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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Department of Behavioral Health and Developmental Services
Virginia Administrative Code (VAC) citation(s)	12 VAC35-105
Regulation title(s)	Rules and Regulations For Licensing Providers by the Department of Behavioral Health and Developmental Services
Action title	Compliance with Virginia's Settlement Agreement with US DOJ
Date this document prepared	April 12, 2018

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to eighteen months), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation. This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

This regulatory action is brought in accordance with § 2.2-4011 A of the Code of Virginia. The intent of this regulatory action is to ensure compliance with the requirements of the U. S. Department of Justice's Settlement Agreement with Virginia (United States of America v. Commonwealth of Virginia, Civil Action No. 3:12cv059-JAG), which includes provisions of quality and risk management. Quality improvement measures are required of CSBs for services they provide, but are not currently in the DBHDS Licensing Regulations for other providers. The proposed amendments will provide clarifications to and expand the requirements for the quality practices for the health, safety, care, and treatment for 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.

Emergency Authority

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006. Please explain why this is an emergency situation as described above, and provide specific citations to the Code of Virginia or the Appropriation Act, if applicable.

The purpose of this regulation is to comply with requirements of the U.S. Department of Justice's Settlement Agreement with Virginia. This action is brought in compliance with Code of Virginia § 2.2-4011(A).

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

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

The draft emergency regulation is intended to establish requirements needed immediately to address the concerns of health and safety of individuals receiving services from DBHDS-licensed providers of adult services.

Since the Settlement Agreement was signed, and related to these draft changes, the definition of 'developmental disability' was expanded to include 'intellectual disability' in the Code of Virginia, which occurred in the 2017 Session of the General Assembly (HB1775). Also, the changes to Medicaid Waivers took effect in the past year. Both of these developments impact these regulations.

Legal basis

Other than the emergency authority described above, please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and 2) the promulgating entity, i.e., agency, board, or person.

Sections 37.2-203 and 37.2-304 of the Code of Virginia authorize 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 proposed amendments to the Licensing Regulations as emergency regulations, with approval of the Governor. The draft emergency regulation is intended to establish requirements needed immediately to address the concerns of health and safety of individuals receiving services from DBHDS-licensed providers of adult services.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

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 (*United States of America v. Commonwealth of Virginia, Civil Action No. 3:12cv059-JAG*). 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 risk management, 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; and
  - Requires a quality improvement plan that is reviewed and updated at least annually.
- 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, and to track and monitor less serious incidents:
    - Level I: incidents without injury, but potential for harm (tracked, but not reported);
    - Level II: serious injuries, unplanned hospitalizations, choking, ingestion of hazardous materials; diagnosis of decubitus ulcers, bowel obstructions, or aspiration pneumonia (reported when they occur during provision of service or on the provider premises); and
    - Level III: deaths, sexual assaults, suicide attempts resulting in hospitalization (reported regardless of where or when they occur).
- Strengthened expectations for case management by adding assessment for unidentified risks, status of previously identified risks, whether the plan is being implemented appropriately and remains appropriate for the individual.

Need

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

The amendments to the Licensing Regulations are essential to the health, safety, and welfare of the Settlement Agreement population because there will be enhanced requirements for providers to establish effective risk management and quality improvement processes, and to have improved reporting of serious incidents and injuries to allow the Commonwealth to obtain more consistent data regarding the prevalence of serious incidents; and, strengthen expectations for case management to ensure the individual's plan is appropriate and implemented correctly and that potential risks are identified for individuals.

The emergency process does not allow for public comment. However, an initial draft was posted for public comment; comments were received, considered, and amendments were made to the draft. DBHDS addressed immediately relevant substantive concerns in a revised draft. Namely, concerns related to the following: (1) the amended definition of group homes; (2) the new tiered definition of serious incident and its reporting requirements; and (3) the background check timeline for direct care employees. Comments not addressed in the revisions will be taken up for the proposed stage, and in a separate action reviewing and revising all of Chapter 105 as the result of a periodic review in December.

Substance

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

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, and likely impact of proposed requirements
20		"Day support service" means structured programs of activity or training services for adults with an intellectual disability or a developmental disability, generally in clusters of two or more continuous hours per day provided to groups or individuals in nonresidential community-based settings…."	• 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>

		"Developmental disabilities" means autism or a severe, chronic disability that meets all of the following conditions identified in 42 CFR 435.1009: 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: a. Self-care; b. Understanding and use of language; c. Learning; d. Mobility; e. Self-direction; or f. Capacity for independent living.	• Definition of "developmental disabilities" was amended to match Code of Virginia Title 37.2.
		N/A	• Addition of a general definition for "developmental services" from Code of Virginia Title 37.2.
		N/A	• Addition of a general definition for "direct care position."
		N/A	• Addition of a general definition for "informed choice."
		N/A	<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>
		N/A	• Addition of a general definition for "informed consent" which matches the

			definition of informed consent from the Human Rights Regulations (12VAC35-115-30). "Informed consent" means the voluntary written agreement of an individual, or that individual's authorized representative, to surgery, electroconvulsive treatment, use of psychotropic medications, or any other treatment or service that poses a risk of harm greater than that ordinarily encountered in daily life or for participation in human research. To be voluntary, informed consent must be given freely and without: undue inducement; any element of force, fraud, deceit, or duress; or, any form of constraint or coercion.
		"Mental retardation (intellectual disability)" means a disability originating before the age of 18 years….	• Change the term to "intellectual disability" to reflect § 37.2-100 of the Code of Virginia.
		N/A	• Addition of a definition for "intermediate care facility/individuals with intellectual disability." "Intermediate care facility/individuals with intellectual disability" or "ICF/IID" means a facility or distinct part of a facility certified by the Virginia Department of Health as meeting the federal certification regulations for an intermediate care facility for individuals with intellectual disability and persons with related conditions and that addresses the total needs of the residents, which include physical, intellectual, social, emotional, and habilitation providing active treatment as defined in 42 CFR 435.1010 and 42 CFR 483.440.
		N/A	• Addition of a definition for "missing." "Missing" means a circumstance in which an individual is not physically present when and where he should be and his absence cannot be accounted for or explained by his supervision needs or pattern of behavior.
		"Qualified Mental Retardation Professional (QMRP)" means a person who possesses at least …	• Change the term to Qualified Developmental Disability Professional (QDDP) to reflect § 37.2-100 of the Code of Virginia.
		N/A	

