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COMMONWEALTH of VIRGINIA

DEPARTMENT OF
BEHAVIORAL HEALTH AND DEVELOPMENTAL SERVICES
Post Office Box 1797
Richmond, Virginia 23218-1797

March 26, 2020

To: Members, State Board
Interested Stakeholders

Fr: Ruth Anne Walker
State Board Liaison

Re: Call for Emergency Meeting of the State Board April 2, 2020

Cc: Daniel Carey, MD, Secretary of Health and Human Resources
Alison G. Land, Commissioner, DBHDS
Heidi R. Dix, Deputy Commissioner, DBHDS
Dev Nair, Ph.D., Assistant Commissioner, DBHDS
Allyson K. Tysinger, Assistant Attorney General

In light of the current state of emergency, Paula Mitchell, Chair, canceled initial plans for the State Board to meet in person in Burkeville. However, the board will meet electronically, without a quorum physically assembled, in accordance with Code of Virginia 2.2-3708.2.A.3. and Executive Order 51. There will be only one action item on the agenda, namely, to vote on the draft language to amend the Rules and Regulations for Licensing Providers by the Department of Behavioral Health and Developmental Services [12VAC35-105] ("Licensing Regulations") for the Final Stage of the regulatory action titled, "Compliance with Virginia's Settlement Agreement with US DOJ."

This emergency meeting is being held to take up the agenda item because the Commonwealth has to comply with the Settlement Agreement with the U.S. Department of Justice. One of the things that must be done to comply is to update the Licensing Regulations. If the Licensing Regulations are not amended, Virginia could be found in violation of a federal court order. The State Board's consideration of the final stage amendments to the Licensing Regulations permits the Commonwealth to "return impacted areas to pre-event conditions" so that it can meet the terms of the Settlement Agreement. Thus, the requirements of § 2.2-3708.2.A.3. are met and the State Board may meet electronically without a quorum physically assembled to consider the amendments to the Licensing Regulations that are necessary to comply with the Settlement Agreement.

In announcing and conducting this emergency meeting, the Virginia Freedom of Information Act requires that a policy for emergency meetings be in place before an emergency meeting can be held. This requirement is met through the Bylaws of the State Board. The following are excerpts from Article 5 of the Bylaws that demonstrate the structure is established (underline added):

b. ***Special Meetings -*** *The Chair, the Vice Chair in the event of the Chair's disability or of a vacancy in that office, or any three members of the Board may call special or emergency meetings of the Board at the dates, times, and places specified in the call for these meetings*

h. ***Public Comment -*** *The agenda for each meeting of the Board shall indicate that public comment will be received at the beginning of the meeting. Public comment will be subject to the time limitations deemed appropriate by the Chair.*

- For this meeting, receipt of public comment will be handled differently, while still in accordance with the bylaws. Any person seeking to make comment to the State Board must submit comment in writing by 5 p.m. on April 1, 2020, via email (ruthanne.walker@dbhds.virginia.gov). Comment will be received into the record at the beginning of the meeting and viewable to members and the public via electronic means. Any public comment received will be added to the minutes of the meeting.

j. **Electronic Meetings –** Members may participate through electronic communication means from a remote location that is not open to the public in the event of an emergency or personal matter, or temporary or permanent disability or other medical condition, or when a member is more than 60 miles from the primary meeting location. The electronic communication must be properly noticed and meet FOIA requirements, including that a quorum must be physically assembled at the primary or central meeting location and that the public body make arrangements for the voice of the remote participant to be heard by all persons at the primary or central meeting location. In accordance with § 2.2-3708.2 A.3, certain requirements shall not apply if a meeting is called when the Governor has declared a state of emergency.

- As required by FOIA:
- The access to the meeting is posted with the meeting announcement (via Adobe Connect in which members and staff will be able to be heard; all other participants will be able to listen; all participants will be able to view the screen if online).
- The vote on the draft language for the Final Stage for this action to amend the Licensing Regulations shall be taken by roll call vote.
- The minutes will reflect that the meeting was an emergency meeting conducted electronically.

Please let me know if you have any questions about the information in the packet or the conduct of the meeting. I can be reached by email (ruthanne.walker@dbhds.virginia.gov), or (804) 247-1933. Thank you.

Enclosure

COMMONWEALTH of VIRGINIA

STATE BOARD OF BEHAVIORAL HEALTH AND DEVELOPMENTAL SERVICES

DRAFT CALLED EMERGENCY MEETING AGENDA

9:30 a.m., Thursday, April 2, 2020

Electronic Meeting

The board will meet electronically, without a quorum physically assembled, in accordance with Code of Virginia 2.2-3708.2.A.3. and Executive Order 51. For a full explanation, see the Call for Emergency Meeting Memo in this packet on page 1.

- To submit public comment: Written comment may be submitted via email no later than 5:00 p.m. on Wednesday, April 1, 2020, to ruthanne.walker@dbhds.virginia.gov.
- To observe and listen to the meeting: See full instructions on the last page. It is possible to listen only using a phone, or listen and view online via a computer.

No committee meetings are to be held. The next regular meetings are planned for July 15, 2020.

EMERGENCY SESSION AGENDA

via Adobe Connect or conference call, at 9:30 a.m.

I.	9:30	**Call to Order and Introductions**	Paula Mitchell *Chair*	
II.	9:35	**Approval of April 2, 2020, Agenda** ➢ *Action Required*		**3**
III.	9:40	**Public Comment** Written comments received by 5 p.m. on April 1, 2020, will be received into by the State Board and included in the minutes for the record.		
IV.	9:45	**Regulatory Actions**: **A. Final Stage: Compliance with Virginia's Settlement Agreement with US DOJ** ➢ *Action Required*	Ruth Anne Walker *Director, Office of Regulatory Affairs* Jae Benz *Director, Office of Licensing* Emily Bowles *Assistant Director for Licensing, Quality, Regulatory Compliance, and Training Office of Licensing*	**5**
V.	10:30	**Commissioner's Update on COVID-19**	Alison G. Land, FACHE *Commissioner*	

XIV.	10:45	**Adjournment**		

(Note: Times may run slightly ahead of or behind schedule.)

Meeting Dates for 2020:

April: 2 (Thurs)	~~Piedmont Geriatric Hospital (PGH), **Crewe**~~ **Electronic emergency meeting**
July: 15 (Wed)	Central Office, DBHDS, **Richmond**
Oct: 14 (Wed)	Southwestern Virginia Mental Health Institute (SWVMHI), **Marion**
Dec: 2 (Wed)	Central Office, DBHDS, **Richmond**

MEMORANDUM

To: Members, State Board of Behavioral Health and Developmental Services

Fr: Ruth Anne Walker

Date: March 26, 2020

Re: Regulatory Package – One Action Item

I. Final Stage for Permanent Adoption

(https://www.townhall.virginia.gov/um/chartstandardstate.pdf)

Background: 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) (DOJ Settlement Agreement), the State Board of Behavioral Health and Developmental Services adopted an emergency regulation that became effective on September 1, 2018, and is set to expire on August 28, 2020.

This regulatory action was necessary to facilitate compliance with the DOJ Settlement Agreement by enhancing quality improvement and risk management regulatory provisions, and by expanding quality practices for the health, safety, care, and treatment of adults who receive services from DBHDS licensed service providers.

Purpose: 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.

Action Requested: Initiate final stage action for the following regulation.

Pkg #	VAC Citation	Title	Date of Last Activity
I.	Rules and Regulations for Licensing Providers by the Department of Behavioral Health and Developmental Services [12VAC35-105]	Compliance with Virginia's Settlement Agreement with US DOJ	Close of the proposed stage public comment period. 1/10/2020

Explanation
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.

Substance
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 in the Town Hall form below.
Changes since the proposed stage are indicated between square brackets [ ].
All other marked changes are from the proposed stage.

DRAFT

Compliance with Virginia's Settlement Agreement with US DOJ
Draft Amendments for Final Stage (see changes in brackets [ ])

Article 2
Definitions

12VAC35-105-20. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Abuse" ~~(§ 37.2-100 of the Code of Virginia)~~ means any act or failure to act by an employee or other person responsible for the care of an individual in a facility or program operated, licensed, or funded by the department, excluding those operated by the Virginia Department of Corrections, that was performed or was failed to be performed knowingly, recklessly, or intentionally, and that caused or might have caused physical or psychological harm, injury, or death to ~~a person~~ an individual receiving care or treatment for mental illness, ~~mental retardation (intellectual disability)~~ developmental disabilities, or substance abuse ~~(substance use disorders)~~. Examples of abuse include acts such as:

1. Rape, sexual assault, or other criminal sexual behavior;

2. Assault or battery;

3. Use of language that demeans, threatens, intimidates, or humiliates the ~~person~~ individual;

4. Misuse or misappropriation of the ~~person's~~ individual's assets, goods, or property;

5. Use of excessive force when placing ~~a person~~ an individual in physical or mechanical restraint;

6. Use of physical or mechanical restraints on ~~a person~~ an individual that is not in compliance with federal and state laws, regulations, and policies, professional accepted standards of practice, or ~~the person's~~ his individualized services plan; or

7. Use of more restrictive or intensive services or denial of services to punish ~~the person~~ an individual or that is not consistent with ~~the person's~~ his individualized services plan.

"Activities of daily living" or "ADLs" means personal care activities and includes bathing, dressing, transferring, toileting, grooming, hygiene, feeding, and eating. An individual's degree of independence in performing these activities is part of determining the appropriate level of care and services.

"Admission" means the process of acceptance into a service as defined by the provider's policies.

"Authorized representative" means a person permitted by law or 12VAC35-115 to authorize the disclosure of information or consent to treatment and services or participation in human research.

"Behavior intervention" means those principles and methods employed by a provider to help an individual receiving services to achieve a positive outcome and to address challenging behavior in a constructive and safe manner. Behavior intervention principles and methods ~~must~~ shall be employed in accordance with the individualized services plan and written policies and procedures governing service expectations, treatment goals, safety, and security.

"Behavioral treatment plan," "functional plan," or "behavioral support plan" means any set of documented procedures that are an integral part of the individualized services plan and are developed on the basis of a systematic data collection, such as a functional assessment, for the purpose of assisting individuals to achieve the following:

1. Improved behavioral functioning and effectiveness;
2. Alleviation of symptoms of psychopathology; or
3. Reduction of challenging behaviors.

"Brain injury" means any injury to the brain that occurs after birth, but before age 65, that is acquired through traumatic or nontraumatic insults. Nontraumatic insults may include anoxia, hypoxia, aneurysm, toxic exposure, encephalopathy, surgical interventions, tumor, and stroke. Brain injury does not include hereditary, congenital, or degenerative brain disorders or injuries induced by birth trauma.

~~"Care" or "treatment"~~ "Care," "treatment," or "support" means the individually planned therapeutic interventions that conform to current acceptable professional practice and that are intended to improve or maintain functioning of an individual receiving services delivered by a provider.

"Case management service" or "support coordination service" means services that can include assistance to individuals and their family members in ~~assessing~~ accessing needed services that are responsive to the ~~person's individual~~ individual's needs. Case management services include identifying potential users of the service; assessing needs and planning services; linking the individual to services and supports; assisting the individual directly to locate, develop, or obtain needed services and resources; coordinating services with other providers; enhancing community integration; making collateral contacts; monitoring service delivery; discharge planning; and advocating for individuals in response to their changing needs. "Case management service" does not include assistance in which the only function is maintaining service waiting lists or periodically contacting or tracking individuals to determine potential service needs.

"Clinical experience" means providing direct services to individuals with mental illness or the provision of direct geriatric services or special education services. Experience may include supervised internships, practicums, and field experience.

"Commissioner" means the Commissioner of the Department of Behavioral Health and Developmental Services.

"Community gero-psychiatric residential services" means 24-hour care provided to individuals with mental illness, behavioral problems, and concomitant health problems who are usually age 65 or older in a geriatric setting that is less intensive than a psychiatric hospital but more intensive than a nursing home or group home. Services include assessment and individualized services planning by an interdisciplinary services team, intense supervision, psychiatric care, behavioral treatment planning and behavior interventions, nursing, and other health related services.

~~"Community intermediate care facility/mental retardation" or "ICF/MR" means a residential facility in which care is provided to individuals who have mental retardation (intellectual disability) or a developmental disability who need more intensive training and supervision than may be available in an assisted living facility or group home. Such facilities shall comply with Title XIX of the Social Security Act standards and federal certification requirements, provide health or rehabilitative services, and provide active treatment to individuals receiving services toward the achievement of a more independent level of functioning or an improved quality of life.~~

"Complaint" means an allegation of a violation of this chapter or a provider's policies and procedures related to this chapter.

"Co-occurring disorders" means the presence of more than one and often several of the following disorders that are identified independently of one another and are not simply a cluster of symptoms resulting from a single disorder: mental illness, ~~mental retardation (intellectual disability)~~ a developmental disability, ~~or~~ substance abuse (substance use disorders)~~;~~, or brain injury~~; or developmental disability~~.

"Co-occurring services" means individually planned therapeutic treatment that addresses in an integrated concurrent manner the service needs of individuals who have co-occurring disorders.

"Corrective action plan" means the provider's pledged corrective action in response to cited areas of noncompliance documented by the regulatory authority. ~~A corrective action plan must be completed within a specified time.~~

"Correctional facility" means a facility operated under the management and control of the Virginia Department of Corrections.

"Crisis" means a deteriorating or unstable situation often developing suddenly or rapidly that produces acute, heightened, emotional, mental, physical, medical, or behavioral distress ~~or any situation or circumstance in which the individual perceives or experiences a sudden loss of the individual's ability to use effective problem-solving and coping skills~~.

"Crisis stabilization" means direct, intensive nonresidential or residential direct care and treatment to nonhospitalized individuals experiencing an acute crisis that may jeopardize their current community living situation. Crisis stabilization is intended to avert hospitalization or rehospitalization; provide normative environments with a high

assurance of safety and security for crisis intervention; stabilize individuals in crisis; and mobilize the resources of the community support system, family members, and others for ongoing rehabilitation and recovery.

