# Proposed Regulation
# Agency Background Document

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| **Agency name** | Department of Behavioral Health and Developmental Services |
| **Virginia Administrative Code (VAC) citation(s)** | 12 VAC35-105 |
| **Regulation title(s)** | Rules and Regulations For Licensing Providers by the Department of Behavioral Health and Developmental Services |
| **Action title** | Compliance with Virginia's Settlement Agreement with US DOJ |
| **Date this document prepared** | ~~March 1, 2019~~ October 17, 2019 |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

## Brief Summary

*Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.*

This proposed regulatory action was initiated through an emergency/NOIRA in accordance with § 2.2-4011 A of the Code of Virginia. An emergency regulation was approved by the Governor effective September 1, 2018. The intent of this regulatory action is to ensure compliance with the requirements of the Settlement Agreement between the United States Department of Justice and Virginia (*United States of America v. Commonwealth of Virginia*, Civil Action No. 3:12cv059-JAG) ("Settlement Agreement"), which includes provisions of quality and risk management. Quality improvement measures are required of CSBs for services they provide, but are not currently in the DBHDS Licensing Regulations for other providers. The proposed amendments will provide clarifications to, and expand the requirements for, the quality practices for the health, safety, care, and treatment of adults who receive services from service providers.

## Acronyms and Definitions

*Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.*

"Department" or "DBHDS" means the Department of Behavioral Health and Developmental Services.
"State Board" means the State Board of Behavioral Health and Developmental Services.

## Mandate and Impetus

*Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, board decision, etc.). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."*

The purpose of this regulation is to comply with requirements of the Settlement Agreement. This proposed regulatory action was initiated through an emergency/NOIRA in compliance with Code of Virginia § 2.2-4011 A.

The Independent Reviewer has stated that without revisions to the Licensing Regulations, the Commonwealth will continue to be unable to come into compliance with the quality and risk management provisions of the Settlement Agreement. In his 11th Report to the Court, the Independent Reviewer stated:

> *The DBHDS Licensing Regulations have long been, and continue to be, an obstacle to substantial progress toward compliance with many provisions of the Settlement Agreement... Its most recent draft revisions to the Licensing Regulations, dated July 17, 2017, [correction: dated July 7, 2017] show an improved alignment with some provisions of the Agreement, including a clarification of expectations around root cause analysis, risk triggers and thresholds, risk management programs and quality improvement programs. … It is the Independent Reviewer's considered opinion that, without revisions to its Licensing Rules and Regulations, the Commonwealth will continue to be unable to make substantial progress toward implementing the required quality and risk management system…*

The emergency regulation established requirements needed immediately to address concerns related to the health and safety of individuals receiving services from providers of services, other than Children's Residential Facilities, licensed by the Department of Behavioral Health and Developmental Services. The purpose of this regulation is to comply with requirements of the Settlement Agreement. The Settlement Agreement includes provisions requiring development and implementation of quality and risk management processes.

This regulatory action addresses several items that have been cited by the Independent Reviewer as obstacles to compliance with the provisions of the Settlement Agreement, facilitates the submission of necessary information by providers after a serious incident occurs and the development of the required quality and risk management processes, and strengthens case management services as required by the Settlement Agreement.

Specifically, the amendments (i) enhance the requirements of providers for establishing effective risk management and quality improvement processes by requiring the person leading risk management activities to have training and expertise in investigations, root cause analysis, and data analysis; requiring

annual risk assessments, to include review of the environment, staff competence, seclusion and restraint, serious incidents, and risk triggers and thresholds; and requiring a quality improvement plan that is reviewed and updated at least annually; (ii) improve reporting of serious incidents and injuries to allow the Commonwealth to obtain more consistent data regarding the prevalence of serious incidents by establishing three levels of incidents and requiring providers to report on and conduct root cause analysis of more serious incidents and to track and monitor less serious incidents; and (iii) strengthen expectations for case management by adding assessment for unidentified risks, status of previously identified risks, and assessing whether the risk management plan is being implemented appropriately and remains appropriate for the individual.

Since the Settlement Agreement was signed, the definition of “developmental services” was expanded to make providers of services for individuals with developmental disabilities subject to licensure rather than providers of services for individuals with only intellectual disabilities, and changes have been made to Medicaid waivers recently. Both of these developments impact the amendments in this action.

## Legal Basis

*Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity’s overall regulatory authority.*

Section 37.2-203 of the Code of Virginia authorizes the Board to adopt regulations that may be necessary to carry out the provisions of Title 37.2 and other laws of the Commonwealth administered by the commissioner and the department. In compliance with § 2.2-4011 A, consultation was requested of, and a letter received from, the Office of the Attorney General stating that the Board has the authority to adopt the amendments to the Licensing Regulations as emergency regulations, with approval of the Governor. An emergency regulation was approved by the Governor effective September 1, 2018. The emergency regulation established requirements needed immediately to address the concerns of health and safety of individuals receiving services from DBHDS-licensed providers of services, other than Children’s Residential services. This proposed regulatory action is the next step in the process for permanent adoption.

## Purpose

*Please explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it’s intended to solve.*

The purpose of this regulatory action is to address several items that have been cited by the Independent Reviewer as obstacles to compliance with the provisions of the Settlement Agreement. This regulatory action will facilitate the submission of necessary information by providers after a serious incident occurs, the development of the required quality and risk management processes, and strengthen case management services as required by the Settlement Agreement.

Specifically these amendments will:

- Enhance the requirements of providers for establishing effective risk management and quality improvement processes:
    - Requires the person leading risk management activities to have training and experience in investigations, root cause analysis, and data analysis;
    - Requires annual risk assessments, to include review of the environment, staff competence,

seclusion and restraint; serious incidents; and risk triggers and thresholds;
    - Requires policies and procedures for a quality improvement program which includes a quality improvement plan that is reviewed and updated at least annually; and
    - Requires providers to conduct a root cause analysis 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.
- Improve reporting of serious incidents and injuries to allow the Commonwealth to obtain more consistent data regarding the prevalence of serious incidents:
    - Establishes three levels of incidents; requires providers to report on and conduct root cause analysis of more serious incidents that occur within the provision of the providers services or on their property, and to track and monitor serious incidents:
        - Level I: incidents without injury, but potential for harm (tracked, but not reported);
        - Level II: serious injuries, an individual who is or was missing, unplanned hospitalizations, choking incidents that require direct physical intervention by another person, ingestion of hazardous materials; diagnosis of decubitus ulcers, bowel obstructions, or aspiration pneumonia (reported when they occur during provision of service or on the provider premises); and
        - Level III: deaths, sexual assaults, suicide attempts resulting in hospitalization (reported regardless of where they occurred within the provision of the provider's services or on their premises).
- Strengthened expectations for case management by adding assessment for unidentified risks, status of previously identified risks, whether the plan is being implemented appropriately and remains appropriate for the individual.

## Substance

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.*

Please see below the chart for changes to existing sections. DBHDS has determined that these changes will be beneficial to the population served because they are essential to the health, safety, and welfare of individuals served and because there will be enhanced requirements for providers to establish effective risk management and quality improvement processes, improved reporting of serious incidents and injuries to allow the Commonwealth to obtain more consistent data regarding the prevalence of serious incidents, and strengthened expectations for case management to ensure the individual's plan is appropriate and implemented correctly and that potential risks are identified. DBHDS has narrowly focused the amendments for this action to only address the concerns of the Independent Reviewer so as not to unduly impact the system.

## Issues

*Please identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.*

The amendments to the Licensing Regulations are essential to the health, safety, and welfare of individuals served because there will be enhanced requirements for providers to establish effective risk management and quality improvement processes, and to have improved reporting of serious incidents and injuries to allow the Commonwealth to obtain more consistent data regarding the prevalence of

serious incidents; and, strengthen expectations for case management to ensure the individual's plan is appropriate and implemented correctly and that potential risks are identified for individuals.

## Requirements More Restrictive than Federal

*Please identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.*

There are no requirements more restrictive than applicable federal requirements.

## Agencies, Localities, and Other Entities Particularly Affected

*Please identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.*

Other State Agencies Particularly Affected

The Department of Medical Assistance Services (DMAS) regulations and funding streams are complementary to these regulations and the licensed services they address.

Localities Particularly Affected

There are no localities particularly affected.

Other Entities Particularly Affected

Any person, entity, or organization offering services that are licensed, funded, or operated by the department.

## Economic Impact

*Pursuant to § 2.2-4007.04 of the Code of Virginia, please identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that this is change versus the status quo.*

**Impact on State Agencies**

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| *For your agency*: projected costs, savings, fees or revenues resulting from the regulatory change, including:<br>a) fund source / fund detail;<br>b) delineation of one-time versus on-going | There are no projected costs to the Department of Behavioral Health and Developmental Services. Any costs related to provider reporting in the proposed regulation can be absorbed through current staff. |

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| expenditures; and<br>c) whether any costs or revenue loss can be absorbed within existing resources | |
| *For other state agencies*: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures. | None. |
| *For all agencies:* Benefits the regulatory change is designed to produce. | The proposed regulatory change will allow DBHDS to comply with the Settlement Agreement, saving the Commonwealth time and resources due to litigation. |

**Impact on Localities**

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| Projected costs, savings, fees or revenues resulting from the regulatory change. | Many community services boards provide ID/DD services and will be affected similarly to private providers (see "impact on other entities"). |
| Benefits the regulatory change is designed to produce. | The proposed regulations will allow more targeted reporting to DBHDS by providers, freeing up valuable staff time, while putting more preventive measures in place for the safety of individuals receiving services. |

**Impact on Other Entities**

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| Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect. | All providers of DBHDS licensed services, other than children's residential facilities. |
| Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that:<br>a) is independently owned and operated and;<br>b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million. | Approximately 1,100 service providers licensed by DBHDS will be affected by this regulatory action. This is all of the DBHDS licensed service providers except for the licensed children's residential facility providers who will not be affected by this regulatory action. |
| All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to:<br>a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses;<br>b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change;<br>c) fees;<br>d) purchases of equipment or services; and<br>e) time required to comply with the requirements. | Many of the functions included in the proposed regulations are already being done on a smaller scale by providers, meaning there is already staff in place to support this work.<br><br>Under the proposed changes to the "fire safety" section of the code, 12VAC35-10-320 and 12VAC35-105-590, providers are required to evaluate each individual in their care and provide appropriate environmental supports and adequate staff to safely evacuate all individuals during an emergency. This could potentially create a need for providers to hire additional staff to meet this requirement, but it is likely that most providers already have adequate staff for this purpose. |

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| | Under code section 12VAC35-105-520, providers are also responsible for designating a member of their staff for risk management. That person must have training and expertise in conducting investigations, root cause analysis, and data analysis. This individual will likely be responsible for conducting root cause analyses in the event of a Level II or Level III serious incident that occur during the provision of a service or on the provider's premises. Hiring such an individual may require a salary increase for current staff, though the exact amount is unknown.<br><br>Additionally, providers must 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. These risk assessment reviews will require additional staff time and resources, but may or may not be absorbed by existing staff. |
| Benefits the regulatory change is designed to produce. | The proposed regulations will allow more targeted reporting to DBHDS by providers, freeing up valuable staff time, while putting more preventive measures in place for the safety of patients. |

## Alternatives

*Please describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.*

There are no alternatives to these regulatory changes.

## Regulatory Flexibility Analysis

*Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.*

There are no other alternative regulatory methods, consistent with health, safety, environmental, and

economic welfare, that will accomplish the objectives of applicable law that will assure the Commonwealth's compliance with the requirements of the Settlement Agreement. Please see the Independent Reviewer's 11th Report to the Court in which he stated the following: "The DBHDS Licensing Regulations have long been, and continue to be, an obstacle to substantial progress toward compliance with many provisions of the Settlement Agreement." The proposed regulatory changes are intended to establish requirements needed to address concerns related to the health and safety of individuals receiving services from DBHDS-licensed providers of services, other than Children's Residential services.

There are no exemptions of small providers from all or any part of the requirements contained in the regulatory change.

## Periodic Review and Small Business Impact Review Report of Findings

*If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, please indicate whether the regulatory change meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable.*

*In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.*

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Neither a periodic review nor a small business impact review was conducted related to this action.

## Public Comment

*Please summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. If no comment was received, enter a specific statement to that effect.*

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The following amendments were made to the language of the regulatory action in order to address issues raised in comments received during the NOIRA public comment period as well as concerns relayed directly to licensing staff since the Emergency Regulations became effective on September 1, 2018.