			• Addition of a definition for “quality improvement plan.” "Quality improvement plan" means a detailed work plan developed by a provider that defines steps the provider will take to review the quality of services it provides and to manage initiatives to improve quality. It consists of systematic and continuous actions that lead to measurable improvement in the services, supports, and health status of the individuals receiving services.
		N/A	• Addition of a definition for “risk management.” "Risk management" means an integrated system-wide program to ensure the safety of individuals, employees, visitors, and others through identification, mitigation, early detection, monitoring, evaluation, and control of risks.
		N/A	• Addition of general definition of “root cause analysis.” "Root cause analysis" means a method of problem solving designed to identify the underlying causes of a problem. The focus of a root cause analysis is on systems, processes, and outcomes that require change to reduce the risk of harm.
		N/A	• Addition of a definition for “serious incident.” The definition of serious incident now includes the definition of serious injury. Serious incidents are broken down by levels which correspond with additional requirements for reporting and root cause analysis within 12VAC35-105-160 and 12VAC35-105-160. "Serious incident" means any event or circumstance that causes or could cause harm to the health, safety, or well-being of an individual. The term serious incident includes death and serious injury. "Level I serious incident" means a serious incident that occurs or originates during the provision of a service or on the premises of the provider and does not meet the definition of a Level II or Level III serious incident. “Level I serious incidents” do not result in significant harm to individuals, but may include events that result in minor injuries that do not require medical attention, or events that have the

		N/A	potential to cause serious injury, even when no injury occurs. "Level II serious incident" means a serious incident that occurs or originates during the provision of a service or on the premises of the provider that results in a significant harm or threat to the health and safety of an individual that does not meet the definition of a Level III serious incident. "Level II serious incident" also includes a significant harm or threat to the health or safety of others caused by an individual. "Level II serious incidents" include: 1. A serious injury; 2. An individual who is missing; 3. An emergency room or urgent care facility visit when not used in lieu of a primary care physician visit; 4. An unplanned psychiatric or unplanned medical hospital admission; 5. Choking incidents that require direct physical intervention by another person; 6. Ingestion of any hazardous material. 7. A diagnosis of: a. A decubitus ulcer or an increase in severity of level of previously diagnosed decubitus ulcer; b. A bowel obstruction; or c. Aspiration pneumonia. "Level III serious incident" means a serious incident whether or not the incident occurs while in the provision of a service or on the provider's premises and results in: 1) Any death of an individual; 2) A sexual assault of an individual; 3) A serious injury of an individual that results in or likely will result in permanent physical or psychological impairment; 4) A suicide attempt by an individual admitted for services that results in a hospital admission. • Addition of a definition for "systemic deficiency." "Systemic deficiency" means violations of regulations documented by the department that demonstrate multiple or repeat defects in the operation of one or more services.
30			• Amend language to align with the Code of Virginia Title 37.2 and the Centers for Medicare & Medicaid Services.
50		D. A license shall not be issued or	• Amend language to align with Code of Virginia Title 37.2.

		renewed unless the provider is affiliated with a local human rights committee.	• Remove the following language to reflect changes to the Human Rights Regulations (12VAC35-115-30): ~~A license shall not be issued or renewed unless the provider is affiliated with a local human rights committee.~~
120		The commissioner may grant a variance to a specific regulation if he determines that such a variance will not jeopardize the health, safety or welfare of individuals and upon demonstration by the provider requesting such variance that complying with the regulation would be a hardship unique to the provider. A provider shall submit a request for a variance in writing to the commissioner. A variance may be time limited or have other conditions attached to it. The department must approve a variance prior to implementation.	• Clarifying amendments: The commissioner may grant a variance to a specific regulation if he determines that such a variance will not jeopardize the health, safety, or welfare of individuals. A provider shall submit a request for ~~and upon demonstration by the provider requesting~~ such variance in writing to the commissioner. The request shall demonstrate that complying with the regulation would be a hardship unique to the provider and that the variance will not jeopardize the health, safety, or welfare of individuals. The department may limit the length of time a variance will be effective. ~~A provider shall submit a request for a variance in writing to the commissioner. A variance may be time limited or have other conditions attached to it. The department must approve a variance prior to implementation.~~ The provider shall not implement a variance until it has been approved in writing by the commissioner.
150		The provider including its employees, contractors, students, and volunteers shall comply with: 1. These regulations; 2. The terms and stipulations of the license; 3. All applicable federal, state, or local laws and regulations including: a. Laws regarding employment practices including the Equal Employment Opportunity Act; b. The Americans with Disabilities Act and the Virginians with Disabilities Act; c. Occupational Safety and Health Administration regulations; d. Virginia Department of Health regulations; e. Laws and regulations of the Virginia Department of Health Professions regulations; f. Virginia Department of Medical Assistance Services regulations; g. Uniform Statewide Building Code; and h. Uniform Statewide Fire Prevention Code.	• After 3(b) amend, in accordance with CMS Final Rule, to include: For home and community-based services waiver settings subject to these regulations, 42 CFR § 441.301(c)(1)-(4) Home and Community-Based Services: Waiver Requirements (for person-centered planning and community-based settings);

