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Final Regulation Agency Background Document

Agency name	Department of Behavioral Health and Developmental Services
Virginia Administrative Code (VAC) citation(s)	12VAC35-105
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	April 9, 2020

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.

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 community services boards (CSBs) for services they provide, but were not previously in the DBHDS Licensing Regulations for other providers. The 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.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On April 2, 2020, the State Board of Behavioral Health and Developmental Disabilities adopted amendments to the Rules and Regulations for Licensing Providers by the Department of Behavioral Health and Developmental Services, "Licensing Regulations" [12VAC35-105], in order to comply with Virginia's Settlement Agreement with US DOJ and to respond to comments received in the proposed stage.

Mandate and Impetus

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously-reported information, include a specific statement to that effect.

The purpose of this regulation is to bring the department's Licensing Regulations into compliance with the terms of the Settlement Agreement. This regulatory action was initiated through an emergency/NOIRA action in compliance with Code of Virginia § 2.2-4011 A. The [emergency regulation](#) took effect on September 1, 2018.

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 DBHDS. 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 individual's service plan is being implemented appropriately and remains appropriate for the individual.

Since the Settlement Agreement was signed, the definition of "developmental services" was expanded in the [Code of Virginia](#) 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 final 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 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 (except that a psychiatric admission in accordance with the individual’s Wellness and Recovery Action Plan (WRAP) shall not constitute an unplanned admission), 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 by an individual admitted for services, other than licensed emergency services, resulting in a hospital admission (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 service 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.

The substantive regulatory changes in this action include provisions that will improve the health, safety, and welfare of individuals served by licensed providers and facilitate compliance with the DOJ Settlement Agreement, including:

- Enhanced serious incident reporting requirements that will improve consistency between providers and reduce unnecessary reporting while ensuring that truly serious incidents are reported, tracked, and acted upon to prevent their recurrence;
- Improve provider risk management and quality improvement programs, including by ensuring that serious incident investigation and root cause analyses are conducted and acted upon;
- Clarify the requisite qualifications and training of staff with risk management responsibilities;
- Clarify provider responsibilities with respect to disputing, implementing, monitoring, and amending corrective action plans;
- Ensure the providers employ minimal fire safety measures;

- Ensure that individuals are able to exercise informed choice during the person-centered planning process;
- Strengthen expectations for case management, as required by the DOJ Settlement Agreement;

A detailed list of all regulatory changes is provided below.

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 they will ensure that providers establish effective risk management and quality improvement processes; enhance data collection regarding the prevalence of serious incidents; and strengthen case management, person-centered planning processes, and overall risk management throughout the services system. Changes between the proposed stage and final stage of these regulations will improve clarity and reduce provider burdens, while increasing risk management and quality improvement processes at every Level of the service delivery system.

Requirements More Restrictive than Federal

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously-reported information, 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 list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously-reported information, 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 except children’s residential services.

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.

All comments submitted to Town Hall are viewable here. <https://www.townhall.virginia.gov/L/ViewComments.cfm?stageid=8546> A few other comments were received directly. To view those in full as submitted, contact John Cimino, john.cimino@dbhds.virginia.gov

Section	Comment	<u>Changes to proposed draft</u>
12VAC 35-115-20 Definitions		
<ul style="list-style-type: none"> Applied Behavior Analysis 	Three commenters submitted identical comments recommending the addition of a definition of “Applied Behavior Analysis” (ABA) and recommending that applied behavior analysis provided in a clinic setting be added to the list of outpatient services.	No changes made. This regulatory action is limited to the changes that are necessary to comply with the terms of the DOJ Settlement Agreement. The recommended change falls outside the scope of this limited regulatory action. The department will consider the recommended change during the upcoming Licensing Regulations ‘overhaul’ (response to periodic review).
<ul style="list-style-type: none"> Abuse 	One commenter suggested that the proposed definition of “abuse” is too vague and open to frequent misinterpretation, and noted that it is impossible to accurately predict whether an action “might cause psychological harm”.	No changes made. The definition of “abuse” in this chapter, as amended herein, is identical to the definition of “abuse” in the Code of Virginia § 37.2-100. Regulatory definitions align with definitions in the Code of Virginia whenever possible.
<ul style="list-style-type: none"> Direct Care Position 	One commenter noted that while the term “direct care position” is defined in the regulations, the only provision within the regulations where that phrase is actually used is deleted in the proposed revisions. Another commenter suggested that the definition of “direct care position” is vague and includes those who supervise individuals who provide direct care in addition to those who provide direct care.	Although the phrase “direct care position” is proposed for deletion from the one place where it was previously used, the phrase has now been inserted in several places to improve consistency in terminology throughout the regulation. Furthermore, the phrase “direct care position” is defined in Code of Virginia § 37.2-506, and in order to ensure consistency between these regulations and the Code of Virginia,

Section	Comment	<u>Changes to proposed draft</u>
		the department will continue to define the term in accordance with the definition as it appears in the Code of Virginia. Regulatory definitions align with definitions in the Code of Virginia whenever possible.
<ul style="list-style-type: none"> • Missing 	<p>Several commenters sought additional clarification on the definition of the term “missing” and the implications of this definition for serious incident reporting. One commenter suggested striking “when and where he should be” and “explained by his supervision needs or patterns of behavior” from the definition of “missing”.</p>	<p>No changes made. Additional clarification on the definition of “missing” and when and how providers should report missing individuals as Level II serious incidents was provided through guidance. Any additional clarifications will be provided through guidance and technical assistance.</p>
<ul style="list-style-type: none"> • QDDP 	<p>One commenter noted that the Qualified Developmental Disability Professional (QDDP) definition does not have an option to qualify based on years of experience in lieu of one of the academic degrees enumerated in the current definition. This commenter noted that this inhibits some individuals’ professional development who do not have the resources or ability to obtain a degree. Two commenters suggested creating a new category of professional called “QDDP functional equivalent” for individuals who do not meet the definition of a QDDP because of the educational requirement, but who have sufficient experience to substitute for the educational component.</p>	<p>No change made. This regulatory action is limited to addressing changes to the regulations that are necessary to comply with the DOJ Settlement Agreement. The recommended changes fall outside the limited scope of this action. The commenters’ suggestions will be considered during the upcoming response to periodic review of the Licensing Regulations (‘overhaul’).</p>
<ul style="list-style-type: none"> • Risk Management 	<p>One commenter recommended striking the word “ensure” and replacing it with “support” in the definition of “risk management”, suggesting that “providers cannot ensure safety.”</p>	<p>No change made. The requirement that providers develop effective risk management systems to ensure the safety of the individuals that they serve is a central focus of this regulatory action and the Settlement Agreement.</p>
<ul style="list-style-type: none"> • Serious Incident 	<p>One commenter requested amendments to the definition of “serious incident” to clarify that serious incidents that result from the actions of an individual receiving services are captured by the definition, and to ensure that such</p>	<p>No change made. The definition of “serious incident” encompasses events and circumstances that cause or could cause harm to the health, safety, or well-being of an individual, regardless of who initiated the actions that</p>

Section	Comment	<u>Changes to proposed draft</u>
	<p>actions are prevented from occurring through risk management, crisis response, behavioral intervention, and corrective action plans.</p>	<p>brought about such events and circumstances.</p> <p>In addition, the definition of Level II serious incident includes significant harm to threat to the health or safety of others caused by an individual.</p> <p>Therefore, the requested change is unnecessary.</p>
<ul style="list-style-type: none"> • Level II Serious Incident 	<p>The department received numerous comments on the proposed definition of “Level II serious incident.” Several commenters requested additional clarification on the reporting of an “unplanned psychiatric ... admission” as a “Level II serious incident”, or removal of “unplanned psychiatric ... admission” from the definition of a “Level II serious incident” altogether. One commenter asked whether an individual who is “ECO’d” but who later decides to voluntarily admit themselves to the hospital would be included within the definition.</p> <p>One commenter expressed concern about the removal of “urgent care facility visits” when not used in lieu of a primary care physician visit. The commenter noted that some injuries that do not necessitate an emergency room visit and may be treated in an urgent care facility. Conversely, several commenters expressed concern that defining all emergency room visits as Level II serious incidents would result in an increased burden on providers. These commenters recommended reverting back to language that only defines emergency room visits as Level II serious incidents when not used “in lieu of a primary care physician visit.”</p>	<p>Changes made.</p> <p>The definition of “Level II serious incident” has been amended to clarify that a psychiatric admission that is in accordance with an individual’s wellness recovery action plan (WRAP) shall not constitute an “unplanned admission for the purposes of this Chapter.” Additional guidance and technical assistance will be provided as needed to ensure that providers are able to meet the regulatory requirements.</p> <p>No changes have been made to the proposed language regarding emergency room visits. Urgent care facility visits were removed from the requirement because they often involve less serious incidents that do not rise to the severity of a Level II serious incident, and a categorical rule in this instance would result in significant over-reporting. Emergency room visits, however, are more likely to evidence an injury or risk of injury of sufficient severity to constitute a Level II serious incident.</p> <p>Furthermore, the department received numerous comments during previous phases of this regulatory action that convincingly suggested that the phrase “in lieu of a primary care physician visit” was too vague and imprecise, and would therefore result in inconsistent interpretation and application. For these reasons, the department believes that it is important to capture all emergency room visits within the definition of Level II serious incidents.</p>