**1)** 12VAC35-105-20. Definitions.
  - **a.** Level II serious incident
    - i. An individual who is or was missing;
      - Language was added to clarify that providers should report if an individual is or was missing. Based on the effective Emergency Regulations, which state "an individual who is missing" providers were not sure whether they should report that an individual went missing if the individual was found before the provider had the opportunity to report the incident. The proposed language

now states that a Level II serious incident includes an individual who is or was missing.

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

- The department received comments during both the NOIRA public comment period as well as the public comment period for the DBHDS Office of Licensing Guidance for Serious Incident Reporting that the language stating a provider should report an emergency room visit or urgent care facility visit when not used in lieu of a primary care physician visit was confusing. Providers stated it was difficult to determine when an emergency room visit or urgent care facility visit was used in lieu of a primary care physician visit. The department agreed and this language was removed from the definition.

**b.** Level III serious incident

i. ~~3. A serious injury of an individual that results in or likely will result in permanent physical or psychological impairment;~~

- This language was removed entirely in the proposed language of the regulations based on comments received during the public comment period. Commenters felt that this standard (results in or likely will result in) was subjective and created an undue burden on providers for reporting injuries which occurred outside of the provision of the provider's services and may have no relation at all to the services the individual receives or the OL regulations. Serious injuries that occur within the provision of services or on the provider's premises will still be reported as Level II serious incidents (serious injury).

**c.** Suicide attempt –

- A definition was added for the term "suicide attempt." Public comment and feedback to licensing staff from providers expressed the desire to have a concrete definition for a suicide attempt as providers are required to report a suicide attempt that results in a hospital admission by an individual admitted for services as a Level III serious incident. This definition is a minorly amended version of the Centers for Disease Control and Prevention definition of suicide attempt.

**2)** 12VAC35-105-160. Reviews by the department; requests for information; required reporting.

**a.** 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. The root cause analysis shall include at least the following information: (i) a detailed description of what happened; (ii) 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 (iii) identified solutions to mitigate its reoccurrence~~.~~ when applicable. A more detailed root cause analysis, including convening a team, collecting and analyzing data, mapping processes, and charting causal factors should be considered based upon the circumstances of the incident.

- This requirement was amended in the proposed language of the regulations in response to public comments stating the requirement to conduct a root cause analysis (RCA) on Level III serious incidents that occur outside of the provision of the provider's services and off the provider's premises is unduly burdensome to the provider. In addition, providers generally will have limited knowledge of the incident as it occurred outside of their services and therefore conducting a meaningful RCA may be difficult. The language in the proposed language states that providers shall only conduct a root cause analysis 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.

Please see the attached document detailing specific comments received by DBHDS during the public comment period along with the agency response.

## Public Participation

*Please include a statement that in addition to any other comments on the regulatory change, the agency is seeking comments on the costs and benefits of the regulatory change and the impacts of the regulated community. Also, indicate whether a public hearing will be held to receive comments.*

In addition to any other comments, the State Board of Behavioral Health and Developmental Services is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: 1) projected reporting, recordkeeping and other administrative costs; 2) probable effect of the regulation on affected small businesses; and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments for the public comment file may do so from November 11, 2019 - through January 10, 2020, through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Written comments must include the name and address of the commenter. Comments may also be submitted by mail, email, or fax to Emily Bowles, Assistant Director for Licensing, Quality, Regulatory Compliance, and Training, DBHDS Office of Licensing, 1220 Bank Street, P.O. Box 1797, Richmond, VA 23218-1797; or email emily.bowles@dbhds.virginia.gov; phone (804) 225-3281, fax (804) 692-0066, TDD: (804) 371-8977. In order to be considered, comments must be received by 11:59 pm on January 10, 2020.

**A public hearing is scheduled** following the publication of this stage, and notice of the hearing is posted on the Virginia Regulatory Town Hall website (https://townhall.virginia.gov) and on the Commonwealth Calendar website (https://commonwealthcalendar.virginia.gov/). Both oral and written comments may be submitted at that time.

| **Date / Time** | 11/18/2019 10:00 am |
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| **Location** | (New) Fairfield Area Library, FA Meeting Room<br>1401 N Laburnum Ave, Richmond, VA 23223<br>10 a.m. - 12 p.m.<br>• Link here for details. |

## Detail of Changes

*Please list all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation.*

*If the regulatory change will be a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory change. Delete inapplicable tables.*

*If the regulatory change is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below. Please include citations to the specific section(s) of the regulation that are changing.*

For changes to existing regulation(s), please use the following chart:

| Current section number | Proposed new section number, if applicable | Current requirement | Proposed change, intent, and likely impact of proposed requirements |
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| 20 | | "Day support service" means structured programs of activity or training services for adults with an intellectual disability or a developmental disability, generally in clusters of two or more continuous hours per day provided to groups or individuals in nonresidential community-based settings…."<br><br>"Developmental disabilities" means autism or a severe, chronic disability that meets all of the following conditions identified in 42 CFR 435.1009:<br>1. Attributable to cerebral palsy, epilepsy, or any other condition, other than mental illness, that is found to be closely related to mental retardation (intellectual disability) because this condition results in impairment of general intellectual functioning or adaptive behavior similar to behavior of individuals with mental retardation (intellectual disability) and requires treatment or services similar to those required for these individuals;<br>2. Manifested before the individual reaches age 18;<br>3. Likely to continue indefinitely; and<br>4. Results in substantial functional limitations in three or more of the following areas of major life activity:<br>a. Self-care;<br>b. Understanding and use of language;<br>c. Learning;<br>d. Mobility;<br>e. Self-direction; or<br>f. Capacity for independent living.<br><br>N/A<br><br>N/A | • Removes "activity or training service" language and replaces, with training, assistance, and specialized supervision in the acquisition, retention or improvement of self-help, socialization, and adaptive skills.<br><br>• Definition of "developmental disabilities" was amended to match Code of Virginia Title 37.2.<br><br>• Addition of a general definition for "developmental services" from Code of Virginia Title 37.2.<br><br>• Addition of a general definition for "direct care position." |

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| | | N/A | • Addition of a general definition for “informed choice.” |
| | | N/A | "Informed choice" means a decision made after considering options based on adequate and accurate information and knowledge. These options are developed through collaboration with the individual and his authorized representative, as applicable, and the provider with the intent of empowering the individual and his authorized representative to make decisions that will lead to positive service outcomes. |
| | | N/A | • Addition of a general definition for “informed consent” which matches the definition of informed consent from the Human Rights Regulations (12VAC35-115-30).<br><br>"Informed consent" means the voluntary written agreement of an individual, or that individual's authorized representative, to surgery, electroconvulsive treatment, use of psychotropic medications, or any other treatment or service that poses a risk of harm greater than that ordinarily encountered in daily life or for participation in human research. To be voluntary, informed consent must be given freely and without: undue inducement; any element of force, fraud, deceit, or duress; or, any form of constraint or coercion. |
| | | “Mental retardation (intellectual disability)" means a disability originating before the age of 18 years…. | • Change the term to “intellectual disability” to reflect § 37.2-100 of the Code of Virginia. |
| | | N/A | • Addition of a definition for “intermediate care facility/individuals with intellectual disability.”<br><br>"Intermediate care facility/individuals with intellectual disability" or "ICF/IID" means a facility or distinct part of a facility certified by the Virginia Department of Health as meeting the federal certification regulations for an intermediate care facility for individuals with intellectual disability and persons with related conditions and that addresses the total needs of the residents, which include physical, intellectual, social, emotional, and habilitation providing active treatment as |

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| | | | defined in 42 CFR 435.1010 and 42 CFR 483.440. |
| | | N/A | • Addition of a definition for "missing."<br><br>"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. |
| | | "Qualified Mental Retardation Professional (QMRP)" means a person who possesses at least … | • Change the term to Qualified Developmental Disability Professional (QDDP) to reflect § 37.2-100 of the Code of Virginia. |
| | | N/A | • Addition of a definition for "quality improvement plan."<br><br>"Quality improvement plan" means a detailed work plan developed by a provider that defines steps the provider will take to review the quality of services it provides and to manage initiatives to improve quality. It consists of systematic and continuous actions that lead to measurable improvement in the services, supports, and health status of the individuals receiving services. |
| | | N/A | • Addition of a definition for "risk management."<br><br>"Risk management" means an integrated system-wide program to ensure the safety of individuals, employees, visitors, and others through identification, mitigation, early detection, monitoring, evaluation, and control of risks. |
| | | N/A | • Addition of general definition of "root cause analysis."<br><br>"Root cause analysis" means 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. |
| | | N/A | • Addition of a definition for "serious incident." The definition of serious incident now includes the definition of serious injury. Serious incidents are broken down by levels which correspond |

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| | | | with additional requirements for reporting and root cause analysis within 12VAC35-105-160 and 12VAC35-105-160.<br><br>"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" also includes a significant harm or threat to the health or safety of others caused by an individual. "Level II serious incidents" include:<br>1. A serious injury;<br>2. An individual who is missing;<br>3. An emergency room or urgent care facility visit when not used in lieu of a primary care physician visit;<br>4. An unplanned psychiatric or unplanned medical hospital admission;<br>5. Choking incidents that require direct physical intervention by another person;<br>6. Ingestion of any hazardous material.<br>7. A diagnosis of:<br>a. A decubitus ulcer or an increase in severity of level of previously diagnosed decubitus ulcer;<br>b. A bowel obstruction; or<br>c. Aspiration pneumonia.<br>"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:<br>1) Any death of an individual;<br>2) A sexual assault of an individual;<br>3) A serious injury of an individual that results in or likely will result in permanent physical or psychological impairment;<br>4) A suicide attempt by an individual |

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| | | N/A | admitted for services that results in a hospital admission.<br><br>• Addition of a definition for "systemic deficiency."<br><br>"Systemic deficiency" means violations of regulations documented by the department that demonstrate multiple or repeat defects in the operation of one or more services. |
| 30 | | | • Amend language to align with the Code of Virginia Title 37.2 and the Centers for Medicare & Medicaid Services. |
| 50 | | D. A license shall not be issued or renewed unless the provider is affiliated with a local human rights committee. | • Amend language to align with Code of Virginia Title 37.2.<br>• Remove the following language to reflect changes to the Human Rights Regulations (12VAC35-115-30): ~~A license shall not be issued or renewed unless the provider is affiliated with a local human rights committee.~~ |
| 120 | | The commissioner may grant a variance to a specific regulation if he determines that such a variance will not jeopardize the health, safety or welfare of individuals and upon demonstration by the provider requesting such variance that complying with the regulation would be a hardship unique to the provider. A provider shall submit a request for a variance in writing to the commissioner. A variance may be time limited or have other conditions attached to it. The department must approve a variance prior to implementation. | • Clarifying amendments:<br>The commissioner may grant a variance to a specific regulation if he determines that such a variance will not jeopardize the health, safety, or welfare of individuals. A provider shall submit a request for ~~and upon demonstration by the provider requesting~~ such variance in writing to the commissioner. The request shall demonstrate that complying with the regulation would be a hardship unique to the provider and that the variance will not jeopardize the health, safety, or welfare of individuals. The department may limit the length of time a variance will be effective. ~~A provider shall submit a request for a variance in writing to the commissioner. A variance may be time limited or have other conditions attached to it. The department must approve a variance prior to implementation.~~ The provider shall not implement a variance until it has been approved in writing by the commissioner. |
| 150 | | The provider including its employees, contractors, students, and volunteers shall comply with:<br>1. These regulations;<br>2. The terms and stipulations of the license;<br>3. All applicable federal, state, or local laws and regulations including:<br>a. Laws regarding employment | • After 3(b) amend, in accordance with CMS Final Rule, to include:<br>For home and community-based services waiver settings subject to these regulations, 42 CFR § 441.301(c)(1)-(4) Home and Community-Based Services: Waiver Requirements (for person-centered planning and community-based |

