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## **Article 1. General Provisions.**

### **12VAC35-109-10. Definitions.**

"Abuse" as defined by § 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 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; and
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.

"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.

"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" 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 and desires. Case management services include: identifying potential users of the service; assessing needs and planning services using a person centered approach; 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 and revising the service plan as indicated; discharge planning; and monitoring 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 future service needs.

"Center-based day support service" means structured programs for adults with a developmental disability provided to groups or individuals in nonresidential center-based settings. The programs shall provide services for the individual to acquire, retain, or improve skills of self-help, socialization, community integration, employability, and adaptation. Day support services shall focus on enabling the individual to attain or maintain his highest potential level of functioning. Day support services shall offer opportunities for peer interaction and community integration and the enhancement of social networks. Day support services are designed to enhance the following: self-care and hygiene, eating, task learning, community

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resource utilization, environmental and behavioral skills, social skills, medication management, and transportation skills. Providers of this service shall meet all physical site requirements within this chapter.

"Center-based respite care service" means providing temporary, short-term, time limited substitute care of an individual for the purpose of providing relief to the individual's unpaid primary caregiver. Persons providing respite care are recruited, trained, and supervised by a licensed provider. Respite services will be provided in a licensed location maintained by the provider.

"Center-based therapeutic day treatment for children and adolescents" or "center-based TDT" 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. Therapeutic center-based interventions are provided within an office or clinic setting. This service combines psychotherapeutic interventions with education and mental health or substance abuse treatment to provide supports so that at-risk children maintain placement within their school and home. This service shall include assessment; interventions to build daily living skills or enhance social skills; care coordination; and individual, group, or family counseling.

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

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

"Comprehensive assessment" means a comprehensive and written assessment that updates and finalizes the initial assessment. The comprehensive assessment shall consider the individual's needs, strengths, goals, preferences, and abilities within the individual's cultural context and shall be completed in a time period appropriate to the nature and scope of the service provided. The comprehensive assessment includes all relevant social, psychological, medical, and level of care information as the basis for the development of the person-centered comprehensive ISP. The comprehensive assessment may be completed at the time of initial assessment if it includes all elements of the comprehensive assessment. In the event a comprehensive assessment is completed at the time of an initial assessment the provider is not required to update the assessment.

"Contracted employee" or "contractor" means a person that enters into an agreement with a provider to provide specialized services for a specified period of time.

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

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

"Developmental disability" as defined by § 37.2-100 of the Code of Virginia 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

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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.

"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.

"Emergency services (crisis intervention)" means unscheduled and sometimes scheduled crisis intervention, 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 shall provide immediate mental health care in the most appropriate and least restrictive environment available including the home or community, to assist individuals who are experiencing acute psychiatric dysfunction requiring immediate clinical attention or experiencing crisis events originating from behavioral or mental health support needs. Emergency services shall include assessment, short-term counseling designed to stabilize the individual, and care coordination. Emergency services also may include walk-ins, home visits, office visits, jail interventions, and preadmission screening activities associated with the judicial process or telephone contacts.

"Individual" or "individual receiving services" as defined by § 37.2-100 of the Code of Virginia 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.

"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. An assessment is not a service.

“Initial individualized service plan” or “initial ISP” means a written plan developed and implemented within 24 hours of admission to address immediate service, health, and safety needs as identified within the individual’s initial assessment.

"Licensed mental health professional" or "LMHP" means a physician, licensed clinical psychologist, licensed professional counselor, licensed clinical social worker, licensed substance abuse treatment

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practitioner, licensed marriage and family therapist, certified psychiatric clinical nurse specialist, licensed behavior analyst, or licensed psychiatric/mental health nurse practitioner.

“Licensed mental health professional-resident” or “LMHP-R” means the same as “resident” as defined in 18VAC115-20-10 for licensed professional counselors, 18VAC115-50-10 for licensed marriage and family therapists or 18VAC115-60-10 for licensed substance abuse treatment practitioners. A LMHP-resident shall be in continuous compliance with the regulatory requirements of the applicable counseling profession for supervised practice.

"LMHP-resident in psychology" or "LMHP-RP" means an individual in a residency, as that term is defined in 18VAC125-20-10, program for clinical psychologists. An LMHP-resident in psychology shall be in continuous compliance with the regulatory requirements for supervised experience as found in 18VAC125-20-65.

"LMHP-supervisee in social work," "LMHP-supervisee," or "LMHP-S" means the same as "supervisee" as defined in 18VAC140-20-10 for licensed clinical social workers. An LMHP-supervisee in social work shall be in continuous compliance with the regulatory requirements for supervised practice as found in 18VAC140-20-50.

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

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

"Medication administration" means the legally permitted 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, as enumerated in § 54.1-3408 of the Code of Virginia.

"Medication assisted opioid treatment" means an intervention of administering or dispensing of medications, such as methadone, buprenorphine, or naltrexone approved by the U.S. Food and Drug Administration for the purpose of treating 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.

“Mental health intensive outpatient services” 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:

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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 inter-disciplinary ambulatory treatment within a stable environment that is of greater intensity than intensive outpatient, but of lesser intensity than inpatient.

"Mental illness" as defined by § 37.2-100 of the Code of Virginia 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.

"Neglect" as defined by § 37.2-100 of the Code of Virginia means 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.

"Partial hospitalization service" means short-term, non-residential, medically-directed services for individuals who require intensive, highly coordinated, structured and inter-disciplinary ambulatory treatment within a stable environment. Partial hospitalization services are expected to improve or maintain the individual's symptoms and level of functioning, and prevent relapse or hospitalization. Partial hospitalization services are appropriate for individuals with a serious mental illness or co-occurring substance abuse (substance use disorder) that has resulted in functional impairment which substantially interferes with or limits one or more major life activities.

"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.

"Personally identifiable information." "PII," or "individually identifiable health information" means information that is a subset of health information, including demographic information collected from an individual, and:

(1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) that identifies the individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

"Program sponsor" means the person named in the application for certification described in 42 C.F.R. § 8.11(b) as responsible for the operation of the opioid treatment program and who assumes responsibility

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for all its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician as the medical director.

“Protected health information” or PHI” as defined by 45 C.F.R. §160.103 means individually identifiable health information:

- (1) Except as provided in paragraph (2) of this definition that is: (i) transmitted by electronic media; (ii) maintained in electronic media; or (iii) transmitted or maintained in any other form or medium.
- (2) Protected health information excludes individually identifiable health information: (i) in education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g; (ii) in records described at 20 U.S.C.1232g(a)(4)(B)(iv); (iii) in employment records held by a covered entity in its role as employer; and (iv) regarding a person who has been deceased for more than 50 years.

"Provider" as defined by § 37.2-403 of the Code of Virginia 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 or (ii) residential services for persons with brain injury. The person, entity, or organization shall include a hospital as defined in § 32.1-123, 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 § 54.1-3501, 54.1-3601, or 54.1-3701.

"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. Experience may be substituted for education if the person has five years of paid experience in providing direction, development, and implementation, direct supervision, and monitoring to the service provided. QDDPs are responsible for approving assessments and individual service plans or treatment plans to ensure appropriate services are provided to meet the needs of individuals receiving services. The QDDP shall have documented experience developing, conducting, and approving assessments and individual service plans or treatment plans.

"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



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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-trainee" or "QMHP-T" means a person who is receiving supervised training to qualify as a qualified mental health professional and is registered with the board.

"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.

"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 assessment.

"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. Seclusion shall only be utilized within an inpatient hospital and only in an emergency.

"Service" as defined by § 37.2-403 of the Code of Virginia means:

1. Planned individualized interventions intended to reduce or ameliorate mental illness, developmental disabilities, or substance abuse through care, treatment, training, habilitation, or other supports that are delivered by a provider to persons with mental illness, developmental disabilities, or substance abuse. 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
2. 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.

"Substance abuse (substance use disorders)" as defined by § 37.2-100 of the Code of Virginia 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

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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 structured treatment provided to individuals who require more intensive services than an outpatient service can provide, consisting primarily of counseling and education about addiction-related and mental health challenges delivered a minimum of three service hours per service day to achieve 9 to 19 hours of services per week for adults or a minimum of two service hours per service day to achieve 6 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 referrals.

"Substance abuse outpatient service" means substance abuse treatment delivered to individuals for less than 9 hours of service per week for adults, or less than 6 hours per week for adolescents, on an individual, group, or family basis, and usually in a clinic or similar facility or in another location. 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 specifically 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.
4. Substance abuse services or an office practice that provides professionally directed aftercare, individual, and other addiction services to individuals according to a predetermined regulator schedule of fewer than 9 contact hours a week.

"Substance abuse partial hospitalization services" 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.

