Chapter DHS 75

COMMUNITY SUBSTANCE USE SERVICE STANDARDS

Note: Chapter HFS 75 was renumbered to chapter DHS 75 under s. 13.92 (4) (b) 1., Stats., and corrections made under s. 13.92 (4) (b) 7., Stats., Register November 2008 No. 635. Chapter DHS 75 was reprinted Register December 2010 No. 660 to reflect a Note revision in s. DHS 75.03 (24). **Chapter DHS 75 as it existed on October 31, 2021, is repealed and a new Chapter DHS 75 is created Register October 2021 No. 790, effective October 1, 2022.**

Subchapter I — General Provisions

DHS 75.01 Authority and purpose. This chapter is promulgated under the authority of ss. 46.973 (2) (c), 51.42 (7) (b), 51.4224, and 51.45 (8) and (9), Stats., to establish standards for community substance use prevention and treatment services under ss. 51.42 and 51.45, Stats. Sections 51.42 (1) and 51.45 (1) and (7), Stats., provide that a full continuum of substance use services be available to Wisconsin citizens.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; correction in numbering made under s. 13.92 (4) (b) 1., Stats., Register October 2021 No. 790.

DHS 75.02 Applicability. (1) This chapter shall apply to all of the following:

(a) A publicly or privately operated facility providing substance use treatment services, in accordance with ss. 51.01 (19) and 51.45 (8) (c), Stats.

(b) A publicly or privately operated facility providing substance use treatment services approved by the state opioid treatment authority.

(c) A substance use service that receives funds under ch. 51, Stats., is funded through the department as the federally designated single state agency for substance use services, receives substance abuse prevention and treatment funding or other funding specifically designed for providing services under ss. DHS 75.14 to 75.15, where certification is required by a contract with the department.

(d) An intoxicated driver service described in s. DHS 75.15.

(e) A publicly or privately operated service that requests certification by the department.

(2) The provision of substance use treatment services to a patient in the state of Wisconsin via telehealth, regardless of the location of the program or facility, shall constitute the practice of substance use services in the state of Wisconsin and shall meet the requirements of this chapter.

(3) This chapter shall not apply to a general medical service that delivers substance use treatment services as an adjunct to general medical care, unless that service meets the definition of a "program" under 42 CFR 2.11.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.03 Definitions. In this chapter:

(1) "Adult" means an individual aged 18 or older.

(2) "Administrative discharge" means discharge of a patient from a service that is initiated by the service for reasons including program policies, behavioral concerns, or provider−initiated termination.

(3) "Applicant" means an individual or entity that has requested certification by the department as a community substance use service under this rule.

(4) "Approved placement criteria" means ASAM or other similar placement criteria that may be approved by the department.

(5) "ASAM" means the American Society of Addiction Medicine.

(6) "ASAM placement criteria" means the ASAM Criteria: Treatment Criteria for Addictive, Substance−Related, and Co−Occurring Conditions (3rd ed., Oct. 24, 2013), which is a multi−dimensional set of placement criteria for assessing substance use patient risk and need areas and establishing treatment service level of care.

(7) "Assessment update" means the procedure by which a clinical staff of a service, operating within the scope of their practice, gathers relevant information to update prior assessment data, including updated substance use history, mental health symptoms and functioning, newly identified or changing behavioral and physical health needs, and significant psycho−social changes that may impact treatment or overall functioning, including a review of level of care placement criteria, if applicable.

(8) "Available on a 24−hour basis" means that the designated staff of a service that is available in−person or on−call, including by phone or other real−time electronic communication.

(9) "Behavioral health" means the spectrum encompassing mental health and substance use disorders occurring either independently or simultaneously.

(10) "Caregiver" means a person as defined in s. 48.685 (1) (ag) or 50.065 (1) (ag), Stats.

(11) "Case management" means the planning and coordination of services to meet an individual's identified health needs, and assistance provided to the individual for engagement in such services to support the individual's overall treatment and recovery.

(12) "Certification" means approval of a service by the department's division of quality assurance.

(13) "Certified peer specialist" means a person who has lived experience of mental illness or substance use disorders, or both, and has completed a formal training and holds a department certification in the peer specialist model of mental health or substance use disorders support, or both.

(14) "Clinical assessment" means the procedure by which a clinical staff of a service, operating within the scope of their practice, gathers relevant information to evaluate the individual's problem areas, symptoms, functioning, readiness for change, resources, and strengths. Clinical assessment of substance use includes information regarding substance use history, current substance use, impact on functioning, and readiness for change for the purpose of evaluating diagnosis of a substance use disorder and informing treatment services. Clinical assessment of mental health includes mental health symptoms, mental status, and functional assessment for the purpose of evaluating diagnosis of a mental health disorder and informing treatment services.

(15) "Clinical consultation" means the review of a patient's plan of care or collaborative discussion of specific aspects of a patient's risks, needs, and functioning, between a clinical supervisor and other clinical staff of a service, another licensed professional, or both.

(16) "Clinical services" means counseling, assessment, group therapy, family therapy, medication management, or other services that require specialized knowledge and training in the assessment and treatment of mental health and substance use disorders.

(17) "Clinical staff" means all substance abuse counselors, mental health professionals, mental health professionals in training, substance abuse counselors in training, qualified treatment trainees, psychologists, or other qualified staff of a service that deliver screening, assessment, or treatment services under this chapter.

(18) "Clinical staffing" means the review of a patient's plan of care or collaborative discussion of specific aspects of a patient's risks, needs, and functioning, with other clinical staff of a service.

(19) "Clinical supervisor" means any of the following:

(a) An individual who meets the qualifications provided in s. SPS 160.02 (7).

(b) An individual who meets the qualifications in 2017 Wisconsin Act 262 and is practicing within their scope of their education, training and experience.

(20) "Clinical supervision" means the process as defined in s. SPS 160.02 (6).

(21) "Collateral" means information, treatment input, or participation obtained from a party that has knowledge of or relationship with a patient, which may include family members, friends, co−workers, recovery peers, health care providers, probation and parole agents, other law enforcement personnel, child welfare workers, referral sources, clinical records, legal records, or professional public databases.

(22) "Co−mingled groups" means a therapeutic or psycho−educational group provided by a service that includes mixed population groups, such as gender, age, substance of use, or criminogenic risk.

(23) "Continued stay" means the ongoing provision of an appropriately matched level of care service to an individual's needs, as assessed by ASAM or other department−approved placement criteria.

(24) "Continuing care" means the stage of treatment in which the patient no longer requires counseling at the intensity described in ss. DHS 75.49 to 75.60. Continuing care is designed to support and sustain the process of long−term recovery, provided on an outpatient basis at a frequency agreed upon between the patient and the provider.

(25) "Co−occurring" means a patient diagnosed as having both a substance use disorder and a mental health disorder, as listed in the DSM.

(26) "Counseling" means the application of recognized theories, principles, techniques and strategies to facilitate the progress of a patient toward identified treatment goals and objectives.

(27) "Crisis intervention" means services that respond to an individual's behavioral health needs during acute episodes that involve significant distress or risk of harm to self or others.

(28) "Culturally and linguistically appropriate services" or "CLAS" means that all aspects of a service, from an individual's first contact through discharge, are delivered with consideration for the individual's cultural and language needs.

Note: CLAS standards are available from the U.S. Department of Health and Human Services at https://thinkculturalhealth.hhs.gov/assets/pdfs/EnhancedNationalCLASStandards.pdf.

(29) "DEA" means the U.S. drug enforcement administration.

(30) "Department" or "DHS" means the Wisconsin department of health services.

(31) "Determination of medical stability" means a medical evaluation of a patient, including physical examination, obtaining vital signs, gathering relevant medical history, and applicable laboratory testing, to determine whether a patient's presenting problem is primarily medical in nature, whether serious underlying medical illness exists that would render admission to a behavioral health service unsafe or inappropriate, and any referral needs for additional medical care or follow−up.

(32) "Discharge planning" means planning and coordination of treatment and support services associated with the patient's discharge from treatment, including the preparation of a discharge summary as required under s. DHS 75.24 (22).

(33) "DSM" means the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, published by the American Psychiatric Association.

(34) "DSPS" means the Wisconsin department of safety and professional services.

(35) "Dually−credentialed" means a staff of a service that holds licensure and certification as both a mental health professional and a substance abuse counselor, in accordance with professional licensing and credentialing standards established by DSPS. A mental health professional operating within their scope

of practice as a substance abuse counselor under DHS 75.03 (86), meets the definition of dually−credentialed.

(36) "Entity owner" means an individual or partnership that owns or operates the service, is legally responsible for the service, and has authority to either conduct the policy, actions, and affairs of the service, or appoint a governing authority to conduct the policy, actions, and affairs of the service.

(37) "Facility" means the physical building that houses a service, including the rooms, furnishings, and structures therein.

(38) "FDA" means the U.S. food and drug administration.

(39) "Follow−up" means a process used by a treatment provider to periodically assess the referral process and rehabilitation progress of a patient who has been referred for concurrent or subsequent services.

(40) "Governing authority" means the individual or governing body designated by the entity owner that is legally responsible for the operation of a service, and has authority to conduct the policy, actions, and affairs of the service.

(41) "Group counseling" means the application of counseling techniques which involve interaction among members of a group consisting of at least 2 patients but not more than 16 patients with a minimum of one counselor for every 10 patients.

(42) "Incident report" means a written record of an incident involving patient, visitor, or staff health or safety that occurs at the facility or in the course of providing services in the community. Incident reporting is required for health emergencies, incidents of violence, injuries requiring medical attention, or other extraordinary events that interfere with the provision of services and pose a risk to health or safety.

(43) "In−reach," means services that are provided in corrections settings to enhance engagement or to initiate recommended treatment services prior to release from incarceration.

(44) "Intake" means the specific tasks necessary to admit a person to a behavioral health service, such as completion of admission forms, notification of patient rights, explanation of the general nature and goals of the service, review of policies and procedures of the service, and orientation.

(45) "Integrated treatment" means a service that includes both substance use and mental health assessment and treatment services, provided in the same setting, by appropriately credentialed personnel operating within their scope of practice, with appropriate interventions for both conditions included in one comprehensive treatment plan for each patient diagnosed with a co−occurring disorder or disorders.

(46) "Interim services" means services that are provided until an individual is admitted to a substance use treatment program, including education about communicable illnesses, harm−reduction strategies, referral for other services or medical care, and referral for prenatal care for pregnant women; to reduce the adverse health effects of substance use, promote the health of the individual, and reduce the risk of transmission of disease.

(47) "Intervention" means a therapeutic technique or activity that is applied as part of an individual's treatment plan to address behavioral health goals and improve functioning.

(48) "Knowledgeable in addiction treatment" means a clinical staff who possesses postsecondary coursework, continuing education coursework, or supervised professional experience to establish their training and competence in all of the following domains:

(a) Understanding addiction.

(b) Knowledge of addiction treatment and interventions.

(c) Considerations for special populations in substance use treatment.

(d) Assessment of substance use disorders.

(e) Pharmacology for addiction treatment.

(f) Assessing and responding to safety risks related to substance use and employing harm−reduction strategies in addiction treatment.

(49) "Level of care" means the discrete category of patient placement, based on intensity and frequency of treatment provided by a service under ss. DHS 75.15 and 75.49 to 75.60, that is matched to the individual's need based on ASAM or other department−approved placement criteria.

(50) "Licensed professional" means a person who holds one of the following licenses or certifications issued by DSPS, but does not include professionals in training under such licenses or certifications:

(a) A clinical social worker, licensed marriage and family therapist, or licensed professional counselor under ch. 457, Stats.

(b) A psychologist under ch. 455, Stats.

(c) A substance abuse counselor or clinical substance abuse counselor under s. 440.88, Stats.

(51) "Medical director" means a person who is employed as the chief medical officer of a service, who is also licensed to practice medicine or osteopathy under ch. 448, Stats., and who also possesses any of the following qualifications:

(a) A prior certification in addiction medicine by ASAM.

(b) A certification in addiction psychiatry by the American Board of Psychiatry and Neurology.

(c) A subspecialty certification in addiction medicine by a recognized board of the American Board of Medical Specialties.

(d) Completion of a certificate of Added Qualification in Addiction Medicine conferred by the American Osteopathic Association.

(dm) A prior certification by the American Board of Addiction Medicine.

(e) Completion of an accredited residency or fellowship in addiction medicine or addiction psychiatry.

(f) Knowledgeable in addiction treatment and has one year of addiction medicine experience, although certification is preferred.

(g) Working toward certification in addiction medicine or addiction psychiatry and has one year of addiction medicine experience, although certification is preferred.

Note: If a service is not able to secure a medical director who meets the requirement of 1 year of addiction medicine experience, as documented through the service's recruitment efforts, the service may utilize a medical director who has a specific plan to acquire equivalent training and skills within 4 months after beginning employment.

(52) "Medical personnel" means a physician, a physician assistant, nurse prescriber or other health care personnel licensed, at a minimum, to the level of a registered nurse or licensed practical nurse.

(53) "Medical screening" means the examination conducted by medical personnel of a person to ascertain eligibility for admission to a treatment service under this chapter and to assess the person's medical needs.

(54) "Medical services" means services designed to address the medical needs of a patient, which may include a physical examination, evaluating, managing and monitoring health−related risks of withdrawal from alcohol and other substances, administration of medications and behavioral−health related medical care, within the scope of practice of the providing staff member.

(55) "Medication−assisted treatment" means the use of FDA−approved medications, in combination with counseling and behavioral therapies, to treat substance use disorders.

(56) "Mental health professional" means an individual authorized to practice psychology, marriage and family therapy, professional counseling, or clinical social work, pursuant to ch. 455 or 457, Stats.

(57) "Mental health treatment" means the delivery of clinical services for the purpose of addressing a mental health disorder as defined in the DSM.

(58) "Minor" means an individual under the age of 18.

(59) "Motivational approach" means an interactional technique that uses collaboration and empathy in purposeful communication that enhances an individual's motivation for change.

(60) "Nurse prescriber" means an advanced practice nurse authorized under ch. 441 Stats., to issue prescriptions or medication orders.

(61) "Nursing director" means a staff of a service that is at least a registered nurse, but may be licensed or certified as a nurse prescriber, physician assistant, or physician.

(62) "Nursing services" means behavioral health or medical services, provided by a nurse licensed under ch. 441, Stats., and operating within their scope of practice, that support screening, assessment, and treatment for patients of a service.

(63) "Outreach," means services that are provided to enhance engagement or to initiate recommended treatment services.

(64) "Patient" or "client," means an individual who is receiving substance use assessment or treatment services, including emergency services described in s. DHS 75.24 (2), or an individual who has completed intake for a service under this chapter. An individual remains a patient of a service until the date of discharge as established in s. DHS 75.24 (22).

(65) "Physically accessible" means a facility that persons with functional limitations caused by impairments of sight, hearing, coordination, cognition, or perception, or persons with disabilities that cause them to be semi−ambulatory or non−ambulatory may readily enter, leave, and circulate within, and in which they can use public restrooms and elevators.

(66) "Physician" means a person licensed to practice medicine or osteopathy under ch. 448, Stats.

(67) "Physician assistant" means a person licensed under ch. 448 Stats.

(68) "Placement criteria" means a standardized screening and assessment process or tool, such as ASAM placement criteria, that evaluates social, behavioral health, and physical health dimensions to identify an individual's need and risk level to ensure that services are appropriately matched to the patient's needs at the appropriate time.

(69) "Preliminary treatment plan" means an initial plan for care and services that is initiated prior to completion of a comprehensive assessment due to emergent needs of a patient.

(70) "Prescriber" means a physician, physician assistant, or nurse prescriber, who is operating within the scope of their license to deliver services under this chapter.

(71) "Prescription" means a drug or device ordered by a prescriber for treatment.

(72) "Primary counselor" means a substance abuse counselor, mental health professional, or prescriber, who is assigned by the service to develop and implement a patient's individualized treatment program and to evaluate the patient's progress in treatment.

(73) "Psychiatrist" means a person who is licensed under ch. 448, Stats., and board−certified or eligible for certification by the American board of psychiatry and neurology.

(74) "Psychoeducation" means information provided in a didactic format in either a group or individual setting that relates to health and promotes recovery.

(75) "Qualified treatment trainee" or "QTT" means either of the following:

(a) A graduate student who is enrolled in an accredited institution in psychology, counseling, marriage and family therapy, social work, nursing, or a closely related field.

(b) A person with a graduate degree from an accredited institution and course work in psychology, counseling, marriage and family therapy, social work, nursing, or a closely related field, who has not yet completed the applicable supervised practice requirements described under ch. MPSW 4, 12, or 16, or ch. Psy 2.

(76) "Recovery coach" means an individual that works with and supports individuals receiving substance use services to assist with engagement in treatment services or recovery systems, or both.

(77) "Referral" means the establishment of a link between a patient and another service by providing documentation of the patient's needs and recommendations for treatment services to the other service.

(78) "Registered nurse" means a person who is licensed as a registered nurse under ch. 441, Stats.

(79) "Scope" or "scope of practice" means the procedures, actions, and processes that a healthcare practitioner is permitted to undertake in accordance with the terms of their professional license or certification.

