Licensing Regulations

Final DOJ Regulations

October 2020

Virginia Department of
Behavioral Health &
Developmental Services

Goals of the Presentation

- Today we will discuss:
  1. Implementation of the Final DOJ Regulations;
  2. What changed between the emergency regulations and the final regulations;
  3. The purpose of the changes; and
  4. How the changes fit into the big picture.

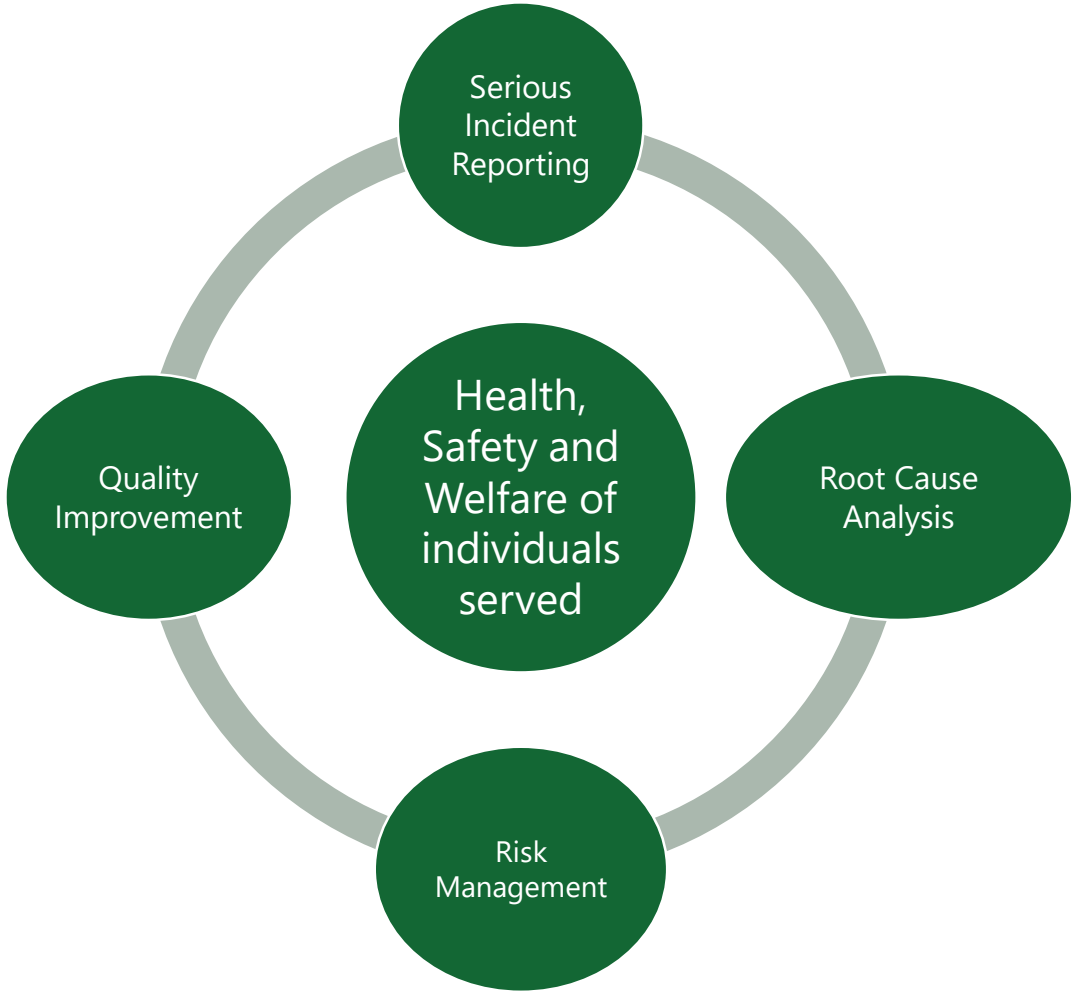
Implementation

- **Effective Date**: **August 1, 2020.**
- However, grace period until **November 1, 2020** so that providers have time to train staff and implement the requirements within the final permanent regulations.
- During grace period, Office of Licensing will not enforce new regulatory provisions that are more strict than emergency regulations