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<ul style="list-style-type: none"> Service 	<p>One commenter expressed concerns about the definition of “service”, noting that “the terms ‘reduce’ and ‘ameliorate’ implies someone with mental health, developmental disabilities (sic) needs to be improved upon or made better.”</p>	<p>No change made. The definition of the term “service” in these regulations is intentionally identical to the definition of “service” in the Code of Virginia § 37.2-403. Regulatory definitions align with definitions in the Code of Virginia whenever possible.</p>
<p><i>12VAC35-105-160. Reviews by the department; requests for information; required reporting.</i></p>		
<ul style="list-style-type: none"> D.2. Incident reports – risk of harm 	<p>A number of commenters expressed concern about the requirement in 12VAC35-105-160(D)(2) that providers report, among other things, the “consequences or risk of harm” that results from Level II and Level III serious incidents. “Risk of harm,” these commenters noted, is speculative, open to interpretation, and asks providers to draw conclusions that they may not have sufficient expertise to draw.</p> <p>Two commenters expressed more general concerns about the Level of detail required in an incident report. These commenters noted that providers have 24 hours to gather information and report to the department.</p>	<p>Change made. The department agrees that “risk of harm” is speculative and will result in different interpretations. “Risk of harm” has been stricken from this subsection. The phrase “risk of harm” has been inserted, however, into subsection 12VAC35-105-160(E) discussing the purpose of the required root cause analyses, which is, in part, to mitigate the risk of future harm, while recognizing the inherent difficulties in foreseeing all risks of future harm. This change will also reduce the immediate burdens placed on providers to complete the initial incident reporting requirements.</p>
<ul style="list-style-type: none"> D.2. Sexual Assault 	<p>One commenter expressed concern about classifying sexual assaults as Level III serious incidents. This commenter worries that requiring the reporting of all sexual assaults “disrespects the preferences of the individual and may inhibit reporting and treatment.”</p>	<p>No changes made. Additional information related to considerations around sexual assault reporting can be found within the department’s “Serious Incident Reporting” guidance document.</p>
<ul style="list-style-type: none"> D.2. Deaths 	<p>One commenter suggested that “expected deaths” should not be classified as Level III serious incidents.</p>	<p>No change made. The department believes that it is important to capture all deaths as Level III serious incidents in order to ensure that they are uniformly reported and evaluated.</p>
<ul style="list-style-type: none"> D.2. Serious incident required reporting 	<p>Several commenters expressed concerns about the requirement that Level II and Level III serious incidents “shall be reported... by telephone to anyone designated by the individual to receive such notice... within 24 hours.” Some commenters found the</p>	<p>Change made. The department agrees that notification by encrypted email may be appropriate in some circumstances, and the regulation is being amended to provide for that flexibility. The department believes</p>

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	<p>required telephonic notification too restrictive, and suggested allowing for notification by encrypted email. Others suggested a longer period than 24 hours, such as by the next business day, for individuals other than the Authorized Representative. One commenter requested clarification about the meaning of the phrase “anyone designated by the individual to receive such notice.”</p>	<p>that concerns about the 24 hour notification period should be alleviated by this change as well. Additional guidance and technical assistance will be provided on this requirement.</p>
<ul style="list-style-type: none"> • E. Root Cause Analyses 	<p>There were a number of comments on the requirement that providers conduct a root cause analysis. Several commenters noted with approval a change that requires root cause analyses for Level III serious incidents only when they occur on the provider’s property or during the provision of services.</p> <p>Several commenters, however, requested that “during the provision of care” be defined or otherwise clarified.</p> <p>Several commenters also expressed concern about the inclusion of language that suggests that a “more detailed root cause analysis,” including, among other steps, “convening a team” should be considered when circumstances warrant. This language, several commenters suggested, is overly prescriptive, ambiguous, and administratively burdensome.</p> <p>Another commenter suggested “clarification that an individual has the right to indicate they do not want the identified solution implemented” when a provider identifies solutions to mitigate the recurrence of a serious incident. This commenter noted that “individuals have the right to choice and dignity of risk.”</p>	<p>Changes made.</p> <p>The department has made changes to provide greater clarity relating to when a provider should conduct a more detailed root cause analysis. The incident management and root cause analysis components of this regulatory action are at the heart of the department’s efforts to fully comply with the Settlement Agreement’s quality and risk management provisions. In the time since the emergency regulation became effective, the department has issued additional guidance related to what constitutes “during the provision of services.”</p> <p>Further guidance and technical assistance to ensure that providers are knowledgeable of and equipped to comply with these requirements while respecting the rights of individuals to choice and dignity will be provided.</p>
<p><i>12VAC35-105-170. Corrective Action Plan.</i></p>		
<ul style="list-style-type: none"> • Corrective Action Plan – Timelines 	<p>Ten commenters recommended the inclusion of a specific timeline for the department to respond in writing to proposed corrective action plans.</p>	<p>No changes made.</p> <p>The department agrees that there should be concrete, consistent timelines for Office of Licensing to</p>

Section	Comment	<u>Changes to proposed draft</u>
		respond to providers. The department will develop these timelines through written protocols.
<i>12VAC35-105-320. Fire inspections.</i>		
<ul style="list-style-type: none"> Sponsored Residential 	<p>The department received 24 comments, most of them identical or nearly identical, recommending the exclusion of Sponsored Residential from this Section, and one comment questioning the relevance of this section to “in-home providers.” Most of the commenters noted the difficulty of obtaining an inspection from a fire marshal for a family home.</p>	<p>Change made. The section has been restored to its previous language, which excludes sponsored residential, and home and non-center based services from the provisions of the Section. In order to fulfill the intent of the previous amendment, additional fire safety related provisions have been added to Section 12VAC35-105-530 Emergency Preparedness and Response Plan.</p>
<i>112VAC35-105-400. Criminal registry background checks and registry searches.</i>		
<ul style="list-style-type: none"> C. & D.2. Documentation 	<p>Three commenters submitted identical comments requesting language changes to this part, included modifying the requirement contained in subsection D.2. that providers maintain “memoranda from the department transmitting the results [of criminal history background checks and registry searches] to the provider” with the phrase “if applicable”; and modifying subsection C. which reads: “The provider shall submit all information required by the department to complete the criminal history background checks and registry searches”, by inserting “to comply with the code of Virginia” between “department” and “to”.</p>	<p>Change made. The department agrees with the proposed amendment to 12VAC35-105-400(D)(2), and the regulation has been amended accordingly. The proposed amendment to 12VAC35-105-400(C), however, is unnecessary and may create confusion rather than clarity. Although this recommendation was provided without explanation, the department believes that the commenter’s intent is to clarify that the department’s requests for information to complete criminal history background checks and registry searches should be consistent with the need to satisfy the background check requirements in Title 37.2 of the Code of Virginia. Because the background check requirements contained in these regulations are consistent with the Code of Virginia’s requirements, this clarification is unnecessary.</p>
<i>12VAC35-105-440. Orientation of new employees, contractors, volunteers, and students.</i>		
<ul style="list-style-type: none"> Orientation 	<p>Several commenters recommended lengthening the period of time in which new employees must receive orientation from fifteen business days to 30 days (two commenters), 45 days (one commenter), or “30 working days” (one commenter); removing the timeframe altogether; exempting small</p>	<p>No changes made. The requirement that new employees receive orientation within 15 business days of their date of hire has been in place since 2002, when the timeframe was extended from 14 days (2 weeks) to 15 business days (3 weeks). Extending this time further</p>

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	providers from the requirement; or removing the time requirement and replacing with a rule that would prevent new employees from providing independent, billable, direct services until orientation has been completed.	would go beyond the purposes of this limited regulatory action. The comment will be reconsidered during the licensing regulatory 'overhaul.'
12VAC35-105-460		
<ul style="list-style-type: none"> Emergency First Aid Training 	Twelve commenters submitted comments requesting clarification about the meaning of "in-person" as used in this subsection, noting that it is conceivable that providers of emergency first aid and cardiopulmonary resuscitation (CPR) training could make their trainings available via video teleconferencing in the future.	No changes made. The department will provide guidance to providers on the application of this regulation to trainings provided via video teleconference technologies if and when such trainings become available.
12VAC35-105-520. Risk Management.		
<ul style="list-style-type: none"> A. Qualifications of Risk Managers 	The department received twenty-four comments on the required qualifications of risk managers. Commenters uniformly described the requirement that persons responsible for risk management have training and expertise in conducting investigations, root cause analysis, and data analysis as "too vague," "overly restrictive," and "unnecessary." A number of commenters specifically noted the difficulties that small business providers would face in meeting this requirement. Some commenters requested additional guidance on what training would be acceptable to satisfy the regulatory requirement.	Change made. The section has been amended to remove the requirement that persons with risk management responsibilities have the previously prescribed "expertise," which the department agrees was too vague. Additional clarification has been added to the types of training that an individual in these positions should receive.
<ul style="list-style-type: none"> D. Uniform Risk Triggers 	Ten commenters requested clarification or removal of the requirement that providers' systemic risk assessment review processes "incorporate uniform risk triggers and thresholds as defined by the department". Several commenters specifically recommended that the department define "uniform risk triggers" and provide training to	No changes made. The department will provide additional guidance and training to providers to ensure that they are able to comply with the requirements of this section.

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	providers to clarify compliance expectations.	
12VAC35-105-590. Provider and Staffing Plan		
<ul style="list-style-type: none"> A.5. Provider Staffing Pan 	One commenter noted, regarding the requirement that provider staffing plans reflect an adequate number of staff required to safely evacuate all individuals during an emergency, that “in-home providers are not present 24 hours a day and cannot be responsible for evacuation in an emergency.”	No change made. This provision does not apply to an in-home provider when they are not providing services.
12VAC35-105-620. Monitoring and Evaluating Service Quality.		
<ul style="list-style-type: none"> C.3. Statewide Performance Measures 	Two commenters noted that this Section requires providers to “include and report on statewide performance measures, if applicable, as required by DBHDS,” but suggested that these were not yet published. One of these commenters recommended removing this language until such time as statewide performance measures are published.	No change made. Statewide performance measures are under development. The “if applicable” qualifier in the event that these measures are not yet in place when the regulations become effective.
12VAC35-105-650. Assessment Policy		
<ul style="list-style-type: none"> F. Initial Assessment and Comprehensive Assessment 	Three commenters noted confusion about how the language in this section, which states that “a comprehensive assessment shall update and finalize the initial assessment” affects same day access services.	No change made, but guidance will be provided to DBHDS staff and external stakeholders to resolve confusion about these requirements in the short term, and the department will revisit these comments during the licensing regulatory ‘overhaul.’
12VAC35-105-660. Individualized Services Plan (ISP)		
<ul style="list-style-type: none"> D. Informed Choice 	One commenter noted that providers’ health records systems may not allow for the inclusion of the information required to be included to verify that an individual participated in and made informed choices about the individual’s planned services; and that some services, such as case management, may not have alternative services. The same commenter sought clarification on what alternatives should be discussed with individuals, what risks individuals should be informed about, and what specific expectations the department	Change made. Clarifying amendments have been made to this section to provide additional guidance on the types of information that should be documented in order to demonstrate that an individual made informed choices about the individual’s services, and how that information may be documented. Amendments were also made to allow for this information to be documented by an individual’s case manager for individuals who have a case manager. Additional guidance and

