Training on Final DOJ Regulations

October 2020

Questions and Answers

The questions from the three October 2020 trainings regarding the final DOJ Regulations have been combined and grouped according to subject matter.

Serious Incident Reporting

1. **Related to Level II or Level III serious incident reporting, (12VAC35-105-160 D.2) when patients are seen in outpatient care, does the provider need to report as unplanned psychiatric evaluation?**

   Unplanned hospital admissions outside of the provision of services or off the provider's premises do not need to be reported as a Level II or Level III serious incident.

2. **Was "risk of harm" deleted from incident reporting requirement?**

   Risk of harm was removed from the requirements of an incident report in response to commenters who noted during the public comment period for the regulations that predicting future harm is too speculative. The root cause analysis provision was amended to include "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.

3. **Are congregate residential providers still considered to be providing services for reporting Level II or Level III incidents when an individual is not actively receiving services (i.e. visiting family)? What about for residential providers in terms of Level II requirements? Is the same criteria for provision of services different?**

   Please refer to Guidance for Serious Incident Reporting

   Providers licensed to provide a "residential service" as defined by 12VAC35-105-20 provide 24-hour support to individuals. However, if an individual receiving residential services experiences a Level II serious incident while actively receiving services from another licensed provider, the residential service provider is not required to report the incident if the provider attempts to verify that the other provider reported the incident. Once a residential provider becomes aware that an individual experienced a Level II serious incident during the provision of another provider's services, the residential provider should reach out directly to the other provider to attempt to verify that the other provider reported the incident. The residential provider should select a consistent manner to document any attempts to verify the submission of an incident report by another provider, as well as the other provider's response. Verification may occur through phone conversations, face-to-face interactions, e-mails, or fax. A simple confirmation from the other provider that they submitted the report is sufficient; the residential provider is not required to receive a copy of the incident report. If the residential provider cannot receive confirmation from the other provider that a serious incident report was submitted, then the residential provider may submit a complaint to the Office of Licensing at olcomplaints@dbhds.virginia.gov.

   In addition, if an individual receiving services is temporarily away from a provider's services for a visit or trip with family, and the individual experiences a Level II serious incident, the incident does not need to be

reported to the Office of Licensing. For example, an individual who receives group home services has a choking incident which requires direct physical intervention while on a family trip to the beach. When the individual returns, their parent informs the provider of the incident. The provider does not need to report the choking incident requiring physical intervention as a Level II serious incident. However, the provider should internally document the report made by the family and based on the specific details surrounding the incident, the provider may need to evaluate individual supports to determine if they are still appropriate.

4. **Has the provision of care definition changed?**

   No, the provision of care definition was not changed in the final regulations. As noted in the Guidance for Serious Incident Reporting, during the provision of service means that the incident occurs when the provider is actively providing a service to the individual. Please refer to Guidance for Serious Incident Reporting

5. **What if EMTs recommend an Emergency Room (ER) visit but the individual or Substitute Decision Maker decline to go to the ER?**

   If the provider calls first responders due to an emergency, and an emergency medical technician (EMT) recommends an ER visit but the individual declines to go, this does not need to be reported as there was no "emergency room visit" as listed within the regulations. Please note that if there was another Level II serious incident which led to the call for first responders, then that should be reported as a Level II serious incident. For example, an individual experiences a choking incident, which requires direct physical intervention, and 911 is dialed. By the time the EMTs arrive, provider staff were able to successfully clear the individual's airway. The EMTs suggest that the individual should still be transported to the emergency room for an evaluation, but the individual refuses to go. The provider does not need to report this as an emergency room visit as the individual refused to go to the emergency room. However, the incident should still be reported as a Level II serious incident as it was a choking incident which required direct physical intervention. If an individual is taken to the emergency room and later refuses care while at the emergency room, this should still be reported as a Level II serious incident as an emergency room visit did occur.

