

DRAFT Fast-Track: MOUD Amendments to Align with Federal Updates

Department of Behavioral Health And Developmental Services

Ch105: Rules and Regulations for Licensing Providers by the Department of Behavioral Health and Developmental Services

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" 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 an individual receiving care or treatment for mental illness, developmental disabilities, or substance abuse. 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 individual;
4. Misuse or misappropriation of the individual's assets, goods, or property;
5. Use of excessive force when placing an individual in physical or mechanical restraint;
6. Use of physical or mechanical restraints on an individual that is not in compliance with federal and state laws, regulations, and policies, professional accepted standards of practice, or his individualized services plan; or
7. Use of more restrictive or intensive services or denial of services to punish 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.

"Addiction" means a primary, chronic disease of brain reward, motivation, memory, and related circuitry. Addiction is defined as the inability to consistently abstain, impairment in behavioral control, persistence of cravings, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death.

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

"Allied health professional" means a professional who is involved with the delivery of health or related services pertaining to the identification, evaluation, and prevention of diseases and disorders, such as a certified substance abuse counselor, certified substance abuse counseling assistant, peer recovery support specialist, certified nurse aide, or occupational therapist.

"ASAM" means the American Society of Addiction Medicine.

"Assertive community treatment service" or "ACT" means a self-contained interdisciplinary community-based team of medical, behavioral health, and rehabilitation professionals who use a

team approach to meet the needs of an individual with severe and persistent mental illness. ACT teams:

1. Provide person-centered services addressing the breadth of an individual's needs, helping him achieve his personal goals;
2. Serve as the primary provider of all the services that an individual receiving ACT services needs;
3. Maintain a high frequency and intensity of community-based contacts;
4. Maintain a very low individual-to-staff ratio;
5. Offer varying levels of care for all individuals receiving ACT services and appropriately adjust service levels according to each individual's needs over time;
6. Assist individuals in advancing toward personal goals with a focus on enhancing community integration and regaining valued roles, such as worker, family member, resident, spouse, tenant, or friend;
7. Carry out planned assertive engagement techniques, including rapport-building strategies, facilitating meeting basic needs, and motivational interviewing techniques;
8. Monitor the individual's mental status and provide needed supports in a manner consistent with the individual's level of need and functioning;
9. Deliver all services according to a recovery-based philosophy of care; and
10. Promote self-determination, respect for the individual receiving ACT as an individual in such individual's own right, and engage peers in promoting recovery and regaining meaningful roles and relationships in the community.

"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 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 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," "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 accessing needed services that are responsive to the 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.

"Clinically managed high-intensity residential care" or "Level of care 3.5" means a substance use treatment program that offers 24-hour supportive treatment of individuals with significant psychological and social problems by credentialed addiction treatment professionals in an interdisciplinary treatment approach. A clinically managed high-intensity residential care program provides treatment to individuals who present with significant challenges, such as physical, sexual, or emotional trauma; past criminal or antisocial behaviors, with a risk of continued criminal behavior; an extensive history of treatment; inadequate anger management skills; extreme impulsivity; and antisocial value system.

"Clinically managed low-intensity residential care" or "Level of care 3.1" means providing an ongoing therapeutic environment for individuals requiring some structured support in which treatment is directed toward applying recovery skills; preventing relapse; improving emotional functioning; promoting personal responsibility; reintegrating the individual into work, education, and family environments; and strengthening and developing adaptive skills that may not have been achieved or have been diminished during the individual's active addiction. A clinically managed low-intensity residential care program also provides treatment for individuals suffering from chronic, long-term alcoholism or drug addiction and affords an extended period of time to establish sound recovery and a solid support system.

"Clinically managed population specific high-intensity residential services" or "Level of care 3.3" means a substance use treatment program that provides a structured recovery environment in combination with high-intensity clinical services provided in a manner to meet the functional limitations of individuals. The functional limitations of individuals who are placed within this level of care are primarily cognitive and can be either temporary or permanent.

"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.

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

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

"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.

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

"Credentialed addiction treatment professional" means a person who possesses one of the following credentials issued by the appropriate health regulatory board: (i) an addiction-credentialed physician or physician with experience or training in addiction medicine; (ii) a licensed nurse practitioner or a licensed physician assistant with experience or training in addiction medicine; (iii) a licensed psychiatrist; (iv) a licensed clinical psychologist; (v) a licensed clinical social worker; (vi) a licensed professional counselor; (vii) a licensed nurse practitioner with experience or training in psychiatry or mental health; (viii) a licensed marriage and family therapist; (ix) a licensed substance abuse treatment practitioner; (x) a resident who is under the supervision of a licensed professional counselor (18VAC115-20-10), licensed marriage and family therapist (18VAC115-50-10), or licensed substance abuse treatment practitioner (18VAC115-60-10) and is registered with the Virginia Board of Counseling; (xi) a resident in psychology who is under supervision of a licensed clinical psychologist and is registered with the Virginia Board of Psychology (18VAC125-20-10); or (xii) a supervisee in social work who is under the supervision of a licensed clinical social worker and is registered with the Virginia Board of Social Work (18VAC140-20-10).