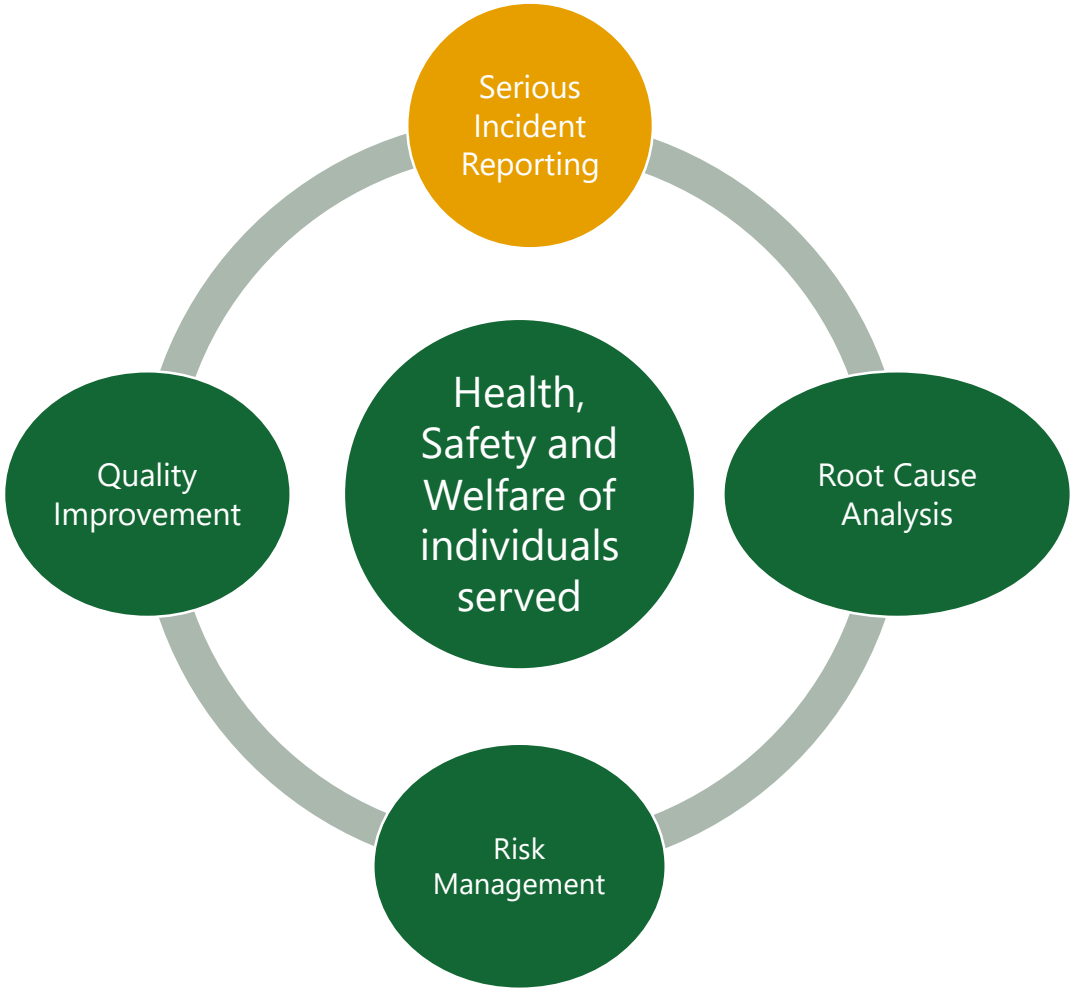
Places Where Final Regs are More Lenient

Regulation	Change
12VAC35-105-20 & 160.D.2.	Providers are no longer required to report an urgent care facility visit as a Level II Serious Incident.
12VAC35-105-20 & 160.D.2.	If an individual is not receiving any services other than from an emergency services provider, and has an unplanned psychiatric or medical hospitalization, the emergency services provider does not need to report the admission as a Level II serious incident.
12VAC35-105-20 & 160.D.2.	If a the provider can demonstrate that an individual has a Wellness Recovery Action Plan (WRAP) that includes the periodic need for psychiatric admission, the provider does not need to report a psychiatric admission as a Level II serious incident.
12VAC35-105-20 & 160.D.2.	Providers do not need to report a serious injury of an individual that results in or likely will result in permanent physical or psychological impairment as a Level III serious incident.
12VAC35-105-20 & 160.D.2.	Emergency services providers do not need to report a suicide attempt which results in hospitalization as a Level III serious incident if the individual is ONLY receiving emergency services.
12VAC35-105-160.D.2.	Providers may provide notification by email in addition to by telephone to anyone identified by the individual to receive notice of serious incidents.
12VAC35-105-160.D.2.	Risk of harm was removed from the requirements of an incident report. The CHRIS system will be updated to reflect this.
12VAC35-105-160.E.	Providers are not required to conduct a Root Cause Analysis for a Level III serious incident which occurred outside of the provision of their services. CHRIS will be updated so that box is not automatically checked when a SIR is submitted for a Level III serious incident. Providers only need to include identified solutions to mitigate its reoccurrence when applicable.

What is the purpose of changes between emergency and final regulations?



Serious Incident Reporting



12VAC35-105-20 – Definitions (Level II Serious Incident)

"Level II serious incident" includes a significant harm or threat to the health or safety of others caused by an individual. Level II serious incidents include:

1. A serious injury;

2. An individual who is **or was** missing;

3. An emergency room ~~or urgent care facility~~ visit ~~when not used in lieu of a primary care physician visit~~;

4. 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 (WRAP) shall not constitute an unplanned admission for the purposes of this chapter.**

12VAC35-105-20 – Definitions (Level III Serious Incident)

- "Level III serious incident" means a serious incident whether or not the incident occurs while in the provision of a service or on the provider's premises and results in:
- 1. Any death of an individual;
- 2. A sexual assault of an individual;
- ~~3. A serious injury of an individual that results in or likely will result in permanent physical or psychological impairment~~; or
- 3. A suicide attempt by an individual admitted for services, **other than licensed emergency services,** that results in a hospital admission.

12VAC35-105-160.C. – Quarterly Reviews

C. 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 with 12VAC35-105-620 to include an analysis of trends, potential systemic issues or causes, indicated remediation, and documentation of steps taken to mitigate the potential for future incidents.

12VAC35-105-160.D.2. – Required Reporting Serious Incidents

D. 2. Level II and Level III serious incidents shall be reported using the department's web-based reporting application and by telephone **or e-mail** to anyone designated by the individual to receive such notice and to the individual's authorized representative within 24 hours of discovery.