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

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### **12VAC35-109-20. Services.**

Providers shall be licensed to provide specific services as defined in this chapter or as determined by the commissioner. The following services shall require a center-based license:

1. Center-based day support services;
2. Mental health intensive outpatient service;
3. Mental health outpatient service;
4. Mental health partial hospitalization;
5. Substance abuse partial hospitalization or Level of Care 2.5;
6. Psychosocial rehabilitation service;
7. Substance abuse intensive outpatient or Level of Care 2.1;
8. Substance abuse outpatient or Level of Care 1.0;
9. Center-based therapeutic day treatment for children and adolescents;
10. Center-based respite service; and
11. Medication assisted opioid treatment programs.

### **12VAC35-109-30. Service descriptions.**

- A. 1. Center-based day support services are for individuals with developmental disabilities that focus on enabling the individual to attain or maintain his highest potential level of functioning. Day support services shall offer opportunities for peer interaction and community integration and are designed to enhance the following: self-care and hygiene, eating, task learning, community resource utilization, environmental and behavioral skills, social skills, medication management, and transportation skills. Providers of center-based day support services shall afford individuals receiving services opportunities to participate in community activities and utilize community resources that are based on their personal interests or preferences. Center-based day support services include services provided in a number of different community locations; however, these services shall not be provided within a residential setting.
2. Center-based day support services include the following services:
  - a. Developing problem-solving abilities; sensory, gross, and fine motor control abilities; and communication and personal care skills;
  - b. Developing self, social, and environmental awareness skills;
  - c. Developing skills as needed in positive behavior, using community resources, community safety, and positive peer interactions, volunteering and participating in educational programs in integrated settings, and forming community connections or relationships;
  - d. Supporting older adults in participating in meaningful retirement activities in their communities (i.e., clubs and hobbies);
  - e. Skill-building and providing routine supports related to activities of daily living (ADLs) and instrumental ADLs (IADLs);
  - f. Monitoring the individual's health and physical condition and providing supports with medication and other medical needs;
  - g. Providing safety supports in a variety of community settings;
  - h. Career planning and resume developing based on career goals, personal interests, and community experiences; and
  - i. Providing routine supports and safety supports with transportation to and from community locations and resources.
- B. Mental health partial hospitalization includes time-limited active treatment interventions that are more intensive than intensive outpatient services, designed to stabilize and ameliorate acute symptoms, and

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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 inter-disciplinary ambulatory treatment within a stable environment that is of greater intensity than intensive outpatient but of lesser intensity than inpatient. These programs typically have direct access to psychiatric, medical, and laboratory services. Individuals receiving mental health partial hospitalization services shall be seeking primary treatment for a mental health diagnosis. Individuals may receive services for a co-occurring disorder at the same time.

- C. Mental health intensive outpatient services are provided within a highly structured clinical program provided on an hourly schedule. The program shall include skilled treatment focused on maintaining and improving functional abilities through a time-limited, interdisciplinary approach. This service is provided weekly over a period of time for individuals requiring less intensive interventions than partial hospitalization programs but more intensive services than an outpatient service can provide. This service involves the use of multiple, concurrent interventions and treatment modalities. Individuals receiving mental health intensive outpatient services shall have a primary diagnosis of a mental health disorder. Individuals needing this service shall require a minimum of six hours per week for children or nine hours per week for adults, to a maximum of 19 service hours per week. Mental health intensive outpatient services 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. Individuals receiving mental health intensive outpatient services shall be seeking primary treatment for a mental health diagnosis. Individuals may receive services for a co-occurring disorder at the same time.
- D. Mental health outpatient services include treatment provided on an hourly schedule used to sustain behavioral or emotional gains or to restore cognitive functional levels that have been impaired. Individuals receiving mental health outpatient services shall have a primary diagnosis of a mental health disorder. Mental health outpatient services shall include diagnosis and evaluation, screening and intake, and counseling, as defined in § 54.1-3500 of the Code of Virginia. Counseling may be individual counseling, family counseling, or group counseling. Mental health outpatient services may include individual, family, or group counseling; psychotherapy; behavior management; psychological testing and assessment; laboratory and other ancillary services; medical services; and medication management. Mental health outpatient services shall be for a maximum of six hours per week for children and nine hours per week for adults. Mental health outpatient services includes services provided within a practitioner's office or a mental health clinic. Individuals receiving mental health outpatient services shall be seeking primary treatment for a mental health diagnosis. Individuals may receive services for a co-occurring disorder at the same time. Outpatient services shall not include practitioners who hold a license issued by a health regulatory board of the Department of Health Professions or who are 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.
- E. Psychosocial rehabilitation services include a program of two or more consecutive hours a day provided to groups of individuals in a community setting who require a reduction of impairments due to a mental illness and restoration to the best possible functional level in order to remain in the community. The service provides a consistent, structured environment to restore an individual's ability to manage mental illness. The service provides education about mental illness, substance use disorders, and appropriate medication to avoid complication and relapse, and independent living skills.

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- F. Substance abuse partial hospitalization includes short-term, non-residential interventions that are more intensive than intensive outpatient services. These services are a minimum of 20 hours per week of skilled treatment services, which may include individual and group counseling, medication management, family therapy, educational groups, and occupational and recreational therapy. Individuals receiving substance abuse partial hospitalization services shall have a primary diagnosis of a substance use disorder. Individuals receiving substance abuse partial hospitalization services shall be seeking primary treatment for a substance use disorder. Individuals may receive services for a co-occurring disorder at the same time. Providers of co-occurring enhanced programs shall comply with the provisions of 12VAC35-109-390.
- G. Substance abuse intensive outpatient services include structured programming for 6-19 hours per week for children and 9-19 hours per week for adults, consisting primarily of counseling and education about addiction, mental illness, and recovery. Individuals receiving substance abuse intensive outpatient services shall have a primary diagnosis of a substance use disorder. Individuals receiving substance abuse intensive outpatient services shall be seeking primary treatment for a substance use disorder. Individuals may receive services for a co-occurring disorder at the same time. Providers of co-occurring enhanced programs shall comply with the provisions of 12VAC35-109-430.
- H. Substance abuse outpatient services are addiction services provided in regularly scheduled sessions of fewer than 6 hours per week for children and fewer than 9 hours per week for adults. Individuals receiving substance abuse outpatient services shall have a primary diagnosis of a substance use disorder. Individuals receiving substance abuse outpatient services shall be seeking primary treatment for a substance use disorder. Individuals may receive services for a co-occurring disorder at the same time. Providers of co-occurring enhanced programs shall comply with the provisions of 12VAC35-109-470. Outpatient services shall not include practitioners who hold a license issued by a health regulatory board of the Department of Health Professions or who are 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.
- I. Medication assisted opioid treatment includes services that use FDA-approved medications in combination with counseling and behavioral therapies to provide treatment of substance use disorders.
- J. Center-based therapeutic day treatment services for children and adolescents include assessment; interventions to build daily living skills or enhance social skills, care coordination; and individual, group, or family counseling. center-based TDT includes services provided within an office or clinic setting.
- K. Center-based respite services include 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 caregiver within a center-based setting. Persons providing respite care are recruited, trained, and supervised by a licensed provider. Providers who provide center-based respite services shall have both the service and the site licensed.

**12VAC35-109-40. Screening.**

- A. Providers shall implement screening policies and procedures that include:
  - 1. Identification, qualification, training, and duties of employees responsible for screening;
  - 2. Minimum required elements of screening for a center-based setting including:
    - a. Date of contact;

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- b. Legal name, preferred name, date of birth, sex, and gender of the individual;
  - c. Address and telephone number of the individual, if applicable;
  - d. The reason or reasons why the individual is requesting services;
  - e. Current reported diagnoses and medical conditions;
  - f. Medical symptoms;
  - g. Medications currently being used, including recent increases, decreases, discontinuation, misuse, or overdose of prescription medication;
  - h. Recent or current substance use or dependence including risk for intoxication or substance withdrawal; and
  - i. Status of the individual including his referral to other services, further assessment, placement on a waiting list for services, or admission to the service.
3. Methods to identify other appropriate services to assist individuals who are not admitted.
- B. The provider shall retain documentation of the individual's screening for six months. Documentation shall be included in the individual's record if the individual is admitted to the service.
  - C. The provider shall review all elements of the screening at the time of assessment to ensure all elements are up to date.

#### **12VAC35-109-50. Assessment.**

- 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. In these assessments, 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 appropriately qualified employees or contractors who are responsible for conducting, obtaining or updating assessments and medical screenings. 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. The provider shall use previous assessments or relevant history within the course of treatment, if applicable, as noted within subsection G 5.
- E. Providers shall utilize an assessment tool that shall meet the requirements laid out in subsection F for an initial assessment, and subsection G for a comprehensive assessment. Providers may utilize a standardized state or federally sanctioned assessment tool that does not meet the criteria laid out within these regulations, as long as the tool has been approved by the department.
- F. 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, or obtain information from other qualified providers in order to 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.
  1. The initial assessment shall assess immediate service, health, and safety needs, and at a minimum include the individual's:
    - a) Diagnosis;
    - b) Presenting needs including the individual's stated needs, psychiatric needs, support needs, and the onset and duration of needs;

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- c) Current medical issues;
- d) Current medications;
- e) Current and past substance use, including co-occurring mental health and substance use disorders; and
- f) At-risk behavior to self and others; and
- g) Risk factors that will impact the individual's ability to seek treatment or to participate in services.