"Crisis" means a deteriorating or unstable situation often developing suddenly or rapidly that produces acute, heightened, emotional, mental, physical, medical, or behavioral distress.

"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 training, assistance, and specialized supervision in the acquisition, retention, or improvement of self-help, socialization, and adaptive skills for adults with a developmental disability 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 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 nine years of age, inclusive, who has a substantial developmental delay or specific congenital or acquired condition may be considered to have a developmental disability

without meeting three or more of the criteria described in clauses (i) through (v) if the individual without services and supports has a high probability of meeting those criteria later in life.

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

"Diagnostic and Statistical Manual of Mental Disorders" or "DSM" means the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition, DSM-5, of the American Psychiatric Association.

"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.

"Individual" or "individual receiving services" means a current direct recipient of public or private mental health, developmental, or substance abuse treatment, rehabilitation, or habilitation services and includes the terms "consumer," "patient," "resident," "recipient," or "client". When the term is used in this chapter, the requirement applies to every individual receiving licensed services from the provider.

"Individualized services plan" or "ISP" means a comprehensive and regularly updated written plan that describes the individual's needs, the measurable goals and objectives to address those needs, and strategies to reach the individual's goals. An ISP is person-centered, empowers the individual, and is designed to meet the needs and preferences of the individual. The ISP is developed through a partnership between the individual and the provider and includes an individual's treatment plan, habilitation plan, person-centered plan, or plan of care, which are all considered individualized service plans.

"Informed choice" means a decision made after considering options based on adequate and accurate information and knowledge. These options are developed through collaboration with the individual and his authorized representative, as applicable, and the provider with the intent of empowering the individual and his authorized representative to make decisions that will lead to positive service outcomes.

"Informed consent" means the voluntary written agreement of an individual, or that individual's authorized representative, to surgery, electroconvulsive treatment, use of psychotropic medications, or any other treatment or service that poses a risk of harm greater than that ordinarily encountered in daily life or for participation in human research. To be voluntary, informed consent must be given freely and without undue inducement; any element of force, fraud, deceit, or duress; or any form of constraint or coercion.

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

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

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

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

"Intensity of service" means the number, type, and frequency of staff interventions and other services provided during treatment at a particular level of care.

"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 developmental disability. Intensive in-home service is usually time-limited and is provided typically in the residence of an individual who is at risk of being moved to out-of-home placement or who is being transitioned back home from an out-of-home placement. The service includes 24-hour per day emergency response; crisis treatment; individual and family counseling; life, parenting, and communication skills; and case management and coordination with other services.

"Intermediate care facility/individuals with intellectual disability" or "ICF/IID" means a facility or distinct part of a facility certified by the Virginia Department of Health as meeting the federal certification regulations for an intermediate care facility for individuals with intellectual disability and persons with related conditions and that addresses the total needs of the residents, which include physical, intellectual, social, emotional, and habilitation, providing active treatment as defined in 42 CFR 435.1010 and 42 CFR 483.440.

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

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

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

"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 the presence 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.

"Medically managed intensive inpatient service" or "Level of care 4.0" means an organized service delivered in an inpatient setting, including an acute care general hospital, psychiatric unit in a general hospital, or a freestanding psychiatric hospital. This service is appropriate for individuals whose acute biomedical and emotional, behavioral, and cognitive problems are so severe that they require primary medical and nursing care. Services at this level of care are managed by a physician who is responsible for diagnosis, treatment, and treatment plan decisions in collaboration with the individual.

"Medically monitored intensive inpatient treatment" or "Level of care 3.7" means a substance use treatment program that provides 24-hour care in a facility under the supervision of medical personnel. The care provided includes directed evaluation, observation, medical monitoring, and addiction treatment in an inpatient setting. The care provided may include the use of medication to address the effects of substance use. This service is appropriate for an individual whose subacute biomedical, emotional, behavioral, or cognitive problems are so severe that they require inpatient treatment but who does not need the full resources of an acute care general hospital or a medically managed intensive inpatient treatment program.

"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 opioid treatment" means an intervention of administering or dispensing of medications, such as methadone, buprenorphine, or naltrexone approved by the federal Food and Drug Administration for the purpose of treating opioid use disorder.~~

"Medication for opioid use disorder" or "MOUD" means medications, including opioid agonist medications, approved by the Food and Drug Administration for the use in the treatment of opioid use disorder.

"Medication assisted treatment" or "MAT" means the use of U.S. Food and Drug Administration approved medications in combination with counseling and behavioral therapies to provide treatment of substance use disorders. Medication assisted treatment includes medications for opioid use disorder as well as medications for treatment of alcohol use disorder.

"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" or "MCHSS" means the provision of recovery-oriented services to individuals with long-term, severe mental illness. MCHSS 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. MCHSS may be provided in any setting in which the individual's needs can be addressed, skills training applied, and recovery experienced.