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| | | practices including the Equal Employment Opportunity Act;<br>b. The Americans with Disabilities Act and the Virginians with Disabilities Act;<br>c. Occupational Safety and Health Administration regulations;<br>d. Virginia Department of Health regulations;<br>e. Laws and regulations of the Virginia Department of Health Professions regulations;<br>f. Virginia Department of Medical Assistance Services regulations;<br>g. Uniform Statewide Building Code; and<br>h. Uniform Statewide Fire Prevention Code. | settings); |
| 155 | | | • Replace "mental retardation (intellectual disability)" with the term "developmental disability" in accordance with Code of Virginia Chapter 37.2. |
| 160 | | | • Amend to require the provider to review all Level 1 serious incidents, at least once per quarter. This requirement enhances the requirements of providers for establishing effective risk management and quality improvement processes as required by the Settlement Agreement.<br>• Amend to require a root cause analysis of Level II and Level III serious incidents. The requirement for the root cause analysis will help providers to identify trends and prevent the reoccurrence of serious incidents as part of the quality improvement plan.<br>• Amend to align reporting of abuse, neglect, seclusion and restraint with the Office of Human Rights Regulations.<br>• Amend to require reporting of all level II and level III serious incidents to the department. Strengthened serious incident reporting will allow the Commonwealth to obtain more consistent data regarding the prevalence of serious incidents in accordance with the Settlement Agreement.<br><br>B. The provider shall cooperate fully with inspections and investigations, and shall provide all information requested ~~to assist representatives from~~ by the department ~~who conduct inspections~~.<br>C. The provider shall collect, maintain, and review at least quarterly all Level I |

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| | | B. The provider shall cooperate fully with inspections and provide all information requested to assist representatives from the department who conduct inspections.<br>C. The provider shall collect, maintain, and report or make available to the department the following information:<br>1. Each allegation of abuse or neglect shall be reported to the assigned human rights advocate and the individual's authorized representative within 24 hours from the receipt of the initial allegation. Reported information shall include the type of abuse, neglect, or exploitation that is alleged and whether there is physical or psychological injury to the individual.<br>2. Each instance of death or serious injury shall be reported in writing to the department's assigned licensing specialist within 24 hours of discovery and by phone to the individual's authorized representative within 24 hours. Reported information shall include the following: the date and place of the individual's death or serious injury; the nature of the individual's injuries and the treatment received; and the circumstances of the death or serious injury. Deaths that occur in a hospital as a result of illness or injury occurring when the individual was in a licensed service shall be reported.<br>3. Each instance of seclusion or restraint that does not comply with the human rights regulations or approved variances or that results in injury to an individual shall be reported to the individual's authorized representative and the assigned human rights advocate within 24 hours.<br>D. The provider shall submit, or make available, reports and information that the department requires to establish compliance with these regulations and | 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.<br>D. The provider shall collect, maintain, and report or make available to the department the following information:<br>1. Each allegation of abuse or neglect shall be reported to the ~~assigned human rights advocate and the individual's authorized representative within 24 hours from the receipt of the initial allegation. Reported information shall include the type of abuse, neglect, or exploitation that is alleged and whether there is physical or psychological injury to the individual~~ department as provided in 12VAC35-115-230 A.<br>2. ~~Each instance of death or serious injury~~ Level II and Level III serious incidents shall be reported using the department's web-based reporting application and by phone to anyone designated by the individual to receive such notice and to the individual's authorized representative ~~in writing to the department's assigned licensing specialist~~ within 24 hours of discovery ~~and by phone to the individual's authorized representative within 24 hours~~. Reported information shall include the information specified by the department as required in its web-based reporting application but at least the following: the date, ~~and~~ place, and circumstances of the ~~individual's death or serious injury~~ serious incident~~;~~. For serious injuries and deaths, the reported information shall also include the nature of the individual's injuries or circumstances of the death and ~~the~~ any treatment received~~; and the circumstances of the death or serious injury~~. 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. Deaths that occur in a hospital as a result of illness or injury occurring when the individual was in a licensed service shall be reported.<br>3. ~~Each instance~~ Instances of seclusion or restraint ~~that does not comply with the human rights regulations or approved variances or that results in injury to an individual shall be reported to the individual's authorized representative and the assigned~~ |

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| | | applicable statutes.<br>E. Records that are confidential under federal or state law shall be maintained as confidential by the department and shall not be further disclosed except as required or permitted by law; however, there shall be no right of access to communications that are privileged pursuant to § 8.01-581.17 of the Code of Virginia.<br>F. Additional information requested by the department if compliance with a regulation cannot be determined shall be submitted within 10 business days of the issuance of the licensing report requesting additional information. Extensions may be granted by the department when requested prior to the due date, but extensions shall not exceed an additional 10 business days.<br>G. Applicants and providers shall not submit any misleading or false information to the department.<br>12VAC35-105. | ~~human rights advocate~~ ~~within 24 hours~~ shall be reported to the department as provided in 12VAC35-115-230 C 4.<br>E. A root cause analysis shall be conducted by the provider within 30 days of discovery of Level II and Level III serious incidents. The root cause analysis shall include at least the following information: (i) a detailed description of what happened; (ii) 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 (iii) identified solutions to mitigate its reoccurrence.<br>~~D~~F. The provider shall submit, or make available, reports and information that the department requires to establish compliance with these regulations and applicable statutes.<br>~~E~~G. Records that are confidential under federal or state law shall be maintained as confidential by the department and shall not be further disclosed except as required or permitted by law; however, there shall be no right of access to communications that are privileged pursuant to § 8.01-581.17 of the Code of Virginia.<br>~~F~~H. Additional information requested by the department if compliance with a regulation cannot be determined shall be submitted within 10 business days of the issuance of the licensing report requesting additional information. Extensions may be granted by the department when requested prior to the due date, but extensions shall not exceed an additional 10 business days.<br>~~G~~I. Applicants and providers shall not submit any misleading or false information to the department. |
| 170 | | E. Upon receipt of the corrective action plan, the department shall review the plan and determine whether the plan is approved or not approved. The provider has an additional 10 business days to submit a revised corrective action plan after receiving a notice that the plan submitted has not been approved by the department. | • Amend to provide additional clarity of the next steps to follow if the department does not approve a provider's revised plan.<br><br>E. Upon receipt of the corrective action plan, the department shall review the plan and determine whether the plan is approved or not approved. The provider has an additional 10 business days to submit a revised corrective action plan after receiving a notice that ~~the plan submitted has not been approved by~~ the department has not approved the revised plan. If the submitted revised corrective action plan is still unacceptable, the provider shall follow the |

| | | | dispute resolution process identified in 12VAC35-105-170 F. |
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| 320 | | 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. | • Amend to remove the size limitation, and to require staff to assess each individual and based on the results of that assessment; ensure that the provider has adequate environmental supports and staff to safely evacuate each resident during an emergency. Also, amend to remove the exception for certain types of facilities.<br><br>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). 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. ~~This section does not apply to correctional facilities or home and noncenter-based or sponsored residential home services.~~ |
| 330 | | | • Amend language (~~A community ICF/MR~~ An ICF/IID) to align with the Centers for Medicare & Medicaid Services. |
| 400 | | A. Providers shall comply with the background check requirements for direct care positions outlined in §§ 37.2-416, 37.2-506, and 37.2-607 of the Code of Virginia for individuals hired after July 1, 1999.<br>B. Prior to a new employee beginning his duties, the provider shall obtain the employee's written consent and personal information necessary to obtain a search of the registry of founded complaints of child abuse and neglect maintained by the Virginia Department of Social Services.<br>C. The provider shall develop a written policy for criminal history and registry checks for all employees, contractors, | • Amend language to align with Code of Virginia Title 37.2 and 63.2.<br><br>A. Providers shall comply with the requirements for obtaining criminal history background ~~check~~ checks ~~requirements for direct care positions~~ as outlined in §§ 37.2-416, 37.2-506, and 37.2-607 of the Code of Virginia for individuals hired after July 1, 1999.<br>~~B. Prior to a new employee beginning his duties, the provider shall obtain the employee's written consent and personal information necessary to obtain a search of the registry of founded complaints of child abuse and neglect maintained by the Virginia Department of Social Services.~~<br>~~C.~~B. The provider shall develop a written policy for criminal history background checks and registry ~~checks~~ searches ~~for all employees, contractors, students, and volunteers~~. The policy shall require at a minimum a disclosure statement ~~from the employee, contractor, student, or volunteer~~ |

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| | | students, and volunteers. The policy shall require at a minimum a disclosure statement from the employee, contractor, student, or volunteer stating whether the person has ever been convicted of or is the subject of pending charges for any offense and shall address what actions the provider will take should it be discovered that an employee, student, contractor, or volunteer has a founded case of abuse or neglect or both, or a conviction or pending criminal charge.<br>D. The provider shall submit all information required by the department to complete the background and registry checks for all employees and for contractors, students, and volunteers if required by the provider's policy.<br>E. The provider shall maintain the following documentation:<br>1. The disclosure statement; and<br>2. Documentation that the provider submitted all information required by the department to complete the background and registry checks, memoranda from the department transmitting the results to the provider, and the results from the Child Protective Registry check. | stating whether the person has ever been convicted of or is the subject of pending charges for any offense and shall address what actions the provider will take should it be discovered that ~~an employee, student, contractor, or volunteer~~ person has a founded case of abuse or neglect or both, or a conviction or pending criminal charge.<br>~~D.~~C. The provider shall submit all information required by the department to complete the criminal history background checks and registry ~~checks~~ searches ~~for all employees and for contractors, students, and volunteers if required by the provider's policy~~.<br>~~E.~~D. The provider shall maintain the following documentation:<br>1. The disclosure statement from the applicant stating whether he has ever been convicted of or is the subject of pending charges for any offense; and<br>2. Documentation that the provider submitted all information required by the department to complete the criminal history background checks and registry ~~checks~~ searches, memoranda from the department transmitting the results to the provider, and the results from the Child Protective Registry ~~check~~ search. |
| 440 | | New employees, contractors, volunteers, and students shall be oriented commensurate with their function or job-specific responsibilities within 15 business days. The provider shall document that the orientation covers each of the following policies, procedures, and practices:<br>1. Objectives and philosophy of the provider;<br>2. Practices of confidentiality including access, duplication, and dissemination of any portion of an individual's record;<br>3. Practices that assure an individual's rights including orientation to human | • Amend to require providers to include serious incident reporting in orientation for new employees. This addition ensures that new employees are properly trained and aware of the department's reporting requirements, and that the Commonwealth receives all necessary information regarding serious incidents.<br><br>New employees, contractors, volunteers, and students shall be oriented commensurate with their function or job-specific responsibilities within 15 business days. The provider shall document that the orientation covers each of the following policies, procedures, and practices:<br>1. Objectives and philosophy of the provider;<br>2. Practices of confidentiality including access, duplication, and dissemination of any portion of an individual's record;<br>3. Practices that assure an individual's rights including orientation to human rights regulations;<br>4. Applicable personnel policies; |

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| | | rights regulations;<br>4. Applicable personnel policies;<br>5. Emergency preparedness procedures;<br>6. Person-centeredness;<br>7. Infection control practices and measures; and<br>8. Other policies and procedures that apply to specific positions and specific duties and responsibilities. | 5. Emergency preparedness procedures;<br>6. Person-centeredness;<br>7. Infection control practices and measures; and<br>8. Other policies and procedures that apply to specific positions and specific duties and responsibilities.<br>9. Serious incident reporting, including when, how, and under what circumstances a serious incident report must be submitted and the consequences of failing to report a serious incident to the department in accordance with these regulations. |
| 450 | | | • Amend to add "serious incident reporting" to those subjects a provider must ensure frequency of retraining as part of an overall training policy for staff.<br><br>The provider shall provide training and development opportunities for employees to enable them to support the individuals ~~served~~ receiving services and to carry out ~~the~~ their job responsibilities ~~of their jobs~~. The provider shall develop a training policy that addresses the frequency of retraining on serious incident reporting, medication administration, behavior intervention, emergency preparedness, and infection control, to include flu epidemics. Employee participation in training and development opportunities shall be documented and accessible to the department. |
| 460 | | There shall be at least one employee or contractor on duty at each location who holds a current certificate (i) issued by the American Red Cross, the American Heart Association, or comparable authority in standard first aid and cardiopulmonary resuscitation (CPR) or (ii) as an emergency medical technician. A licensed medical professional who holds a current professional license shall be deemed to hold a current certificate in first aid, but not in CPR. | • Amend to clarify that the certification process shall include a hands-on, in-person demonstration of first-aid and CPR.<br><br>There shall be at least one employee or contractor on duty at each location who holds a current certificate (i) issued by the American Red Cross, the American Heart Association, or comparable authority in standard first aid and cardiopulmonary resuscitation (CPR) or (ii) as an emergency medical technician. A licensed medical professional who holds a current professional license shall be deemed to hold a current certificate in first aid, but not in CPR. The certification process shall include a hands-on, in-person demonstration of first aid and CPR competency. |
| 520 | | | • Amend to require the person leading risk |