(80) "Screening" means a process for determining the initial needs and presenting problems of a patient in order to determine what services are indicated and to facilitate linkage or referral to appropriate services.

(81) "Service" means a structured delivery system for providing substance use prevention, intervention, or treatment services.

(82) "Signature" or "signed" means a signature that meets the requirements in s. 990.01 (38), Stats.

(83) "Special population" means an identified group, based on demographic or other specific traits, of patients or prospective patients of a service whose needs require special consideration or attention related to admission practices or service delivery.

(84) "Substance" means a psychoactive agent or chemical, including nicotine, which principally affects the central nervous system and alters mood or behavior.

(85) "Substance abuse counselor," or "counselor," means any of the following:

(a) A clinical substance abuse counselor as defined in s. SPS 160.02 (5).

(b) A substance abuse counselor as defined in s. SPS 160.02 (26).

(c) A substance abuse counselor−in−training as defined in s. SPS 160.02 (27).

(d) An individual who holds a physician, psychologist, clinical social worker, marriage and family therapist, or professional counselor license granted under ch. 448, 455, or 457, Stats., and practices within their scope.

(86) "Substance use," or "substance abuse," means the use of any mood−altering substance in a manner that interferes with, or poses a risk of interfering with, an individual's educational, vocational, health, behavioral, financial, legal, or social functioning.

(87) "Substance use disorder" means a diagnosis of substance use disorder listed in the DSM.

(88) "Substance use treatment" means the delivery of clinical services for the purpose of addressing a substance use disorder as defined in the DSM.

(89) "Telehealth" means the use of digital information and communication technologies, such as computers and mobile devices, for the provision of health care services remotely.

(90) "Transfer" means the movement of a patient from one level of care to another, which either takes place at the same location or by physically moving the patient to a different site or service for the new level of care.

(91) "Transitional−age youth" means youth between the ages of 16 to 24 that are establishing skills related to independence, independent living, vocational and educational development, and addressing the life−stage areas of independence, identity−formation, and autonomy.

(93) "Trauma−informed" means an approach that recognizes the contribution of psychologically distressing events to an individual's presenting symptoms and response to interventions, and the strong correlation between trauma and behavioral health disorders. This approach to care emphasizes environmental and personal safety, and trusting and collaborative provider−patient relationships.

(94) "Treatment" means the planned provision of services that are responsive to a patient's individual needs to assist the patient through the process of recovery.

(95) "Treatment plan" means identified goals, objectives, and resources agreed upon by the patient and the service to be utilized in facilitation of the patient's recovery.

(96) "Treatment planning" means the process by which the service and the patient and, whenever possible, the patient's family, consider the patient's presenting problems to identify and prioritize problems needing resolution, establish goals, and decide on interventions and resources to be applied.

(97) "Treatment service" means a service provided under ss. DHS 75.49 to 75.60.

(98) "Treatment services" means the interventions and resources applied by a service to address the needs and goals identified in a patient's treatment plan.

(99) "Unlicensed staff" means any mental health professional in training, a substance abuse counselor in training, a qualified treatment trainee, and any clinical staff of a service that are not fully and independently licensed.

(100) "Variance" means the granting of an alternate means of meeting a requirement in this chapter.

(101) "Waiver" means the granting of an exemption from a requirement of this chapter.

(102) "Withdrawal" means the development of a psychological and physical syndrome caused by the abrupt cessation of or reduction in heavy and prolonged substance use. The symptoms include clinically significant distress or impairment in social, occupational, or other important areas of functioning and are not due to a general medical condition or better accounted for by another mental disorder.

(103) "Withdrawal management" means a service, or component of a service, that provides care and interventions to address an individual's physical or psychosocial needs related to acute intoxication or withdrawal. Withdrawal management includes intoxication monitoring, management of acute symptoms, interruption of habitual and compulsive use, and engagement in ongoing treatment services.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; correction in (10), (19), (50) (c), (56), (64), (75) (b), (85) (d) made under s. 35.17, Stats., and correction in numbering in (43), (51) (dm) made under s. 13.92 (4) (b) 1., Stats., Register October 2021 No. 790.

Subchapter II — Certification

DHS 75.04 Application requirements. An application for initial certification shall be on a form provided by the department and shall be accompanied by all of the following:

(1) Service policies and procedures required by this chapter.

(2) All fees required under ss. 51.04 and 51.45 (8) (a), Stats.

(3) Additional information needed for certification that is requested by the department.

Note: Certification information and applications can be found at: https://www.dhs.wisconsin.gov/regulations/aoda/certification.htm.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.05 Department action. (1) INITIAL CERTIFICATION. (a) Within 60 days after receipt of a complete application, the department shall review the application and either approve or deny the certification.

(b) A certification issued by the department shall be only for persons named in the application. A certification may not be transferred or assigned without following the change of ownership provisions in s. DHS 75.07.

(c) A certification is valid until suspended or revoked by the department, except for opioid treatment programs.

(d) Opioid treatment programs shall be certified in accordance with s. 51.4224 (2), Stats.

(2) CERTIFICATION DENIAL. The department shall deny a certification to any applicant who does not substantially comply with any provision of this chapter, or who is not fit and qualified as specified in s. DHS 75.30, or who has failed to pay any fee or any outstanding amounts due to the department. The department shall provide the reasons for denial and the process for appeal of the denial in a written notice to the applicant.

(3) CERTIFICATION SUSPENSION OR REVOCATION. The department may suspend or revoke certification for any of the reasons and under the conditions specified under ss. 51.032 and 51.45 (8) (a), Stats., or for failure to comply with this chapter. The department shall provide the reasons for suspension or revocation and the process for appeal of the suspension or revocation in a written notice to the applicant.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; correction in (2) made under s. 13.92 (4) (b) 7., Stats., Register October 2021 No. 790.

DHS 75.06 Biennial forms and fees. (1) Every 24 months, on a date determined by the department, the service shall submit the biennial forms provided by the department, and shall submit payment of the certification continuation fees under ss. 51.04 and 51.45 (8) (a), Stats., except for opioid treatment programs under s. DHS 75.59.

(2) For opioid treatment programs, the service shall submit required reports in accordance with s. 51.4223, Stats.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.07 Change of ownership. (1) CHANGE OF OWNERSHIP. A change of ownership of a service occurs when the service does any of the following:

(a) Removes, adds, or substitutes an individual as a partner in the association, dissolving the existing partnership and creating a new partnership.

(b) Removes, adds, or substitutes any member in a limited liability company.

(c) Makes a change in a corporate structure under which the same corporation no longer continues to be responsible for making operational decisions or for the consequences of those decisions.

(2) DUTIES OF THE TRANSFEROR. (a) The transferor shall notify the department within 30 days before the change of ownership of a service and shall include the name and contact information of the transferee.

(b) The transferor remains responsible for the operation of the service until the department issues certification to the transferee, unless the service voluntarily closes and relocates all clients.

(c) The transferor shall disclose to the transferee any existing department waiver, variance, or outstanding deficiencies. The transferee shall apply for continuation of any existing waivers or variances, if necessary.

(d) The transferor shall follow the requirements for transferring financial responsibility under ch. 51, Stats.

(e) The transferor shall notify a clients or client's legal representative no less than 7 days in advance of the transfer of ownership.

(3) DUTIES OF THE TRANSFEREE. When there is a change of ownership, the transferee shall notify the department of the transfer, and shall submit a complete application as required under s. DHS 75.04 at least 30 days prior to the final transfer date.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.08 Agency closure. (1) Any service that intends to close shall provide written notice to each client by mail or electronic mail to the client's last known address, to each client's legal representative, if applicable, and the department at least 30 days before closing. The notice shall include the client's right to obtain treatment records as prescribed in s. DHS 92.05 and ch. DHS 94.

(2) The service shall provide assistance to clients for continuity of necessary services, including written notice of alternate service providers.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.09 Ongoing compliance and enforcement actions. (1) INSPECTIONS. (a) The department may make announced and unannounced inspections of a certified service to verify compliance with this chapter, to investigate complaints received regarding the services provided, or as part of an investigation into the cause of death of a client.

(b) To ensure compliance with this chapter and other applicable statutes and regulations, the department shall have access to all service documents, open and closed client records, and staff member files at any time.

(2) ENFORCEMENT. (a) *Statement of deficiency.* Upon determining that the service is in violation of any requirement of this chapter, the department shall promptly serve a statement of deficiency to the governing authority or entity owner or designated representative of the service.

(b) *Plan of correction.* 1. Within 10 business days of receipt of the statement of deficiency, the service shall submit a plan of correction to the department for approval, detailing how the service will correct the violation or how the service has corrected the violation. The department may require that a plan of correction be submitted for approval within a shorter specified time for violations the department determines may be harmful to the health, safety, welfare, or rights of clients.

2. The department may require the service to modify the proposed plan of correction before the department approves the plan of correction.

3. Failure to submit an approved plan of correction shall be grounds for denial, suspension, or revocation of the certification.

(3) APPEALS. (a) If the department denies, revokes, suspends, or refuses to renew certification, the service may request an administrative hearing under ch. 227, Stats.

(b) A request for a hearing shall be received in writing to the department of administration's division of hearings and appeals within 10 days after the date of the notice of the department's action under s. DHS 75.05.

(c) If a timely request for hearing is made, the department's decision to revoke, suspend, or refuse to renew certification is stayed pending the outcome of the appeal, unless the department finds that the health, safety or welfare of patients requires that the action take effect immediately. A finding of a requirement for immediate action shall be made in writing by the department.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.10 Investigation, notification, and reporting requirements. (1) DEATH REPORTING. (a) *Patient death related to physical restraint, psychotropic medication, or suicide.* No later than 24 hours after a service becomes aware of the death of a patient, the service shall report the death to the department if there is reasonable cause to believe the death was related to the use of a physical restraint or psychotropic medication, or was a suicide.

(b) *Patient death related to an accident or injury.* When a patient dies as a result of an incident or accident at the service location not related to the use of a physical restraint, psychotropic medication, or suicide, the service shall send a report to the department within 3 working days of the patient's death.

Note: Information and forms for statutorily reportable deaths and reporting procedures can be found at: https://www.dhs.wisconsin.gov/regulations/report−death/definitions.htm.

(2) INVESTIGATING AND REPORTING ABUSE, NEGLECT, OR MISAPPROPRIATION OF PROPERTY. (a) *Caregiver abuse or neglect.* 1. When a service receives a report of an allegation of abuse or neglect of a client, or misappropriation of property at the service location, the service shall take immediate steps to ensure the safety of all clients.

2. The service shall investigate and document any allegation of abuse or neglect of a client, or misappropriation of property by a caregiver. If the service's investigation concludes that the alleged abuse or neglect of a client or misappropriation of property meets the definition of abuse or neglect of a client, or of misappropriation of property, the service shall report the incident to the department on a form provided by the department, within 7 calendar days from the date the service knew or should have known about the abuse, neglect, or misappropriation of property. The service shall maintain documentation of any investigation.

(b) *Other reporting.* Filing a report under sub. (1) or (2) does not relieve the service or other person of any obligation to report an incident to any other authority, including law enforcement, the coroner and DSPS.

(3) NOTIFICATION OF CHANGES AFFECTING A CLIENT. (a) The service shall immediately notify the client's legal representative, as applicable, when there is an incident or injury to the client or a significant change in the client's physical or mental condition.

(b) The service shall immediately notify the client's legal representative, as applicable, when there is an allegation of physical, sexual, or mental abuse, or neglect of a client. The service shall notify the client's legal representative within 72 hours when there is an allegation of misappropriation of property.

(c) The service shall give the client or the client's legal representative, as applicable, a 30−day written notice of any change in charges for services that will be in effect for more than 30 days.

(4) DOCUMENTATION. All written reports required under this section shall include, at a minimum, the time, date, place, individuals involved, details of the occurrence, and the action taken by the provider to ensure clients' health, safety and well−being.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.11 General records and retention. (1) The service shall retain all records required under this chapter for 7 years, unless otherwise specified in subs. (2) and (3).

(2) Client records shall be retained as specified in ch. DHS 92 and in 42 CFR part 2.

(3) Employee records shall be retained for 3 years following an employee's separation from employment at the service.

(4) A service shall have a written policy and procedure for administrative review and maintenance of records related to incident reports.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; correction in (1) made under ss. 13.92 (4) (b) 4. and 35.17, Stats., and correction in (2) made under s. 35.17, Stats., Register October 2021 No. 790.

DHS 75.12 Telehealth services. (1) All requirements in this chapter shall also be applicable to telehealth services delivered under this chapter.

(2) Services delivered through telehealth shall be of sufficient quality to be functionally equivalent to face−to−face services.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.13 Waivers and variances. (1) EXCEPTION TO A REQUIREMENT. (a) The department may grant a waiver or variance if the department determines that the proposed waiver or variance will not jeopardize the health, safety, welfare, or rights of any client.

(b) A written request for a waiver or variance shall be sent to the department on a form provided by the department and includes

justification that the waiver or variance will not adversely affect the health, safety, or welfare of any client for the requested action.

(c) A written request for a variance shall include a description of an alternative means planned to meet the intent of the requirement.

(d) In considering whether to approve a waiver or variance, the department will consider whether the requested waiver or variance increases patient access to care or sufficiently supports the efficient and economic operation of a service.

(2) RESCINDING WAIVER OR VARIANCE. The department may rescind a waiver or variance if any of the following occurs:

(a) The department determines the waiver or variance has adversely affected the health, safety, or welfare of a client.

(b) The service fails to comply with any of the conditions of the waiver or variance as granted.

(c) Rescinding the waiver or variance is required by federal or state law.

(d) There is no longer sufficient justification that the waiver or variance increases patient access to care or sufficiently supports the efficient and economic operation of a service.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

Subchapter III — Prevention and Intervention Service Requirements

DHS 75.14 Prevention service. (1) SERVICE DESCRIPTION. A prevention service makes use of universal, selective, and indicated prevention services as defined by s. DHS 75.14 (3). Prevention services may be focused on reducing behaviors and actions that increase the risk of misusing substances or being affected by another person's substance use.

(2) APPLICABILITY. This section shall apply to prevention services when required by contract with the department, or when a prevention service requests certification.

(3) DEFINITIONS. In this section:

(a) "Prevention" has the meaning given in s. SPS 160.02 (21).

(b) "Prevention domain" refers to content areas that professionals working in substance use prevention shall be knowledgeable in. The prevention domains include any of the following:

1. Planning and evaluation.
2. Prevention education and service delivery.
3. Communication.
4. Community organization.
5. Public policy and environmental change.
6. Professional growth and responsibility, including ethics.

(c) "Prevention service" means the organized application of strategies and interventions that are provided to reduce the overall harms and burden of substance use for an identified community or group.

(d) "Prevention strategy" means activities targeted to a specific population or the larger community that are designed to be implemented before the onset of problems as a means to prevent substance use or its detrimental effects from occurring.

(e) "Target population" means the identified community or group that a prevention strategy is aimed to impact.

(f) "Universal, selective, and indicated prevention strategy" means different levels of risk that are addressed through community−based substance use prevention efforts, where universal prevention efforts focus on general audiences who have not been identified based on substance use−related risk, selective prevention efforts focus on audiences with known risk factors for a substance use−related problem, and indicated prevention efforts focus on audiences who are already experiencing a substance use−related problem.

(4) GENERAL REQUIREMENTS. (a) *Governing authority or entity owner.* The governing authority or entity owner of a service shall do all of the following:

1. Designate a member or representative of the governing body that is legally responsible for the operation of a service that has the authority to conduct the policy, actions, and affairs of the service, to complete the entity owner background check and to be the entity owner responsible for a service.

2. Appoint a service director whose qualifications, authority, and duties are defined in writing.

3. Establish written policies and procedures for the operation of the service and exercise general direction over the service, to ensure the following:

a. Compliance with local, state and federal laws.

b. That no person will be denied service or discriminated against on the basis of sex, race, color, creed, sexual orientation, disability, or age, in accordance with 45 CFR part 92 and Title VI of the Civil Rights Act of 1964, as amended, 42 USC. 2000d, Title XI of the Education Amendments of 1972, 20 USC 1681−1686 and s. 504 of the Rehabilitation Act of 1973, as amended, 29 USC 794, and the Americans with Disabilities Act of 1990, as amended, 42 USC 12101−12213.

(b) *Caregiver background check.* At the time of hire, employment, or contract, and every 4 years after, the service shall conduct and document a caregiver background check following the procedures in s. 50.065, Stats., and ch. DHS 12. A service shall not employ or contract with a person who has been convicted of a crime or offense, or has a governmental finding of misconduct, found in s. 50.065, Stats., and ch. DHS 12, Appendix A, unless the person has been approved under the department's rehabilitation process as defined in ch. DHS 12.

