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DEPARTMENT OF
BEHAVIORAL HEALTH AND DEVELOPMENTAL SERVICES
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MEMORANDUM

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

Fr: Ruth Anne Walker, Director of Regulatory Affairs

Cc: William R. Frank, State Board Liaison

Date: February 13, 2019

Re: Meeting Packet for February 25, 2019

Please find enclosed for your review the Board packet for the regular meeting scheduled for Monday, February 25, 2019, in the DBHDS Central Office, 13th Floor Conference Room, 1220 Bank Street, Richmond, VA 23219.

There are two regulatory items, both to amend *12-VAC35-105 Rules and Regulations For Licensing Providers by the Department of Behavioral Health and Developmental Services* ("Licensing Regulations") through the standard process:

- Regulatory Action 5040, Compliance with Virginia's Settlement Agreement with US DOJ: Proposed stage (which must occur before March 3rd). Amendments are recommended to respond to stakeholder comments.
- Regulatory Action 4928, Adds OTs, OTAs, and editing definitions of QMHP, etc.: Final stage (which must occur after February 23rd). No additional amendments are recommended.

In both cases, there is an emergency regulation in place and the requested actions are to move to the next stage of the process. Details on the requests for action are included with each item. If you have any questions on the regulatory items between now and the meeting, please let me know. Will is available for any logistical questions or specific requests.

The next meeting following this one will be on April 9-10 in Fairfax.

Thank you.

I. Draft February Agenda and Draft Minutes – December Regular Meeting

DRAFT AGENDA

REGULAR MEETING
Monday, February 25, 2019
12:00 p.m. – 2:00 p.m.
DBHDS Central State Office, 13th Floor Board Room, Jefferson Building
1220 Bank Street, Richmond, VA

1.	12:00	**Call to Order**	Paula Mitchell *Chair*	
2.	12:05	**Approval of February 25, 2019 Agenda** ➢ *Action Required*		
3.	12:10	**Approval of Draft Minutes** **Regular Meeting, December 5, 2018** ➢ *Action Required*		**p.2**
4.	12:15	**Public Comment** (*3 minute limit per speaker*)		
5.		**Regulatory Actions**: *12-VAC35-105 Rules and Regulations For Licensing Providers by the Department of Behavioral Health and Developmental Services* A. Action 5040, Compliance with Virginia's Settlement Agreement with US DOJ: Proposed stage (which must occur before March 3rd). ➢ *Action Required* B. Action 4928, Adds OTs, OTAs, and editing definitions of QMHP, etc.: Final stage (which must occur after February 23rd). ➢ *Action Required*	Ruth Anne Walker *Director of Regulatory Affairs* Dev Nair, *Assistant Commissioner, Division of Compliance, Legislative, and Regulatory Affairs* Jae Benz, *Director, Office of Licensing* Emily Bowles *Legal Coordinator, Office of Licensing*	**p.5-49 and attach.** **p.50**
6.		**Next Meeting Information** • Public hearing to be held Item 5.A. above, once approved.	Paula Mitchell *Chair*	
7.		**Adjournment**		

DRAFT MINUTES – December Meeting

STATE BOARD OF BEHAVIORAL HEALTH AND DEVELOPMENTAL SERVICES
DRAFT MEETING MINUTES
December 5, 2018
Virginia Department of Aging and Rehabilitation Services
1610 Forrest Avenue, Suite 100, Richmond VA

Wednesday December 5, 2018	**Regular Meeting**
Members Present	Paula N. Mitchell **Chair**, Elizabeth Hilscher **Vice-Chair**, Sandra Price-Stroble, Jack Bruggeman, Moira Mazzi, Becky Graser, Varun Choudhary, and Calendria Jones
Members Absent	Djuna Osborne
Staff Present	Will Frank, Legislative Affairs Director Ruth Anne Walker, Director of Regulatory Affairs Nathan Miles, Director of Budget Development and Financial Analysis Josie Mace, Financial and Policy Analyst By phone: Cheryl DeHaven, Recovery Services Coordinator, Office of Recovery Services; Emily Bowles, Legal Coordinator, Office of Licensing
Call to Order	At 12:50 p.m. Chair Paula Mitchell called the meeting to order.
Approval of Draft Agenda	The Board unanimously adopted the December 5, meeting agenda.
Approval of Draft Minutes- October 3 meeting	The Board unanimously approved the minutes.
Introductions	Chair Paula Mitchell called for the introductions of those present and welcomed new member Dr. Varun Choudhary.
Public Comment	There was no public comment.
Commissioner's	Commissioner Hughes Melton presented his report.

Report

Regulatory Actions:	Ruth Anne Walker, DBHDS Director of Regulatory Affairs, provided an update on DBHDS regulatory actions, including review of the results of the November 19, 2018, public hearing on the peer recovery specialist regulation. The Board unanimously approved draft minutes as final for the special called meeting on October 15, 2018. At Ms. Walker's request, the Board set a date for an additional regular meeting on February 25, 2019, for two specific time-sensitive actions: consider draft proposed- stage language on the DOJ response regulation and initiation of the proposed stage; and, consider moving the QMHP regulation to the final stage.
DBHDS Budget Submissions	Nathan Miles, DBHDS Director of Budget Development and Financial Analysis and Josie Mace, DBHDS Financial and Policy Analyst reviewed the DBHDS submissions to be included into the Governor's introduced budget.
Policy Development and Evaluation Committee Report	Committee Chair Beth Hilscher reported on the work of reviewing board policies.
Miscellaneous	
Board Liaison Reports	The Board recommended this item be moved to the next meeting.
State Board Annual Report	Will Frank reviewed the draft State Board Annual Report and provided it to members for their review.
Next Meeting Information	The next meeting will be held in April 2019.
Adjournment	Having no other business, Paula Mitchell adjourned the meeting at 3:30 p.m.

II. Compliance with Virginia's Settlement Agreement with US DOJ: Proposed stage (which must occur before March 3rd).

Background: When the Settlement Agreement was signed, it was understood that the licensing regulations would need to be changed. First, the definition of 'developmental disability' was expanded to include 'intellectual disability' in the Code of Virginia, which occurred in the 2017 Session of the General Assembly (HB1775). Also, the changes to Medicaid Waivers took effect in the past year.

The Independent Reviewer has stated that without the draft amendments, the Commonwealth will continue to be unable to come into compliance with the quality and risk management provisions of the Settlement Agreement. Also, during a status hearing on December 19, 2017, Judge Gibney asked when the proposed amendments would be before the Board and expressed a desire for quick completion. Judge Gibney's request came in light of the Settlement Agreement Independent Reviewer's statement in the 11th Report to the Court:

> *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 licensing regulations continue, however, to restrict the Commonwealth from requiring submission of information or attendance at trainings related to developing the required quality and risk management processes. 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 Board adopted the emergency regulation on April 11, 2018. It was signed by the Governor on July 5, 2018, with a delayed effective date of September 1, 2018. The emergency regulation established requirements needed immediately to address the concerns of health and safety of individuals receiving services from providers of adult services licensed by the Department of Behavioral Health and Developmental Services. The purpose of this regulation is to comply with requirements of the U.S. Department of Justice's Settlement Agreement with Virginia. The Settlement Agreement includes provisions of quality and risk management.

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

Since the Settlement Agreement was signed, the definition of "developmental disability" was expanded to include "intellectual disability" in the Code of Virginia (Chapter 458 of the 2017 Acts of Assembly), and changes have been made to Medicaid waivers in the past year. Both of these developments impact the amendments in this action.

Purpose: The proposed amendments to the regulations are intended to address issues raised in comments received during the NOIRA public comment period held from August 8 – September 5, 2018. Staff reviewed the 11 comments received (see attached chart of comments with agency responses at the end of this package), and revised the language.

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

1) 12VAC35-105-20. Definitions.

a. Level II serious incident

i. An individual who is or was missing;

- Language was added to clarify that providers should report if an individual is or was missing. Based on the effective Emergency Regulations, which state "an individual who is missing" providers were not sure whether they should report that an individual went missing if the individual was found before the provider had the opportunity to report the incident. The proposed draft now states that a Level II serious incident includes an individual who is or was missing.

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

- The department received comments during both the NOIRA public comment period as well as the public comment period for

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

iii. An unplanned psychiatric or unplanned medical hospital admission of an individual receiving services other than licensed emergency services;

- An exemption for reporting of unplanned psychiatric or unplanned medical hospital admissions by licensed emergency services was added in order to better align with guidance document language and to reduce unnecessary reporting burdens on emergency service providers.

b. Level III serious incident

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

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

ii. ~~4~~ 3. A suicide attempt by an individual admitted for services, other than licensed emergency services, that results in a hospital admission.

- An exemption for reporting of suicide attempts by licensed emergency services was added in order to better align with guidance document language and to reduce unnecessary reporting burdens on emergency service providers.

c. Suicide attempt –

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

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

a. C. The provider shall collect, maintain, and review at least quarterly all ~~Level I~~ serious incidents, including Level I serious incidents, as part of the quality improvement program in accordance with 12VAC35-105-620 to include an analysis of trends, potential systemic issues or causes, indicated remediation, and documentation of steps taken to mitigate the potential for future incidents.

- Amended in the proposed draft of the regulations to clarify that provider shall collect, maintain, and review at least quarterly all serious incidents, including Level I serious incidents.

b. E. A root cause analysis shall be conducted by the provider within 30 days of discovery of Level II serious incidents and any Level III serious incidents that occur during the provision of a service or on the provider's premises. The root cause analysis shall include at least the following information: (i) a detailed description of what happened; (ii) an analysis of why it happened, including identification of all identifiable underlying causes of the incident that were under the control of the provider; and (iii) identified solutions to mitigate its reoccurrence~~.~~ when applicable. A more detailed root cause analysis, including convening a team, collecting and analyzing data, mapping processes, and charting causal factors should be considered based upon the circumstances of the incident.