"Day support service" means structured programs of ~~activity or training services~~ training, assistance, and specialized supervision in the acquisition, retention, or improvement of self-help, socialization, and adaptive skills 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. Day support services may provide opportunities for peer interaction and community integration and are designed to enhance the following: self-care and hygiene, eating, toileting, task learning, community resource utilization, environmental and behavioral skills, social skills, medication management, prevocational skills, and transportation skills. The term "day support service" does not include services in which the primary function is to provide employment-related services, general educational services, or general recreational services.

"Department" means the Virginia Department of Behavioral Health and Developmental Services.

"Developmental ~~disabilities~~" disability" 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~~ of an individual that (i) is attributable to a mental or physical impairment or a combination of mental and physical impairments other than a sole diagnosis of mental illness; (ii) is manifested before the individual reaches 22 years of age; (iii) is likely to continue indefinitely; (iv) results in substantial functional limitations in three or more of the following areas of major life activity: self-care, receptive and expressive language, learning, mobility, self-direction, capacity for independent living, or economic self-sufficiency; and (v) reflects the individual's need for a combination and sequence of special interdisciplinary or generic services, individualized supports, or other forms of assistance that are of lifelong or extended duration and are individually planned and coordinated. An individual from birth to nine years of age, inclusive, who has a substantial developmental delay or specific congenital or acquired condition may be considered to have a developmental disability without meeting three or more of the criteria described in clauses (i) through (v) if the individual without services and supports has a high probability of meeting those criteria later in life.

"Developmental services" means planned, individualized, and person-centered services and supports provided to individuals with developmental disabilities for the purpose of enabling these individuals to increase their self-determination and independence, obtain employment, participate fully in all aspects of community life,

advocate for themselves, and achieve their fullest potential to the greatest extent possible.

"Direct care position" means any position that includes responsibility for (i) treatment, case management, health, safety, development, or well-being of an individual receiving services or (ii) immediately supervising a person in a position with this responsibility.

"Discharge" means the process by which the individual's active involvement with a service is terminated by the provider, individual, or authorized representative.

"Discharge plan" means the written plan that establishes the criteria for an individual's discharge from a service and identifies and coordinates delivery of any services needed after discharge.

"Dispense" means to deliver a drug to an ultimate user by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery (§ 54.1-3400 et seq. of the Code of Virginia).

"Emergency service" means unscheduled and sometimes scheduled crisis intervention, stabilization, and referral assistance provided over the telephone or face-to-face, if indicated, available 24 hours a day and seven days per week. Emergency services also may include walk-ins, home visits, jail interventions, and preadmission screening activities associated with the judicial process.

"Group home or community residential service" means a congregate service providing 24-hour supervision in a community-based home having eight or fewer residents. Services include supervision, supports, counseling, and training in activities of daily living for individuals whose individualized services plan identifies the need for the specific types of services available in this setting.

"HCBS Waiver" means a Medicaid Home and Community Based Services Waiver.

"Home and noncenter based" means that a service is provided in the individual's home or other noncenter-based setting. This includes noncenter-based day support, supportive in-home, and intensive in-home services.

~~"IFDDS Waiver" means the Individual and Family Developmental Disabilities Support Waiver.~~

"Individual" or "individual receiving services" means a ~~person receiving services that are licensed under this chapter whether that person is referred to as a patient, consumer, client, resident, student, individual, recipient, family member, relative, or other term~~ current direct recipient of public or private mental health, developmental, or substance abuse treatment, rehabilitation, or habilitation services and includes the terms "consumer," "patient," "resident," "recipient," or "client". When the term is used in this chapter, the requirement applies to every individual receiving licensed services from the provider.

"Individualized services plan" or "ISP" means a comprehensive and regularly updated written plan that describes the individual's needs, the measurable goals and objectives to address those needs, and strategies to reach the individual's goals. An ISP is person-centered, empowers the individual, and is designed to meet the needs and preferences of the individual. The ISP is developed through a partnership between the

individual and the provider and includes an individual's treatment plan, habilitation plan, person-centered plan, or plan of care, which are all considered individualized service plans.

"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.

"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.

"Initial assessment" means an assessment conducted prior to or at admission to determine whether the individual meets the service's admission criteria; what the individual's immediate service, health, and safety needs are; and whether the provider has the capability and staffing to provide the needed services.

"Inpatient psychiatric service" means intensive 24-hour medical, nursing, and treatment services provided to individuals with mental illness or substance abuse (substance use disorders) in a hospital as defined in § 32.1-123 of the Code of Virginia or in a special unit of such a hospital.

"Instrumental activities of daily living" or "IADLs" means meal preparation, housekeeping, laundry, and managing money. A person's degree of independence in performing these activities is part of determining appropriate level of care and services.

"Intellectual disability" means a disability originating before 18 years of age, characterized concurrently by (i) significant subaverage intellectual functioning as demonstrated by performance on a standardized measure of intellectual functioning administered in conformity with accepted professional practice that is at least two standard deviations below the mean and (ii) significant limitations in adaptive behavior as expressed in conceptual, social, and practical adaptive skills.

"Intensive community treatment service" or "ICT" means a self-contained interdisciplinary team of at least five full-time equivalent clinical staff, a program assistant, and a full-time psychiatrist that:

1. Assumes responsibility for directly providing needed treatment, rehabilitation, and support services to identified individuals with severe and persistent mental illness, especially those who have severe symptoms that are not effectively remedied by available treatments or who because of reasons related to their mental illness resist or avoid involvement with mental health services;

2. Minimally refers individuals to outside service providers;

3. Provides services on a long-term care basis with continuity of caregivers over time;

4. Delivers 75% or more of the services outside program offices; and

5. Emphasizes outreach, relationship building, and individualization of services.

"Intensive in-home service" means family preservation interventions for children and adolescents who have or are at-risk of serious emotional disturbance, including individuals who also have a diagnosis of ~~mental retardation (intellectual disability)~~ developmental disability. Intensive in-home service is usually time-limited and is provided typically in the residence of an individual who is at risk of being moved to out-of-home placement or who is being transitioned back home from an out-of-home placement. The service includes 24-hour per day emergency response; crisis treatment; individual and family counseling; life, parenting, and communication skills; and case management and coordination with other services.

"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.

"Investigation" means a detailed inquiry or systematic examination of the operations of a provider or its services regarding an alleged violation of regulations or law. An investigation may be undertaken as a result of a complaint, an incident report, or other information that comes to the attention of the department.

"Licensed mental health professional" or "LMHP" means a physician, licensed clinical psychologist, licensed professional counselor, licensed clinical social worker, licensed substance abuse treatment practitioner, licensed marriage and family therapist, certified psychiatric clinical nurse specialist, licensed behavior analyst, or licensed psychiatric/mental health nurse practitioner.

"Location" means a place where services are or could be provided.

"Medically managed withdrawal services" means detoxification services to eliminate or reduce the effects of alcohol or other drugs in the individual's body.

"Mandatory outpatient treatment order" means an order issued by a court pursuant to § 37.2-817 of the Code of Virginia.

"Medical detoxification" means a service provided in a hospital or other 24-hour care facility under the supervision of medical personnel using medication to systematically eliminate or reduce effects of alcohol or other drugs in the individual's body.

"Medical evaluation" means the process of assessing an individual's health status that includes a medical history and a physical examination of an individual conducted by a licensed medical practitioner operating within the scope of his license.

"Medication" means prescribed or over-the-counter drugs or both.

"Medication administration" means the direct application of medications by injection, inhalation, ingestion, or any other means to an individual receiving services by (i) persons legally permitted to administer medications or (ii) the individual at the direction and in the presence of persons legally permitted to administer medications.

"Medication assisted treatment (Opioid treatment service)" means an intervention strategy that combines outpatient treatment with the administering or dispensing of

synthetic narcotics, such as methadone or buprenorphine (suboxone), approved by the federal Food and Drug Administration for the purpose of replacing the use of and reducing the craving for opioid substances, such as heroin or other narcotic drugs.

"Medication error" means an error in administering a medication to an individual and includes when any of the following occur: (i) the wrong medication is given to an individual, (ii) the wrong individual is given the medication, (iii) the wrong dosage is given to an individual, (iv) medication is given to an individual at the wrong time or not at all, or (v) the wrong method is used to give the medication to the individual.

"Medication storage" means any area where medications are maintained by the provider, including a locked cabinet, locked room, or locked box.

"Mental Health Community Support Service ~~(MHCSS)~~" or "MCHSS" means the provision of recovery-oriented services to individuals with long-term, severe mental illness. MHCSS includes skills training and assistance in accessing and effectively utilizing services and supports that are essential to meeting the needs identified in the individualized services plan and development of environmental supports necessary to sustain active community living as independently as possible. MHCSS may be provided in any setting in which the individual's needs can be addressed, skills training applied, and recovery experienced.

"Mental illness" means a disorder of thought, mood, emotion, perception, or orientation that significantly impairs judgment, behavior, capacity to recognize reality, or ability to address basic life necessities and requires care and treatment for the health, safety, or recovery of the individual or for the safety of others.

~~"Mental retardation (intellectual disability)" means a disability originating before the age of 18 years characterized concurrently by (i) significantly subaverage intellectual functioning as demonstrated by performance on a standardized measure of intellectual functioning administered in conformity with accepted professional practice that is at least two standard deviations below the mean; and (ii) significant limitations in adaptive behavior as expressed in conceptual, social, and practical adaptive skills (§ 37.2-100 of the Code of Virginia).~~

"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.

"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~~ an individual receiving care or treatment for mental illness, ~~mental retardation (intellectual disability)~~ developmental disabilities, or substance abuse ~~(substance use disorders)~~.

"Neurobehavioral services" means the assessment, evaluation, and treatment of cognitive, perceptual, behavioral, and other impairments caused by brain injury that affect an individual's ability to function successfully in the community.

"Outpatient service" means treatment provided to individuals on an hourly schedule, on an individual, group, or family basis, and usually in a clinic or similar facility or in another location. Outpatient services may include diagnosis and evaluation, screening

and intake, counseling, psychotherapy, behavior management, psychological testing and assessment, laboratory and other ancillary services, medical services, and medication services. "Outpatient service" specifically includes:

1. Services operated by a community services board or a behavioral health authority established pursuant to Chapter 5 (§ 37.2-500 et seq.) or Chapter 6 (§ 37.2-600 et seq.) of Title 37.2 of the Code of Virginia;

2. Services contracted by a community services board or a behavioral health authority established pursuant to Chapter 5 (§ 37.2-500 et seq.) or Chapter 6 (§ 37.2-600 et seq.) of Title 37.2 of the Code of Virginia; or

3. Services that are owned, operated, or controlled by a corporation organized pursuant to the provisions of either Chapter 9 (§ 13.1-601 et seq.) or Chapter 10 (§ 13.1-801 et seq.) of Title 13.1 of the Code of Virginia.

"Partial hospitalization service" means time-limited active treatment interventions that are more intensive than outpatient services, designed to stabilize and ameliorate acute symptoms, and serve as an alternative to inpatient hospitalization or to reduce the length of a hospital stay. Partial hospitalization is focused on individuals with serious mental illness, substance abuse (substance use disorders), or co-occurring disorders at risk of hospitalization or who have been recently discharged from an inpatient setting.

"Person-centered" means focusing on the needs and preferences of the individual; empowering and supporting the individual in defining the direction for his life; and promoting self-determination, community involvement, and recovery.

"Program of assertive community treatment service" or "PACT" means a self-contained interdisciplinary team of at least 10 full-time equivalent clinical staff, a program assistant, and a ~~full-~~ full-time or part-time psychiatrist that:

1. Assumes responsibility for directly providing needed treatment, rehabilitation, and support services to identified individuals with severe and persistent mental illnesses, including those who have severe symptoms that are not effectively remedied by available treatments or who because of reasons related to their mental illness resist or avoid involvement with mental health services;

2. Minimally refers individuals to outside service providers;

3. Provides services on a long-term care basis with continuity of caregivers over time;

4. Delivers 75% or more of the services outside program offices; and

5. Emphasizes outreach, relationship building, and individualization of services.

"Provider" means any person, entity, or organization, excluding an agency of the federal government by whatever name or designation, that delivers (i) services to individuals with mental illness, ~~mental retardation (intellectual disability)~~ developmental disabilities, or substance abuse (substance use disorders)~~,~~ or (ii) ~~services to individuals who receive day support, in-home support, or crisis stabilization services funded through the IFDDS Waiver, or (iii)~~ residential services for individuals with brain injury. The person, entity, or organization shall include a hospital as defined in § 32.1-123 of the Code of Virginia, community services board, behavioral health authority, private provider, and any other similar or related person, entity, or organization. It shall not include any individual practitioner who holds a license issued by a health regulatory

board of the Department of Health Professions or who is exempt from licensing pursuant to §§ 54.1-2901, 54.1-3001, 54.1-3501, 54.1-3601, and 54.1-3701 of the Code of Virginia.

"Psychosocial rehabilitation service" means a program of two or more consecutive hours per day provided to groups of adults in a nonresidential setting. Individuals must demonstrate a clinical need for the service arising from a condition due to mental, behavioral, or emotional illness that results in significant functional impairments in major life activities. This service provides education to teach the individual about mental illness, substance abuse, and appropriate medication to avoid complication and relapse and opportunities to learn and use independent skills and to enhance social and interpersonal skills within a consistent program structure and environment. Psychosocial rehabilitation includes skills training, peer support, vocational rehabilitation, and community resource development oriented toward empowerment, recovery, and competency.

"Qualified developmental disability professional" or "QDDP" means a person who possesses at least one year of documented experience working directly with individuals who have a developmental disability and who possesses one of the following credentials: (i) a doctor of medicine or osteopathy licensed in Virginia, (ii) a registered nurse licensed in Virginia, (iii) a licensed occupational therapist, or (iv) completion of at least a bachelor's degree in a human services field, including sociology, social work, special education, rehabilitation counseling, or psychology.