2. For providers treating substance use disorders, at the time of the initial assessment the provider shall:

- a) Identify individuals with a high-risk for medical complications or who may pose a danger to themselves or others; and
- b) Assess substances used and time of last use;

3. The comprehensive assessment may be completed at the time of initial assessment if it includes all elements noted within subsection G. In the event a comprehensive assessment is completed at the time of an initial assessment, the provider is not required to update the assessment unless a reassessment is medically or clinically indicated.

G. A comprehensive assessment shall update and finalize the initial assessment, unless the comprehensive assessment is completed at the time of 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 developmental services. It shall address:

1. Onset and duration of needs;
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 including unsuccessful interventions and outcomes. The provider shall ensure previous assessments are utilized to note unsuccessful interventions as required by 12VAC35-109-60 D; center-based respite providers are exempt from this requirement.
6. Financial situation, financial resources, financial support and benefits, and whether the individual has the means to meet his financial needs;
7. Health history and current medical care needs, to include:
  - a. Allergies, including allergies to food and medications;
  - 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;
  - i. Serious illnesses and chronic conditions of the individual's parents, siblings, and significant others in the same household; and
  - 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 dependence, and circumstances that increase the individual's risk for mental illness or substance use issues;

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9. History of abuse, neglect, sexual or domestic violence, or other trauma including psychological trauma;
10. Legal competency 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, fall risk, communication needs, and mobility and adaptive equipment needs.

H. The provider shall retain documentation of the individual's assessments in the individual's record for a minimum of six years after the individual's discharge in accordance with § 54.1-2910.4 of the Code of Virginia.

**12VAC35-109-60. Individualized services plan (ISP); Individualized supports plan; Service planning.**

- 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.
  1. Providers of developmental services shall develop and implement a plan for supports, which is a component of the comprehensive individual support plan, no later than 24 hours after admission. The initial plan for supports shall address immediate health and safety needs, may include assessment activities, and shall continue in effect until the ongoing comprehensive plan of supports is developed or the individual is discharged, whichever comes first. Providers shall collaborate with the individual's planning team to develop and implement the initial person-centered plan for supports, for the first 60 days. An ongoing comprehensive plan for supports shall be completed within 60 days.
  2. Providers of mental health or substance abuse services shall develop and implement the initial ISP no later than 24 hours after admission to address immediate service, health, and safety needs and shall continue implementation until the comprehensive ISP is developed or the individual is discharged, whichever comes first. The provider shall develop and implement an initial person-centered ISP for the first 30 days. The provider shall implement a person-centered, comprehensive ISP based upon the nature and scope of services as soon as possible after admission but no later than 30 days after admission. Providers of short-term intensive services that are typically provided for less than 30 days shall implement a comprehensive ISP no later than 48 hours after admission.
- B. If an individual has a case manager, informed choice shall be governed by 12VAC35-112. Case management service specific requirements. If the individual does not have a case manager, the initial ISP and the comprehensive ISP shall be developed based on the respective assessment with the participation and informed choice of the individual receiving services.
  1. To ensure the individual's participation and informed choice, the following shall be explained to the individual or his authorized representative, as applicable, in a reasonable and comprehensible manner:



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- a) The proposed services to be delivered;
  - b) Any alternative services that might be advantageous for the individual; and
  - c) Any accompanying risks or benefits of the proposed alternative services.
2. If no alternative services are available to the individual, it shall be clearly documented within the ISP or within documentation attached to the ISP, that alternative services were not available as well as any steps taken to identify if alternative services were available.
  3. Whenever there is a change to an individual's ISP it shall be clearly documented within the ISP or within documentation attached to the ISP that:
    - a. The individual participated in the development of or revision to the ISP;
    - b. The proposed and alternative services and their respective risks and benefits were explained to the individual or the individual's authorized representative, and;
    - c. The reasons the individual or the individual's authorized representative chose the option included in the ISP.

**12VAC35-109-70. ISP requirements.**

- A. The initial ISP shall be based on the individual's immediate service, health, and safety needs identified in the initial assessment. The initial ISP shall include:
  1. Relevant and attainable goals, measurable objectives, and specific strategies for addressing needs and preferences consistent with a center-based setting as documented within the individual's initial assessment;
  2. Services and supports and frequency of services planned to accomplish the goals including relevant psychological, mental health, substance abuse, behavioral, developmental, medical, rehabilitation, training, and nursing needs and supports;
  3. The role of the individual and others, including the individual's family, if appropriate, in implementing the services plan; and
  4. Target dates for accomplishment of goals and objectives.
- B. The comprehensive ISP shall be based on the individual's needs, strengths, abilities, personal preferences, goals, and natural supports identified in the comprehensive assessment. The comprehensive ISP shall include:
  1. Relevant and attainable goals, measurable objectives, and specific strategies for addressing each need documented within the individual's comprehensive assessment, including documentation that the individual's needs require a provider-operated center-based setting;
  2. Services and supports required to accomplish the goals including relevant psychological, mental health, substance abuse, behavioral, developmental, medical, rehabilitation, training, and nursing needs and supports;
  3. The frequency at which services and supports must be provided to accomplish the individual's goals;
  4. The role of the individual and others, including the individual's family, if appropriate, in implementing the ISP;

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5. A communication plan for individuals with communication barriers, including language barriers;
  6. A behavioral support or treatment plan, if applicable;
  7. A safety plan that addresses identified risks to the individual or to others, including a fall risk plan, if applicable;
  8. A crisis or recovery plan, if applicable;
  9. Target dates for accomplishment of goals and objectives;
  10. Identification of employees or contractors responsible for coordination and integration of services, including employees of other agencies, if applicable;
  11. A transportation plan, if applicable
  12. Recovery plans, if applicable;
  13. Services the individual elects to self-direct, if applicable; and
  14. Projected discharge plan and estimated length of stay within the service.
- C. Both the initial and comprehensive 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.
1. If the signature of the individual receiving services or the authorized representative cannot be obtained, the provider shall document attempts to obtain the necessary signature and the reason why it was unobtainable. The provider shall continue to make attempts to obtain the necessary signature for the length of time the ISP is in effect. An attempt to obtain the necessary signature shall occur at a minimum each time the provider reviews the ISP as required by 12VAC35-109-80 E.
  2. The ISP shall be distributed to the individual and others authorized to receive it prior to the implementation of the ISP. The provider shall document within the individual's record that the ISP was distributed.
- D. The provider shall designate a person who shall be responsible for developing, implementing, reviewing, and revising each individual's ISP in collaboration with the individual or authorized representative, as appropriate.
- E. Employees or contractors who are responsible for implementing the ISP shall demonstrate a working knowledge of the objectives and strategies contained in the individual's current ISP, including the individual's detailed health and safety protocols. In addition, the following shall occur:
1. Providers shall educate and train employees or contractors who are responsible for implementing the ISP on the objectives and strategies contained within the individual's current ISP.
  2. After training on the individual's current ISP, providers shall maintain documentation of the employee or contractor's education, training, and competency demonstrated through supervision.

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3. When changes occur to an individual's ISP, employees or contractors who are responsible for implementing the ISP shall be made aware of changes as applicable to their duties and shall be competent to implement the revised ISP.

- F. 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.
- G. Whenever possible the identified goals in the ISP shall be written in the words of the individual receiving services.
- H. The provider shall use signed and dated progress notes to document the implementation of the goals and objectives contained within the ISP.
- I. A copy of the individual's most current ISP shall be readily accessible at the center where the individual receives services.

#### **12VAC35-109-80. Reassessments and ISP reviews.**

A. 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. Reassessment shall include documented justification that the individual's needs continue to require a provider-operated center-based setting.

B. The provider shall actively involve the individual and authorized representative, if applicable, in reassessments. The provider shall consider the individual's needs, strengths, goals, preferences, and abilities within the individual's cultural context.

C. Providers shall complete changes to the ISP as a result of any reassessment, if necessary or if desired by the individual. If an assessment indicates no changes to the ISP are necessary, the provider shall document that no changes are necessary and the reasoning.

D. If necessary as a result of a reassessment, providers shall complete changes to medical protocols or collaborate with other providers to ensure changes are made to medical, behavioral, or any other corresponding protocols.

E. The provider shall complete quarterly reviews of the ISP in writing at least every three months from the date of the implementation of the comprehensive ISP or whenever there is a reassessment. The review of the ISP shall be conducted in a person-centered manner to determine if services are being delivered as described within the ISP. The individual receiving services and the authorized representative, if applicable, shall be included in the ISP review, to determine if the individual's treatment needs and preferences are being met and the individual is satisfied with the services provided.

- 1. A review of the ISP shall evaluate the individual's progress toward meeting the 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. A review of the ISP shall document evidence of or lack 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, or goals and objectives the individual has not made progression toward, the provider and any appropriate planning

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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. The provider shall retain documentation of this meeting and the individual's informed choice within the individual's record. Documentation of the quarterly review shall be added to the individual's record no later than 15 calendar days from the date the review was due to be completed, with the exception of case management services.