(c) *Personnel records.* Employee records shall be available upon request at the service for review by the department. A separate record for each employee shall be maintained, kept current, and at a minimum, include:

1. A written job description including duties, responsibilities and qualifications required for the employee.

2. Beginning date of employment.

3. Qualifications based on education or experience.

4. A completed caregiver background check following procedures under s. 50.065, Stats., and ch. DHS 12.

5. A copy of a signed statement regarding confidentiality of client information.

6. Documentation of any required training.

7. A copy of any required licenses or certifications.

(d) *Confidentiality.* A service shall have written policies, procedures, and staff training to ensure compliance with confidentiality provisions of 42 CFR part 2, 45 CFR parts 164 and 170, s. 51.30, Stats., and ch. DHS 92. Each staff member shall sign a statement acknowledging responsibility to maintain confidentiality of personal information about persons served.

(5) REQUIRED PERSONNEL. (a) *Prevention professional.* A professional employed by the service shall be knowledgeable and skilled in areas of substance use prevention, including prevention domains, prevention services, and program implementation.

(b) *Training.* Staff shall receive ongoing training to improve skills and knowledge in the prevention domains and in the implementation of prevention services.

(6) OPERATION OF THE PREVENTION SERVICE. (a) *General.* A prevention service shall utilize recognized best practices for evidence−based substance use prevention.

(b) *Strategies employed by the prevention service.* 1. 'Comprehensive approach.' A prevention service shall employ a comprehensive approach that targets universal, selective, and indicated populations, and uses strategies which seek to prevent substance use and its effects.

2. 'Information dissemination.' The prevention service shall provide awareness and knowledge of the nature and extent of the identified problem and generate knowledge and awareness of available prevention services via one−way communication with the public. Examples of methods that may be used to carry out this strategy include the following:

a. Operation of an information clearinghouse.

b. Development and distribution of a resource directory.

c. Media campaigns.

d. Development and distribution of brochures.

e. Radio and TV public service announcements.

f. Speaking engagements.

g. Participation in health fairs and other health promotion activities.

3. 'Education.' The prevention service shall provide two−way communication between staff and a client or clients, that is directed towards affecting critical life and social skills, including decision−making, refusal skills, critical analysis, and systematic judgment abilities. Examples of activities that may be conducted and methods used in carrying out this strategy include the following:

a. Classroom or small group sessions.

b. Parenting and family management classes.

c. Peer leader or helper programs.

d. Education programs for youth groups.

e. Groups for children with family members who use substances.

4. 'Alternative activities.' The prevention service shall provide activities that assist in building resiliency and exclude alcohol, tobacco, and other drug use to targeted populations. The assumption is that constructive and healthy activities offset the attraction to, or otherwise meet the needs that may be fulfilled by, alcohol, tobacco, and other drugs. Alternative activities also provide a means of character−building and may promote healthy relationships between youth and adults, in that participants may internalize the values and attitudes of the individuals involved in establishing the prevention services objectives. Examples of activities that may be promoted or conducted under this strategy include the following:

a. Drug−free dances and parties.

b. Youth or adult leadership activities.

c. After−school activities such as participation in athletic activities, music lessons, art clubs or the school newspaper.

d. Community drop−in centers.

e. Community service activities.

5. 'Problem identification and stand−alone referral.' The prevention service shall implement methods to identify individuals who have demonstrated at−risk behavior, such as illegal or age−inappropriate use of tobacco or alcohol, or first use of illicit drugs, and determine if the individual's behavior can be reversed through education. This strategy does not include activities designed to determine if a person is in need of treatment. Examples of activities that may be conducted and methods used in carrying out this strategy include the following:

a. Employee assistance programs.

b. Student assistance programs.

c. Educational programs for individuals charged with driving while under the influence or driving while intoxicated.

6. 'Environmental.' The prevention service shall establish community standards, codes, and attitudes, aimed at reducing the prevalence of at−risk behavior among the general population. Examples of methods that may be used in carrying out this strategy include the following:

a. Promoting the establishment and review of policies for schools, government, and civic groups related to the use of alcohol, tobacco, and drugs.

b. Providing technical assistance to communities to maximize local enforcement procedures governing availability and distribution of alcohol, tobacco, and other drugs.

c. Reduce youth alcohol, tobacco, and drug exposure by modifying alcohol and tobacco advertising practices.

d. Supporting local enforcement procedures to limit violent behavior.

e. Establishing policies that create opportunities for youth to become involved in their communities.

7. 'Community−based process.' The prevention service shall implement processes that enhance the ability of the community to more effectively provide prevention services for behaviors that lead to substance use. Activities under this strategy include organizing, planning, enhancing the efficiency and effectiveness of services implementation, interagency collaboration, coalition building and networking. Examples of activities that may be conducted and methods used in carrying out this strategy include the following:

a. Community and volunteer training, such as neighborhood action training and training of key people in the system.

b. Systematic planning in the above prevention strategy areas.

c. Multi−agency coordination and collaboration.

d. Facilitating access to services and funding.

e. Active participation in a community prevention coalition.

(c) *Goals and objectives.* A prevention service shall have written operational goals and objectives that specify the strategies by which they will be achieved and the target population served.

(d) *Documentation of coordination.* A prevention service shall provide written documentation of coordination with other human service agencies, organizations or services that share similar goals.

(e) *Records.* A prevention service shall maintain records on the number of individuals served by implementation of each prevention strategy and retain records necessary for meeting certification and funding requirements.

(7) PREVENTION SERVICE EVALUATION. (a) *Prevention evaluation outcomes.* A prevention service shall have an evaluation process that measures the outcomes of the services provided.

(b) *Prevention evaluation by consumers.* A prevention service shall evaluate the views of consumers about the services they are provided and shall adjust goals and objectives accordingly.

(c) *Prevention service written policy.* A prevention service shall have a written policy and a defined process to provide individuals with the opportunity to express opinions regarding ongoing services, staff, and the methods by which individual prevention activities are offered.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; correction in (1) made under s. 13.92 (4) (b) 7., Stats., and correction in (4) (a) 3. b., (d) made under s. 35.17, Stats., Register October 2021 No. 790.

DHS 75.15 Intervention service and intoxicated driver services.

(1) SERVICE DESCRIPTION FOR AN INTERVENTION SERVICE. Intervention services are delivered in a wide variety of settings and are designed to explore and address risk factors that appear to be related to substance use, to assist the individual in recognizing the consequences of harmful substance use, and to provide information for individuals to make behavioral changes. Intervention services may include screening, brief intervention and referral, psychoeducational services, pre−treatment intervention groups, case management, health education, outreach and in−reach programs, problem identification, information dissemination, alternative education, intoxicated driver assessments, and support services provided to reduce the effects of substance−related concerns by identifying and engaging the individual to change behavior or to participate in treatment or other wellness services.

(2) APPLICABILITY. This section shall apply to any of the following:

(a) Intervention services, as required by contract with the department.

(b) Intoxicated driver services.

(c) An intervention service that requests certification.

(3) SERVICE DESCRIPTION FOR INTOXICATED DRIVER SERVICES. Intoxicated driver intervention services are specific services within the Intoxicated Driver Program under ch. DHS 62, utilized to reduce risk of reoccurrence of impaired driving. These services include intoxicated driver assessments, driver safety planning and monitoring, and alternative education services.

(4) DEFINITIONS. In this section:

(a) "Alternative education" means a course of traffic safety instruction that is designed to meet the goals of a group dynamic traffic safety program or a multiple offender traffic safety program for clients that cannot be accommodated by a group dynamic traffic safety program or multiple offender traffic safety program.

(b) "Intervention service" means a service provided to an individual who, at the time of screening and assessment, does not appear to meet the criteria for a diagnosis of substance use disorder or for referral to treatment services but is at risk of developing problems related to substance use.

(5) GENERAL REQUIREMENTS FOR INTERVENTION SERVICES AND INTOXICATED DRIVER SERVICES. (a) *Governing authority or entity owner.* The governing authority or entity owner of a service shall do all of the following:

1. Designate a member or representative of the governing body that is legally responsible for the operation of a service that has the authority to conduct the policy, actions, and affairs of the service, to complete the entity owner background check and to be the entity owner responsible for a service.

2. Appoint a service director whose qualifications, authority, and duties are defined in writing.

3. Establish written policies and procedures for the operation of the service and exercise general direction over the service. Policies and procedures must be written to insure all of the following:

a. Compliance with local, state, and federal laws.

b. That no person will be denied service or discriminated against on the basis of sex, race, color, creed, sexual orientation, disability, or age, in accordance with 45 CFR part 92 and Title VI of the Civil Rights Act of 1964, as amended, 42 USC 2000d, Title XI of the Education Amendments of 1972, 20 USC 1681−1686 and s. 504 of the Rehabilitation Act of 1973, as amended, 29 USC 794, and the Americans with Disabilities Act of 1990, as amended, 42 USC 12101−12213.

(b) *Caregiver background check.* At the time of hire, employment, or contract, and every 4 years after, the service shall conduct and document a caregiver background check following the procedures in s. 50.065, Stats., and ch. DHS 12. A service shall not employ or contract the service if the person has been convicted of the crimes or offenses, or has a governmental finding of misconduct, found in s. 50.065, Stats., and ch. DHS 12, Appendix A, unless the person has been approved under the department's rehabilitation process, as defined in ch. DHS 12.

(c) *Personnel records.* Employee records shall be available upon request at the service for review by the department. A separate record for each employee shall be maintained, kept current, and at a minimum, include:

1. A written job description including duties, responsibilities and qualifications required for the employee.

2. Beginning date of employment.

3. Qualifications based on education or experience.

4. A completed caregiver background check following procedures under s. 50.065, Stats., and ch. DHS 12.

5. A copy of a signed statement regarding confidentiality of client information.

6. Documentation of any required training.

7. A copy of any required licenses or certifications.

(d) *Confidentiality.* A service shall have written policies, procedures and staff training to ensure compliance with confidentiality provisions of 42 CFR part 2, 45 CFR parts 164 and 170, and s. 51.30, Stats., and ch. DHS 92. Each staff member shall sign a statement acknowledging his or her responsibility to maintain confidentiality of personal information about persons served.

(e) *Policies, procedures, and service description.* A service shall develop written policies, procedures, and service descriptions for each intervention service to be provided.

(f) *Submissions to department.* The service shall submit each service description, along with written policies and procedures, to the department with the initial certification application, and submit any updates to the department when needed.

(g) *Staff knowledge and training.* Service staff shall have knowledge, training, and experience in the service which they are responsible for providing, including substance use intervention, screening, and referral.

(h) *Referral.* The service shall develop and maintain a written record of certified substance use treatment resources for referral, and shall refer clients as indicated for further assessment and treatment services.

(i) *Evaluation.* The service shall have an evaluation plan that includes goals of the service, measurable outcomes and objectives related to the service goals, and an annual report of progress related to goals and objectives that is available to the department and the public.

(6) LOCATION OF SERVICE DELIVERY. An intervention service, other than an intoxicated driver service designated under s. DHS 62.04, may be provided in a variety of settings, such as clinical offices, schools, workplaces, community centers, or an individual's home, with the length of service varying according to the type of activity and needs of the individual. An intervention service that provides services in community settings shall ensure the following:

(a) All requirements of this chapter are able to be met in the setting.

(b) The service shall have written policies and procedures concerning community−based service delivery.

(c) The service shall provide annual training for all staff that deliver services in the community regarding in−home and community safety, and avoiding sexual or other exploitative relationships with clients. A record of each training shall be available to the department upon request.

(7) CASE RECORDS FOR PERSONS RECEIVING INTERVENTION SERVICES. (a) A service shall keep a case record for every person receiving intervention services, except where the only contact is made by telephone.

(b) A case record prepared under this subsection shall include all of the following information:

1. The individual's name, address, phone contact information, date of birth, and relevant demographic information.

2. The individual's admission date.

3. Substance use information about the individual and the reason for referral.

4. The results of any screening completed.

5. A sufficient assessment of the individual's dimensional risk and severity of need to determine preliminary level of care.

6. Service recommendations, referrals, and follow−up services and activities completed for the individual.

7. Documentation of each contact the service has with the client or a collateral source.

(8) ADDITIONAL REQUIREMENTS FOR INTOXICATED DRIVER SERVICES. (a) If an intervention service is designated by a county human service board under s. DHS 62.04 as an intoxicated driver

assessment facility, the intervention service shall also comply with the requirements under ch. DHS 62.

(b) A public or private treatment facility designated by a county as the intoxicated driver program assessment service shall be certified under this section prior to conducting intoxicated driver program assessments.

(c) In addition to sub. (7) (b), a case record for an intoxicated driver assessment service shall include a copy of the department−approved intoxicated driver assessment tools, the driver safety plan, progress reports, and verification of service completion or evidence of noncompliance.

(9) ALTERNATIVE EDUCATION PROGRAMS FOR INTOXICATED DRIVERS. (a) *General.* 1. Alternative education programs shall be modeled after group dynamic traffic safety and multiple offender traffic safety program. An alternative education program shall be conducted in a constructive, interactive, and trusting atmosphere and that include all of the following as part of its curriculum:

a. Review and discussion of operating while intoxicated laws and penalties.

b. Discussion of the central causes and consequences of operating while intoxicated.

c. Discussion of the effects of alcohol and substances on the mind, body, and driving ability.

d. Discussion of the psycho−social factors involved in substance use.

e. Education about blood alcohol concentration.

f. Education about substance use and substance use disorders, and where participants are in regards to severity of substance use.

g. Education about, and assistance in developing and following a personal change plan.

2. In addition to the content and objectives under subd. 1., programs in lieu of a multiple offender traffic safety program shall involve concerned others, such as a spouse, parent, adult relative, or other appropriate person approved by the instructor, and shall provide education on basic skills in the areas of stress−reduction, substance use refusal, interpersonal communication, and anger management.

3. Classroom instruction time for programs that are in lieu of group dynamic traffic safety programs shall be a minimum of 16 hours.

4. Classroom instruction time for programs that are in lieu of multiple offender traffic safety programs shall be a minimum of 24 hours, including a group−oriented follow−up session. The group−oriented follow−up session shall be held within 3 months after completion of the initial 23 hours of the program. If a participant's residence is 60 miles or more from the site of the group−oriented follow−up session, the follow−up session may be conducted by telephone with the participant and a concerned other, such as a spouse, parent, adult relative, or other appropriate person.

5. Classroom instruction time may not exceed 8 hours per day.

6. A report of course completion or non−completion shall be submitted to the intoxicated driver assessment facility designated under s. DHS 62.04 (1) for each client assessed by that facility.

7. The effectiveness of alternative education programs shall be evaluated by administering pretests and posttests of knowledge gained by participants, changed attitudes of participants, and participant satisfaction surveys.

(b) *Instructor qualifications.* Instructors conducting alternative education shall have the following qualifications:

1. Substance use service experience equal to one of the following:

a. Two years of employment experience or a comparable amount of experience and education in the area of substance use counseling, assessment, education, or treatment, or related fields such as student assistance program director or employee assistance program director.

b. Completed a minimum of a one−semester, 3−credit, 45−hour course in the areas of substance use disorder education or treatment from an accredited college or university.

2. Group process experience equal to one of the following:

a. Two years of employment experience in group process work or group counseling as a treatment or education professional.

b. Completed a minimum of a one−semester, 3−credit, 45−hour course in the area of group work methods, group counseling or group process from an accredited college or university.

c. Bachelor's or master's degree in guidance counseling, psychology, behavioral studies or social work.

3. Hold a valid driver's license from the state of Wisconsin or from the jurisdiction in which the person resides. Programs having nonresident instructors shall maintain a record of the nonresident's driver's license and traffic conviction status in the past 12 months.

4. Possess a satisfactory driving record as defined under s. Trans 106.02 (11).

a. An individual may not be employed as an instructor until 6 months after the date of any traffic conviction that results in an accumulation of 7 or more points against the individual's driver's license, or until 12 months from the date of an operating while intoxicated conviction under s. 23.33, 30.68, 346.63, 350.101, 940.09, or 940.25, Stats., or an order under s. 343.305, Stats.

b. Instructors under this section are not eligible to receive a 3−point reduction by completing a traffic safety course.

c. Once employed as an instructor under this section, an individual's failure to maintain a satisfactory driving record shall result in the suspension of the individual's instruction duties for 6 months from the date of conviction for a violation which places the point total over 6 points or for 12 months from the date of an operating while intoxicated conviction. If additional points are incurred or the individual is convicted of operating while intoxicated during the suspension period, the individual's instruction duties shall be suspended for 12 months from the date of conviction for a violation which results in points or for 24 months from the date of an operating while intoxicated conviction.

5. Instructors shall document receiving a minimum of 6 hours of continuing education in a related area, approved by the department, during each 12 months that the individual is employed as an instructor under this section. This training may include formal courses awarding credits or continuing education units, workshops, seminars, or correspondence courses.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; correction in (5) (a) 2. b., (8) (a), (9) (b) 4. a. made under s. 35.17, Stats., and correction in (8) (c) made under s. 13.92 (4) (b) 7., Stats., Register October 2021 No. 790.

Subchapter IV — Treatment Service General Requirements

DHS 75.16 Applicability of treatment service general requirements. This subchapter establishes general requirements that apply to the 11 types of community substance use treatment services under ss. DHS 75.49 to 75.59. General requirements apply to all treatment services certified under this chapter, unless otherwise specified.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; correction made under s. 35.17, Stats., Register October 2021 No. 790.