155			• Replace “mental retardation (intellectual disability)” with the term “developmental disability” in accordance with Code of Virginia Chapter 37.2.
160		B. The provider shall cooperate fully with inspections and provide all information requested to assist representatives from the department who conduct inspections. C. The provider shall collect, maintain, and report or make available to the department the following information:	• 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. 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 Office of 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. B. The provider shall cooperate fully with inspections and investigations, and shall provide all information requested ~~to assist representatives from~~ by the department ~~who conduct inspections~~. C. The provider shall collect, maintain, and review at least quarterly all Level I serious incidents as part of the quality improvement program in accordance with 12VAC35-105-620 to include an analysis of trends, potential systemic issues or causes, indicated remediation, and documentation of steps taken to mitigate the potential for future incidents. D. The provider shall collect, maintain, and report or make available to the 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 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~~

		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. 2. Each instance of death or serious injury shall be reported in writing to the department's assigned licensing specialist within 24 hours of discovery and by phone to the individual's authorized representative within 24 hours. Reported information shall include the following: the date and place of the individual's death or serious injury; the nature of the individual's injuries and the treatment received; and the circumstances of the death or serious injury. Deaths that occur in a hospital as a result of illness or injury occurring when the individual was in a licensed service shall be reported. 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. D. The provider shall submit, or make available, reports and information that the department requires to establish compliance with these regulations and applicable statutes. 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. 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.	~~whether there is physical or psychological injury to the individual~~ department as provided in 12VAC35-115-230 A. 2. ~~Each instance of death or serious injury~~ Level II and Level III serious incidents shall be reported using the department's web-based reporting application and by phone to anyone designated by the individual to receive such notice and to the individual's authorized representative ~~in writing to the department's assigned licensing specialist~~ within 24 hours of discovery ~~and by phone to the individual's authorized representative within 24 hours~~. Reported information shall include the information specified by the department as required in its web-based reporting application but at least the following: the date~~,~~ ~~and~~ place, and circumstances of the ~~individual's death or serious injury~~ serious incident~~;~~. For serious injuries and deaths, the reported information shall also include the nature of the individual's injuries or circumstances of the death and ~~the~~ any treatment received~~; and the circumstances of the death or serious injury~~. For all other Level II and Level III serious incidents, the reported information shall also include the consequences or risk of harm that resulted from the serious incident. Deaths that occur in a hospital as a result of illness or injury occurring when the individual was in a licensed service shall be reported. 3. ~~Each instance~~ Instances of seclusion or restraint ~~that does not comply with the human rights regulations or approved variances or that results in injury to an individual shall be reported to the individual's authorized representative and the assigned human rights advocate within 24 hours~~ shall be reported to the department as provided in 12VAC35-115-230 C 4. E. A root cause analysis shall be conducted by the provider within 30 days of discovery of Level II and Level III serious incidents. The root cause analysis shall include at least the following information: (i) a detailed description of what happened; (ii) an analysis of why it happened, including identification of all identifiable underlying causes of the incident that were under the control of the provider; and (iii) identified solutions to mitigate its reoccurrence. ~~D~~F. The provider shall submit, or make available, reports and information that the department requires to establish compliance

		Extensions may be granted by the department when requested prior to the due date, but extensions shall not exceed an additional 10 business days. G. Applicants and providers shall not submit any misleading or false information to the department. 12VAC35-105.	with these regulations and applicable statutes. ~~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. ~~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. ~~G~~I. Applicants and providers shall not submit any misleading or false information to the department.
170		E. Upon receipt of the corrective action plan, the department shall review the plan and determine whether the plan is approved or not approved. The provider has an additional 10 business days to submit a revised corrective action plan after receiving a notice that the plan submitted has not been approved by the department.	• Amend to provide additional clarity of the next steps to follow if the department does not approve a provider's revised plan. E. Upon receipt of the corrective action plan, the department shall review the plan and determine whether the plan is approved or not approved. The provider has an additional 10 business days to submit a revised corrective action plan after receiving a notice that ~~the plan submitted has not been approved by~~ the department has not approved the revised plan. If the submitted revised corrective action plan is still unacceptable, the provider shall follow the dispute resolution process identified in 12VAC35-105-170 F.
320		The provider shall document at the time of its original application and annually thereafter that buildings and equipment in residential service	• Amend to remove the size limitation, and to require staff to assess each individual and based on the results of that assessment; ensure that the provider has adequate environmental supports and staff to safely evacuate each resident during an emergency. Also, amend to remove the exception for certain types of facilities. 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~~

		locations serving more than eight individuals are maintained in accordance with the Virginia Statewide Fire Prevention Code (13VAC5-51). This section does not apply to correctional facilities or home and noncenter-based or sponsored residential home services.	~~individuals~~ are maintained in accordance with the Virginia Statewide Fire Prevention Code (13VAC5-51). The provider shall evaluate each individual and, based on that evaluation, shall provide appropriate environmental supports and adequate staff to safely evacuate all individuals during an emergency. ~~This section does not apply to correctional facilities or home and noncenter-based or sponsored residential home services.~~
330			• Amend language (~~A community ICF/MR~~ An ICF/IID) to align with the Centers for Medicare & Medicaid Services.
400		A. Providers shall comply with the background check requirements for direct care positions outlined in §§ 37.2-416, 37.2-506, and 37.2-607 of the Code of Virginia for individuals hired after July 1, 1999. 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. 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. D. The provider shall submit all information required by the department to complete the background and registry checks for all employees and	• Amend language to align with Code of Virginia Title 37.2 and 63.2. A. Providers shall comply with the requirements for obtaining criminal history background ~~check~~ checks ~~requirements for direct care positions~~ as outlined in §§ 37.2-416, 37.2-506, and 37.2-607 of the Code of Virginia for individuals hired after July 1, 1999. ~~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.~~ ~~C.~~B. The provider shall develop a written policy for criminal history background checks and registry ~~checks~~ searches ~~for all employees, contractors, students, and volunteers~~. The policy shall require at a minimum a disclosure statement ~~from the employee, contractor, student, or volunteer~~ stating whether the person has ever been convicted of or is the subject of pending charges for any offense and shall address what actions the provider will take should it be discovered that ~~an employee, student, contractor, or volunteer~~ person has a founded case of abuse or neglect or both, or a conviction or pending criminal charge. ~~D.~~C. The provider shall submit all information required by the department to complete the criminal history background checks and registry ~~checks~~ searches ~~for all employees and for contractors, students, and volunteers if required by the provider's policy~~. ~~E.~~D. The provider shall maintain the following documentation: 1. The disclosure statement from the applicant stating whether he has ever been