- This requirement was amended in the proposed draft of the regulations in response to public comments stating the requirement to conduct a root cause analysis on Level III serious incidents that occur outside of the provision of the provider's services and off the provider's premises is unduly burdensome to the provider. In addition, providers generally will have limited knowledge of the incident as it occurred outside of their services and therefore conducting a meaningful RCA may be difficult. The language in the proposed draft states that providers shall only conduct a root cause analysis within 30 days of discovery of Level II serious incidents and any Level III serious incidents that occur during the provision of a service or on the provider's premises.

3) 12VAC35-105-170. Corrective action plan.

a. G. The provider shall ~~monitor implementation of~~ implement and monitor the approved corrective action ~~and include a plan for monitoring~~ plan. The provider shall ~~incorporate corrective actions in~~ monitor implementation and effectiveness of approved corrective actions as part of its quality ~~assurance activities~~ improvement program ~~specified in~~ required by 12VAC30-105-620.

- This language was amended in the proposed draft of the regulatory action to better reflect the original intent of the Emergency Regulation related to monitoring the implementation and effectiveness of approved corrective actions.

4) 12VAC35-105-620. Monitoring and evaluating service quality.

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

- This language was amended in the proposed draft to clarify that the provider must have written policies and procedures for a quality improvement program.

Action Requested: Adopt the amendments and initiate the proposed stage for permanent adoption of the following regulation.
(http://townhall.virginia.gov/um/chartstandardstate.pdf)

VAC Citation	Title	Date of Last Activity
12 VAC 35-105	Rules and Regulations For Licensing Providers by the Department of Behavioral Health and Developmental Services	09/01/2018 (emergency adopted; expires 02/29/2020)

CHAPTER 105
RULES AND REGULATIONS FOR LICENSING PROVIDERS BY THE DEPARTMENT OF BEHAVIORAL HEALTH AND DEVELOPMENTAL SERVICES

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;

7. Use of more restrictive or intensive services or denial of services to punish ~~the person~~ an individual or that is not consistent with 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," 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 (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 ~~these regulations~~ this chapter or a provider's policies and procedures related to ~~these regulations~~ 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 his 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" 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.~~

"Developmental disability" means a severe, chronic disability of an individual that (i) is attributable to a mental or physical impairment, or a combination of mental and physical impairments, other than a sole diagnosis of mental illness; (ii) is manifested before the individual reaches 22 years of age; (iii) is likely to continue indefinitely; (iv) results in substantial functional limitations in three or more of the following areas of major life activity: self-care, receptive and expressive language, learning, mobility, self-direction, capacity for independent living, or economic self-sufficiency; and (v) reflects the individual's need for a combination and sequence of special interdisciplinary or generic

services, individualized supports, or other forms of assistance that are of lifelong or extended duration and are individually planned and coordinated. An individual from birth to age nine years, inclusive, who has a substantial developmental delay or specific congenital or acquired condition may be considered to have a developmental disability without meeting three or more of the criteria described in clauses (i) through (v) ~~of this definition~~ if the individual, without services and supports, has a high probability of meeting those criteria later in life.

"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,~~ current direct recipient of public or private mental health, developmental, or substance abuse treatment, rehabilitation, or habilitation services and includes the terms "consumer," ~~client~~ "patient," "resident," ~~student, individual,~~ "recipient," ~~family member, relative,~~ or ~~other term~~ "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~~ An individual's degree of independence in performing these activities is part of determining the appropriate level of care and services.

"Intellectual disability" means a disability, originating before the age of 18 years, 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 (ICT)~~ community treatment service" or "ICT service" 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 ~~(LMHP)~~" 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 (as of 2/21/19).

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

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

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 ~~(QDDP)~~" or "QDDP" means a person who possesses at least one year of documented experience working directly with individuals who have a developmental disability and one of the following credentials: (i) a doctor of medicine or osteopathy licensed in Virginia, (ii) a registered nurse licensed in Virginia, or (iii) 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. It 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-Adult ~~(QMHP-A)~~" or "QMHP-A" means a person in the human services field who is trained and experienced in providing psychiatric or mental health services to ~~individuals~~ adults who have a mental illness; including (i) a doctor of medicine or osteopathy licensed in Virginia; (ii) a doctor of medicine or osteopathy, specializing in psychiatry and licensed in Virginia; (iii) an individual with a master's degree in psychology from an accredited college or university with at least one year of clinical experience; (iv) a social worker: an individual with at least a bachelor's degree in human services or related field (social work, psychology, psychiatric rehabilitation, sociology, counseling, vocational rehabilitation, human services counseling, or other degree deemed equivalent to those described) from an accredited college and with at least one year of clinical experience providing direct services to individuals with a diagnosis of mental illness; (v) a person with at least a bachelor's degree from an accredited college in an unrelated field that includes at least 15 semester credits (or equivalent) in a human services field and who has at least three years of clinical experience; (vi) a Certified Psychiatric Rehabilitation Provider (CPRP) registered with the United States Psychiatric Rehabilitation Association (USPRA); (vii) a registered nurse licensed in Virginia with at least one year of clinical experience; or (viii) any other licensed mental health professional.

"Qualified Mental Health Professional-Child ~~(QMHP-C)~~" or "QMHP-C" means a person in the human services field who is trained and experienced in providing psychiatric or mental health services to children who have a mental illness. To qualify as a QMHP-C, the individual must have the designated clinical experience and must either (i) be a doctor of medicine or osteopathy licensed in Virginia; (ii) have a master's degree in psychology from an accredited college or university with at least one year of clinical experience with children and adolescents; (iii) have a social work bachelor's or master's degree from an accredited college or university with at least one year of documented clinical experience with children or adolescents; (iv) be a registered nurse with at least one year of clinical experience with children and adolescents; (v) have at least a bachelor's degree in a human services field or in special education from an accredited college with at least one year of clinical experience ~~with~~ providing direct services to children and adolescents with a diagnosis of mental illness, or (vi) be a licensed mental health professional.

"Qualified Mental Health Professional-Eligible ~~(QMHP-E)~~" or "QMHP-E" means a person who has: (i) at least a bachelor's degree in a human service field or special education from an accredited college without one year of clinical experience or (ii) at least a bachelor's degree in a nonrelated field and is enrolled in a master's or doctoral clinical program, taking the equivalent of at least three credit hours per semester and is employed by a provider that has a triennial license issued by the department and has a department and DMAS-approved supervision training program.

~~"Qualified Mental Retardation Professional (QMRP)" means a person who possesses at least one year of documented experience working directly with individuals who have mental retardation (intellectual disability) or other developmental disabilities and one of the following credentials: (i) a doctor of medicine or osteopathy licensed in Virginia, (ii) a registered nurse licensed in Virginia, or (iii) completion of at least a bachelor's degree in a human services field, including, but not limited to sociology, social work, special education, rehabilitation counseling, or psychology.~~

"Qualified Paraprofessional in Mental Health ~~(QPPMH)~~" or "QPPMH" means a person who must, at a minimum, meet 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; or (iii) has a minimum of 90 hours classroom training and 12 weeks of experience under the direct personal supervision of a QMHP-Adult providing services to individuals with mental illness and at least one year of experience (including the 12 weeks of supervised experience).

"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 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; ~~or urgent care facility visit when not used in lieu of a primary care physician visit;~~

4. An unplanned psychiatric or unplanned medical hospital admission 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.

"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 serious injury of an individual that results in or likely will result in permanent physical or psychological impairment; or~~

~~4~~ 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" ~~or "services"~~ 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~~ Medicaid ~~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 non-fatal, self-directed, potentially injurious behavior with an intent to die as a result of the behavior regardless of whether it results in injury.

"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 and under certain circumstances up to 21 with serious emotional disturbances, substance use, or co-occurring disorders or (ii) children from birth through age seven 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~~ community ~~Treatment~~ 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, ~~Human Rights Regulations (12VAC35-115) or~~ including this chapter and 12VAC35-115, has violations of human rights or licensing regulations that pose a threat to the health or safety of individuals ~~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;

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

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 in writing to the department's assigned licensing specialist~~ Level II and Level III serious incidents shall be reported 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 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. The root cause analysis shall include at least the following information: (i) a detailed description of what happened; (ii) an analysis of why it happened, including identification of all identifiable underlying causes of the incident that were under the control of the provider; and (iii) identified solutions to mitigate its reoccurrence~~.~~ when applicable. A more detailed root cause analysis, including convening a team, collecting and analyzing data, mapping processes, and charting causal factors should be considered based upon the circumstances of the incident.

~~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.

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.

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, 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 revised corrective action plans, 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~~ implement and monitor the approved corrective action ~~and include a plan for monitoring~~ plan. The provider shall ~~incorporate corrective actions in~~ monitor implementation and effectiveness of approved corrective actions as part of its quality ~~assurance activities~~ improvement program ~~specified in~~ required by 12VAC30-105-620.

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). ~~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.

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 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, 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

12VAC35-105-520. Risk management.

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 least annually to identify and respond to practices, situations, and policies that could result in the risk of

harm to individuals receiving services. The risk assessment review shall address (i) the environment of care; (ii) clinical assessment or reassessment processes; (iii) staff competence and adequacy of staffing; (iv) use of high risk procedures, including seclusion and restraint; and (v) a review of serious incidents. This process shall incorporate uniform risk triggers and thresholds as defined by the department.