DHS 75.17 Governing authority or entity owner requirements. (1) GOVERNING AUTHORITY OR ENTITY OWNER REQUIREMENTS. The governing authority or entity owner of a service shall do all of the following:

(a) Designate a member or representative of the governing body that is legally responsible for the operation of a service that has the authority to conduct the policy, actions, and affairs of the

service, to complete the entity owner background check and to be the entity owner responsible for a service.

(b) Appoint a service director whose qualifications, authority, and duties are defined in writing.

(c) Establish written policies and procedures for the operation of the service and exercise general direction over the service, including the following:

1. Ensure compliance with local, state, and federal laws.

2. Ensure compliance with patient rights requirements as specified in this chapter and in ch. DHS 94 and s. 51.61, Stats.

3. Ensure that no person will be denied service or discriminated against on the basis of sex, race, color, creed, sexual orientation, disability, or age, in accordance with 45 CFR part 92 and Title VI of the Civil Rights Act of 1964, as amended, 42 USC 2000d, Title XI of the Education Amendments of 1972, 20 USC 1681−1686 and s. 504 of the Rehabilitation Act of 1973, as amended, 29 USC 794, and the Americans with Disabilities Act of 1990, as amended, 42 USC 12101−12213.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; correction in (1) (c) 3. made under s. 35.17, Stats., Register October 2021 No. 790.

DHS 75.18 General requirements for service staff.

(1) SERVICE DIRECTOR. (a) A service shall have a service director.

(b) The service director shall be responsible for all of the following:

1. Administration and overall operation of the service.

2. Ensuring that appropriate policies and procedures for the service are developed and carried out in compliance with this chapter.

3. Administrative oversight of the job performance and actions of service staff members.

4. Compliance with regulations governing the care and treatment of patients and the standards of practice for behavioral health professions.

(c) Unless otherwise specified for a specific level of care, the service director, or staff member designated by the director to be responsible for the operation of the service, shall be readily available, at all times the service is in operation. That person may provide direct counseling or other duties consistent with their scope of practice, in addition to being responsible for the service operation.

(2) CLINICAL SUPERVISOR. (a) A service shall have a clinical supervisor, either on staff or through a contracted agreement, to provide clinical supervision or clinical consultation to clinical staff of a service, as required within this chapter, and consistent with applicable professional licensure and certification requirements.

(b) The clinical supervisor is responsible for professional development of clinical staff, and for ensuring delivery of appropriate clinical services to patients of a service.

(c) Any staff who provides clinical supervision shall be a clinical supervisor, as defined in s. DHS 75.03 (19). A clinical supervisor who is on staff of the service and meets the requirements of a substance abuse counselor or mental health professional may provide direct counseling services in addition to supervisory responsibilities.

(3) SUBSTANCE ABUSE COUNSELORS. A service shall have a substance abuse counselor, as defined in s. DHS 75.03 (85), available during the hours of operation of clinical services.

(4) PRESCRIBERS. A service may have prescribers that provide medical services and clinical consultation services. The service shall ensure appropriate training and oversight of prescribers.

(5) NURSES. A service may have nurses that provide nursing services to support mental health and substance use treatment. The service shall ensure appropriate training and oversight of nursing staff.

(6) MENTAL HEALTH PROFESSIONALS. (a) A service may have mental health professionals or prescribers that deliver mental health treatment services. All staff who provide mental health treatment, except prescribers knowledgeable in psychiatry, shall meet the appropriate qualifications under ch. 455 or ch. 457, Stats.

(b) For service levels of care in ss. DHS 75.49 to 75.59 that require a mental health professional, the role of substance abuse counselor and mental health professional may be occupied by the same individual with appropriate credentialing, and providing they are operating within the scope of their practice.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; correction in (2) (c), (3), (6) (a) made under s. 35.17, Stats., Register October 2021 No. 790.

DHS 75.19 Personnel requirements.

(1) CAREGIVER BACKGROUND CHECK. At the time of hire, employment, or contract, and every 4 years after, the service shall conduct and document a caregiver background check following the procedures in s. 50.065, Stats., and ch. DHS 12. A service shall not employ or contract the service if the person has been convicted of the crimes or offenses, or has a governmental finding of misconduct, found in s. 50.065, Stats., and ch. DHS 12, unless the person has been approved under the department's rehabilitation process, as defined in ch. DHS 12.

(2) PERSONNEL RECORDS. Employee records shall be available upon request at the service for review by the department. A separate record for each employee shall be maintained, kept current, and at a minimum, include:

(a) A written job description including duties, responsibilities and qualifications required for the employee.

(b) Beginning date of employment.

(c) Qualifications based on education or experience.

(d) A completed caregiver background check following procedures under s. 50.065, Stats., and ch. DHS 12.

(e) A copy of a signed statement regarding confidentiality of client information.

(f) Documentation of any required training.

(g) A copy of any required licenses or certifications.

(3) CLINICAL SUPERVISION. A service shall have written policies and procedures for the provision of clinical supervision to unlicensed staff, qualified treatment trainees, and recovery support staff. Clinical supervision for substance abuse counselors, mental health professionals in−training, and qualified treatment trainees shall be in accordance with requirements in ch. SPS 162, chs. MPSW 4, 12, and 16, and ch. Psy 2. A record of clinical supervision shall be made available to the department upon request.

(4) STAFF DEVELOPMENT. (a) A service shall have written policies and procedures for determining staff training needs, formulating individualized training plans, and documenting the progress and completion of staff development goals.

(b) The requirements in this subsection may be met through documentation on an employee's annual performance evaluation that addresses professional development goals.

(c) Minimum training requirements for clinical staff include all of the following:

1. Assessment and management of suicidal individuals.

2. Safety planning for behavioral health emergencies.

3. Assessment and treatment planning for co−occurring disorders.

(d) Documentation of training shall be made available to the department upon request.

(e) Documented training for areas identified in par. (c) shall occur within 2 months of hire for new clinical staff, unless the service is able to provide documentation of the staff member's previous training, professional education, or supervised experience addressing these areas.

(5) UNIVERSAL PRECAUTIONS. A service shall have written policies and procedures for infection control and prevention that adheres to federal occupational safety and health administration bloodborne pathogens standards in 29 CFR 1910.1030.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; correction in (3), (4) (e) made under s. 35.17, Stats., Register October 2021 No. 790.

DHS 75.20 Patient case records. (1) GENERAL TREATMENT SERVICE CASE RECORDS. (a) With respect to general treatment service case records, the service shall do all of the following:

1. Maintain a case record for each patient.

2. The service director or another designated staff member shall be responsible for the maintenance and security of patient case records.

3. Safeguard and maintain patient case records in accordance with applicable state and federal security requirements, including all applicable security requirements specified in ch. DHS 92, 42 CFR part 2, 45 CFR parts 164 and 170, and ss. 146.816 and 146.82, Stats.

4. Maintain each case record in a format that provides for consistency and facilitates information retrieval.

5. Whenever an edit to a signed entry in a patient's case record is made, the service shall document the date of the edit, the name of the individual making the edit, and a brief statement about the reason for the edit, if the prior version of the edited information is not retained by the service.

(b) A patient's case record shall include all of the following:

1. The patient's name, physical residence, address, and phone contact information.

2. The patient's date of birth, self−identified gender, and self−identified race or ethnic origin.

3. Consent for treatment forms signed by the patient or the patient's legal guardian, if applicable, that are maintained in accordance with s. DHS 94.03.

4. An acknowledgment by the patient or the patient's legal guardian, if applicable, that the service policies and procedures were explained to the patient or the patient's legal guardian.

5. A copy of the signed and dated patient notification that was reviewed with and provided to the patient or the patient's legal guardian, if applicable, which identifies patient rights, and explains provisions for confidentiality and the patient's recourse in the event that the patient's rights have been abused.

6. Results of all screening, examinations, tests, and other assessment information.

7. A completed copy of the standardized placement criteria and level of care assessment at admission, and subsequent reviews of level of care placement criteria.

8. Treatment plans, including all reviews and updates to the treatment plan.

9. Records for any medications prescribed or administered by the service, including any medication consent records required by s. DHS 94.09.

10. Copies of any incident reports or documentation of medication errors applicable to the patient.

11. Records for any medical services provided by the service.

12. Reports from referring sources, as applicable.

13. Records of any referrals by the service, including documentation that referral follow−up activities occurred.

14. Correspondence relevant to the patient's care and treatment, including dated summaries of relevant telephone or electronic contacts and letters.

15. Consents authorizing disclosure of specific information about the patient.

16. Progress notes that include documentation of all services provided.

17. Clinical consultation and staffing notes, as applicable.

18. Any safety plans developed during the patient's treatment.

19. Documentation of each transfer from one level of care to another. Documentation shall identify the applicable criteria from ASAM or other department−approved placement criteria, and shall include the dates the transfer was recommended and initiated.

20. Discharge documentation.

(c) For patients that discharge from a service and are subsequently re−admitted, a new case record shall be established for each episode of care.

(d) A patient's case record shall be maintained in accordance with ch. DHS 92.

(e) If the service discontinues operations or is taken over by another service, records containing patient identifying information shall be turned over to the replacement service, as permitted by applicable state and federal confidentiality requirements.

(2) CASE RECORDS FOR PERSONS RECEIVING ONLY SCREENING AND REFERRAL. A treatment service shall have a written policy and procedure regarding case records for individuals that receive only screening, consultation, or referral services. The policy and procedure shall include:

(a) Information to be obtained for phone and in−person screening, consultation, or referral.

(b) Assurance that screening includes an individual's pregnancy status.

(c) Assurance that screening, consultation, and referral procedures address individual risks and needs.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; correction in (1) (a) 3., (b) 3., 9. made under s. 35.17, Stats., Register October 2021 No. 790.

DHS 75.21 Confidentiality. A service shall have written policies, procedures and staff training to ensure compliance with applicable confidentiality provisions of 42 CFR part 2, 45 CFR parts 164 and 170, ss. 51.30, 146.816 and 146.82, Stats., and ch. DHS 92. Each staff member shall sign a statement acknowledging responsibility to maintain confidentiality of personal information about persons served.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; correction made under s. 35.17, Stats., Register October 2021 No. 790.

DHS 75.22 Services for minors. (1) APPLICATION. A service under this chapter that delivers treatment services to minors shall identify within their application to the department each level of care that will provide treatment services for minors.

(2) STATUTORY REQUIREMENTS. A service that delivers treatment services to minors shall adhere to all applicable requirements outlined in ss. 51.13, 51.138, 51.14, 51.47 and 51.48, Stats.

(3) FAMILY INVOLVEMENT. Services for minors shall include the involvement of a parent, guardian, or other family members whenever possible.

(4) STAFF QUALIFICATIONS. Staff delivering services to minors shall have training, experience, or education specific to the treatment of substance use and mental health for minors and shall practice within their scope. A record of relevant training, experience, or education shall be documented in the personnel record.

(5) STAFF TRAINING. A service that delivers treatment services to minors shall provide training to clinical staff in the areas of adolescent development, family systems, child abuse and neglect, and involuntary treatment laws for minors, unless the service is able to provide documentation of the staff member's previous training, professional education, or supervised experience addressing these areas. A record of required training shall be documented in the personnel record.

(6) SEPARATION OF SERVICES. Services for minors shall be separate from adult services, with the exception of specialized groups addressing the needs of transitional−age youth. Services for tran-

sitional−age youth shall be separate from other services for minors or adults.

(7) POLICIES AND PROCEDURES. A service that delivers treatment services to minors shall have written policies and procedures to address specific safety needs of minors, including consideration of vulnerability related to adult populations served within the facility, adequacy of supervision for service delivery, and services addressing specific needs of youth.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.23 Service levels of care. (1) SERVICE LEVELS OF CARE. (a) Services delivered under this chapter shall adhere to standardized levels of care as defined in this chapter. A service shall apply the ASAM criteria or other department−approved placement criteria to determine the appropriate level of care, and services shall be delivered consistent with that level of care.

(b) A service shall not deliver or purport to deliver a service for which they do not possess certification by the department under this chapter.

(2) USE OF ASAM OR OTHER DEPARTMENT−APPROVED PLACEMENT CRITERIA. (a) A service shall utilize ASAM placement criteria or other department−approved placement criteria to determine the level of care that is matched to a patient's needs and risk level.

(b) In order to be approved by the department, other placement criteria must include all of the following:

1. A multi−dimensional assessment tool that captures behavioral health, physical health, readiness for change, social risk levels and directly correlates risk level to service levels of care based on frequency and intensity of the service.

2. Proof that the criteria is accepted and utilized within professional organizations in the field of healthcare and allows for consistency of interpretation across settings and providers.

Note: Copies of the ASAM Criteria: Treatment Criteria for Addictive, Substance−Related, and Co−Occurring Conditions (published October 24, 2013) are on file in the department's division of care and treatment services and the legislative reference bureau, and may be obtained from ASAM at 11400 Rockville Pike, Suite 200, Rockville, MD 20852, or https://www.asam.org/asam−criteria/text.

(3) LEVEL OF CARE TRANSFER. A service that offers more than one level of care under this chapter shall identify in the clinical record which level of care the patient is receiving based on the clinical assessment. When a level of care transfer is completed as indicated by assessment or treatment plan review, the service shall document the level of care transfer in the record and shall thereafter meet the service requirements for the indicated level of care.

(4) CONCURRENT SERVICES. (a) If a patient is receiving services in more than one level of care at a given time, the service shall adhere to all applicable standards for each level of care, and to the level of care standard with the highest requirement when more than one apply.

(b) If a patient is receiving services in more than one level of care at a given time, the patient shall be listed on a roster or patient list for each level of care in which they receive services.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.24 Service operations. (1) SCREENING. (a) A service shall complete an initial screening for an individual that presents for services. The screening shall include all of the following:

1. Sufficient assessment of dimensional risk and severity of need to determine preliminary level of care.

2. A determination of the patient's needs for immediate services related to withdrawal risk, acute intoxication, overdose risk, induction of pharmacotherapy, or emergency medical needs.

3. An assessment of the patient's suicide risk.

(b) A screening is preliminary, and is either confirmed or modified based on completion of the full assessment and ASAM or other department−approved level of care placement criteria.

(c) The screening completed under this subsection may be combined with a more comprehensive assessment.

(2) EMERGENCY SERVICES. If a need is identified for immediate services related to withdrawal, acute intoxication, overdose, or other reason, the service may initiate treatment prior to completion of the comprehensive assessment or treatment plan. The patient's record for emergency services shall include documentation of all of the following:

(a) A preliminary treatment plan for the patient.

(b) A consent for services to be received, signed by the patient or the patient's legal guardian.

(c) A progress note for all services delivered to the patient.

(d) A reason for the initiation of emergency services and a completed initial screening that evaluates biomedical, mental health, and substance use indicators, and guides decision−making regarding the initial level of care placement and referral.

(3) AFTER HOURS EMERGENCY RESPONSE. A service shall have a written policy and procedure for how the clinic will provide or arrange for, the provision of services to address a patient's behavioral health emergency or crisis during hours when its offices are closed, or when staff members are not available to provide behavioral health services.

(4) SAFETY PLANNING. (a) When a patient's pattern of behavior or acute symptoms of a substance use or mental health disorder indicate the likelihood for significant, imminent harm to the individual or others, including affected family members, the service shall develop a safety plan within 24 hours of the contact.

(b) The service shall have written policies and procedures that outline the requirements and process for safety planning.

(5) OPIOID OVERDOSE REVERSAL. (a) A service shall have Naloxone on−site at each facility and branch location, to be administered in the event of an opioid overdose.

(b) Naloxone medication shall be maintained and unexpired, and shall be stored in an accessible location.

(c) The service shall have written policies and procedures for administration of Naloxone by service staff.

(d) The service shall train all staff in recognition of overdose symptoms and administration of Naloxone.

(e) Administration of Naloxone by the service to any individual shall be documented in the clinical record or in a facility incident report.

(6) SERVICE DELIVERY FOR INTOXICATED INDIVIDUALS. A service shall have written policies and procedures regarding clinically−appropriate response and services for individuals that present with symptoms of acute intoxication, withdrawal, or at risk of withdrawal. The policies and procedures shall include the following:

(a) The process for obtaining medical consultation, when indicated.

(b) The process for admitting the patient to a higher level of care, withdrawal management service, or direct linkage to medical services, when indicated.

(c) The process for ensuring the safety of an intoxicated individual or persons experiencing withdrawal, including an individual operating while intoxicated.

(d) The process for follow−up and treatment engagement after an intervention for acute intoxication or withdrawal.

(7) TOBACCO USE DISORDER TREATMENT AND SMOKE−FREE FACILITY. A service shall have written policies outlining the service's approach to assessment and treatment for concurrent tobacco use disorders, and the facility's policy regarding a smoke−free environment.

(8) CULTURALLY AND LINGUISTICALLY APPROPRIATE SERVICES. A service shall have a written policy and procedure for assessing the cultural and linguistic needs of the population to be served, and to ensure that services are responsive and appropriate to the cultural and linguistic needs of the community to be served.