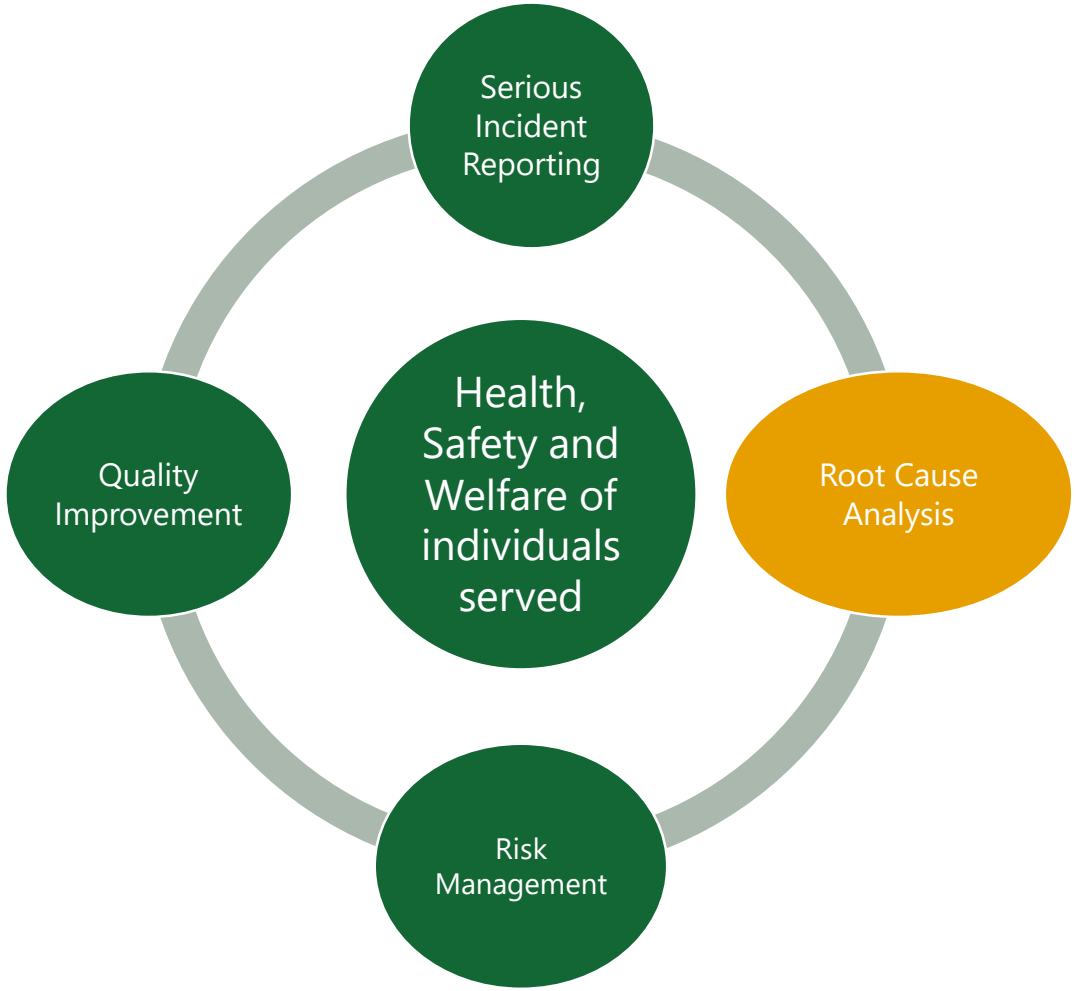
- Language was edited to allow for notification by email in addition to by telephone to anyone identified by the individual to receive notice of serious incidents.

12VAC35-105-160.D.2 – Required Reporting Serious Incidents

D.2… For all other Level II and Level III serious incidents, the reported information shall also include the consequences ~~**or risk of harm**~~ that resulted from the serious incident….

- Risk of harm was removed from the information required to be included in an incident report in response to commenters who noted that predicting future harm is too speculative.

Root Cause Analysis



Root Cause Analysis

- “Root cause analysis” (RCA), as defined by 12VAC35-105-20, is “a method of problem solving designed 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.”

12VAC35-105-160.E. Required Reporting (RCA)

E. A root cause analysis 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.**

12VAC35-105-160.E. - Example

- Individual 1 receives MH outpatient services from Provider A.
- Individual 1 passes away from a heart attack while at home alone.
- Although this incident meets the definition of a Level III serious incident (any death of an individual) and should be reported to the Office of Licensing via CHRIS, Provider A does not need to conduct a root cause analysis, because the Level III serious incident did not occur while the individual was receiving services or on the provider's premises.

12VAC35-105-160.E. - Example Continued

- Individual 2 died by suicide on Provider A's premises after service hours.
- Individual 2 was discovered the following day by staff.
- As this incident involves the death of an individual, it should be reported to the Office of Licensing as a Level III serious incident.
- In addition, because this death occurred on Provider A's premises, a root cause analysis would be required for this Level III serious incident, even though the individual was not receiving services at the time of the death.

12VAC35-105-160.E.1. – Serious Incidents (RCA)

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**.
  - Although risk of harm may be difficult to predict, the focus of risk mitigation strategies should be to reduce future risks.

12VAC35-105-160.E.2. – Serious Incidents (RCA)

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**
- **Charting causal factors should be conducted**

12VAC35-105-160.E.2.a – Serious Incidents (RCA)

2. At a minimum, the policy shall require for the provider to conduct a more detailed root cause analysis when:

a. A threshold number, as specified in 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;

12VAC35-105-160.E.2.a - Example

- Provider B operates four group homes and serves a total of 16 individuals (4 per residence). Provider B's policy states that it will conduct a more detailed root cause analysis whenever two or more similar level II serious incidents occur at any one group home in a six month period.
- In January, Individual 2 was found to be missing from Group Home C at a time when Individual 2 would normally be expected to be present, but was located later that evening. In March, Individual 2 was found to be missing from Group Home C again, and was located again later that evening. Because two level II serious incidents occurred at Group Home C within a six month period, per Provider B's policy, a more detailed root cause analysis must be conducted.