~~C.~~ D. The provider shall conduct and document that a safety inspection has been performed at least annually of each service location owned, rented, or leased by the provider. Recommendations for safety improvement shall be documented and implemented by the provider.

~~D.~~ E. The provider shall document serious injuries to employees, contractors, students, volunteers, and visitors that occur during the provision of a service or on the provider's property. Documentation shall be kept on file for three years. The provider shall evaluate serious injuries at least annually. Recommendations for improvement shall be documented and implemented by the provider.

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. The 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. An individual who is a QMHP-E may not provide this type of supervision.

7. Supervision of ~~mental retardation (intellectual disability)~~ developmental 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 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.

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

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 or short-term services shall meet the requirements for the initial assessment at a minimum. Non-intensive 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. To ensure the individual's participation and informed choice, the provider shall explain to the individual or his authorized representative, as applicable, in a reasonable and comprehensible manner, the proposed services to be delivered, alternative services that might be advantageous for the individual, and accompanying risks or benefits. The provider shall clearly document that this information was explained to the individual or his authorized representative and the reasons the individual or his authorized representative chose the option included in the ISP.

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.

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- 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 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.

III. Add OTs, OTAs, and editing definitions of QMHP, QMRP, Paraprofessionals in the Licensing Regulations

Background: This regulatory action was initiated in compliance with Chapters 136 and 418, and Chapter 136, of the 2017 Acts of Assembly. Certain definitions are deferred, in accordance with Chapter 418, to the Department of Health Professions' Board of Counseling (18VAC115-80). An emergency regulation became effective on December 18, 2017, and expires June 17, 2019.

Purpose: This final stage regulatory action is brought as the next step of the standard process to comply with Chapters 136 and 418 regarding who shall be included in the definitions of qualified mental health professionals, qualified mental retardation professionals, and qualified paraprofessionals in mental health. Also, per Chapter 136, the language adds occupational therapists and occupational therapy assistants in certain definitions of the above named professional categories, and corresponding educational and clinical experience for occupational therapists and occupational therapy assistants must be established that are substantially equivalent to comparable professionals listed in the current licensing regulations.

No comments were received during the proposed stage (public hearing and comment forum). There are no recommendations for additional amendments.

Additional request: The emergency regulation expires on June 17, 2019. If the final stage is approved by the Governor's Office in time for publication in the *Virginia Register* for a 30-day comment period no later than April 24, 2019, then the action would become effective on May 23, 2019. There would be no need for an extension on the emergency regulation. However, it seems prudent to make the request now.

Action Requested: Initiate final stage on the regulation listed below and authorize staff to request an extension to the emergency regulation should it be needed.
(http://townhall.virginia.gov/UM/chartstandardstate.pdf)

VAC Citation	Title	Date of Last Activity
12 VAC 35-105	Rules and Regulations For Licensing Providers by the Department of Behavioral Health and Developmental Services	Emergency/NOIRA stage published 01/08/2018 (regulation effective 12/18/2017 and expires 06/17/18)

Next Steps:

- If approved, staff initiates the final stage and if needed, requests an extension to the emergency regulation in late March.

CHAPTER 105
RULES AND REGULATIONS FOR LICENSING PROVIDERS BY THE DEPARTMENT OF BEHAVIORAL HEALTH AND DEVELOPMENTAL SERVICES

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 receiving care or treatment for mental illness, mental retardation (intellectual disability), 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;

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

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

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

7. Use of more restrictive or intensive services or denial of services to punish the person or that is not consistent with 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.

Regulatory Item III. Add OTs, OTAs, and editing definitions of QMHP, QMRP, Paraprofessionals in the Licensing Regulations

"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 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" 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" means services that can include assistance to individuals and their family members in assessing needed services that are responsive to the person's individual 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 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.

Regulatory Item III. Add OTs, OTAs, and editing definitions of QMHP, QMRP, Paraprofessionals in the Licensing Regulations

"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 (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 these regulations or a provider's policies and procedures related to these regulations.

"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), or substance abuse (substance use disorders); 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 his 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 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" 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.

"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.

"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. When the term is used, 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.

"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.

"Intensive Community Treatment (ICT) service" 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). 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.

"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 ~~(LMHP)~~" 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 (as of 2/21/19).

"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)" 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).

"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).

"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 (PACT) service" means a self-contained interdisciplinary team of at least 10 full-time equivalent clinical staff, a program assistant, and a full- 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), or substance abuse (substance use disorders), (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 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 DBHDS or a provider licensed by DBHDS.

"Qualified Mental Health Professional-Adult ~~(QMHP-A)~~" or "QMHP-A" means a person ~~in the human services field who is trained and experienced in providing psychiatric or mental health services to individuals who have a mental illness; including (i) a doctor of medicine or osteopathy licensed in Virginia; (ii) a doctor of medicine or osteopathy, specializing in psychiatry and licensed in Virginia; (iii) an individual with a master's degree in psychology from an accredited college or university with at least one year of clinical experience; (iv) a social worker: an individual with at least a bachelor's degree in human services or related field (social work, psychology, psychiatric rehabilitation, sociology, counseling, vocational rehabilitation, human services counseling or other degree deemed equivalent to those described) from an accredited college and with at least one year of clinical experience providing direct services to individuals with a diagnosis of mental illness; (v) a person with at least a bachelor's degree from an accredited college in an unrelated field that includes at least 15 semester credits (or equivalent) in a human services field and who has at least three years of clinical experience; (vi) a Certified Psychiatric Rehabilitation Provider (CPRP) registered with the United States Psychiatric Rehabilitation Association (USPRA); (vii) a registered nurse licensed in Virginia with at least one year of clinical experience; or (viii) any other licensed mental health professional~~ 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 DBHDS or a provider licensed by DBHDS. 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 ~~(QMHP-C)~~" or "QMHP-C" means a person ~~in the human services field who is trained and experienced in providing psychiatric or mental health services to children who have a mental illness. To qualify as a QMHP-C, the individual must have the designated clinical experience and must either (i) be a doctor of medicine or osteopathy licensed in Virginia; (ii) have a master's degree in psychology from an accredited college or university with at least one year of clinical experience with children and adolescents; (iii) have a social work bachelor's or master's degree from an accredited college or university with at least one year of documented clinical experience with children or adolescents; (iv) be a registered nurse with at least one year of clinical experience with children and adolescents; (v) have at least a bachelor's degree in a human services field or in special education from an accredited college with at least one year of clinical experience with children and adolescents, or (vi) be a licensed mental health professional~~ 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 DBHDS or a provider licensed by DBHDS. 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 ~~(QMHP-E)~~" or "QMHP-E" means a person ~~who has: (i) at least a bachelor's degree in a human service field or special education from an accredited college without one year of clinical experience or (ii) at least a bachelor's degree in a nonrelated field and is enrolled in a master's or doctoral clinical program, taking the equivalent of at least three credit hours per semester and is employed by a provider that has a triennial license issued by the department and has a department and DMAS-approved supervision training program~~ 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 ~~Mental Retardation~~ Developmental Disability Professional ~~(QMRP)~~" or "QDDP" means a person who possesses at least one year of documented experience working directly with individuals who have ~~mental retardation (intellectual disability) or other developmental disabilities~~ 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, ~~or~~ (iii) a licensed occupational therapist, or (iv) completion of at least a bachelor's degree in a human services field, including~~, but not limited to~~ social work, special education, rehabilitation counseling, or psychology.

"Qualified Paraprofessional in Mental Health ~~(QPPMH)~~" or "QPPMH" means a person who must~~, at a minimum,~~ 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; ~~or~~ (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-Adult~~ QMHO-A providing services to individuals with mental illness and at least one year of experience (including the 12 weeks of supervised experience).

"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), the concept of recovery does not apply in the sense that individuals with mental retardation (intellectual disability) will need supports throughout their entire lives although these may change over time. With supports, individuals with mental retardation (intellectual 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, 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 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.

"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 injury" means any injury resulting in bodily 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" or "services" means (i) planned individualized interventions intended to reduce or ameliorate mental illness, mental retardation (intellectual disability), 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), 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, halfway house, and other residential services; (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 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.

"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.

"Therapeutic day treatment for children and adolescents" means a treatment program that serves (i) children and adolescents from birth through age 17 and under certain circumstances up to 21 with serious emotional disturbances, substance use, or co-occurring disorders or (ii) children from birth through age seven 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.

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;

2. Types of services offered;

3. The service description; and

4. Number of people to be served at a given time.

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, 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) 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 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 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.

12VAC35-105-1370. Treatment team and staffing plan.

A. Services are delivered by interdisciplinary teams.

1. PACT and ICT teams shall include the following positions:

a. Team Leader - one full time QMHP-Adult with at least three years experience in the provision of mental health services to adults with serious mental illness. The team leader shall oversee all aspects of team operations and shall routinely provide direct services to individuals in the community.

b. Nurses - PACT and ICT nurses shall be full-time employees or contractors with the following minimum qualifications: A registered nurse (RN) shall have one year of experience in the provision of mental health services to adults with serious mental illness. A licensed practical nurse (LPN) shall have three years of experience in the provision of mental health services to adults with serious mental illness. ICT teams shall have at least one qualified full-time nurse. PACT teams shall have at least three qualified full-time nurses at least one of whom shall be a qualified RN.

c. One full-time vocational specialist and one full-time substance abuse specialist. These staff members shall provide direct services to individuals in their area of specialty

and provide leadership to other team members to also assist individuals with their self identified employment or substance abuse recovery goals.

d. Peer specialists - one or more full-time equivalent QPPMH or QMHP-Adult who is or has been a recipient of mental health services for severe and persistent mental illness. The peer specialist shall be a fully integrated team member who provides peer support directly to individuals and provides leadership to other team members in understanding and supporting individuals' recovery goals.

e. Program assistant - one full-time person with skills and abilities in medical records management shall operate and coordinate the management information system, maintain accounts and budget records for individual and program expenditures, and provide receptionist activities.

f. Psychiatrist - one physician who is board certified in psychiatry or who is board eligible in psychiatry and is licensed to practice medicine in Virginia. An equivalent ratio to 20 minutes (.008 FTE) of psychiatric time for each individual served must be maintained. The psychiatrist shall be a fully integrated team member who attends team meetings and actively participates in developing and implementing each individual ISP.