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	<p>has in relation to these.</p> <p>Another commenter suggested that ensuring and documenting informed consent is the role of the individual's case manager and not the provider.</p>	<p>technical assistance will be provided to ensure that providers understand these expectations.</p>
<p>12VAC35-105-675. Reassessments and ISP reviews.</p>		
<ul style="list-style-type: none"> D.3. Meetings when goals not accomplished 	<p>Two commenters noted that "requiring a team meeting when individuals do not meet specific objectives is difficult," and asked for clarification on the provider's obligations under this section. Specifically, the commenters ask "if an objective on the ISP states that the client will visit their 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?"</p>	<p>No changes made.</p> <p>The department will provide additional guidance and technical assistance as needed to ensure that providers understand this regulatory provision. The regulation does not require providers to "bring the whole team together" whenever a planned objective is not achieved. It does require providers to meet with "any appropriate treatment team members" when it determines, based on its tri-monthly review of the ISP, that goals and objectives were not achieved by their target date. Which treatment team members, if any, are appropriate under the circumstances is a fact specific question, which must be determined on a case-by-case basis.</p>
<p>12VAC35-105-1245. Case management direct assessments.</p>		
<ul style="list-style-type: none"> Documentation 	<p>Three commenters requested clarification on the documentation that would be necessary to establish compliance with the face-to-face meeting and direct assessment expectations.</p>	<p>No changes made.</p> <p>The department will provide additional guidance and technical assistance to case managers on the expectations in this section and how to document meetings in a manner that verifies compliance with those expectations.</p>
<p>12VAC35-105-1250. Qualifications of Case Management Employees or Contractors.</p>		
<ul style="list-style-type: none"> D. Core Curriculum 	<p>One commenter noted that "while we support the requirement that case managers serving individuals with developmental disability (sic) shall complete the DBHDS core competency-based curriculum within 30 days of hire no allowance is made for when the DBHDS training system is unavailable.</p>	<p>No changes made.</p> <p>This requirement is an important component of the Commonwealth's compliance with the Settlement Agreement and will not be amended.</p>

Section	Comment	<u>Changes to proposed draft</u>
General comments		
<ul style="list-style-type: none"> Economic impact on regulated entities 	<p>Six commenters disagreed with the department’s economic impact statement or otherwise noted the administrative financial impact on regulated entities of the additional risk management and quality improvement components of these regulations. One commenter suggested that these requirements were not factored into the existing provider rate methodology. One commenter noted that “the financial cost for ensuring appropriate training occurs is not small and we encourage the Office of Licensing to support the provision of regular, high-quality training across the Commonwealth on topics such as root cause analysis, risk management, data analysis, and investigation skills.”</p>	<p>No changes made. DBHDS believes these new regulations will be cost neutral. The new regulations were previously put in place with an emergency provision, meaning providers should be in compliance or in planning to utilize existing resources to come into compliance. The new requirements of the permanent regulations may impose some administrative costs to providers, but will save administrative resources by categorizing reported incidents and improving compliance and quality and risk management at facilities. Most facilities licensed by DBHDS have personnel possessing the qualifications as outlined in the regulations. The only individual required to have such qualifications is a risk manager for the facility. DBHDS will use existing resources to provide necessary trainings and support to any risk manager not previously trained. The staff time required to adhere to the new regulations is minimal and, as a result, the provider rate methodology is likely not affected.</p> <p>Additionally, Without these regulations, the Commonwealth, DBHDS, and all licensed providers face falling out of compliance with the DOJ Settlement Agreement, which would lead to significantly more expensive measures for all parties than compliance with these regulations.</p> <p>The department is committed to supporting providers to ensure that requisite training occurs and that they have the tools necessary to carry out effective risk management and quality improvement programs. The department will continue to provide guidance and technical assistance to providers in these areas.</p>
<ul style="list-style-type: none"> Regulatory alignment 	<p>Several commenters made general comments about the need for increased consistency within and</p>	<p>No changes made. These comments are beyond the scope of this limited regulatory action,</p>

Section	Comment	Changes to proposed draft
	across regulatory agencies. One commenter made the general recommendation that the department “improve consistency and clarity among all relevant regulatory language.” Two providers suggested the development of a “crosswalk among licensure, human rights, Medicaid Waiver and HCBS.”	the department will consider the commenter’s recommendations during the licensing regulation overhaul. DBHDS and DMAS have collaborated while drafting the regulations for the planned ‘overhaul’ action to ensure that the agencies’ regulations include as much alignment as possible.
<ul style="list-style-type: none"> CARF Accreditation 	Two commenters recommended that providers with a full three-year Commission on Accreditation of Rehabilitation Facilities (CARF) accreditation be granted “deemed status”, and be exempt from DBHDS licensing requirements.	No changes made. This recommendation is beyond the scope of this limited action, but will be considered during the licensing ‘overhaul.’

Detail of Changes Made Since the Previous Stage

*Please list all changes made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Please put an asterisk next to any substantive changes.*

Current chapter-section number	New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
20		<p><u>"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:</u></p> <ol style="list-style-type: none"> <u>1. A serious injury;</u> <u>2. An individual who is or was missing;</u> <u>3. An emergency room visit;</u> 	<p><u>"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:</u></p> <ol style="list-style-type: none"> <u>1. A serious injury;</u> <u>2. An individual who is or was missing;</u> <u>3. An emergency room visit;</u> 	<ul style="list-style-type: none"> Quality improvement plan was put in alphabetic order with other definitions. The definition of a “Level II serious incident” was amended to exclude psychiatric admissions when in accordance with an individual’s wellness recovery action plan (WRAP) from the definition. This change will reduce unnecessary serious

		<p><u>4. An unplanned psychiatric or unplanned medical hospital admission of an individual receiving services other than licensed emergency services</u></p> <p><u>5. Choking incidents that require direct physical intervention by another person;</u></p> <p><u>6. Ingestion of any hazardous material; or</u></p> <p><u>7. A diagnosis of:</u></p> <p><u>a. A decubitus ulcer or an increase in severity of level of previously diagnosed decubitus ulcer;</u></p> <p><u>b. A bowel obstruction;</u></p> <p><u>or</u></p> <p><u>c. Aspiration pneumonia.</u></p>	<p><u>4. An unplanned psychiatric or unplanned medical hospital admission of an individual receiving services other than licensed emergency services [, except that a psychiatric admission in accordance with the individual's Wellness Recovery Action Plan (WRAP) shall not constitute an unplanned admission for the purposes of this Chapter] ;</u></p> <p><u>5. Choking incidents that require direct physical intervention by another person;</u></p> <p><u>6. Ingestion of any hazardous material; or</u></p> <p><u>7. A diagnosis of:</u></p> <p><u>a. A decubitus ulcer or an increase in severity of level of previously diagnosed decubitus ulcer;</u></p> <p><u>b. A bowel obstruction;</u></p> <p><u>or</u></p> <p><u>c. Aspiration pneumonia.</u></p>	<p>incident reporting and reduce provider burdens by decreasing the number of incidents for which root cause analyses and other risk management activities must be completed.</p>
150		<p>The provider including its employees, contractors, students, and volunteers shall comply with:</p> <p>3. All applicable federal, state, or local laws and regulations including:</p> <p>c. <u>For home and community-based services waiver settings subject to this chapter, 42 CFR 441.301(c)(1) through (4) contents of request for a waiver.</u></p>	<p>The provider including its employees, contractors, students, and volunteers shall comply with:</p> <p>3. All applicable federal, state, or local laws and regulations including:</p> <p>c. <u>For home and community-based services waiver settings subject to this chapter, 42 CFR 441.301(c)(1) through (4) [contents of request for a waiver] ;</u></p>	<ul style="list-style-type: none"> Removed unnecessary language referring to the title for a cited federal regulation for ease of reading and clarity.
160		<p><u>D.</u> The provider shall collect, maintain, and report or make available to the</p>	<p><u>D.</u> The provider shall collect, maintain, and report or make available to the</p>	<ul style="list-style-type: none"> Edits were made to the structure of this section for clarity. “Risk of harm” was removed from the