(9) INTAKE AND ADMISSION. (a) A service shall have written policies and procedures for intake, including all of the following:

1. A written consent for treatment, which shall be signed by the prospective patient before admission is completed.

2. Information concerning communicable illnesses, such as sexually transmitted infections, hepatitis, tuberculosis, and HIV, and shall refer patients with communicable illness for treatment when appropriate.

3. Policies regarding admission of a patient under court order, that shall be in accordance with ss. 51.15, 51.20, and 51.45 (12), Stats.

4. A method for informing the patient about, and obtaining the patient's signed acknowledgment of having been informed and understanding all of the following:

a. The general nature and purpose of the service.

b. Patient rights and the protection of privacy provided by confidentiality laws.

c. Service regulations governing patient conduct, the types of infractions that result in corrective action or discharge from the service, and the process for review or appeal.

d. The hours during which services are available.

e. Procedures for follow−up after discharge.

f. Information about the cost of treatment, who will be billed, and the accepted methods of payment if the patient will be billed.

g. Sources of collateral information that may be used for screening and assessment.

(b) If the patient is seeking treatment related to opioid use, and the service does not provide medication−assisted treatment for patients with opioid use disorders, the service shall provide information about the benefits and effectiveness of medication as an effective treatment for opioid use disorders. If the patient is not already receiving medication treatment, the service shall obtain the patient's written consent to participate in non−medication treatment, shall provide a referral to a service that offers medication−assisted treatment for opioid use disorders.

(10) FIRST PRIORITY FOR SERVICES. (a) A service shall prioritize admission in the following order:

1. First, pregnant women who inject drugs.

2. Second, pregnant women that use drugs or alcohol.

3. Third, persons who inject drugs.

4. All others.

(b) When a waitlist exists for services for pregnant women, the service shall either initiate interim services or notify the department within 2 business days.

(c) When a waitlist exists for services for individuals who inject drugs, the service shall either initiate interim services or notify the department within 14 business days.

(11) CLINICAL ASSESSMENT. (a) Clinical staff of a service, operating within the scope of their knowledge and practice, shall assess each patient through interviews, information obtained during intake, counselor observation, and collateral information.

(b) The service shall promote assessments that are trauma−informed.

(c) If a comprehensive clinical assessment has been conducted by a referring substance use treatment service and is less than 90 days old, the assessment may be utilized in lieu of conducting another one.

(d) Information for the assessment shall include the following:

1. The clinical staff's evaluation of the patient, and documentation of psychological, social, and physiological signs and symptoms of substance use and/or mental health disorders, based on criteria in the DSM.

2. The summarized results of all psychometric, cognitive, vocational, and physical examinations provided as part of the assessment.

3. History of substance use that includes all of the following:

a. Substances used.

b. Duration of use for each substance.

c. Frequency and amount of use.

d. Method of administration.

e. Status of use immediately prior to entering into treatment.

f. Consequences and effects of use.

g. Withdrawal and overdose history.

4. Documentation about the current mental and physical health status of the patient.

5. Psychosocial history information shall include all of the following areas that relate to the patient's presenting problem:

a. Family.

b. Significant relationships.

c. Legal.

d. Social.

e. Financial.

f. Education.

g. Employment.

h. Treatment history.

i. Other factors that appear to have a relationship to the patient's substance use and physical and mental health.

6. The clinical assessment shall include any collateral information gathered during the clinical assessment. Collateral information may include one of more of the following:

a. Review of Wisconsin Prescription Drug Monitoring Program database.

b. Records of the patient's legal history.

c. Information from referral sources.

d. Consultation with the patient's physician or other medical or behavioral health provider.

e. Consultation with department of corrections or child protective services when applicable.

f. Information from the patient's family or significant others.

g. Results of toxicology testing.

7. Level of care recommendation based on ASAM or other department−approved placement criteria.

(e) If no collateral information is obtained to inform the assessment, the service shall document the reason for not including collateral information.

(f) The clinical staff's recommendations for treatment shall be included in a summary of the assessment that is consistent with diagnosis and level of care placement criteria.

(g) If an assessing substance abuse counselor identifies symptoms of a mental health disorder during the assessment process, the substance abuse counselor shall refer the individual to an appropriately credentialed provider for a comprehensive mental health assessment, unless the substance abuse counselor is also a licensed mental health professional.

(h) If the assessing clinical staff identifies symptoms of a physical health problem during the assessment process, the service shall refer the individual for a physical health assessment conducted by medical personnel.

(i) If the assessing clinical staff identifies that an individual is pregnant at the time of the assessment, the service shall make a referral for prenatal care or ensure that the patient is already receiving prenatal care, and document efforts to coordinate care with prenatal care providers.

(j) In the event that the assessed level of care is not available, a service shall:

1. Document accurately the level of care indicated by the clinical assessment.

2. Indicate on the treatment plan what alternative level of care is available or agreed upon.

3. Identify on the treatment plan what efforts will be made to access the appropriate level of care, additional services or supports that will be offered to bridge the gap in level of care, and ongoing assessment for clinical needs and level of care review.

(k) For assessments completed by a substance abuse counselor in−training or a graduate student QTT, the assessment and recommendations shall be reviewed and signed by the clinical supervisor within 7 days of the assessment date.

(L) For a patient receiving mental health services under s. DHS 75.50 or 75.56 who does not have a co−occurring substance use disorder, the requirement for ASAM or other department−approved level of care placement criteria is not required.

(12) REFERRAL. (a) A service shall have written policies and procedures for referring patients to other community service providers and for coordinating care with other providers.

(b) Policies and procedures shall include a description of follow−up activities to be completed to support that recommended care is received.

(c) Follow−up shall occur within one week of the referral.

(13) TREATMENT PLAN. (a) Clinical staff of a service shall develop a treatment plan for each patient.

(b) A patient's treatment plan shall represent an agreement between the service and the patient regarding needs identified in the clinical assessment, the patient's identified treatment goals, and treatment interventions and resources to be applied.

(c) When feasible, the treatment plan shall be developed in collaboration and with input from the patient's family or significant other, or other supportive persons identified by the patient.

(d) The treatment plan shall be signed by the patient, the primary counselor, and other behavioral health clinical staff, identified in the treatment plan.

(e) A treatment plan completed by a substance abuse counselor in−training or a graduate student QTT shall be reviewed and signed by the clinical supervisor within 14 days of the development of the plan or the next treatment plan review, whichever is earlier.

(f) The content of the treatment plan shall describe the identified needs and specify individualized treatment goals that are expressed in behavioral and measurable terms.

(g) The treatment plan shall specify each intervention applied to reach the treatment goals.

(h) The treatment plan shall be reviewed at the interval required by the patient's level of care or based on the patient's needs and clinical indication. The review shall be documented with a summary of progress and the signature of the patient and primary counselor.

(i) The treatment plan review shall include an updated level of care assessment which follows ASAM or other department−approved placement criteria and recommends continued stay, transfer, or discharge.

(j) An updated treatment plan shall be established during the review if there is a change in the patient's needs, goals, or interventions and resources to be applied. The updated treatment plan shall be signed by the patient, the primary counselor, and any other behavioral health clinical staff identified in the treatment plan.

(k) Treatment plan reviews and updates completed by a substance abuse counselor in−training or graduate student QTT shall be reviewed and signed by the clinical supervisor within 14 days of the review and update.

(L) For patients with co−occurring disorders receiving services under ss. DHS 75.50, 75.51, 75.52, 75.54, 75.55, 75.56, and 75.59 service shall assign dually−credentialed clinicians whenever possible. When this is not possible, the service shall ensure that mental health needs and substance use needs are included in the treatment plan, and met by appropriately credentialed personnel.

(m) For a patient receiving mental health services under s. DHS 75.50 or 75.56 who does not have a co−occurring substance use disorder, the requirement for ASAM or other department−approved level of care placement criteria and review is not required.

(14) CLINICAL CONSULTATION. (a) A service shall have a written policy and procedure that outlines the structure for clinical consultation.

(b) Clinical consultation applies to all clinical staff of a service.

(c) Clinical consultation shall be documented in the patient's case record.

(d) Clinical consultation for unlicensed staff shall be completed with a clinical supervisor and shall be documented with the clinical supervisor's signature. Clinical consultation for licensed professionals may occur with a clinical supervisor or another licensed professional who is a staff of the service.

(e) Clinical consultation is required for any of the following:

1. When a patient's substance use or mental health poses a significant risk to the individual, their family, or the community.

2. When a safety plan has been developed, per s. DHS 75.24 (4).

3. When an individual's symptoms, pattern of substance use, risk level, or placement criteria indicate transfer to a higher level of care.

(f) When a safety plan requires ongoing monitoring, clinical consultation shall be completed at clinically−determined intervals until the risk level is reduced or appropriately managed with services or collateral supports.

(g) When the recommended level of care cannot be determined, or is not available, or the individual has declined the recommended level of care, clinical consultation shall be completed at clinically−determined intervals until the appropriate level of care is determined, or obtained, or the individual's risk level decreases.

(15) CLINICAL STAFFING. (a) A service shall have a written policy and procedure that outlines the structure for clinical staffing.

(b) Clinical staffing applies to all clinical staff of a service, and includes the clinical supervisor and medical personnel. Clinical staffing is facilitated at intervals appropriate to the individual's needs and as prescribed based on the level of care.

(c) For clinical staffing required under ss. DHS 75.49 to 75.59, the following shall apply:

1. Clinical staffing shall include the clinical supervisor of the service.

2. Clinical staffing shall include a patient's prescriber or medical personnel, if applicable.

3. Clinical staffing may be combined with treatment plan review and level of care review.

4. Clinical staffing shall be documented in the patient's clinical record.

(16) PROGRESS NOTES. (a) A service shall document in the patient's record each contact the service has with a patient or with a collateral source.

(b) Notes shall be entered by the staff member providing the service to document the content of the contact with the patient or a collateral source; or, if notes are entered by a designee, this must be specified.

(c) Progress notes shall include chronological documentation of treatment that is directly related to the patient's treatment plan, and documentation of the patient's response to treatment.

(d) The person making the entry shall sign and date the note, and if a designee, shall indicate who provided the service.

(17) GROUP COUNSELING. (a) A service may offer group counseling.

(b) A service shall have written policies and procedures regarding group counseling that include, at minimum, the following:

1. Participant confidentiality.

2. Group rules for safety.

3. Consideration of needs related to special populations or considerations for co−mingled groups.

4. Assurance that groups are trauma−informed.

(c) Each group therapy contact shall be documented as a progress note in each patient's case record.

(18) FAMILY SERVICES. (a) When requested by a patient's affected family member or significant other, the service shall offer or refer for supportive services, such as counseling, support groups, or education.

(b) A service shall involve a patient's family members and significant others in assessment, treatment planning, transfers of care, safety planning, and discharge whenever feasible.

(c) A service shall have written policies and procedures to address confidentiality, conflicts of interest, and ethics related to family services.

(19) MEDICAL SERVICES. (a) All medical services provided under this chapter shall be provided by appropriately credentialed staff operating within their scope of practice,

(b) Prescribers providing substance use treatment services or supervision of substance use treatment services shall be knowledgeable in addiction treatment.

(c) For medical needs of a patient that exceed the scope of the service under this chapter, the service shall coordinate with appropriate medical providers.

(d) A service may offer medication management for treatment of substance use disorders or mental health disorders. A service shall have written policies and procedures for medication management services, including:

1. Prescribing policies and practices.

2. Prescriber checks and use of the Wisconsin Prescription Drug Monitoring Program database.

3. Procedures for obtaining and updating patient consents for medications received.

4. Procedures for reporting and reviewing medication errors via facility incident reports or other documentation.

(e) When a patient's treatment includes medication management, it shall be documented as a goal in the patient's treatment plan. The treatment plan shall be signed by the prescriber.

(f) If a patient is prescribed medication as part of the treatment plan, the service shall obtain a separate consent that indicates that the prescriber has explained to the patient, or the patient's legal representative, if applicable, the nature, risks and benefits of the medication and that the patient, or legal representative, understands the explanation and consents to the use of the medication.

(g) A service shall maintain medication records that allow for ongoing monitoring of any medication prescribed or administered by the service, and documentation of any adverse drug reactions or medication errors. Medication orders shall specify the name of the medication, dose, route of administration, frequency of administration, name of the prescriber who prescribed the medication, prescriber signature, and staff administering the medication, if applicable.

(h) A service that receives, stores, or dispenses medications shall have written policies and procedures regarding storage, dispensing, and disposal of medications, including:

1. Patient name, medication name, amount of medication, dosage, date of receipt, and date of dispensing or disposal.

2. Safeguards to prevent the diversion of medication.

(i) A non−residential service that receives, stores, or dispenses medications shall comply with 21 CFR 1301.72. The medication storage area shall be clean, and shall be separated by a wall from any restroom, cleaning products, or any food−preparation or storage area.

(j) A residential service under ss. DHS 75.53 to 75.58, shall follow the requirements for medication storage provided in s. DHS 75.39.

(20) DRUG TESTING SERVICES. (a) A service shall have written policies and procedures for drug testing, breath analysis, and toxicology services. Patients of a service shall be informed of these policies and procedures upon admission.

(b) A service may utilize drug testing information in conjunction with patient self−report, behavioral observations, collateral information, and clinical assessment to make determinations regarding patient care.

(c) A service shall have a method for obtaining confirmation of drug testing results.

(d) A service shall inform patients of the costs for drug testing services.

(e) A service shall obtain informed consent before releasing patient drug testing results. The service is responsible for ensuring that the patient understands possible consequences of disclosure of drug testing information.

(21) TRANSFER. If the service transfers a patient to another provider or if a change is made in the patient's level of care, the transfer or change in the level of care shall be documented in the patient's case record. A transfer summary shall be entered into the patient's case record, including the following:

(a) The date of the transfer.

(b) A completed copy of the standardized placement criteria and level of care recommended.

(c) Documentation of communication and follow−up that ensures continuity of care from one provider or level of care to another.

(22) DISCHARGE. (a) A patient may be discharged from a service for any of the following reasons:

1. Successful completion of recommended services and treatment plan goals.

2. No longer meeting placement criteria for any level of care in the substance use treatment system.

3. Patient discontinuation of services.

4. Administrative discharge.

5. Death of the patient.

(b) A service shall have written policies and procedures for the service director's review of administrative discharge or discharges due to patient dissatisfaction or attrition.

(c) A service shall have written policies and procedures for the service director's review of discharges due to patient death from overdose.

(d) A discharge summary shall be entered into the patient's case record, including the following:

1. A completed copy of the standardized placement criteria and level of care indicated.

2. Recommendations regarding care after discharge.

3. A description of the reasons for discharge.

4. The patient's treatment status and condition at discharge.

5. A final evaluation of the patient's progress toward the goals identified in the treatment plan.

(e) The discharge summary shall include a notation indicating the reason that any items from par. (d) were not able to be provided at discharge, if applicable.

(23) CONTINUING CARE SERVICES. (a) An outpatient substance use treatment service under s. DHS 75.49 or an outpatient integrated behavioral health treatment service under s. DHS 75.50 may provide ongoing recovery monitoring, continuing care, aftercare, or behavioral health check−ups at the outpatient level of care.

(b) A patient who has completed services and been discharged may continue contact with the provider at agreed upon intervals without completing a new clinical assessment, intake, or treatment plan.

(c) Each contact with a patient in continuing care service shall be documented in a progress note.

(d) If, during the provision of continuing care services, there is indication that a higher level of care or additional services may be needed due to substance use relapse or other behavioral, mental, or physical health indicators, the service shall complete an updated level of care placement criteria screening or updated mental health assessment and make appropriate referrals and transfers of care.

(e) The continuing care service shall obtain valid and updated releases of information for any referrals or collateral communications regarding patients in continuing care.

(f) Continuing care services may not provide medical services.

(g) The death of a patient in continuing care services shall be subject to reporting as specified in s. DHS 75.10 (1).

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; correction in (11) (b), (13) (m), (14) (e) 2., (g) made under s. 35.17, Stats., and correction in numbering in (21) made under s. 13.92 (4) (b) 1., Stats., Register October 2021 No. 790.

DHS 75.25 Outcome monitoring and quality improvement plan. (1) A service shall have a written plan for monitoring outcomes and improving service quality, which includes all of the following:

(a) Measurable goals relating to service quality, participant satisfaction, and outcomes.

(b) Related initiatives for service improvement and key indicators of identified goals and outcomes.

(c) An annual report that summarizes the service's quality improvement activities and program outcomes. The report shall be available to patients and their families, the public, and the department upon request.

(2) A service shall have a process for collecting, analyzing, and reporting a patient's demographic and outcome data. At minimum, the following data shall be recorded at admission and discharge:

(a) The patient's living situation.

(b) The patient's substance use.

(c) The patient's employment status and education.

(d) The patient's arrests within the past 30 days.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; correction in numbering in sub. (2) made under s. 13.92 (4) (b) 1., Stats., Register October 2021 No. 790.

Subchapter V — Residential Service Facility Requirements

DHS 75.26 Applicability. (1) This subchapter applies to residential services certified under ss. DHS 75.53 to 75.58.

(2) A residential service that is approved as a hospital under ch. DHS 124 is not required to meet the requirements in this subchapter.