2. QMHP-Adult and mental health professional standards:

a. At least 80% of the clinical employees or contractors, not including the program assistant or psychiatrist, shall ~~meet QMHP-Adult standards and shall~~ be QMHP-As qualified to provide the services described in 12VAC35-105-1410.

b. Mental health professionals - At least half of the clinical employees or contractors, not including the team leader or nurses and including the peer specialist if that person holds such a degree, shall hold a master's degree in a human service field.

3. Staffing capacity:

a. An ICT team shall have at least five full-time equivalent clinical employees or contractors. A PACT team shall have at least 10 full-time equivalent clinical employees or contractors.

b. ICT and PACT teams shall include a minimum number of employees (counting contractors but not counting the psychiatrist and program assistant) to maintain an employee to individual ratio of at least 1:10.

c. ICT teams may serve no more than 80 individuals. PACT teams may serve no more than 120 individuals.

d. A transition plan shall be required of PACT teams that will allow for "start-up" when newly forming teams are not in full compliance with the PACT model relative to staffing patterns and individuals receiving services capacity.

B. ICT and PACT teams shall meet daily Monday through Friday or at least four days per week to review and plan routine services and to address or prevent emergency and crisis situations.

C. ICT teams shall operate a minimum of 8 hours per day, 5 days per week and shall provide services on a case-by-case basis in the evenings and on weekends. PACT teams shall be available to individuals 24 hours per day and shall operate a minimum of 12 hours each weekday and 8 hours each weekend day and each holiday.

D. The ICT or PACT team shall make crisis services directly available 24 hours a day but may arrange coverage through another crisis services provider if the team coordinates with the crisis services provider daily. The PACT team shall operate an after-hours on-call system and be available to individuals by telephone or in person.

IV. Regulatory Matrix

REGULATORY ACTIVITY STATUS REPORT: FEBRUARY 2019 (REVISED 02/11/19)

Board **STATE BOARD OF BEHAVIORAL HEALTH AND DEVELOPMENTAL SERVICES**

VAC CITATION	CHAPTER TITLE (FULL TITLE)	REGULATIONS IN PROCESS			LAST ACTIVITY	LAST PERIODIC REVIEW*
		PURPOSE	STAGE	STATUS		
12 VAC 35-46	**Children's Residential** (*Regulations for Children's Residential Facilities*)	To articulate requirements to assure the health, safety, care, and treatment for children who receive services from providers licensed by DBHDS.	**Periodic Review Completed; *under development***	• ***Current:*** *Comment period ended 02/08/2018. Staff will initiate draft revisions and seek stakeholder comment in coming months.*	01/22/2013	12/05/2017
12 VAC 35-105	**Licensing-Adult** (*Rules and Regulations for Licensing Facilities and Providers of Mental Health, Mental Retardation and Substance Abuse Services*)	To provide specific standards for licensing of organizations and facilities providing behavioral health and developmental disability services. ('Overhaul')	***Periodic Review Completed***	• ***Current:*** *Comment period 12/15/2017. Staff is initiating revisions and will seek stakeholder comment.*		12/05/2017
12 VAC 35-105		*General Assembly in progress: upon approval of the 2020 General Assembly, to support the realignment of behavioral health services including ASAM criteria.*		• ***TBA.***		
12 VAC 35-105 Certain sections.		In accordance with the CMS Final Rule and the Settlement Agreement: clarifications for the health, safety, care and treatment for adults who receive services from providers of residential services.	**Emergency/ NOIRA to *Proposed***	• **Current:** Emergency effective 09/1/2018 (expires 02/29/2020). ➢ *Action Requested: Initiate proposed stage.*	09/01/2018	
12 VAC 35-105 Sections 20, 590, and 1370.		In accordance with Chapter 136 of the 2017 General Assembly to include OTs and OTAs as QMHPs.	**Proposed to *Final***	• **Current:** Emergency regulation effective until 06/17/2019. ➢ *Action Requested: Initiate final stage.*	11/21/2018	
12 VAC 35-105 Section 675.		ISPs: To allow documentation of each quarterly review or a revised assessment 'no later than 15 calendar days from the date the review was due to be completed.'	**Fast Track**	• **Current: Governor approved 01/04/2019.** Comment period will end on 03/06/2019. *Expected effective: 03/21/2019.*	01/04/2019	

Continued -

IV. Regulatory Matrix

12 VAC 35-180	**Human Research** (*Regulations to Assure the Protection of Participants in Human Research*)	To define policy and review requirements to protect individuals who are participants in human research performed by facilities or programs operated, funded, or licensed by the department.	**Fast Track as the result of a Periodic Review**	• **Current:** From DPB to HHR 12/12/2018.	11/12/2009	10/05/2017
12 VAC 35-210	**Facility Temporary Leave** (*Regulations to Govern Temporary Leave from State Mental Health and Mental Retardation Facilities*)	To establish the general process and requirements related to temporary leave from state facilities, including the conditions for granting leave.	**Fast Track as the result of a Periodic Review**	• **Current:** Governor approved 12/12/2018. *Expected effective: 02/21/2019.*	12/12/2018	07/19/2017
12 VAC 35-230	**IFSP** (*Operation of the Individual and Family Support Program*)	To assist individuals with developmental disabilities (DD) who are on a waiting list for waiver services and their family members to access needed services.	**Periodic Review Completed**	• **Current:** Per OAG, retain. Report filed on Town Hall 01/17/2019.	01/17/2019	12/05/2017
12VAC35-250	**Peers** (*Peer Recovery Specialists*)	To establish certification requirements for peer recovery specialists (Item 311.B. of the *2016 Appropriation Act*).	**Proposed *to Final***	• **Current:** Governor approved 01/14/2017. *Expected effective: 03/06/2019*.	01/14/2017	--

*Shows the last time the Periodic Review feature on Town Hall was used for this regulation. A comprehensive periodic review may also have been included during other standard regulatory actions.

State Board of Behavioral Health and Developmental Services
Division of Quality Management and Development – Office of Licensing
COMMENTS ON: EMERGENCY REGULATION – COMPLIANCE WITH VIRGINIA'S SETTLEMENT AGREEMENT WITH US DOJ.

Stage	Emergency NOIRA (Action 5040)
VAC	2VAC35-105
Window:	**August 5 – September 6, 2018**

#	Commenter Name	Commenter Organization	Date	Time	Comment Title	Comments	Response
1	Jan Longman	Arlington County DHS	8/28/18	12:40 PM	Comments from Arlington	We applaud DBHDS efforts to improve these regulations and clarify expectations. We support the removal of the requirement of reporting for Level 1 serious incidents and the clarification that Case Managers are not required to duplicate Level II reporting of incidents that occur in other licensed programs. **12VAC-35-105-20 Definitions** The definition of "**Licensed mental health professional**" does not have a proposed change but should be expanded to include Licensed Nurse Practitioners. The proposed definition of "**serious incident'** as *any event or circumstance that causes or could cause harm to the health, safety, or well-being of an individual* does not sufficiently identify serious incidents and could result in significant over-interpretation. Unemployment, homelessness, witnessing a crime, loss of a caregiver, lack of legal presence, addiction of a family member, deployment or serious illness of a parent, etal are examples of circumstances that could cause harm to the well-being of an individual and I believe are outside the intent of this regulation and the purview of DBHDS. The proposed definition of "**Level II serious incident**" needs further clarification. *"during the provision of a service or on the premises of a provider"* particularly as it applies to "an individual who is missing." Are we correct in assuming that a missing person is only a reportable Level II incident for providers who are responsible for individuals 24 hours per day? Would a missed appointment with a Case Manager, Psychiatrist, Therapist, ICT or Skill Building provider be interpreted to occurring "during *the provision of a service*" and thus be reportable as a Level II incident since they could represent "*circumstances in which an individual is not physically present when and where he should be and his absence cannot be accounted for or explained by his supervision needs or patterns of behavior*". Also in the proposed definition of "**Level II serious incident**" #7a, a decubitus ulcer is only reportable if diagnosed. This could be a disincentive for a provider in seeking medical treatment for suspected ulcers which is not the intent of the regulation. The proposed definition of "**Level III serious incident**" needs clarification specifically as it applies to: 1. *"A sexual assault of an individual."* Guidance issued by DBHDS further states "*Providers shall report to the department and other relevant authorities as required by law that an individual alleges they were sexually assaulted, whether*	Thank you for your comment. Effective 2/21/2019 licensed psychiatric/mental health nurse practitioners will be added to the Office of Licensing regulatory definition of licensed mental health professional. Additional information related to this regulatory action can be found on the Virginia Regulatory Town Hall website. The definition of serious incident takes into account that every serious incident that may occur cannot be explicitly listed in the regulations. However, Level I and Level II serious incidents are incidents which only occur with the provision of the provider's services or on the premises of the provider. Therefore, the mentioned examples would not be tracked (if Level I) or reported to the department (if Level II) unless they occurred within the provision of the provider's services or on their property. Missed appointments are not required to be reported as Level II serious incidents. Please see the effective DBHDS Office of Licensing Guidance for Serious Incident Reporting for additional guidance related to reporting Level II serious incidents. The requirement to report only those decubitus ulcers that have been diagnosed is to ensure accurate reporting. Reporting a serious incident does not imply that a provider has done anything wrong; however, failure to seek appropriate medical attention would be criteria for neglect. The department recognizes that reporting an allegation of sexual assault could impact the therapeutic relationship of the individual with the provider; therefore, reporting should be trauma-informed and respect the therapeutic relationship. Please see the DBHDS Office of Licensing