[~~"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. A quality improvement plan consists of systematic and continuous actions that lead to measurable improvement in the services, supports, and health status of the individuals receiving services.~~]

"Qualified mental health professional" or "QMHP" means a person who by education and experience is professionally qualified and registered by the Board of Counseling in accordance with 18VAC115-80 to provide collaborative mental health services for adults or children. A QMHP shall not engage in independent or autonomous practice. A QMHP shall provide such services as an employee or independent contractor of the department or a provider licensed by the department.

"Qualified mental health professional-adult" or "QMHP-A" means a person who by education and experience is professionally qualified and registered with the Board of Counseling in accordance with 18VAC115-80 to provide collaborative mental health services for adults. A QMHP-A shall provide such services as an employee or independent contractor of the department or a provider licensed by the department. A QMHP-A may be an occupational therapist who by education and experience is professionally qualified and registered with the Board of Counseling in accordance with 18VAC115-80.

"Qualified mental health professional-child" or "QMHP-C" means a person who by education and experience is professionally qualified and registered with the Board of Counseling in accordance with 18VAC115-80 to provide collaborative mental health services for children. A QMHP-C shall provide such services as an employee or independent contractor of the department or a provider licensed by the department. A

QMHP-C may be an occupational therapist who by education and experience is professionally qualified and registered with the Board of Counseling in accordance with 18VAC115-80.

"Qualified mental health professional-eligible" or "QMHP-E" means a person receiving supervised training in order to qualify as a QMHP in accordance with 18VAC115-80 and who is registered with the Board of Counseling.

"Qualified paraprofessional in mental health" or "QPPMH" means a person who must meet at least one of the following criteria: (i) registered with the United States Psychiatric Association (USPRA) as an Associate Psychiatric Rehabilitation Provider (APRP); (ii) has an associate's degree in a related field (social work, psychology, psychiatric rehabilitation, sociology, counseling, vocational rehabilitation, human services counseling) and at least one year of experience providing direct services to individuals with a diagnosis of mental illness; (iii) licensed as an occupational therapy assistant, and supervised by a licensed occupational therapist, with at least one year of experience providing direct services to individuals with a diagnosis of mental illness; or (iv) has a minimum of 90 hours classroom training and 12 weeks of experience under the direct personal supervision of a QMHP-A providing services to individuals with mental illness and at least one year of experience (including the 12 weeks of supervised experience).

["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. A quality improvement plan consists of systematic and continuous actions that lead to measurable improvement in the services, supports, and health status of the individuals receiving services.]

"Recovery" means a journey of healing and transformation enabling an individual with a mental illness to live a meaningful life in a community of his choice while striving to achieve his full potential. For individuals with substance abuse (substance use disorders), recovery is an incremental process leading to positive social change and a full return to biological, psychological, and social functioning. For individuals with ~~mental retardation (intellectual disability)~~ a developmental disability, the concept of recovery does not apply in the sense that individuals with ~~mental retardation (intellectual disability)~~ a developmental disability will need supports throughout their entire lives although these may change over time. With supports, individuals with ~~mental retardation (intellectual disability)~~ a developmental disability are capable of living lives that are fulfilling and satisfying and that bring meaning to themselves and others whom they know.

"Referral" means the process of directing an applicant or an individual to a provider or service that is designed to provide the assistance needed.

"Residential crisis stabilization service" means (i) providing short-term, intensive treatment to nonhospitalized individuals who require multidisciplinary treatment in order to stabilize acute psychiatric symptoms and prevent admission to a psychiatric inpatient unit; (ii) providing normative environments with a high assurance of safety and security for crisis intervention; and (iii) mobilizing the resources of the community support system, family members, and others for ongoing rehabilitation and recovery.

"Residential service" means providing 24-hour support in conjunction with care and treatment or a training program in a setting other than a hospital or training center. Residential services provide a range of living arrangements from highly structured and intensively supervised to relatively independent requiring a modest amount of staff support and monitoring. Residential services include residential treatment, group ~~or community~~ homes, supervised living, residential crisis stabilization, community gero-psychiatric residential, ~~community intermediate care facility-MR~~ ICF/IID, sponsored residential homes, medical and social detoxification, neurobehavioral services, and substance abuse residential treatment for women and children.

"Residential treatment service" means providing an intensive and highly structured mental health, substance abuse, or neurobehavioral service, or services for co-occurring disorders in a residential setting, other than an inpatient service.

"Respite care service" means providing for a short-term, ~~time limited~~ time-limited period of care of an individual for the purpose of providing relief to the individual's family, guardian, or regular care giver. Persons providing respite care are recruited, trained, and supervised by a licensed provider. These services may be provided in a variety of settings including residential, day support, in-home, or a sponsored residential home.

"Restraint" means the use of a mechanical device, medication, physical intervention, or hands-on hold to prevent an individual receiving services from moving his body to engage in a behavior that places him or others at imminent risk. There are three kinds of restraints:

1. Mechanical restraint means the use of a mechanical device that cannot be removed by the individual to restrict the individual's freedom of movement or functioning of a limb or portion of an individual's body when that behavior places him or others at imminent risk.

2. Pharmacological restraint means the use of a medication that is administered involuntarily for the emergency control of an individual's behavior when that individual's behavior places him or others at imminent risk and the administered medication is not a standard treatment for the individual's medical or psychiatric condition.

3. Physical restraint, also referred to as manual hold, means the use of a physical intervention or hands-on hold to prevent an individual from moving his body when that individual's behavior places him or others at imminent risk.

"Restraints for behavioral purposes" means using a physical hold, medication, or a mechanical device to control behavior or involuntary restrict the freedom of movement of an individual in an instance when all of the following conditions are met: (i) there is an emergency; (ii) nonphysical interventions are not viable; and (iii) safety issues require an immediate response.

"Restraints for medical purposes" means using a physical hold, medication, or mechanical device to limit the mobility of an individual for medical, diagnostic, or surgical purposes, such as routine dental care or radiological procedures and related post-procedure care processes, when use of the restraint is not the accepted clinical practice for treating the individual's condition.

"Restraints for protective purposes" means using a mechanical device to compensate for a physical or cognitive deficit when the individual does not have the option to remove the device. The device may limit an individual's movement, for example, bed rails or a gerichair, and prevent possible harm to the individual or it may create a passive barrier, such as a helmet to protect the individual.

"Restriction" means anything that limits or prevents an individual from freely exercising his rights and privileges.

"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.

"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.

"Screening" means the process or procedure for determining whether the individual meets the minimum criteria for admission.

"Seclusion" means the involuntary placement of an individual alone in an area secured by a door that is locked or held shut by a staff person, by physically blocking the door, or by any other physical means so that the individual cannot leave it.

"Serious incident" means any event or circumstance that causes or could cause harm to the health, safety, or well-being of an individual. The term "serious incident" includes death and serious injury.

"Level I serious incident" means a serious incident that occurs or originates during the provision of a service or on the premises of the provider and does not meet the definition of a Level II or Level III serious incident. Level I serious incidents do not result in significant harm to individuals, but may include events that result in minor injuries that do not require medical attention or events that have the potential to cause serious injury, even when no injury occurs. "Level II serious incident" means a serious incident that occurs or originates during the provision of a service or on the premises of the provider that results in a significant harm or threat to the health and safety of an individual that does not meet the definition of a Level III serious incident.

"Level II serious incident" includes a significant harm or threat to the health or safety of others caused by an individual. Level II serious incidents include:

1. A serious injury;

2. An individual who is or was missing;

3. An emergency room visit;

4. An unplanned psychiatric or unplanned medical hospital admission of an individual receiving services other than licensed emergency services [~~;~~ , except that a psychiatric admission in accordance with the individual's Wellness Recovery Action Plan (WRAP) shall not constitute an unplanned admission for the purposes of this Chapter.]

5. Choking incidents that require direct physical intervention by another person;

6. Ingestion of any hazardous material; or

7. A diagnosis of:

a. A decubitus ulcer or an increase in severity of level of previously diagnosed decubitus ulcer;

b. A bowel obstruction; or

c. Aspiration pneumonia.

"Level III serious incident" means a serious incident whether or not the incident occurs while in the provision of a service or on the provider's premises and results in:

1. Any death of an individual;

2. A sexual assault of an individual; or

3. A suicide attempt by an individual admitted for services, other than licensed emergency services, that results in a hospital admission.

"Serious injury" means any injury resulting in bodily hurt, damage, harm, or loss that requires medical attention by a licensed physician, doctor of osteopathic medicine, physician assistant, or nurse practitioner ~~while the individual is supervised by or involved in services, such as attempted suicides, medication overdoses, or reactions from medications administered or prescribed by the service~~.

"Service" means (i) planned individualized interventions intended to reduce or ameliorate mental illness, ~~mental retardation (intellectual disability)~~ developmental disabilities, or substance abuse (substance use disorders) through care, treatment, training, habilitation, or other supports that are delivered by a provider to individuals with mental illness, ~~mental retardation (intellectual disability)~~ developmental disabilities, or substance abuse (substance use disorders). Services include outpatient services, intensive in-home services, opioid treatment services, inpatient psychiatric hospitalization, community gero-psychiatric residential services, assertive community treatment and other clinical services; day support, day treatment, partial hospitalization, psychosocial rehabilitation, and habilitation services; case management services; and supportive residential, special school, halfway house, in-home services, crisis stabilization, and other residential services; and (ii) ~~day support, in-home support, and crisis stabilization services provided to individuals under the IFDDS Waiver; and (iii)~~ planned individualized interventions intended to reduce or ameliorate the effects of brain injury through care, treatment, or other supports ~~or~~ provided in residential services for persons with brain injury.

"Shall" means an obligation to act is imposed.

"Shall not" means an obligation not to act is imposed.

"Skills training" means systematic skill building through curriculum-based psychoeducational and cognitive-behavioral interventions. These interventions break down complex objectives for role performance into simpler components, including basic cognitive skills such as attention, to facilitate learning and competency.

"Social detoxification service" means providing nonmedical supervised care for the individual's natural process of withdrawal from use of alcohol or other drugs.

"Sponsored residential home" means a service where providers arrange for, supervise, and provide programmatic, financial, and service support to families or

persons (sponsors) providing care or treatment in their own homes for individuals receiving services.

"State board" means the State Board of Behavioral Health and Developmental Services. The board has statutory responsibility for adopting regulations that may be necessary to carry out the provisions of Title 37.2 of the Code of Virginia and other laws of the Commonwealth administered by the commissioner or the department.

"State methadone authority" means the Virginia Department of Behavioral Health and Developmental Services that is authorized by the federal Center for Substance Abuse Treatment to exercise the responsibility and authority for governing the treatment of opiate addiction with an opioid drug.

"Substance abuse (substance use disorders)" means the use of drugs enumerated in the Virginia Drug Control Act (§ 54.1-3400 et seq.) without a compelling medical reason or alcohol that (i) results in psychological or physiological dependence or danger to self or others as a function of continued and compulsive use or (ii) results in mental, emotional, or physical impairment that causes socially dysfunctional or socially disordering behavior; and (iii), because of such substance abuse, requires care and treatment for the health of the individual. This care and treatment may include counseling, rehabilitation, or medical or psychiatric care.

"Substance abuse intensive outpatient service" means treatment provided in a concentrated manner for two or more consecutive hours per day to groups of individuals in a nonresidential setting. This service is provided over a period of time for individuals requiring more intensive services than an outpatient service can provide. Substance abuse intensive outpatient services include multiple group therapy sessions during the week, individual and family therapy, individual monitoring, and case management.

"Substance abuse residential treatment for women with children service" means a 24-hour residential service providing an intensive and highly structured substance abuse service for women with children who live in the same facility.

"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.

"Supervised living residential service" means the provision of significant direct supervision and community support services to individuals living in apartments or other residential settings. These services differ from supportive in-home service because the provider assumes responsibility for management of the physical environment of the residence, and staff supervision and monitoring are daily and available on a 24-hour basis. Services are provided based on the needs of the individual in areas such as food preparation, housekeeping, medication administration, personal hygiene, treatment, counseling, and budgeting.

"Supportive in-home service" (formerly supportive residential) means the provision of community support services and other structured services to assist individuals, to strengthen individual skills, and that provide environmental supports necessary to attain and sustain independent community residential living. Services include drop-in or friendly-visitor support and counseling to more intensive support, monitoring, training, in-home support, respite care, and family support services. Services are based on the needs of the individual and include training and assistance. These services normally do

not involve overnight care by the provider; however, due to the flexible nature of these services, overnight care may be provided on an occasional basis.

"Systemic deficiency" means violations of regulations documented by the department that demonstrate multiple or repeat defects in the operation of one or more services.

"Therapeutic day treatment for children and adolescents" means a treatment program that serves (i) children and adolescents from birth through ~~age~~ 17 years of age and under certain circumstances up to 21 years of age with serious emotional disturbances, substance use, or co-occurring disorders or (ii) children from birth through ~~age~~ seven years of age who are at risk of serious emotional disturbance, in order to combine psychotherapeutic interventions with education and mental health or substance abuse treatment. Services include: evaluation; medication education and management; opportunities to learn and use daily living skills and to enhance social and interpersonal skills; and individual, group, and family counseling.

"Time out" means the involuntary removal of an individual by a staff person from a source of reinforcement to a different, open location for a specified period of time or until the problem behavior has subsided to discontinue or reduce the frequency of problematic behavior.

"Volunteer" means a person who, without financial remuneration, provides services to individuals on behalf of the provider.

Part II
Licensing Process

12VAC35-105-30. Licenses.

A. Licenses are issued to providers who offer services to individuals who have mental illness, ~~mental retardation (intellectual disability)~~ a developmental disability, or substance abuse (substance use disorders)~~; have developmental disability and are served under the IFDDS Waiver;~~ or have brain injury and are receiving residential services.