6. **Is an ER visit a Level II serious incident or only if admitted to the hospital? What if the person comes home the same day?**

   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.

7. **DBHDS received several inquiries (during the provider trainings as well as during the public comment period for the Guidance on Serious Incident Reporting) related to whether or not a psychiatric admission in accordance with a Crisis Action Plan or any other type of advanced planning are also exempt from reporting as a Level II serious incident or only admissions in accordance with a Wellness Recovery Action Plan (WRAP).**

   This request is being researched and reviewed; additional information will be forthcoming to all providers in the form of a formal guidance document once a decision has been made. All guidance documents are subject to a 30 day public comment period before their effective date, which will be available via the Virginia Regulatory Town Hall. DBHDS provides direct notice to all providers prior to the start of any public comment period. To date, all psychiatric admissions other than those in accordance with an individual's WRAP plan are considered to be unplanned psychiatric admissions.

8. **Does "during the provision of service" include telephonic/telehealth? For example, if you are speaking on the phone to a client and directing them to the ED for psychiatric screening and an incident occurs, would a provider submit an incident report?**

   "[D]uring the provision of a service" means that the incident occurs when the provider is actively providing a service to the individual. If a provider is providing a licensed service remotely in accordance with the individual's service plan (e.g., via phone or video, consistent with agency COVID protocols) and a Level II incident occurs, the provider is required to submit a serious incident report. Please note that exemptions exist for Level II serious incidents which occur when an individual is only receiving licensed emergency services, including emergency room visits and unplanned hospital admissions.

9. **Do CHRIS reports need to be made for non-licensed services being funded by CSA or commercial funders?**

   The Rules and Regulations for Licensing Providers by the Department of Behavioral Health and Developmental Services, including the requirement for submitting serious incident reports, apply to only licensed providers.

10. **What is the definition of unplanned hospitalization?**

    If an individual is admitted to the hospital and it is not planned, then it should be reported. An example of a planned hospital admission would be admission for a planned surgery or procedure.

    If an individual is receiving case management services at the time of an unplanned psychiatric or unplanned medical hospital admission, the case manager is only required to report the incident if the admission occurred while the case manager was actively providing case management service to the individual.

11. **If an individual is transported to the ER to be evaluated for a psychiatric admission but is screened out and not admitted, should this be reported as a Level II incident?**

    Yes, a visit to the ER, even if it does not constitute an admission, should be reported as a Level II serious incident unless the individual was only receiving licensed emergency services.

12. **The definition of serious incident states that it requires medical attention by a physician. If an individual was seen at Urgent Care for an injury, would this be a Level II serious incident?**

    A "**Serious incident**" means any event or circumstance that causes or could cause harm to the health, safety, or well-being of an individual. The term "serious incident" includes death and serious injury. "Level I serious incident" means a serious incident that occurs or originates during the provision of a service or on the premises of the provider and does not meet the definition of a Level II or Level III serious incident. Level I serious incidents do not result in significant harm to individuals, but may include events that result in minor injuries that do not require medical attention or events that have the potential to cause serious injury, even when no injury occurs.

    A **serious injury** means "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. The regulations do not stipulate where that medical attention must be provided.

13. **Level II and Level III serious shall be reported using the department's web-based reporting application (CHRIS) and by telephone or email to anyone designated by the individual to receive such notice and to the individual's authorized representative within 24 hours of discovery. Is texting allowable?**

All Level II and Level III serious incidents shall be reported to the Office of Licensing via the CHRIS reporting system. This is the only acceptable method of reporting an incident to the department. Please refer to Guidance for Serious Incident Reporting

Separately, a Level II and Level III serious incident must also be reported to anyone designated by the individual to receive such notice and to the individual's authorized representative within 24 hours of discovery. This notification may be done by telephone or email. This notification may not be done via text.

Root Cause Analysis (RCA)

1. **Please provide examples of RCA thresholds for various service types?**

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.