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| | | A. The provider shall designate a person responsible for risk management.<br>B. The provider shall implement a written plan to identify, monitor, reduce, and minimize risks associated with personal injury, infectious disease, property damage or loss, and other sources of potential liability.<br>C. The provider shall conduct and document that a safety inspection has been performed at least annually of each service location owned, rented, or leased by the provider. Recommendations for safety improvement shall be documented and implemented by the provider.<br>D. The provider shall document serious injuries to employees, contractors, students, volunteers, and visitors. Documentation shall be kept on file for three years. The provider shall evaluate injuries at least annually. Recommendations for improvement shall be documented and implemented by the provider. | management activities to have training in risk management, investigations, root cause analysis, and data analysis.<br>• Amend to require annual risk assessments, to include review of the environment, staff competence, seclusion and restraint; serious incidents; and risk triggers & thresholds.<br><br>A. The provider shall designate a person responsible for the risk management function who has training and expertise in conducting investigations, root cause analysis, and data analysis.<br>B. The provider shall implement a written plan to identify, monitor, reduce, and minimize ~~risks associated with~~ harms and risk of harm including personal injury, infectious disease, property damage or loss, and other sources of potential liability.<br>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: (i) the environment of care; (ii) clinical assessment or reassessment processes; (iii) staff competence and adequacy of staffing; (iv) use of high risk procedures, including seclusion and restraint; and (v) a review of serious incidents. This process shall incorporate uniform risk triggers and thresholds as defined by the department.<br>~~C~~ D. The provider shall conduct and document that a safety inspection has been performed at least annually of each service location owned, rented, or leased by the provider. Recommendations for safety improvement shall be documented and implemented by the provider.<br>~~D~~ E. The provider shall document serious injuries to employees, contractors, students, volunteers, and visitors that occur during the provision of a service or on the provider's property. Documentation shall be kept on file for three years. The provider shall evaluate serious injuries at least annually. Recommendations for improvement shall be documented and implemented by the provider. |
| 580 | | | • Amend language to align with Code of Virginia Title 37.2 and newly adopted person-centered language. |

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| 590 | | | • Amend language to align with Code of Virginia Title 37.2.<br>• Amend to include that providers must have sufficient staff to safely evacuate all individuals during an emergency in accordance with 12VAC35-105-320. |
| 620 | | The provider shall implement written policies and procedures to monitor and evaluate service quality and effectiveness on a systematic and ongoing basis. Input from individuals receiving services and their authorized representatives, if applicable, about services used and satisfaction level of participation in the direction of service planning shall be part of the provider's quality assurance system. The provider shall implement improvements, when indicated. | • Amend to require each provider develop and implement a quality improvement program in accordance with the Settlement Agreement. Amendments also include requirements for what each provider's quality improvement program shall include.<br><br>The provider shall develop and implement a quality improvement program sufficient to identify, ~~written policies and procedures to~~ monitor, and evaluate clinical and service quality and effectiveness on a systematic and ongoing basis. The program shall: (i) include a quality improvement plan that is reviewed and updated at least annually; (ii) establish measurable goals and objectives; (iii) include and report on statewide performance measures, if applicable, as required by DBHDS; (iv) utilize standard quality improvement tools, including root cause analysis; (v) implement a process to regularly evaluate progress toward meeting established goals and objectives; and (vi) incorporate any corrective action plans pursuant to 12VAC35-105-170. Input from individuals receiving services and their authorized representatives, if applicable, about services used and satisfaction level of participation in the direction of service planning shall be part of the provider's quality ~~assurance system~~ improvement plan. The provider shall implement improvements, when indicated. |
| 650 | | | • Amend language to align with Code of Virginia Title 37.2. |
| 660 | | B. The provider shall develop an initial person-centered ISP for the first 60 | • Amend to include language which ensures that an individual is able to make an informed choice in regards to decisions reflected in both the initial and comprehensive Individualized Services Plans (ISP). A provider must document that the necessary information was provided and why the individual chose the option included in the ISP.<br><br>B. The provider shall develop and implement an initial person-centered ISP for |

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| | | days for mental retardation (intellectual disability) and developmental disabilities services or for the first 30 days for mental health and substance abuse services. This ISP shall be developed and implemented within 24 hours of admission to address immediate service, health, and safety needs and shall continue in effect until the ISP is developed or the individual is discharged, whichever comes first.<br>C. The provider shall implement a person-centered comprehensive ISP as soon as possible after admission based upon the nature and scope of services but no later than 30 days after admission for providers of mental health and substance abuse services and 60 days after admission for providers of mental retardation (intellectual disability) and developmental disabilities services. | the first 60 days for ~~mental retardation (intellectual disability) and~~ developmental ~~disabilities~~ services or for the first 30 days for mental health and substance abuse services. This ISP shall be developed and implemented within 24 hours of admission to address immediate service, health, and safety needs and shall continue in effect until the ISP is developed or the individual is discharged, whichever comes first.<br>C. The provider shall implement a person-centered comprehensive ISP as soon as possible after admission based upon the nature and scope of services but no later than 30 days after admission for providers of mental health and substance abuse services and 60 days after admission for providers of ~~mental retardation (intellectual disability) and~~ developmental ~~disabilities~~ services.<br>D. The initial ISP and the comprehensive shall be developed based on the respective assessment with the participation and informed choice of the individual receiving services. To ensure the individual's participation and informed choice, the provider shall explain to the individual or his authorized representative, as applicable, in a reasonable and comprehensible manner, the proposed services to be delivered, alternative service or services that might be advantageous for the individual, and accompanying risks or benefits. The provider shall clearly document that this information was explained to the individual or his authorized representative and the reasons the individual or his authorized representative chose the option included in the ISP. |
| 665 | | | • Amend to include that the ISP shall be distributed to the individual and others authorized to receive it.<br><br>B. The ISP shall be signed and dated at a minimum by the person responsible for implementing the plan and the individual receiving services or the authorized representative in order to document agreement. If the signature of the individual receiving services or the authorized representative cannot be obtained, the provider shall document his attempt attempts to obtain the necessary signature and the reason why he was unable to obtain it. The ISP shall be distributed to the individual and others authorized to receive it. |

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| 675 | | A. Reassessments shall be completed at least annually and when there is a need based on the medical, psychiatric, or behavioral status of the individual.<br>B. The provider shall update the ISP at least annually. The provider shall review the ISP at least every three months from the date of the implementation of the ISP or whenever there is a revised assessment based upon the individual's changing needs or goals. These reviews shall evaluate the individual's progress toward meeting the plan's goals and objectives and the continued relevance of the ISP's objectives and strategies. The provider shall update the goals, objectives, and strategies contained in the ISP, if indicated, and implement any updates made. | • Amend to include that the ISP shall be updated any time assessments identify risks, injuries, needs, or change in status of the individual.<br>• Amend to include that ISP reviews shall include documentation of evidence of progression towards all goals and objectives.<br>• Amend to require that whenever a goal is not met by the target date, the treatment team members shall meet to review the reasons for lack of progress and provide the individual an opportunity to make an informed choice of how to proceed. This language was adopted from the Medicaid and CHIP Managed Care Final Rule.<br><br>A. Reassessments shall be completed at least annually and ~~when~~ any time there is a need based on changes in the medical, psychiatric, ~~or~~ behavioral, or other status of the individual.<br>B. Providers shall complete changes to the ISP as a result of the assessments.<br>C. The provider shall update the ISP at least annually and any time assessments identify risks, injuries, needs, or change in status of the individual.<br>D. The provider shall review the ISP at least every three months from the date of the implementation of the ISP or whenever there is a revised assessment based upon the individual's changing needs or goals.<br>1. These reviews shall evaluate the individual's progress toward meeting the ~~plan's~~ ISP's goals and objectives and the continued relevance of the ISP's objectives and strategies. The provider shall update the goals, objectives, and strategies contained in the ISP, if indicated, and implement any updates made.<br>2. These reviews shall document evidence of progression towards or achievement of a specific targeted outcome for each goal and objective.<br>3. For goals and objectives that were not accomplished by the identified target date, the provider and any appropriate treatment team members shall meet to review the reasons for lack of progress and provide the individual an opportunity to make an informed choice of how to proceed. |

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| 691 | | B. The transfer summary shall include at a minimum the following:<br>1. Reason for the individual's transfer;<br>2. Documentation of involvement by the individual or his authorized representative, as applicable, in the decision to and planning for the transfer; | • Replace term "involvement" with "informed consent" for clarification.<br><br>B. The transfer summary shall include at a minimum the following:<br>1. Reason for the individual's transfer;<br>2. Documentation of ~~involvement~~ informed choice by the individual or his authorized representative, as applicable, in the decision to and planning for the transfer; |
| 800 | | E. Injuries resulting from or occurring during the implementation of behavior interventions shall be recorded in the individual's services record and reported to the assigned human rights advocate and the employee or contractor responsible for the overall coordination of services. | • Amend to align with the regulatory reporting requirements in the Human Rights Regulations (12VAC35-115).<br><br>E. Injuries resulting from or occurring during the implementation of behavior interventions seclusion or restraint shall be recorded in the individual's services record and reported to the assigned human rights advocate and the employee or contractor responsible for the overall coordination of services department as provided in 12VAC35-115-230 C. |
| 830 | | | • Amend to include "emergency" before "behavior management" for clarification.<br><br>B. Devices used for mechanical restraint shall be designed specifically for emergency behavior management of human beings in clinical or therapeutic programs.<br>C. Application of time out, seclusion, or restraint shall be documented in the individual's record and include the following:<br>1. Physician's order for seclusion or mechanical restraint or chemical restraint;<br>2. Date and time;<br>3. Employees or contractors involved;<br>4. Circumstances and reasons for use including other emergency behavior management techniques attempted;<br>5. Duration;<br>6. Type of technique used; and<br>7. Outcomes, including documentation of debriefing of the individual and staff involved following the incident. |
| 1140 | | | • Amend language to align with Code of Virginia Title 37.2. |
| NEW | 1245 | | • Add new section with strengthened expectations for case management as required by the Settlement Agreement. The new expectations require case managers to assess for unidentified |

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| | | | risks, review the status of previously identified risks, assess whether the individual's plan is being implemented appropriately, and assess whether the individual's plan is still appropriate for the individual.<br><br>Case managers shall meet with each individual face-to-face as dictated by the individual's needs. At face-to-face meetings, the case manager shall (i) observe and assess for any previously unidentified risks, injuries, needs, or other changes in status; (ii) assess the status of previously identified risks, injuries, or needs, or other change in status; (iii) assess whether the individual's service plan is being implemented appropriately and remains appropriate for the individual; and (iv) assess whether supports and services are being implemented consistent with the individual's strengths and preferences and in the most integrated setting appropriate to the individual's needs. |
| 1250 | | | • Add additional requirement for case managers serving individuals with developmental disabilities to complete the DBHDS core competency-based curriculum within 30 days of hire to strengthen case management as required by the Settlement Agreement.<br><br>D. Case managers serving individuals with developmental disability shall complete the DBHDS core competency-based curriculum within 30 days of hire. |
| 1360 | | | • Amend language to align with Code of Virginia Title 37.2. |

## "Changes from the Emergency Regulation"

| Current section number | New section number, if applicable | Current requirement | Change, intent, rationale, and likely impact of new requirements |
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| 20 | | "Developmental disability" means a severe, chronic disability of an individual that (i) is attributable to a mental or physical impairment, or a combination of mental and physical impairments, other than a sole diagnosis of mental illness; (ii) is manifested before the individual reaches 22 years of age; (iii) is likely to continue indefinitely; (iv) results in substantial functional limitations in three or more of the following areas of major life activity: self-care, receptive and expressive language, learning, mobility, self-direction, capacity for independent living, or economic self-sufficiency; and (v) reflects the individual's need for a combination and sequence of special interdisciplinary or generic services, individualized supports, or other forms of assistance that are of lifelong or extended duration and are individually planned and coordinated. An individual from birth to age nine years, inclusive, who has a substantial developmental delay or specific congenital or acquired condition may be considered to have a developmental disability without meeting three or more of the criteria described in clauses (i) through (v) of this definition if the individual, without services and supports, has a high probability of meeting those criteria later in life. | • Removes "of this definition" language behind (v).<br><br>"Developmental disability" means a severe, chronic disability of an individual that (i) is attributable to a mental or physical impairment, or a combination of mental and physical impairments, other than a sole diagnosis of mental illness; (ii) is manifested before the individual reaches 22 years of age; (iii) is likely to continue indefinitely; (iv) results in substantial functional limitations in three or more of the following areas of major life activity: self-care, receptive and expressive language, learning, mobility, self-direction, capacity for independent living, or economic self-sufficiency; and (v) reflects the individual's need for a combination and sequence of special interdisciplinary or generic services, individualized supports, or other forms of assistance that are of lifelong or extended duration and are individually planned and coordinated. An individual from birth to age nine years, inclusive, who has a substantial developmental delay or specific congenital or acquired condition may be considered to have a developmental disability without meeting three or more of the criteria described in clauses (i) through (v) ~~of this definition~~ if the individual, without services and supports, has a high probability of meeting those criteria later in life. |
| | | "Program of Assertive Community Treatment service" means a self-contained interdisciplinary team of at least 10 full-time equivalent clinical staff, a program assistant, and a full-time or part-time psychiatrist that: | • Added the abbreviation, PACT, to the general definition of program of assertive community treatment. |