"Mental health intensive outpatient service" means a structured program of skilled treatment services focused on maintaining and improving functional abilities through a time-limited, interdisciplinary approach to treatment. This service is provided over a period of time for individuals requiring more intensive services than an outpatient service can provide and may include individual, family, or group counseling or psychotherapy; skill development and psychoeducational activities; certified peer support services; medication management; and psychological assessment or testing.

"Mental health 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. Mental health 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. Mental health outpatient service specifically includes:

1. Mental health 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. Mental health 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. Mental health 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.

"Mental health 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 provided through a minimum of 20 hours per week of skilled treatment services focused on individuals who require intensive, highly coordinated, structured, and interdisciplinary ambulatory treatment within a stable environment that is of greater intensity than intensive outpatient, but of lesser intensity than inpatient.

"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.

"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.

"Motivational enhancement" means a person-centered approach that is collaborative, employs strategies to strengthen motivation for change, increases engagement in substance use services, resolves ambivalence about changing substance use behaviors, and supports individuals to set goals to change their substance use.

"Neglect" means the failure by 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 an individual receiving care or treatment for mental illness, developmental disabilities, or substance abuse.

"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.

"Opioid treatment practitioner" means a health care professional who is appropriately licensed by a State to prescribe or dispense medications for opioid use disorders and, as a result, is authorized to practice within an opioid treatment program.

"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.

"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, developmental disabilities, or substance abuse (substance use disorders) or (ii) residential services for individuals with brain injury. The person, entity, or organization shall include a hospital as defined in § 32.1-123 of the Code of Virginia, community services board, behavioral health authority, private provider, and any other similar or related person, entity, or organization. It shall not include any individual practitioner who holds a license issued by a health regulatory board of the Department of Health Professions or who is exempt from licensing pursuant to §§ 54.1-2901, 54.1-3001, 54.1-3501, 54.1-3601, and 54.1-3701 of the Code of Virginia.

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

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

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

an employee or independent contractor of the department or a provider licensed by the department.

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

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

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

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

"Quality improvement plan" means a detailed work plan developed by a provider that defines steps the provider will take to review the quality of services it provides and to manage initiatives to improve quality. A quality improvement plan consists of systematic and continuous actions that lead to measurable improvement in the services, supports, and health status of the individuals receiving services.

"Recovery" means a journey of healing and transformation enabling an individual with a mental illness to live a meaningful life in a community of his choice while striving to achieve his full potential. For individuals with substance abuse (substance use disorders), recovery is an incremental process leading to positive social change and a full return to biological, psychological, and social functioning. For individuals with a developmental disability, the concept of recovery does not apply in the sense that individuals with a developmental disability will need supports throughout their entire lives although these may change over time. With supports, individuals with 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 homes, supervised living, residential crisis stabilization, community gero-psychiatric residential, ICF/IID, sponsored residential homes, ~~medical and social detoxification,~~ withdrawal management and neurobehavioral services.

"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 involuntarily restrict the freedom of movement of an individual in an instance when all of the following conditions are met: (i) there is an emergency; (ii) nonphysical interventions are not viable; and (iii) safety issues require an immediate response.

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

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

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

"Risk management" means an integrated system-wide program to ensure the safety of individuals, employees, visitors, and others through identification, mitigation, early detection, monitoring, evaluation, and control of risks.

"Root cause analysis" means a method of problem solving designed to identify the underlying causes of a problem. The focus of a root cause analysis is on systems, processes, and outcomes that require change to reduce the risk of harm.

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

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

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

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

"Level II serious incident" means a serious incident that occurs or originates during the provision of a service or on the premises of the provider that results in a significant harm or threat to the health and safety of an individual that does not meet the definition of a Level III serious incident.

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

1. A serious injury;
2. An individual who is or was missing;
3. An emergency room visit;
4. An unplanned psychiatric or unplanned medical hospital admission of an individual receiving services other than licensed emergency services, except that a psychiatric admission in accordance with the individual's Wellness Recovery Action Plan shall not constitute an unplanned admission for the purposes of this chapter;
5. Choking incidents that require direct physical intervention by another person;
6. Ingestion of any hazardous material; or
7. A diagnosis of:
 - a. A decubitus ulcer or an increase in severity of level of previously diagnosed decubitus ulcer;
 - b. A bowel obstruction; or
 - c. Aspiration pneumonia.

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

1. Any death of an individual;
2. A sexual assault of an individual; or
3. A suicide attempt by an individual admitted for services, other than licensed emergency services, that results in a hospital admission.

"Serious injury" means any injury resulting in bodily hurt, damage, harm, or loss that requires medical attention by a licensed physician, doctor of osteopathic medicine, physician assistant, or nurse practitioner.

"Service" means (i) planned individualized interventions intended to reduce or ameliorate mental illness, 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, developmental disabilities, or substance abuse (substance use disorders). Services include outpatient services, intensive in-home services, medication ~~assisted~~ opioid for opioid use disorder 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) planned individualized interventions intended to reduce or ameliorate the effects of brain injury through care, treatment, or other supports 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.