#	Commenter Name	Commenter Organization	Date	Time	Comment Title	Comments	Response
						or not the alleged assault occurred within the provision of the provider's services or on their property." We support the reporting of sexual assaults that occur on the premises of a provider or against those individuals for whom we have 24-hour responsibility, we do not support reporting of all sexual assaults revealed by our clients to DBHDS. 1. Reporting of assaults should be the prerogative of victims with capacity. Trauma Informed Care principals emphasize that the survivor have a genuine choice to direct reporting of victimization when possible. 2. Regulations indicate assaults should be reported within 24 hours of discovery. Clients often reveal assaults years after they occur. If the assault occurred in the community, what purpose would the reporting serve? 3. What role would DBHDS have in investigating/mitigating sexual assaults that occur in the community? 4. "Sexual assault" is not defined 5. Guidance in the Violence Against Women Act (VAWA) cautions against sharing information beyond minimum necessary since even the most secure systems can be compromised leaving sensitive information exposed, and survivors in danger and often unwilling to disclose their abuse and get help	Guidance for Serious Incident Reporting for additional guidance related to the reporting of unplanned hospital admissions and the sexual assault of an individual.
						1. *"A serious injury of an individual that results in or likely will result in permanent physical or psychological impairment".* Further guidance issued by DBHDS states "*For example, providers shall report if an individual had to have a leg amputated as a result of a car accident whether or not the car accident occurred within the provision of the provider's services or on their property."* We support the reporting of serious injuries that occur on the premises of a provider, during the provision of services, or for those individuals for whom we have 24-hour responsibility, we do not support reporting of all injuries of this type to DBHDS. What role would DBHDS have in investigating/mitigating serious injuries sustained by clients in outpatient programs that occur in the community? While providers have a role in helping individuals process the trauma and linking to needed resources, we have no capacity for root cause analysis or mitigation of traffics accidents, acts of god, acts or war, crime, etc.	The language relating to a serious injury of an individual that results in or likely will result in permanent physical or psychological impairment has been removed in the proposed draft of the regulation.
						The definitions of QMHP-A and QMHP-C are not aligned with the new requirements for those staff to be registered with the Board of Counseling which can lead to misinterpretation of the requirements necessary to deliver services.	A separate Emergency Regulation aligning the Office of Licensing regulatory definitions of QMHP-A and QMHP-C with the Board of Counseling is currently in effect. This action became, effective 12/18/2017, and can be found on the Virginia Regulatory Town Hall.
						12VAC35-105-160. Reviews by the department; requests for information; required reporting. *"E. A root cause analysis shall be conducted by the provider within 30 days of discovery of Level II and Level III serious incidents. The root cause analysis shall include at least the following information: (i) a detailed description of what happened; (ii) an analysis of why it happened, including identification of all identifiable underlying causes of the incident that were under the control of the provider; and (iii) identified solutions to mitigate its reoccurrence."* We support the root cause analysis following most incidents classified as Level II or	The language related to the requirement to conduct root

#	Commenter Name	Commenter Organization	Date	Time	Comment Title	Comments	Response
						Level III, conducting an analysis on the expected deaths from natural causes of individuals in outpatient programs is unnecessarily burdensome. **12 VAC35-105-1245** *"Case managers shall meet with each individual face-to-face as dictated by the individual's needs. At face-to-face meetings, the case manager shall (i) observe and assess for any previously unidentified risks, injuries, needs, or other changes in status; (ii) assess the status of previously identified risks, injuries, or needs, or other change in status; (iii) assess whether the individual's service plan is being implemented appropriately and remains appropriate for the individual; and (iv) assess whether supports and services are being implemented consistent with the individual's strengths and preferences and in the most integrated setting appropriate to the individual's needs."* Clients are often seen face to face by their case managers multiple times per month – a frequency interval for this extensive documentation requirement would be helpful. **12VAC35-105-1250. Qualifications of case management employees or contractors** *"D. Case managers serving individuals with developmental disability shall complete the DBHDS core competency-based curriculum within 30 days of hire."* There is no contingency here for when the DBHDS portal is not available for over 30 days and DBHDS has no back-up training plan. We have experienced an outage of over 30 days in the past.	cause analysis has been narrowed in the proposed draft of the regulations and now states that a root cause analysis shall be conducted by the provider within 30 days of discovery of Level II serious incidents and any Level III serious incidents that occur during the provision of a service or on the provider's premises. In addition, providers are only required to identify solutions to mitigate the reoccurrence of a serious incident when applicable. Documentation should be completed for each face-to-face meeting with the case manager. This regulation will be enforced only if the DBHDS core competency-based curriculum is available to the new employee within 30 days of hire.
2	Joanna Wise Barnes	ServiceSource, Inc.	9/4/18	3:07 PM	12VAC35-105. Rules and Regulations for Licensing Providers by the DBHDS	• 12VAC35-105-20, Definitions of serious incidents – Level II definition #6, "Ingestion of any hazardous material" which must be reported "If any individual drinks, swallows, or absorbs a material that is hazardous to their health…it shall be reported." We serve many individuals who engage in PICA. Calls to the Poison Control Center direct us on whether to seek emergency care, or if we can provide treatment and monitoring at our sites. We request requiring reporting only when the individual is taken to receive emergency or urgent professional medical care after ingesting any material, rather than after each occurrence of ingesting by individuals who engage in PICA. (Responses to their PICA behavior are driven not only by the Poison Control Center, but by individual protocols, behavior plans, and/or physician's orders.) • 12VAC35-105-20, Definitions of serious incidents – "Level III serious incident means serious incidents whether or not the incident occurs on the provider's premises or within the provision of services. All providers that are made aware of a level III serious incident are required to report even if this results in duplicative reporting." Level III, definition #1, "Any death of an individual" – When using the CHRIS system to report deaths of individuals who did not die while in our licensed program, the system requires providers to answer questions to which we lack answers. After choosing "yes" or "no" as required, we can only explain in a random textbox within CHRIS that the answers are in fact unknown. We ask that instead of using CHRIS, a provider be required to notify OL of all deaths via a documented phone call or encrypted email. Only the provider in whose care the individual died should be required to enter the	Thank you for your comment. The DBHDS Office of Licensing Guidance for Serious Incident Reporting language related to the ingestion of any hazardous material has been amended to state the following: "If an individual drinks, swallows, or absorbs a material that causes significant harm to the individual or is a threat to their health and safety, the provider should report this as a Level II serious incident." The department feels that the death of an individual receiving services is important enough to merit notification from all providers providing services. Under the new proposed draft of the regulation, providers who were not actively providing services at the time of the death will not have to conduct a root cause analysis on the death.

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						death into the CHRIS system. • 12VAC35-105-160, "Amend to require reporting of all level II and level III serious incidents to the department," "A root cause analysis shall be conducted by the provider within 30 days of the discovery of Level II and Level III serious incidents," and "The provider shall submit, or make available, reports and information that the department requires to establish compliance with these regulations and application statutes." We appreciate the importance of tracking, analyzing, and reporting data on serious incidents state-wide. This is important to monitor services and to protect the safety of individuals served, not just for compliance with the Settlement Agreement. We request that the Comprehensive Human Rights Information System (CHRIS) be updated, or that another "web-based reporting application" replace it. The system used should be user-friendly and should require entry of all mandated information and only that information, specific to categories of serious incidents, so that only one reporting mechanism is used. Providers appreciate the availability of OHR staff to train and re-train staff on the use of CHRIS; such training is not a substitute for resolving system issues that now use considerable staff hours due to technical difficulties. • Sections 20 and 691 – These sections and probably others refer to the individual and/or the individual's "authorized representative." "Authorized representative" has a specific definition in the Code of Virginia. If the regulations intentionally reference that Code definition, then the term "legal guardian" should be added to these and other sections where only an authorized representative is mentioned. If on the other hand, "authorized representative" is intended as a generic term, then perhaps "substitute decision-maker" should be used instead. 12VAC35-115-145 does use the generic term "substitute decision making."	The department is currently in the process of updating CHRIS to be more user-friendly for reporting of serious incidents in accordance with the emergency regulations. The DBHDS Office of Licensing regulation, 12VAC35-105-20, defines authorized representative as "a person permitted by law or 12VAC35-115 to authorize the disclosure of information or consent to treatment and services or participation in human research."
3	Carlinda Kleck	Loudoun County Dept. of MHSADS	9/4/18	4:58 PM	Comments on Draft Emergency Licensing Regulations	**Loudoun County MHSADS Comments on Emergency Licensing Regulations** **12VAC35-105-20. Definitions.** **"Serious Incident" –** • Determining if a hospital admission is a level II may be subjective and result in inconsistent reporting among providers. Unplanned psychiatric/medical hospital admission: what constitutes an unplanned hospital admission? For example, there are circumstances where an individual may be ECO'ed but decide to voluntarily admit herself to the hospital. At what point in the process is it "unplanned?" • Defining "a sexual assault of an individual" as a level III incident poses a risk to the therapeutic relationship and violates an individual's rights to privacy. An individual who has been a victim of the sexual assault has been violated and should not be further violated by the provider disclosing the information to DBHDS if the assault did not occur during service provision "A sexual assault of an individual" should be moved to a level II incident. • Defining "a serious injury of an individual that results in or likely will result in permanent physical or psychological impairment" as a level III incident presents multiple challenges in implementation. First, there is ambiguity in interpreting what "results in or likely results in permanent physical or psychological impairment." Who determines when it causes or likely will cause "permanent" impairment? Second, requiring this to be reported to DBHDS when not occurring during service delivery, creates an undue burden for providers. Individuals do not have to tell providers about situations that occur outside of service provision. How does reporting this information to DBHDS provide useful data for the provider or DBHDS? How does this help those	Thank you for your comment. Please see the DBHDS Office of Licensing Guidance for Serious Incident Reporting for additional guidance related to the reporting of unplanned hospital admissions and the sexual assault of an individual. The department recognizes that reporting an allegation of sexual assault could impact the therapeutic relationship of the individual with the provider; therefore, reporting should be trauma-informed and respect the therapeutic relationship. The language relating to a serious injury of an individual that results in or likely will result in permanent physical or psychological impairment has been removed in the proposed draft of the regulation.