12VAC35-105-160.E.2.b.– Serious Incidents (RCA)

2.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 – a suicide attempt by the same individual that results in a hospital admission within a six-month period.

12VAC35-105-160.E.2.c. – Serious Incidents (RCA)

2.c. A threshold number, as specified in 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 or Level III serious incidents occur across all of the provider's locations within a six-month period; or

12VAC35-105-160.E.2.c - Example

- Provider B operates four group homes and serves a total of 16 individuals (4 per residence). Provider B's policy states that it will conduct a more detailed root cause analysis whenever four or more similar level II or level III serious incidents occur in a six month period across all of Provider B's group homes.
- Over the course of six months four individuals who receive services from Provider B were brought to the emergency room for treatment of injuries. Provider B, per its policy, must conduct a more detailed root cause analysis, because four similar level II serious incidents occurred within a six month period of time.

12VAC35-105-160.E.2.d. – Serious Incidents (RCA)

2.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.

12VAC35-105-160.J. – Serious Incidents (RCA)

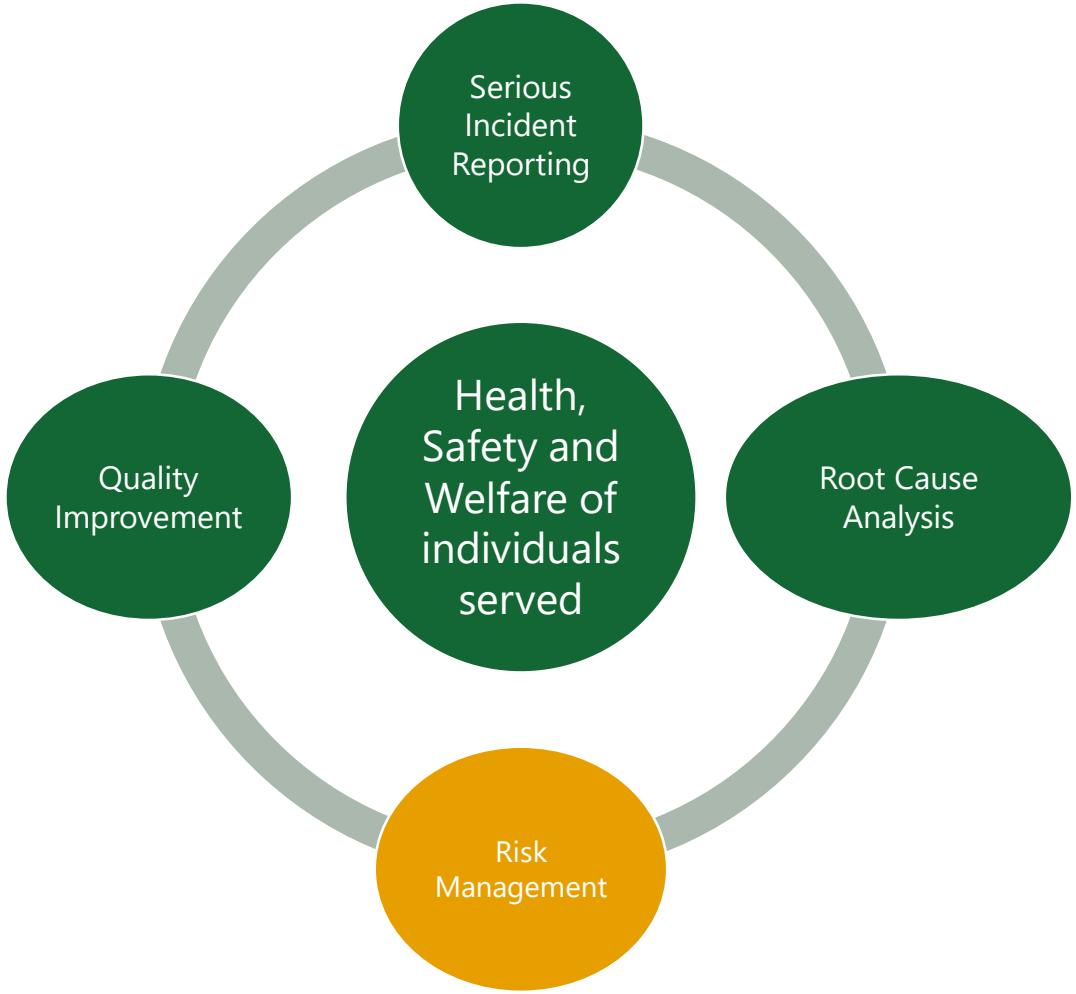
J. The provider shall develop and implement a serious incident management policy, which shall be consistent with this Section, and which shall describe the processes by which the provider will document, analyze, and report to the department information related to serious incidents.

- *Section J. is new language intended to ensure consistent application of the requirements of section 160 by providers.*

12VAC35-105-160.– Serious Incidents

- For additional information related to 12VAC35-105-160, please visit the DBHDS Office of Licensing's Guidance on Incident Reporting Requirements.
- In addition, an updated draft of the DBHDS Office of Licensing Guidance for Serious Incident Reporting has been uploaded to the Town Hall for a public comment period which began on September 28, 2020, and will close on October 28, 2020. Once OL has had the opportunity to review the public comments and make any needed changes, the updated guidance will be published as effective.