"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" or "Level of care 2.1" means structured treatment provided to individuals who require more intensive services than is normally provided in an outpatient service but do not require inpatient services. Treatment consists primarily of counseling and education about addiction-related and mental health challenges delivered a minimum of nine to 19 hours of services per week for adults or six to 19 hours of services per week for children and adolescents. Within this level of care an individual's needs for psychiatric and medical services are generally addressed through consultation and referrals.

"Substance abuse outpatient service" or "Level of care 1.0" means a center based substance abuse treatment delivered to individuals for fewer than nine hours of service per week for adults

or fewer than six hours per week for adolescents on an individual, group, or family basis. Substance abuse 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. Substance abuse outpatient service includes substance abuse services or an office practice that provides professionally directed aftercare, individual, and other addiction services to individuals according to a predetermined regular schedule of fewer than nine contact hours a week. Substance abuse outpatient service also includes:

1. Substance abuse 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. Substance abuse 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. Substance abuse 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.

"Substance abuse partial hospitalization services" or "Level of care 2.5" means a short-term, nonresidential substance use treatment program provided for a minimum of 20 hours a week that uses multidisciplinary staff and is provided for individuals who require a more intensive treatment experience than intensive outpatient treatment but who do not require residential treatment. This level of care is designed to offer highly structured intensive treatment to those individuals whose condition is sufficiently stable so as not to require 24-hour-per-day monitoring and care, but whose illness has progressed so as to require consistent near-daily treatment intervention.

"Suicide attempt" means a nonfatal, self-directed, potentially injurious behavior with an intent to die as a result of the behavior regardless of whether it results in injury.

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

"Supportive in-home service" (formerly supportive residential) means the provision of community support services and other structured services to assist individuals, to strengthen individual skills, and that provide environmental supports necessary to attain and sustain independent community residential living. Services include drop-in or friendly-visitor support and counseling to more intensive support, monitoring, training, in-home support, respite care, and family support services. Services are based on the needs of the individual and include training and assistance. These services normally do not involve overnight care by the provider; however, due to the flexible nature of these services, overnight care may be provided on an occasional basis.

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

"Therapeutic day treatment for children and adolescents" means a treatment program that serves (i) children and adolescents from birth through 17 years of age and under certain circumstances up to 21 years of age with serious emotional disturbances, substance use, or co-occurring disorders or (ii) children from birth through seven years of age who are at risk of serious emotional disturbance, in order to combine psychotherapeutic interventions with education and

mental health or substance abuse treatment. Services include: evaluation; medication education and management; opportunities to learn and use daily living skills and to enhance social and interpersonal skills; and individual, group, and family counseling.

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

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

"Withdrawal management" means the dispensing of medication approved for MOUD in decreasing doses to an individual to alleviate adverse physical effects incident to withdrawal from the continuous or sustained use of an opioid and as a method of bringing the individual to an opioid-free state within such a period. Long-term withdrawal management refers to the process of medication tapering that exceeds 30 days.

12VAC35-105-30. Licenses.

A. Licenses are issued to providers who offer services to individuals who have mental illness, a developmental disability, or substance abuse (substance use disorders) 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. Assertive community treatment (ACT);
2. Case management;
3. Clinically managed high-intensity residential care or Level of care 3.5;
4. Clinically managed low-intensity residential care or Level of care 3.1;
5. Clinically managed population specific high-intensity residential or Level of care 3.3;
6. Community gero-psychiatric residential;
7. ICF/IID;
8. Residential crisis stabilization;
9. Nonresidential crisis stabilization;
10. Day support;
11. Day treatment, includes therapeutic day treatment for children and adolescents;
12. Emergency;
13. Group home and community residential;
14. Inpatient psychiatric;
15. Intensive in-home;
16. Medically managed intensive inpatient service or Level of care 4.0;
17. Medically monitored intensive inpatient treatment or Level of care 3.7;
18. ~~Medication-assisted opioid~~ Medication for opioid use disorder treatment;
19. Mental health community support;
20. Mental health intensive outpatient;
21. Mental health outpatient;
22. Mental health partial hospitalization;
23. Psychosocial rehabilitation;
24. Residential treatment;

25. Respite care;
26. Sponsored residential home;
27. Substance abuse intensive outpatient;
28. Substance abuse outpatient;
29. Substance abuse partial hospitalization;
30. Supervised living residential; and
31. 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.

12VAC35-105-925. Standards for the evaluation of new licenses for providers of services to individuals with opioid addiction.

A. Applicants requesting an initial license to provide a service for the treatment of opioid addiction through the use of methadone or any other opioid treatment medication or controlled substance shall supply information to the department that demonstrates the appropriateness of the proposed service in accordance with this section.

B. The proposed site of the service shall comply with § 37.2-406 of the Code of Virginia.

C. In jurisdictions without zoning ordinances, the department shall request that the local governing body advise it as to whether the proposed site is suitable for and compatible with use as an office and the delivery of health care services. The department shall make this request when it notifies the local governing body of a pending application.