	<p>department the following information: 2. Each instance of death or serious injury <u>Level II and Level III serious incidents</u> shall be reported in writing to the department's assigned licensing specialist using the <u>department's web-based reporting application and by telephone to anyone designated by the individual to receive such notice and to the individual's authorized representative</u> within 24 hours of discovery and by phone to the individual's authorized representative within 24 hours. Reported information shall include the <u>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 that resulted from the serious incident.</u></p>	<p>department the following information: 1. Each allegation of abuse or neglect shall be reported to the assigned human rights advocate and the individual's authorized representative <u>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</u> <u>department as provided in 12VAC35-115-230 A.</u> 2. Each instance of death or serious injury Level II and Level III serious incidents shall be reported in writing to the department's assigned licensing specialist using the department's web-based reporting application and by telephone [or e-mail] to anyone designated by the individual to receive such notice and to the individual's authorized representative <u>within 24 hours of discovery and by phone to the individual's authorized representative within 24 hours.</u> Reported information shall include the <u>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</u></p>	<p>requirements of an incident report in response to comments that convincingly suggested that this language is too speculative.</p> <ul style="list-style-type: none"> • Mitigation of future risk of harm was added to the purposes of the solutions identified during a root cause analysis to clarify the intent of these analyses. • Language was edited to allow for notification by email in addition to by telephone to anyone identified by the individual to receive notice of serious incidents. This will reduce provider burden while still ensuring that appropriate individuals are informed of serious incidents. • The requirement for a more detailed root cause analysis has been modified to add greater clarity to the circumstances when a more detailed root cause analysis must be conducted, and to require providers to develop policies and procedures related to this requirement. • A new subsection, J., was included to require providers to develop a serious incident management policy in order to ensure consistent
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		<p>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.</p> <p><u>3. Each instance</u> <u>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 human rights advocate within 24 hours shall be reported to the department as provided in 12VAC35-115-230 C 4.</u></p> <p><u>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</u></p>	<p>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.</p> <p><u>3. Each instance</u> <u>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 human rights advocate within 24 hours shall be reported to the department as provided in 12VAC35-115-230 C 4.</u></p> <p><u>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</u></p>	<p>application of the requirements of this section by providers.</p>
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		<p><u>analysis of why it happened, including identification of all identifiable underlying causes of the incident that were under the control of the provider; and c.(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.</u></p>	<p><u>a service or on the provider's premises. [1.] The root cause analysis shall include at least the following information: [(i) a a. A] detailed description of what happened; [(ii) an b. An] analysis of why it happened, including identification of all identifiable underlying causes of the incident that were under the control of the provider; and [(iii) identified c. Identified] solutions to mitigate its reoccurrence [and future risk of harm] 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. 2. The provider shall develop and implement a root cause analysis policy for determining when a more detailed root cause analysis including convening a team, collecting and analyzing data, mapping processes, and charting causal factors should be conducted. At a minimum, the policy shall require for the provider to conduct a more detailed root cause analysis when:</u> <u>a. A threshold number, as specified in the provider's policy based</u></p>	
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		N/A	<p><u>on the provider's size, number of locations, service type, number of individuals served, and the unique needs of the individuals served by the provider, of similar</u></p> <p><u>Level II serious incidents occur to the same individual or at the same location within a six month period;</u></p> <p><u>b. Two or more of the same Level III serious incidents occur to the same individual or at the same location within a six month period;</u></p> <p><u>c. A threshold number, as specified in the provider's policy based on the provider's size, number of locations, service type, number of individuals served, and the unique needs of the individuals served by the provider, of similar Level II or Level III serious incidents occur across all of the provider's locations within a six month period; and</u></p> <p><u>d. A death occurs as a result of an acute medical event that was not expected in advance or based on a person's known medical condition.]</u></p> <p><u>[J. The provider shall develop and implement a serious incident management policy, which shall be consistent with this Section, and which shall describe the processes by which the provider will document, analyze, and report to the department</u></p>	
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			<p>information related to serious incidents.]</p>	
<p>170</p>		<p>G. The provider shall <u>implement and monitor implementation of the approved corrective action and include a plan for monitoring in.</u> <u>The provider shall monitor implementation and effectiveness of approved corrective actions as part of its quality assurance activities improvement program</u> specified in required by 12VAC30-105-620.</p>	<p>G. The provider shall <u>implement [and monitor implementation of the approved corrective action and include a plan for monitoring in.</u> <u>The provider shall monitor implementation and effectiveness of approved corrective actions as part of its quality assurance activities improvement program</u> specified in required by 12VAC30-105-620. <u>their written corrective action plan for each violation cited by the date of completion identified in the plan.</u> <u>H. The provider shall monitor implementation and effectiveness of approved corrective actions as part of its quality improvement program required by 12VAC35-105-620. If the provider determines that an approved corrective action was fully implemented, but did not prevent the recurrence of a regulatory violation or correct any systemic deficiencies, the provider shall:</u> <u>1. Continue implementing the corrective action plan and put into place additional measures to prevent the recurrence of the cited violation and address identified systemic deficiencies;</u> <u>or</u> <u>2. Submit a revised corrective action plan to</u></p>	<ul style="list-style-type: none"> • Amendments were made to this Section to clarify provider requirements for monitoring and amending corrective action plans as a component of the provider's quality improvement plan.

			<u>the department for approval.]</u>	
320		The provider shall document at the time of its original application and annually thereafter that buildings and equipment in residential service locations servicing more than eight individuals are maintained in accordance with the Virginia Statewide Fire Prevention Code (13VAC5-51). This section does not apply to correctional facilities or home and noncenter-based or sponsored residential home services. The 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.	The provider shall document at the time of its original application and annually thereafter that buildings and equipment in residential service locations [servicing more than eight individuals] are maintained in accordance with the Virginia Statewide Fire Prevention Code (13VAC5-51). <u>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.</u> This section does not apply to correctional facilities or home and noncenter-based or sponsored residential home services.]	<ul style="list-style-type: none"> • In response to significant public comment, the proposed amendments to this Section have been stricken, and the language reverted back to as it appeared prior to the proposed stage of this action. • Language related to fire safety has been added below to 12VAC35-105-530 to accomplish the intent of the proposed amendments, which is to ensure that all providers adhere to a basic level of fire safety precautions for the health and safety of individuals.
400		2. Documentation that the provider submitted all information required by the department to complete the <u>criminal history background checks</u> and registry checks searches , memoranda from the department transmitting the results to the provider, and the results from the Child Protective Registry check search .	2. Documentation that the provider submitted all information required by the department to complete the <u>criminal history background checks</u> and registry checks searches , memoranda from the department transmitting the results to the provider, [<u>if applicable</u>] and the results from the Child Protective Registry check search .	<ul style="list-style-type: none"> • The words “if applicable” were added to Subsection 2 of this section to clarify that there are providers, namely CSBs, who do not obtain memoranda from the department related to criminal history background checks and will not have such documentation to maintain.
500		B. The provider shall not rely on students or volunteers for the provision of direct care services. The provider staffing plan shall not	B. The provider shall not rely on students or volunteers [for the provision of direct care services to supplant direct care positions] .	<ul style="list-style-type: none"> • This section was included in the final stage. • Language changes only for consistency and alignment with

		include volunteers or students.	The provider staffing plan shall not include volunteers or students.	regulatory and statutory definitions.
520		<p>A. The provider shall designate a person responsible for <u>the risk management function who has training and expertise in conducting investigations, root cause analysis, and data analysis.</u></p> <p>B. The provider shall implement a written plan to identify, monitor, reduce, and minimize risks <u>associated with harms and risk of harm, including personal injury, infectious disease, property damage or loss, and other sources of potential liability.</u></p> <p>C. The provider shall <u>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;</u></p>	<p>A. The provider shall designate a person responsible for <u>the risk management function who has [completed department approved] training [and expertise in, which shall include training related to risk management, understanding of individual risk screening,] conducting investigations, root cause analysis, and [data analysis the use of data to identify risk patterns and trends]</u>.</p> <p>B. The provider shall implement a written plan to identify, monitor, reduce, and minimize risks associated with <u>harms and risk of harm, including personal injury, infectious disease, property damage or loss, and other sources of potential liability.</u></p> <p>C. The provider shall <u>conduct systemic risk assessment reviews at least annually to identify and respond to practices, situations, and policies that could result in the risk of harm to individuals receiving services. The risk assessment review shall address [at least the following:]</u> <u>The risk assessment review shall address [at least the following:</u> (i) the 1. The] <u>environment of care; [</u> (ii) clinical 2. Clinical] <u>assessment or</u></p>	<ul style="list-style-type: none"> • Amendments were made to this section to clarify the necessary qualifications of risk management staff. The requirement that such staff have “expertise” in risk management has been removed in response to commenters who found this requirement too vague; and additional detail has been provided as to the specific types of department approved training that a risk management staff will be expected to complete. • Subsection C was reformatted to promote clarity and ease of reading. • New Subsection D was added to provide greater clarity on the essential components of a systemic risk assessment review process, including uniform risk triggers and thresholds, to be further defined by the department.

		<p><u>and (v) a review of serious incidents. This process shall incorporate uniform risk triggers and thresholds as defined by the department. This process shall incorporate uniform risk triggers and thresholds as defined by the department</u></p> <p>G. 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.</p> <p>D. E. The provider shall document serious injuries to employees, contractors, students, volunteers, and visitors <u>that occur during the provision of a service or on the provider's property.</u> Documentation shall be kept on file for three years. The provider shall evaluate <u>serious</u> injuries at least annually. Recommendations for improvement shall be documented and implemented by the provider</p>	<p><u>reassessment processes; [(iii) staff 3. Staff] competence and adequacy of staffing; [(iv) use 4. Use] of high risk procedures, including seclusion and restraint; and [(v) a 5. A] review of serious incidents. [This process shall incorporate uniform risk triggers and thresholds as defined by the department.</u></p> <p><u>D. The systemic risk assessment process shall incorporate uniform risk triggers and thresholds as defined by the department.]</u></p> <p>G. [D. E.] 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.</p> <p>D. [E.-F.] The provider shall document serious injuries to employees, contractors, students, volunteers, and visitors <u>that occur during the provision of a service or on the provider's property.</u> Documentation shall be kept on file for three years. The provider shall evaluate <u>serious</u> injuries at least annually. Recommendations for improvement shall be documented and</p>	
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			<p>implemented by the provider.</p>	
<p>530</p>		<p>A. The provider shall develop a written emergency preparedness and response plan for all of its services and locations that describes its approach to emergencies throughout the organization or community. This plan shall include an analysis of potential emergencies that could disrupt the normal course of service delivery including emergencies that would require expanded or extended care over a prolonged period of time. The plan shall address:</p> <p>5. Written emergency response procedures for initiating the response and recovery phase of the plan including a description of how, when, and by whom the phases will be activated. This includes assessing the situation; protecting individuals receiving services, employees, contractors, students, volunteers, visitors, equipment, and vital records; and restoring services. Emergency procedures shall address:</p> <p>9. Schedule for testing the implementation of</p>	<p>A. The provider shall develop a written emergency preparedness and response plan for all of its services and locations that describes its approach to emergencies throughout the organization or community. This plan shall include an analysis of potential emergencies that could disrupt the normal course of service delivery including emergencies that would require expanded or extended care over a prolonged period of time. The plan shall address:</p> <p>5. Written emergency response procedures for initiating the response and recovery phase of the plan including a description of how, when, and by whom the phases will be activated. This includes assessing the situation; protecting individuals receiving services, employees, contractors, students, volunteers, visitors, equipment, and vital records; and restoring services. Emergency procedures shall address: <u>[e. Evacuation procedures, including for individuals who need evacuation assistance;]</u></p>	<ul style="list-style-type: none"> • This section was included in the final stage. • Added to the requirements of a provider’s emergency preparedness and response plan requirement that this plan include “evacuation procedures, including for individuals who need evacuation assistance. • Added to requirement that emergency planning drills be conducted an expectation that Fire and evacuation drills be conducted at least monthly, and that the provider evaluate each individual to determine their support needs during an emergency and ensure that appropriate environmental supports and adequate staff are provided in emergency situations. • These provisions will improve provider emergency planning efforts and ensure that the health and safety needs of individuals are met in emergency situations requiring evacuation.