Risk Management



12VAC35-105-520.A. – Risk Management

A. 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.**

- *Amendments were made to this section to clarify the necessary qualifications of risk management staff.*

12VAC35-105-520.B. – Risk Management

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.

- *This is not new language*

12VAC35-105-520 – Risk Management Plan

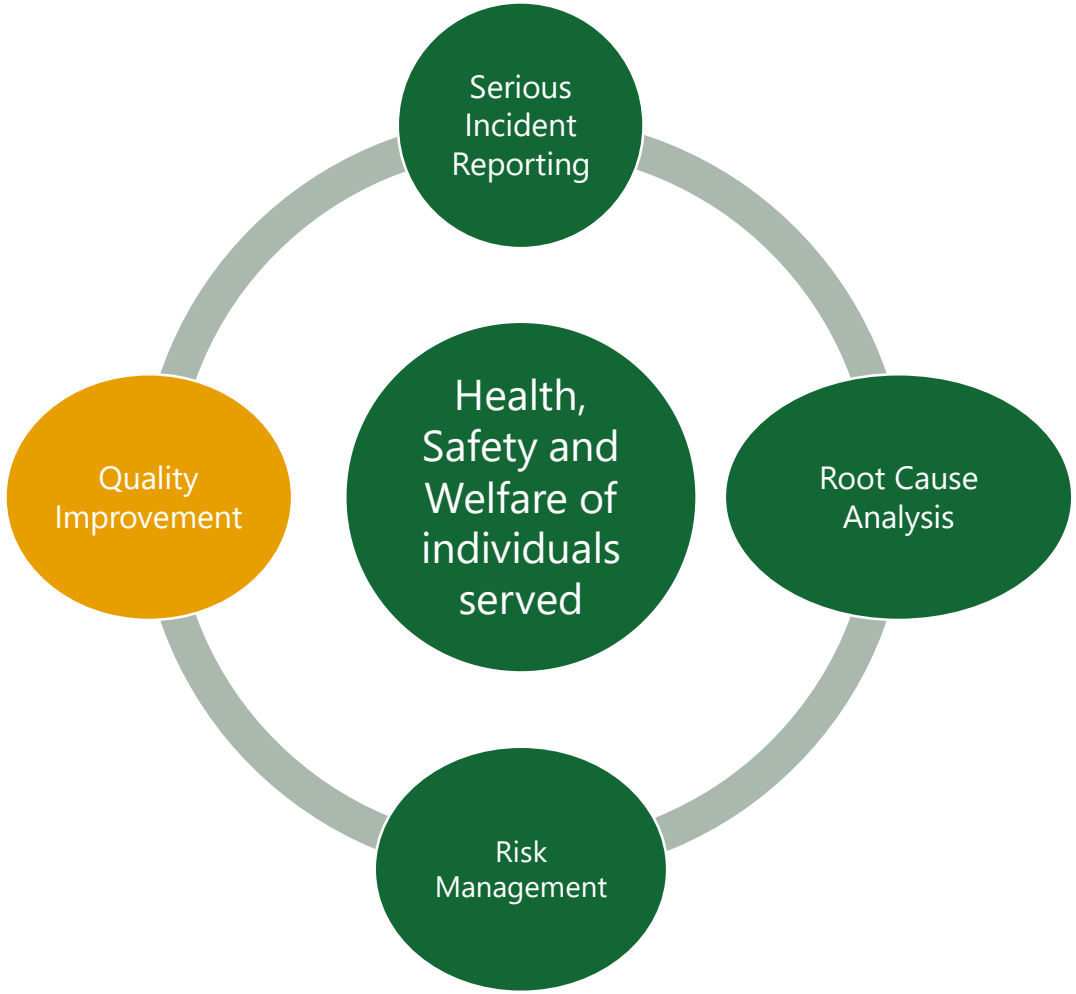
- **RM Plan is <u>Not</u>:**
  - **A copy and paste from the regulations**
  - **A "to do" list for the person designated as responsible for risk management**

- **RM Plan is:**
  - Specific to your organization (identifying high risk procedures)
  - Living document which is updated as new risks are identified
  - Annual review of serious incidents
  - Systemic risk assessment
  - And more

12VAC35-105-520 – Risk Management

- For additional information related to 12VAC35-105-520, please visit the DBHDS Office of Licensing's Guidance on Risk Management.
- In addition, the Office of Licensing will be hosting additional, more detailed trainings related to the Risk Management provisions within the Final Regulations in late October and November.

Quality Improvement/CAPs



12VAC35-105-170 – Corrective Action Plans

B. The provider shall submit to the department ~~and implement~~ a written corrective action plan for each violation cited.

C. The corrective action plan shall include a:

3. Signature of the person responsible for ~~the service~~ **oversight of the implementation of the pledged corrective action.**

E. Upon receipt of the corrective action plan, the department shall review the plan and determine whether the plan is approved or not approved…. If the submitted revised corrective action plan is ~~still unacceptable~~ **not approved**, the provider shall follow the dispute resolution process identified in this section.

12VAC35-105-170.G. – Corrective Action Plans

G. The provider shall implement their written corrective action plan for each violation cited by the identified date of completion.