		for contractors, students, and 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.	convicted of or is the subject of pending charges for any offense; and 2. Documentation that the provider submitted all information required by the department to complete the criminal history background checks and registry ~~checks~~ searches, memoranda from the department transmitting the results to the provider, and the results from the Child Protective Registry ~~check~~ search.
440		New employees, contractors, volunteers, and students shall be oriented commensurate with their function or job-specific responsibilities within 15 business days. The provider shall document that the orientation covers each of the following policies, procedures, and practices: 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.	• 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. 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. 9. Serious incident reporting, including when, how, and under what circumstances a serious incident report must be submitted and the consequences of failing to report a serious incident to the department in accordance with these regulations.
450			• Amend to add "serious incident reporting" to those subjects a provider must ensure frequency of retraining as

			part of an overall training policy for staff. The provider shall provide training and development opportunities for employees to enable them to support the individuals ~~served~~ receiving services and to carry out ~~the~~ their job responsibilities ~~of their jobs~~. The provider shall develop a training policy that addresses the frequency of retraining on serious incident reporting, medication administration, behavior intervention, emergency preparedness, and infection control, to include flu epidemics. Employee participation in training and development opportunities shall be documented and accessible to the department.
460		There shall be at least one employee or contractor on duty at each location who holds a current certificate (i) issued by the American Red Cross, the American Heart Association, or comparable authority in standard first aid and cardiopulmonary resuscitation (CPR) or (ii) as an emergency medical technician. A licensed medical professional who holds a current professional license shall be deemed to hold a current certificate in first aid, but not in CPR.	• Amend to clarify that the certification process shall include a hands-on, in-person demonstration of first-aid and CPR. There shall be at least one employee or contractor on duty at each location who holds a current certificate (i) issued by the American Red Cross, the American Heart Association, or comparable authority in standard first aid and cardiopulmonary resuscitation (CPR) or (ii) as an emergency medical technician. A licensed medical professional who holds a current professional license shall be deemed to hold a current certificate in first aid, but not in CPR. The certification process shall include a hands-on, in-person demonstration of first aid and CPR competency.
520		A. The provider shall designate a person responsible for risk management. 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.	• 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 & thresholds. A. The provider shall designate a person responsible for the risk management function who has training and expertise in conducting investigations, root cause analysis, and data analysis. 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,

		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. D. The provider shall document serious injuries to employees, contractors, students, volunteers, and visitors. Documentation shall be kept on file for three years. The provider shall evaluate injuries at least annually. Recommendations for improvement shall be documented and implemented by the provider.	infectious disease, property damage or loss, and other sources of potential liability. C. The provider shall conduct systemic risk assessment reviews at least annually to identify and respond to practices, situations, and policies that could result in the risk of harm to individuals receiving services. The risk assessment review shall address: (i) the environment of care; (ii) clinical assessment or reassessment processes; (iii) staff competence and adequacy of staffing; (iv) use of high risk procedures, including seclusion and restraint; and (v) a review of serious incidents. This process shall incorporate uniform risk triggers and thresholds as defined by the department. ~~C~~ D. The provider shall conduct and document that a safety inspection has been performed at least annually of each service location owned, rented, or leased by the provider. Recommendations for safety improvement shall be documented and implemented by the provider. ~~D~~ E. The provider shall document serious injuries to employees, contractors, students, volunteers, and visitors that occur during the provision of a service or on the provider's property. Documentation shall be kept on file for three years. The provider shall evaluate serious injuries at least annually. Recommendations for improvement shall be documented and implemented by the provider.
580			• Amend language to align with Code of Virginia Title 37.2 and newly adopted person-centered language.
590			• Amend language to align with Code of Virginia Title 37.2. • Amend to include that providers must have sufficient staff to safely evacuate all individuals during an emergency in accordance with 12VAC35-105-320.
620		The provider shall implement written policies and procedures to monitor and evaluate service quality and effectiveness on a systematic and	• Amend to require each provider develop and implement a quality improvement program in accordance with the Settlement Agreement. Amendments also include requirements for what each provider's quality improvement program shall include. The provider shall develop and implement a quality improvement program sufficient to identify, ~~written policies and procedures to~~ monitor, and evaluate clinical and service

		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.	quality and effectiveness on a systematic and ongoing basis. The program shall: (i) include a quality improvement plan that is reviewed and updated at least annually; (ii) establish measurable goals and objectives; (iii) include and report on statewide performance measures, if applicable, as required by DBHDS; (iv) utilize standard quality improvement tools, including root cause analysis; (v) implement a process to regularly evaluate progress toward meeting established goals and objectives; and (vi) incorporate any corrective action plans pursuant to 12VAC35-105-170. Input from individuals receiving services and their authorized representatives, if applicable, about services used and satisfaction level of participation in the direction of service planning shall be part of the provider's quality ~~assurance system~~ improvement plan. The provider shall implement improvements, when indicated.
650			• Amend language to align with Code of Virginia Title 37.2.
660		B. The provider shall develop an initial person-centered ISP for the first 60 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. 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	• 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. B. The provider shall develop and implement 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. 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.