D. Applicants shall demonstrate that the building or space to be used to provide the proposed service is suitable for the treatment of opioid addiction by submitting documentation of the following:

1. The proposed site complies with the requirements of the local building regulatory entity;
2. The proposed site complies with local zoning laws or ordinances, including any required business licenses;
3. In the absence of local zoning ordinances, the proposed site is suitable for and compatible with use as offices and the delivery of health care services;
4. In jurisdictions where there are no parking ordinances, the proposed site has sufficient off-street parking to accommodate the needs of the individuals being served and prevent the disruption of traffic flow;
5. The proposed site can accommodate individuals during periods of inclement weather;
6. The proposed site complies with the Virginia Statewide Fire Prevention Code; and
7. The applicant has a written plan to ensure security for storage of methadone at the site, which complies with regulations of the Drug Enforcement Agency (DEA), and the Virginia Board of Pharmacy.

E. Applicants shall submit information to demonstrate that there are sufficient personnel available to meet the following staffing requirements and qualifications:

1. The program sponsor means the person responsible for the operation of the opioid treatment program and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling behavioral health, or social services at the program at any of its medication units. The

program sponsor is responsible for ensuring the program is in continuous compliance with all federal, state, and local laws and regulations.

2. The program director or manager shall be licensed or certified by the applicable Virginia health regulatory board or registered as eligible for this license or certification with relevant training, experience, or both, in the treatment of individuals with opioid addiction. The program director is responsible for the day-to-day management of the program.

3. The medical director shall be a ~~board-certified addictionologist or have successfully completed or will complete within one year a course of study in opiate addiction that is approved by the department~~ physician licensed to practice medicine in the Commonwealth of Virginia with relevant training, experience, or both, in the treatment of individuals with opioid addiction; and:

a. Is responsible for ensuring all medical, ~~psychiatric, nursing, pharmacy, toxicology, and other~~ and behavioral health services offered by the ~~medication-assisted opioid medication for opioid use disorder~~ treatment provider are conducted in compliance with federal regulations at all times; and

b. Shall be physically present at the program for a sufficient number of hours to ensure regulatory compliance and carry out those duties specifically assigned to the medical director by regulation.

4. A minimum of one ~~pharmacist~~ health care professional who is appropriately licensed by the Commonwealth of Virginia to prescribe and dispense medications for opioid use disorders.

5. Nurses.

6. Counselors shall be licensed or certified by the applicable Virginia health regulatory board or eligible for this license or certification.

7. Personnel to provide support services.

8. Have linkage with or access to psychological, medical, and psychiatric consultation.

9. Have access to emergency medical and psychiatric care through affiliations with more intensive levels of care.

10. Have the ability to conduct or arrange for appropriate laboratory and toxicology tests.

11. Ensure all clinical staff, whether employed by the provider or available through consultation, contract, or other means, are qualified by training and experience and appropriately licensed, certified, or registered by the appropriate health regulatory board to serve individuals admitted to the service.

F. The applicant may provide peer recovery specialists (PRS). Peer recovery specialists shall be professionally qualified by education and experience in accordance with 12VAC35-250. A registered peer recovery specialist shall be a PRS registered with the Board of Counseling in accordance with 18VAC115-70 and provide such services as an employee or independent contractor of DBHDS, a provider licensed by the DBHDS, a practitioner licensed by or holding a permit issued from the Department of Health Professions, or a facility licensed by the Virginia Department of Health.

G. If there is a change in or loss of any staff in the positions listed or any change in the provider's ability to comply with the requirements in subsection E of this section, the provider shall formally notify the Substance Abuse and Mental Health Services Administration (SAMHSA) and DBHDS. The provider shall also submit a plan to SAMHSA and DBHDS for immediate coverage within three weeks.

H. Applicants shall submit a description for the proposed service that includes:

1. Proposed mission, philosophy, and goals of the provider;

2. Care, treatment, and services to be provided, including a comprehensive discussion of levels of care provided and alternative treatment strategies offered;
3. Proposed hours and days of operation;
4. Plans for onsite security and services adequate to ensure the safety of patients, staff, and property; and
5. A diversion control plan for dispensed medications, including policies for use of drug screens.

I. Applicants shall, in addition to the requirements of 12VAC35-105-580 C 2, provide documentation of their capability to provide the following services and support directly or by arrangement with other specified providers when such services and supports are (i) requested by an individual being served or (ii) identified as an individual need, based on the assessment conducted in accordance with 12VAC35-105-60 B and included in the individualized services plan:

1. General.
 - a. Psychological services;
 - b. Social services;
 - c. Vocational services;
 - d. Educational services, including HIV/AIDS education and other health education services; and
 - e. Employment services.
2. Initial medical examination services.
3. Special services for pregnant patients.
4. Initial and periodic, individualized, patient-centered assessment and treatment services.
5. Counseling services.
6. Drug abuse testing services.
7. Case management services, including medical monitoring and coordination, with onsite and offsite treatment services provided as needed.

J. Applicants shall submit documentation of contact with community services boards or behavioral health authorities in their service areas to discuss their plans for operating in the area and to develop joint agreements, as appropriate.