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						receiving services? Finally, this may also violate an individual's right to privacy. For example, if an individual were in an accident outside of service delivery and required amputation, why would DBHDS need to know this information? **12VAC35-105-160. Reviews by the department; requests for information; required reporting.** • The required components of the root cause analysis described in E do not allow for the dignity of risk and imply that all Level II and Level III incidents have feasible mitigating solutions for identification. Accidents happen, which cannot be prevented. Section (iii) needs to be modified to indicate identifying "solutions to mitigate its reoccurrence" as possible. Further, there should be clarification that an individual has the right to indicate they do not want the identified solutions implemented. It must be clear that individuals have the right to choice and dignity of risk.	The language related to the requirement to conduct root cause analysis was narrowed in the proposed draft of the regulation and now states that a root cause analysis shall be conducted by the provider within 30 days of discovery of Level II serious incidents and any Level III serious incidents that occur during the provision of a service or on the provider's premises. In addition, providers are only required to identify solutions to mitigate the reoccurrence of a serious incident when applicable.
4		Henrico Area Mental Health & Developmental Services	9/5/18	12:40 PM	Definition of Serious Incident	105-20 Definition of Serious Incident Level II 2. An individual who is missing for any period of time…does this mean while in our care as in residential or day programs. Does this apply to all services such as outpatient services? Please define "time". This should be a more focused reporting for residential and day services. Level II 4. If a client comes to the CSB to see a nurse and it is recommended to go to the doctor how would we know if the ER was being used in lieu of a primary care visit? Is this reportable? Does this include urgent care visit in lieu of seeing the PCP, even when the PCP offices are closed? How do we handle voluntary hospitalizations, are they considered unplanned? Are they reportable? We would only report hospitalizations we help with in level II? Considerations should be made to remove psychiatric hospitalizations as a reportable requirement. Level II. 7. a-b. How will we know if a decubitus ulcer or a bowel obstruction occurred or originated on our premises or during provision of services for all licensed services such as outpatient services? Should be focused just for residential services. Level III. For level III reporting, does the individual have the right to know what is being reporting to the state regarding what is shared with the provider? Level III. 2. Sexual assault of an individual. In an outpatient service this has serious impacts on the therapeutic relationship as the individual may feel additionally victimized by the reporting and questioning from a root cause analysis completed. Shouldn't the individual provide authorization to report, what about their right to privacy? This should not be a level III reporting and should be moved to level II. Level III. 3. If a client was in a car accident, would this be reportable in Level III? How does one assess, at the time, if something is "likely" to result in permanent physical or psychological (especially psychological) impairment? What is your definition of psychological impairment? To report to DBHDS when not occurring during service delivery, creates an undue burden for providers. Individuals do not have to tell providers about situations that occur outside of service provision. Level III. 4. Suicide Attempt.– What constitutes a suicide attempt? If a person talks about suicide and has a voluntary admission is that behavioral or suicidal?Is this reportable?	Thank you for your comment. The proposed draft of this regulation has been amended to clarify that a provider shall report if an individual is or was missing. This language has been removed from the proposed draft of the regulations. A diagnosis of decubitus ulcer or an increase in severity of level of a previously diagnosed decubitus ulcer should be reported as a Level II serious incident once the provider has sought and obtained a diagnosis from a medical professional. Please see the DBHDS Office of Licensing Guidance for Serious Incident Reporting for additional guidance related to the reporting of the sexual assault of an individual. The department recognizes that reporting an allegation of sexual assault could impact the therapeutic relationship of the individual with the provider; therefore, reporting should be trauma-informed and respect the therapeutic relationship. The language relating to a serious injury of an individual that results in or likely will result in permanent physical or psychological impairment has been removed from the proposed draft of the regulations. A definition of "suicide attempt" has been added to the proposed draft of the regulations.

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						Level III. How will we do a root cause analysis for events that happen not on our premises, as many Level III situations will occur that way?	The language related to the requirement to conduct root cause analysis has been narrowed in the proposed draft of the regulations and now states that a root cause analysis shall be conducted by the provider within 30 days of discovery of Level II serious incidents and any Level III serious incidents that occur during the provision of a service or on the provider's premises.
5	Leslie Sharp	NRVCS	9/5/18	3:42 PM	Licensing Regulations	• *"A sexual assault of an individual."* "*Providers shall report to the department and other relevant authorities as required by law that an individual alleges they were sexually assaulted, whether or not the alleged assault occurred within the provision of the provider's services or on their property."* ○ The reporting of sexual assaults that occur on the premises of a provider or against those individuals for whom we have 24-hour responsibility would be appropriate but reporting of all sexual assaults revealed by our clients to DBHDS would pose a risk to therapy and violates an individual's rights to privacy. Sexual assault is a legal term and what role should the provider have in investigating something that occurred in the community and should be investigated by the police. Regulations indicate assaults should be reported within 24 hours of discovery. Clients often reveal assaults years after they occur as part of therapy. • *"E. A root cause analysis shall be conducted by the provider within 30 days of discovery of Level II and Level III serious incidents. The root cause analysis shall include at least the following information: (i) a detailed description of what happened; (ii) an analysis of why it happened, including identification of all identifiable underlying causes of the incident that were under the control of the provider; and (iii) identified solutions to mitigate its reoccurrence."* ○ For Level II incidents, there should be an accumulation of incidents to trigger a RCA such as two level 2 incidents w/in a 30 day period as an example. Also conducting an analysis on the expected deaths from natural causes of individuals in outpatient programs would be more burdensome to programs. • *A serious injury of an individual that results in or likely will result in permanent physical or psychological impairment". "For example, providers shall report if an individual had to have a leg amputated as a result of a car accident whether or not the car accident occurred within the provision of the provider's services or on their property."* ○ There is ambiguity in what "results in or likely results in permanent physical or psychological impairment." What determines when it causes or likely will cause "permanent" impairment? This should be spelled out more.	Thank you for your comment. Please see the DBHDS Office of licensing Guidance for Serious Incident Reporting for additional language related to the reporting of the sexual assault of an individual. The language related to the requirement to conduct root cause analysis has been narrowed in the proposed draft of the regulations and now states that a root cause analysis shall be conducted by the provider within 30 days of discovery of Level II serious incidents and any Level III serious incidents that occur during the provision of a service or on the provider's premises. Therefore, a provider would not be required to conduct a root cause analysis on the natural death of an individual receiving outpatient services unless the individual died while they were actively receiving outpatient services or on the premises of the provider. This language has been removed from the proposed draft of the regulations.
6		Henrico Area Mental Health & Developmental Services	9/5/18	3:59 PM	Comments on Licensing Regulations	105-20 Definitions **Definition of Missing -** Further clarification is needed for this definition as it relates to all services. The definition seems broad. For example; If a person is expected to arrive at 10:00 for an appointment and they no show and we are unable to reach them, are they missing? If they no show for a second appointment is that missing? For individuals in outpatient services living on their own this information would not be	Thank you for your comment. Please see the DBHDS Office of licensing Guidance for Serious Incident Reporting for additional guidance related to reporting when an individual is missing.