		providers of mental retardation (intellectual disability) and developmental disabilities services.	D. The initial ISP and the comprehensive shall be developed based on the respective assessment with the participation and informed choice of the individual receiving services. To ensure the individual's participation and informed choice, the provider shall explain to the individual or his authorized representative, as applicable, in a reasonable and comprehensible manner, the proposed services to be delivered, alternative service or services that might be advantageous for the individual, and accompanying risks or benefits. The provider shall clearly document that this information was explained to the individual or his authorized representative and the reasons the individual or his authorized representative chose the option included in the ISP.
665			• Amend to include that the ISP shall be distributed to the individual and others authorized to receive it. B. The ISP shall be signed and dated at a minimum by the person responsible for implementing the plan and the individual receiving services or the authorized representative in order to document agreement. If the signature of the individual receiving services or the authorized representative cannot be obtained, the provider shall document his attempt attempts to obtain the necessary signature and the reason why he was unable to obtain it. The ISP shall be distributed to the individual and others authorized to receive it.
675			• 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 team members shall meet to review the reasons for lack of progress and provide the individual an opportunity to make an informed choice of how to proceed. This language was adopted from the Medicaid and CHIP Managed Care Final Rule.

		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. 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.	A. Reassessments shall be completed at least annually and ~~when~~ any time there is a need based on changes in the medical, psychiatric, ~~or~~ behavioral, or other status of the individual. B. Providers shall complete changes to the ISP as a result of the assessments. C. The provider shall update the ISP at least annually and any time assessments identify risks, injuries, needs, or change in status of the individual. D. The provider shall review the ISP at least every three months from the date of the implementation of the ISP or whenever there is a revised assessment based upon the individual's changing needs or goals. 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. 2. These reviews shall document evidence of progression towards or achievement of a specific targeted outcome for each goal and objective. 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.
691		B. The transfer summary shall include at a minimum the following: 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;	• Replace term "involvement" with "informed consent" for clarification. B. The transfer summary shall include at a minimum the following: 1. Reason for the individual's transfer; 2. Documentation of ~~involvement~~ informed choice by the individual or his authorized representative, as applicable, in the decision to and planning for the transfer;
800		E. Injuries resulting from or occurring during the implementation of behavior interventions shall be recorded in the individual's services record and	• Amend to align with the regulatory reporting requirements in the Human Rights Regulations (12VAC35-115). E. Injuries resulting from or occurring during the implementation of behavior interventions seclusion or restraint shall be recorded in the individual's services record and reported to

		reported to the assigned human rights advocate and the employee or contractor responsible for the overall coordination of services.	the assigned human rights advocate and the employee or contractor responsible for the overall coordination of services <u>department as provided in 12VAC35-115-230 C</u>.
830			• Amend to include “emergency” before “behavior management” for clarification. B. Devices used for mechanical restraint shall be designed specifically for <u>emergency</u> behavior management of human beings in clinical or therapeutic programs. C. Application of time out, seclusion, or restraint shall be documented in the individual's record and include the following: 1. Physician's order for seclusion or mechanical restraint or chemical restraint; 2. Date and time; 3. Employees or contractors involved; 4. Circumstances and reasons for use including other <u>emergency</u> behavior management techniques attempted; 5. Duration; 6. Type of technique used; and 7. Outcomes, including documentation of debriefing of the individual and staff involved following the incident.
1140			• Amend language to align with Code of Virginia Title 37.2.
NEW	1245		• Add new section with strengthened expectations for case management as required by the Settlement Agreement. The new expectations require case managers to assess for unidentified 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. <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 change in status; (iii) assess whether the individual's service plan is being implemented appropriately and remains appropriate for the individual; and (iv) assess whether supports</u>

			and services are being implemented consistent with the individual's strengths and preferences and in the most integrated setting appropriate to the individual's needs.
1250			• Add additional requirement for case managers serving individuals with developmental disabilities to complete the DBHDS core competency-based curriculum within 30 days of hire to strengthen case management as required by the Settlement Agreement. D. Case managers serving individuals with developmental disability shall complete the DBHDS core competency-based curriculum within 30 days of hire.
1360			• Amend language to align with Code of Virginia Title 37.2.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

There are no alternatives to this regulatory action.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments. Please also indicate whether a Regulatory Advisory Panel or a Negotiated Rulemaking Panel has been used in the development of the emergency regulation and whether it will also be used in the development of the permanent regulation.

The emergency process does not include public comment. However, prior to formally submitting a draft to the State Board, DBHDS posted an initial draft for public comment through a general notice on Town Hall and an email to stakeholders in order to identify and address legitimate provider concerns. Comments were received, considered, and amendments were made to the initial draft. DBHDS addressed immediately relevant substantive concerns in a revised draft. Over 225 comments were received, which resulted in some changes to the initial draft, as summarized below:

- Group homes – the original amendments added language that would have prohibited having any live-in staff in group homes. Stakeholders overwhelmingly identified this as problematic (almost 200 comments), noting that there were a number of homes that relied on a model of live-in staff. The provision was intended to ensure that 24 hour awake supervision is available in group homes. This

initial amendment prohibiting the practice was removed and supervision will be addressed by ensuring that staffing is appropriate for 24 hour awake coverage.

- Serious incidents –
  - Provide better clarity for "level I" serious incidents; addressed by clarifying that a level I serious incident involves incidents where there is only minor injury (medical attention not required) or the incident could have resulted in a serious injury;
  - Requests to remove the requirement for all level I serious incidents to have a root cause analysis (RCA).
  - Request to change the requirement for reporting all hospitalizations to reporting *unplanned* hospitalizations. This was changed.
  - Concern that the definition of "missing" did not allow for individual autonomy and would require reporting anytime staff did not know an individual's location. The definition of missing was changed to take into account the supervision needs of the individual.
- Background check of prospective employees – Concerns were expressed that a new requirement that employers complete a criminal background check prior to *hiring* a new employee would have detrimental effects on hiring.