		<p>the plan and conducting emergency preparedness drills.</p> <p>N/A</p> <p>N/A</p>	<p>9. Schedule for testing the implementation of the plan and conducting emergency preparedness drills. <u>[a. Fire and evacuation drills shall be conducted at least monthly.]</u> <u>[B. The provider shall evaluate each individual and, based on that evaluation, shall provide appropriate environmental supports and adequate staff to safely evacuate all individuals during an emergency.]</u></p> <p><u>[I. All provider locations shall be equipped with at least one approved type ABC portable fire extinguisher with a minimum rating of 2A10BC installed in each kitchen.</u></p> <p><u>J. All provider locations shall have an appropriate number of properly installed smoke detectors based on the size of the location, which shall include at a minimum:</u></p> <p><u>1. Smoke detectors on each level of multi-level buildings, including the basement;</u></p> <p><u>2. Smoke detectors in each bedroom in locations with bedrooms;</u></p> <p><u>3. An additional smoke detector in any area adjacent to any bedroom in localities with bedrooms;</u></p> <p><u>4. Any additional smoke detectors necessary to comply with all applicable federal and state laws and</u></p>	<ul style="list-style-type: none"> • Specifies minimum fire safety precautions of providers, including smoke alarm and fire extinguisher requirements.
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			<p><u>regulations and local ordinances.</u> <u>K. Smoke detectors shall be tested monthly for proper operation.</u> <u>L. All provider locations shall maintain a floor plan identifying locations of:</u> <u>1. Exits;</u> <u>2. Primary and secondary evacuation routes;</u> <u>3. Accessible egress routes;</u> <u>4. Portable fire extinguishers; and</u> <u>5. Flashlights</u> <u>M. This section does not apply to home and noncenter-based services.]</u></p>	
590		<p>F. Staff in direct care positions providing brain injury services shall have at least a high school diploma and two years of experience working with individuals with disabilities or shall have successfully completed an approved training curriculum on brain injuries within six months of employment.</p>	<p>F. [Direct care staff who provide <u>Staff in direct care positions providing</u>] brain injury services shall have at least a high school diploma and two years of experience working with individuals with disabilities or shall have successfully completed an approved training curriculum on brain injuries within six months of employment.</p>	<ul style="list-style-type: none"> • This non-substantive language change increases consistency in language use throughout regulations and aligns regulatory language with definitions in the Code of Virginia.
620		<p>The provider shall <u>develop and</u> implement written policies and procedures to <u>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</u></p>	<p>[<u>A.</u>] The provider shall <u>develop and</u> implement written policies and procedures to <u>for a quality improvement program sufficient to identify, monitor, and evaluate clinical and service quality and effectiveness on a systematic and ongoing basis.</u> [<u>B.</u>] The [<u>quality improvement</u>] <u>program shall utilize standard quality improvement</u></p>	<ul style="list-style-type: none"> • This section was rearranged largely to aid in readability and comprehension. • Added requirement that the provider's policies and procedures include "criteria for amending corrective actions when reviews determine the corrective action has not been effective at preventing the

		<p><u>shall include a quality improvement plan that (i) is reviewed and updated at least annually; defines measurable goals and objectives; includes and reports on statewide performance measures, if applicable, as required by DBHDS; monitors implementation and effectiveness of approved corrective action plans pursuant to 12VAC35-105-170; and 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 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 assurance system improvement plan. The provider shall implement improvements, when indicated.</u></p>	<p><u>tools, including root cause analysis, and shall include a quality improvement plan [. that C. The quality improvement plan shall: (i) is 1. Be] reviewed and updated at least annually; [(ii) defines 2. Define] measurable goals and objectives; [(iii) includes 3. Include] and [reports report] on statewide performance measures, if applicable, as required by DBHDS; [(iv) monitors 4. Monitor] implementation and effectiveness of approved corrective action plans pursuant to 12VAC35-105-170; and [(v) includes 5. Include] ongoing monitoring and evaluation of progress toward meeting established goals and objectives. [D.] The provider's policies and procedures shall include the criteria the provider will use to establish [: 1. Establish measurable goals and objectives; 2. Update the provider's quality improvement plan; and 3. Submit revised corrective action plans to the department for approval or continue implementing the corrective action plan and put into place additional measures to prevent the recurrence of the cited violation and address identified</u></p>	<p>recurrence of the regulatory violation.</p>
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			<p><u>systemic deficiencies when reviews determine that a corrective action was fully implemented but did not prevent the recurrence of the cited regulatory violation or correct a systemic deficiency pursuant to 12VAC35-105-170.</u> <u>E.]</u> 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.</p>	
660		<p><u>D. The initial ISP and the comprehensive ISP 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 the individual's authorized representative, as applicable, in a reasonable and comprehensible manner the proposed services to be delivered, alternative services that might be advantageous for the individual, and accompanying risks or</u></p>	<p><u>D. The initial ISP and the comprehensive ISP shall be developed based on the respective assessment with the participation and informed choice of the individual receiving services. [</u> <u>1.] To ensure the individual's participation and informed choice, the [provider following] shall [be explain explained] to the individual or the individual's authorized representative, as applicable, in a reasonable and comprehensible manner [:</u> <u>the a. The] proposed services to be delivered [:</u></p>	<ul style="list-style-type: none"> • This section has been restructured to aid in readability and comprehension • Changes to language have been made to clarify expectations

		<p><u>benefits. The provider shall clearly document that the individual's information was explained to the individual or the individual's authorized representative and c. the reasons the individual or the individual's authorized representative chose the option included in the ISP.</u></p>	<p><u>b. Any] alternative services that might be advantageous for the individual [;] and [c. Any] accompanying risks or benefits [of the proposed and alternative services] . [The provider shall clearly document that the individual's information was explained to the individual or the individual's authorized representative and the reasons the individual or the individual's authorized representative chose the option included in the ISP.</u></p> <p><u>2. If no alternative services are available to the individual, it shall be clearly documented within the ISP, or within documentation attached to the ISP, that alternative services were not available as well as any steps taken to identify if alternative services were available.</u></p> <p><u>3. Whenever there is a change to an individual's ISP, it shall be clearly documented within the ISP, or within documentation attached to the ISP that:</u></p> <p><u>a. The individual participated in the development of or revision to the ISP;</u></p> <p><u>b. The proposed and alternative services and their respective risks and benefits were explained to the individual or the individual's authorized representative, and;</u></p>	
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			c. The reasons the individual or the individual's authorized representative chose the option included in the ISP.]	
665		N/A	Updated language in Subsection D, as follows: D. Employees or contractors who are responsible for implementing the ISP shall demonstrate a working knowledge of the objectives and strategies contained in the individual's current ISP [, including an individual's detailed health and safety protocols] .	<ul style="list-style-type: none"> Language related to what employees and contractors must demonstrate knowledge of was updated to incorporate language from the DOJ Settlement Agreement.

Detail of All Changes Proposed in this Regulatory Action

Please list all changes proposed in this action and the rationale for the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Please put an asterisk next to any substantive changes.

Current section number	Proposed new section number, if applicable	Current requirement	Change, intent, and likely impact of proposed requirements
20		<p>"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...."</p> <p>"Developmental disabilities" means autism or a severe, chronic disability that meets all of the following</p>	<ul style="list-style-type: none"> Removes "activity or training service" language and replaces, with <u>training, assistance, and specialized supervision in the acquisition, retention or improvement of self-help, socialization, and adaptive skills.</u>

	<p>conditions identified in 42 CFR 435.1009:</p> <ol style="list-style-type: none"> 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; 2. Manifested before the individual reaches age 18; 3. Likely to continue indefinitely; and 4. Results in substantial functional limitations in three or more of the following areas of major life activity: <ol style="list-style-type: none"> a. Self-care; b. Understanding and use of language; c. Learning; d. Mobility; e. Self-direction; or f. Capacity for independent living. 	<ul style="list-style-type: none"> • Definition of “developmental disabilities” was amended to match Title 37.2 of the Code of Virginia.
	N/A	<ul style="list-style-type: none"> • Addition of a general definition for “developmental services” from Title 37.2 of the Code of Virginia.
	N/A	<ul style="list-style-type: none"> • Addition of a general definition for “direct care position.”
	N/A	<ul style="list-style-type: none"> • Addition of a general definition for “informed choice.” <p><u>"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.</u></p>