B. Providers shall be licensed to provide specific services as defined in this chapter or as determined by the commissioner. These services include:

1. Case management;
2. Community gero-psychiatric residential;
3. ~~Community intermediate care facility-MR~~ ICF/IID;
4. Residential crisis stabilization;
5. Nonresidential crisis stabilization;
6. Day support;
7. Day treatment, includes therapeutic day treatment for children and adolescents;
8. Group home and community residential;
9. Inpatient psychiatric;
10. Intensive ~~Community Treatment~~ community treatment (ICT);
11. Intensive in-home;

12. Managed withdrawal, including medical detoxification and social detoxification;

13. Mental health community support;

14. Opioid treatment/medication assisted treatment;

15. Emergency;

16. Outpatient;

17. Partial hospitalization;

18. Program of assertive community treatment (PACT);

19. Psychosocial rehabilitation;

20. Residential treatment;

21. Respite care;

22. Sponsored residential home;

23. Substance abuse residential treatment for women with children;

24. Substance abuse intensive outpatient;

25. Supervised living residential; and

26. Supportive in-home.

C. A license addendum shall describe the services licensed, the disabilities of individuals who may be served, the specific locations where services are to be provided or administered, and the terms and conditions for each service offered by a licensed provider. For residential and inpatient services, the license identifies the number of individuals each residential location may serve at a given time.

12VAC35-105-50. Issuance of licenses.

A. The commissioner may issue the following types of licenses:

1. A conditional license ~~shall~~ may be issued to a new provider for services that demonstrates compliance with administrative and policy regulations but has not demonstrated compliance with all the regulations.

a. A conditional license shall not exceed six months.

b. A conditional license may be renewed if the provider is not able to demonstrate compliance with all the regulations at the end of the license period. A conditional license and any renewals shall not exceed 12 successive months for all conditional licenses and renewals combined.

c. A provider holding a conditional license for a service shall demonstrate progress toward compliance.

d. A provider holding a conditional license shall not add services or locations during the conditional period.

e. A group home or community residential service provider shall be limited to providing services in a single location, serving no more than four individuals during the conditional period.

2. A provisional license may be issued to a provider for a service that has demonstrated an inability to maintain compliance with all applicable regulations, including this chapter and 12VAC35-115, has violations of human rights or

licensing regulations that pose a threat to the health or safety of individuals ~~being served~~ receiving services, has multiple violations of human rights or licensing regulations, or has failed to comply with a previous corrective action plan.

a. A provisional license may be issued at any time.

b. The term of a provisional license shall not exceed six months.

c. A provisional license may be renewed; but a provisional license and any renewals shall not exceed 12 successive months for all provisional licenses and renewals combined.

d. A provider holding a provisional license for a service shall demonstrate progress toward compliance.

e. A provider holding a provisional license for a service shall not increase its services or locations or expand the capacity of the service.

f. A provisional license for a service shall be noted as a stipulation on the provider license. The stipulation shall also indicate the violations to be corrected and the expiration date of the provisional license.

3. A full license shall be issued after a provider or service demonstrates compliance with all the applicable regulations.

a. A full license may be granted to a provider for service for up to three years. The length of the license shall be in the sole discretion of the commissioner.

b. If a full license is granted for three years, it shall be referred to as a triennial license. A triennial license shall be granted to providers for services that have demonstrated full compliance with ~~the~~ all applicable regulations. The commissioner may issue a triennial license to a provider for service that had violations during the previous license period if those violations did not pose a threat to the health or safety of individuals ~~being served~~ receiving services, and the provider or service has demonstrated consistent compliance for more than a year and has a process in place that provides sufficient oversight to maintain compliance.

c. If a full license is granted for one year, it shall be referred to as an annual license.

d. The term of the first full renewal license after the expiration of a conditional or provisional license shall not exceed one year.

B. The commissioner may add stipulations on a license issued to a provider that may place limits on the provider or to impose additional requirements on the provider.

C. A license shall not be transferred or assigned to another provider. A new application shall be made and a new license issued when there is a change in ownership.

~~D. A license shall not be issued or renewed unless the provider is affiliated with a local human rights committee.~~

~~E.~~ D. No service shall be issued a license with an expiration date that is after the expiration date of the provider license.

~~F.~~ E. A license shall continue in effect after the expiration date if the provider has submitted a renewal application before the date of expiration and there are no grounds

to deny the application. The department shall issue a letter stating the provider or service license shall be effective for six additional months if the renewed license is not issued before the date of expiration.

12VAC35-105-120. Variances.

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~~. 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.

12VAC35-105-150. Compliance with applicable laws, regulations and policies.

The provider including its employees, contractors, students, and volunteers shall comply with:

1. ~~These regulations~~ This chapter;
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. 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~~] ;
   d. Occupational Safety and Health Administration regulations;
   ~~d.~~ e. Virginia Department of Health regulations;
   ~~e. Laws and regulations of the~~ f. Virginia Department of Health Professions regulations;
   ~~f.~~ g. Virginia Department of Medical Assistance Services regulations;
   ~~g.~~ h. Uniform Statewide Building Code; and
   ~~h.~~ i. Uniform Statewide Fire Prevention Code.
4. Section 37.2-400 of the Code of Virginia and related human rights regulations adopted by the state board; and
5. The provider's own policies. All required policies shall be in writing.

12VAC35-105-155. Preadmission screening, discharge planning, involuntary commitment, and mandatory outpatient treatment orders.

A. Providers responsible for complying with §§ 37.2-505 and 37.2-606 of the Code of Virginia regarding community ~~service~~ services board and behavioral health authority

preadmission screening and discharge planning shall implement policies and procedures that include:

1. Identification, qualification, training, and responsibilities of employees responsible for preadmission screening and discharge planning.

2. Completion of a discharge plan prior to an individual's discharge in consultation with the state facility that:

a. Involves the individual or his authorized representative and reflects the individual's preferences to the greatest extent possible consistent with the individual's needs.

b. Involves mental health, ~~mental retardation (intellectual disability)~~ developmental disability, substance abuse, social, educational, medical, employment, housing, legal, advocacy, transportation, and other services that the individual will need upon discharge into the community and identifies the public or private agencies or persons that have agreed to provide them.

B. Any provider who serves individuals through an emergency custody order, temporary detention order, or mandatory outpatient treatment order shall implement policies and procedures to comply with §§ 37.2-800 through 37.2-817 of the Code of Virginia.

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

A. The provider shall permit representatives from the department to conduct reviews to:

1. Verify application information;

2. Assure compliance with this chapter; and

3. Investigate complaints.

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 serious incidents, including Level I serious incidents, as part of the quality improvement program in accordance with 12VAC35-105-620 to include an analysis of trends, potential systemic issues or causes, indicated remediation, and documentation of steps taken to mitigate the potential for future incidents.

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 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 ~~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 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 serious incidents and any Level III serious incidents that occur during the provision of 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)~~ b. ~~a~~ A] 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

[~~(iii)~~ c. ~~i~~ I] dentified 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:

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 serviced, 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;

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;

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 serviced, 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

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.]

[~~D.~~ F.] The provider shall ~~submit, or~~ make available and, when requested, submit reports and information that the department requires to establish compliance with these regulations and applicable statutes.

[~~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.

[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 information related to serious incidents.]

12VAC35-105-170. Corrective action plan.

A. If there is noncompliance with any applicable regulation during an initial or ongoing review, inspection, or investigation, the department shall issue a licensing report describing the noncompliance and requesting the provider to submit a corrective action plan for each violation cited.

B. The provider shall submit to the department [~~and implement~~] a written corrective action plan for each ~~regulation with which it is found to be in violation as identified in the licensing report~~ violation cited.

C. The corrective action plan shall include a:

1. ~~Description~~ Detailed description of the corrective actions to be taken that will minimize the possibility that the violation will occur again and correct any systemic deficiencies;

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].

D. The provider shall submit a corrective action plan to the department within 15 business days of the issuance of the licensing report. ~~Extensions~~ One extension 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.

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~~ not approved] , the provider shall follow the dispute resolution process identified in this section.

F. When the provider disagrees with a citation of a violation or the disapproval of [~~the~~ a] revised corrective action [plan~~s~~] , 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.

G. The provider shall 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.

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:

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

2. Submit a revised corrective action plan to the department for approval.]

12VAC35-105-320. Fire inspections.

The provider shall document at the time of its original application and annually thereafter that buildings and equipment in residential service locations [serving more than eight individuals] are maintained in accordance with the Virginia Statewide Fire Prevention Code (13VAC5-51). [~~The provider shall evaluate each individual and, based on that evaluation, shall provide appropriate environmental supports and adequate staff to safely evacuate all individuals during an emergency.~~ This section does not apply to correctional facilities or home and noncenter-based or sponsored residential home services.]

Article 3
Physical Environment of ~~Residential/Inpatient~~ Residential and Inpatient Service Locations

12VAC35-105-330. Beds.

A. The provider shall not operate more beds than the number for which its service location ~~or locations are~~ is licensed.

B. ~~A community ICF/MR~~ An ICF/IID may not have more than 12 beds at any one location. This applies to new applications for services and not to existing services or locations licensed prior to December 7, 2011.

12VAC35-105-400. Criminal ~~registry~~ background checks and registry searches.

A. Providers shall comply with the requirements for obtaining criminal history background ~~check requirements for direct care positions~~ checks 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 for all employees, contractors, students, and volunteers~~ searches. 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 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 for all employees and for contractors, students, and volunteers if required by the provider's policy~~ searches.

~~E.~~ D. The provider shall maintain the following documentation:

1. The disclosure statement from the applicant stating whether he has ever been convicted of or is the subject of pending charges for any offense; and

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, [if applicable] and the results from the Child Protective Registry ~~check~~ search.

12VAC35-105-440. Orientation of new employees, contractors, volunteers, and students.

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; and

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 this chapter.

12VAC35-105-450. Employee training and development.

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.

12VAC35-105-460. Emergency medical or first aid training.

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.

Article 5

Health and Safety Management

12VAC35-105-500. Students and Volunteers.

A. The provider shall implement a written policy that clearly defines and communicates the requirements for the use and responsibilities of students and volunteers including selection and supervision.

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.

12VAC35-105-520. Risk management.

A. The provider shall designate a person responsible for 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].

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.

C. The provider shall conduct systemic risk assessment reviews at least annually to identify and respond to practices, situations, and policies that could result in the risk of harm to individuals receiving services. The risk assessment review shall address [at least the following:]

[~~(i)~~ 1. ~~t~~T] he environment of care;

[~~(ii)~~ 2. ~~c~~C] linical assessment or reassessment processes;

[(iii) 3. ~~s~~S] taff competence and adequacy of staffing;

[(iv) 4. ~~u~~U] se of high risk procedures, including seclusion and restraint; and

[(v) 5. ~~a~~A] review of serious incidents. This process shall incorporate uniform risk triggers and thresholds as defined by the department.

[D. ~~This Process~~ The systemic risk assessment review process] shall incorporate uniform risk triggers and thresholds as defined by the department.

~~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 improvement shall be documented and implemented by the provider.

~~D.~~ [~~E.~~ F.]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.

12VAC35-105-530. Emergency Preparedness and Response Plan.

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:

1. Specific procedures describing mitigation, preparedness, response, and recovery strategies, actions, and responsibilities for each emergency.

2. Documentation of coordination with the local emergency authorities to determine local disaster risks and community-wide plans to address different disasters and emergency situations.

3. The process for notifying local and state authorities of the emergency and a process for contacting staff when emergency response measures are initiated.

4. Written emergency management policies outlining specific responsibilities for provision of administrative direction and management of response activities, coordination of logistics during the emergency, communications, life safety of employees, contractors, students, volunteers, visitors, and individuals receiving services, property protection, community outreach, and recovery and restoration.

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:

a. Warning and notifying individuals receiving services;

b. Communicating with employees, contractors, and community responders;

c. Designating alternative roles and responsibilities of staff during emergencies including to whom they will report in the provider's organization command structure and when activated in the community's command structure;

d. Providing emergency access to secure areas and opening locked doors;

[e. Evacuation procedures, including for individuals who need evacuation assistance;]

[~~e.~~ f.] Conducting evacuations to emergency shelters or alternative sites and accounting for all individuals receiving services;

[~~f.~~ g.] Relocating individuals receiving residential or inpatient services, if necessary;

[~~g.~~ h.] Notifying family members or authorized representatives;

[~~h.~~ i.] Alerting emergency personnel and sounding alarms;

[~~i.~~ j.] Locating and shutting off utilities when necessary; and

[~~j.~~ k.] Maintaining a 24 hour telephone answering capability to respond to emergencies for individuals receiving services.

6. Processes for managing the following under emergency conditions:

a. Activities related to the provision of care, treatment, and services including scheduling, modifying, or discontinuing services; controlling information about individuals receiving services; providing medication; and transportation services;

b. Logistics related to critical supplies such as pharmaceuticals, food, linen, and water;

c. Security including access, crowd control, and traffic control; and

d. Back-up communication systems in the event of electronic or power failure.

7. Specific processes and protocols for evacuation of the provider's building or premises when the environment cannot support adequate care, treatment, and services.

8. Supporting documents that would be needed in an emergency, including emergency call lists, building and site maps necessary to shut off utilities, designated escape routes, and list of major resources such as local emergency shelters.

9. Schedule for testing the implementation of the plan and conducting emergency preparedness drills. Fire and evacuation drills shall be conducted at least monthly.]

[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.]

[~~B.~~ C.] The provider shall implement annual emergency preparedness and response training for all employees, contractors, students, and volunteers. This training shall also be provided as part of orientation for new employees and cover responsibilities for:

1. Alerting emergency personnel and sounding alarms;

2. Implementing evacuation procedures, including evacuation of individuals with special needs (i.e., deaf, blind, nonambulatory);

3. Using, maintaining, and operating emergency equipment;

4. Accessing emergency medical information for individuals receiving services; and

5. Utilizing community support services.

[~~C.~~ D.] The provider shall review the emergency preparedness plan annually and make necessary revisions. Such revisions shall be communicated to employees, contractors, students, volunteers, and individuals receiving services and incorporated into training for employees, contractors, students, and volunteers and into the orientation of individuals to services.

