serves 25 individuals. The provider’s RCA policy states that when three (3) or more of the same Level II serious incidents occur to the same individual within a six (6) month period, the provider conducts a more detailed RCA. The provider reports a Level II serious incident regarding a missing person in May and then two Level II serious incidents involving missing persons in August. Based on the provider’s RCA policy, a more detailed RCA is conducted because the threshold was met when three of the same Level II serious incidents occurred at the same location within six months. (*Missing means a circumstance in which an individual is not physically present when and where he should be and his absence cannot be accounted for or explained by his supervision needs or pattern of behavior.)

   Example – A supportive in-home provider for thirty (30) individuals with developmental disabilities has a RCA policy that states a more detailed RCA will be conducted when two (2) of similar Level II serious incidents occur to the same individual or at the same location within a six (6) month period. The provider reports a Level II serious incident involving a fall with fracture in December, another individual sustains a fall with fracture in March. The provider conducts a more detailed RCA because their policy is that two similar incidents occur within 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”

   Example – An Intensive in-home provider serving 50 individuals has a RCA policy that when 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, the provider will conduct a more detailed RCA. The provider reports a Level III serious incident of a suicide attempt by an individual that results in hospital admission in March. In June the provider reports a Level III serious incident of a suicide attempt that results in hospital admission by the same individual. The provider conducts a more detailed RCA in accordance with the provider’s policy.

c. “A threshold number, as specified in the provider’s policy based on the provider’s size, number of locations, service types, number of individuals served, and the unique needs of the individuals served by the provider, of similar Level II or Level III serious incidents occurs across all of the provider’s locations within a six month period”

   Example - A supervised living residential service provider with three (3) locations serving 6-8 individuals per location has a policy that when three (3) similar Level II or Level III serious incidents occur across all of the provider’s locations within a six month period, the provider will conduct a more detailed RCA. In July the provider reports a missing individual at Location A; in August, the provider reports a missing individual at Location B; in September, the provider reports a missing individual at Location A. The provider conducts a more detailed RCA in accordance with the provider‘s policy.

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.”

Example – A developmental services group home reports a death of an individual. The individual with no known medical conditions died of a massive heart attack. The provider's RCA policy requires a RCA for any death that occurs as a result of an acute medical event that was not expected in advance or based on a person's known medical condition.

Example – An individual is receiving services at a substance abuse intensive outpatient location and during service the individual experiences a seizure and suddenly dies. The individual had no known medical conditions. The provider conducts a more detailed RCA because this was a Level III serious incident that was not expected in advance or based on the person's known medical condition.

51. There is incident of alleged abuse and neglect that results in injury, we complete two CHRIS reports (one on the abuse side and one for the serious injury). The investigation is submitted for the alleged abuse, are we required to complete a RCA for the serious injury in this case?

Yes a RCA needs to be completed if it is a Level II serious incident. In this case if the incident is a serious injury. 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.

52. For some instances, the RCA would not be applicable. It would be helpful to have an OL approved list of which incidents fall into this category so there is consistent application of regulation across specialists. And providers are clear as well.

A RCA must be completed for all Level II serious incidents and all Level III serious incidents which occur within the provision of services or on the provider's property. A RCA does not need to be conducted for Level I. Please remember that even when a root cause analysis is not required, 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 with12VAC35-105-620to include an analysis of trends, potential systemic issues or causes, indicated remediation, and documentation of steps taken to mitigate the potential for future incidents.

53. Do we have to do a more detailed root cause when we reach a threshold for unrelated, random deaths for Mental Health Case Management clients?

RCAs are required only for level II serious incidents and level III serious incidents that occur during the provision of services or on the provider's property; so a more detailed RCA would be required for a death that occurs as a result of an acute medical event that was not expected in advance or based on the person's known medical condition only if the death occurred during the provision of services or on the provider's premises. If the MH case management service was not being provided, and the individuals were not on the provider's premises, then the RCA would not be required.

General Questions

54. What relationship, if any, is there between 12VAC35-105 and 12VAC35-46?
12VAC35-46 applies to children's residential services. 12VAC35-105 applies to all other DBHDS licensed services. Chapter 46 are regulations that apply only to children's residential providers -- Chapter 105 applies to all other licensed providers and NOT children's residential providers.

55. Will this information be reviewed and support provided at the upcoming provider roundtable meetings?
The power point presentations have been posted to the Office of Licensing website. Additional training opportunities will be considered.

56. Has DBHDS considered creating a crosswalk with The Joint Commission standards? Also need a crosswalk AMONG Human Rights regulations, waiver regulations, licensing and CARF.
This is not something that we currently have in development but could be created in the future as a tool.