- *The change was intended to clarify providers' responsibilities for monitoring and amending or supplementing corrective action plans as a component of the providers' quality improvement plans.*

12VAC35-105-170.H. – Corrective Action Plans

H. The provider shall monitor implementation and effectiveness of approved corrective actions as part of its qualify improvement program required by 12VAC30-105-620. If the provider determines in the course of its monitoring activities that the corrective actions were implemented, but were ineffective at preventing the recurrence of the violation or at correcting any systemic deficiencies, the provider shall:

1. 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; or

2. Submit a revised corrective action plan to the department for approval.

12VAC35-105-170.H. – Corrective Action Plans

- In order to demonstrate compliance with this regulation, each provider must show proof of monitoring all CAPs for implementation and effectiveness.
- If after completion of the planned activities the provider determines that the issue that led to a citation occurred again, then the provider shall implement the provider's own policies and procedures for updating the provider's quality improvement plan, if applicable, or submitting revised corrective action plans, pursuant to 12VAC35-105-620.D. This may include determining whether or not the CAP was implemented as intended.

12VAC35-105-170.H. – Corrective Action Plans

1. If the CAP was not fully implemented as intended, the provider should evaluate and address any barriers to implementation.

2. If the CAP was fully implemented, the provider should assess the reasons that the issue recurred and make a determination as to whether changes to the corrective action plan are necessary.

12VAC35-105-170.H. – Corrective Action Plans

- While prevention of a second regulatory violation may not always be possible, prevention is the goal. If a second regulatory violation occurs, the provider should always analyze whether the current CAP is the most effective means of preventing reoccurrence or if additional steps could be taken.
- A provider may determine after review that the recurrence of a regulatory violation was not due to the insufficiency of the implemented corrective actions, and that the planned corrective actions remain the most effective means of preventing or substantially mitigating future recurrences. **If this is the case, then the provider should clearly document through the quality improvement program the basis for this conclusion and continue** implementing the planned corrective actions without additional measures.
- If the provider determines that revisions to the CAP are necessary, those revisions should be submitted to the licensing specialist for review and approval. The provider should document through the quality improvement program, if applicable, when it is determined that an issue has been corrected and monitoring may be discontinued.

12VAC35-105-170.H. – Example

- After an unannounced inspection, Provider A receives a licensing report that includes the second citation for late reporting of a serious incident within a one-year period.
- As part of the CAP, Provider A decides to amend the agency-wide training policy to include a test that requires a 90% passing score, and amend the new supervisor training to include review of the incident reporting requirements. The training policy is revised to state that all employees will be trained on the serious incident reporting requirements and must pass a test with a score of 90% or higher within the first 30 days of employment and prior to working alone with individuals.
- Provider A successfully implements the CAP by revising the training policy and ensuring all employees passed the test with a score of 90% or higher by the completion date outlined in the CAP. However, on January 1st, the provider self-identifies the failure to report a serious incident in a timely manner through the quality assurance process implemented as a result of the initial corrective action. The provider's quality assurance process involved tracking the timeliness of reporting each serious incident on a quarterly basis. A review of the data identified three instances (out of 25 serious incidents) when reports were not made within 24 hours.

12VAC35-105-170.H. – Example (Continued)

- Provider A determines that the approved CAP was fully implemented. However, it did not correct the identified systemic deficiency. Provider A has two options:
  - 1) to continue implementing the CAP and put into place additional measures to prevent the recurrence of the cited violation and address identified systemic deficiencies; or
  - 2) submit a revised CAP to the department for approval. If the provider determined that the approved corrective actions are the most effective means of addressing the issue, then this rationale should be documented through the quality improvement program and the provider may continue implementing the approved corrective actions.

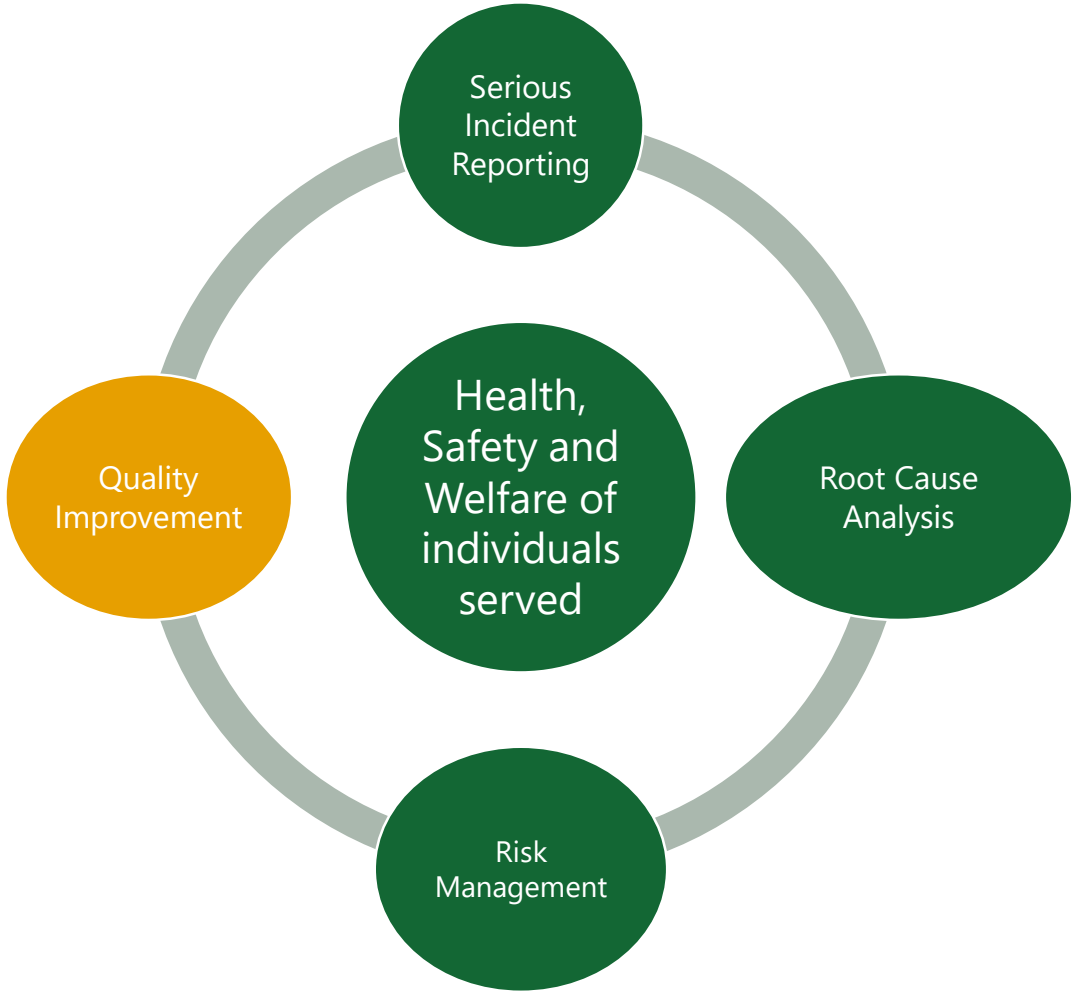
12VAC35-105-170.H. – Example (Continued)