[~~D.~~ E.] In the event of a disaster, fire, emergency or any other condition that may jeopardize the health, safety, or welfare of individuals, the provider shall take appropriate action to protect the health, safety, and welfare of individuals receiving services and take appropriate actions to remedy the conditions as soon as possible.

[~~E.~~ F.] Employees, contractors, students, and volunteers shall be knowledgeable in and prepared to implement the emergency preparedness plan in the event of an emergency. The plan shall include a policy regarding regularly scheduled emergency preparedness training for all employees, contractors, students, and volunteers.

[~~F.~~ G.] In the event of a disaster, fire, emergency, or any other condition that may jeopardize the health, safety, or welfare of individuals, the provider should first respond and stabilize the disaster or emergency. After the disaster or emergency is stabilized, the provider should report the disaster or emergency to the department, but no later than 24 hours after the incident occurs.

[~~G.~~ H.] Providers of residential services shall have at all times a three-day supply of emergency food and water for all residents and staff. Emergency food supplies should include foods that do not require cooking. Water supplies shall include one gallon of water per person per day. [~~This section does not apply to home and noncenter-based services.~~]

[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.

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:

1. At least one smoke detector on each level of multi-level buildings, including the basement;

2. At least one smoke detector in each bedroom in locations with bedrooms;

3. At least one smoke detector in an area adjacent to any bedroom in locations with bedrooms; and

4. Any additional smoke detectors necessary to comply with all applicable federal and state laws and regulations and local ordinances.

K. Smoke detectors shall be tested monthly for proper operation.

L. All provider locations shall maintain a floor plan identifying locations of:

1. Exits;

2. Primary and secondary evacuation routes;

3. Accessible egress routes;

4. Portable fire extinguishers; and

5. Flashlights

M. This section does not apply to home and noncenter-based services.]

12VAC35-105-580. Service description requirements.

A. The provider shall develop, implement, review, and revise its descriptions of services offered according to the provider's mission and shall make service descriptions available for public review.

B. The provider shall outline how each service offers a structured program of individualized interventions and care designed to meet the individuals' physical and emotional needs; provide protection, guidance and supervision; and meet the objectives of any required individualized services plan.

C. The provider shall prepare a written description of each service it offers. Elements of each service description shall include:

1. Service goals;

2. A description of care, treatment, ~~training~~ skills acquisition, or other supports provided;

3. Characteristics and needs of individuals to ~~be served~~ receive services;

4. Contract services, if any;

5. Eligibility requirements and admission, continued stay, and exclusion criteria;

6. Service termination and discharge or transition criteria; and

7. Type and role of employees or contractors.

D. The provider shall revise the written service description whenever the operation of the service changes.

E. The provider shall not implement services that are inconsistent with its most current service description.

F. The provider shall admit only those individuals whose service needs are consistent with the service description, for whom services are available, and for which staffing levels and types meet the needs of the individuals ~~served~~ receiving services.

G. The provider shall provide for the physical separation of children and adults in residential and inpatient services and shall provide separate group programming for adults and children, except in the case of family services. The provider shall provide for the safety of children accompanying parents receiving services. Older adolescents transitioning from school to adult activities may participate in ~~mental retardation (intellectual disability)~~ developmental day support services with adults.

H. The service description for substance abuse treatment services shall address the timely and appropriate treatment of pregnant women with substance abuse (substance use disorders).

I. If the provider plans to serve individuals as of a result of a temporary detention order to a service, prior to admitting those individuals to that service, the provider shall submit a written plan for adequate staffing and security measures to ensure the individual can ~~be served~~ receive services safely within the service to the department for approval. If the plan is approved, the department ~~will~~ shall add a stipulation to the license authorizing the provider to serve individuals who are under temporary detention orders.

12VAC35-105-590. Provider staffing plan.

A. The provider shall implement a written staffing plan that includes the types, roles, and numbers of employees and contractors that are required to provide the service. This staffing plan shall reflect the:

1. Needs of the individuals ~~served~~ receiving services;

2. Types of services offered;

3. Service description; ~~and~~

4. Number of ~~people~~ individuals to ~~be served~~ receive services at a given time; and

5. Adequate number of staff required to safely evacuate all individuals during an emergency.

B. The provider shall develop a written transition staffing plan for new services, added locations, and changes in capacity.

C. The provider shall meet the following staffing requirements related to supervision.

1. The provider shall describe how employees, volunteers, contractors, and student interns will be supervised in the staffing plan and how that supervision will be documented.

2. Supervision of employees, volunteers, contractors, and student interns shall be provided by persons who have experience in working with individuals receiving services and in providing the services outlined in the service description.

3. Supervision shall be appropriate to the services provided and the needs of the individual. Supervision shall be documented.

4. Supervision shall include responsibility for approving assessments and individualized services plans, as appropriate. This responsibility may be delegated to an employee or contractor who meets the qualification for supervision as defined in this section.

5. Supervision of mental health, substance abuse, or co-occurring services that are of an acute or clinical nature such as outpatient, inpatient, intensive in-home, or day treatment shall be provided by a licensed mental health professional or a mental health professional who is license-eligible and registered with a board of the Department of Health Professions.

6. Supervision of mental health, substance abuse, or co-occurring services that are of a supportive or maintenance nature, such as psychosocial rehabilitation or mental health supports, shall be provided by a QMHP-A, a licensed mental health professional, or a mental health professional who is license-eligible and registered with a board of the Department of Health Professions. An individual who is a QMHP-E may not provide this type of supervision.

7. Supervision of ~~mental retardation (intellectual disability)~~ <u>developmental</u> services shall be provided by a person with at least one year of documented experience working directly with individuals who have ~~mental retardation (intellectual disability) or other~~ developmental disabilities and holds at least a bachelor's degree in a human services field such as sociology, social work, special education, rehabilitation counseling, nursing, or psychology. Experience may be substituted for the education requirement.

8. ~~Supervision of individual and family developmental disabilities support (IFDDS) services shall be provided by a person possessing at least one year of documented experience working directly with individuals who have developmental disabilities and is one of the following: a doctor of medicine or osteopathy licensed in Virginia; a registered nurse licensed in Virginia; or a person holding at least a bachelor's degree in a human services field such as sociology, social work, special education, rehabilitation counseling, or psychology. Experience may be substituted for the education requirement. 9.~~ Supervision of brain injury services shall be provided at a minimum by a clinician in the health professions field who is trained and experienced in providing brain injury services to individuals who have a brain injury diagnosis including~~:~~ (i) a doctor of medicine or osteopathy licensed in Virginia; (ii) a psychiatrist who is a doctor of medicine or osteopathy specializing in psychiatry and licensed in Virginia; (iii) a psychologist who has a master's degree in psychology from a college or university with at least one year of clinical experience; (iv) a social worker who has a bachelor's degree in human services or a related field (social work, psychology, psychiatric evaluation, sociology, counseling, vocational rehabilitation, human services counseling, or other degree deemed equivalent to those described) from an accredited college or university with at least two years of clinical experience providing direct services to individuals with a diagnosis of brain injury; (v) a Certified Brain Injury Specialist; (vi) a registered nurse licensed in Virginia with at least one year of clinical experience; or (vii) any other licensed rehabilitation professional with one year of clinical experience.

D. The provider shall employ or contract with persons with appropriate training, as necessary, to meet the specialized needs of and to ensure the safety of individuals ~~being served~~ receiving services in residential services with medical or nursing needs; speech, language, or hearing problems; or other needs where specialized training is necessary.

E. Providers of brain injury services shall employ or contract with a neuropsychologist or licensed clinical psychologist specializing in brain injury to assist, as appropriate, with initial assessments, development of individualized services plans, crises, staff training, and service design.

F. [~~Direct care staff who provide~~ 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.

12VAC35-105-620. Monitoring and evaluating service quality.

[A.] The provider shall 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.

[B.] The [quality improvement] program shall utilize standard quality improvement tools, including root cause analysis, and shall include a quality improvement plan [. ~~that~~]

[C. The quality improvement plan shall:]

[~~(i)~~ 1. ~~Is~~ Be] reviewed and updated at least annually;

[2. ~~d~~D] efine [~~s~~] measurable goals and objectives;

[3. ~~i~~I] nclude [~~s~~] and report [~~s~~] on statewide performance measures, if applicable, as required by DBHDS;

[4. ~~m~~ M] onitor [~~s~~] implementation and effectiveness of approved corrective action plans pursuant to 12VAC35-105-170; and

[5. ~~i~~I] nclude [~~s~~] 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 [:]

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 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.]

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

12VAC35-105-650. Assessment policy.

A. The provider shall implement a written assessment policy. The policy shall define how assessments will be conducted and documented.

B. The provider shall actively involve the individual and authorized representative, if applicable, in the preparation of initial and comprehensive assessments and in subsequent reassessments. In these assessments and reassessments, the provider shall consider the individual's needs, strengths, goals, preferences, and abilities within the individual's cultural context.

C. The assessment policy shall designate employees or contractors who are responsible for conducting assessments. These employees or contractors shall have experience in working with the needs of individuals who are being assessed, the assessment ~~tool or~~ tools being utilized, and the provision of services that the individuals may require.

D. Assessment is an ongoing activity. The provider shall make reasonable attempts to obtain previous assessments or relevant history.

E. An assessment shall be initiated prior to or at admission to the service. With the participation of the individual and the individual's authorized representative, if applicable, the provider shall complete an initial assessment detailed enough to determine whether the individual qualifies for admission and to initiate an ISP for those individuals who are admitted to the service. This assessment shall assess immediate service, health, and safety needs, and at a minimum include the individual's:

1. Diagnosis;

2. Presenting needs including the individual's stated needs, psychiatric needs, support needs, and the onset and duration of problems;

3. Current medical problems;

4. Current medications;

5. Current and past substance use or abuse, including co-occurring mental health and substance abuse disorders; and

6. At-risk behavior to self and others.

F. A comprehensive assessment shall update and finalize the initial assessment. The timing for completion of the comprehensive assessment shall be based upon the nature and scope of the service but shall occur 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. It shall address:

1. Onset and duration of problems;

2. Social, behavioral, developmental, and family history and supports;

3. Cognitive functioning including strengths and weaknesses;

4. Employment, vocational, and educational background;

5. Previous interventions and outcomes;

6. Financial resources and benefits;

7. Health history and current medical care needs, to include:

a. Allergies;

b. Recent physical complaints and medical conditions;

c. Nutritional needs;

d. Chronic conditions;

e. Communicable diseases;

f. Restrictions on physical activities if any;

g. Restrictive protocols or special supervision requirements;

h. Past serious illnesses, serious injuries, and hospitalizations;

~~h.~~ i. Serious illnesses and chronic conditions of the individual's parents, siblings, and significant others in the same household; and

~~i.~~ j. Current and past substance use including alcohol, prescription and nonprescription medications, and illicit drugs.

8. Psychiatric and substance use issues including current mental health or substance use needs, presence of co-occurring disorders, history of substance use or abuse, and circumstances that increase the individual's risk for mental health or substance use issues;

9. History of abuse, neglect, sexual, or domestic violence, or trauma including psychological trauma;

10. Legal status including authorized representative, commitment, and representative payee status;

11. Relevant criminal charges or convictions and probation or parole status;

12. Daily living skills;

13. Housing arrangements;

14. Ability to access services including transportation needs; and

15. As applicable, and in all residential services, fall risk, communication methods or needs, and mobility and adaptive equipment needs.

G. Providers of short-term intensive services including inpatient and crisis stabilization services shall develop policies for completing comprehensive assessments within the time frames appropriate for those services.

H. Providers of ~~non-intensive~~ nonintensive or short-term services shall meet the requirements for the initial assessment at a minimum. ~~Non-intensive~~ Nonintensive services are services provided in jails, nursing homes, or other locations when access to records and information is limited by the location and nature of the services. Short-term services typically are provided for less than 60 days.

I. Providers may utilize standardized state or federally sanctioned assessment tools that do not meet all the criteria of 12VAC35-105-650 as the initial or comprehensive assessment tools as long as the tools assess the individual's health and safety issues and substantially meet the requirements of this section.

J. Individuals who receive medication-only services shall be reassessed at least annually to determine whether there is a change in the need for additional services and the effectiveness of the medication.

12VAC35-105-660. Individualized services plan (ISP).

A. The provider shall actively involve the individual and authorized representative, as appropriate, in the development, review, and revision of a person-centered ISP. The individualized services planning process shall be consistent with laws protecting confidentiality, privacy, human rights of individuals receiving services, and rights of minors.

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.

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.

[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 [:]

[a. ~~t~~T] he proposed services to be delivered [~~,~~ ;]

[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.~~]

[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.

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:

a. The individual participate in the development of or revision to the ISP;

b. The proposed and alternative services and their respective risks and benefits were 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.]

12VAC35-105-665. ISP requirements.

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:

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;

3. The role of the individual and others in implementing the service plan;

4. A communication plan for individuals with communication barriers, including language barriers;

5. A behavioral support or treatment plan, if applicable;

6. A safety plan that addresses identified risks to the individual or to others, including a fall risk plan;

7. A crisis or relapse plan, if applicable;

8. Target dates for accomplishment of goals and objectives;

9. Identification of employees or contractors responsible for coordination and integration of services, including employees of other agencies; ~~and~~

10. Recovery plans, if applicable; and

11. Services the individual elects to self direct, if applicable.

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.

C. The provider shall designate a person who ~~will~~ shall be responsible for developing, implementing, reviewing, and revising each individual's ISP in collaboration with the individual or authorized representative, as appropriate.

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] .

E. Providers of short-term intensive services such as inpatient and crisis ~~stabilization~~ services that are typically provided for less than 30 days shall implement a policy to develop an ISP within a timeframe consistent with the length of stay of individuals.

F. ~~The ISP shall be consistent with the plan of care for individuals served by the IFDDS Waiver. G.~~ When a provider provides more than one service to an individual the provider may maintain a single ISP document that contains individualized objectives and strategies for each service provided.