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						timely. It is recommended to narrow the focus to residential and day services. **Definition of QDDP -** The definition of QDDP seems to be different in the draft licensing regulations than in the waiver emergency regulations and the waiver definition. The emergency regulations are more flexible for providers since it allows a substitution of experience for education whereas the licensing definition requires a BA, MD or an RN. Many providers have supervisory staff who have extensive experience but may not have completed their BA or their degree may not be in a human services area, suggesting for consistency, to use the same language as in the waiver emergency regulations. **105-160 - Reviews by the dept and added required reporting -** Regulating that every serious incident must have an identified solution to mitigate its reoccurrence may not apply all incidents, for example; deaths as a result of natural causes. Level III, how will we do a root cause analysis for incident that are not on our premises, as many Level III situations may occur that way. For example; if a client dies in a car accident, how/would we do a root cause analysis of this situation? The requirement to complete a root cause analysis should be changed to complete a root cause analyses when patterns or trends occur. **105-400 - Criminal background checks and registry searches -** Requiring a disclosure statement from the applicant for pending charges for any offense is not something we would be legally able to ask.	The definition of QDDP in the emergency regulations has not changed from the licensing regulations previously in effect. The defined term was changed from "Qualified Mental Retardation Professional (QMRP)" to "Qualified developmental disability professional or QDDP." The language related to the requirement to conduct root cause analysis was narrowed in the proposed draft and now states that a root cause analysis shall be conducted by the provider within 30 days of discovery of Level II serious incidents and any Level III serious incidents that occur during the provision of a service or on the provider's premises. In addition, providers are only required to identify solutions to mitigate the reoccurrence of a serious incident when applicable. Requiring a disclosure statement from applicants is not a new requirement within the Licensing Regulations. In addition, the requirement is similar to those of other state licensing entities.
7		Henrico Area Mental Health & Developmental Services	9/5/18	4:11 PM	Comments on Licensing Regulations	**Thank-you for the opportunity to provide comments.** **105-520 - Risk Management -** The wording in the regulations "incorporate uniform risk triggers and thresholds as defined by the department" is undefined and should either be removed from regulations or defined in regulations as this leaves it open for interpretation. **105-580 - Service description requirements -** C.2. A description of care, treatment, training skills acquisition, or other supports provided. The term "acquisition" is awkward language. **105-650 - Assessment Policy -** F. A. comprehensive assessment shall update and finalize the initial assessment. There are questions regarding this requirement and Same Day Access Services. We have received feedback that two separate assessments are needed; the initial assessment and the comprehensive assessment, on our SDA form we now have to identify which part is the initial and which part is the comprehensive. This needs clarification as it relates to the State's SDA initiatives. **105-665 - ISP requirements -** A.11. Does this only apply to DD Waiver CD services? The ISP shall be distributed to the individual and others authorized to receive it. What if the individual does not want a copy of the ISP? **105-675 - Reassessments and ISP reviews -** A. Update the ISP whenever there is "any" kind of change? Is the review not sufficient? Definitely, if something new that needs addressing but does this include every improvement outside of the review period? D.2. Currently this is documented that the individual has met an objective, what additional documentation is being proposed?	Thank you for your comment. The department will be defining uniform risk triggers and thresholds. These will be communicated to providers through a formal guidance document which will be subject to public comment prior to finalizing. This comment exceeds the scope of the current regulatory action. We will consider your comment during additional regulatory reviews in the future. This requirement applies to all licensed providers. If the individual does not want a copy of the ISP, the provider should document that the individual was offered a copy of the ISP and refused. The regulation states that reassessments shall be completed at least annually and any time there is a need based on changes in the medical, psychiatric, behavioral, or other status of the individual. This language in regulation 675 was broken out from a paragraph in effort to be more clear. DBHDS found that providers were not "documenting evidence of progression towards or achieved for EACH goal and objective". The provider must do this for both the goal and the objective. The phrase "documented evidence" is emphasized also in the regulation now. The previous regulation just said "evaluate" and was not specific in

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						D.3. Requiring a team meeting when individuals do not meet specific objectives is difficult. Individuals may have many objectives to reach a goal and have several goals. Requiring a team meeting each time a specific objective is not meet will feel punitive to an individual who is trying to reach their goals and may dramatically impact direct service time. How is the team defined? So if an objective on the ISP that the client will visit the primary care office in the next quarter, and the client cancels the visit, do we bring the whole team together to discuss why the client cancelled the appointment? Requiring the team to meet should be removed.	stating to document this evaluation. A treatment team is defined by who is identified on the ISP as being required to deliver specific interventions (665.A.9). The provider should be in contact with all treatment team members, as appropriate (with releases of information) to ensure appropriate delivery of services. The regulations also states, "as appropriate". If there are certain team members that are not able to meet, then the provider should be documenting the attempt to meet and the reason why it could not be accomplished. However, the provider is required to be proactive with an individual's care and if the provider is actively delivering services, then the provider should know well ahead of time if an individual is meeting their goals/objectives. This requirement in regulation is to assist in better quality care deliver among all individuals and all services.
						105-691 - Transition of individuals among services - Further clarification is needed to define transition/transfer. If an individual moves from one case management team to another case management team is this a transfer needing a transfer summary.	This comment exceeds the scope of the current regulatory action. We will consider your comment during additional regulatory reviews in the future.
						105-1245 - Case Management direct assessments - This is too ambiguous—who determines how often the individual's needs dictate face-to-face contact? We have some occasions, when we are seeing case management clients multiple times in the same week for MH case management—would we have to do (I,ii,iii,iv)at each face-to-face visit?	Documentation should be completed for each face-to-face meeting with the case manager.
8	Don Sherman	Rockbridge Area Community Services	9/5/18	4:53 PM	12VAC35-105 Root Cause Analysis	The process of completing a Root Cause Analysis can be useful in determining the factors which contributed to an incident and therefore can be valuable to efforts in addressing systemic issues. However, not all incidents require the methodology of a Root Cause Analysis to understand the contributing factors and underlying issues of an incident. Many accidents, injuries, and deaths are attributable to individual and self-evident causes. In such cases the exercise of conducting a Root Cause Analysis will yield no new or useful information to the provider. Additionally, there are incidents which occur where providers will not have the means to determine all or even some of the factors which contributed to the incident. This is likely to be the case for some Level III incidents which occur outside of the purview of the providers' services and facilities. In cases where providers are unable to accurately determine the factors which contributed to an incident it makes little practical sense to complete a Root Cause Analysis. For these reasons we recommend that the regulations be revised to state that during their review of incidents providers will take reasonable steps to determine the underlying causes of Level II and Level III incidents. The regulations can then highlight the utilization of Root Cause Analysis as a preferred method for determining the factors which contributed to incident This maintains the requirement that providers examine incidents to determine their root causes but offers greater latitude to providers regarding how they meet this requirement. In cases where the cause of an incident is obvious providers may not need to take additional actions and in cases where providers could not reasonably know the cause of an incident they are free	Thank you for your comment. The language related to the requirement to conduct root cause analysis was narrowed in the proposed draft of the regulations and now states that a root cause analysis shall be conducted by the provider within 30 days of discovery of Level II serious incidents and any Level III serious incidents that occur during the provision of a service or on the provider's premises. In addition, providers are only required to identify solutions to mitigate the reoccurrence of a serious incident when applicable.

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						from the obligation of conducting a fruitless Root Cause Analysis.	
9	Melanie Bond, Psy.D	Hampton-Newport News Community Services Board	9/5/18	5:31 PM	Response to Proposed Changes to DBHDS – Emergency Regulations	**Hampton – Newport News Community Services Board** **Response to Proposed Changes to DBHDS – Emergency Regulations** 1. **12VAC35-105-20. Definitions.** *"Serious incident" means any event or circumstance that causes or could cause harm to the health, safety, or well-being of an individual. The term "serious incident" includes death and serious injury. "Level I serious incident" means a serious incident that occurs or originates during the provision of a service or on the premises of the provider and does not meet the definition of a Level II or Level III serious incident. "Level I serious incidents" do not result in significant harm to individuals, but may include events that result in minor injuries that do not require medical attention or events that have the potential to cause serious injury, even when no injury occurs. "Level II serious incident" means a serious incident that occurs or originates during the provision of a service or on the premises of the provider that results in a significant harm or threat to the health and safety of an individual that does not meet the definition of a Level III serious incident. "Level II serious incident" includes a significant harm or threat to the health or safety of others caused by an individual. "Level II serious incidents" include: 1. A serious injury; 2. An individual who is missing; 3. An emergency room or urgent care facility visit when not used in lieu of a primary care physician visit; 4. An unplanned psychiatric or unplanned medical hospital admission; 5. Choking incidents that require direct physical intervention by another person; 6. Ingestion of any hazardous material; or 7. A diagnosis of: a. A decubitus ulcer or an increase in severity of level of previously diagnosed decubitus ulcer; b. A bowel obstruction; or c. Aspiration pneumonia. "Level III serious incident" means a serious incident whether or not the incident occurs while in the provision of a service or on the provider's premises and results in: 1. Any death of an individual; 2. A sexual assault of an individual; 3. A serious injury of an individual that results in or likely will result in permanent physical or psychological impairment; or 4. A suicide attempt by an individual admitted for services that results in a hospital admission.* • The new assignment of Levels to serious incidents does not improve the accuracy or efficiency of reporting for Providers. This assignment system is confusing, inconsistent/contradicting and does not adequately address some of the most common types of incidents experienced by Providers. For example, serious incidents occurring offsite, but reported to Case Managers outside of service provision, are notably difficult to categorize in the existing reporting infrastructure. The proposed Level system, and subsequent guidance offered by DBHDS, do not offer the direction needed for adequate application. • Level III incidents, such as sexual assault, may fall outside of the jurisdiction of a Provider to investigate, as it might impede the work of a law enforcement entity. • In accordance to the proposed regulations, Level III serious incidents include those *that result in or likely will result in permanent physical or psychological impairment*. This is a highly subjective descriptor and, given the parameters for reporting serious incidents (e.g., timeframes), as well as completing the subsequent investigations, it is unlikely if the information needed to make this type of assumption would be available at the time of completion. • The Definitions do not acknowledge or define the position of ***Qualified Mental Health Case Manager (QCM).*** Is a QCM equivalent to a QMHP? If not, a separate, distinct definition for a QCM should be provided, with information as to what qualifications distinguish it from the QMHP classification. **12VAC35-105-160. Reviews by the department; requests for information;**	Thank you for your comment. The language relating to a serious injury of an individual that results in or likely will result in permanent physical or psychological impairment has been removed from the proposed draft of the regulations.