4. A review of the ISP shall note the:

- a. Individual's family involvement, if any, in the individual's treatment;
- b. Change if the individual no longer needs the intensity of care provided within a center-based setting;
- c. Individual's progress towards discharge; and
- d. Status of the individual's discharge planning.

G. The provider shall ensure after each reassessment that the individual's most current ISP is easily accessible at the center at which the individual receives services.

**12VAC35-109-90. Progress notes or other documentation.**

- A. The provider shall have a policy or process to ensure that progress notes are consistent in format across the provider's service. The policy shall include the timeframe in which progress notes shall be entered into the individual's record.
- B. The provider shall use signed and dated progress notes or other documentation to document the services provided. Progress notes shall, at a minimum:
  1. Be legible and readable;
  2. Record events of the individual's interaction with the staff writing the progress note, including care provided and events relevant to diagnosis and treatment or care of the individual;
  3. Have a narrative component;
  4. Describe needed follow-up care or note which objective within the ISP will receive focus the next time the individual receives services; and
  5. Be signed and dated by the staff who rendered the service.
- C. The provider shall document if the individual no longer needs the intensity of care provided within a center-based setting.
- D. Communication logs, information notes, and supervision notes shall not be considered progress notes.

**12VAC35-109-100. Staffing.**

- A. For the purpose of this section the term supervision shall mean the ongoing process performed by a direct supervisor who monitors the performance of direct care staff and provides regular documented consultation and instruction with respect to the skills and competencies of the direct care staff. Supervision may be delegated to an employee or contractor who meets the qualifications for supervision as defined within this section. Any person providing supervision shall:
  1. Have experience in working with individuals receiving services and in providing the services outlined in the provider's service description; and
  2. Have the responsibility for approving assessments and ISPs, as appropriate.
- B. The provider shall have a written staffing policy and staffing plan as required by 12VAC35-105-310. The staffing policy shall require, at a minimum, that supervision shall be:

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1. Appropriate to the services provided and the needs of the individual; and
  2. Documented.
- C. The provider shall meet the following staffing requirements related to supervision:
1. Supervision of mental health, substance abuse, or co-occurring services that are of an acute or clinical nature such as outpatient 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 under the Department of Health Professions.
  2. Supervision of mental health, substance abuse, or co-occurring services that are of a supportive or maintenance nature, such as psychosocial rehabilitation, 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. A person who is a QMHP-E may not provide this type of supervision.
- D. Supervision of developmental services shall be provided by a person with at least one year of documented experience working directly with individuals who have 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 education if the person has five years paid experience in providing direction, development, implementation, and monitoring of the service provided. Supervisors responsible for approving assessments and ISPs or treatment plans to ensure appropriate services are provided to meet the needs of individuals receiving services shall have documented experience developing, conducting, and approving assessments and ISPs or treatment plans. The supervisor's experience shall meet the requirements listed within the employee's job description required by 12VAC35-105-280.
- E. Center-based day support services shall meet the following staffing requirements:
1. A ODDP; and
  2. Additional staff sufficient to meet the needs of the individuals receiving services.
- F. Mental health partial hospitalization services shall meet the following staffing requirements:
1. A board certified or board eligible psychiatrist. For services serving children under the age of 14, the psychiatrist must be a board certified or board eligible child and adolescent psychiatrist;
  2. A licensed nurse practitioner;
  3. A licensed mental health professional; and
  4. A peer recovery specialist (PRS) certified in accordance with 12VAC35-250.
  5. Staff shall be cross-trained to understand mental illness, signs, and symptoms of substance use disorders, and be able to understand and explain the uses of psychotropic medication and interactions with substance use and other addiction disorders.
  6. Individual, group, and family therapy and crisis intervention shall be provided by a LMHP, LMHP-R, LMHP-RP, or LMHP-S.
  7. Health literacy counseling or psychoeducational interventions must be provided by a LMHP, LMHP-R, LMHP-RP, LMHP-S, Nurse Practitioner, physician assistant, occupational therapist, or a RN or LPN with at least one year clinical experience.
  8. Crisis treatment shall be provided by a LMHP, LMHP-R, LMHP-RP, LMHP-S, QMHP-A, QMHP-C, or QMHP-T.
  9. Skills restoration, skills development, and care coordination shall be provided by a LMHP, LMHP-R, LMHP-RP, LMHP-S, QMHP-A, QMHP-C, or QMHP-T.

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10. Peer recovery support services shall be provided by a PRS certified in accordance with 12VAC35-250.
- G. Mental health intensive outpatient services shall meet the following staffing requirements:
1. A clinical director who shall be a licensed clinical psychologist, licensed professional counselor, or licensed clinical social worker, or a licensed marriage and family therapist;
  2. Physician, nurse practitioner, or physician assistant;
  3. A licensed mental health professional;
  4. A QMHP; and
  5. A peer recovery specialist certified in accordance with 12VAC35-250.
  6. Staff shall be cross-trained to understand mental illness, signs and symptoms of substance use disorders, understand and be able to explain the uses of psychotropic medications, and understand the interaction substance use and other addictive disorders have on mental illness.
  7. Staffing ratios of mental health intensive outpatient services shall not exceed one staff member per five individuals. Clinical supervision of staff ratio shall not exceed one supervisor for six direct care workers. This provision shall not supersede 12VAC35-106-280. Staff shall have education, training, and experience working with individuals receiving services, including diagnosis and age and in providing the services outlined in the service description.
  8. Individual, group, and family therapy shall be provided by a LMHP LMHP-R, LMHP-RP, or LMHP-S.
  9. Skills restoration, skills development, crisis treatment, and care coordination shall be provided by a LMHP, LMHP-R, LMHP-RP, LMHP-S, QMHP-A, QMHP-C, or QMHP-T.
  10. Health literacy counseling and psychoeducation interventions shall be provided by a LMHP, LMHP-R, LMHP-RP, LMHP-S, nurse practitioner, physician assistant, occupational therapist, or a registered nurse or licensed practical nurse with at least one year of clinical experience.
  11. Peer recovery support services shall be provided by a PRS certified in accordance with 12VAC35-250.
- H. Mental health outpatient services shall meet the following staffing requirements:
1. A LMHP, LMHP-R, LMHP-RP, or a LMHP-S who shall conduct an intake interview with the individual, record medical history, conduct an intake assessment, record a diagnosis, and develop the ISP; and
  2. Staff sufficient to fulfill the services described within the provider's service description.
- I. Medication assisted opioid treatment services shall meet the following staffing requirements:
1. A program sponsor;
  2. A program director;
  3. A medical director;
  4. A pharmacist;
  5. Nurses;
  6. Counselors;
  7. Personnel to provide support services; and
  8. Linkage or access to psychological, psychiatric, and medical consultation.
  9. These staff shall meet the credential requirements of 12VAC35-109-210 E.
- J. Psychosocial rehabilitation services shall meet the following staffing requirements:

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1. A comprehensive needs assessment shall be conducted by a LMHP, LMHP-R, LMHP-RP, or LMHP-S.
  2. Services shall be provided by a LMHP, LMHP-R, LMHP-RP, LMHP-S, QMHP-A, QMHP-C, QMHP-T or a QPPMH under the supervision of a QMHP-A, QMHP-C, or LMHP.
  3. Services that continue more than six months shall be reviewed by a LMHP, LMHP-R, LMHP-RP, or LMHP-S. The LMHP, LMHP-R, LMHP-RP, or LMHP-S shall determine and document the continued need for the service.
- K. Substance abuse partial hospitalization services shall meet the following staffing requirements:
1. Have an interdisciplinary team of addiction treatment professionals, which may include counselors, psychologists, social workers, and addiction-credentialed physicians. Physicians treating individuals in this level shall have specialty training or experience in addiction medicine;
  2. Have staff able to obtain and interpret information regarding the individual's biopsychosocial needs;
  3. Have staff trained to understand the signs and symptoms of mental illness and to understand and be able to explain the uses of psychotropic medications and their interactions with substance-related disorders; and
  4. Ensure all clinical staff 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.
- L. Substance abuse intensive outpatient services shall meet the following staffing requirements:
1. Have an interdisciplinary team of appropriately credentialed addiction treatment professionals, which may include counselors, psychologists, social workers, and addiction-credentialed physicians. Physicians shall have specialty training or experience in addiction medicine or addiction psychiatry;
  2. Have program staff that are able to obtain and interpret information regarding the individual's biopsychosocial needs;
  3. Have program staff trained to understand the signs and symptoms of mental illness and to understand and be able to explain the uses of psychotropic medications and their interactions with substance use and other addictive disorders; and
  4. Ensure all clinical staff 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.
- M. Substance abuse outpatient services shall meet the following staffing requirements:
1. Have appropriately credentialed or licensed treatment professionals who assess and treat substance-related mental and addictive disorders;
  2. Have program staff who are capable of monitoring stabilized mental health problems and recognizing any instability of individuals with co-occurring mental health conditions;
  3. Provide medication management services by a licensed independent practitioner with prescribing authority; and
  4. Ensure all clinical staff 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.