~~H.~~ G. Whenever possible the identified goals in the ISP shall be written in the words of the individual receiving services.

12VAC35-105-675. Reassessments and ISP reviews.

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 a 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 toward 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.

12VAC35-105-691. Transition of individuals among service.

A. The provider shall implement written procedures that define the process for transitioning an individual between or among services operated by the provider. At a minimum the policy shall address:

1. The process by which the provider will assure continuity of services during and following transition;

2. The participation of the individual or his authorized representative, as applicable, in the decision to move and in the planning for transfer;

3. The process and timeframe for transferring the access to individual's record and ISP to the destination location;

4. The process and timeframe for completing the transfer summary; and

5. The process and timeframe for transmitting or accessing, where applicable, discharge summaries to the destination service.

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;

3. Current psychiatric and known medical conditions or issues of the individual and the identity of the individual's health care providers;

4. Updated progress of the individual in meeting goals and objectives in his ISP;

5. Emergency medical information;

6. Dosages of all currently prescribed medications and over-the-counter medications used by the individual when prescribed by the provider or known by the case manager;

7. Transfer date; and

8. Signature of employee or contractor responsible for preparing the transfer summary.

C. The transfer summary may be documented in the individual's progress notes or in information easily accessible within an electronic health record.

Article 6

Behavior Interventions

12VAC35-105-800. Policies and procedures on behavior interventions and supports.

A. The provider shall implement written policies and procedures that describe the use of behavior interventions, including seclusion, restraint, and time out. The policies and procedures shall:

1. Be consistent with applicable federal and state laws and regulations;

2. Emphasize positive approaches to behavior interventions;

3. List and define behavior interventions in the order of their relative degree of intrusiveness or restrictiveness and the conditions under which they may be used in each service for each individual;

4. Protect the safety and well-being of the individual at all times, including during fire and other emergencies;

5. Specify the mechanism for monitoring the use of behavior interventions; and

6. Specify the methods for documenting the use of behavior interventions.

B. Employees and contractors trained in behavior support interventions shall implement and monitor all behavior interventions.

C. Policies and procedures related to behavior interventions shall be available to individuals, their families, authorized representatives, and advocates. Notification of policies does not need to occur in correctional facilities.

D. Individuals receiving services shall not discipline, restrain, seclude, or implement behavior interventions on other individuals receiving services.

E. Injuries resulting from or occurring during the implementation of ~~behavior interventions~~ seclusion or restraint shall be ~~recorded in the individual's services record and~~ reported to the ~~assigned human rights advocate and the employee or contractor responsible for the overall coordination of services~~ department as provided in 12VAC35-115-230 C.

12VAC35-105-830. Seclusion, restraint, and time out.

A. The use of seclusion, restraint, and time out shall comply with applicable federal and state laws and regulations and be consistent with the provider's policies and procedures.

B. Devices used for mechanical restraint shall be designed specifically for emergency 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 emergency 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.

Article 3

Services in Department of Corrections Correctional Facilities

12VAC35-105-1140. Clinical and security coordination.

A. The provider shall have formal and informal methods of resolving procedural and programmatic issues regarding individual care arising between the clinical and security employees or contractors.

B. The provider shall demonstrate ongoing communication between clinical and security employees to ensure individual care.

C. The provider shall provide cross-training for the clinical and security employees or contractors that includes:

1. Mental health, ~~mental retardation (intellectual disability)~~ developmental disability, and substance abuse education;

2. Use of clinical and security restraints; and

3. Channels of communication.

D. Employees or contractors shall receive periodic in-service training, and have knowledge of and be able to demonstrate the appropriate use of clinical and security restraint.

E. Security and behavioral assessments shall be completed at the time of admission to determine service eligibility and at least weekly for the safety of individuals, other persons, employees, and visitors.

F. Personal grooming and care services for individuals shall be a cooperative effort between the clinical and security employees or contractors.

G. Clinical needs and security level shall be considered when arrangements are made regarding privacy for individual contact with family and attorneys.

H. Living quarters shall be assigned on the basis of the individual's security level and clinical needs.

I. An assessment of the individual's clinical condition and needs shall be made when disciplinary action or restrictions are required for infractions of security measures.

J. Clinical services consistent with the individual's condition and plan of treatment shall be provided when security detention or isolation is imposed.

12VAC35-105-1245. Case management direct assessments.

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.

12VAC35-105-1250. Qualifications of case management employees or contractors.

A. Employees or contractors providing case management services shall have knowledge of:

1. Services and systems available in the community including primary health care, support services, eligibility criteria and intake processes and generic community resources;

2. The nature of serious mental illness, ~~mental retardation (intellectual disability)~~ developmental disability, substance abuse (substance use disorders), or co-occurring disorders depending on the individuals ~~served~~ receiving services, including clinical and developmental issues;

3. Different types of assessments, including functional assessment, and their uses in service planning;

4. Treatment modalities and intervention techniques, such as behavior management, independent living skills training, supportive counseling, family education, crisis intervention, discharge planning, and service coordination;

5. Types of mental health, developmental, and substance abuse programs available in the locality;

6. The service planning process and major components of a service plan;

7. The use of medications in the care or treatment of the population served; and

8. All applicable federal and state laws and regulations and local ordinances.

B. Employees or contractors providing case management services shall have skills in:

1. Identifying and documenting an individual's need for resources, services, and other supports;

2. Using information from assessments, evaluations, observation, and interviews to develop service plans;

3. Identifying and documenting how resources, services, and natural supports such as family can be utilized to promote achievement of an individual's personal habilitative or rehabilitative and life goals; and

4. Coordinating the provision of services by diverse public and private providers.

C. Employees or contractors providing case management services shall have abilities to:

1. Work as team members, maintaining effective ~~inter-~~ inter-agency and intra-agency working relationships;

2. Work independently performing position duties under general supervision; and

3. Engage in and sustain ongoing relationships with individuals receiving services.

D. Case managers serving individuals with developmental disability shall complete the DBHDS core competency-based curriculum within 30 days of hire.

Article 7

Intensive Community Treatment and Program of Assertive Community Treatment Services

12VAC35-105-1360. Admission and discharge criteria.

A. Individuals must meet the following admission criteria:

1. Diagnosis of a severe and persistent mental illness, predominantly schizophrenia, other psychotic disorder, or bipolar disorder that seriously impairs functioning in the community. Individuals with a sole diagnosis of substance addiction or abuse or ~~mental retardation (intellectual disability)~~ developmental disability are not eligible for services.

2. Significant challenges to community integration without intensive community support including persistent or recurrent difficulty with one or more of the following:

a. Performing practical daily living tasks;

b. Maintaining employment at a self-sustaining level or consistently carrying out homemaker roles; or

c. Maintaining a safe living situation.

3. High service needs indicated due to one or more of the following:

a. Residence in a state hospital or other psychiatric hospital but clinically assessed to be able to live in a more independent situation if intensive services were provided or anticipated to require extended hospitalization, if more intensive services are not available;

b. Multiple admissions to or at least one recent long-term stay (30 days or more) in a state hospital or other acute psychiatric hospital inpatient setting within the past two years; or a recent history of more than four interventions by psychiatric emergency services per year;

c. Persistent or very recurrent severe major symptoms (e.g., affective, psychotic, suicidal);

d. Co-occurring substance addiction or abuse of significant duration (e.g., greater than six months);

e. High risk or a recent history (within the past six months) of criminal justice involvement (e.g., arrest or incarceration);

f. Ongoing difficulty meeting basic survival needs or residing in substandard housing, homeless, or at imminent risk of becoming homeless; or

g. Inability to consistently participate in traditional office-based services.

B. Individuals receiving PACT or ICT services should not be discharged for failure to comply with treatment plans or other expectations of the provider, except in certain circumstances as outlined. Individuals must meet at least one of the following criteria to be discharged:

1. Change in the individual's residence to a location out of the service area;

2. Death of the individual;

3. Incarceration of the individual for a period to exceed a year or ~~long term~~ long-term hospitalization (more than one year); however, the provider is expected to prioritize these individuals for PACT or ICT services upon ~~their~~ the individual's anticipated return to the community if the individual wishes to return to services and the service level is appropriate to his needs;

4. Choice of the individual with the provider responsible for revising the ISP to meet any concerns of the individual leading to the choice of discharge; or

5. Significant sustained recovery by the individual in all major role areas with minimal team contact and support for at least two years as determined by both the individual and ICT or PACT team.

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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	March 26, 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 (pending) 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 comments were submitted directly. To receive those in full as submitted, please email ruthanne.walekr@dbhds.virginia.gov.

Section	Comment	Changes to proposed draft
12VAC 35-115-20 Definitions		
• **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).
• **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.
• **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, the department will continue to define

Section	Comment	Changes to proposed draft
		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.
• **Missing**	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".	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.
• **QDDP**	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.	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').
• **Risk Management**	One commenter recommended striking the word "ensure" and replacing it with "support" in the definition of "risk management", suggesting that "providers cannot ensure safety."	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.
• **Serious Incident**	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 actions are prevented from occurring	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 brought about such events and

Section	Comment	Changes to proposed draft
	through risk management, crisis response, behavioral intervention, and corrective action plans.	circumstances. 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. Therefore, the requested change is unnecessary.
• **Level II Serious Incident**	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. 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."	Changes made. 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. 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. 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.
• **Service**	One commenter expressed concerns	No change made.

Section	Comment	Changes to proposed draft
	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."	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.
12VAC35-105-160. Reviews by the department; requests for information; required reporting.		
• **D.2. Incident reports – risk of harm**	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. 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.	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.
• **D.2. Sexual Assault**	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."	No changes made. Additional information related to considerations around sexual assault reporting can be found within the department's "Serious Incident Reporting" guidance document.
• **D.2. Deaths**	One commenter suggested that "expected deaths" should not be classified as Level III serious incidents.	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.
• **D.2. Serious incident required reporting**	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 required telephonic notification too restrictive, and suggested allowing for	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 that concerns about the 24 hour notification period should be

Section	Comment	Changes to proposed draft
	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."	alleviated by this change as well. Additional guidance and technical assistance will be provided on this requirement.
• **E. Root Cause Analyses**	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. Several commenters, however, requested that "during the provision of care" be defined or otherwise clarified. 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. 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."	Changes made. 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." 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.
12VAC35-105-170. Corrective Action Plan.		
• **Corrective Action Plan – Timelines**	Ten commenters recommended the inclusion of a specific timeline for the department to respond in writing to proposed corrective action plans.	No changes made. The department agrees that there should be concrete, consistent timelines for Office of Licensing to respond to providers. The department will develop these timelines through

Section	Comment	Changes to proposed draft
		written protocols.
12VAC35-105-320. Fire inspections.		
• **Sponsored Residential**	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.	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.
112VAC35-105-400. Criminal registry background checks and registry searches.		
• **C. & D.2. Documentation**	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".	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.
12VAC35-105-440. Orientation of new employees, contractors, volunteers, and students.		
• **Orientation**	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 providers from the requirement; or removing the time requirement and	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 would go beyond the purposes of this limited regulatory action. The

Section	Comment	Changes to proposed draft
	replacing with a rule that would prevent new employees from providing independent, billable, direct services until orientation has been completed.	comment will be reconsidered during the licensing regulatory 'overhaul.'
12VAC35-105-460		
• 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.		
• 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.
• 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 providers to clarify compliance expectations.	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.

Section	Comment	Changes to proposed draft
12VAC35-105-590. Provider and Staffing Plan		
• 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.		
• 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		
• 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)		
• 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 has in relation to these. Another commenter suggested that	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 technical assistance will be provided to ensure that providers understand these expectations.

Section	Comment	Changes to proposed draft
	ensuring and documenting informed consent is the role of the individual's case manager and not the provider.	
12VAC35-105-675. Reassessments and ISP reviews.		
• D.3. Meetings when goals not accomplished	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?"	No changes made. The department and 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.
12VAC35-105-1245. Case management direct assessments.		
• Documentation	Three commenters requested clarification on the documentation that would be necessary to establish compliance with the face-to-face meeting and direct assessment expectations.	No changes made. 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.
12VAC35-105-1250. Qualifications of Case Management Employees or Contractors.		
• D. Core Curriculum	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.	No changes made. This requirement is an important component of the Commonwealth's compliance with the Settlement Agreement and will not be amended.
General comments		
• Economic impact on regulated	Six commenters disagreed with the department's economic impact	No changes made. DBHDS believes these new

Section	Comment	Changes to proposed draft
entities	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 he provision of regular, high-quality training across the Commonwealth on topics such as root cause analysis, risk management, data analysis, and investigation skills."	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. 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. 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.
• Regulatory alignment	Several commenters made general comments about the need for increased consistency within and across regulatory agencies. One commenter made the general recommendation that the department "improve consistency and clarity	No changes made. These comments are beyond the scope of this limited regulatory action, the department will consider the commenter's recommendations during the licensing regulation overhaul.

