**Serious Incidents and the Annual Systemic**

**Risk Assessment 160.C, 520.C.1-5 and 520.D**

**(January 2024)**

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| **Purpose:** The purpose of this document is to assist the Licensing Specialist with assessing the provider’s quarterly review of serious incidents and each component of the annual systemic risk assessment. |
| **Definitions:*** **"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. "Level II serious incident" means a serious incident that occurs or originates during the provision of a service or on the premises of the provider that results in a significant harm or threat to the health and safety of an individual that does not meet the definition of a Level III 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 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 shall not constitute an unplanned admission for the purposes of this chapter;5. Choking incidents that require direct physical intervention by another person;6. Ingestion of any hazardous material; or7. A diagnosis of:a. A decubitus ulcer or an increase in severity of level of previously diagnosed decubitus ulcer;b. A bowel obstruction; orc. Aspiration pneumonia.* **"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; or3. A suicide attempt by an individual admitted for services, other than licensed emergency services, that results in a hospital admission.* **"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.* **Systemic Risk Assessment (SRA)** is a tool used for careful examination of what the provider identifies as internal and external factors or situations that could cause harm to individuals served or that could negatively impact the organization. The risk assessment should lead to a better understanding of actual or potential risks and how best to minimize those risks. Systemic risk assessments vary depending on numerous factors such as an organization’s size, population served, location, or business model.  The risk assessment process is focused on identifying both existing and potential harms and risks of harm.  The systemic risk assessment is a tool you should use to inform your risk management systems.
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| **Regulations:*** **160.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.
* **520.C:** The provider shall conduct systemic risk assessment reviews at least annually to identify and respond to practices, situations, and policies that could result in the risk of harm to individuals receiving services. The risk assessment review shall address at least the following:

**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.* **520.D:** The systemic risk assessment process shall incorporate uniform risk triggers and thresholds as defined by the department.
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| **Please Note:** **160.C:** * Non-Determined should be marked if the provider does not have any Level I, II, or III serious incidents to review since January 1, 2023.
* Non-Determined should be marked if the provider has not served any individuals.

**520.C.1-5*** If a systemic risk assessment is not completed the provider will be cited for non-compliance with 520.C.1, 520.C.2, 520.C.3, 520.C.4 and 520.C.5.
* If any component of the systemic risk assessment are not addressed the provider will be cited for that specific regulation.