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| | | 1. Assumes responsibility for directly providing needed treatment, rehabilitation, and support services to identified individuals with severe and persistent mental illnesses, including those who have severe symptoms that are not effectively remedied by available treatments or who because of reasons related to their mental illness resist or avoid involvement with mental health services;<br>2. Minimally refers individuals to outside service providers;<br>3. Provides services on a long-term care basis with continuity of caregivers over time;<br>4. Delivers 75% or more of the services outside program offices; and<br>5. Emphasizes outreach, relationship building, and individualization of services. | "Program of ~~A~~assertive ~~C~~community ~~T~~treatment service" or "PACT service" means a self-contained interdisciplinary team of at least 10 full-time equivalent clinical staff, a program assistant, and a full-time or part-time psychiatrist that: 1. Assumes responsibility for directly providing needed treatment, rehabilitation, and support services to identified individuals with severe and persistent mental illnesses, including those who have severe symptoms that are not effectively remedied by available treatments or who because of reasons related to their mental illness resist or avoid involvement with mental health services;<br>2. Minimally refers individuals to outside service providers;<br>3. Provides services on a long-term care basis with continuity of caregivers over time;<br>4. Delivers 75% or more of the services outside program offices; and<br>5. Emphasizes outreach, relationship building, and individualization of services. |
| | | "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. | • Addition of "or was missing" under Level II serious incident to clarify that providers should report an individual who is or was missing as a Level II serious incident.<br>• Removed "or urgent care facility visit when not used in lieu of a primary care physician visit language." Providers are now required to report an emergency room visit as a Level II serious incident.<br>• Removed language requiring providers to report a serious injury of an individual that results in or likely will result in permanent physical or |

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| | | "Level II serious incident" also includes a significant harm or threat to the health or safety of others caused by an individual. "Level II serious incidents" include:<br>1. A serious injury;<br>2. An individual who is missing;<br>3. An emergency room or urgent care facility visit when not used in lieu of a primary care physician visit;<br>4. An unplanned psychiatric or unplanned medical hospital admission;<br>5. Choking incidents that require direct physical intervention by another person;<br>6. Ingestion of any hazardous material.<br>7. A diagnosis of:<br>a. A decubitus ulcer or an increase in severity of level of previously diagnosed decubitus ulcer;<br>b. A bowel obstruction; or<br>c. Aspiration pneumonia.<br>"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:<br>1) Any death of an individual;<br>2) A sexual assault of an individual;<br>3) A serious injury of an individual that results in or likely will result in permanent physical or psychological impairment;<br>4) A suicide attempt by an individual admitted for services that results in a hospital admission. | psychological impairment as a Level III serious incident.<br>• An exemption for reporting of unplanned psychiatric of unplanned medical hospital admissions by licensed emergency services was added.<br>• An exemption for reporting of suicide attempts resulting in a hospital admission by licensed emergency services was added.<br><br>"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:<br>1. A serious injury;<br>2. An individual who is or was missing;<br>3. An emergency room visit; ~~or urgent care facility visit when not used in lieu of a primary care physician visit;~~<br>4. An unplanned psychiatric or |

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| | | N/A | unplanned medical hospital admission of an individual receiving services other than licensed emergency services;<br>5. Choking incidents that require direct physical intervention by another person;<br>6. Ingestion of any hazardous material; or<br>7. A diagnosis of:<br>a. A decubitus ulcer or an increase in severity of level of previously diagnosed decubitus ulcer;<br>b. A bowel obstruction; or<br>c. Aspiration pneumonia.<br>"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:<br>1. Any death of an individual;<br>2. A sexual assault of an individual; or<br>~~3. A serious injury of an individual that results in or likely will result in permanent physical or psychological impairment; or~~<br>~~4~~ 3. A suicide attempt by an individual admitted for services, other than licensed emergency services, that results in a hospital admission.<br><br>• Addition of a general definition for “suicide attempt.”<br><br>“Suicide attempt” means a non-fatal, self-directed, potentially injurious behavior with an intent to die as a result of the behavior regardless of whether it results in injury. |
| 50 | | 2. A provisional license may be issued to a provider for a service that has demonstrated an inability to maintain compliance with Human Rights Regulations (12VAC35-115) or this chapter, has violations of human rights or licensing regulations that pose a threat to the health or safety of individuals receiving services, has multiple violations of human rights or licensing regulations, or has failed to comply with a previous corrective action plan. | • Amended to remove the short form reference to the Human Rights Regulations.<br><br>2. A provisional license may be issued to a provider for a service that has demonstrated an inability to maintain compliance with all applicable regulations, ~~Human Rights Regulations (12VAC35-~~ |

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| | | | ~~115) or~~ including this chapter and 12VAC35-115, has violations of human rights or licensing regulations that pose a threat to the health or safety of individuals receiving services, has multiple violations of human rights or licensing regulations, or has failed to comply with a previous corrective action plan. |
| 160 | | C. The provider shall collect, maintain, and review at least quarterly all 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.<br><br>E. A root cause analysis shall be conducted by the provider within 30 days of discovery of Level II and Level III serious incidents. The root cause analysis shall include at least the following information: (i) a detailed description of what happened; (ii) 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 (iii) identified solutions to mitigate its reoccurrence. | • Amended to clarify that providers shall collect, maintain, and review at least quarterly all serious incidents, including Level I serious incidents.<br><br>C. The provider shall collect, maintain, and review at least quarterly all ~~Level I~~ 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.<br><br>• Amended the requirements for when providers must conduct a root cause analysis on a Level III serious incident. Providers shall only conduct a root cause analysis 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.<br>• Amended to provide clarification that a more detailed root cause analysis may be necessary depending on the circumstances of the serious incident.<br><br>E. A root cause analysis shall be conducted by the provider within 30 days of discovery of Level II |

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| | | F. The provider shall submit, or make available reports and information that the department requires to establish compliance with these regulations and applicable statutes. | 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: (i) a detailed description of what happened; (ii) 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 (iii) identified solutions to mitigate its reoccurrence~~.~~ when applicable. A more detailed root cause analysis, including convening a team, collecting and analyzing data, mapping processes, and charting causal factors should be considered based upon the circumstances of the incident.<br><br>• Amended to provide clarification that providers may need to make available and submit requested documentation to the department when requested.<br><br>F. The provider shall ~~submit, or~~ make available and, when requested, submit reports and information that the department requires to establish compliance with these regulations and applicable statutes. |
| 170 | | G. The provider shall implement and monitor the approved corrective action plan. The provider shall incorporate corrective actions in its quality improvement program specified in 12VAC30-105-620. | • Amended to include that providers shall monitor implementation and effectiveness of approved corrective actions as part of their quality improvement program.<br><br>G. The provider shall implement and monitor the approved corrective action plan. The provider shall ~~incorporate corrective actions in~~ monitor implementation and effectiveness of approved corrective actions as |

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| | | | part of its quality improvement program ~~specified in~~ required by 12VAC30-105-620. |
| 620 | | The provider shall develop and implement a quality improvement program sufficient to identify, monitor, and evaluate clinical and service quality and effectiveness on a systematic and ongoing basis. The program shall (i) include a quality improvement plan that is reviewed and updated at least annually; (ii) establish measurable goals and objectives; (iii) include and report on statewide performance measures, if applicable, as required by DBHDS; (iv) utilize standard quality improvement tools, including root cause analysis; (v) implement a process to regularly evaluate progress toward meeting established goals and objectives; and (vi) incorporate any corrective action plans pursuant to 12VAC35-105- 170. Input from individuals receiving services and their authorized representatives, if applicable, about services used and satisfaction level of participation in the direction of service planning shall be part of the provider's quality improvement plan. The provider shall implement improvements, when indicated. | • Amended to include that providers shall monitor implementation and effectiveness of approved corrective actions as part of their quality improvement program.<br>• Amended to clarify what components should be included in the provider's quality improvement plan, which is part of their quality improvement program.<br><br>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. The program shall utilize standard quality improvement tools, including root cause analysis, and shall ~~(i)~~ include a quality improvement plan that (i) is reviewed and updated at least annually; (ii) ~~establish~~ defines measurable goals and objectives; (iii) includes and reports on statewide performance measures, if applicable, as required by DBHDS; (iv) ~~utilize standard quality improvement tools, including root cause analysis; (v) implement a process to regularly evaluate progress toward meeting established goals and objectives; and (vi) incorporate any~~ monitors implementation and effectiveness of approved corrective action plans pursuant to 12VAC35-105-170; and (v) includes ongoing monitoring and evaluation of progress toward meeting established goals and objectives. The provider's policies and procedures shall include the criteria the provider will use to establish measurable goals and |

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| | | | objectives. Input from individuals receiving services and their authorized representatives, if applicable, about services used and satisfaction level of participation in the direction of service planning shall be part of the provider's quality improvement plan. The provider shall implement improvements, when indicated. |

If the regulatory change is intended to replace an emergency regulation, and is identical to the emergency regulation, please choose and fill out the appropriate chart template from the choices above. In this case "current section number" or "current chapter-section number" would refer to the **pre**-emergency regulation.

If the regulatory change is intended to replace an emergency regulation, but includes changes made since the emergency regulation, please create two charts:

1. A chart describing changes from the **pre-emergency** regulation to the regulatory change, as described in the paragraph above; or if a new chapter is being promulgated, a chart describing the proposed new regulation.
2. A chart describing changes from the **emergency** regulation to the regulatory change. For the second chart please use the following title: "Changes from the Emergency Regulation." In this case "current section number" or "current chapter-section number" would refer to the **emergency** regulation.

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| **1** | Jan Longman | Arlington County DHS | 8/28/18 | 12:40 PM | Comments from Arlington | We applaud DBHDS efforts to improve these regulations and clarify expectations. We support the removal of the requirement of reporting for Level 1 serious incidents and the clarification that Case Managers are not required to duplicate Level II reporting of incidents that occur in other licensed programs.<br><br>**12VAC-35-105-20 Definitions**<br><br>The definition of "**Licensed mental health professional**" does not have a proposed change but should be expanded to include Licensed Nurse Practitioners.<br><br>The proposed definition of "**serious incident'** as *any event or circumstance that causes or could cause harm to the health, safety, or well-being of an individual* does not sufficiently identify serious incidents and could result in significant over-interpretation. Unemployment, homelessness, witnessing a crime, loss of a caregiver, lack of legal presence, addiction of a family member, deployment or serious illness of a parent, etal are examples of circumstances that could cause harm to the well-being of an individual and I believe are outside the intent of this regulation and the purview of DBHDS.<br><br>The proposed definition of "**Level II serious incident**" needs further clarification. *"during the provision of a service or on the premises of a provider"* particularly as it applies to "an individual who is missing." Are we correct in assuming that a missing person is only a reportable Level II incident for providers who are responsible for individuals | Thank you for your comment.<br><br>Effective 2/21/2019 licensed psychiatric/mental health nurse practitioners will be added to the Office of Licensing regulatory definition of licensed mental health professional. Additional information related to this regulatory action can be found on the [Virginia Regulatory Town Hall](#) website.<br><br>The definition of serious incident takes into account that every serious incident that may occur cannot be explicitly listed in the regulations. However, Level I and Level II serious incidents are incidents which only occur with the provision of the provider's services or on the premises of the provider. Therefore, the mentioned examples would not be tracked (if Level I) or reported to |