(3) A residential service that is approved under ch. DHS 83 as a community−based residential facility meets the facility requirements outlined in ss. DHS 75.29, 75.30, 75.33, 75.34, 75.40, 75.41, 75.45, and 75.46.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.27 Organizational requirements. Before operating or expanding a residential service, a facility shall meet all residential facility requirements included in this subchapter.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.28 Definitions. In this subchapter:

(1) "Ambulatory" means the ability to walk without difficulty or help.

(2) "Non−ambulatory" means a person who is unable to walk, but who may be mobile with the help of a wheelchair or other mobility devices.

(3) "Semi−ambulatory" means a person who is able to walk with difficulty or only with the assistance of an aid such as crutches, cane, or walker.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.29 Application for initial certification. (1) In order to meet the requirements in ss. DHS 75.30 to 75.46, an application for initial licensure as a residential service shall be on a form provided by the department, and shall be accompanied by all of the following:

(a) A floor plan specifying dimensions of the facility, exits, and planned room usage.

(b) An explanation of the 24−hour staffing pattern for the service.

(c) A statement indicating whether the service will provide treatment services for patients that are non−ambulatory or semi−ambulatory. If a service provides treatment services for patients that are non−ambulatory or semi−ambulatory, the floor plan shall include ramped exits to grade.

(d) Municipal zoning approval or occupancy permit.

(e) The results of an approved fire inspection completed within the last 12 months.

(f) Fireplace and chimney inspections completed within the last 12 months, if applicable.

(g) The results of furnace inspection completed within the last 12 months.

(h) The results of smoke and heat detector inspection completed within the last 12 months.

(i) The results of sprinkler inspection completed within the last 12 months.

(j) Well water test results completed within the last 12 months, if applicable.

(k) Building emergency evacuation plan.

(L) A disaster recovery plan in the case of flood, gas leak, electrical outage, or other emergency.

(m) Service policies and procedures.

(n) All required fees.

(o) Evidence that the applicant has 60 days of projected operating funds in reserve.

(p) Any additional information requested by the department.

(2) A residential service shall not make changes to service specifications under sub. (1) (a) to (c) without prior notification to the department.

(3) A residential service shall provide updated documents from sub. (1) upon department request.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.30 Fit and qualified standards. (1) ELIGIBILITY. An applicant may not be certified unless the department determines the applicant is fit and qualified to operate a service.

(2) STANDARDS. In determining whether an applicant is fit and qualified, the department shall consider all of the following:

(a) *Compliance history.* The applicant's history of compliance with Wisconsin or any other state's licensing requirements and with any federal certification requirements, including any license or certification revocation or denial.

(b) *Criminal history.* The applicant's arrest history and criminal records, including whether any crime is substantially related to the care of a client, as provided in s. DHS 12.06.

(c) *Financial history.* The applicant's financial stability, including outstanding debts or amounts due to the department or

other government agencies, including unpaid forfeitures and fines and bankruptcies.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.31 Services for non−ambulatory or semi−ambulatory patients. (1) A residential service that provides treatment services for patients that are non−ambulatory shall meet the requirements under subchs. IX, X, XI of ch. DHS 83 for class A non−ambulatory and class C non−ambulatory facilities.

(2) A residential service that provides treatment services for patients that are semi−ambulatory shall meet the requirements under subchs. IX, X, and XI of ch. DHS 83 for class A semi−ambulatory and class C semi−ambulatory facilities.

(3) A residential service shall not provide treatment services for non−ambulatory or semi−ambulatory patients unless certified by the department under this chapter or under ch. DHS 83 to do so. A residential service shall be understood as serving only ambulatory patients unless specified within the service application and certification.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.32 General facility requirements. (1) HOURS OF OPERATION. A residential service shall operate 24 hours per day, 7 days per week.

(2) GENERAL. The facility of the residential service shall be constructed and maintained so that it is functional for assessment and treatment and for the delivery of health services appropriate to the needs of the community and with due regard for protecting the health and safety of the patients.

(3) CAPACITY. No residential service shall have more residents at any given time than the maximum capacity indicated on the department−approved certification.

(4) PHYSICAL SEPARATION. A residential service facility shall be physically separated from other entities, programs, and services. A residential service facility's living areas shall be separate and secure from non−resident entry and use.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.33 Residential personnel requirements. (1) STAFF ORIENTATION AND TRAINING. A residential service shall meet the staff training and orientation requirements in ss. DHS 83.19 to 83.21 and 83.23 to 83.25. A service shall maintain documentation of required training in each staff member's personnel record.

(2) STAFFING. A residential service shall meet the staffing requirements under s. DHS 83.36.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.34 Residential service records. A residential service shall meet the requirements for general records under s. DHS 83.13.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.35 Residential services for minors. (1) A residential service that provides services to minors shall maintain physically separate and secure living areas for minors and adults, unless there is a documented clinical need for an exception to this age requirement for transitional age youth, and this exception is approved by the service director.

(2) A residential service that provides services to minors shall have a written policy and procedure for addressing the educational needs of each participating minor.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.36 Residential services for parents with residing minors. A residential service that allows for minors to reside at the facility while their parent or guardian receives treatment services at the facility, shall ensure the following:

(1) The service shall have written policies and procedures that address the safety of residing minors, supervision of residing minors, family services and supports, and behavioral expectations and interventions for residing minors.

(2) A residing family shall not share a bedroom with other residents of the service.

(3) A service with residing minors shall have a written policy and procedure for addressing the educational needs of each residing minor.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.37 Emergency medical care for residents. (1) A residential service shall have written policies and procedures for training staff members in life−sustaining techniques, which may include cardiopulmonary resuscitation, use of an automated external defibrillator, and emergency first aid.

(2) A residential service shall have a written plan for the provision of emergency medical care for patients.

(3) A residential service shall have a written plan for the provision of emergency transportation for patients needing emergency medical services.

(4) Residential service staff shall be trained to implement the plan for emergency medical care and emergency transportation within 14 days of hire and annually thereafter.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.38 Seclusion and restraints. (1) A service under this chapter is prohibited from the use of seclusion or restraints, unless the service meets all requirements outlined in s. 51.61 (1) (i), Stats.

(2) A service under this chapter is prohibited from the use of seclusion or restraint as part of a treatment program, except in emergency situations as provided in s. 51.61 (1) (i), Stats.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.39 Medications. A residential service shall meet the requirements for medications under s. DHS 75.24 (19) or 83.37, whichever standard is higher. The medication storage area shall be clean, and shall be separated by a wall from any restroom, cleaning products, or any food−preparation or storage area.

Note: This section is created eff. 10−1−22 by CR 20−047.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; correction made under s. 35.17, Stats., Register October 2021 No. 790.

DHS 75.40 Infection control program. A residential service shall meet the requirements for an infection control program under s. DHS 83.39.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.41 Food service. A residential service shall meet the requirements for food service under s. DHS 83.41.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.42 Physical environment. (1) A residential service shall meet the requirements for physical environment under ss. DHS 83.43 to 83.46.

(2) A residential service that provides physical examinations or medical services shall have a patient examination or medical room. The patient examination or medical room shall contain all of the following:

(a) A wall that physically separates the patient examination or medical room from other bedrooms, living areas, staff areas, or facility common areas.

(b) A curtain for privacy.

(c) A functioning sink that is equipped with appropriate equipment and supplies for infection prevention.

(d) A medical examination table.

(3) A residential service that has a patient examination or medical room shall have written policies and procedures in place to ensure the room is appropriate for physical examinations or medical services. These polices shall, at minimum, contain provisions for all of the following:

(a) Removal of soiled linens after each use.

(b) Cleaning of surfaces, equipment, and floors after each use.

(c) Designating the room as an examination or medical room and prohibiting non−medical uses of the room.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.43 Safety. (1) A residential service shall meet the requirements for safety under ss. DHS 83.47 to 83.51.

(2) A residential service shall have written policies and procedures for ensuring that the facility and staffing arrangements are adequate for the needs of the population to be served. Policies and procedures shall include:

(a) Safety of facility entrances and exits.

(b) Facility design such as ligature risk prevention, tamper−resistant electrical outlets, control of sharps, impact resistant glass, and anchoring of furniture.

(c) Search of patients and property.

(d) Levels of staff observation required to address patient needs.

(e) Co−mingled populations.

(3) Policies and procedures shall be reviewed annually, and any required modifications shall be completed.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.44 Guests and visitors. A residential service shall have written policies and procedures regarding guests and visitors. Policies and procedures shall include:

(1) Areas prohibited from guest and visitor access.

(2) Procedures to ensure confidentiality for service patients.

(3) Management of risks such as the delivery of drugs or alcohol by guests and visitors, the possession or delivery of weapons or other contraband by guests and visitors, or potential violent behavior of guests or visitors.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.45 Building design. A residential service shall meet the requirements for building design under ss. DHS 83.52 to 83.61.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.46 Requirements for new construction, remodeling, additions, or newly−certified existing structures. A residential service shall meet the requirements for building design under ss. DHS 83.62 to 83.64.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

Subchapter VI — Additional Requirements for Treatment Service Levels of Care

DHS 75.47 Applicability of other requirements. (1) RELATIONSHIP TO TREATMENT SERVICE GENERAL REQUIREMENTS. The requirements for a treatment service provided in subch. IV apply to this subchapter as the minimum standards for any service in this subchapter. If a requirement in any section of this subchapter is inconsistent with, or poses a more restrictive standard than a similar provision in subch. IV, the requirement is this subchapter shall control.

(2) RELATIONSHIP TO RESIDENTIAL SERVICE FACILITY REQUIREMENTS. The requirements for a residential treatment service provided in subch. V apply to this subchapter as the minimum standards for residential services under this subchapter. If a requirement regarding any residential services in this subchapter is inconsistent with, or poses a more restrictive standard than a similar provision in subch. V, the requirement is this subchapter shall control.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.48 Service requirements by level of care tables. (1) Table 75.48 (1) establishes additional requirements for outpatient levels of care.

DHS 75.48 (1) Service requirements by level of care, outpatient

	DHS 75.49 Outpatient Substance Use Treatment Service	DHS 75.50 Outpatient Integrated Behavioral Health Treatment Service	DHS 75.51 Intensive Outpatient Treatment Service	DHS 75.52 Day Treatment or Partial Hospitalization Treatment Service
(a) Adult services frequency requirements	Is less than 9 hours of treatment services per patient per week.	Is less than 9 hours of treatment services per patient per week.	At least 9 hours of treatment services per patient per week.	1. At least 15 hours of treatment services per patient per week. 2. At least one hour of individual counseling per week. 3. The maximum amount of time between clinical services shall not exceed 72 hours in any 7−day period.
(b) Minor services frequency requirements	Is less than 6 hours of treatment services per patient per week.	Is less than 6 hours of treatment services per patient per week.	At least 6 hours of treatment services per patient per week.	1. At least 12 hours of treatment services per patient per week. 2. At least one hour of individual counseling per week. 3. The maximum amount of time between clinical services shall not exceed 72 hours in any 7−day period.

DHS 75.48 (1) Service requirements by level of care, outpatient (Continued)				
	DHS 75.49 Outpatient Substance Use Treatment Service	**DHS 75.50 Outpatient Integrated Behavioral Health Treatment Service**	**DHS 75.51 Intensive Outpatient Treatment Service**	**DHS 75.52 Day Treatment or Partial Hospitalization Treatment Service**
(c) Service director requirements				Service director or an identified designee must be available on−site during the hours of operation of clinical services.
(d) Medical director requirements			Required either as an employee of the service or through a written agreement to provide medical oversight and consultation regarding clinical operations of the service.	Required either as an employee of the service or through a written agreement to provide medical oversight and consultation regarding clinical operations of the service.
(e) Substance abuse counselor requirements			Required to be available on−site during the hours of on−site operation of clinical services.	Required to be available on−site during the hours of on−site operation of clinical services.
(f) Mental health professional requirements		Required to be available during the hours of operation of clinical services.	Required either as an employee of the service or through a written agreement, to provide coordinated and concurrent services for the treatment of patients with co−occurring mental health disorders.	Required to be available during the hours of operation of clinical services.
(g) Additional personnel requirements				Requires at least one full−time counselor for every 15 patients enrolled in the service.
(h) Assessment completion	Required by the third appointment.	Required by the third appointment.	Required by the third appointment.	Required by the third appointment.
(i) Use of prior assessment	For returning patients, an assessment update shall be completed if 90 days have passed since the initial assessment. If one year has passed, a new comprehensive assessment is required.	For returning patients, an assessment update shall be completed if 90 days have passed since the initial comprehensive assessment. If one year has passed, a new comprehensive assessment is required.	For returning patients, an assessment update shall be completed if 90 days have passed since the initial comprehensive assessment. If six months have passed, a new comprehensive assessment is required.	1. A new assessment, less than 30 days old, is required for each admission. 2. If a comprehensive assessment has been conducted by a referring substance use treatment provider and is less than 30 days old, the assessment may be utilized.

DHS 75.48 (1) Service requirements by level of care, outpatient (Continued)				
	DHS 75.49 Outpatient Substance Use Treatment Service	**DHS 75.50 Outpatient Integrated Behavioral Health Treatment Service**	**DHS 75.51 Intensive Outpatient Treatment Service**	**DHS 75.52 Day Treatment or Partial Hospitalization Treatment Service**
(j) Updated assessment, continuously enrolled patients	An assessment update shall be completed not less than once per year.	An assessment update shall be completed not less than once per year.	An assessment update shall be completed not less than once per year.	
(k) Intake completion	Required by the end of the session following the assessment.	Required by the end of the session following the assessment.	Required by the end of the session following the assessment.	Required by the end of the session following the assessment.
(L) Treatment plan completion	Required before the second session following the assessment.	Required before the second session following the assessment.	Required before the second session following the assessment.	Required before the second session following the assessment.
(m) Treatment plan review frequency	Required every 90 days or 6 treatment sessions, whichever is longer, unless there is a clinical reason to review more frequently.	Required every 90 days or 6 treatment sessions, whichever is longer, unless there is a clinical reason to review more frequently.	Required every 14 days, unless there is a clinical reason to review more frequently.	Required every 14 days, unless there is a clinical reason to review more frequently.
(n) Clinical staffing			Required every 14 days for each patient.	Required every 14 days for each patient.
(o) Additional requirements for discharge or transfer	Summary required within 30 days after the discharge or transfer date.	Summary required within 30 days after the discharge or transfer date.	Summary required within 30 days after the discharge or transfer date.	Summary required within 14 days after the discharge or transfer date.
(p) Operational requirements			A service shall provide services at times that allow most patients to maintain employment or attend school.	1. A service shall make efforts to provide services at times that allow patients to maintain employment or attend school. 2. Service staff members shall be trained in life−sustaining techniques and emergency first aid. Documentation of training shall be available to the department upon request.

(2) Table 75.48 (2) establishes additional requirements for residential levels of care.

DHS 75.48 (2) Service requirements by level of care, residential				
	DHS 75.53 Transitional Residential Treatment Service	**DHS 75.54 Medically Monitored Residential Treatment Service**	**DHS 75.55 Medically Managed Inpatient Treatment Service**	**DHS 75.56 Adult Residential Integrated Behavioral Health Stabilization Service**
(a) Required treatment services	At least 6 hours of treatment services per patient per week.	1. At least 20 hours of treatment services per patient per week. 2. At least one hour of individual counseling per patient per week.	1. At least 12 hours of treatment services per patient per week. 2. At least one hour of individual counseling per patient per week.	
(b) Service director requirements		Service director or an identified designee must be available on−site during hours of operation.		Service director or an identified designee must be available on−site during hours of operation.
(c) Medical director		Required either as an employee of the service or through a written agreement, to provide medical oversight and consultation regarding the clinical operations of the service.	Required to provide medical oversight and consultation regarding the clinical operations of the service.	Required either as an employee of the service or through a written agreement, to provide medical oversight and consultation regarding the clinical operations of the service.
(d) Physician requirements	Requires a prescriber knowledgeable in addiction treatment available to provide medical and clinical consultation, either as an employee of the service or through a written agreement.		1. Requires a physician available to provide consultation, medication management, and medication−assisted treatment services. 2. Requires a consulting psychiatrist, or a consulting clinical psychologist licensed under ch. 455, Stats., who will be available as needed, with a written agreement to that effect.	1. Requires a psychiatrist either as an employee of the service or through a written agreement, to provide treatment services for patients with mental health disorders. 2. Requires a prescriber knowledgeable in addiction treatment available on a 24−hour basis.
(e) Substance abuse counselor requirements		Required to be available on−site during the hours of on−site operation of clinical services.		
(f) Mental health professional requirements	Required either as an employee of the service or through written agreement, to provide coordinated and concurrent services for the treatment of individuals with co−occurring mental health disorders.	Required to be available during the hours of operation of clinical services.	Required to be available during the hours of operation of clinical services.	Required to be available during the hours of operation of clinical services.