**520.D*** As presented during trainings, DBHDS has defined risk triggers and thresholds as care concerns which are identified through the IMUs review of serious incident reporting.
* If a provider has not had any care concerns, their systemic risk assessment review process would still need to outline how they would address care concerns if they were to occur. If the provider outlines how they would address care concerns if they were to occur, then the provider would be marked Compliant. If it does not, then the provider would be marked Non-Compliant.
* This regulation should NOT be marked as Non Determined.
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| **Regulation** | **What the regulation****specifies:** | **What questions to ask yourself****to determine compliance:** | **The provider would be given a rating of Non-Compliance:** |
| **160.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. | * Were the two quarterly reviews of all serious incidents including Level I, Level II and Level III incidents requested for review?
* If the provider did not have any Level I, II, or III serious incidents to review during the last two quarters, did the provider must look back to 1/1/2023 to see if they had any serious incidents and provide the quarterly review for those?
* Did this review include an analysis of trends, potential systemic issues or causes, indicated remediation, and documentation of steps taken to mitigate the potential for future incidents?
* If there were no serious incidents within the past year, does the provider have documentation to reflect why a quarterly review was not completed?
* If there were no serious incidents within the past year, does not have a form to show what the provider would use to document serious incidents if they were to occur?
 | * If there is no proof of quarterly reviews of all serious incidents including.
* If the quarterly review does not include an analysis of trends, potential systemic issues or causes, indicated remediation, and documentation of steps taken to mitigate the potential for future incidents.
* If the provider has not had any serious incidents within the past year, and there is no documentation to reflect why a quarterly review was not completed.
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| **520.C.1** | The provider shall conduct systemic risk assessment reviews at least annually to identify and respond to practices, situations, and policies that could result in the risk of harm to individuals receiving services. The risk assessment review shall address at least the following:1. The environment of care
 | * Does the provider have a document that shows that they have identified and responded to practices, situations, and policies that could result in the risk of harm to individuals receiving services specific to the environment of care?
 | * If the provider does not have an annual SRA that shows that they have identified and responded to practices, situations and policies that could result in the risk of harm to individuals receiving services that addresses the environment of care.
* If the provider just includes the results of their safety inspection(s).
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| **520.C.2** | The provider shall conduct systemic risk assessment reviews at least annually to identify and respond to practices, situations, and policies that could result in the risk of harm to individuals receiving services. The risk assessment review shall address at least the following:2. Clinical assessment or reassessment processes | * Does the provider have a document that shows that they have identified and responded to practices, situations, and policies that could result in the risk of harm to individuals receiving services specific to clinical assessment or reassessment processes?
 | * If the provider does not have an annual SRA that shows that they have identified and responded to practices, situations and policies that could result in the risk of harm to individuals receiving services that addresses Clinical assessment or reassessment processes.
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| **520.C.3** | The provider shall conduct systemic risk assessment reviews at least annually to identify and respond to practices, situations, and policies that could result in the risk of harm to individuals receiving services. The risk assessment review shall address at least the following:3. Staff competence and adequacy of staffing | * Does the provider have a document that shows that they have identified and responded to practices, situations, and policies that could result in the risk of harm to individuals receiving services specific to staff competence and adequacy of staffing?
 | * If the provider does not have an annual SRA that shows that they have identified and responded to practices, situations and policies that could result in the risk of harm to individuals receiving services that addresses staff competence and adequacy of staffing.
* If the provider does not address both staff competence and adequacy of staffing.
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| **520.C.4** | The provider shall conduct systemic risk assessment reviews at least annually to identify and respond to practices, situations, and policies that could result in the risk of harm to individuals receiving services. The risk assessment review shall address at least the following:4. Use of high risk procedures, including seclusion and restraint; and | * Does the provider have a document that shows that they have identified and responded to practices, situations, and policies that could result in the risk of harm to individuals receiving services specific to the use of high-risk procedures, including seclusion and restraint?
 | * If the provider does not have an annual SRA that shows that they have identified and responded to practices, situations and policies that could result in the risk of harm to individuals receiving services that addresses use of high-risk procedures, including seclusion and restraint.
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| **520.C.5** | * The provider shall conduct systemic risk assessment reviews at least annually to identify and respond to practices, situations, and policies that could result in the risk of harm to individuals receiving services. The risk assessment review shall address at least the following:
* 5. A review of serious incidents.
 | * Does the provider have a document that shows that they have completed a review of serious incidents including consideration of harms and risks identified and lessons learned from the provider’s quarterly reviews of all serious incidents conducted pursuant to 12VAC35-105-160.C?
* Does this include an analysis of trends, from incidents and investigations, potential systemic issues or causes, indicated remediation, and documentation of steps taken to mitigate the potential for future incidents?
* Is there documented evidence that data is being tracked in order to evaluate trends and patterns over time?
* If there is a year of data, did the provider use this baseline data to assess the effectiveness of their Risk Management System?
 | * If the provider does not use data at the individual and/or provider level, including at minimum data from incidents and investigations, to identify and address trends and patterns of harm and risk of harm (defined as care concerns) in the events reported.
* If there is no evidence that the provider is tracking data in order to evaluate trends and patterns over time, including year-over-year as applicable.
* If after a year of tracking data, the provider did not use this baseline data to assess the effectiveness of their Risk Management System.
* If the provider did not use their data to summarize findings and make recommendations which may include remediation and planned/implemented steps taken to mitigate the potential for future incidents.
* **If the LS determines the provider did not meet any of the requirements listed above and are “Non-Compliant” then the LS must clearly document in the citation the specific reason for noncompliance addressing each area as indicated above.**
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| **520.D** | The systemic risk assessment process shall incorporate uniform risk triggers and thresholds as defined by the department. | * Can the provider demonstrate that care concerns were reviewed? Their process should outline what would occur if a threshold was met.
* How did they document if there was a need or no need for further action?
* If the provider determined further action was needed, did it occur?
* How are they monitoring to see if their action mitigated further risks?
* If the provider has not had any care concerns, does their systemic risk assessment review process would still need to outline how they would address care concerns if they were to occur?
* Did the provider utilize CHRIS to generate reports on incidents that have been identified as Care Concern Thresholds?
 | * The LS can use CONNECT to determine if the DD service met the care concern threshold. The LS must run the *Individual Care Concern by Provider Query*. The LS should go back to of the 1/1/2023 to the current inspection date.
* If the provider’s systemic risk assessment does not include a review of care concerns.
* If the provider did not document if further action was needed or not.
* If the provider determined further action was needed but there is no documentation that action was taken.
* If they are not monitoring their actions to mitigate further risks.
* If a provider has not had any care concerns, their systemic risk assessment review process would still need to outline how they would address care concerns if they were to occur. If the provider outlines how they would address care concerns if they were to occur, then the provider would be marked Compliant. If it does not, then the provider would be marked Non-Compliant.
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**Regarding 520.B-E, if the provider is Non-Compliant with any component of these regulations, then one of the following statements shall be included:**

If the provider **HAS completed the required risk management training**, the recommendation will include the following language:

*The licensing specialist recommends the provider review regulation 12VAC35-105-520 as well as the Guidance for Risk Management (August 2020). Based on the provider’s Attestation of Risk Management Training, the provider will not be required to take the training again.*

**OR**

If the provider **HAS NOT completed the required risk management training**, the citation will include the following language:

*The licensing specialist recommends the provider review regulation 12VAC35-105-520 as well as the Guidance for Risk Management (August 2020). As part of the provider’s Corrective Action Plan (CAP): 1. The provider’s designated person responsible for risk management shall complete the required risk management training (see Crosswalk of DBHDS Approved Risk Management Training and Risk Management Attestation); 2. The provider will need to submit the completed DBHDS Risk Management (RM) Attestation with the CAP as evidence of compliance; and 3. The CAP must include a detailed description/specific steps indicating how the provider is using the training in order to address this specific area of non-compliance*.