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| | | | | | | 24 hours per day? Would a missed appointment with a Case Manager, Psychiatrist, Therapist, ICT or Skill Building provider be interpreted to occurring "during *the provision of a service*" and thus be reportable as a Level II incident since they could represent "*circumstances 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 patterns of behavior*".<br><br>Also in the proposed definition of "**Level II serious incident**" #7a, a decubitus ulcer is only reportable if diagnosed. This could be a disincentive for a provider in seeking medical treatment for suspected ulcers which is not the intent of the regulation.<br><br>The proposed definition of "**Level III serious incident**" needs clarification specifically as it applies to:<br><br>1. *"A sexual assault of an individual."* Guidance issued by DBHDS further states "*Providers shall report to the department and other relevant authorities as required by law that an individual alleges they were sexually assaulted, whether or not the alleged assault occurred within the provision of the provider's services or on their property.*" We support the reporting of sexual assaults that occur on the premises of a provider or against those individuals for whom we have 24-hour responsibility, we do not support reporting of all sexual assaults revealed by our clients to DBHDS.<br><br>1. Reporting of assaults should be the prerogative of victims with capacity. Trauma Informed Care principals emphasize that the survivor have a | the department (if Level II) unless they occurred within the provision of the provider's services or on their property.<br><br>Missed appointments are not required to be reported as Level II serious incidents. Please see the effective DBHDS Office of Licensing Guidance for Serious Incident Reporting for additional guidance related to reporting Level II serious incidents.<br><br>The requirement to report only those decubitus ulcers that have been diagnosed is to ensure accurate reporting. Reporting a serious incident does not imply that a provider has done anything wrong; |

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| | | | | | | genuine choice to direct reporting of victimization when possible.<br>2. Regulations indicate assaults should be reported within 24 hours of discovery. Clients often reveal assaults years after they occur. If the assault occurred in the community, what purpose would the reporting serve?<br>3. What role would DBHDS have in investigating/mitigating sexual assaults that occur in the community?<br>4. "Sexual assault" is not defined<br>5. Guidance in the Violence Against Women Act (VAWA) cautions against sharing information beyond minimum necessary since even the most secure systems can be compromised leaving sensitive information exposed, and survivors in danger and often unwilling to disclose their abuse and get help<br><br>1. *"A serious injury of an individual that results in or likely will result in permanent physical or psychological impairment".* Further guidance issued by DBHDS states "*For example, providers shall report if an individual had to have a leg amputated as a result of a car accident whether or not the car accident occurred within the provision of the provider's services or on their property."* We support the reporting of serious injuries that occur on the premises of a provider, during the provision of services, or for those individuals for whom we have 24-hour responsibility, we do not support reporting of all injuries of this type to DBHDS. What role would DBHDS have in investigating/mitigating serious | however, failure to seek appropriate medical attention would be criteria for neglect.<br><br>The department recognizes that reporting an allegation of sexual assault could impact the therapeutic relationship of the individual with the provider; therefore, reporting should be trauma-informed and respect the therapeutic relationship. Please see the DBHDS Office of Licensing Guidance for Serious Incident Reporting for additional guidance related to the reporting of unplanned hospital admissions and the sexual assault of an individual. |

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| | | | | | | injuries sustained by clients in outpatient programs that occur in the community? While providers have a role in helping individuals process the trauma and linking to needed resources, we have no capacity for root cause analysis or mitigation of traffics accidents, acts of god, acts or war, crime, etc.<br><br>The definitions of QMHP-A and QMHP-C are not aligned with the new requirements for those staff to be registered with the Board of Counseling which can lead to misinterpretation of the requirements necessary to deliver services.<br><br>12VAC35-105-160. Reviews by the department; requests for information; required reporting.<br><br>*"E. A root cause analysis shall be conducted by the provider within 30 days of discovery of Level II and Level III serious incidents. The root cause analysis shall include at least the following information: (i) a detailed description of what happened; (ii) 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 (iii) identified solutions to mitigate its reoccurrence."*<br><br>We support the root cause analysis following most incidents classified as Level II or Level III, conducting an analysis on the expected deaths from natural causes of individuals in outpatient programs is unnecessarily burdensome.<br><br>**12 VAC35-105-1245** | The language relating to a serious injury of an individual that results in or likely will result in permanent physical or psychological impairment has been removed in the proposed language of the regulation. |

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| | | | | | | *"Case managers shall meet with each individual face-to-face as dictated by the individual's needs. At face-to-face meetings, the case manager shall (i) observe and assess for any previously unidentified risks, injuries, needs, or other changes in status; (ii) assess the status of previously identified risks, injuries, or needs, or other change in status; (iii) assess whether the individual's service plan is being implemented appropriately and remains appropriate for the individual; and (iv) assess whether supports and services are being implemented consistent with the individual's strengths and preferences and in the most integrated setting appropriate to the individual's needs."* Clients are often seen face to face by their case managers multiple times per month – a frequency interval for this extensive documentation requirement would be helpful.<br><br>**12VAC35-105-1250. Qualifications of case management employees or contractors**<br><br>*"D. Case managers serving individuals with developmental disability shall complete the DBHDS core competency-based curriculum within 30 days of hire."* There is no contingency here for when the DBHDS portal is not available for over 30 days and DBHDS has no back-up training plan. We have experienced an outage of over 30 days in the past. | A separate Emergency Regulation aligning the Office of Licensing regulatory definitions of QMHP-A and QMHP-C with the Board of Counseling is currently in effect. This action became, effective 12/18/2017, and can be found on the Virginia Regulatory Town Hall.<br><br>The language related to the requirement to conduct root cause analysis has been narrowed in the proposed language of |

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| | | | | | | | the regulations and now states that 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. In addition, providers are only required to identify solutions to mitigate the reoccurrence of a serious incident when applicable.<br><br>Documentation should be completed for each face-to-face meeting with the case manager. |

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| | | | | | | | This regulation will be enforced only if the DBHDS core competency-based curriculum is available to the new employee within 30 days of hire. |
| **2** | Joanna Wise Barnes | ServiceSource, Inc. | 9/4/18 | 3:07 PM | 12VAC35-105. Rules and Regulations for Licensing Providers by the DBHDS | • 12VAC35-105-20, Definitions of serious incidents – Level II definition #6, "Ingestion of any hazardous material" which must be reported "If any individual drinks, swallows, or absorbs a material that is hazardous to their health…it shall be reported." We serve many individuals who engage in PICA. Calls to the Poison Control Center direct us on whether to seek emergency care, or if we can provide treatment and monitoring at our sites. We request requiring reporting only when the individual is taken to receive emergency or urgent professional medical care after ingesting any material, rather than after each occurrence of ingesting by individuals who engage in PICA. (Responses to their PICA behavior are driven not only by the Poison Control Center, but by individual protocols, behavior plans, and/or physician's orders.)<br>• 12VAC35-105-20, Definitions of serious incidents – "Level III serious incident means serious incidents whether or not the incident occurs on the provider's premises or within the provision of services. All providers that are made aware of a level III serious incident are required to report even if this results in duplicative reporting." Level III, definition #1, "Any | Thank you for your comment.<br><br>The DBHDS Office of Licensing Guidance for Serious Incident Reporting language related to the ingestion of any hazardous material has been amended to state the following: "If an individual drinks, swallows, or absorbs a material that causes significant harm to the individual or is a threat to their health and safety, the provider should report this as a Level II serious incident." |

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| | | | | | | death of an individual" – When using the CHRIS system to report deaths of individuals who did not die while in our licensed program, the system requires providers to answer questions to which we lack answers. After choosing "yes" or "no" as required, we can only explain in a random textbox within CHRIS that the answers are in fact unknown. <u>We ask that instead of using CHRIS, a provider be required to notify OL of all deaths via a documented phone call or encrypted email. Only the provider in whose care the individual died should be required to enter the death into the CHRIS system.</u><br>• 12VAC35-105-160, "Amend to require reporting of all level II and level III serious incidents to the department," "A root cause analysis shall be conducted by the provider within 30 days of the discovery of Level II and Level III serious incidents," and "The provider shall submit, or make available, reports and information that the department requires to establish compliance with these regulations and application statutes." We appreciate the importance of tracking, analyzing, and reporting data on serious incidents state-wide. This is important to monitor services and to protect the safety of individuals served, not just for compliance with the Settlement Agreement. <u>We request that the Comprehensive Human Rights Information System (CHRIS) be updated, or that another "web-based reporting application" replace it. The system used should be user-friendly and should require entry of all mandated information and only that information, specific to categories of serious incidents, so that only one reporting mechanism is used.</u> Providers appreciate the availability of OHR staff to train and re-train staff on the use of CHRIS; such training is not a substitute for resolving system issues that now use considerable staff hours due to technical difficulties. | The department feels that the death of an individual receiving services is important enough to merit notification from all providers providing services. Under the new proposed language of the regulation, providers who were not actively providing services at the time of the death will not have to conduct a root cause analysis on the death.<br><br>The department is currently in the process of updating CHRIS to be more user-friendly for reporting of serious incidents in accordance with the emergency regulations. |

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| | | | | | | • Sections 20 and 691 – These sections and probably others refer to the individual and/or the individual's "authorized representative." "Authorized representative" has a specific definition in the Code of Virginia. If the regulations intentionally reference that Code definition, then the term "legal guardian" should be added to these and other sections where only an authorized representative is mentioned. If on the other hand, "authorized representative" is intended as a generic term, then perhaps "substitute decision-maker" should be used instead. 12VAC35-115-145 does use the generic term "substitute decision making." | The DBHDS Office of Licensing regulation, 12VAC35-105-20, defines authorized representative as "a person permitted by law or 12VAC35-115 to authorize the disclosure of information or consent to treatment and services or participation in human research." |
| 3 | Carlinda Kleck | Loudoun County Dept. of MHSADS | 9/4/18 | 4:58 PM | Comments on Draft Emergency Licensing Regulations | **Loudoun County MHSADS Comments on Emergency Licensing Regulations**<br>**12VAC35-105-20. Definitions.**<br>**"Serious Incident" –**<br>• Determining if a hospital admission is a level II may be subjective and result in inconsistent reporting among providers. Unplanned psychiatric/medical hospital admission: what constitutes an unplanned hospital admission? For example, there are circumstances where an individual may be ECO'ed but decide to voluntarily admit herself to the hospital. At what point in the process is it "unplanned?"<br>• Defining "a sexual assault of an individual" as a level III incident poses a risk to the therapeutic relationship | Thank you for your comment.<br><br>Please see the DBHDS Office of Licensing Guidance for Serious Incident Reporting for additional guidance related to the reporting of unplanned hospital admissions and the sexual assault of an individual. The department recognizes |

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| | | | | | | and violates an individual's rights to privacy. An individual who has been a victim of the sexual assault has been violated and should not be further violated by the provider disclosing the information to DBHDS if the assault did not occur during service provision "A sexual assault of an individual" should be moved to a level II incident.<br>• Defining "a serious injury of an individual that results in or likely will result in permanent physical or psychological impairment" as a level III incident presents multiple challenges in implementation. First, there is ambiguity in interpreting what "results in or likely results in permanent physical or psychological impairment." Who determines when it causes or likely will cause "permanent" impairment? Second, requiring this to be reported to DBHDS when not occurring during service delivery, creates an undue burden for providers. Individuals do not have to tell providers about situations that occur outside of service provision. How does reporting this information to DBHDS provide useful data for the provider or DBHDS? How does this help those receiving services? Finally, this may also violate an individual's right to privacy. For example, if an individual were in an accident outside of service delivery and required amputation, why would DBHDS need to know this information?<br>**12VAC35-105-160. Reviews by the department; requests for information; required reporting.**<br>• The required components of the root cause analysis described in E do not allow for the dignity of risk and imply that all Level II and Level III incidents have feasible mitigating solutions for identification. Accidents happen, which cannot be prevented. Section (iii) needs to be modified to indicate identifying "solutions to mitigate its reoccurrence" as possible. Further, there should be | that reporting an allegation of sexual assault could impact the therapeutic relationship of the individual with the provider; therefore, reporting should be trauma-informed and respect the therapeutic relationship.<br><br>The language relating to a serious injury of an individual that results in or likely will result in permanent physical or psychological impairment has been removed in the proposed language of the regulation. |

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| | | | | | | clarification that an individual has the right to indicate they do not want the identified solutions implemented. It must be clear that individuals have the right to choice and dignity of risk. | The language related to the requirement to conduct root cause analysis was narrowed in the proposed language of the regulation and now states that 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. In addition, providers are only required to identify solutions to mitigate the reoccurrence of a serious incident when applicable. |
| **4** | | Henrico Area Mental Health & Developmental Services | 9/5/18 | 12:40 PM | Definition of Serious Incident | 105-20 Definition of Serious Incident<br>Level II 2. An individual who is missing for any period of time…does this mean while in our care as in residential or day programs. Does this apply to all services such as outpatient services? Please define "time". This should be a more focused reporting for residential and day services.<br>Level II 4. If a client comes to the CSB to see a nurse and it is recommended to go to the doctor how would we know if the ER was being used in lieu of a primary care visit? Is this reportable? Does this include urgent care visit in lieu of seeing the PCP, even when the PCP offices are closed? | Thank you for your comment.<br>The proposed language of this regulation has been amended to clarify that a provider shall report if an individual is or was missing.<br>This language has |