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- N. Center-based therapeutic day treatment services for children and adolescents shall meet the following staffing requirements:
1. A licensed clinician or a LMHP, LMHP-R, LMHP-RP, or LMHP-S; and
  2. A QMHP-C.
- O. Center-based respite services shall meet the following staffing requirements:
1. A QDDP; and
  2. Staff shall meet the requirements of 12VAC35-106-280.

**12VAC35-109-110. Health care policy.**

A. The provider shall implement a policy appropriate to the scope and level of service the provider provides that addresses provision of adequate and appropriate medical care. This policy shall describe:

1. How medical care needs will be assessed, including circumstances that will prompt the decision to obtain a medical assessment.
2. How ISPs will address any medical care needs appropriate to the scope and level of service.
3. To what extent the provider will provide, arrange, or support the individual with the provision of medical and dental services identified at admission.
4. To what extent the provider will provide, arrange, or support the individual with the provision of routine ongoing and follow-up medical and dental services after admission.
5. How the provider will communicate the results of physical examinations, medical assessments, diagnostic tests, treatments, or examinations conducted by the provider to the individual and authorized representative, as appropriate.
6. How the provider will keep accessible to staff and contractors on duty the names, addresses, and phone numbers of the individual's medical and dental providers.
7. To what extent the provider will ensure a means for facilitating and arranging, as appropriate, transportation to medical and dental appointments and medical tests.
8. How the provider will ensure the provision of emergency medical services for each individual.

B. The provider shall implement written policies to identify any individuals who are at risk for falls and develop and implement a fall prevention and management plan and program for each at-risk individual.

C. The provider shall implement written infection control measures including the use of universal precautions.

D. The provider shall report outbreaks of infectious diseases to the Department of Health pursuant to § 32.1-37 of the Code of Virginia.

E. All employees, contractors, students, or volunteers in substance abuse outpatient services shall receive tuberculosis education on an annual basis. The education shall focus on self-presentation in the event of exposure to active tuberculosis or the development of symptoms of active tuberculosis disease.

**12VAC35-109-120. Emergency preparedness and response plan.**

- A. The scope of emergency preparedness in relation to this section applies to disasters as defined by §44.146.16 of the Code of Virginia.
- B. The provider shall develop a written emergency preparedness and response plan for all services and locations. This plan shall include:
  1. Annexes dedicated to the highest-priority hazards as indicated by the vulnerability analysis which include documentation of specific plans, policies, and procedures to prevent, mitigate,



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- prepare for, respond to, and recover from the hazards most likely to disrupt provider operations.
2. Procedures for emergency medical drills and a schedule to conduct emergency medical drills;
  3. An evacuation plan which includes:
    - a. Documented, current consideration of local and regional sites that could function as evacuation locations or stop-over points, including documentation of any arrangements the provider has made with such sites.
    - b. Policy and procedure for executing an evacuation or individual relocation to include individual and staff tracking and preservation of all critical services (pharmacy, feeding, etc.).
    - c. Policy and procedure for handling personal health information (PHI) during an evacuation or relocation to ensure the PHI is both properly secured and accessible at the new location (or by new service providers) to allow for proper continuity of care.
  4. The provider shall develop a written communication plan detailing:
    - a. The process for notifying local and state authorities of an emergency;
    - b. The process for notifying and communicating with staff, employees, contractors, volunteers, and community responders during emergencies.
    - c. The process for warning, notifying, and communicating with individuals receiving services.
    - d. The process for notifying and communicating with family members or authorized representatives; during emergencies.
  5. The provider shall develop a written continuity of operations plan detailing:
    - a) Delegation of authority under emergency conditions;
    - b) Succession planning for emergency conditions.
    - c) Indication of which services are critical to the health and well-being of the individual(s) receiving services that must continue, services less critical that may be delayed, ancillary services that may be discontinued during emergency circumstances, and triggers with regard to the activation of the plan for continuity of these services. Documented plans for continuity of activities related to the provision of care, treatment, and services including scheduling, modifying, or discontinuing services; PII and PHI access and security; providing medication; and transportation services.
5. The provider shall implement annual emergency preparedness and response training for all employees, contractors, students, and volunteers pursuant to 12VAC35-106-300 B. This training shall also be provided during the onboarding of new employees. This training shall include:
- a. Activation and notification for the emergency plan;
  - b. Evacuation procedures that include individuals with functional and accessibility needs;
  - c. Use, maintenance, and operation of any emergency equipment;
  - d. Medical record stewardship during emergencies; and
  - e. Utilization of community support services in emergencies.
6. The provider shall document review of the emergency preparedness plan and continuity of operations plan annually and make necessary revisions. Any revisions shall be communicated to employees, contractors, students, volunteers, and individuals receiving services; incorporated into

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training for employees, contractors, students, and volunteers; and incorporated into the orientation of individuals to services, as appropriate.

**12VAC35-109-130. Food service.**

A. Any location where the provider is responsible for preparing or serving food shall request inspection and shall obtain approval by state or local health authorities regarding food service and general sanitation at the time of the original application and annually thereafter. Documentation of the three most recent inspections and approval shall be kept on file.

B. A provider preparing and serving food shall:

1. Implement a written plan for the provision of food service that ensures access to nourishing, well-balanced, varied, and healthy meals;
2. Make reasonable efforts to prepare meals that consider the cultural background, personal preferences, and food habits and that meet the dietary needs of the individuals receiving services; and
3. Assist individuals who require assistance feeding themselves in a manner that effectively addresses any deficits.

C. Providers shall implement a policy to monitor each individual's food consumption and nutrition for:

1. Warning signs of changes in physical or mental status related to nutrition; and
2. Compliance with any needs determined by the ISP or prescribed by a physician, nutritionist, or health care professional.

**12VAC35-109-140. Laundry areas.**

A. Appropriate space and equipment in good repair shall be provided if laundry is done at the location.

B. For all services in which it is appropriate:

1. A clean quantity of linens shall be available at all times to provide for proper care and comfort of individuals receiving services.
2. Linens and other laundry must be handled, stored and processed to control the spread of infection.
3. Clean linens shall be stored in a clean and dry area accessible to staff.
4. Soiled linens shall be stored in covered containers in separate, well ventilated areas and shall not accumulate.
5. Soiled linen shall not be sorted, laundered, rinsed or stored in bathrooms, resident rooms, kitchens or food storage areas.
6. Arrangements for laundering individual's personal clothing shall be provided. If laundry facilities are not provided on premises, commercial laundry services shall be utilized.

**12VAC35-109-150. Building inspection and classification.**

All locations shall be inspected and approved as required by the appropriate building regulatory entity. Documentation of approval shall be a Certificate of Use and Occupancy indicating the building is classified for its proposed licensed purpose. The provider shall submit a copy of the Certificate of Use and Occupancy to the department for new locations.

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**12VAC35-109-160. Physical environment.**

- A. The physical environment, design, structure, furnishings, and lighting shall be appropriate to the individuals receiving services and the services provided.
- B. The physical environment shall be accessible to individuals with physical and sensory disabilities, if applicable.
- C. The physical environment and furnishings shall be clean, dry, free of foul odors, safe, and well-maintained.
- D. Floor surfaces and floor coverings shall promote mobility in areas used by individuals and shall promote maintenance of sanitary conditions. There shall be clear pathways of egress through the service setting, free of tripping hazards, to ensure that all individuals can move about the setting safely. Any electrical cords, extension cords, or power strips utilized by the provider shall be properly secured and not be placed anywhere that the cord can cause trips or falls.
- E. Heat shall be evenly distributed in all rooms occupied by individuals such that a temperature no less than 68 degrees Fahrenheit is maintained, unless otherwise mandated by state or federal authorities. Natural or mechanical ventilation to the outside shall be provided in all rooms used by individuals. Individual or mechanical ventilating systems shall be provided in all rooms occupied by individuals when the temperature in those rooms exceeds 80 degrees Fahrenheit.
- F. Plumbing shall be maintained in good operational condition. Adequate hot and cold running water of a safe and appropriate temperature shall be available. Hot water accessible to individuals receiving services shall be maintained within a range of 100-120° Fahrenheit. Precautions shall be taken to prevent scalding from running water.
- G. Adequate provision shall be made for the collection and legal disposal of garbage and waste materials.
- H. The physical environment, structure, furnishings, and lighting shall be kept free of vermin, rodents, insects, and other pests.
- I. If smoking is permitted, the provider shall make provisions for alternate smoking areas that are separate from the service environment.
- J. For all program areas added after September 19, 2002, minimum room height shall be 7-1/2 feet.

**12VAC35-109-170. Building and grounds.**

- A. The interior and exterior of all buildings shall be safe, properly maintained, clean, and in good working order. This includes, but is not limited to, required locks, mechanical devices, indoor and outdoor equipment, and furnishings.
- B. The provider shall have policies for infrastructure concerns including utility shut-off.