DHS 75.48 (2) Service requirements by level of care, residential (Continued)				
	DHS 75.53 Transitional Residential Treatment Service	**DHS 75.54 Medically Monitored Residential Treatment Service**	**DHS 75.55 Medically Managed Inpatient Treatment Service**	**DHS 75.56 Adult Residential Integrated Behavioral Health Stabilization Service**
(g) Nurse requirements				Requires a registered nurse or prescriber to be available on−site on a 24−hour basis.
(h) Counselor−patient ratio requirements		At least one full−time substance abuse counselor for every 15 patients enrolled in the service.	At least one full−time substance abuse counselor for every 10 patients enrolled in the service.	At least one full−time counselor for every 10 patients enrolled in the service.
(i) Assessment completion	1. Required at the time of or prior to admission. 2. If a comprehensive assessment has been conducted by a referring substance use treatment provider and is less than 30 days old, the assessment may be utilized in lieu of conducting another one.	1. Required at the time of or prior to admission. 2. If a comprehensive assessment has been conducted by a referring substance use treatment provider and is less than 30 days old, the assessment may be utilized in lieu of conducting another one.	1. Required within 4 days of admission. 2. Use of prior assessment under DHS 75.24 (11) (c) shall not apply.	1. Required within 4 days of admission. 2. Use of prior assessment under DHS 75.24 (11) (c) shall not apply.
(j) Additional assessment requirements	1. For patients continuously enrolled in services, an assessment update shall be completed not less than every six months. 2. The service shall have a written and documented procedure for reviewing assessments and level of care placement during clinical consultation or clinical supervision that occurs within 7 days of the assessment.	A physician, physician assistant, registered nurse, or clinical supervisor shall review and co−sign the assessment and level of care placement within 7 days of the assessment.	A prescriber shall review and co−sign the assessment and level of care placement within 2 working days following the assessment.	The clinical assessment and level of care placement shall be reviewed at the next clinical consultation staffing following the assessment.

DHS 75.48 (2) Service requirements by level of care, residential (Continued)				
	DHS 75.53 Transitional Residential Treatment Service	**DHS 75.54 Medically Monitored Residential Treatment Service**	**DHS 75.55 Medically Managed Inpatient Treatment Service**	**DHS 75.56 Adult Residential Integrated Behavioral Health Stabilization Service**
(k) Intake requirements	Intake shall be completed within 24 hours of admission.	Intake shall be completed within 24 hours of admission.	1. Intake shall be completed within 24 hours of admission, or as soon as the patient is able to complete the intake. 2. Admission shall be by order of a physician. The physician's referral shall be in writing or indicated by the physician's signature on the placement criteria summary. 3. Admission is appropriate only if the person to be admitted is determined appropriate for placement in this level of care by the application of ASAM or other department−approved placement criteria.	Intake shall be completed within 24 hours of admission, or as soon as the patient is able to complete the intake.
(L) Medical screening requirements	1. Required no later than 7 days after the patient's admission to identify health problems and to screen for communicable illnesses, unless there is documentation that a screening was completed less than 90 days prior to admission. Medical screening shall be documented in the patient's case record. 2. A patient continuously enrolled in treatment shall receive an annual follow−up medical screening.	Required no later than 7 days after the patient's admission to identify health problems and screen for communicable illnesses, unless there is documentation that a screening was completed less than 30 days prior to admission. Medical screening shall be documented in the patient's case record.	Required no later than 24 hours after the patient's admission to identify health problems and to screen for communicable illnesses. Medical screening shall be documented in the patient case record.	1. Required no later than 12 hours after the patient's admission to identify health problems and to screen for communicable illnesses. Medical screening shall be documented in the patient case record. 2. A physician shall review and document the medical status of a patient within 72 hours after admission.
(m) Treatment plan completion	Required within one week of admission.	Required within 5 days of admission.	1. A preliminary treatment plan is required within 48 hours of admission. 2. A treatment plan consistent with ss. DHS 75.24 (13) is required within 4 days of admission.	1. A preliminary treatment plan is required within 48 hours of admission. 2. A treatment plan consistent with ss. DHS 75.24 (13) is required within 4 days of admission.

DHS 75.48 (2) Service requirements by level of care, residential (Continued)				
	DHS 75.53 Transitional Residential Treatment Service	**DHS 75.54 Medically Monitored Residential Treatment Service**	**DHS 75.55 Medically Managed Inpatient Treatment Service**	**DHS 75.56 Adult Residential Integrated Behavioral Health Stabilization Service**
(n) Treatment plan review frequency	Required every 6 weeks, unless there is a clinical reason to review more frequently.	Required weekly, unless there is a clinical reason to review more frequently.	Required daily.	Required daily.
(o) Additional treatment plan requirements		The patient's treatment plan shall include a preliminary discharge plan outlining step down services and a plan for ongoing support. The discharge plan shall be reviewed and updated weekly, in conjunction with the treatment plan.	The preliminary and ongoing treatment plans shall include a preliminary discharge plan outlining step down services and a plan for ongoing support. The discharge plan shall be reviewed and updated in conjunction with the treatment plan.	1. The preliminary and ongoing treatment plans shall include a determination and ongoing review of the level of observation needed to address the patient's needs and any safety concerns. 2. The preliminary and ongoing treatment plans shall include a preliminary discharge plan outlining step down services and a plan for ongoing support. The discharge plan shall be reviewed and updated in conjunction with the treatment plan.
(p) Clinical staffing frequency	Required every 30 days for each patient.	Required every 7 days for each patient.	Required daily for each patient.	Required daily for each patient.

DHS 75.48 (2) Service requirements by level of care, residential (Continued)				
	DHS 75.53 Transitional Residential Treatment Service	**DHS 75.54 Medically Monitored Residential Treatment Service**	**DHS 75.55 Medically Managed Inpatient Treatment Service**	**DHS 75.56 Adult Residential Integrated Behavioral Health Stabilization Service**
(q) Additional requirements for discharge or transfer	Summary required within 14 days after the discharge or transfer date.	1. Summary required within 14 days after the discharge or transfer date. 2. The service shall facilitate linkage and referral for follow−up and additional services that are consistent with the patient's ASAM placement criteria or other department−approved level of care placement criteria.	1. Summary required within 48 hours after the discharge or transfer date. 2. The service shall facilitate linkage and referral for follow−up and additional services that are consistent with the patient's ASAM placement criteria or other department−approved level of care placement criteria.	1. Summary required within 48 hours after the discharge or transfer date. 2. The service shall facilitate linkage and referral for follow−up and additional services that are consistent with the patient's ASAM placement criteria or other department−approved level of care placement criteria. 3. Documentation of linkage and follow−up shall be reviewed and signed by the clinical supervisor.
(r) Operational requirements			Before operating or expanding a medically managed inpatient treatment service, the service shall be approved as a hospital under ch. DHS 124.	1. The service shall have written agreements with community behavioral health service providers or systems to provide care after the patient is discharged from the service. 2. The service shall maintain an automated external defibrillator device on−site and shall train staff in its use. Documentation of training shall be available to the department upon request.

(3) Table 75.48 (3) establishes additional requirements for residential withdrawal management levels of care.

DHS 75.48 (3) Service Requirements by Level of Care, Withdrawal Management		
	DHS 75.57 Residential Withdrawal Management Service	**DHS 75.58 Residential Intoxication Monitoring Service**
(a) Exemptions from general requirements	1. This service is exempt from the requirements of s. DHS 75.24 (11) regarding assessment. 2. This service is exempt from the requirements of s. DHS 75.24 (13) regarding treatment planning.	1. This service is exempt from ss. DHS 75.18 (2) requiring a clinical supervisor. 2. This service is exempt from the requirements of s. DHS 75.24 (11) regarding assessment. 3. This service is exempt from the requirements of s. DHS 75.24 (13) regarding treatment planning.
(b) Medical director	Required either as an employee of the service or through a written agreement, to provide medical oversight and consultation regarding the clinical operations of the service.	
(c) Physician requirements	Available on a 24−hour basis.	
(d) Nurse requirements	Registered nurse available on−site on a 24−hour basis.	
(e) Additional personnel requirements	Requires a substance abuse counselor to provide consultation for each patient prior to discharge.	1. Requires at least one staff person trained in the recognition of withdrawal symptoms available on−site on a 24−hour basis. 2. Requires a substance abuse counselor to provide consultation for each patient prior to discharge.
(f) Additional assessment requirements	Each patient shall receive sufficient assessment of dimensional risk and severity of need to determine preliminary level of care and appropriate referral for continuing services.	Each patient shall receive sufficient assessment of dimensional risk and severity of need to determine preliminary level of care and appropriate referral for continuing services.
(g) Intake completion requirement	Within 24 hours of admission, or as soon as the patient is able to complete the intake.	Within 24 hours of admission, or as soon as the patient is able to complete the intake.
(h) Medical screening requirements	1. Required no later than 12 hours after the patient's admission to identify health problems and to screen for communicable illnesses. Medical screening shall be documented in the patient case record. 2. A physician shall review and document the medical status of a patient within 72 hours after admission.	Each patient shall be screened by medical personnel before admission to the service, unless the service has documentation of the patient's current physical condition.

DHS 75.48 (3) Service Requirements by Level of Care, Withdrawal Management (Continued)		
	DHS 75.57 Residential Withdrawal Management Service	**DHS 75.58 Residential Intoxication Monitoring Service**
(i) Additional treatment plan requirements	Each patient shall have a written plan, completed prior to discharge, for step down or transfer to ongoing treatment services and that addresses discharge needs and ongoing supports. The plan shall be reviewed and signed by the clinical supervisor.	Each patient shall have a written plan, completed prior to discharge, for linkage and referral to ongoing treatment services and that addresses discharge needs and ongoing supports.
(j) Clinical staffing frequency	Required daily for each patient.	Required daily for each patient.
(k) Additional requirements for discharge or transfer	1. Summary required within 48 hours after the discharge or transfer date. 2. The service shall facilitate linkage for follow−up and additional services that are consistent with the patient's assessment of dimensional risk and severity of need. 3. Documentation of linkage and follow−up shall be reviewed and signed by the clinical supervisor.	1. Summary required within 48 hours after the discharge or transfer date. 2. The service shall facilitate linkage and referral for follow−up and additional services that are consistent with the patient's assessment of dimensional risk and severity of need.
(L) Operational requirements	1. The service shall have written agreements with community behavioral health service providers or systems to provide care after the patient is discharged from the service. 2. The service shall maintain an automated external defibrillator device on−site and shall train staff in its use. Documentation of training shall be available to the department upon request.	1. The service shall have written agreements with community behavioral health service providers or systems for referral after the patient is discharged from the service. 2. The service shall maintain an automated external defibrillator device on−site and shall train staff in its use. Documentation of training shall be available to the department upon request.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; correction in (2) (d) made under s. 35.17, Stats., Register October No 790.

DHS 75.49 Outpatient substance use treatment service. (1) SERVICE DESCRIPTION. In this section, "outpatient substance use treatment service" means a non−residential treatment service totaling less than 9 hours of treatment services per patient per week for adults and less than 6 hours of treatment services per patient per week for minors, in which substance use treatment personnel provide screening, assessment, and treatment for substance use disorders. Outpatient substance use treatment services may include intake, evaluation and diagnosis, medication management, nursing services, case management, drug testing, counseling, individual therapy, group therapy, family therapy, psychoeducation, vocational services, peer support services, recovery coaching, outreach activities, and recovery support services to ameliorate symptoms and restore effective functioning.

(2) LOCATION OF SERVICE DELIVERY. (a) An outpatient substance use treatment service may provide services at one or more offices. If a service provides outpatient substance use treatment services at more than one office, all of the following shall apply:

1. The service shall designate one office as its main office.
2. All notices under this chapter will be sent to the main office.
3. Each office providing the service shall comply with the applicable requirements of this chapter.
4. The service shall adopt written policies and procedures to ensure that the service director is able to carry out the oversight and other responsibilities specified under s. DHS 75.18 (1) with respect to all other offices.

(b) A service may provide outpatient substance use treatment services in the community or other locations, provided all requirements of this chapter are able to be met in the setting.

(c) A service that provides outpatient substance use treatment services in the community shall have written policies and procedures for community−based service delivery.

(d) A service that provides outpatient substance use treatment services in the community shall provide annual training for all staff that deliver services in the community regarding in−home and community safety, and avoiding sexual or other exploitative relationships with patients. A record of each training shall be available to the department upon request.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; correction in (2) (b) made under s. 35.17, Stats., Register October 2021 No. 790.

DHS 75.50 Outpatient integrated behavioral health treatment service. (1) SERVICE DESCRIPTION. In this section, "outpatient integrated behavioral health treatment service" means a non−residential treatment service totaling less than 9 hours of treatment services per patient per week for adults, and less than 6 hours of treatment services per patient per week for minors, in which substance use and mental health treatment personnel provide screening, assessment and treatment for substance use and mental health disorders. Patients in this setting may receive treatment services for a substance use disorder, a mental health disorder, or both. Outpatient integrated behavioral health treatment services may include intake, evaluation and diagnosis, medication management, nursing services, case management, drug testing, counseling, individual therapy, group therapy, family therapy, psychoeducation, vocational services, peer support services, recovery coaching, outreach activities, and recovery support services to ameliorate symptoms and restore effective functioning.

(2) COMBINED CERTIFICATION. Certification for this level of care shall not be located with s. DHS 75.49 outpatient substance use treatment service or with a ch. DHS 35 community mental health treatment service at the same service location.

(3) LOCATION OF SERVICE DELIVERY. (a) An outpatient integrated behavioral health treatment service may provide services at one or more offices. If a service provides outpatient substance use treatment services at more than one office, all of the following shall apply:

1. The service shall designate one office as its main office.

2. All notices under this chapter will be sent to the main office.

3. Each office providing the service shall comply with the applicable requirements of this chapter.

4. The service shall adopt written policies and procedures to ensure that the service director is able to carry out the oversight and other responsibilities specified under s. DHS 75.18 (1) with respect to all other offices.

(b) A service may provide outpatient integrated behavioral health treatment services in the community or other locations, provided all requirements of this chapter are able to be met in the setting.

(c) A service that provides outpatient integrated behavioral health treatment services in the community shall have written policies and procedures for community−based service delivery.

(d) A service that provides outpatient integrated behavioral health treatment services in the community shall provide annual training for all staff that deliver services in the community regarding in−home and community safety, and avoiding sexual or other exploitative relationships with patients. A record of each training shall be available to the department upon request.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.51 Intensive outpatient treatment service. (1) SERVICE DESCRIPTION. In this section, "intensive outpatient treatment service" means a non−residential treatment service totaling at least 9 hours of treatment services per patient per week for adults and at least 6 hours of treatment services per patient per week for minors, in which substance use treatment personnel provide assessment and treatment for substance use disorders under the oversight of a medical director. Intensive outpatient treatment services may include screening, intake, evaluation and diagnosis, medication management, nursing services, case management, drug testing, counseling, individual therapy, group therapy, family therapy, psychoeducation, vocational services, peer support services, recovery coaching, outreach activities, and recovery support services to ameliorate symptoms and restore effective functioning. Intensive outpatient treatment services address patient needs for mental health, psychiatric, or medical services through integrated co−occurring treatment or through coordinated services, consultation, and referrals.

(2) LOCATION OF SERVICE DELIVERY. (a) An intensive outpatient treatment service may provide case management and outreach services in the community or other locations, provided all requirements of this chapter are able to be met in that setting.

(b) A service that provides intensive outpatient case management and outreach services in the community shall have written policies and procedures for community−based service delivery.