K. Applicants shall provide policies and procedures that shall address assessment, administration, and regulation of medication and dose levels appropriate to the individual. The policies and procedures shall at a minimum require that each individual served be assessed every six months by the treatment team to determine if that individual is appropriate for safe and voluntary medically supervised withdrawal from opioid analgesics, including methadone or buprenorphine, alternative therapies including other medication assisted treatments, or continued federally approved pharmacotherapy treatment for opioid addiction.

L. Applicants shall submit policies and procedures describing services they will provide to individuals who wish to discontinue ~~medication-assisted opioid~~ medication for opioid use disorder treatment services.

M. Applicants shall provide assurances that the service will have a community liaison responsible for developing and maintaining cooperative relationships with community organizations, other service providers, local law enforcement, local government officials, and the community at large.

N. The department shall conduct announced and unannounced reviews and complaint investigations in collaboration with the Virginia Board of Pharmacy and DEA to determine compliance with the regulations.

12VAC35-105-930. Registration, certification, or accreditation.

A. The medication ~~assisted opioid~~ for opioid use disorder treatment service shall maintain current registration or certification with:

1. The federal Drug Enforcement Administration;
2. The federal Department of Health and Human Services; and
3. The Virginia Board of Pharmacy.

B. A provider of medication ~~assisted opioid~~ for opioid use disorder treatment services shall maintain accreditation with an entity approved under federal regulations.

12VAC35-105-935. Criteria for patient admission.

A. Before a medication ~~assisted opioid~~ for opioid use disorder treatment program may admit an individual, the individual shall meet the criteria for admission as defined by the provider's policies. The provider's policy regarding admission shall at a minimum require the individual to (i) meet diagnostic criteria for opioid use disorder as defined within the DSM; and (ii) meet the admission criteria of Level 1.0 of ASAM. The policies shall be consistent with subsections B through E of this section.

B. A medication ~~assisted opioid~~ for opioid use disorder treatment program ~~program's physician shall assess individuals to determine if the individual is appropriate for~~ shall maintain current procedures that are designed to ensure that individuals are admitted to short-term or long-term detoxification ~~withdrawal management treatment by qualified personnel, such as a program physician who determines that such treatment is appropriate for the specific individual by applying established diagnostic criteria, documented in the program's procedures. An individual with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the medication-assisted opioid treatment program physician for other forms of treatment. A program shall not admit an individual for more than two detoxification treatment episodes in one year.~~

C. A medication ~~assisted opioid~~ for opioid use disorder treatment program shall maintain current procedures designed to ensure that individuals are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria, that the person is currently ~~addicted~~ has an addiction to an opioid drug, ~~and that the individual became addicted at least one year before admission for treatment.~~ In addition, a program physician shall ensure that each individual voluntarily chooses maintenance treatment, that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the individual, and that each individual provides informed written consent to treatment.

D. ~~A person younger than 18 years of age is required to have had two documented unsuccessful attempts at short term detoxification or drug free treatment within a 12-month period to be eligible for maintenance treatment. No individual younger than 18 years of age may be admitted to maintenance treatment unless~~ without parent, legal guardian, or responsible adult designated by the relevant state authority consents in writing to such treatment.

E. ~~If clinically appropriate, the program physician may waive the requirement of a one-year history of addiction under subsection C of this section, for individuals released from penal institutions (within six months after release), for pregnant patients (program physician must certify pregnancy), and for previously treated individuals (up to two years after discharge).~~

12VAC35-105-945. Criteria for patient discharge.

Before a medication ~~assisted opioid~~ for opioid use disorder treatment program may discharge or transfer an individual, the individual shall meet the criteria for discharge or transfer as defined

by the provider's policies, which shall include provisions for the discharge or transfer of individuals who have:

1. Achieved the goals of the treatment services and no longer require medication ~~assisted opioid~~ for opioid use disorder treatment level of care;
2. Been unable to achieve the goals of the individual's treatment but could achieve the individual's goals with a different type of treatment; or
3. Achieved the individual's original treatment goals but have developed new treatment challenges that can only be adequately addressed in a different type of treatment.

12VAC35-105-960. Initial and periodic assessment services.

A. The provider shall require each individual to undergo an initial medical examination. The initial medical examination is comprised of two parts:

1. A screening examination to ensure that the individual meets the criteria for admission in accordance with 12VAC35-105-935 and that there are no contraindications to treatment with MOUD; and
2. A full history and examination, including a physical examination, to determine the individual's broader health status, with lab testing as determined to be required by an appropriately licensed practitioner. An individual's refusal to undergo lab testing for co-occurring physical health conditions should not preclude access to treatment, provided such refusal does not have the potential to negatively impact treatment with medications.

B. Both the screening examination and the full history and examination shall be completed by an appropriately licensed practitioner. When the examination is performed outside of the provider's service:

1. The written results, narrative of the examination, and available lab testing results, must be transmitted, consistent with applicable privacy laws, to the provider and verified by an opioid treatment practitioner; and

2. If the original examination was not conducted by an opioid treatment practitioner, the screening shall occur not more than seven days prior to the provider's admission.