	<p>do so, including nourishment, treatment, care, goods, or services necessary to the health, safety, or welfare of a person receiving care or treatment for mental illness, mental retardation (intellectual disability), or substance abuse (substance use disorders).</p> <p>"Qualified Mental Retardation Professional (QMRP)" means a person who possesses at least ...</p> <p>N/A</p> <p>N/A</p> <p>N/A</p>	<p>retardation (intellectual disabilities)" with "developmental disabilities".</p> <p>"Neglect" means the failure by an individual a person, or a program or facility operated, licensed, or funded by the department, excluding those operated by the Department of Corrections, responsible for providing services to do so, including nourishment, treatment, care, goods, or services necessary to the health, safety, or welfare of a person <u>an individual</u> receiving care or treatment for mental illness, mental retardation (intellectual disability) <u>developmental disabilities</u>, or substance abuse (substance use disorders).</p> <ul style="list-style-type: none"> • Change the term to Qualified Developmental Disability Professional (QDDP) to reflect § 37.2-100 of the Code of Virginia. • Addition of a definition for "quality improvement plan." Reordered definitions between proposed and final draft. <p><u>"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.</u></p> <ul style="list-style-type: none"> • Addition of a definition for "risk management." <p><u>"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.</u></p> <ul style="list-style-type: none"> • Addition of general definition of "root cause analysis."
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		N/A	<p><u>"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.</u></p> <ul style="list-style-type: none"> • 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 with additional requirements for reporting and root cause analysis within 12VAC35-105-160 and 12VAC35-105-520 • The definition of "serious incident" was amended between the proposed and final stage to exclude psychiatric admissions that are in accordance with an individual's Wellness Recovery Action Plan (WRAP) from the definition of a "level II serious incident". <p><u>"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.</u></p> <p><u>"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.</u></p> <p><u>"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.</u></p> <p><u>"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:</u></p> <ol style="list-style-type: none"> <u>1. A serious injury;</u> <u>2. An individual who is or was missing;</u> <u>3. An emergency room visit;</u> <u>4. An unplanned psychiatric or unplanned medical hospital admission</u>
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		<p>N/A</p>	<p><u>of an individual receiving services other than licensed emergency services, except that a psychiatric admission in accordance with the individual's Wellness Recovery Action Plan (WRAP) shall not constitute an unplanned admission for the purposes of this Chapter;</u> <u>5. Choking incidents that require direct physical intervention by another person;</u> <u>6. Ingestion of any hazardous material;</u> <u>or</u> <u>7. A diagnosis of:</u> <u>a. A decubitus ulcer or an increase in severity of level of previously diagnosed decubitus ulcer;</u> <u>b. A bowel obstruction; or</u> <u>c. Aspiration pneumonia.</u> <u>"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:</u> <u>1) Any death of an individual;</u> <u>2) A sexual assault of an individual; or</u> <u>3) A suicide attempt by an individual admitted for services, other than licensed emergency services, that results in a hospital admission.</u></p> <ul style="list-style-type: none"> • Addition of a definition for "suicide attempt" <p><u>"Suicide attempt" means a nonfatal, self-directed, potentially injurious behavior with an intent to die as a result of the behavior regardless of whether it results in injury.</u></p> <ul style="list-style-type: none"> • Addition of a definition for "systemic deficiency." <p><u>"Systemic deficiency" means violations of regulations documented by the department that demonstrate multiple or repeat defects in the operation of one or more services.</u></p>
<p>30</p>			<ul style="list-style-type: none"> • Amend language to align with Title 37.2 of the Code of Virginia and the Centers for Medicare and Medicaid Services (CMS).
<p>50</p>		<p>D. A license shall not be issued or renewed unless the provider is</p>	<ul style="list-style-type: none"> • Amend language to align Title 37.2 of the Code of Virginia. • Remove the following language to reflect changes to the Human Rights Regulations: A license shall not be

		affiliated with a local human rights committee.	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.	<ul style="list-style-type: none"> Clarifying amendments: 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. <u>A provider shall submit a request for 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.</u>
150		The provider including its employees, contractors, students, and volunteers shall comply with: <ol style="list-style-type: none"> These regulations; The terms and stipulations of the license; All applicable federal, state, or local laws and regulations including: <ol style="list-style-type: none"> Laws regarding employment practices including the Equal Employment Opportunity Act; The Americans with Disabilities Act and the Virginians with Disabilities Act; Occupational Safety and Health Administration regulations; Virginia Department of Health regulations; Laws and regulations of the Virginia Department of Health Professions regulations; Virginia Department of Medical Assistance Services regulations; Uniform Statewide Building Code; and Uniform Statewide Fire Prevention Code. 	<ul style="list-style-type: none"> After 3(b) amend, in accordance with CMS Final Rule, to include: <u>For home and community-based services waiver settings subject to these regulations, 42 CFR § 441.301(c)(1)-(4);</u> along with minor language changes. <ol style="list-style-type: none"> These regulations <u>This chapter;</u> The terms and stipulations of the license; All applicable federal, state, or local laws and regulations including: <ol style="list-style-type: none"> Laws regarding employment practices including the Equal Employment Opportunity Act; The Americans with Disabilities Act and the Virginians with Disabilities Act; <u>For home and community-based services waiver settings subject to this chapter, 42 CFR 441.301(c)(1) through (4) [, contents of request for a waiver] ;</u> <u>Occupational Safety and Health Administration regulations;</u>

			<p>d. <u>e.</u> Virginia Department of Health regulations;</p> <p>e. <u>Laws and regulations of the</u> f. <u>Virginia</u> Department of Health Professions regulations;</p> <p>f. <u>g.</u> Virginia Department of Medical Assistance Services regulations;</p> <p>g. <u>h.</u> Uniform Statewide Building Code; and</p> <p>h. <u>i.</u> Uniform Statewide Fire Prevention Code.</p> <p>4. Section 37.2-400 of the Code of Virginia and related human rights regulations adopted by the state board; and</p> <p>5. The provider's own policies. All required policies shall be in writing.</p>
155			<ul style="list-style-type: none"> • Replace “mental retardation (intellectual disability)” with the term “developmental disability” in accordance with Title 37.2 of the Code of Virginia.
160			<ul style="list-style-type: none"> • 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. • Amend to require a root cause analysis of Level II and Level III serious incidents that occur during the provision of a service or on the provider's premises. 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. • Amend to align reporting of abuse, neglect, seclusion and restraint with the Human Rights Regulations. • 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. • Final regulation amended to allow reporting of serious incidents to authorized representatives and others designated by individual by e-mail, in addition to by telephone, to provide

		<p>B. The provider shall cooperate fully with inspections and provide all information requested to assist representatives from the department who conduct inspections.</p> <p>C. The provider shall collect, maintain, and report or make available to the department the following information:</p> <p>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.</p> <p>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</p>	<p>additional flexibility and ease burden on providers.</p> <ul style="list-style-type: none"> • Removed requirement to report "risk of harm" on incident reports to remove ambiguity and ease burden on providers. • Added mitigation of future risk of harm to the purposes of the solutions identified through root cause analysis. • Added requirement that provider develop its own root cause analysis & incident management policies. <p>B. The provider shall cooperate fully with inspections <u>and investigations, and shall provide all information requested to assist representatives from by the department who conduct inspections.</u></p> <p>C. <u>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.</u></p> <p>D. The provider shall collect, maintain, and report or make available to the department the following information:</p> <p>1. <u>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.</u></p> <p>2. <u>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 telephone or e-mail to anyone designated by the individual to receive such notice and to the individual's authorized representative within 24 hours of discovery and by phone to the individual's authorized representative within 24 hours.</u> Reported information shall include <u>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</u></p>
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	<p>was in a licensed service shall be reported.</p> <p>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.</p> <p>D. The provider shall submit, or make available, reports and information that the department requires to establish compliance with these regulations and applicable statutes.</p> <p>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.</p> <p>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.</p> <p>G. Applicants and providers shall not submit any misleading or false information to the department. 12VAC35-105.</p>	<p><u>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 that resulted from the serious incident.</u> 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.</p> <p>3. Each instance <u>Instances</u> 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 shall be reported to the department as provided in 12VAC35-115-230 C 4.</p> <p><u>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.</u></p> <p>[1.] <u>The root cause analysis shall include at least the following information:</u></p> <p>[(i) a. a A] <u>detailed description of what happened;</u></p> <p>[(ii) b. a A] <u>n analysis of why it happened, including identification of all identifiable underlying causes of the incident that were under the control of the provider; and</u></p> <p>[(iii) c. i I] <u>identified solutions to mitigate its reoccurrence [and future risk of harm] when applicable.</u></p> <p>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.</p> <p>[2. The provider shall develop and implement a root cause analysis policy for determining when a more detailed root cause analysis including convening a team, collecting and analyzing data, mapping processes, and charting causal factors should be conducted. At a minimum, the policy shall require for the provider to</p>
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			<p><u>conduct a more detailed root cause analysis when:</u></p> <p><u>a. A threshold number, as specified in the provider's policy based on the provider's size, number of locations, service type, number of individuals served, and the unique needs of the individuals served by the provider, of similar Level II serious incidents occur to the same individual or at the same location within a six month period;</u></p> <p><u>b. Two or more of the same Level III serious incidents occur to the same individual or at the same location within a six month period;</u></p> <p><u>c. A threshold number, as specified in the provider's policy based on the provider's size, number of locations, service type, number of individuals served, and the unique needs of the individuals served by the provider, of similar Level II or Level III serious incidents occur across all of the provider's locations within a six month period; and</u></p> <p><u>d. A death occurs as a result of an acute medical event that was not expected in advance or based on a person's known medical condition.]</u></p> <p>[D. F.] The provider shall submit, or make available <u>and, when requested, submit</u> reports and information that the department requires to establish compliance with these regulations and applicable statutes.</p> <p>[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.</p> <p>[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.</p> <p>[G. I.] Applicants and providers shall not submit any misleading or false information to the department.</p> <p>[J. The Provider shall develop and implement a serious incident management</p>
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		<p><u>policy, which shall be consistent with this Section, and which shall describe the processes by which the provider will document, analyze, and report to the department information related to serious incidents.]</u></p>
170		<ul style="list-style-type: none"> • Amend to provide additional clarity of the next steps to follow if the department does not approve a provider’s revised plan. <p>B. The provider shall submit to the department and implement a written corrective action plan for each for which it is found to be in violation as identified in the licensing report violation cited.</p> <p>C. The corrective action plan shall include a:</p> <ol style="list-style-type: none"> 1. Description <u>Detailed description</u> of the corrective actions to be taken that will minimize the possibility that the violation will occur again <u>and correct any systemic deficiencies</u>; 2. Date of completion for each corrective action; and 3. Signature of the person responsible for the service oversight of the implementation of the pledged corrective action. <p>D. The provider shall submit a corrective action plan to the department within 15 business days of the issuance of the licensing report. Extensions <u>One extension</u> may be granted by the department when requested prior to the due date, but extensions shall not exceed an additional 10 business days. An immediate corrective action plan shall be required if the department determines that the violations pose a danger to individuals receiving the service.</p> <p>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 <u>has not approved the revised plan. If the submitted revised corrective action plan is [still unacceptable not approved]</u>, the provider</p>