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| | | | | | | How do we handle voluntary hospitalizations, are they considered unplanned? Are they reportable? We would only report hospitalizations we help with in level II? Considerations should be made to remove psychiatric hospitalizations as a reportable requirement.<br><br>Level II. 7. a-b. How will we know if a decubitus ulcer or a bowel obstruction occurred or originated on our premises or during provision of services for all licensed services such as outpatient services? Should be focused just for residential services.<br><br>Level III. For level III reporting, does the individual have the right to know what is being reporting to the state regarding what is shared with the provider?<br><br>Level III. 2. Sexual assault of an individual. In an outpatient service this has serious impacts on the therapeutic relationship as the individual may feel additionally victimized by the reporting and questioning from a root cause analysis completed. Shouldn't the individual provide authorization to report, what about their right to privacy? This should not be a level III reporting and should be moved to level II.<br><br>Level III. 3. If a client was in a car accident, would this be reportable in Level III? How does one assess, at the time, if something is "likely" to result in permanent physical or psychological (especially psychological) impairment? What is your definition of psychological impairment? To report to DBHDS when not occurring during service delivery, creates an undue burden for providers. Individuals do not have to tell providers about situations that occur outside of service provision.<br><br>Level III. 4. Suicide Attempt.– What constitutes a suicide attempt? If a person talks about suicide and has a voluntary admission is that behavioral or suicidal?Is this | been removed from the proposed language of the regulations.<br><br>A diagnosis of decubitus ulcer or an increase in severity of level of a previously diagnosed decubitus ulcer should be reported as a Level II serious incident once the provider has sought and obtained a diagnosis from a medical professional.<br><br>Please see the DBHDS Office of Licensing Guidance for Serious Incident Reporting for additional guidance related to the reporting of the sexual assault of an individual. The department recognizes that reporting an allegation of sexual assault could impact the therapeutic relationship of the individual with the provider; therefore, reporting should be |

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| | | | | | | reportable?<br><br>Level III. How will we do a root cause analysis for events that happen not on our premises, as many Level III situations will occur that way? | trauma-informed and respect the therapeutic relationship.<br><br>The language relating to a serious injury of an individual that results in or likely will result in permanent physical or psychological impairment has been removed from the proposed language of the regulations.<br><br>A definition of "suicide attempt" has been added to the proposed language of the regulations.<br><br>The language related to the requirement to conduct root cause analysis has been narrowed in the proposed language of the regulations and now states that 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 |

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| | | | | | | | incidents that occur during the provision of a service or on the provider's premises. |
| **5** | Leslie Sharp | NRVCS | 9/5/18 | 3:42 PM | Licensing Regulations | • *"A sexual assault of an individual." "Providers shall report to the department and other relevant authorities as required by law that an individual alleges they were sexually assaulted, whether or not the alleged assault occurred within the provision of the provider's services or on their property."*<br>○ The reporting of sexual assaults that occur on the premises of a provider or against those individuals for whom we have 24-hour responsibility would be appropriate but reporting of all sexual assaults revealed by our clients to DBHDS would pose a risk to therapy and violates an individual's rights to privacy. Sexual assault is a legal term and what role should the provider have in investigating something that occurred in the community and should be investigated by the police. Regulations indicate assaults should be reported within 24 hours of discovery. Clients often reveal assaults years after they occur as part of therapy.<br>• *"E. A root cause analysis shall be conducted by the provider within 30 days of discovery of Level II and Level III serious incidents. The root cause analysis shall include at least the following information: (i) a detailed description of what happened; (ii) 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 (iii) identified solutions to mitigate its reoccurrence."*<br>○ For Level II incidents, there should be an accumulation of incidents to trigger a RCA such as two level 2 incidents w/in a 30 day period as | Thank you for your comment.<br><br>Please see the DBHDS Office of licensing Guidance for Serious Incident Reporting for additional language related to the reporting of the sexual assault of an individual.<br><br>The language related to the requirement to conduct root cause analysis has been narrowed in the proposed language of the regulations and now states that a root cause analysis shall be conducted by the provider within 30 days of discovery of Level II serious incidents and |

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| | | | | | | an example. Also conducting an analysis on the expected deaths from natural causes of individuals in outpatient programs would be more burdensome to programs.<br><br>• *A serious injury of an individual that results in or likely will result in permanent physical or psychological impairment". "For example, providers shall report if an individual had to have a leg amputated as a result of a car accident whether or not the car accident occurred within the provision of the provider's services or on their property."*<br>○ There is ambiguity in what "results in or likely results in permanent physical or psychological impairment." What determines when it causes or likely will cause "permanent" impairment? This should be spelled out more. | any Level III serious incidents that occur during the provision of a service or on the provider's premises. Therefore, a provider would not be required to conduct a root cause analysis on the natural death of an individual receiving outpatient services unless the individual died while they were actively receiving outpatient services or on the premises of the provider.<br><br>This language has been removed from the proposed language of the regulations. |
| 6 | | Henrico Area Mental Health & Developmental Services | 9/5/18 | 3:59 PM | Comments on Licensing Regulations | 105-20 Definitions<br>**Definition of Missing -** Further clarification is needed for this definition as it relates to all services. The definition seems broad. For example; If a person is expected to arrive at 10:00 for an appointment and they no show and we are unable to reach them, are they missing? If they no show for a second appointment is that missing? For individuals in outpatient services living on their own this information would not be timely. It is recommended to narrow the focus to residential and day services. | Thank you for your comment.<br><br>Please see the DBHDS Office of licensing Guidance for Serious Incident Reporting for additional guidance related to reporting when an individual is missing. |

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| | | | | | | **Definition of QDDP -** The definition of QDDP seems to be different in the draft licensing regulations than in the waiver emergency regulations and the waiver definition. The emergency regulations are more flexible for providers since it allows a substitution of experience for education whereas the licensing definition requires a BA, MD or an RN. Many providers have supervisory staff who have extensive experience but may not have completed their BA or their degree may not be in a human services area, suggesting for consistency, to use the same language as in the waiver emergency regulations.<br><br>**105-160 - Reviews by the dept and added required reporting -** Regulating that every serious incident must have an identified solution to mitigate its reoccurrence may not apply all incidents, for example; deaths as a result of natural causes. Level III, how will we do a root cause analysis for incident that are not on our premises, as many Level III situations may occur that way. For example; if a client dies in a car accident, how/would we do a root cause analysis of this situation? The requirement to complete a root cause analysis should be changed to complete a root cause analyses when patterns or trends occur.<br><br>**105-400 - Criminal background checks and registry searches -** Requiring a disclosure statement from the applicant for pending charges for any offense is not something we would be legally able to ask. | The definition of QDDP in the emergency regulations has not changed from the licensing regulations previously in effect. The defined term was changed from “Qualified Mental Retardation Professional (QMRP)” to “Qualified developmental disability professional or QDDP.”<br><br>The language related to the requirement to conduct root cause analysis was narrowed in the proposed language and now states that 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. In addition, providers are |

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| | | | | | | | only required to identify solutions to mitigate the reoccurrence of a serious incident when applicable.<br><br>Requiring a disclosure statement from applicants is not a new requirement within the Licensing Regulations. In addition, the requirement is similar to those of other state licensing entities. |
| 7 | | Henrico Area Mental Health & Developmental Services | 9/5/18 | 4:11 PM | Comments on Licensing Regulations | **Thank-you for the opportunity to provide comments.**<br><br>**105-520 - Risk Management -** The wording in the regulations "incorporate uniform risk triggers and thresholds as defined by the department" is undefined and should either be removed from regulations or defined in regulations as this leaves it open for interpretation.<br><br>**105-580 - Service description requirements -** C.2. A description of care, treatment, training skills acquisition, or other supports provided. The term "acquisition" is awkward language.<br><br>**105-650 - Assessment Policy -** F. A. comprehensive assessment shall update and finalize the initial assessment. There are questions regarding this requirement and Same Day Access Services. We have received feedback that two separate assessments are needed; the initial assessment and the comprehensive assessment, on our SDA form we now have to identify which part is the initial and which part is the comprehensive. This needs clarification as it relates to the State's SDA initiatives. | Thank you for your comment.<br><br>The department will be defining uniform risk triggers and thresholds. These will be communicated to providers through a formal guidance document which will be subject to public comment prior to finalizing.<br><br>This comment exceeds the scope of the current regulatory action. We will consider your comment during additional regulatory reviews in the future. |

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| | | | | | | **105-665 - ISP requirements -** A.11. Does this only apply to DD Waiver CD services? The ISP shall be distributed to the individual and others authorized to receive it. What if the individual does not want a copy of the ISP?<br><br>**105-675 - Reassessments and ISP reviews -** A. Update the ISP whenever there is "any" kind of change? Is the review not sufficient? Definitely, if something new that needs addressing but does this include every improvement outside of the review period?<br><br>D.2. Currently this is documented that the individual has met an objective, what additional documentation is being proposed?<br><br>D.3. Requiring a team meeting when individuals do not meet specific objectives is difficult. Individuals may have many objectives to reach a goal and have several goals. Requiring a team meeting each time a specific objective is not meet will feel punitive to an individual who is trying to reach their goals and may dramatically impact direct service time. How is the team defined? So if an objective on the ISP that the client will visit the primary care office in the next quarter, and the client cancels the visit, do we bring the whole team together to discuss why the client cancelled the appointment? Requiring the team to meet should be removed. | This requirement applies to all licensed providers. If the individual does not want a copy of the ISP, the provider should document that the individual was offered a copy of the ISP and refused.<br><br>The regulation states that reassessments shall be completed at least annually and any time there is a need based on changes in the medical, psychiatric, behavioral, or other status of the individual.<br><br>This language in regulation 675 was broken out from a paragraph in effort to be more clear. DBHDS found that providers were not "documenting evidence of progression towards or achieved for EACH goal and objective". The provider must do this |

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| | | | | | | **105-691 - Transition of individuals among services -** Further clarification is needed to define transition/transfer. If an individual moves from one case management team to another case management team is this a transfer needing a transfer summary.<br><br>**105-1245 - Case Management direct assessments -** This is too ambiguous—who determines how often the individual's needs dictate face-to-face contact? We have some occasions, when we are seeing case management clients multiple times in the same week for MH case management—would we have to do (I,ii,iii,iv)at each face-to-face visit? | for both the goal and the objective. The phrase "documented evidence" is emphasized also in the regulation now. The previous regulation just said "evaluate" and was not specific in stating to document this evaluation.<br><br>A treatment team is defined by who is identified on the ISP as being required to deliver specific interventions (665.A.9). The provider should be in contact with all treatment team members, as appropriate (with releases of information) to ensure appropriate delivery of services. The regulations also states, "as appropriate". If there are certain team members that are not able to meet, then the provider should be documenting the attempt to meet and the reason why it could not be accomplished. Howeve |

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| | | | | | | | r, the provider is required to be proactive with an individual's care and if the provider is actively delivering services, then the provider should know well ahead of time if an individual is meeting their goals/objectives. This requirement in regulation is to assist in better quality care deliver among all individuals and all services.<br><br>This comment exceeds the scope of the current regulatory action. We will consider your comment during additional regulatory reviews in the future.<br><br>Documentation should be completed for each face-to-face meeting with the case manager. |
| 8 | Don Sherman | Rockbridge Area Community | 9/5/18 | 4:53 PM | 12VAC35-105 Root Cause | The process of completing a Root Cause Analysis can be useful in determining the factors which contributed to an incident and therefore can be valuable to efforts in addressing systemic issues. However, not all incidents | Thank you for your comment.<br><br>The language related to |