**12VAC35-109-180. Floor plan and building modifications.**

- A. All services shall submit floor plans with room dimensions to the department for new locations. New locations require a modification application to be submitted to the department as required by 12VAC35-106-80 at least 30 days prior to opening the new location.
- B. Within the modification application to be submitted to the department as required by 12VAC35-106-80, the provider shall submit building plans and specifications for any planned construction at a new location, changes in the use of existing locations, and any structural modifications or additions including renovations to existing locations where services are provided.

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C. The provider shall submit an interim plan to the department addressing the health and safety of individuals and continued service delivery if new construction involving structural modifications, additions, or renovations to existing buildings is planned. The interim plan shall be submitted along with the modification application which is required by 12VAC35-106-80.

**12VAC35-109-190. Lighting.**

A. Artificial lighting shall be by electricity.

B. All areas within buildings shall be lighted for safety and the lighting shall be sufficient for the activities being performed.

C. Lighting in halls shall be adequate at night for safe egress.

D. Operable flashlights or battery-powered lanterns shall be available for each staff member on the premises between dusk and dawn to use in emergencies.

E. Outside entrances and parking areas shall be lighted as appropriate for protection against injuries and intruders.

**12VAC35-109-200. Sewer and water inspections.**

A. Service locations shall be on a public water and sewage system or on a nonpublic water and sewage system. Prior to a location being licensed, the provider shall obtain the report from the building inspector pertaining to the septic system and its capacity. Nonpublic water and sewer systems shall be maintained in good working order and in compliance with local and state laws.

B. Service locations that are not on a public water system shall have a water sample tested prior to being licensed and annually by an accredited, independent laboratory for the absence of coliform. The water sample shall also be tested for lead or nitrates if recommended by the local health department. Documentation of the three most recent inspections shall be kept on file.

**Article 2. Additional requirements for medication assisted opioid treatment providers.**

**12VAC35-109-210. 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;

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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 receiving services 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 U.S. 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(s) named in the application for licensing and shall have relevant training, experience, or both, in the treatment of individuals with opioid addiction.
2. The program director 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.
3. The medical director shall be a physician. The medical director shall have completed an accredited residency training program.
4. A minimum of one pharmacist.
5. A minimum of one registered nurse (RN) staffed with licensed practical nurses (LPNs), if warranted to meet the needs and number of patients served. All LPNs hired shall be supervised by a RN.
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 which shall include at least one security guard trained in accordance with 12VAC35-106-300.
8. Have linkage with or access to psychological, psychiatric, and medical consultation.
9. Have access to emergency medical, psychological, and psychiatric care through affiliations with providers of 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. A PRS shall be professionally qualified by education and experience in accordance with 12VAC35-105-250. 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

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practitioner licensed by or holding a permit issued from the Department of Health Professions, or a facility licensed by the Department of Health.

G. If there is a change in or loss of any staff in the positions listed in subsections E 1-4, the department requires written notification and a plan for immediate coverage within one week.

H. The personnel in the positions in subsection E shall have the following responsibilities as reflected within written job descriptions as submitted by the applicant:

1. The program sponsor shall be responsible for the operation of the OTP and shall assume responsibility for all its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling 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 shall be responsible for the day-to-day management of the program.
3. The medical director shall be responsible for ensuring all medical, psychiatric, nursing, pharmacy, toxicology, and other services offered by the OTP are conducted in compliance with federal regulations at all times; and, shall be 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. The medical director shall be present at a minimum one hour per week for every 50 enrolled patients.
4. Counselors shall meet the following primary caseload requirements: The ratio of full-time equivalent individual counselors to individuals receiving services shall be no greater than one to fifty. Counselor to individuals receiving shall be individually determined based on the specific needs of the individual receiving services and allow the individual access to the primary counselor more frequently if needed or requested by the individual.
5. I. 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 ~~on-site~~ 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.

J. 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 receiving services 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 Services

- a. Medical;
- b. Counseling;
- c. Social;

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- d. Vocational;
- e. Educational, including HIV/AIDS education and other health education services; and
- f. Employment.

2. Initial medical examination services.

3. Special services for pregnant patients.

4. Initial and periodic, individualized, patient-centered assessment and treatment services.

5. Drug abuse testing services.

6. Case management services, including medical monitoring and coordination, with onsite and offsite treatment services provided as needed.

7. All staff shall be trained in first aid, CPR, and naloxone administration.

K. 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.

L. Applicants shall provide policies and procedures that address assessment, administration, and regulation of medication including dose levels appropriate to the individual. The policies and procedures shall at a minimum require that each individual receiving services to 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 (MATs), or continued federally approved pharmacotherapy treatment for opioid addiction.

M. Applicants shall submit policies and procedures describing services they will provide to individuals who wish to discontinue opioid treatment services.

N. 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.

O. 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.

**12VAC35-109-220. Registration, certification or accreditation.**

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

- 1. The federal DEA;
- 2. The federal Department of Health and Human Services; and
- 3. The Virginia Board of Pharmacy.

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

**12VAC35-109-230. Criteria for patient admission.**

Underlined = new language.

A. Before a medication assisted opioid 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: 1) meet diagnostic criteria for opioid use disorder as defined within the DSM; and 2) meet the admission criteria of Level 1.0 of ASAM. The policies shall be consistent with subsections B - E.

B. Detoxification treatment. A medication assisted opioid treatment program shall maintain current procedures that are designed to ensure that individuals are admitted to short or long-term detoxification 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. An individual with two or more unsuccessful detoxification episodes within a twelve 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. Maintenance treatment. A medication assisted opioid 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 to an opioid drug, and that the individual became addicted at least 1 year before admission for treatment. In addition, a program physician shall ensure that each individual voluntarily chooses maintenance treatment, and 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. Maintenance treatment for persons under age 18. A person under 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 under 18 years of age may be admitted to maintenance treatment unless parent, legal guardian, or responsible adult designated by the relevant state authority consents in writing to such treatment.

E. Maintenance treatment admission exceptions. If clinically appropriate, the program physician may waive the requirement of a 1-year history of addiction under paragraph C of this section, for individuals released from penal institutions (within 6 months after release), for pregnant patients (program physician must certify pregnancy), and for previously treated individuals (up to 2 years after discharge).

**12VAC35-109-240. Criteria for involuntary termination from treatment.**

A. The provider shall establish criteria for involuntary termination from treatment that describe the rights of the individual receiving services and the responsibilities and rights of the provider.

B. The provider shall establish a grievance procedure as part of the rights of the individual.

C. On admission, the individual shall be given a copy of the criteria and shall sign a statement acknowledging receipt of same. The signed acknowledgement shall be maintained in the individual's service record.

D. Upon admission and annually all individuals shall sign an authorization for disclosure of information to allow programs access to the Virginia Prescription Monitoring System. Failure to comply shall be grounds for nonadmission to the program.

**12VAC35-109-250. Criteria for patient discharge.**

Before a medication assisted opioid 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:



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1. Achieved the goals of the treatment services and no longer require medication assisted opioid 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.

**12VAC35-109-260. Service operation schedule.**

A. The service's days of operation shall meet the needs of the individuals receiving services. If the service dispenses or administers a medication requiring daily dosing, the service shall operate seven days a week, 12 months a year, except for official state holidays. Prior approval from the state methadone authority shall be required for additional closed days.

B. The service may close on Sundays if the following criteria are met:

1. The provider develops and implements policies and procedures that address recently inducted individuals receiving services, individuals not currently on a stable dose of medication, patients that present noncompliance treatment behaviors, and individuals who previously picked up take-home medications on Sundays, security of take-home medication doses, and health and safety of individuals receiving services.
2. The provider receives prior approval from the state opioid treatment authority (SOTA) for Sunday closings. Each program must have a policy that addresses medication for the newly inducted patients and those who are deemed at-risk, i.e., still actively using illicit substances or medical issues that may warrant closer monitoring of medication. This policy must include openings on Sundays for the population described above.
3. Once approved, the provider shall notify individuals receiving services in writing at least 30 days in advance of their intent to close on Sundays. The notice shall address the risks to the individuals and the security of take-home medications. All individuals shall receive an orientation addressing take-home policies and procedures, and this orientation shall be documented in the individual's service record prior to receiving take-home medications.
4. The provider shall establish procedures for emergency access to dosing information 24 hours a day, seven days a week. This information may be provided via an answering service, pager, or other electronic measures. Information needed includes the individual's last dosing time and date, and dose.

C. Medication dispensing hours shall include at least two hours each day of operation outside normal working hours, i.e., before 9 a.m. and after 5 p.m. The SOTA may approve an alternative schedule if that schedule meets the needs of the population served.

**12VAC35-109-270. Initial and periodic assessment services.**

A. The 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. A complete physical examination shall be conducted annually, or more frequently if there is a change in the individual's physical or mental condition. 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.

B. The program physician shall review a consent to treatment form with the individual and sign the form prior to the individual receiving the first dose of medication.

Underlined = new language.