		<p>the plan submitted has not been approved by the department.</p> <p>F. When the provider disagrees with a citation of a violation the provider shall discuss this disagreement with the licensing specialist initially. If the disagreement is not resolved, the provider may ask for a meeting with the licensing specialist's supervisor, in consultation with the director of licensing, to challenge a finding of noncompliance. The determination of the director is final.</p> <p>G. The provider shall monitor implementation of the approved corrective action and include a plan for monitoring in its quality assurance activities specified in 12VAC30-105-620.</p>	<p><u>shall follow the dispute resolution process identified in this section.</u></p> <p>F. When the provider disagrees with a citation of a violation <u>or the disapproval of [the a] revised corrective action [plans]</u>, the provider shall discuss this disagreement with the licensing specialist initially. If the disagreement is not resolved, the provider may ask for a meeting with the licensing specialist's supervisor, in consultation with the director of licensing, to challenge a finding of noncompliance. The determination of the director is final.</p> <p>G. The provider shall <u>implement [and monitor implementation of the approved corrective action and include a plan for monitoring in. The provider shall monitor implementation and effectiveness of approved corrective actions as part of its quality assurance activities improvement program specified in required by 12VAC30-105-620. their written corrective action plan for each violation cited by the date of completion identified in the plan.</u></p> <p>H. <u>The provider shall monitor implementation and effectiveness of approved corrective actions as part of its quality improvement program required by 12VAC35-105-620. If the provider determines that an approved corrective action was fully implemented, but did not prevent the recurrence of a regulatory violation or correct any systemic deficiencies, the provider shall:</u></p> <ol style="list-style-type: none"> <u>1. Continue implementing the corrective action plan and put into place additional measures to prevent the recurrence of the cited violation and address identified systemic deficiencies; or</u> <u>2. Submit a revised corrective action plan to the department for approval.]</u>
<p>320</p>		<p>The provider shall document at the time of its original application and annually thereafter that buildings and equipment in residential service locations 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.</p>	<ul style="list-style-type: none"> • Language restored during final action to language as it was prior to the proposed amendments <p>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</p>

			<p>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.]</p>
330			<ul style="list-style-type: none"> • Amend language (A community ICF/MR An ICF/IID) to align with CMS.
400		<p>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.</p> <p>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.</p> <p>C. The provider shall develop a written policy for criminal history and registry checks for all employees, contractors, 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.</p> <p>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</p>	<ul style="list-style-type: none"> • Amend language to align Title 37.2 of the Code of Virginia and 63.2. • Added "if applicable" to D.2. in response to public comment to clarify that only providers who are required to obtain memoranda from the department pertaining to criminal history background checks and registry searches are required to maintain documentation of this memorandum. <p>A. Providers shall comply with the <u>requirements for obtaining criminal history background check checks</u> 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.</p> <p>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.</p> <p>C. B. The provider shall develop a written policy for criminal history <u>background checks</u> and registry <u>checks searches</u> for all employees, contractors, 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 a <u>person</u> has a founded case of abuse or neglect or both, or a conviction or pending criminal charge.</p> <p>D. C. The provider shall submit all information required by the department to complete the <u>criminal history background checks</u> and registry <u>checks searches</u> for all</p>

		<p>volunteers if required by the provider's policy. E. The provider shall maintain the following documentation: 1. The disclosure statement; and 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.</p>	<p>employees and for contractors, students, and volunteers if required by the provider's policy. E-D. The provider shall maintain the following documentation: 1. The disclosure statement <u>from the applicant stating whether he has ever been convicted of or is the subject of pending charges for any offense</u>; and 2. Documentation that the provider submitted all information required by the department to complete the <u>criminal history background checks</u> and registry <u>checks searches</u>, memoranda from the department transmitting the results to the provider, [<u>if applicable</u>,] and the results from the Child Protective Registry <u>check search</u>.</p>
<p>440</p>		<p>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: 1. Objectives and philosophy of the provider; 2. Practices of confidentiality including access, duplication, and dissemination of any portion of an individual's record; 3. Practices that assure an individual's rights including orientation to human rights regulations; 4. Applicable personnel policies; 5. Emergency preparedness procedures; 6. Person-centeredness; 7. Infection control practices and measures; and 8. Other policies and procedures that apply to specific positions and specific duties and responsibilities.</p>	<ul style="list-style-type: none"> 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. <p>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: 1. Objectives and philosophy of the provider; 2. Practices of confidentiality including access, duplication, and dissemination of any portion of an individual's record; 3. Practices that assure an individual's rights including orientation to human rights regulations; 4. Applicable personnel policies; 5. Emergency preparedness procedures; 6. Person-centeredness; 7. Infection control practices and measures; and 8. Other policies and procedures that apply to specific positions and specific duties and responsibilities-; <u>and</u> 9. <u>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 this chapter..</u></p>

<p>450</p>		<p>The provider shall provide training and development opportunities for employees to enable them to support the individuals served and to carry out the responsibilities of their jobs. The provider shall develop a training policy that addresses the frequency of retraining on 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.</p>	<ul style="list-style-type: none"> 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. <p>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 <u>serious incident reporting</u>, 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.</p>
<p>460</p>		<p>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.</p>	<ul style="list-style-type: none"> Amend to clarify that the certification process shall include a hands-on, in-person demonstration of first-aid and CPR. <p>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. <u>The certification process shall include a hands-on, in-person demonstration of first aid and CPR competency.</u></p>
<p>500</p>		<p>B. The provider shall not rely on students or volunteers for the provision of direct care services. The provider staffing plan shall not include volunteers or students.</p>	<ul style="list-style-type: none"> Language change only to ensure consistent use of language throughout regulations and better align regulatory language with regulatory and statutory definitions. <p>B. The provider shall not rely on students or volunteers [for the provision of direct care services to supplant direct care positions]. The provider staffing plan shall not include volunteers or students.</p>

520		<p>A. The provider shall designate a person responsible for risk management.</p> <p>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.</p> <p>N/A</p> <p>N/A</p> <p>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.</p>	<ul style="list-style-type: none"> • Amend to require the person leading risk management activities to have training in risk management, investigations, root cause analysis, and data analysis. • Amend to require annual risk assessments, to include review of the environment, staff competence, seclusion and restraint; serious incidents; and risk triggers and thresholds. <p>A. The provider shall designate a person responsible for <u>the risk management function who has [completed department approved] training [and expertise in, which shall include training related to risk management, understanding of individual risk screening,] conducting investigations, root cause analysis, and [data analysis the use of data to identify risk patterns and trends]</u>.</p> <p>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.</p> <p>C. The provider shall conduct systemic risk assessment reviews at least annually to <u>identify and respond to practices, situations, and policies that could result in the risk of harm to individuals receiving services. The risk assessment review shall address [at least the following:]</u></p> <ul style="list-style-type: none"> [(i) 1. the environment of care; [(ii) 2. clinical assessment or reassessment processes; [(iii) 3. staff competence and adequacy of staffing; [(iv) 4. use of high risk procedures, including seclusion and restraint; and [(v) 5. a review of serious incidents. [This process shall incorporate uniform risk triggers and thresholds as defined by the department. <p><u>D. This Process</u> The systemic risk assessment review process] shall incorporate uniform risk triggers and thresholds as defined by the department.</p> <p>C. [D. E.]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</p>
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<p>530</p>		<p>A. The provider shall develop a written emergency preparedness and response plan for all of its services and locations that describes its approach to emergencies throughout the organization or community. This plan shall include an analysis of potential emergencies that could disrupt the normal course of service delivery including emergencies that would require expanded or extended care over a prolonged period of time. The Plan Shall Address:</p> <p>5. Written emergency response procedures for initiating the response and recovery phase of the plan including a description of how, when, and by whom the phases will be activated. This includes assessing the situation; protecting individuals receiving services, employees, contractors, students, volunteers, visitors, equipment, and vital records; and restoring services. Emergency procedures shall address:</p> <p>N/A</p> <p>N/A</p>	<ul style="list-style-type: none"> • Added language to ensure minimal fire safety precaution <p>A. The provider shall develop a written emergency preparedness and response plan for all of its services and locations that describes its approach to emergencies throughout the organization or community. This plan shall include an analysis of potential emergencies that could disrupt the normal course of service delivery including emergencies that would require expanded or extended care over a prolonged period of time. The plan shall address:</p> <p>5. Written emergency response procedures for initiating the response and recovery phase of the plan including a description of how, when, and by whom the phases will be activated. This includes assessing the situation; protecting individuals receiving services, employees, contractors, students, volunteers, visitors, equipment, and vital records; and restoring services. Emergency procedures shall address:</p> <p>[<u>e. Evacuation procedures, including for individuals who need evacuation assistance:</u>]</p> <p>9. Schedule for testing the implementation of the plan and conducting emergency preparedness drills.</p> <p>[<u>a. Fire and evacuation drills shall be conducted at least monthly.</u>]</p>

		N/A	<p>[<u>B. The provider shall evaluate each individual and, based on that evaluation, shall provide appropriate environmental supports and adequate staff to safely evacuate all individuals during an emergency.]</u></p> <p>[<u>I. All provider locations shall be equipped with at least one approved type ABC portable fire extinguisher with a minimum rating of 2A10BC installed in each kitchen.</u></p> <p><u>J. All provider locations shall have an appropriate number of properly installed smoke detectors based on the size of the location, which shall include at a minimum:</u></p> <ol style="list-style-type: none"> <u>1. Smoke detectors on each level of multi-level buildings, including the basement;</u> <u>2. Smoke detectors in each bedroom in locations with bedrooms;</u> <u>3. An additional smoke detector in any area adjacent to any bedroom in localities with bedrooms;</u> <u>4. Any additional smoke detectors necessary to comply with all applicable federal and state laws and regulations and local ordinances.</u> <p><u>K. Smoke detectors shall be tested monthly for proper operation.</u></p> <p><u>L. All provider locations shall maintain a floor plan identifying locations of:</u></p> <ol style="list-style-type: none"> <u>1. Exits;</u> <u>2. Primary and secondary evacuation routes;</u> <u>3. Accessible egress routes;</u> <u>4. Portable fire extinguishers; and</u> <u>5. Flashlights</u> <p><u>M. This section does not apply to home and noncenter-based services.]</u></p>
580			<ul style="list-style-type: none"> • Amend language to align Title 37.2 of the Code of Virginia and newly adopted person-centered language.
590			<ul style="list-style-type: none"> • Amend language to align Title 37.2 of the Code of Virginia. • Amend to include that providers must have sufficient staff to safely evacuate all individuals during an emergency in accordance with 12VAC35-105-320.
620			<ul style="list-style-type: none"> • Amend to require each provider develop and implement a quality improvement program in accordance with the Settlement Agreement. Amendments also