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| | | Services | | | Analysis | require the methodology of a Root Cause Analysis to understand the contributing factors and underlying issues of an incident. Many accidents, injuries, and deaths are attributable to individual and self-evident causes. In such cases the exercise of conducting a Root Cause Analysis will yield no new or useful information to the provider.<br>Additionally, there are incidents which occur where providers will not have the means to determine all or even some of the factors which contributed to the incident. This is likely to be the case for some Level III incidents which occur outside of the purview of the providers' services and facilities. In cases where providers are unable to accurately determine the factors which contributed to an incident it makes little practical sense to complete a Root Cause Analysis.<br>For these reasons we recommend that the regulations be revised to state that during their review of incidents providers will take reasonable steps to determine the underlying causes of Level II and Level III incidents. The regulations can then highlight the utilization of Root Cause Analysis as a preferred method for determining the factors which contributed to incident This maintains the requirement that providers examine incidents to determine their root causes but offers greater latitude to providers regarding how they meet this requirement. In cases where the cause of an incident is obvious providers may not need to take additional actions and in cases where providers could not reasonably know the cause of an incident they are free from the obligation of conducting a fruitless Root Cause Analysis. | the requirement to conduct root cause analysis was narrowed in the proposed language of the regulations and now states that 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. In addition, providers are only required to identify solutions to mitigate the reoccurrence of a serious incident when applicable. |
| **9** | Melanie Bond, Psy.D | Hampton-Newport News Community Services Board | 9/5/18 | 5:31 PM | Response to Proposed Changes to DBHDS – | **Hampton – Newport News Community Services Board**<br>**Response to Proposed Changes to DBHDS – Emergency Regulations**<br>1. **12VAC35-105-20. Definitions.**<br>*"Serious incident" means any event or circumstance that causes or could cause harm to the health, safety, or well-* | Thank you for your comment. |

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| | | | | | Emergency Regulations | *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 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; 5. Choking incidents that require direct physical intervention by another person; 6. Ingestion of any hazardous material; or 7. A diagnosis of: a. A decubitus ulcer or an increase in severity of level of previously diagnosed decubitus ulcer; b. A bowel obstruction; or c. 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; 3. A serious injury of an individual that results in or likely will result in permanent physical or psychological impairment; or 4. A suicide attempt by an individual admitted for services that results in a hospital admission.*<br>• The new assignment of Levels to serious incidents does not improve the accuracy or efficiency of | The language relating to a serious injury of an individual that results in |

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| | | | | | | reporting for Providers. This assignment system is confusing, inconsistent/contradicting and does not adequately address some of the most common types of incidents experienced by Providers. For example, serious incidents occurring offsite, but reported to Case Managers outside of service provision, are notably difficult to categorize in the existing reporting infrastructure. The proposed Level system, and subsequent guidance offered by DBHDS, do not offer the direction needed for adequate application.<br>• Level III incidents, such as sexual assault, may fall outside of the jurisdiction of a Provider to investigate, as it might impede the work of a law enforcement entity.<br>• In accordance to the proposed regulations, Level III serious incidents include those *that result in or likely will result in permanent physical or psychological impairment*. This is a highly subjective descriptor and, given the parameters for reporting serious incidents (e.g., timeframes), as well as completing the subsequent investigations, it is unlikely if the information needed to make this type of assumption would be available at the time of completion.<br>• The Definitions do not acknowledge or define the position of ***Qualified Mental Health Case Manager (QCM).*** Is a QCM equivalent to a QMHP? If not, a separate, distinct definition for a QCM should be provided, with information as to what qualifications distinguish it from the QMHP classification.<br>**12VAC35-105-160. Reviews by the department; requests for information; required reporting.**<br>1. *The provider shall collect, maintain, and review at least quarterly all 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* | or likely will result in permanent physical or psychological impairment has been removed from the proposed language of the regulations.<br><br>Providers are not required to report Level I serious incidents. This is a decrease in previous reporting requirements to the department. The reason for provider monitoring of Level I serious incidents quarterly is to minimize the risk of the occurrence of additional Level I, II, or III incidents in the future.<br><br>The department will be |

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| | | | | | | *remediation, and documentation of steps taken to mitigate the potential for future incidents.*<br>• Given the amount of additional reporting, analysis and outcome maintenance the regulatory standards mandate, quarterly review of Level I incidents, which are frequent in number, is superfluous and burdensome on an already overtaxed system. At a minimum, an annual review of trends would be sufficient.<br>*E. A root cause analysis shall be conducted by the provider within 30 days of discovery of Level II and Level III serious Regulations Volume 34, Issue 25 Virginia Register of Regulations August 6, 2018 2510 incidents. The root cause analysis shall include at least the following information: (i) a detailed description of what happened; (ii) 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 (iii) identified solutions to mitigate its reoccurrence.*<br>• Implementation of this requirement should be delayed until: DBHDS has provided adequate training to Providers on how to conduct a Root Cause Analysis (RCA) that meets the Department's standards; provides the method by which Providers should document RCAs to ensure the Department's standards are met.<br>• RCAs **should not** be applied universally to all Level II and Level III serious incidents. Deaths of unknown cause, some sexual assaults offsite and outside of service provision, etc. are types of events when an RCA should not apply.<br>• Sensitivity to the nature of "investigating" and/or completing RCAs with victims of assault, especially ones of a sexual nature, does not appear to have | posting provider trainings on the provisions of the effective Emergency Regulations in upcoming weeks. In addition, please see The DBHDS Office of Licensing Guidance for Serious Incident Reporting for additional guidance related to conducting a Root Cause Analysis.<br><br>The language related to the requirement to conduct root cause analysis was narrowed in the proposed language and now states that 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. In addition, providers are only required to identify solutions to mitigate the reoccurrence of a serious incident when applicable. |

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| | | | | | | been applied in the development of this regulatory standard. This requirement should be rescinded.<br><br>**12VAC35-105-520. Risk management.**<br>*C. The provider shall conduct systemic risk assessment reviews at least annually to*<br>*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 (i) the environment of care; (ii) clinical assessment or reassessment processes; (iii) staff competence and adequacy of staffing; (iv) use of high risk procedures, including seclusion and restraint; and (v) a review of serious incidents. This process shall incorporate uniform risk triggers and thresholds as defined by the department.*<br>• Implementation of this requirement should be delayed until: DBHDS has provided adequate training to Providers on how to conduct systemic risk assessments that meet the Department's standards, with special emphasis on the "uniform risk triggers and thresholds" as defined by the department, per the proposed regulations. Given the DOJ's scrutiny and the Department's increased emphasis in this area, it is imperative Providers have the support and training, facilitated by DBHDS, to ensure this standard is adequately applied.<br><br>**12VAC35-105-675. Reassessments and ISP reviews.**<br>*D. 3. For goals and objectives that were not accomplished by the identified target date, the provider and any appropriate treatment team members shall meet to review the reasons for lack of progress and provide the individual an opportunity to make an informed choice of how to proceed.* | The department recognizes that reporting an allegation of sexual assault could impact the therapeutic relationship of the individual with the provider; therefore, reporting should be trauma-informed and respect the therapeutic relationship.<br><br>The department will provide additional information related to uniform risk triggers and thresholds as they are identified by the department. In addition, the department will be posting trainings related to provisions within the emergency regulations within the next few weeks. |

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| | | | | | | • This section should read "the provider **and/or** any appropriate treatment team members" to more adequately represent Providers offering services to individuals in mental health and ARTS programming. Although it is recognized a treatment team approach would be ideal in progress review, this option is not always readily available, even with care coordination support. The proposed writing of this portion of regulation might result in over interpretation or misapplication. | A treatment team is defined by who is identified on the ISP as being required to deliver specific interventions (665.A.9). The provider should be in contact with all treatment team members, as appropriate (with releases of information) to ensure appropriate delivery of services. The regulations also states, "as appropriate". If there are certain team members that are not able to meet, then the provider should document the attempt to meet and the reason why it could not be accomplished. However, the provider is required to be proactive with an individual's care and if the provider is actively delivering services, then the provider should know well ahead of time if an |

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<tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>individual is meeting their goals/objectives. This requirement in regulation is to assist in better quality care delivery among all individuals and all services.</td></tr>
<tr><td>10</td><td>Kim Black</td><td>Hope House Foundation</td><td>9/5/18</td><td>8:53 PM</td><td>Public Comment Licensing Regulations 12VAC35-105</td><td>HHF Public Comment<br>Rules and Regulations For Licensing Providers by the Department of Behavioral Health and Developmental Services [12 VAC 35 ? 105]<br><table><tr><th>Section</th><th>Comment</th><th>Action</th></tr><tr><td>12VAC-35-105-20 Definitions</td><td>The proposed definition of “serious incident’ does not sufficiently identify serious incidents and could result in significant over-interpretation.</td><td>Remove ‘or could cause harm…”</td></tr><tr><td></td><td>Level II Serious Incident – Guidance Doc</td><td>Requiring a licensed residential provider to report on an incident that occurs within the confines of another licensed program/setting will cause the data regarding</td></tr></table></td><td>Thank you for your comment.<br><br><u>The DBHDS Office of Licensing Guidance for Serious Incident Reporting</u> language related to the reporting of Level II serious incidents by residential services providers was amended to state: “Providers licensed to provide a ‘residential service’ as defined by 12VAC35-105-20 provide 24-hour support to individuals.</td></tr>
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| | | | | | | | | serious incidents to be inaccurate due to duplicate reporting of the same incident. It is also inefficient for staff in both settings.<br><br>Remove the example at the top of page two related to this requirement and remove the language regarding residential providers being required to report all incidents as it goes beyond what the regulations require. | 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 they verify that the other provider reported the incident.” |
| | | | | | | | Ingestion of any hazardous material | The example is to broad and makes this reporting requirement unmanageable. Add the clarification that if medical treatment is | The DBHDS Office of Licensing Guidance for Serious Incident Reporting language related to the ingestion of any hazardous material has been amended to state the following: “If an individual drinks, swallows, or absorbs a material that causes significant harm to the |

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| | | | | | | | | necessary after consulting Poison Control then the incident is reportable. | individual or is a threat to their health and safety, the provider should report this as a Level II serious incident.” |
| | | | | | | | Unplanned Medical Hospitalization | The provider cannot control when a hospital might admit someone for observation vs. treatment and it would seem that if someone is admitted for observation only, the incident does not meet the requirement to report. | Providers are required to report the unplanned hospital admission of an individual for any reason. |
| | | | | | | 12VAC35-105-320 Fire inspections | If a provider is scheduled only to provi de services on certain days of the week and is not present during a fire, the provider cannot staff to evacuate during a fire. | Distinguish between types of providers as previously done in regulation. “Doe s not apply to non-center based providers. ” | The regulatory requirement to maintain the provider’s building and equipment in accordance with the Statewide Fire Prevention Code applies only to residential service locations. All providers are required to maintain adequate staff to safely evacuate all individuals during an emergency. |
| | | | | | | 12VAC35-105-520 Risk | Section A. | Clarify what DBHDS will accept to | Provider will be required to provide |

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<tr><td>Management</td><td></td><td>support expertise or DBHDS should provide a training available to providers that meets criteria.</td></tr>
<tr><td>12VAC35-105-590 Provider Staffing Plan</td><td>Adequate number of staff required to safely evacuate all individuals during an emergency</td><td>Distinguish between types of providers as previously done in regulation. “Does not apply to non-center based providers.”</td></tr>
<tr><td>12VAC35-105-660 Individualized Services plan (ISP)</td><td>Section D.</td><td>Clarify that this is the role of the case manager not each provider.</td></tr>
</table></td><td>evidence of training and expertise. The provider should confirm this training and expertise in accordance to 430.A.,2., 4., and 5 " This individual should have documented knowledge and skill in the areas of investigations, RCA, and data analysis.<br>The DBHDS Office of Licensing regulations did not previously distinguish between types of providers for this regulation. All providers are required to maintain adequate staff to safely evacuate all individuals during an emergency.<br><br>This is the role of the licensed provider and not just the case manager. All providers are responsible for the ISP that is with the individual and the provider's services.</td></tr>
<tr><td>11</td><td>Eva-Elizabeth Chisholm</td><td>L'Arche Greater Washington</td><td>9/5/18</td><td>11:29 PM</td><td>RE: Root Cause analysis;</td><td>RE: the Root Cause Analysis: Additional training and information should be offfered to providers in order for this new expecation to be implemented well. As others have noted, there are certain circumstances when an RCA</td><td>Thank you for your comment.<br><br>Guidance related to</td></tr>
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| | | DC | | | role definitions | would not be feasible, due to the nature of the incident or the environment in which the incident occured.<br><br>RE: the QIDP/QDDP definitions: limiting the requirments to specific degrees removes from consideration professionals with significant experience in the field. Is it possible to include relevant work experiece as qualifying a professional to serve in this capacity? | expectations for root cause analysis can be found within the Guidance for Serious Incident Reporting. In addition, the Office of Licensing will be posting trainings on the emergency regulations this spring.<br><br>This comment exceeds the scope of the current regulatory action. We will consider your comment during additional regulatory reviews in the future. |