C. Upon admission and annually, all individuals shall sign an authorization for disclosure of information to allow programs access to the Virginia Prescription Monitoring System (PMP). Failure to comply with this requirement shall be grounds for denial of admission to the program. Programs shall run a PMP report at admission, every quarter, and more frequently as needed.. The program physician shall provide this report. The report shall be stored in the individual's file and must be marked "DO NOT DUPLICATE."

D. The program shall have a policy to ensure that coordination of care is in place with any prescribing physician. The policy shall at a minimum require:

1. The provider to coordinate treatment services for individuals who are prescribed benzodiazepines and prescription narcotics with the treating physician.
2. The coordination shall be the responsibility of the provider's physician.
3. The documentation of the coordination.

E. Initial tests offered by the provider shall include viral hepatitis, HIV and other sexually transmitted infections. On admission, all individuals shall be offered testing for HIV/AIDS. The individual may sign a notice of refusal without prejudice. The individual shall be certified as tuberculosis (TB) free upon admission and annually by a qualified licensed professional.

**12VAC35-109-280. Special services for individuals who are pregnant.**

- A. The program shall ensure that every pregnant woman has the opportunity for prenatal care, prenatal education, and postpartum follow-up, either:
1. Onsite; or
  2. By referral to appropriate healthcare providers.
- B. The program shall provide or make referrals to individuals for:
1. Breastfeeding information;
  2. Basic infant development and child care;
  3. Neonatal abstinence syndrome;
  4. Dangers of continued illicit substance abuse on the developing fetus;
  5. Parenting skills; and
  6. Family planning.
- C. All attempts and refusals to get the individual to comply with prenatal needs shall be documented. If prenatal care is not available onsite or the pregnant woman refuses care or referral, the program shall offer her basic prenatal instruction on:
1. Maternal care;
  2. Physical care;
  3. Diet and nutrition;
  4. Care coordination with the OB/GYN, specifically to address pain management needs for post-delivery;
  5. Risks of not seeking prenatal care; and
  6. A resource list of prenatal care providers and hospitals.
- D. When providing medication use for women who are pregnant, opioid-addicted, and in opioid treatment, the program shall:

Underlined = new language.

1. Maintain women who become pregnant during treatment on the pre-pregnancy dosage, if effective, and apply the same dosing principles as used with any other woman who is not pregnant, if applicable.
2. Ensure that the initial methadone dose and the subsequent induction and maintenance dosing strategy for a woman who is newly admitted and pregnant reflect the same effective dosing protocol used for all other persons served.
3. Monitor the methadone dose carefully, especially during the third trimester.
4. Ensure that if a pregnant woman elects to withdraw from methadone:
  - a) A physician experienced in addiction medicine supervises the withdrawal process; and
  - b) Regular fetal assessments, as appropriate for gestational age, are part of the withdrawal.

**12VAC35-109-290. Counseling sessions.**

A. The provider shall offer face-to-face counseling sessions (either individual, group, or family) totaling one hour minimum. The provider shall document details of each session including the length within the individual's service record. The counseling sessions shall occur:

1. Every week for the first six months of the first year of the individual's treatment.
2. At least every two weeks for the second six months of the first year of an individual's treatment.
3. At least every month in the second year of the individual's treatment.
4. 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, as determined by the counselor. The counselor shall document the justification for the frequency of face-to-face counseling sessions and the progress the individual has made in treatment.

B. The failure of an individual to participate in counseling sessions shall be addressed as part of the overall treatment process.

**12VAC35-109-300. Drug screens.**

Providers of MAT shall:

1. Perform at least one random drug screen per month period unless the conditions in subdivision 2 of this subsection apply;
2. Perform a random weekly drug screen whenever an individual's drug screen indicates continued illicit drug use or when clinically and environmentally indicated;
3. Analyze drug screens for opiates, methadone (if ordered), benzodiazepines, and cocaine. In addition, drug screens for other drugs that have the potential for addiction shall be performed when clinically and environmentally indicated; and
4. Implement a written policy on how the results of drug screens shall be used to direct treatment.

**12VAC35-109-310. Take home medications.**

Underlined = new language.

A. Prior to dispensing regularly scheduled take-home medication, the provider shall ensure the individual demonstrates a level of current lifestyle stability as evidenced by the following:

1. Regular clinic attendance, including dosing and participation in counseling or group sessions;
2. Absence of recent alcohol abuse and illicit drug use;
3. Absence of significant behavior problems;
4. Absence of recent criminal activities, charges, or convictions;
5. Stability of the individual's home environment and social relationships;
6. Length of time in treatment;
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 judgement of the physician in consultation with the treatment team and shall be documented in the individual's service record.

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

1. A single take-home dose for a 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 C 1 of this subsection) and the individual shall ingest all other doses under the supervision of an employee trained in medication administration.
3. Two doses per week in the second 90 days of treatment (beyond that in C 1 of this subsection).
4. Three doses per week in the third 90 days of treatment (beyond that in C 1 of this subsection).
5. A maximum 6-day supply of take-home doses in the remaining months of the first year of treatment.
6. A maximum 2-week supply of take-home medication after one year of continuous treatment and with monthly visits made by the individual.
7. One month's supply of take-home medication after 2 years of continuous treatment.

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

E. OTPs shall maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's 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 the use of childproof containers.

F. The individual must have a locking box to transport the take-home medication.

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

**12VAC35-109-320. Prevention of duplication of medication services.**

Underlined = new language.

To prevent duplication of medication assisted opioid treatment services to an individual, prior to admission of the individual, the provider shall implement a written policy and procedures for contacting every medication assisted opioid treatment service within a 50-mile radius. If the individual lives more than 50 miles from the clinic, then the provider shall also conduct an assessment for dual enrollment within a 50 mile radius of the person's home address before admission.

**12VAC35-109-330. Guests.**

A. For the purpose of this section, a “guest” is a patient of a medication assisted opioid 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.

B. The provider shall have a policy that identifies whether or not it will provide guest dosing to individual guests.

C. If the program provides guest dosing, the provider shall have a policy that includes:

1. Exclusionary or ineligibility criteria, if applicable;
2. The right to refuse to guest dose;
3. Financial arrangements;
4. Drug testing, if applicable;
5. Required documentation needed from the referring program and from the guest; and
6. Notification of the arrangements made back to the referring program.

D. The provider shall implement written procedures for guest dosing that include:

1. Staff time for making arrangements for guest dosing;
2. Number of days guest dosing will be allowed;
3. Services to be provided to the guests; and
4. Other considerations, as appropriate.

E. 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.

F. Guests may receive medication for up to 28 days. To continue receiving medication after 28 days, the guest must be admitted to the service.

G. The provider shall implement policy and procedures that address the transfer of individuals from one clinic to another.

**12VAC35-109-340. Detoxification prior to involuntary discharge.**

Providers of MAT shall give an individual who is being involuntarily discharged an opportunity to detoxify from opioid agonist medication. The detoxification period shall be at least 10 days prior but not more than 30 days prior to his discharge from the service, unless the state methadone authority has granted an exception.

**12VAC35-109-350. Opioid agonist medication renewal.**

Underlined = new language.

Providers of MAT shall ensure that physician orders for opioid agonist medication are reevaluated and renewed at least every six months.

**12VAC35-109-360. Security of opioid agonist medication supplies.**

- A. At a minimum, the provider shall secure opioid agonist medication supplies by restricting access to medication areas to medical or pharmacy personnel.
- B. The provider shall reconcile the medication inventory monthly. C. The provider shall keep inventory records, including the monthly reconciliation, for three years.
- D. The provider shall maintain a current plan to control the diversion of medication to unprescribed or illegal uses.

**Article 3. Additional requirements for ASAM providers.**

**12VAC35-109-370. Substance abuse partial hospitalization services program criteria.**

A substance abuse partial hospitalization program shall meet the following programmatic requirements. The program shall:

1. Offer no fewer than 20 hours of programming per week in a structured program. Services may include individual and group counseling, medication management, family therapy, peer recovery support services, educational groups, or occupational and recreational therapy;
2. Provide a combination of individual and group therapy as deemed appropriate by a licensed professional and included in an assessment and treatment plan;
3. Provide medical and nursing services as deemed appropriate by a licensed professional and included in an assessment and treatment plan;
4. Provide motivational enhancement and engagement strategies appropriate to an individual's stage of readiness to change and level of comprehension;
5. Have direct affiliations with other easily accessible levels of care or coordinate through referral to more or less intensive levels of care and other services;
6. Provide family and caregiver treatment services as deemed appropriate by a licensed professional and included in an assessment and treatment plan;
7. Provide educational and informational programming adaptable to individual needs;
8. Ensure and document that the length of service shall be determined by the individual's condition and functioning;
9. Make emergency services available by telephone 24 hours a day, seven days a week when the program is not in session; and
10. Make MAT available for all individuals. MAT may be provided by facility staff or coordinated through alternative resources.

**12VAC35-109-380. Substance abuse partial hospitalization admission criteria.**

Before a substance abuse partial hospitalization 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 require the individual to, at a minimum:

Underlined = new language.