C. Assuming no contraindications, an individual may begin MOUD treatment after the screening examination is completed.

~~D. The individual's full history and examination shall be completed individual shall have a complete physical examination prior to admission to the service unless the individual is transferring from another licensed medication assisted opioid treatment service in Virginia. The provider shall maintain the report of the individual's physical examination in the individual's service record. The results of serology and other tests shall be available within 14 days of admission.~~

E. Serology testing and other testing as deemed medically appropriate by the program physician based on the screening and physical examination may form part of the examination.

~~BF. In evaluating an individual for treatment, face-to-face or audio-visual telemedicine platforms shall be used for evaluation. When not available, a provider may use audio-only devices, but only when the individual is in the presence of a licensed practitioner who is registered to prescribe and dispense controlled medications. The licensed practitioner shall document being physically present during the audio-only evaluation through signature in the individual's record. The program physician shall review the examination results and order treatment medications as indicated.~~

G. The program physician shall review a consent to treatment form with the patient and sign the form shall document informed written consent prior to the individual receiving the first dose of medication.

~~C.H.~~ The provider shall maintain the report of the individual's physical examination in the individual's service record.

~~D.I.~~ The program shall have a policy to ensure that coordination of care is in place with any prescribing physician.

~~E.J.~~ The provider shall coordinate treatment services for individuals who are prescribed benzodiazepines and prescription narcotics with the treating physician. The coordination shall be the responsibility of the provider's physician and shall be documented.

12VAC35-105-970. Counseling sessions.

~~A.~~ The provider shall conduct face-to-face counseling sessions (either individual or group) at a frequency tailored to each individual based on an individualized assessment and the individual's care plan that was created after shared decision-making between the individual and the clinical team. At a minimum, the provider shall conduct one in-person session once a month for the first year of the individual's treatment and quarterly during the second year. ~~for the first year of an individual's treatment and every month in the second year of the individual's treatment. After two years, the number of face to face counseling sessions that an individual receives shall be based on the individual's progress in treatment.~~ The failure of an individual to participate in counseling sessions shall be addressed as part of the overall treatment process.

~~B.~~ Counseling may be provided directly or through referral. If counseling is provided through referral the provider shall verify and include counseling notes within individual records.

12VAC35-105-990. Take-home medication.

~~A.~~ Determinations for take-home approval shall be based on the clinical judgement of the physician in consultation with the treatment team and shall be documented in the individual's service record. Prior to dispensing regularly scheduled take-home medication, the ~~provider~~ medical director or other program medical practitioner shall ensure the individual demonstrates that the therapeutic benefits of unsupervised doses outweigh the risk ~~a level of current lifestyle stability as evidenced by the following criteria:~~

- ~~1. Regular clinic attendance, including dosing and participation in counseling or group sessions;~~ Absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of harm as it relates to the potential for overdose, or the ability to function safely;
- ~~2. Absence of recent alcohol abuse and illicit drug use;~~ Regularity of attendance for supervised medication administration;
- ~~3. Absence of significant behavior problems;~~ Absence of serious behavioral problems that endanger the individual, the public or others;
- ~~4. Absence of recent criminal activities, charges, or convictions;~~ Absence of known recent diversion activity;
- ~~5. Stability of the individual's home environment and social relationships;~~ Whether take-home medication can be safely transported and stored; and
- ~~6. Length of time in treatment;~~ Any other criteria that the medical practitioner considers relevant to the individual's safety and the public's health.
- ~~7. Ability to ensure take home medications are safely stored; and~~
- ~~8. Demonstrated rehabilitative benefits of take home medications outweigh the risks of possible diversion.~~

~~B.~~ Determinations for the take-home approval shall be based on the clinical judgment of the physician in consultation with the treatment team and shall be documented in the individual's service record. Any individual in comprehensive maintenance treatment that is assessed to be

appropriate to handle take-home medication shall undergo continued assessment and management to ensure suitability.

C. If it is determined that an individual in comprehensive maintenance treatment is appropriate for handling take-home medication, including take-home medication for provider closures, the amount of take-home medication shall not exceed:

1. No take-home medication for the first seven days of treatment.

~~A single take-home dose for one day when the clinic is closed for business, including Sundays and state or federal holidays.~~

2. ~~A single dose each week during the first 90 days of treatment (beyond that in subdivision 1 of this subsection). The individual shall ingest all other doses under the supervision of a medication administration trained employee. A maximum of a five-day consecutive supply of take-home doses from 8 days of treatment to 30 days of treatment.~~

3. ~~Two doses per week in the second 90 days of treatment (beyond that in subdivision 1 of this subsection). A maximum of a 14 day supply of take-home doses from 30 days of treatment to 60 days of treatment.~~

4. ~~Three doses per week in the third 90 days of treatment (beyond that in subdivision 1 of this subsection). A maximum of a 28 day consecutive supply of take-home medication after 60 days of treatment.~~

5. ~~A maximum six-day supply of take-home doses in the remaining months of the first year of treatment.~~

6. ~~A maximum two-week supply of take-home medication after one year of continuous treatment.~~

7. ~~One month's supply of take-home medication after two years of continuous treatment with monthly visits made by the individual served.~~

C. Exceptions to the take-home schedule listed within subsection C may be made if approved by the SOTA or designee.

D. No medication shall be dispensed to individuals in short-term ~~detoxification~~ withdrawal management treatment or interim maintenance treatment for unsupervised take-home use.