		<p>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.</p>	<p>include requirements for what each provider's quality improvement program shall include.</p> <p>[A.] The provider shall <u>develop and implement written policies and procedures to for a quality improvement program sufficient to identify, monitor, and evaluate clinical and service quality and effectiveness on a systematic and ongoing basis.</u></p> <p>[B.] The [<u>quality improvement</u>] <u>program shall utilize standard quality improvement tools, including root cause analysis, and shall include a quality improvement plan [. that]</u></p> <p>[C. The quality improvement plan shall:]</p> <p>[(1) 1. be] <u>reviewed and updated at least annually;</u></p> <p>[2. d] <u>efine [s] measurable goals and objectives;</u></p> <p>[3. i] <u>nclude [s] and report [s] on statewide performance measures, if applicable, as required by DBHDS;</u></p> <p>[4. m-M] <u>onitor [s] implementation and effectiveness of approved corrective action plans pursuant to 12VAC35-105-170; and</u></p> <p>[5. i] <u>nclude [s] ongoing monitoring and evaluation of progress toward meeting established goals and objectives.</u></p> <p>[D.] The provider's policies and procedures shall include the criteria the provider will use to [:]</p> <p>1. <u>Establish measurable goals and objectives;</u></p> <p>[2. <u>Update the provider's quality improvement plan; and</u></p> <p>3. <u>Submit revised corrective action plans to the department for approval or continue implementing the corrective action plan and put into place additional measures to prevent the recurrence of the cited violation and address identified systemic deficiencies when reviews determine that a corrective action was fully implemented but did not prevent the recurrence of the cited regulatory violation or correct a systemic deficiency pursuant to 12VAC35-105-170.]</u></p> <p>[E.] <u>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</u></p>
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			<p>of the provider's quality improvement plan. <u>The provider shall implement improvements, when indicated.</u></p>
650			<ul style="list-style-type: none"> • Amend language to align Title 37.2 of the Code of Virginia.
660		<p>B. The provider shall develop an initial person-centered ISP for 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.</p> <p>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.</p>	<ul style="list-style-type: none"> • 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. • Language changes have been made since the proposed stage to provide greater clarity and flexibility in the documentation requirements for establishing compliance with informed choice provisions. <p>B. The provider shall develop <u>and implement</u> an initial person-centered ISP for 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.</p> <p>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.</p> <p><u>D. The initial ISP and the comprehensive ISP shall be developed based on the respective assessment with the participation and informed choice of the individual receiving services.</u></p> <p><u>[1.] To ensure the individual's participation and informed choice, [the provider- the following] shall [be] explain [ed] to the individual or the individual's authorized representative, as applicable, in a reasonable and comprehensible manner [:]</u></p>

			<p>[a. the] he proposed services to be delivered [;]</p> <p>[b. Any] alternative services that might be advantageous for the individual [;] and</p> <p>[c. Any] accompanying risks or benefits [of the proposed and alternative services] .</p> <p>[The provider shall clearly document that the individual's information was explained to the individual or the individual's authorized representative and the reasons the individual or the individual's authorized representative chose the option included in the ISP.]</p> <p>[2. If no alternative services are available to the individual, it shall be clearly documented within the ISP, or within documentation attached to the ISP, that alternative services were not available as well as any steps taken to identify if alternative services were available.</p> <p>3. Whenever there is a change to an individual's ISP, it shall be clearly documented within the ISP, or within documentation attached to the ISP that:</p> <p>a. The individual participate in the development of or revision to the ISP;</p> <p>b. The proposed and alternative services and their respective risks and benefits were explained to the individual or the individual's authorized representative, and;</p> <p>c. The reasons the individual or the individual's authorized representative chose the option included in the ISP.]</p>
665		<p>A. The comprehensive ISP shall be based on the individual's needs, strengths, abilities, personal preferences, goals, and natural supports identified in the assessment. The ISP shall include:</p> <ol style="list-style-type: none"> 1. Relevant and attainable goals, measurable objectives, and specific strategies for addressing each need; 2. Services and supports and frequency of services required to accomplish the goals including relevant psychological, mental health, substance abuse, behavioral, medical, 	<ul style="list-style-type: none"> • Amend to include that the ISP shall be distributed to the individual and others authorized to receive it. • Amend to align with Settlement Agreement requirements. <p>A. The comprehensive ISP shall be based on the individual's needs, strengths, abilities, personal preferences, goals, and natural supports identified in the assessment. The ISP shall include:</p> <ol style="list-style-type: none"> 1. Relevant and attainable goals, measurable objectives, and specific strategies for addressing each need; 2. Services and supports and frequency of services required to accomplish the goals including relevant psychological, mental health, substance abuse, behavioral, medical, rehabilitation, training, and nursing needs and supports;

		<p>rehabilitation, training, and nursing needs and supports;</p> <p>3. The role of the individual and others in implementing the service plan;</p> <p>4. A communication plan for individuals with communication barriers, including language barriers;</p> <p>5. A behavioral support or treatment plan, if applicable;</p> <p>6. A safety plan that addresses identified risks to the individual or to others, including a fall risk plan;</p> <p>7. A crisis or relapse plan, if applicable;</p> <p>8. Target dates for accomplishment of goals and objectives;</p> <p>9. Identification of employees or contractors responsible for coordination and integration of services, including employees of other agencies; and</p> <p>10. Recovery plans, if applicable.</p> <p>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. If the signature of the individual receiving services or the authorized representative cannot be obtained, the provider shall document his attempt to obtain the necessary signature and the reason why he was unable to obtain it.</p> <p>D. Employees or contractors who are responsible for implementing the ISP shall demonstrate a working knowledge of the objectives and strategies contained in the individual's current ISP.</p>	<p>3. The role of the individual and others in implementing the service plan;</p> <p>4. A communication plan for individuals with communication barriers, including language barriers;</p> <p>5. A behavioral support or treatment plan, if applicable;</p> <p>6. A safety plan that addresses identified risks to the individual or to others, including a fall risk plan;</p> <p>7. A crisis or relapse plan, if applicable;</p> <p>8. Target dates for accomplishment of goals and objectives;</p> <p>9. Identification of employees or contractors responsible for coordination and integration of services, including employees of other agencies; and</p> <p>10. Recovery plans, if applicable; <u>and</u></p> <p>11. <u>Services the individual elects to self direct, if applicable.</u></p> <p>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 <u>in order to document agreement</u>. If the signature of the individual receiving services or the authorized representative cannot be obtained, the provider shall document his attempt <u>attempts</u> to obtain the necessary signature and the reason why he was unable to obtain it. <u>The ISP shall be distributed to the individual and others authorized to receive it.</u></p> <p>D. Employees or contractors who are responsible for implementing the ISP shall demonstrate a working knowledge of the objectives and strategies contained in the individual's current ISP, <u>including an individual's detailed health and safety protocols.</u></p>
675			<ul style="list-style-type: none"> • Amend to include that the ISP shall be updated any time assessments identify risks, injuries, needs, or change in status of the individual. • Amend to include that ISP reviews shall include documentation of evidence of progression towards all goals and objectives. • Amend to require that whenever a goal is not met by the target date, the treatment

		<p>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.</p> <p>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.</p>	<p>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 Children's Health Insurance Program (CHIP) Managed Care Final Rule.</p> <p>A. Reassessments shall be completed at least annually and when any time there is a need based on <u>changes in</u> the medical, psychiatric, or behavioral, <u>or other</u> status of the individual.</p> <p>B. <u>Providers shall complete changes to the ISP as a result of the assessments.</u></p> <p>C. <u>The provider shall update the ISP at least annually and any time assessments identify risks, injuries, needs, or change in status of the individual.</u></p> <p>D. <u>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.</u></p> <p><u>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.</u></p> <p><u>2. These reviews shall document evidence of progression towards or achievement of a specific targeted outcome for each goal and objective.</u></p> <p><u>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.</u></p>
691		<p>B. The transfer summary shall include at a minimum the following:</p> <ol style="list-style-type: none"> 1. Reason for the individual's transfer; 2. Documentation of involvement by the individual or his authorized representative, as applicable, in the decision to and planning for the transfer; 	<ul style="list-style-type: none"> • Replace term "involvement" with "informed consent" for clarification. <p>B. The transfer summary shall include at a minimum the following:</p> <ol style="list-style-type: none"> 1. Reason for the individual's transfer; 2. Documentation of involvement <u>informed choice</u> by the individual or his authorized representative, as applicable, in the decision to and planning for the transfer;

800		<p>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.</p>	<ul style="list-style-type: none"> Amend to align with the regulatory reporting requirements in the Human Rights Regulations. <p>E. Injuries resulting from or occurring during the implementation of behavior interventions <u>seclusion or restraint</u> 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 <u>department</u> as provided in 12VAC35-115-230 C.</p>
830		<p>B. Devices used for mechanical restraint shall be designed specifically for behavior management of human beings in clinical or therapeutic programs.</p>	<ul style="list-style-type: none"> Amend to include "emergency" before "behavior management" for clarification. <p>B. Devices used for mechanical restraint shall be designed specifically for <u>emergency</u> behavior management of human beings in clinical or therapeutic programs.</p>
1140			<ul style="list-style-type: none"> Amend language to align Title 37.2 of the Code of Virginia.
NEW	1245		<ul style="list-style-type: none"> 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 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. <p><u>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 changes 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.</u></p>

1250		N/A	<ul style="list-style-type: none"> • 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. <p><u>D. Case managers serving individuals with developmental disability shall complete the DBHDS core competency-based curriculum within 30 days of hire.</u></p>
1360			<ul style="list-style-type: none"> • Amend language to align Title 37.2 of the Code of Virginia.