- In accordance with the provider's quality improvement policy, Provider A conducts an analysis into why the CAP was not effective. Provider A's analysis determines that while the staff pass a test, applying the knowledge to real life situations is more difficult. As a result, Provider A determines that the CAP will continue to be implemented, but also will make sure to talk through real life scenarios and examples during each staff meeting. Provider A also implements a motto with all staff, "When in doubt, talk it out," to encourage staff to call a supervisor if they have any questions about whether an occurrence may be considered a Level II or Level III serious incident.
- After one year, the provider determines through quarterly monitoring that 100% of serious incidents were reported within 24 hours. Based on attaining the objectives of the CAP, the provider determines that this issue was successfully addressed and closes it as a quality improvement goal, consistent with the policies and procedures.

12VAC35-105-170.H. – Corrective Action Plans

- For additional information related to 12VAC35-105-170.H., please visit the DBHDS Office of Licensing's Guidance on Corrective Action Plans.

Quality Improvement



12VAC35-105-620 – Quality Improvement

A. The provider shall develop and implement **written policies and procedures for** a quality improvement program sufficient to identify, monitor, and evaluate clinical and service quality and effectiveness on a systematic and ongoing basis.

B. The quality improvement program shall utilize standard quality improvement tools, including root cause analysis, and shall include a quality improvement plan.

12VAC35-105-620 – Quality Improvement

C. The quality improvement plan shall:

1. Be reviewed and updated at least annually;
2. Define measurable goals and objectives;
3. Include and report on statewide performance measures, if applicable, as required by DBHDS;
4. **Monitor implementation and effectiveness of approved corrective action plans pursuant to 12VAC35-105-170;** and
5. Include ongoing monitoring and evaluation of progress toward meeting established goals and objectives.

12VAC35-105-620 – Quality Improvement

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

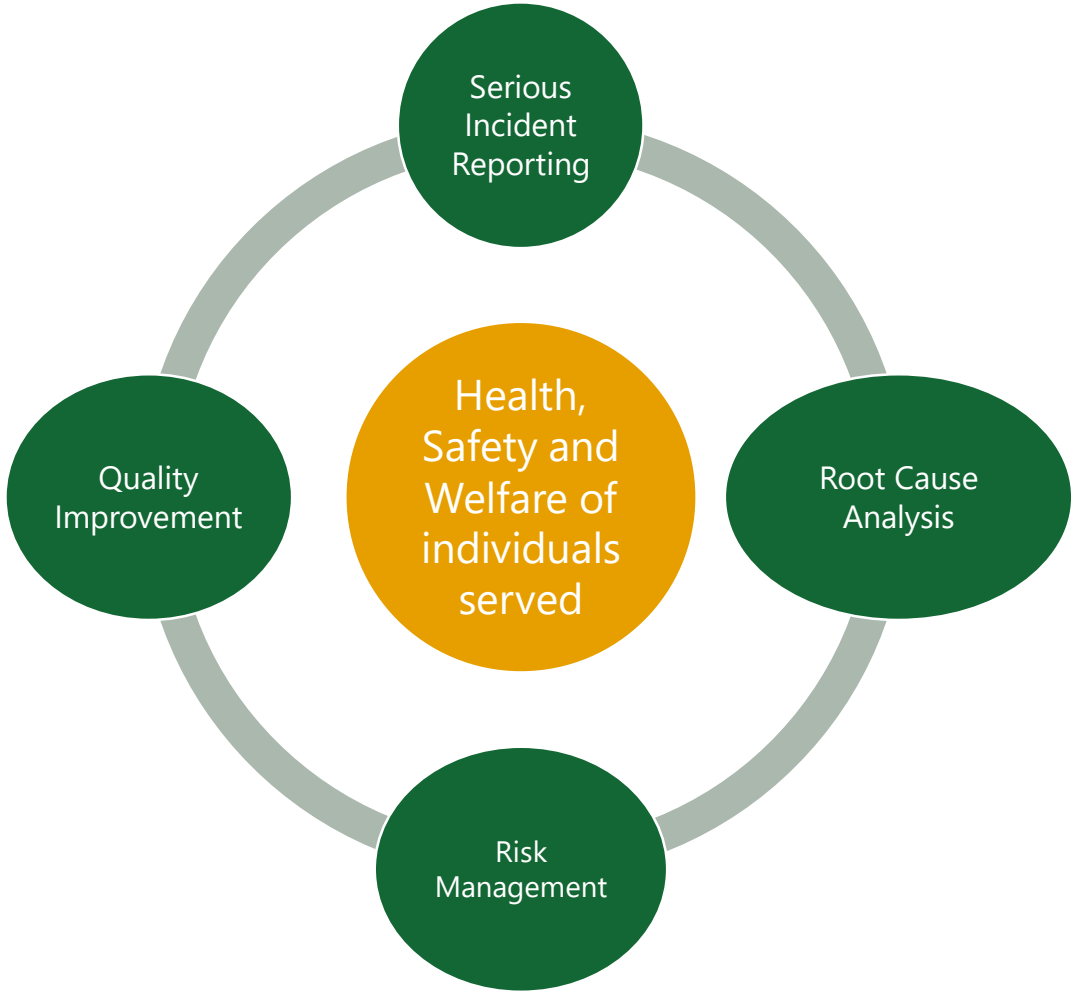
3. Submit revised corrective action plans to the department for approval or continue implementing the corrective action plan and put into place additional measures to prevent the recurrence of the cited violation and address identified systemic deficiencies when reviews determine that a corrective action was fully implemented but did not prevent the recurrence of the cited regulatory violation or correct a systemic deficiency pursuant to 123VAC35-105-170.