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						required reporting. 1. *The provider shall collect, maintain, and review at least quarterly all Level I serious incidents as part of the quality improvement program in accordance with 12VAC35-105-620 to include an analysis of trends, potential systemic issues or causes, indicated remediation, and documentation of steps taken to mitigate the potential for future incidents.* • Given the amount of additional reporting, analysis and outcome maintenance the regulatory standards mandate, quarterly review of Level I incidents, which are frequent in number, is superfluous and burdensome on an already overtaxed system. At a minimum, an annual review of trends would be sufficient.	Providers are not required to report Level I serious incidents. This is a decrease in previous reporting requirements to the department. The reason for provider monitoring of Level I serious incidents quarterly is to minimize the risk of the occurrence of additional Level I, II, or III incidents in the future.
						E. A root cause analysis shall be conducted by the provider within 30 days of discovery of Level II and Level III serious Regulations Volume 34, Issue 25 Virginia Register of Regulations August 6, 2018 2510 incidents. The root cause analysis shall include at least the following information: (i) a detailed description of what happened; (ii) an analysis of why it happened, including identification of all identifiable underlying causes of the incident that were under the control of the provider; and (iii) identified solutions to mitigate its reoccurrence. • Implementation of this requirement should be delayed until: DBHDS has provided adequate training to Providers on how to conduct a Root Cause Analysis (RCA) that meets the Department's standards; provides the method by which Providers should document RCAs to ensure the Department's standards are met. • RCAs **should not** be applied universally to all Level II and Level III serious incidents. Deaths of unknown cause, some sexual assaults offsite and outside of service provision, etc. are types of events when an RCA should not apply.	The department will be posting provider trainings on the provisions of the effective Emergency Regulations in upcoming weeks. In addition, please see The DBHDS Office of Licensing Guidance for Serious Incident Reporting for additional guidance related to conducting a Root Cause Analysis. The language related to the requirement to conduct root cause analysis was narrowed in the proposed draft and now states that a root cause analysis shall be conducted by the provider within 30 days of discovery of Level II serious incidents and any Level III serious incidents that occur during the provision of a service or on the provider's premises. In addition, providers are only required to identify solutions to mitigate the reoccurrence of a serious incident when applicable.
						• Sensitivity to the nature of "investigating" and/or completing RCAs with victims of assault, especially ones of a sexual nature, does not appear to have been applied in the development of this regulatory standard. This requirement should be rescinded.	The department recognizes that reporting an allegation of sexual assault could impact the therapeutic relationship of the individual with the provider; therefore, reporting should be trauma-informed and respect the therapeutic relationship.
						12VAC35-105-520. Risk management. *C. The provider shall conduct systemic risk assessment reviews at least annually to identify and respond to practices, situations, and policies that could result in the risk of harm to individuals receiving services. The risk assessment review shall address (i) the environment of care; (ii) clinical assessment or reassessment processes; (iii) staff competence and adequacy of staffing; (iv) use of high risk procedures, including seclusion and restraint; and (v) a review of serious incidents. This process shall incorporate uniform risk triggers and thresholds as defined by the department.* • Implementation of this requirement should be delayed until: DBHDS has provided adequate training to Providers on how to conduct systemic risk assessments that meet the Department's standards, with special emphasis on the "uniform risk triggers and thresholds" as defined by the department, per the proposed regulations. Given the DOJ's scrutiny and the Department's increased emphasis in this area, it is imperative Providers have the support and training, facilitated by DBHDS, to ensure this standard is adequately applied.	The department will provide additional information related to uniform risk triggers and thresholds as they are identified by the department. In addition, the department will be posting trainings related to provisions within the emergency regulations within the next few weeks.

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<tr><td></td><td></td><td></td><td></td><td></td><td></td><td>12VAC35-105-675. Reassessments and ISP reviews.
D. 3. For goals and objectives that were not accomplished by the identified target date, the provider and any appropriate treatment team members shall meet to review the reasons for lack of progress and provide the individual an opportunity to make an informed choice of how to proceed.
• This section should read “the provider <u>and/or</u> any appropriate treatment team members” to more adequately represent Providers offering services to individuals in mental health and ARTS programming. Although it is recognized a treatment team approach would be ideal in progress review, this option is not always readily available, even with care coordination support. The proposed writing of this portion of regulation might result in over interpretation or misapplication.</td><td>A treatment team is defined by who is identified on the ISP as being required to deliver specific interventions (665.A.9). The provider should be in contact with all treatment team members, as appropriate (with releases of information) to ensure appropriate delivery of services. The regulations also states, "as appropriate". If there are certain team members that are not able to meet, then the provider should document the attempt to meet and the reason why it could not be accomplished. However, the provider is required to be proactive with an individual's care and if the provider is actively delivering services, then the provider should know well ahead of time if an individual is meeting their goals/objectives. This requirement in regulation is to assist in better quality care delivery among all individuals and all services.</td></tr>
<tr><td>10</td><td>Kim Black</td><td>Hope House Foundation</td><td>9/5/18</td><td>8:53 PM</td><td>Public Comment Licensing Regulations 12VAC35-105</td><td>HHF Public Comment
Rules and Regulations For Licensing Providers by the Department of Behavioral Health and Developmental Services [12 VAC 35 ? 105]
<table>
<tr><th>Section</th><th>Comment</th><th>Action</th></tr>
<tr><td>12VAC-35-105-20 Definitions</td><td>The proposed definition of “serious incident’ does not sufficiently identify serious incidents and could result in significant over-interpretation.</td><td>Remove ‘or could cause harm…”</td></tr>
<tr><td></td><td>Level II Serious Incident – Guidance Doc</td><td>Requiring a licensed residential provider to report on an incident that occurs within the confines of another licensed program/setting will cause the data regarding serious incidents to be inaccurate due to duplicate reporting of the same incident. It is also inefficient for staff in both settings.

Remove the example at the top of page two related to this requirement and remove the language regarding residential providers being required to report all incidents as it goes beyond what the regulations require.</td></tr>
<tr><td></td><td>Ingestion of any hazardous material</td><td>The example is to broad and makes this reporting requirement unmanageable. Add the clarification that if</td></tr>
</table></td><td>Thank you for your comment.

<u>The DBHDS Office of Licensing Guidance for Serious Incident Reporting</u> language related to the reporting of Level II serious incidents by residential services providers was amended to state: “Providers licensed to provide a ‘residential service’ as defined by 12VAC35-105-20 provide 24-hour support to individuals. However, if an individual receiving residential services experiences a Level II serious incident while actively receiving services from another licensed provider, the residential service provider is not required to report the incident if they verify that the other provider reported the incident.”

<u>The DBHDS Office of Licensing Guidance for Serious Incident Reporting</u> language related to the ingestion of any hazardous material has been amended to state the following: “If an individual drinks, swallows, or absorbs a</td></tr>
</table>

#	Commenter Name	Commenter Organization	Date	Time	Comment Title	Comments			Response
								medical treatment is necessary after consulting Poison Control then the incident is reportable.	material that causes significant harm to the individual or is a threat to their health and safety, the provider should report this as a Level II serious incident." Providers are required to report the unplanned hospital admission of an individual for any reason.
							Unplanned Medical Hospitalization	The provider cannot control when a hospital might admit someone for observation vs. treatment and it would seem that if someone is admitted for observation only, the incident does not meet the requirement to report.	
						12VAC35-105-320 Fire inspections	If a provider is scheduled only to provide services on certain days of the week and is not present during a fire, the provider cannot staff to evacuate during a fire.	Distinguish between types of providers as previously done in regulation. "Does not apply to non-center based providers."	The regulatory requirement to maintain the provider's building and equipment in accordance with the Statewide Fire Prevention Code applies only to residential service locations. All providers are required to maintain adequate staff to safely evacuate all individuals during an emergency.
						12VAC35-105-520 Risk Management	Section A.	Clarify what DBHDS will accept to support expertise or DBHDS should provide a training available to providers that meets criteria.	Provider will be required to provide evidence of training and expertise. The provider should confirm this training and expertise in accordance to 430.A.,2., 4., and 5 " This individual should have documented knowledge and skill in the areas of investigations, RCA, and data analysis.
						12VAC35-105-590 Provider Staffing Plan	Adequate number of staff required to safely evacuate all individuals during an emergency	Distinguish between types of providers as previously done in regulation. "Does not apply to non-center based providers."	The DBHDS Office of Licensing regulations did not previously distinguish between types of providers for this regulation. All providers are required to maintain adequate staff to safely evacuate all individuals during an emergency.
						12VAC35-105-660 Individualized Services plan (ISP)	Section D.	Clarify that this is the role of the case manager not each provider.	This is the role of the licensed provider and not just the case manager. All providers are responsible for the ISP that is with the individual and the provider's services.
11	Eva-Elizabeth Chisholm	L'Arche Greater Washington DC	9/5/18	11:29 PM	RE: Root Cause analysis; role definitions	RE: the Root Cause Analysis: Additional training and information should be offfered to providers in order for this new expecation to be implemented well. As others have noted, there are certain circumstances when an RCA would not be feasible, due to the nature of the incident or the environment in which the incident occured. RE: the QIDP/QDDP definitions: limiting the requirments to specific degrees removes from consideration professionals with significant experience in the field. Is it possible to include relevant work experiece as qualifying a professional to serve in this capacity?			Thank you for your comment. Guidance related to expectations for root cause analysis can be found within the Guidance for Serious Incident Reporting. In addition, the Office of Licensing will be posting trainings on the emergency regulations this spring. This comment exceeds the scope of the current regulatory action. We will consider your comment during additional regulatory reviews in the future.