After submitting a formal revised draft to the State Board, the Board voted to further modify the draft in three amendments as noted in the chart of amendments above in Subsection 160 C (adding language) and E (removing initial language requiring root cause analyses for Level I serious incidents), and Subsection 400 D (removing proposed language to require that the employer complete the background check prior to allowing an new employee to interact with individuals unsupervised).

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to **Emily Bowles, Legal Coordinator, Office of Licensing, Virginia Department of Behavioral Health and Developmental Services, P.O. Box 1797, 1220 Bank Street, Richmond, VA 23218-1797, emily.bowles@dbhds.virginia.gov, phone (804)225-3281, fax (804) 692-0066.** Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The regulation is expected to have a positive impact on the family or family stability, in that services for family members will be improved as a result of the changes.

The action is not expected to:

1) Strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children;
2) Encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents;
3) Strengthen or erode the marital commitment; or
4) Increase or decrease disposable family income.

Periodic review/small business impact review announcement

If you wish to use this emergency/NOIRA to announce a periodic review (§ 2.2-4017 & EO-17 (2014)) and a small business impact review (§ 2.2-4007.1) of this regulation, keep the following text. Modify as necessary for your agency. Otherwise, delete this section.

The agency is not conducting a periodic review through this action.

Rules and Regulations for Licensing Providers by the Department of Behavioral Health and Developmental Services [12 VAC 35 - 105]

COMMENT SUMMARY OF PUBLIC COMMENT RECEIVED ON INITIAL 3/1 DRAFT (03/05/18 – 03/16/18);
PLUS AMENDMENTS BY THE STATE BOARD ON 4/11/18

Section	Comment	Changes to initial 3/1 draft after 11-day public comment period reflected in formal draft package; PLUS AMENDMENTS ON 4/11/18
12 VAC 35-115-20 Definitions		
• **Group home**	Stakeholders overwhelmingly reported that 'who do not live in the home' was problematic and would decrease service options and choice for individuals. Also, it was stated that preventing "live-in" staff is a significant policy decision which should be more carefully considered than it in Emergency Regulations.	**This was intended to address the issue of 24-hour supervision versus a caregiver who lives in the home must sleep at some point. The phrase and all amendments were removed, but the issue will be held to consider during the upcoming chapter 'overhaul.' Licensing staff will continue to verify that group homes have adequate staffing to ensure 24-hour awake supervision.**
• **Missing (numerous comments)**	While the intent of the addition of the definition was appreciated, stakeholders overwhelmingly felt the wording should be reconsidered. An individual who is exercising their freedom to move about the home and grounds freely may easily be somewhere staff did not expect them but well within their rights and creating no concern. It was further felt that an unfortunate side effect of this requirement would be that supervision would increase in such a way as to reduce privacy and undermine their freedom to move about the home and grounds freely to reduce the burden of a multitude of frivolous occurrence reports.	**The definition was modified to be more in line with the term in 12VAC35-210, and using language from Connecticut that accounts for an individual's known supervision needs or pattern of behavior.**
• Residential service	It was recommended that, since the definition of ICF/IDD removed the word "community," the word "community" should be deleted in the definition of "residential service."	Agreed; deleted for consistency.
• Risk management	There was a suggestion to change "prevention' to "mitigation."	Amended to the more appropriate word.
• **Serious incident, general.**	Comments noted that allegations of exploitation or theft should not be included as a "serious incident" to be reported to the Office of Licensing as it would be duplicative of the report required under 12VAC35-115 to the Office	**Requirements to report allegations of exploitation, theft, or disaster, fire, or emergency were removed from**

Section	Comment	Changes to initial 3/1 draft after 11-day public comment period reflected in formal draft package; PLUS AMENDMENTS ON 4/11/18
	of Human Rights as an allegation of abuse. It was recommended that this item should be removed from the Serious incident list. It was further noted that "Disaster, fire, emergency or other condition that may jeopardize the health, safety, or welfare" is currently required to be reported in 12VAC35-105-530 F with a focus on what steps the provider has taken to ensure the safety of the individuals and to provide for their care. To include it as a Level 2 Serious Incident requires, among other things, a report on each individual affected (not the program location) and on the event not the provider's implementation of their Emergency Plan. Overall, it was suggested a clearer definition be devised since the referenced overall definition of a serious incident "is likely to lead to adverse effects upon an individual." Using this general definition would suggest that providers report on incidents that may be a potential event, rather than reporting actual incidents.	**serious incident reporting. Amended to address concerns about the overall definition of serious incident: "event or circumstance that causes or could cause, harm to the health, safety or well-being of an individual" . …..**
• **Serious incident: Level I**	While it was noted that serious injuries should be reported regardless, the tiered system was seen as a bit confusing as initially written. Tier 1 had no definition, so it was not clear what types of incidents would fall under that category. The tiers were not all-inclusive which makes it open to interpretation and open to corrective action if done improperly. Comments stated that, to the extent that amendments seem to narrow protections or allow significant discretion to modify the licensing requirements, they demand further thoughtful deliberation. An effective system for licensing and protection from harm must include ongoing review and require providers to respond to and proactively identify systemic risks. The draft amendments could strengthen the system by requiring that recurring Level I serious incidents identified during quarterly review be reported to DBHDS along with Level II and Level III incidents. Stakeholders did not like that the definition for Level I incidents is not a definition but rather a statement that it differs from Levels II or III incidents, and did not include examples provided in describing those levels. A clearer definition was suggested since the referenced overall definition of a serious	**The definition of Level I incidents was revised to state they are those that '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.' DBHDS is not requiring the reporting of Level I incidents, but is requiring that the provider collect, maintain, and review at least quarterly all Level I incidents as part of the quality improvement program, and specifies what should be documented.**