1. Meet diagnostic criteria for a substance use disorder or addictive disorder as defined by the DSM; and
2. Meet the admission criteria of Level 2.5 of ASAM, including the specific criteria for adult and adolescent populations.

**12VAC35-109-390. Substance abuse partial hospitalization discharge criteria.**

Before a substance abuse partial hospitalization 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 ASAM 2.5 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.

**12VAC35-109-400. Substance abuse partial hospitalization co-occurring enhanced programs.**

A. Substance abuse partial hospitalization co-occurring enhanced programs shall offer psychiatric services appropriate to the individual's mental health condition. Such services shall be available by telephone and onsite or closely coordinated offsite, within a shorter time than in a co-occurring capable program.

B. Substance abuse partial hospitalization co-occurring enhanced programs shall be staffed by appropriately credentialed mental health professionals who assess and treat co-occurring mental disorders. Intensive case management shall be delivered by cross-trained, interdisciplinary staff through mobile outreach and shall involve engagement-oriented addiction treatment and psychiatric programming. All clinical staff shall be qualified by training and experience and appropriately licensed, certified, or registered by the appropriate health regulatory board to serve individuals admitted to the service.

C. Substance abuse partial hospitalization co-occurring enhanced programs shall offer intensive case management, assertive community treatment, medication management, and psychotherapy.

**12VAC35-109-410. Substance abuse intensive outpatient services program criteria.**

A substance abuse intensive outpatient program shall meet the following programmatic requirements. The program shall:

1. Offer a minimum of 3 service hours per service day for adults and a minimum of two service hours per service day for children and adolescents. Service hours shall be no fewer than 9 hours and no more than 19 hours of programming per week for adults and no fewer than 6 hours and no more than 19 hours of services per week for children and adolescents. Service hours shall be offered in a structured environment;
2. Ensure psychiatric and other medical consultation shall be available within 24 hours by telephone and within 72 hours in person;
3. Offer consultation in case of emergency related to an individual's substance use disorder by telephone 24 hours a day, 7 days a week when the treatment program is not in session;
4. Provide a combination of individual and group therapy as deemed appropriate by a licensed professional and included in an assessment and treatment plan;

Underlined = new language.

5. Have direct affiliations with other easily accessible levels of care or coordinate through referral to more or less intensive levels of care and other services;
6. Provide family and caregiver treatment and peer recovery support services as deemed appropriate by a licensed professional and included in an assessment and treatment plan;
7. Provide education and informational programming adaptable to individual needs and developmental status;
8. Ensure and document that the length of service shall be determined by the individual's condition and functioning; and
9. Make MAT available for all individuals. MAT may be provided by facility staff or coordinated through alternative resources.

**12VAC35-109-420. Substance abuse intensive outpatient services admission criteria.**

Before a substance abuse intensive outpatient service 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 require the individual to, at a minimum:

1. Meet diagnostic criteria for a substance use disorder or addictive disorder as defined by the DSM; and
2. Meet the admission criteria of Level 2.1 of ASAM, including the specific criteria for adult and adolescent populations.

**12VAC35-109-430. Substance abuse intensive outpatient services discharge criteria.**

Before a substance abuse intensive outpatient service 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 ASAM 2.1 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.

**12VAC35-109-440. Substance abuse intensive outpatient services co-occurring enhanced programs.**

A. Substance abuse intensive outpatient services co-occurring enhanced programs shall offer psychiatric services appropriate to the individual's mental health condition. Such services shall be available by telephone and onsite or closely coordinated offsite, within a shorter time than in a co-occurring capable program.

B. Substance abuse intensive outpatient services co-occurring enhanced programs shall be staffed by appropriately credential mental health professionals who assess and treat co-occurring mental disorders. Capacity to consult with an addiction psychiatrist shall be available. All clinical staff shall be qualified by training and experience and appropriately licensed, certified, or registered by the appropriate health regulatory board to serve individuals admitted to the service.

C. Substance abuse intensive outpatient services co-occurring enhanced programs shall offer intensive case management, assertive community treatment, medication management, and psychotherapy.



Underlined = new language.

**12VAC35-109-450. Substance abuse outpatient service program criteria.**

Substance abuse outpatient service programs shall meet the following programmatic requirements. The program shall:

1. Offer no more than 9 hours of programming a week for adults or no more than 6 hours per week for adolescents;
2. Ensure emergency services are available by telephone 24 hours a day, 7 days a week;
3. Provide individual or group counseling, motivational enhancement, family therapy, educational groups, occupational and recreational therapy, psychotherapy, addiction, and pharmacotherapy as indicated by each individual's needs;
4. For individuals with mental illness, ensure the use of psychotropic medication, mental health treatment, and that the individual's relationship to substance abuse disorders shall be addressed as the need arises;
5. Provide medical, psychiatric, psychological, laboratory, and toxicology services onsite or through consultation or referral. Medical and psychiatric consultation shall be available within 24 hours by telephone, or if in person, within a timeframe appropriate to the severity and urgency of the consultation requested;
6. Have direct affiliations with other easily accessible levels of care or coordinate through referral to more or less intensive levels of care and other services; and
7. Ensure through documentation that the duration of treatment varies with the severity of the individual's illness and response to treatment.

**12VAC35-109-460. Substance abuse outpatient service admission criteria.**

Before a substance abuse outpatient service 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:

1. Meet diagnostic criteria for a substance use disorder or addictive disorder as defined by the DSM; and
2. Meet the admission criteria of Level 1.0 of ASAM, including the specific criteria for adult and adolescent populations.

**12VAC35-109-470. Substance abuse outpatient services discharge criteria.**

Before a substance abuse outpatient service 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 ASAM 1.0 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.

Underlined = new language.

**12VAC35-109-480. Substance abuse outpatient services co-occurring enhanced programs.**

A. Substance abuse outpatient services co-occurring enhanced programs shall offer ongoing intensive case management for highly crisis-prone individuals with co-occurring disorders.

B. Substance abuse outpatient services co-occurring enhanced programs shall include credentialed mental health trained personnel who are able to assess, monitor, and manage the types of severe and chronic mental disorders seen in a Level 1 setting as well as other psychiatric disorders that are mildly unstable. Staff shall be knowledgeable about management of co-occurring mental and substance-related disorders, including assessment of the individual's stage of readiness to change and engagement of individuals who have co-occurring mental disorders. All clinical staff shall be qualified by training and experience and appropriately licensed, certified, or registered by the appropriate health regulatory board to serve individuals admitted to the service.

C. Substance abuse outpatient services co-occurring enhanced programs shall offer therapies to actively address, monitor, and manage psychotropic medication, mental health treatment, and interaction with substance-related and addictive disorders.

**12VAC35-109-490. Mental health partial hospitalization program criteria.**

Mental health partial hospitalization programs shall meet the following programmatic requirements. The program shall:

1. Have a multidisciplinary team under the direction of a physician, which provides structured schedules for individuals receiving services;
2. Offer services for a minimum of 20 hours per week, a minimum of 5 days per week, 4 hours per day;
3. Provide emergency assistance 24 hours a day, 7 days a week;
4. Provide individualized treatment planning, daily individual, group and family therapy, skill restoration, skill development, and health literacy counseling and psychoeducation interventions;
5. Provide medication management as well as clinically indicated psychiatric and medical consultation services. Referrals for consultation to external prescribing providers shall be made via formal agreement. The provider shall coordinate medication management with all existing providers;
6. Provide medical, psychological, psychiatric, laboratory, and toxicology services by consult or referral; and
7. Provide care coordination through referrals to higher and lower levels of care, as well as community and social supports.

**12VAC35-109-500. Mental health intensive outpatient program criteria.**

1. Mental health intensive outpatient programs shall meet the following programmatic requirements. The program shall: Have a multidisciplinary team that, at a minimum, consists of a licensed clinical psychologist, licensed professional counselor, licensed clinical social worker (LCSW), or a licensed marriage and family therapist (LMFT); a physician, nurse practitioner, or physician assistant; a LMHP, LMHP-R, LMHP-RP, or LMHP-S; QMHP-A, QMHP-C or QMHP-E; a PRS certified in accordance with 12VAC35-250; and occupational therapists;

Underlined = new language.

2. Offer services between 9 and 19 hours a week for adults and between 6 and 19 hours a week for children and adolescents, with programming to occur across a minimum of 3 days a week;
3. Provide structured schedules for individual's served;
4. Provide care coordination activities that seek to support recovery and movement into a lower level of care;
5. Identify additional needs to support recovery and connect the individual and natural supports to appropriate referrals to meet these needs; and
6. Provide assessment; treatment planning; individual, family, and group therapy; skills restoration; skill development health literacy counseling and psychoeducation activities; crisis treatment; and peer recovery support services.

**12VAC35-109-510. Mental health outpatient program criteria.**

Mental health outpatient programs shall ensure the LMHP, LMHP-R, LMHP-RP or LMHP-S shall conduct an intake interview, record the medical history, conduct the intake assessment, record a diagnosis, and develop the ISP.