Section	Comment	Changes to proposed draft
	among all relevant regulatory language." Two providers suggested the development of a "crosswalk among licensure, human rights, Medicaid Waiver and HCBS."	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.
• 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		"Level II serious incident" includes a significant harm or threat to the health or safety of others caused by an individual. Level II serious incidents include: 1. A serious injury; 2. An individual who is or was missing; 3. An emergency room visit; 4. An unplanned psychiatric or unplanned medical	"Level II serious incident" includes a significant harm or threat to the health or safety of others caused by an individual. Level II serious incidents include: 1. A serious injury; 2. An individual who is or was missing; 3. An emergency room visit; 4. An unplanned psychiatric or unplanned medical	• 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 incident reporting and reduce provider burdens by decreasing the

		hospital admission of an individual receiving services other than licensed emergency services 5. Choking incidents that require direct physical intervention by another person; 6. Ingestion of any hazardous material; or 7. A diagnosis of: a. A decubitus ulcer or an increase in severity of level of previously diagnosed decubitus ulcer; b. A bowel obstruction; or c. Aspiration pneumonia.	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.] 5. Choking incidents that require direct physical intervention by another person; 6. Ingestion of any hazardous material; or 7. A diagnosis of: a. A decubitus ulcer or an increase in severity of level of previously diagnosed decubitus ulcer; b. A bowel obstruction; or c. Aspiration pneumonia.	number of incidents for which root cause analyses and other risk management activities must be completed.
150		The provider including its employees, contractors, students, and volunteers shall comply with: 3. All applicable federal, state, or local laws and regulations including: c. 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.	The provider including its employees, contractors, students, and volunteers shall comply with: 3. All applicable federal, state, or local laws and regulations including: c. 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~~] ;	• Removed unnecessary language referring to the title for a cited federal regulation for ease of reading and clarity.
160		D. The provider shall collect, maintain, and report or make available to the department the following information:	D. The provider shall collect, maintain, and report or make available to the department the following information:	• Edits were made to the structure of this section for clarity. • "Risk of harm" was removed from the requirements of an

		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 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. 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 that resulted from the serious incident. Deaths that occur in a hospital as a result of illness or injury	1. Each allegation of abuse or neglect shall be reported to the ~~assigned human rights advocate and the individual's authorized representative within 24 hours from the receipt of the initial allegation. Reported information shall include the type of abuse, neglect, or exploitation that is alleged and whether there is physical or psychological injury to the individual~~ department as provided in 12VAC35-115-230 A. 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 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	incident report in response to comments that convincingly suggested that this language is too speculative. • 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 application of the requirements of this

		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 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	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 serious incidents and any Level III serious incidents that occur during the provision of a service or on the provider's premises.	section by providers.

		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 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.	[1.] The root cause analysis shall include at least the following information: [~~(i)~~ a. ~~a~~ A] detailed description of what happened; [~~(ii)~~ b. ~~a~~ A] 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 [~~(iii)~~ c. ~~i~~ I] dentified 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.~~ 1. The root cause analysis shall include at least the following information: a. A detailed description of what happened; b. An analysis of why it happened, including identification of all identifiable underlying causes of the incident that were under the control of the provider; and c. Identified solutions to mitigate its reoccurrence and future risk of harm when applicable. [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: 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; 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; 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; or d. A death occurs as a result of an acute medical event that was	

		N/A	not expected in advance or based on a person's known medical condition.] [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 information related to serious incidents.]	
170		G. The provider shall 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.	G. The provider shall 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. 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	• 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.

			regulatory violation or correct any systemic deficiencies, the provider shall: 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 2. Submit a revised corrective action plan to the department for approval.]	
320		The provider shall document at the time of its original application and annually thereafter that buildings and equipment in residential service locations ~~serving more than eight individuals~~ are maintained in accordance with the Virginia Statewide Fire Prevention Code (13VAC5-51). ~~This section does not apply to correctional facilities or home and noncenter-based or sponsored residential home services.~~ 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 [serving more than eight individuals] are maintained in accordance with the Virginia Statewide Fire Prevention Code (13VAC5-51). [~~The provider shall evaluate each individual and, based on that evaluation, shall provide appropriate environmental supports and adequate staff to safely evacuate all individuals during an emergency.~~ This section does not apply to correctional facilities or home and noncenter-based or sponsored residential home services.]	• 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	2. Documentation that the provider submitted all information required by the department to	• The words “if applicable” were added to Subsection 2 of this section 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.	complete the criminal history background checks and registry ~~checks~~ searches, memoranda from the department transmitting the results to the provider, [if applicable] and the results from the Child Protective Registry ~~check~~ search.	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 include volunteers or students.	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.	• Language changes only for consistency and alignment with regulatory and statutory definitions.
520		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, infectious disease, property damage or loss, and other sources of potential liability. C. The provider shall conduct systemic risk assessment reviews at	A. The provider shall designate a person responsible for 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]. 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. C. The provider shall conduct systemic risk assessment reviews at	• 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

		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. 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	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:] [~~(i)~~ 1. ~~t~~T] he environment of care; [~~(ii)~~ 2. ~~c~~C] linical assessment or reassessment processes; [~~(iii)~~ 3. ~~s~~S] taff competence and adequacy of staffing; [~~(iv)~~ 4. ~~u~~U] se of high risk procedures, including seclusion and restraint; and [~~(v)~~ 5. ~~a~~A] review of serious incidents. This process shall incorporate uniform risk triggers and thresholds as defined by the department. [D. ~~This Process~~ The systemic risk assessment review process] shall incorporate uniform risk triggers and thresholds as defined by the department. ~~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 improvement shall be documented and implemented by the provider. ~~D.~~ [~~E.~~ F.]The provider shall document serious	components of a systemic risk assessment review process, including uniform risk triggers and thresholds, to be further defined by the department.

		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	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.	
530		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: 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	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: 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	• 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

		individuals receiving services, employees, contractors, students, volunteers, visitors, equipment, and vital records; and restoring services. Emergency procedures shall address: 9. Schedule for testing the implementation of the plan and conducting emergency preparedness drills. N/A N/A	individuals receiving services, employees, contractors, students, volunteers, visitors, equipment, and vital records; and restoring services. Emergency procedures shall address: [e. Evacuation procedures, including for individuals who need evacuation assistance;] 9. Schedule for testing the implementation of the plan and conducting emergency preparedness drills. [a. Fire and evacuation drills shall be conducted at least monthly.] [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.] [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. 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: 1. Smoke detectors on each level of multi-level buildings, including the	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. • Specifies minimum fire safety precautions of providers, including smoke alarm and fire extinguisher requirements.

			basement; 2. Smoke detectors in each bedroom in locations with bedrooms; 3. An additional smoke detector in an area adjacent to any bedroom in localities with bedrooms; 4. Any additional smoke detectors necessary to comply with all applicable federal and state laws and regulations and local ordinances. K. Smoke detectors shall be tested monthly for proper operation. L. All provider locations shall maintain a floor plan identifying locations of: 1. Exits; 2. Primary and secondary evacuation routes; 3. Accessible egress routes; 4. Portable fire extinguishers; and 5. Flashlights M. This section does not apply to home and noncenter-based services.]	
590		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.	F. [~~Direct care staff who provide~~ 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	• This non-substantive language change increases consistency in language use throughout regulations and aligns regulatory language with definitions in the Code of Virginia.

			months of employment.	
620		The provider shall 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. The program shall utilize standard quality improvement tools, including root cause analysis, and 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	[A.] The provider shall 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. [B.] The [quality improvement] program shall utilize standard quality improvement tools, including root cause analysis, and shall include a quality improvement plan [. that] [C. The quality improvement plan shall:] [~~(i)~~ 1. ~~Is~~ Be] reviewed and updated at least annually; [2. ~~d~~D] efine [~~s~~] measurable goals and objectives; [3. ~~i~~I] nclude [~~s~~] and report [~~s~~] on statewide performance measures, if applicable, as required by DBHDS; [4. ~~m~~M] onitor [~~s~~] implementation and effectiveness of approved corrective action plans pursuant to 12VAC35-105-170; and [5. ~~i~~I] nclude [~~s~~] ongoing monitoring and evaluation of progress toward meeting established goals and objectives. [D.] The provider's policies and procedures shall include the criteria	• 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 recurrence of the regulatory violation.

		direction of service planning shall be part of the provider's quality assurance system improvement plan. The provider shall implement improvements, when indicated.	the provider will use to [:] 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 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.] [E.] Input from individuals receiving services and their authorized representatives, if applicable, about services used and satisfaction level of participation in the direction of service planning shall be part of the provider's quality improvement plan. The provider shall implement improvements, when indicated.	
660		D. The initial ISP and the comprehensive ISP shall be developed based on the respective assessment with the participation and informed choice of	D. The initial ISP and the comprehensive ISP shall be developed based on the respective assessment with the participation and informed choice of the	• This section has been restructured to aid in readability and comprehension • Changes to language have been made to clarify

		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 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.	individual receiving services. [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 [:] [a. ~~t~~T] he proposed services to be delivered [~~,~~ ;] [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.~~] [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. 3. Whenever there is a change to an	expectations

			individual's ISP, it shall be clearly documented within the ISP, or within documentation attached to the ISP that: a. The individual participate in the development of or revision to the ISP; b. The proposed and alternative services and their respective risks and benefits were 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.]	
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] .	• 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		"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 Title 37.2 of the Code of Virginia.
		N/A	• Addition of a general definition for "developmental services" from Title 37.2 of the Code of Virginia.
		N/A	• Addition of a general definition for "direct care position."

		N/A	• Addition of a general definition for “informed choice.” "Informed choice" means a decision made after considering options based on adequate and accurate information and knowledge. These options are developed through collaboration with the individual and his authorized representative, as applicable, and the provider with the intent of empowering the individual and his authorized representative to make decisions that will lead to positive service outcomes.
		N/A	• Addition of a general definition for “informed consent” which matches the definition of informed consent from the Human Rights Regulations [12VAC35-115-30]. "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.
		"Neglect" means the failure by an individual, 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 receiving care or treatment for mental illness, mental retardation (intellectual disability), or substance abuse (substance use disorders).	• Change language in definition of “neglect” to conform to § 37.2-100 of the Code of Virginia by replacing “mental retardation (intellectual disabilities)” with “developmental disabilities“. "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~~ an individual receiving care or treatment for mental illness, ~~mental retardation (intellectual disability)~~ developmental disabilities, or substance abuse ~~(substance use disorders)~~.
		"Qualified Mental Retardation Professional (QMRP)" means a person who possesses at least … N/A	• 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. "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 12VAC35-105-520 • 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”. "Serious incident" means any event or circumstance that causes or could cause harm to the health, safety, or well-being of an individual. The term serious incident includes death and serious injury. "Level I serious incident" means a serious incident that occurs or originates during the provision of a service or on the premises of the provider and does not meet the definition of a Level II or Level III serious incident. “Level I serious incidents” do not result in significant harm to individuals, but may include events that result in minor injuries that do not require medical attention, or events that have the potential to cause serious injury, even when no injury occurs. "Level II serious incident" means a serious incident that occurs or originates during the provision of a service or on the premises of

		N/A	the provider that results in a significant harm or threat to the health and safety of an individual that does not meet the definition of a Level III serious incident. "Level II serious incident" includes a significant harm or threat to the health or safety of others caused by an individual. "Level II serious incidents" include: 1. A serious injury; 2. An individual who is or was missing; 3. An emergency room visit; 4. An unplanned psychiatric or unplanned medical hospital admission of an individual receiving services other than licensed emergency services, except that a psychiatric admission in accordance with the individual's Wellness Recovery Action Plan (WRAP) shall not constitute an unplanned admission for the purposes of this Chapter; 5. Choking incidents that require direct physical intervention by another person; 6. Ingestion of any hazardous material; or 7. A diagnosis of: a. A decubitus ulcer or an increase in severity of level of previously diagnosed decubitus ulcer; b. A bowel obstruction; or c. Aspiration pneumonia. "Level III serious incident" means a serious incident whether or not the incident occurs while in the provision of a service or on the provider's premises and results in: 1) Any death of an individual; 2) A sexual assault of an individual; or 3) A suicide attempt by an individual admitted for services, other than licensed emergency services, that results in a hospital admission. • Addition of a definition for "suicide attempt" "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. • 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 Title 37.2 of the Code of Virginia and the Centers for Medicare and Medicaid Services (CMS).
50		D. A license shall not be issued or renewed unless the provider is affiliated with a local human rights committee.	• Amend language to align 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 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 ~~and upon demonstration by the provider requesting~~. 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.
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	• 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); along with minor language changes. 1. ~~These regulations~~ This chapter; 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;

		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.	b. The Americans with Disabilities Act and the Virginians with Disabilities Act; c. 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~~] ; d. Occupational Safety and Health Administration regulations; ~~d.~~ e. Virginia Department of Health regulations; ~~e. Laws and regulations of the~~ f. Virginia Department of Health Professions regulations; ~~f.~~ g. Virginia Department of Medical Assistance Services regulations; ~~g.~~ h. Uniform Statewide Building Code; and ~~h.~~ i. Uniform Statewide Fire Prevention Code. 4. Section 37.2-400 of the Code of Virginia and related human rights regulations adopted by the state board; and 5. The provider's own policies. All required policies shall be in writing.
155			• Replace “mental retardation (intellectual disability)” with the term “developmental disability” in accordance with Title 37.2 of the Code of Virginia.
160			• Amend to require the provider to review all Level 1 serious incidents, at least once per quarter. This requirement enhances the requirements of providers for establishing effective risk management and quality improvement processes as required by the Settlement Agreement. • 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 additional flexibility and ease burden on providers. • 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.
		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: 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	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 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 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~~. Reported information shall include

		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. Extensions may be granted by the department when requested prior to the due date, but extensions shall not exceed an additional 10 business days.	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 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 serious incidents and any Level III serious incidents that occur during the provision of 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)~~ b. ~~a~~ A] 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 [~~(iii)~~ c. ~~i~~ I] dentified 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,

		G. Applicants and providers shall not submit any misleading or false information to the department. 12VAC35-105.	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: 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 serviced, 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; 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; 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 serviced, 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 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.] [~~D.~~ F.] The provider shall ~~submit, or~~ make available and, when requested, submit reports and information that the department requires to establish compliance with these regulations and applicable statutes. [~~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. [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 information related to serious incidents.]
170		D. The provider shall submit a corrective action plan to the department within 15 business days of the issuance of the licensing report. Extensions 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. 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	• Amend to provide additional clarity of the next steps to follow if the department does not approve a provider's revised plan. 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. C. The corrective action plan shall include a: 1. ~~Description~~ Detailed description of the corrective actions to be taken that will minimize the possibility that the violation will occur again and correct any systemic deficiencies; 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. D. The provider shall submit a corrective action plan to the department within 15 business days of the issuance of the licensing report. ~~Extensions~~ One extension 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. 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

		days to submit a revised corrective action plan after receiving a notice that the plan submitted has not been approved by the department. 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. 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.	revised corrective action plan is [~~still unacceptable~~ not approved] , the provider shall follow the dispute resolution process identified in this section. F. When the provider disagrees with a citation of a violation or the disapproval of [~~the~~ a] revised corrective action [plan~~s~~] , 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. G. The provider shall 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. 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: 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 2. Submit a revised corrective action plan to the department for approval.]
320		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	• Language restored during final action to language as it was prior to the proposed amendments 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

		residential home services.	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 CMS.
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 for contractors, students, and	• 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. 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~~ a 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

		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.	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 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, [if applicable,] 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~~.~~; and 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 this chapter..