Section	Comment	Changes to initial 3/1 draft after 11-day public comment period reflected in formal draft package; PLUS AMENDMENTS ON 4/11/18
	incident "is likely to lead to adverse effects upon an individual." Using this general definition would suggest that providers report on incidents that may be a potential event, rather than reporting actual incidents.	
• **Serious incident Level II**	It was suggested that an addition be made to add "two or more substantially similar Level I serious incidents, or three or more dissimilar." Comments indicated an effective system should also capture critical information on serious incidents, regardless of where they take place or by whom they were caused. Limiting the definition of Level II serious incidents to those that occur while the provider is delivering services or on the provider's premises could allow significant injuries to go unreported. It was recommended instead that the regulations require providers to confirm reporting of any Level II incidents of which they are aware. Also, comments indicated that requiring reporting that occurred outside of services as being a potential intrusion into the individual's privacy (i.e., that the state had no need/right to know about injuries that were not associated with services). Amendments were recommended to the item regarding hospital admissions, as stakeholders wondered if this would include psychiatric as well as medical admissions; if it would be reportable if a client comes to the CSB to see a nurse and it is recommended to go to the ER; if included urgent care visits in lieu of seeing the primary care physician; and other such clarifying questions.	**The draft was amended to change "serious injuries" to have no qualifying words with the term. Also, "an individual who is missing" was modified to have no qualifying words (but as stated above, the definition of "missing" was clarified). And, language around "hospital admission" was included to specify "unplanned psychiatric or unplanned medical."** **No amendments were made to Level III serious incidents, or to "serious injuries" as initially drafted.** **No changes were made to include "two or more substantially similar Level I incidents…" as Level II incidents.**
12VAC35-105-120. Variances.		
• Unlimited authority.	Concern was expressed with the revisions to 12VAC35-105-120, pertaining to the commissioner's authority to grant variances to the licensing regulations. Subsection 1 built in additional requirements for providers seeking a variance. However, Subsection 2 gave the commissioner significant authority to grant variances to the regulations when "he determines necessary to facilitate the development of needed services to address emerging issues." While this authority would be limited where a variance may "jeopardize the health, safety, or welfare of individuals," this seemed to be the only limitation to the authority to waive licensing requirements in a regulatory scheme where the Commissioner may, on his	Agreed; the language in #2 was deleted.

Section	Comment	Changes to initial 3/1 draft after 11-day public comment period reflected in formal draft package; PLUS AMENDMENTS ON 4/11/18
	own initiative, grant variances to the licensing standards to expedite the development of services or induce providers to develop new services. It was felt the licensing regulations should only be waived where they represent a significant burden to a provider and their purpose and effect can be accomplished by other means, without jeopardizing the health, safety and welfare of individuals receiving services. The commenter stated that DBHDS must to have the tools it needs to safely and deliberatively expand community services for people with disabilities. Chief among those tools must be accountability. As providers enter the market and expand, they must be held to the standards and expectations set forth in the licensing regulations. In summary, it was felt the variance amendment is a departure from the current licensing variance scheme; and so there was concern with lack of specific guidelines or review processes for this new and sweeping category of variance.	
12 VAC 35-115-160. Reviews by the department; requests for information, required reporting		
• Ensure reporting.	Some commenters wanted to ensure reporting by requiring providers who are made aware of Level II serious incidents that did not occur on that provider's premises, or during the delivery of services by that provider, to take reasonable steps to ensure that the incident was reported in accordance with this chapter by the responsible party; and where no responsible party can be identified, require the provider to report these incidents.	Additional requirements were not added at this time, but will be considered during the upcoming chapter 'overhaul.'
• C	More specificity was suggested around the maintenance and quarterly review of only Level I incidents, and how this would correspond with the root cause analysis.	Clarifying language was added to the amendments in subsection C in regard to what information will be documented as part of the quality improvement program.
• D: Known risks at time of report. • Level of inquiry required for incidents.	The issue was raised that all consequences of an incident are known at the time of reporting and if a licensing specialist closed a CHRIS report, how it would be documented. Comments received included that investigations are done, but not each incident requires the same level of inquiry. There were questions about the level of information required.	No amendments were made to subsection D for this emergency action, but comments will be held for to consider during the upcoming chapter 'overhaul.'

Section	Comment	Changes to initial 3/1 draft after 11-day public comment period reflected in formal draft package; PLUS AMENDMENTS ON 4/11/18
• Communication, case manager.	It was recommended that language be added to include case managers in the notification " . . . and to the individual's Case Manager, as appropriate."	
• **E.**	Stakeholders indicated that completion of the specified "root cause analysis" within 30 days and then re-reviewing Level I incidents quarterly seemed redundant; Level I review (as described in 160 C) was seen as both sufficient and more comprehensive for this type of incident, and therefore, Level I incidents should be exempted from E. It was also noted that root cause analysis for all serious incidents in all tiers for all DBHDS licensed services will result in extraordinary administrative burden. It was recommended that root cause analysis be defined for specific tiers.	**Amended to remove Level 1 incidents from this section; Level II and Level III serious incidents remain.**
12VAC35-105-320. Fire inspections.		
	It was stated that supervised residential sites may not be able to plan for and adequately staff a site for a fire event that may occur at night when most residents would be asleep. And, that this is type of an event is out of the ordinary and cannot be planned for in advance. A commenter asked if there was a specific time expectation by which all individuals would need to be evacuated because that would inform how to define "adequate staff." A comment was received asking for clarification on where to provide the documentation.	**Amended to require providers to evaluate each individual to determine their specific needs for evacuation. Based on the evaluation, the provider then shall provide appropriate environmental supports and adequate staff to safely evacuate all individuals during an emergency.** **Compliance should be documented as part of the provider's safety plan.**
112VAC35-105-400. Criminal registry background checks and registry searches.		
• **Numerous comments correcting discrepancy with Code of Va.**	It was noted that the form required by DSS contains information which is not relevant to a hiring decision and may be considered inappropriate to be asked prior to employment. Further, commenters stated this section implies that the criminal history background check and the CPS registry report will be available "prior to hiring the applicant" – the Code of Virginia §19.2-389 A 29 specifies that a criminal background check may be completed for	**Agree. This was amended to remove edits conflicting with the Code of Virginia.** **The section was further amended to remove language stating prior to**