2. Do two or more Level III serious incidents of the same individual/same location during a six month period need a more detailed root cause analysis?

A provider shall develop and implement a root cause analysis policy for determining when a more detailed root cause analysis should be conducted. At a minimum, the policy shall require for the provider to conduct a more detailed root cause analysis when "two or more of the same Level III serious incident occur to the same individual or at the same location within a six month period (12VAC35-105-160.E.2.b) and when "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.E.2.d).

3. Please provide clarification between a root cause analysis (RCA) and a more detailed RCA.

A RCA 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 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.

The provider shall develop and implement a root cause analysis policy for determining when a more detailed root cause analysis should be included. The more detailed RCA would include convening a team, collecting and analyzing data, mapping processes, and charting causal factors (12VAC35-105-160.E).

For additional information related to root cause analysis, please visit the Office of Licensing Root Cause Analysis Training.

4. **Is there a standard for the number or percentages of serious incidents that are required to be in the provider's Root Cause Analysis policy?**
   There is not a standard. The RCA policy shall include minimum requirements as outlined in 12VAC35-105-160.2.a-d. The threshold numbers in a RCA policy need to be reasonable based on the elements included in the regulations including the provider's size, number of locations, service type, number of individuals served, and the unique needs of the individual's served.

5. **For more detailed RCA determination, what is meant by the same location? Is that the actual physical location in which the incident occurred? Specifically asking for services that are provided in the community?**

   Location refers to the licensed location; not the exact spot where the incident occurred. For the RCA policy for community based providers for 160.E.2.a which requires "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 individuals served by the provider, of similar Level II serious incidents occur to the same individual or at the same location with a six-month period," it would be incidents that occur to the same individual and not at the same location if the providers does not have any licensed service locations.

6. **Regarding threshold numbers for a more detailed Root Cause Analysis, is that all services/all locations or by licensed services?**

   Threshold numbers should be by licensed services (which includes all locations for that service).

7. **For more detailed RCA, should one be completed for each incident beyond threshold? For example, if the threshold is two, would the provider conduct a more detailed RCA for the third or fourth?**

   Yes, the thresholds are determined by the provider so anything over the threshold should trigger a more detailed RCA in accordance with the provider's RCA policy. The identified root cause may vary according to the nature of the incidents even if similar in nature. In addition, if similar incidents continue to occur, it is possible that the findings of the initial RCA did not identify all the root causes or that the actions taken to mitigate reoccurrence of such incidents were not sufficient. The purpose of a root cause analysis is to identify system vulnerabilities so that they can be eliminated or mitigated. Conducting RCAs should be viewed as an opportunity to address systems issues on an ongoing basis.

8. **Is reference to the thresholds for a more detailed RCA, is this six month period rolling or can you fix that from January to June?**

   This should be on a rolling basis as the provider strives to identify solutions, as applicable, to be taken to keep the situation from occurring again or minimizing the likelihood of its reoccurrence and future risk of harm. Solutions should be both individual-specific and systemic as indicated by the analysis of the incident. RCA is a standard quality improvement tool that should be part of the provider's quality improvement program.

Corrective Action Plans (CAPs)

1. **Will the submission of a revised Corrective Action Plan (CAP) equate to a repeat citation?**
   A provider will not receive a citation for submitting a revised CAP as this is an action occurring in accordance with the regulations (12VAC35-105-170). It is possible the Office of Licensing may identify additional regulatory violations during inspection/investigations which may prompt the provider to evaluate the CAP, but the submission of a revised CAP will not in and of itself prompt the issuance of a repeat citation. Please see the DBHDS Office of Licensing Guidance on Corrective Action Plans for additional information.