- *#3 was amended to add requirement that the provider's policies and procedures include "criteria for amending corrective actions when reviews determine the corrective action has not been effective at remedying the cited regulatory violation*."

12VAC35-105-620 – Quality Improvement

- An updated draft of the DBHDS Office of Licensing's Guidance for a Quality Improvement Program has been uploaded to the Town Hall for a public comment period which began on September 28, 2020 and will close on October 28, 2020. Once OL has had the opportunity to review the public comments and make any needed changes, the updated guidance will be published as effective.
- In addition, the Office of Licensing will be hosting additional, more detailed trainings related to the quality improvement provisions within the Final Regulations in October and November.

Other Health, Safety, and Welfare Concerns



12VAC35-105-320 – Fire Inspections

The provider shall document at the time of its original application and annually thereafter that buildings and equipment in residential service locations **serving more than eight individuals** are maintained in accordance with the Virginia Statewide Fire Prevention Code (13VAC5-51). **This section does not apply to correctional facilities or home and noncenter-based or sponsored residential home services.**

- The section has been restored to its previous language based on stakeholder feedback, which excludes sponsored residential, and home and non-center based services from the provisions of the Section.
- In order to fulfill the intent of the previous amendment, additional fire safety related provisions have been added to Section 12VAC35-105-530 Emergency Preparedness and Response Plan.

12VAC35-105-530 – Emergency preparedness and response plan

A.5. Emergency procedures shall address:

e. Evacuation procedures, including for individuals who need evacuation assistance;

9. Schedule for testing the implementation of the plan and conducting emergency preparedness drills. **Fire and evacuation drills shall be conducted at least monthly.**

B. The provider shall evaluate each individual and, based on that evaluation, shall provide appropriate environmental supports and adequate staff to safely evacuate all individuals during an emergency.

I. All provider locations shall be equipped with at least one approved type ABC portable fire extinguisher with a minimum rating of 2A10BC installed in each kitchen

12VAC35-105-530 – Emergency preparedness and response plan

J. All provider locations shall have an appropriate number of properly installed smoke detectors based on the size of the location, which shall include at a minimum:

1. **At least one smoke detector on each level of multi-level buildings, including the basement;**
2. **At least one smoke detector in each bedroom in locations with bedrooms;**
3. **At least one smoke detector in any area adjacent to any bedroom in locations with bedrooms; and**
4. **Any additional smoke detectors necessary to comply with all applicable federal and state laws and regulations and local ordinances.**

12VAC35-105-530 – Emergency preparedness and response plan

K. Smoke detectors shall be tested monthly for proper operation.

L. All provider locations shall maintain a floor plan identifying locations of:

1. **Exits;**
2. **Primary and secondary evacuation routes;**
3. **Accessible egress routes;**
4. **Portable fire extinguishers; and**
5. **Flashlights.**

M. This section does not apply to home and noncenter-based services.

12VAC35-105-660 – Individualized Services Plan: Informed Choice

1. To ensure the individual's participation and informed choice, ~~the provider shall explain~~ **the following shall be explained** to the individual or the individual's authorized representative, as applicable, in a reasonable and comprehensive manner:

   a. the proposed services to be delivered;

   b. **any** alternative services that might be **available to and** advantageous for the individual;

   c. **any** accompanying risks and benefits **of the proposed and alternative services**.

2. If no alternative services are available to the individual, it shall be clearly documented within the ISP, or within documentation attached to the ISP, that alternative services were not available as well as any steps taken to identify if alternative services were available.

3. Whenever there is a change to an individual's ISP, it shall be clearly documented within the ISP, or within documentation attached to the ISP that:

   a. the individual participated in the development of or revision to the ISP;

   b. the proposed and alternative services and their respective risks and benefits were explained to the individual or the individual's authorized representative, and;

   c. the reasons the individual or the individual's authorized representative chose the option included in the ISP.

12VAC35-105-665.D. – ISP Requirements

D. Employees or contractors who are responsible for implementing the ISP shall demonstrate a working knowledge of the objectives and strategies contained in the individual's current ISP, **including an individual's detailed health and safety protocols.**

- *Language related to what employees and contractors must demonstrate knowledge of was updated to incorporate language from the DOJ Settlement Agreement.*

Questions