Section	Comment	Changes to initial 3/1 draft after 11-day public comment period reflected in formal draft package; PLUS AMENDMENTS ON 4/11/18
	"applicant who accepts employment in any direct care position" – it is clear that to process a criminal background check the offer of employment must have been made and accepted. In addition, even if the process is expedited as expected with the new DBHDS process coming on line this summer, the private sector must still wait for a letter to be prepared and mailed by DBHDS; therefore, the process will not be complete for review "prior to hiring." Also, the CPS registry check takes four to six weeks from submission and again, cannot be reviewed "prior to hiring."	**hiring an applicant, a 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. The amended language requiring criminal history background check and registry search results prior to allowing a new employee to interact with individuals unsupervised was also removed.**
12VAC35-105-660. Individualized services plan (ISP).		
• Unnecessary with current practice.	It was stated that this new language does not "fit" within the person centered process used by DD providers because the documentation from the team meeting (some of which is contained in those sections of the plan prepared by the Case Manager) should be sufficient to explain the individual's choices. Further, the new language in Subsection C that proposes new requirements to document the explanations of risks and benefits to participants raised concern that this appears to be inconsistent with a person-centered planning process. It was questioned why this requirement would pertain to each provider in its own Part V (of the ISP) and it was proposed instead that if this requirement remains, it be limited as a requirement of case managers for the overall ISP, consistent with existing Waiver regulations which identify specific support coordination overall responsibilities (12VAC30-120-515, F. Reevaluation of service need: 1. The Individual Support Plan.). However, another commenter stated the addition of the informed choice provision to 12VAC35-105-660 reinforces the importance of person-centered planning. However, the language requiring the provider to "explain to the individual or his authorized representative" should be changed to "the individual and his authorized representative."	Clarifying amendments were made 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. The term "as applicable" following this text allows for flexibility based on the specific situation and the individual's needs.

Section	Comment	Changes to initial 3/1 draft after 11-day public comment period reflected in formal draft package; PLUS AMENDMENTS ON 4/11/18
• Full participation	Questions were submitted asking what "full participation" means as many individuals and their families (especially those in crisis and those who are very familiar with services) will not want to sit through and discuss all that is entailed in this section to document informed choice. It was asked whether there will be consideration if this is attempted, but the individual/AR does not want this information.	This was amended to remove the word "full." Providers should document that the AR or the individual did not want to sign the ISP.
12VAC35-105-675. Reassessments and ISP reviews.		
• A	In regard to reassessments, and the language "or other" change in status, there was a question of whether that includes housing, job, social issues.	A reassessment should occur anytime a change occurs affecting the current ISP. Please refer to 12VAC35-105-650(f).
• ISP Team.	A question was raised in D.3. about the definition of "the team" that shall meet to review.	The term "team" is person centered and varies based on the specific individual, but clarifying language was added to first reference the provider, and then "appropriate treatment" team "members."
• D, Outcomes, goals, and objectives.	A commenter indicated that in Section D refers to the terms "outcomes, goals and objectives." As a reference, the Waiver regulations use the phrase "The individual's strengths, desired outcomes/goals/objectives, required or desired supports or both, and skill-building needs." We suggest consistent wording across the two sets of regulations. Also, similarly, DBHDS has produced PCP training modules that update the use of terms such as goals and objectives. It is challenging for providers to maintain orientation and training materials to be current with Licensing and Waiver regulations that differ. Further comments on this topic included that, in Subsection D. 3, language indicates action needed when goals and objectives are not accomplished by the identified target date. It was felt that providers lack resources to conduct full quarterly team meetings with the frequency suggested by this regulation, since individuals often do not achieve outcomes. It was also noted that it is common that the individual may make significant progress toward an outcome but "miss the mark" to fully meet the target and date. This regulation would require a quarterly team meeting each time that occurs, with the unintended consequence of this requirement might be an overall lowering of the bar in ISPs, to reduce the number of meetings necessary to	These regulations apply to all DBHDS licensed providers, with the exception of children's residential facilities. As a result, streamlining to match the Waiver regulations would not be appropriate. DBHDS does not require providers to set the target date within the quarter. The target date should be set within an appropriate period of time based on the individual's assessment.

Section	Comment	Changes to initial 3/1 draft after 11-day public comment period reflected in formal draft package; PLUS AMENDMENTS ON 4/11/18
	adjust targets. It was suggested that perhaps if the target for meeting "goals and objectives" could be written as a range rather than a specific number or percentage that a range would be more reasonable and would reduce the number of full team meetings required. Finally, it was noted the language will require additional meetings and increased meeting frequency with the team and individual. Individual circumstances may make this difficult to accomplish.	
• Lack of progress.	A commenter stated that reassessment and ISP reviews do not always result in progress. Also, in D.3., the requirement for the team to meet to review the reasons for lack of progress and provide the individual an opportunity to make an informed choice of how to proceed implies a face to face meeting with all parties working with the individual at every review/reassessment. This is not always possible for all cases and across all disabilities. Documenting care coordination on an ongoing basis and on an as-needed basis should be sufficient.	The regulations just make explicit that ISP reviews should document progress toward goals and should address barriers and update service plans when progress is not occurring as expected. The extent of treatment team meeting/review can be based upon the goals not met and the individual's need.