2. **How do you provide proof of monitoring all CAPs?**
   When developing a CAP, the provider should include planned corrective actions that are targeted to the mitigation or prevention of the recurrence of the regulatory violation that the CAP is intended to address and must be sufficiently detailed to inform the OL of the planned action steps that will be taken to fulfill the goals of the CAP. Planned actions must be verifiable with mechanism for verifying the completion of the planned actions incorporated into the provider's ongoing quality improvement activities, pursuant to 12VAC35-105-620. 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 provider's quality improvement plan shall include the process the provider will use to monitor the implementation of CAPs, including criteria for when a CAP will no longer be subject to monitoring. Please see the DBHDS Office of Licensing's Guidance for a Quality Improvement Program for additional information.

3. **Does this suggest that each CAP should be updated and resubmitted if changes need to occur?**

   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.

   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.
      - 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.

Please see the DBHDS Office of Licensing Guidance on Corrective Action Plans for additional information.

Quality Improvement/Risk Management

1. **If the Guidance for a Quality Improvement Program is not posted until after November 1, 2020, will there be flexibility as a provider makes final changes on quality improvement plans?**

The Office of Licensing has provided flexibility to providers given that the final regulations were effective August 1, 2020, however, per the August 6, 2020 memo, the Office of Licensing monitored provider compliance in accordance with the requirements of the previously effective emergency regulations until November 1, 2020. This gave providers time to train staff and implement the requirements within the permanent regulations. Training on the changes in the regulations was provided prior to November 1, 2020. The Guidance for a Quality Improvement Program does not contain requirements that are not in the regulations but only offers additional guidance.

2. **Does it suffice if the person designated as the risk manager has root cause analysis training from another agency?**

The regulations require department approved training in individual risk screening, conducting investigations, root cause analysis and the use of data to identify risk patterns and trends. Providers should reference the Crosswalk of DBHDS Approved Risk Management Training and the DBHDS Risk Management Attestation on the Office of Licensing webpage.

Please note that these are minimum qualifications. Providers may also provide training in additional areas relevant to the risk management function as well as other training related to these subject areas.

Emergency preparedness and response plan

1. **Do monthly fire drills apply to all providers? Which locations require monthly fire drills and evacuation drills? Will DBHDS post guidance?**

The monthly fire and evacuation drill requirement applies to all providers except providers of home and noncenter-based services. It is expected that fire and evacuation drills will look different based on the location and the service(s) provided. The phrase "fire and evacuation drill" refers to a single requirement to perform training and evaluation drills to test and improve the efficiency and effectiveness of staff and others in carrying out fire and evacuation procedures.

The Office of Licensing will be posting Guidance on Emergency Preparedness and Response Plan.

2. **If conducting monthly fire drills, do we need still have to conduct other types of drills? And the fire drill in the same month?**

Fire and evacuation drills shall be conducted at least monthly irrespective of any other drills. Nothing in the Licensing Regulations overrides or alters any preexisting requirement to conduct fire and evacuation drills. Many licensed settings are already required by the Virginia Statewide Fire Prevention Code (The Virginia Fire Code) to conduct monthly fire drills, including State Regulated Care Facilities (SRCFs). A SRCF is defined in the Virginia Fire Code as "a building with an occupancy in Group R-2, R-3, R-4, or R-5 occupied

by persons in the care of others where program oversight is provided by … the Virginia Department of Behavioral Health and Developmental Services….” SRCFs are required by the Virginia Statewide Fire Prevention Code to conduct monthly emergency evacuation drills with participation of all occupants (2015 Virginia Statewide Fire Prevention Code, Table 405.2, p. 36). Additionally, psychiatric hospitals, detoxification facilities, and other providers classified by the International Fire Code (incorporated by reference into the Virginia Fire Code) as Institutional Group I-2 or I-3 facilities are required to conduct quarterly fire and evacuation drills on each shift (which averages out to once per month), involving all employees; and providers classified as I-4 facilities, including adult day settings, are required to conduct monthly fire and evacuation drills on each shift involving all occupants.

Providers should ensure that they are in compliance with these preexisting requirements in addition to the requirements of the licensing regulations, and should refer to the fire code for information on the minimum requirements of conducting fire and evacuation drills in accordance with its terms.