450		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.	• 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.
500		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.	• Language change only to ensure consistent use of language throughout regulations and better align regulatory language with regulatory and statutory definitions. 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.

520			• 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.
		A. The provider shall designate a person responsible for risk management.	A. The provider shall designate a person responsible for 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].
		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.	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.
		N/A	C. The provider shall conduct systemic risk assessment reviews at least annually to identify and respond to practices, situations, and policies that could result in the risk of harm to individuals receiving services. The risk assessment review shall address [at least the following:] [~~(i)~~ 1. ~~t~~T] he environment of care; [~~(ii)~~ 2. ~~c~~C] linical assessment or reassessment processes; [(iii) 3. ~~s~~S] taff competence and adequacy of staffing; [(iv) 4. ~~u~~U] se of high risk procedures, including seclusion and restraint; and [(v) 5. ~~a~~A] review of serious incidents. This process shall incorporate uniform risk triggers and thresholds as defined by the department.
		N/A	[D. ~~This Process~~ The systemic risk assessment review process] shall incorporate uniform risk triggers and thresholds as defined by the department.
		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	~~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

		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.	improvement shall be documented and implemented by the provider. ~~D.~~ [~~E.~~ F.]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.
530		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: 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: N/A N/A	• Added language to ensure minimal fire safety precaution 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: 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: [e. Evacuation procedures, including for individuals who need evacuation assistance;] 9. Schedule for testing the implementation of the plan and conducting emergency preparedness drills. [a. Fire and evacuation drills shall be conducted at least monthly.] [B. The provider shall evaluate each individual and, based on that evaluation,

		N/A	shall provide appropriate environmental supports and adequate staff to safely evacuate all individuals during an emergency.] [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. 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: 1. Smoke detectors on each level of multi-level buildings, including the basement; 2. Smoke detectors in each bedroom in locations with bedrooms; 3. An additional smoke detector in an area adjacent to any bedroom in localities with bedrooms; 4. Any additional smoke detectors necessary to comply with all applicable federal and state laws and regulations and local ordinances. K. Smoke detectors shall be tested monthly for proper operation. L. All provider locations shall maintain a floor plan identifying locations of: 1. Exits; 2. Primary and secondary evacuation routes; 3. Accessible egress routes; 4. Portable fire extinguishers; and 5. Flashlights M. This section does not apply to home and noncenter-based services.]
580			• Amend language to align Title 37.2 of the Code of Virginia and newly adopted person-centered language.
590			• 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			• 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

		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.	include. [A.] The provider shall 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. [B.] The [quality improvement] program shall utilize standard quality improvement tools, including root cause analysis, and shall include a quality improvement plan [. ~~that~~] [C. The quality improvement plan shall:] [~~(i)~~ 1. ~~Is~~ Be] reviewed and updated at least annually; [2. ~~d~~D] efine [~~s~~] measurable goals and objectives; [3. ~~i~~I] nclude [~~s~~] and report [~~s~~] on statewide performance measures, if applicable, as required by DBHDS; [4. ~~m~~ M] onitor [~~s~~] implementation and effectiveness of approved corrective action plans pursuant to 12VAC35-105-170; and [5. ~~i~~I] nclude [~~s~~] 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 [:] 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 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.] [E.] Input from individuals receiving services and their authorized representatives, if applicable, about services used and satisfaction level of participation in the direction of service planning shall be part of the provider's quality improvement plan. The provider shall implement improvements,

			when indicated.
650			• Amend language to align Title 37.2 of the Code of Virginia.
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 providers of mental retardation (intellectual disability) and developmental disabilities services.	• 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. 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. 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. [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 [:] [a. ŧT] he proposed services to be delivered [;] [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.~~] [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. 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: a. The individual participate in the development of or revision to the ISP; b. The proposed and alternative services and their respective risks and benefits were 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.]
665		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: 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; 3. The role of the individual and others in implementing the service plan;	• 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. 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: 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; 3. The role of the individual and others in implementing the service plan; 4. A communication plan for individuals with communication barriers, including language

		4. A communication plan for individuals with communication barriers, including language barriers; 5. A behavioral support or treatment plan, if applicable; 6. A safety plan that addresses identified risks to the individual or to others, including a fall risk plan; 7. A crisis or relapse plan, if applicable; 8. Target dates for accomplishment of goals and objectives; 9. Identification of employees or contractors responsible for coordination and integration of services, including employees of other agencies; and 10. Recovery plans, if applicable. 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. 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.	barriers; 5. A behavioral support or treatment plan, if applicable; 6. A safety plan that addresses identified risks to the individual or to others, including a fall risk plan; 7. A crisis or relapse plan, if applicable; 8. Target dates for accomplishment of goals and objectives; 9. Identification of employees or contractors responsible for coordination and integration of services, including employees of other agencies; ~~and~~ 10. Recovery plans, if applicable; and 11. Services the individual elects to self direct, if applicable. 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. 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.
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

		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.	Medicaid and Children's Health Insurance Program (CHIP) Managed Care Final Rule. 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	• Amend to align with the regulatory reporting requirements in the Human Rights Regulations. E. Injuries resulting from or occurring during

		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.	the implementation of ~~behavior interventions~~ seclusion or restraint shall be ~~recorded in the individual's services record and~~ reported to the ~~assigned human rights advocate and the employee or contractor responsible for the overall coordination of services~~ department as provided in 12VAC35-115-230 C.
830		B. Devices used for mechanical restraint shall be designed specifically for behavior management of human beings in clinical or therapeutic programs.	• Amend to include “emergency” before “behavior management” for clarification. B. Devices used for mechanical restraint shall be designed specifically for emergency behavior management of human beings in clinical or therapeutic programs.
1140			• Amend language to align Title 37.2 of the Code of Virginia.
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. 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.
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.

		N/A	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 Title 37.2 of the Code of Virginia.

Documents	DRAFT Final Stage Amendments (Action 5040)
VAC	DBHDS Rules and Regulations For Licensing Providers by the Department of Behavioral Health and Developmental Services [12VAC35-105], and 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)
Window:	Opened 3/26/2020/ - 4/1/2020

DBHDS response to comments are in yellow highlight.

Section	Comment	Changes to proposed draft	Comments 3/30/20
12 VAC 35-115-20 Definitions			
• **Level II Serious Incident**	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. 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	Changes made. 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. 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	Expand to WRAP and Crisis plans: If psychiatric admission is included in an individual's crisis plan, then would an admission be considered planned as it would be if the individual has a WRAP plan? If the individual has a WRAP or Crisis plan that includes psychiatric admission and ends up being TDO'd, would that also be considered a planned admission? Original comment: The change to all emergency room visits will increase the amount of incident reports submitted to CHRIS, increase the amount of staff time in reviewing the incident for the root cause analysis. This contradicts the goal stated in the economic impact to allow for more targeted reporting and freeing up valuable staff time.

Section	Comment	Changes to proposed draft	Comments 3/30/20
	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."	to evidence an injury or risk of injury of sufficient severity to constitute a Level II serious incident. 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.	**Response: At this point, the department does not recommend extending the exclusion of psychiatric admissions that are in accordance with an individual's WRAP plan from the definition of a level II serious incident to include psychiatric admissions that are in accordance with any crisis plan. Crisis plans can vary significantly in important ways, including in the processes by which they are produced, the degree of involvement of individuals in their development, and the frequency with which they are updated. A blanket exclusion of psychiatric admissions that are in accordance with a crisis plan, therefore, is inadvisable. However, we have reached out to our subject matter experts in the time since this comment was received to confirm they are agree.** **An admission that is in accordance with an individual's WRAP plan is not considered an unplanned psychiatric admission under the proposed amendments to the Emergency Regulations. The relevant question is whether the admission is in accordance with the individual's WRAP plan, and not whether the admission was voluntary or involuntary at the time of admission.**

Section	Comment	Changes to proposed draft	Comments 3/30/20
12VAC35-105-160. Reviews by the department; requests for information; required reporting.			
• **D.2. Incident reports – risk of harm**	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. 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.	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.	Agree this should be removed from the CHRIS report but adding it to the Root Cause Analysis will still require speculation by investigative staff. Requesting "Risk of Harm" to be removed from RCA. **Response: In the previous draft, providers were asked to include risk of harm when they reported within 24 hours of the incident. The department recognized that this could be burdensome given the short timeframe for reporting, as that meant a lack of time to analyze.** **The "risk of harm" in the current draft refers to risk identified during the root cause analysis process, and includes the qualifier "when applicable," or of recognition that not all risks of harm are predictable. Reducing risks of harm is one of the primary reasons**

Section	Comment	Changes to proposed draft	Comments 3/30/20
			for performing root cause analyses.
• **E. Root Cause Analyses**	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. Several commenters, however, requested that "during the provision of care" be defined or otherwise clarified. 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. 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."	Changes made. 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." 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. Guidance Provided in State Memo: 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	Original Comment It would be helpful to have a definition of "during provision of care" particularly as it relates to case management services. Does this mean when staff are with the person? What happens when the case manager is called and becomes involved or gives guidance is that considered provision of care? In residential services, if a serious incident occurs while the individual is with their family/guardian or at their day program is a root cause analysis not required? The agency is asking for flexibility in defining in their policy how teams are convened. Input for development of a plan for an individual may occur with the team via emails, telephone contact or video conference. Currently staff discuss cases in a variety of ways which does not always include meeting with all providers in one meeting location. **Response: Guidance has been provided on the meaning of "during the provision of services" and additional guidance and technical assistance will be provided. There is nothing in the regulation that defines how providers must convene a team**

Section	Comment	Changes to proposed draft	Comments 3/30/20
		causal factors should be conducted. At a minimum, the policy shall require for the provider to conduct a more detailed root cause analysis when: 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 serviced, 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; 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; Page 26 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 serviced, 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 d. A death	during the root cause analysis process.

Section	Comment	Changes to proposed draft	Comments 3/30/20
		occurs as a result of an acute medical event that was not expected in advance or based on a person's known medical condition.]	
12VAC35-105-650. Assessment policy			
• F. Comprehensive Assessment		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.'	There are questions regarding this requirement and Same Day Access Services. We have received feedback that two separate assessments are needed; the initial assessment and the comprehensive assessment. The initial assessment should be at admission to agency not at every new service that may be added. This needs clarification as it relates to the State's SDA initiatives. **This is outside the scope of this regulatory action, but will be reconsidered during the regulatory overhaul. Please see formal response to public comment:** ***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.'***
General comments			

Section	Comment	Changes to proposed draft	Comments 3/30/20
• Economic impact on regulated entities	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 he provision of regular, high-quality training across the Commonwealth on topics such as root cause analysis, risk management, data analysis, and investigation skills."	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. 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	The impact on entities stated in the NOIRA is not representative of the true impact providers are experiencing. Providers have needed to increase staff doing the work related to increased requirements. This work has not been absorbed without additional costs. There has not been sufficient staff to cover the increased follow-up and expected compliance time frames. Mandated time frames take precedent over other duties such as; 24 hour reporting, 10 day turn around on DD Mortality reviews, 30 day Root Cause Analysis, 10 day Human Rights investigations, CAP response, follow-up on CAPS and HR plans of corrections are examples of the what is required to be managed to avoid further corrective action plans. DBHDS has increased regulatory and guidance oversight throughout their departments. The regulatory impact providers experience from DBHDS is from several departments, such as the Office of Licensure, Office of Human Rights and disability specific program guidance, evidence based programs, and their oversight, expectations and requirements. All of the departments and DBHDS entities are transforming and increasing requirements and expectations that have an overall impact on providers. In addition, there has been an impact on staffing particularly within Case

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		than compliance with these regulations. 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.	Management Services . Increased responsibilities for Developmental Services Case Managers/Support Coordinators is straining the system as the additional work justifies smaller caseloads, while positions remain difficult to fill and there are increasing difficulties in retaining staff members. The reporting and monitoring requirements for our agency are significant and additional funding is needed to assist with Administrative and Quality Assurance work. 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. A coordinated study of the full impact of DBHDS requirements and the economic impact on providers is requested and needed. **Response: See response to comments related to economic impact in previous response to comments.** **DBHDS believes these new regulations will be cost neutral. The new regulations were previously put in place with an**

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			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. 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.

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			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.

MEETING PARTICIPATION INSTRUCTIONS

State Board of Behavioral Health and Developmental Services Emergency Meeting

9:30 a.m. Thursday, April 2, 2020

Time: The Emergency Meeting of the State Board will begin at 9:30 a.m. It is recommended that you connect to the meeting prior to the start time.

Meeting Location: Via Adobe Connect or Phone

THIS PAGE HAS INSTRUCTIONS TO LISTEN ONLY OR TO LISTEN AND OBSERVE THE MEETING.

INSTRUCTIONS:

Members of the State Board and DBHDS staff will have the ability to speak. All other have the ability to view the screen and listen, or listen only:

- **View and listen:**

If you want to view the meeting packet on screen and listen via the Adobe Connect meeting room, go to this site: http://dbhds.acms.com/ruthanne_walker/

You will be prompted there to connect by phone from within the online room. (IMPORTANT NOTE: You do not need the number below if you are using the link; simply go to that web address and follow the prompts.)

- **Listen by phone only:**

If you are only going to listen to the meeting (without accessing Adobe Connect), then use this phone number and passcode:

Conference #: 1-800 832-0736, passcode: 6344030

Please log in ahead of the 9:30 a.m. start time. Please mute all devices (computers or phones).