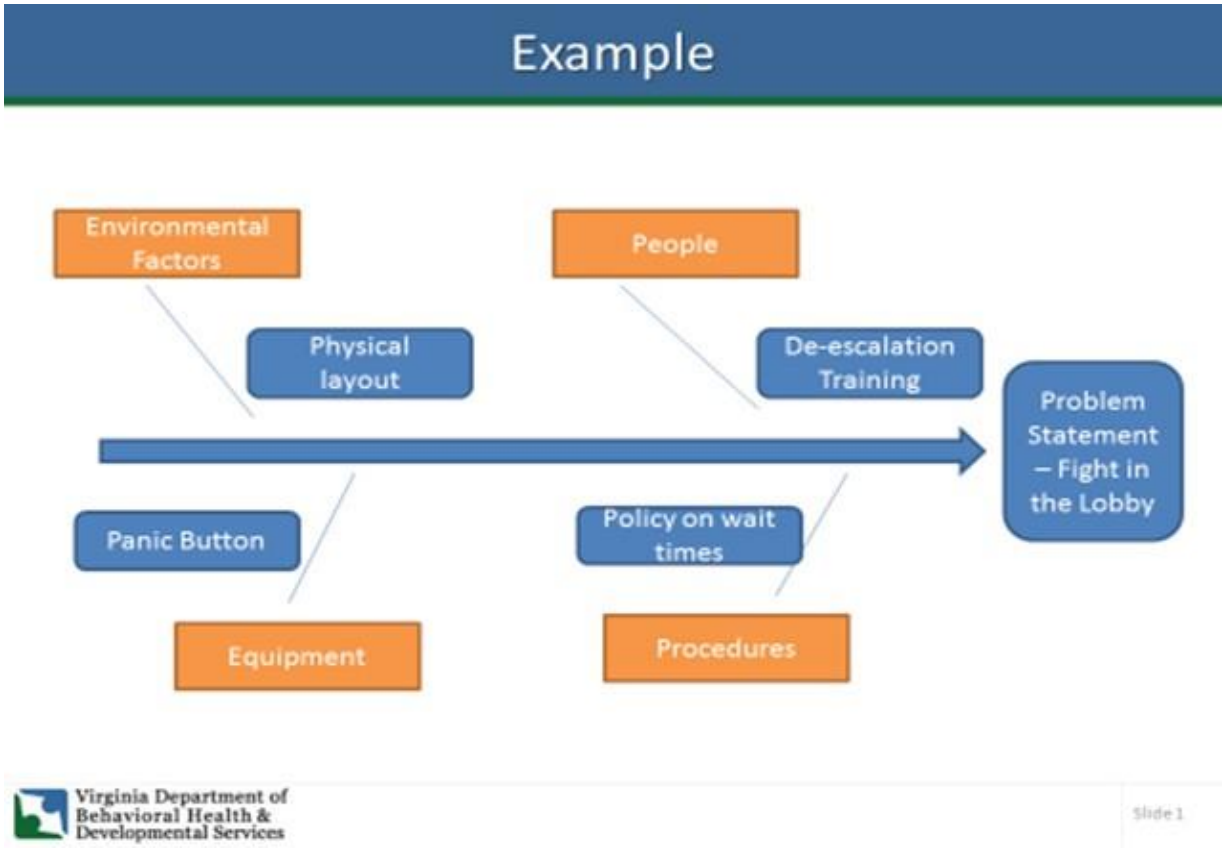
RCA Example – Using Fishbone and 5 Whys

Example – an outpatient clinic decides to complete a more detailed RCA based on its policy. The RCA is shown using both a fishbone diagram and a 5 Whys approach.

Scenario – There were several individuals waiting in the outpatient lobby of a clinic. All individuals were watching TV. Individual A entered the area and became agitated saying "the TV is too loud." Individual A looked for the TV remote and began asking other individuals about the remote. Individual A began pacing and became agitated. Another individual, Individual B, told Individual A that there was no remote and to sit down. Given the number of individuals waiting, there were few chairs available.

Individual B told Individual A to be quiet but Individual B got up from the chair and Individual A tried to sit in Individual B's chair. The two individuals starting pushing each other. Individual A fell and broke a finger.

The provider appointed a team, reviewed data regarding similar incidents that occurred in the clinic lobby, interviewed staff working the day of the incident and then utilized a fishbone diagram as follows:



The fishbone diagram can help identify possible causes by sorting ideas into useful categories. For example, this visual approach begins by drawing the head of the fish or mouth of the fish and identifying the problem statement. By writing the problem statement (i.e. fight in outpatient lobby resulted in a broken finger), the RCA team members have a visual reminder of keeping their focus on the problem.

The team or individual conducting the RCA would draw the major categories of causes of the problem. Some examples of major categories (or bigger bones of the fish) are indicated in orange. The smaller bones (indicated in blue) would be possible considerations.

The team could draw the diagram on a white board and brainstorm to identify all the possible causes. The final "bones" on the fish are then listed under each category. The team may find that there are several causal factors under each category.

The value of using a fishbone is to dig deeper and ask questions about systems and processes that contribute to the problem.

Once the root cause is identified and recommendations to address are made, the team should document the RCA findings and recommendations in compliance with the provider's policy and within 30 days.

Using the same scenario, the team could have used the 5 Whys approach:

Problem Statement – A fight occurred between two individuals in the outpatient lobby which resulted in an individual sustaining a serious injury.

Why did a fight occur?

Individual A became agitated because the TV was too loud.

Why was the TV too loud?

No one could adjust the volume.

Why couldn't anyone adjust the volume?

The remote was not in the lobby area. The receptionist controls the remote.

When responding to the Why questions, it is suggested to stop and ask "if the most recent response were corrected, is it likely the problem would recur?"

Example:

If you were to keep the remote in the lobby available to all individuals, would this prevent a similar incident from occurring?

> No. It actually could cause more incidents. So this is may be a contributing factor, but not the root cause.

Why didn't the receptionist turn down the TV?

The receptionist was not aware that Individual A wanted the TV volume changed or that the interaction between the two individuals was escalating.

Why can't the receptionist see or hear the two individuals?

The receptionist sits in an area that does not allow for line of sight for the entire lobby. The receptionist is behind a window which allows for privacy protection when dealing with PHI.

In this scenario, the root cause could be identified as the physical environment. Recommendations to mitigate reoccurrence could include:

1. The outpatient clinic will install a convex security mirror to allow line of sight of the entire lobby.
2. A sign will be posted directing people to "see the receptionist for change in TV channels or volume."
3. Additional monitoring will be implemented to avoid over-crowding in the lobby.
4. The outpatient clinic will monitor for six months to determine if the changes created any challenges or concerns.