The Licensing regulations do not define the elements of a fire and evacuation drill. Where a fire and evacuation drill is required by the fire code, providers should refer to the fire code for minimum requirements for conducting the fire and evacuation drill. Where a fire and evacuation drill is required by the licensing regulations, but not by the fire code, providers have some flexibility in determining how best to conduct the fire and evacuation drill in order to ensure that it is an effective training and evaluation tool while also minimizing disruptions to services. For example, providers may use a variety of fire safety and evacuation drill formats throughout the year, including a combination of comprehensive drills, silent drills, planned and announced drills, random drills, and even tabletop or scenario based drills. Some providers may find it necessary to plan fire safety and evacuation drills so as to minimize service disruptions and maximize safety. Some drills may involve only employees, while others employees and other building occupants. Providers should ensure that they maintain documentation of the occurrence of fire safety and evacuation drills, including information about the format, timing, efficacy, and outcomes of such drills. This documentation will help the provider both demonstrate compliance with the licensing regulations and provide a basis for evaluating its fire safety preparedness and effectiveness.

3. There is a section that references “adequate” staffing for evacuations. We were wondering how this will be applied. There is concern specifically about 24/7 programs in that usually staffing at night is one person, so compliance seems like it could be subject to a variety of interpretations.

12VAC35-105-590.A - the provider shall implement a written staffing plan that includes the types, roles, and number of employees and contractors that are required to provide the service. This staffing plan shall reflect the 1. needs of the individuals receiving services; 2. types of services offered; 3. service description; 4. number of individuals to receive services at a given time; and 5. adequate number of staff required to safely evacuate all individuals during an emergency.

12VAC35-105-530.B - The emergency preparedness and response plan shall address “specific procedures describing mitigation, preparedness, response, and recovery strategies, actions, and responsibilities for each emergency.

The provider shall address how the staffing plan allows for safe evacuation of all individuals during emergencies which may occur at any time including day or night shift.

Individual Services Plan (ISP): Informed Choice

1. Please clarify “alternative services” in 12VAC35-105-660.D.1.b?

Alternative services relates to whether there is documentation to support an informed choice about the service being provided. For example, if the person resides in a group home, do they understand that there are alternate

service settings that can be chosen such as sponsored home or an apartment setting? If the person is receiving group day support, do they understand that supported employment in place (or combined with) that service is an option? Individuals who want to explore these alternate options can be referred back to their support coordinator/case manager for further discussion and exploration.

2. What is meant by alternative services provided by the provider or other providers?

Alternative services relates to whether there is documentation to support an informed choice about the service being provided. For example, if the person resides in a group home, do they understand that there are alternate service settings that can be chosen such as a sponsored home or an apartment setting? If a person is receiving group day support, do they understand that supported employment in place (or combined with) that service is an option for them? Individuals who want to explore these alternate options can be referred back to their support coordinator/case manager for further discussion and exploration.

3. When there is a change to an ISP, how should the provider document that the individual participated in the development of or revision to the ISP, proposed and alternative services, risks and benefits were explained and the reasons the individual or their authorized representative chose the option?

The provider must have a documented discussion with the individual or the individual's authorized representative. A provider could include this information in a note which should be attached to their ISP or can be included in the ISP.

Individual Support Plan (ISP) Requirements (12VAC35-105-665.D)

1. How does the provider provide evidence that employees and contractors have been trained on the ISP or protocols? Examples please.

Employees or contractors who are responsible for implementing an 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.

Documentation of the training including the topic areas, date of training, and staff trained should be available for review by the Office of Licensing. An example might include a dated staff agenda that outlines topics that were covered including review of specific individuals' ISPs and protocols with signature sheets of staff in attendance. Other agencies such as DMAS may have additional requirements related to training (i.e. DD waiver regulations require confirmation of proficiency with DBHDS established competencies).