E. Medication ~~assisted-opioid for opioid use disorder~~ treatment providers shall maintain current procedures adequate to identify the theft or diversion of take-home medications. These procedures shall require the labeling of containers with the medication ~~assisted-opioid for opioid use disorder~~ treatment providers name, address, and telephone number. Programs shall ensure that the take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child proof containers.

F. The provider shall educate the individual on the safe transportation and storage of take-home medication.

12VAC35-105-1000. Preventing duplication of medication services.

To prevent duplication of medication ~~assisted-opioid for opioid use disorder~~ treatment services to an individual, prior to admission of the individual, the provider shall implement written policy and procedures for contacting every medication ~~assisted-opioid for opioid use disorder~~ treatment service within a 50-mile radius before admitting an individual.

12VAC35-105-1010. Guests.

A. For the purpose of this section a guest is a patient of a medication ~~assisted-opioid for opioid use disorder~~ treatment service in another state or another area of Virginia, who is traveling and is not yet eligible for take-home medication. Guest dosing shall be approved by the individual's home clinic, and the receiving clinic's program physician or medical director.

B. The provider shall not dispense medication to any guest unless the guest has been receiving such medication services from another provider and documentation from that provider has been received prior to dispensing medication.

C. Guests may receive medication for up to 28 days. To continue receiving medication after 28 days, the guest must be admitted to the service. Individuals receiving guest medications as part of a residential treatment service may exceed the 28-day maximum time limit at the medication ~~assisted opioid~~ for opioid use disorder treatment service.

12VAC35-105-1020. Detoxification Withdrawal management prior to involuntary discharge.

The provider shall give an individual who is being involuntarily discharged an opportunity to ~~detoxify~~ withdraw from opioid agonist medication not less than 10 days or not more than 30 days prior to his discharge from the service, unless the state methadone authority has granted an exception.

Article 2

Medically Managed Withdrawal Services

12VAC35-105-1055. ~~Description of level of care provided.~~ (Repealed.)

~~In the service description the provider shall describe the level of services and the medical management provided.~~

12VAC35-105-1060. ~~Cooperative agreements with community agencies.~~ (Repealed.)

~~The provider shall establish cooperative agreements with other community agencies to accept referrals for treatment, including provisions for physician coverage if not provided on-site, and emergency medical care. The agreements shall clearly outline the responsibility of each party.~~

12VAC35-105-1070. ~~Observation area.~~ (Repealed.)

~~The provider shall provide for designated areas for employees and contractors with unobstructed observation of individuals.~~

12VAC35-105-1080. ~~Direct care training for providers of detoxification services.~~ (Repealed.)

A. ~~The provider shall document staff training in the areas of:~~

- ~~1. Management of withdrawal; and~~
- ~~2. First responder training.~~

~~B. Untrained employees or contractors shall not be solely responsible for the care of individuals.~~

12VAC35-105-1090. ~~Minimum number of employees or contractors on duty.~~ (Repealed.)

~~In detoxification service locations, at least two employees or contractors shall be on duty at all times. If the location is within or contiguous to another service location, at least one employee or contractor shall be on duty at the location with trained backup employees or contractors immediately available. In other managed withdrawal settings the number of staff on duty shall be appropriate for the services offered and individuals served.~~

12VAC35-105-1100. ~~Documentation.~~ (Repealed.)

~~Employees or contractors on each shift shall document services provided and significant events in the individual's record.~~

12VAC35-105-1110. ~~Admission assessments.~~ (Repealed.)

~~During the admission process, providers of medically monitored intensive inpatient services shall:~~

- ~~1. Identify individuals with a high risk for medical complications or who may pose a danger to themselves or others;~~
- ~~2. Assess substances used and time of last use;~~
- ~~3. Determine time of last meal;~~
- ~~4. Administer a urine screen;~~
- ~~5. Analyze blood alcohol content or administer a breathalyzer; and~~
- ~~6. Record vital signs.~~

12VAC35-105-1120. Vital signs. (Repealed.)

~~A. Unless the individual refuses, the provider shall take vital signs:~~

- ~~1. At admission and discharge;~~
- ~~2. Every four hours for the first 24 hours and every eight hours thereafter; and~~
- ~~3. As frequently as necessary, until signs and symptoms stabilize for individuals with a high risk profile.~~

~~B. The provider shall have procedures to address situations when an individual refuses to have vital signs taken.~~

~~C. The provider shall document vital signs, all refusals and follow-up actions taken.~~

12VAC35-105-1130. Light snacks and fluids. (Repealed.)

~~The provider shall offer light snacks and fluids to individuals who are not in danger of aspirating.~~