(c) A service that provides intensive outpatient case management and outreach services in the community shall provide annual training for all staff that deliver services in the community regarding in−home and community safety and avoiding sexual or other exploitative relationships with patients. A record of each training shall be available to the department upon request.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.52 Day treatment or partial hospitalization treatment service. In this section, "day treatment service" or "partial hospitalization service" means a medically−monitored and non−residential substance use treatment service totaling 15 or more hours of treatment services per patient per week for adults and 12 or more hours of treatment services per patient per week for minors, in which substance use and mental health treatment personnel provide assessment and treatment for substance use and co−occurring mental health disorders under the oversight of a medical director. Day treatment or partial hospitalization services may include screening, intake, evaluation and diagnosis, medication management, nursing services, case management, drug testing, counseling, individual therapy, group therapy, family therapy, psychoeducation, vocational services, peer support services, recovery coaching, outreach activities, and recovery support services, to ameliorate symptoms and restore effective functioning.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.53 Transitional residential treatment service. In this section, "transitional residential treatment service" means a residential substance use treatment service totaling 6 or more hours of treatment services per patient per week, in which substance use treatment personnel provide assessment and treatment for substance use disorders in a structured and recovery−supportive 24−hour residential setting, under the oversight of a physician or a prescriber knowledgeable in addiction, providing medical supervision and clinical consultation. Transitional residential treatment services may include screening, intake, evaluation and diagnosis, medication management, nursing services, case management, drug testing, counseling, individual therapy, group therapy, family therapy, psychoeducation, vocational services, peer support services, recovery coaching, outreach activities, and recovery support services, to ameliorate symptoms and restore effective functioning.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.54 Medically monitored residential treatment service. In this section, "medically monitored residential treatment service" means a residential substance use treatment service totaling 20 or more hours of treatment services per patient per week, in which substance use and mental health treatment personnel provide assessment and treatment for substance use disorders and co−occurring mental health disorders, under the oversight of a medical director. Medically monitored residential treatment services may include screening, intake, evaluation and diagnosis, medication management, nursing services, case management, drug testing, counseling, individual therapy, group therapy, family therapy, psychoeducation, vocational services, peer support services, recovery coaching, outreach activities, and recovery support services, to ameliorate symptoms and restore effective functioning. Medically monitored residential treatment services are delivered in a 24−hour clinical residential setting. This level of care is appropriate for patients who require a 24−hour supportive treatment environment to develop sufficient recovery

skills and address functional limitations to prevent imminent relapse or dangerous substance use.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.55 Medically managed inpatient treatment. In this section, "medically managed inpatient treatment service" means an inpatient substance use treatment service delivered under the oversight of a medical director in a hospital setting, and includes 24−hour nursing care, physician management, and the availability of sufficient resources to respond to an acute medical or behavioral health emergency. A medically managed inpatient treatment service is appropriate for patients whose acute biomedical, emotional, behavioral, and cognitive problems are so severe that they require primary medical and nursing care. Services delivered in this setting may include screening, assessment, intake, evaluation and diagnosis, medical care, observation and monitoring, physical examination, medication management, nursing services, case management, drug testing, counseling, individual therapy, group therapy, family therapy, psychoeducation, peer support services, recovery coaching, and recovery support services, to ameliorate acute behavioral health symptoms and stabilize functioning. Medically managed inpatient treatment services address patient needs for mental health, psychiatric, or medical services through integrated co−occurring treatment.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.56 Adult residential integrated behavioral health stabilization service. (1) SERVICE DESCRIPTION. In this section, "adult residential integrated behavioral health stabilization service" means a residential behavioral health treatment service, delivered under the oversight of a medical director, that provides withdrawal management and intoxication monitoring, as well as integrated behavioral health stabilization services, and includes nursing care on−site for medical monitoring available on a 24−hour basis. Patients in this setting may receive treatment services for a substance use disorder, a mental health disorder, or both. Adult residential integrated behavioral health stabilization services are appropriate for adult patients whose acute withdrawal signs and symptoms or behavioral health needs are sufficiently severe to require 24−hour care; however, the full resources of a hospital are not required. Services delivered in this setting may include screening, assessment, intake, evaluation and diagnosis, medical care, observation and monitoring, physical examination, determination of medical stability, medication management, nursing services, case management, drug testing, counseling, individual therapy, group therapy, family therapy, psychoeducation, peer support services, recovery coaching, recovery support services, and crisis intervention services, to ameliorate acute behavioral health symptoms and stabilize functioning.

(2) STAFF ORIENTATION AND TRAINING. (a) An adult residential integrated behavioral health stabilization service shall develop and implement an orientation program for all staff and volunteers. The orientation shall be designed to ensure that staff and volunteers know and understand all of the following:

1. The program's general policies and procedures.

2. Applicable parts of chs. 48, 51 and 55, Stats., and any administrative rules related to behavioral health emergency services.

3. Applicable parts of chapter DHS 34 rules concerning emergency mental health service programs.

4. Behavioral health and psychopharmacology concepts applicable to crisis situations.

5. Techniques and procedures for providing non−violent crisis management for patients, including verbal de−escalation, methods for obtaining backup, and acceptable methods for self−protection and protection of the patient and others in emergency situations.

(b) Unlicensed staff working in the clinical setting shall complete a minimum of 40 hours of documented orientation training within 3 months after beginning work with the program.

(c) Staff of an adult residential integrated behavioral health stabilization service shall receive at least 8 hours per year of training on emergency behavioral health services, rules and procedures relevant to the operation of the program, compliance with state and federal regulations, cultural competency in behavioral health services, and current issues in client's rights and services.

(3) ADDITIONAL INTAKE AND ADMISSION REQUIREMENTS. (a) An adult residential integrated behavioral health stabilization service shall have written policies and procedures for the assessment of safety and consideration of safety risks to the patient and others prior to admitting a patient.

(b) An individual with any of the following symptoms, behaviors, or concerns shall be excluded from admission to an adult residential integrated behavioral health stabilization service:

1. Assaultive ideation or assaultive behaviors combined with likelihood to act on those behaviors.

2. Exhibiting active self−injurious behavior.

3. A recent suicide attempt or ongoing suicidal ideation combined with a continued threat or plan to act on suicidal ideation.

(c) The intake screening shall include documentation of the determination and plan for the level of observation needed to address the patient's needs and any safety concerns.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22.

DHS 75.57 Residential withdrawal management service. (1) SERVICE DESCRIPTION FOR RESIDENTIAL WITHDRAWAL MANAGEMENT SERVICE. In this section, "residential withdrawal management service" means a residential substance use treatment service that provides withdrawal management and intoxication monitoring, and includes medically managed 24−hour on−site nursing care, under the supervision of a physician. Residential withdrawal management is appropriate for patients whose acute withdrawal signs and symptoms are sufficiently severe to require 24−hour care; however, the full resources of a hospital are not required. Services delivered in this setting may include screening, assessment, intake, evaluation and diagnosis, medical care, observation and monitoring, physical examination, medication management, nursing services, case management, drug testing, counseling, individual therapy, group therapy, family therapy, psychoeducation, peer support services, recovery coaching, and recovery support services, to ameliorate symptoms of acute intoxication and withdrawal and to stabilize functioning. Services provided in this setting may include community−based withdrawal management and intoxication monitoring services, subject to the requirements listed in this section.

(2) SERVICE DESCRIPTION FOR COMMUNITY−BASED WITHDRAWAL MANAGEMENT. Community−based withdrawal management is a medically−managed withdrawal management service delivered on an outpatient basis by a physician, or other service personnel acting under the supervision of a physician.

(3) ADDITIONAL REQUIREMENTS FOR COMMUNITY−BASED WITHDRAWAL MANAGEMENT. (a) A service that provides community−based withdrawal management shall meet the requirements in this section, however, services may be provided on an outpatient basis, in the community, or in the patient's home.

(b) Community−based withdrawal management services are delivered by medical and nursing professionals under the supervision of physician.

(c) A service that provides community−based withdrawal management services shall have written policies and procedures for the delivery of community−based withdrawal management services.

(d) Residential living areas under this section shall be physically separated from service areas for community−based withdrawal management patients.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; correction in (2) made under s. 35.17, Stats., Register October 2021 No. 790.

DHS 75.58 Residential intoxication monitoring service. (1) SERVICE DESCRIPTION. In this section, "residential intoxication monitoring service" means a residential service that provides 24−hour observation to monitor the safe resolution of alcohol or sedative intoxication and to monitor for the development of alcohol withdrawal for intoxicated patients who are not in need of emergency medical or behavioral healthcare. Residential intoxication monitoring services may include screening, assessment, intake, evaluation and diagnosis, observation and monitoring, case management, drug testing, counseling, individual therapy, group therapy, family therapy, psychoeducation, peer support services, recovery coaching, and recovery support services.

(2) OBSERVATION AND MEDICATION REQUIREMENTS. (a) *Observation.* Trained staff shall observe a patient and record the patient's condition at intervals no greater than every 30 minutes during the first 12 hours following admission.

(b) *Medications.* 1. A residential intoxication monitoring service shall not administer or dispense medications.

2. When a patient has been admitted with prescribed medication, staff shall consult with the patient's physician or other person licensed to prescribe and administer medications to determine the appropriateness of the patient's continued use of the medication while under the influence of alcohol or sedatives.

3. If approval for continued use of prescribed medication is received from a prescriber, the patient may self−administer the medication under the observation of service staff.

(3) PROHIBITED ADMISSIONS. No person may be admitted if any of the following apply:

(a) The person's behavior is determined by the service to be dangerous to self or others.

(b) The person requires professional nursing or medical care.

(c) The person is incapacitated by alcohol and is placed in or is determined to be in need of protective custody by a law enforcement officer as required under s. 51.45 (11) (b), Stats.

(d) The person is under the influence of any substance other than alcohol or a sedative.

(e) The person requires restraints.

(f) The person requires medication normally used for the detoxification process.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; (2) (a) (title) created under s. 13.92 (4) (b) 2., Stats., and correction in (2) (b) 3. made under s. 35.17, Stats., Register October 2021 No. 790.

Subchapter VII — Opioid Treatment Programs and Office−Based Opioid Treatment

DHS 75.59 Opioid treatment program. (1) SERVICE DESCRIPTION. In this section, "opioid treatment program," or "OTP," means a service that provides for the management and rehabilitation of persons with an opioid use disorder through the use of methadone and other FDA−approved medications for the treatment of persons with an opioid use disorder, and also provides a broad range of medical and psychological services, substance use counseling and social services. OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients. An OTP is subject to the oversight of the SOTA.

(2) REQUIREMENTS. To receive certification from the department under this chapter, an OTP shall comply with all requirements included in subch. IV, as applicable, be certified under and follow all requirements included in s. DHS 75.50, and the requirements of this section. If a requirement in this section conflicts with an applicable requirement in subch. IV or s. DHS 75.50, the requirement in this section shall be followed.

(3) DEFINITIONS. In this section:

(a) "Biochemical monitoring" means the collection and analysis of specimens of body fluids such as blood or urine to determine use of licit or illicit drugs.

(b) "Central registry" means an organization that obtains patient identifying information from 2 or more OTPs about individuals applying for maintenance treatment or detoxification treatment for the purpose of preventing an individual's concurrent enrollment in more than one program.

(c) "Clinical probation" means the period of time determined by the treatment team that a patient is required to increase frequency of service attendance due to rule violations.

(d) "Guest dose" means administration of a medication used for the treatment of opioid addiction to a person who is not a client of the program that is administering or dispensing the medication.

(e) "Initial dosing" means the first administration of methadone or other FDA−approved medication for the treatment of opioid use disorder to relieve a degree of withdrawal and drug craving of the patient.

(f) "Maintenance treatment" means the dispensing of a narcotic drug in the treatment of an individual for opioid dependence.

(g) "Mandatory schedule" means the required dosing schedule for a patient and the established frequency that the patient must attend the service.

(h) "Medically−supervised withdrawal" means dispensing, administering, or prescribing of an FDA−approved medication for the treatment of opioid use disorder in gradually decreasing doses to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of opioid drugs. The purpose of medically supervised withdrawal is to bring a patient maintained on maintenance medication to a medication−free state within a target period.

(i) "Medication unit" means a facility established as part of a service but geographically separate from the service, from which licensed private practitioners and community pharmacists are:

1. Permitted to administer and dispense a narcotic drug.

2. Authorized to conduct biochemical monitoring for narcotic drugs.

(j) "Objectively intoxicated person" means a person who is determined through a breathalyzer test to be under the influence of alcohol.

(k) "Opioid addiction" means psychological and physiological dependence on an opiate substance, either natural or synthetic, that is beyond voluntary control.

(L) "Patient identifying information" means the name, address, social security number, photograph or similar information by which the identity of a patient can be determined with reasonable accuracy and speed, either directly or by reference to other publicly available information.

(m) "Phase" means a patient's level of dosing frequency.

(n) "Potentiation" means the increasing of potency and, in particular, the synergistic action of two or more drugs which produces an effect that is greater than the effect of each drug used alone.

(o) "SAMHSA" means the Substance Abuse and Mental Health Services Administration.

(p) "Service physician" means a physician licensed to practice medicine in the jurisdiction in which the service is located, and knowledgeable in addiction treatment, who assumes responsibil-

ity for the administration of all medical services performed by the OTP including ensuring that the service is in compliance with all federal, state and local laws relating to medical treatment of an opioid use disorder with an FDA approved medication for the treatment of an opioid use disorder.

(q) "Program sponsor" means the person named in the application for certification described in 42 CFR 8.11 (b) who is responsible for the operation of the OTP and who assumes responsibility 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 for the position of medical director. The program sponsor is responsible for ensuring the service is in continuous compliance with all federal, state, and local laws and regulations.

(r) "State opioid treatment authority" (SOTA) means the subunit of the department designated by the governor to exercise the responsibility and authority in this state for governing the treatment of a narcotic addiction with a narcotic drug.

(s) "Take−homes" means medications such as methadone that reduce the frequency of a patient's service visits and with the approval of the service physician, are dispensed in an oral form and are in a container that at a minimum discloses the treatment service name, address and telephone number and the patient's name, the dosage amount and the date on which the medication is to be ingested.

(t) "Treatment contracting" means an agreement developed between the primary counselor or the clinic director and the patient in an effort to allow the patient to remain in treatment on condition that the patient adheres to service rules.

(u) "Treatment team" means a team established to evaluate the progress of a patient and consisting of at least the primary counselor, the service staff nurse who administers doses and the clinic director.

(4) STATE OPIOID TREATMENT AUTHORITY. The powers and duties of the SOTA include:

(a) Facilitating the development and implementation of rules, regulations, standards, and evidence−based practices, emerging best practices, or promising practices, to ensure the quality of services delivered by OTPs.

(b) Monitoring and evaluation of program outcomes for service recipients and the community. The SOTA may establish or follow already established performance indicators by accrediting bodies or SAMHSA including improvement in medical condition, recidivism rates, and such other measures as appropriate.

(c) Acting as a liaison between relevant state and federal agencies.

(d) Reviewing opioid treatment guidelines and regulations developed by the federal government.

(e) Delivering technical assistance and informational materials to OTPs as needed.

(f) Performing both scheduled and unscheduled site visits to OTPs in cooperation with department certification office or other oversight agencies, or as designated by the SOTA, when necessary and appropriate, and preparing reports as appropriate to assist the department's certification office or to meet the requirements set forth in s. 51.4223, Stats.

(g) Consulting with the federal government regarding approval or disapproval of requests for exceptions to federal regulations, where appropriate.

(h) Reviewing and approving exceptions to federal and state dosage and take home policies and procedures.

(i) Receiving and addressing service recipient appeals and grievances in partnership with the department's client rights office.

(j) Working cooperatively with other relevant state and local agencies to determine the service need in the location of a proposed program by reviewing data to include overdose deaths, ambulance runs, hospitalizations, etc.

(k) Issuing a list of required evidence−based practices, emerging best practices, and promising practices to be delivered by OTPs, so long as the required practices are recognized by SAMHSA, Centers for Disease Control, or National Institute of Health. The SOTA may also provide a list of recommended evidence−based practices, emerging best practices, and promising practices. The SOTA may update the required practices list and the recommended practices list as needed to reflect advances in outcomes research and medical services for persons living with opioid use disorders. The SOTA shall take into consideration the adequacy of evidence to support the efficacy of the practice, the quality of workforce available, and the current availability of the practice in the state when updating the lists. At least 120 days before issuing the initial required practices list and any revisions to the required practices list, the SOTA shall provide stakeholders with an opportunity to comment and shall take those comments into consideration when updating the required practices list.

(L) Monitoring the central registry to prevent dual enrollments in OTP's and ensure that all required information is entered.

(5) REQUIRED PERSONNEL. (a) *Clinic director.* The service shall designate in writing a clinic director who is responsible for the day to day operation of the service and overall compliance with federal, state and local laws and regulations regarding the operation of OTPs, and for all employees including practitioners, agents, or other persons providing services at the facility. The service shall notify the SOTA in writing within 5 calendar days whenever there is a change in clinic director. If the clinic director is also licensed to provide counseling services they shall carry a caseload of patients that is reasonable to ensure prompt and adequate access to care of those patients while balancing their other business responsibilities to the clinic.

(b) *Medical director.* The service shall designate a physician licensed under ch. 448, Stats., as its medical director. The medical director shall have at least one year of experience in addiction medicine or addiction psychiatry, be licensed to practice medicine or osteopathy, and meet all other requirements listed in s. DHS 75.03 (52). If a service is not able to secure a medical director who meets the one year of experience requirement, as documented through recruitment efforts, there shall be a specific plan for the person to acquire equivalent training and skills within 4 months after beginning employment. The medical director, service physician, or mid−level practitioner that has a federal exception approved by SAMHSA and the SOTA to 42 CFR 8.12 (b), (e), (h), and (i) shall be physically present at the OTP at least 40 percent of the time that the program administers or dispenses medication in order to comply with s. DHS 94.08, assure regulatory compliance, and carry out duties specifically assigned by regulation as required by SAMHSA under 42 CFR 8.12. OTPs in the first 60 days of operation may reduce the time requirement medical directors must be present on site to at least 20 percent of the time that the program administers or dispenses medication. On the 61st day of operation the service shall be subject to the requirements of this rule.

(c) *Nurses.* The service shall have a registered nurse on staff to supervise the dosing process and perform other functions delegated by the physician. A registered nurse shall be physically on the premises any time dosing is occurring.

(d) *Nursing assistants.* The service may employ nursing assistants and related medical ancillary personnel to perform functions permitted under state medical and nursing practice statutes and administrative rules.

(e) *Licensed counselors.* The service shall employ at least one of the following: substance abuse counselors, substance abuse counselors−in training, licensed marriage and family therapists, licensed professional counselors, licensed clinical social workers or clinical substance abuse counselors who are under the supervi-

sion of a clinical supervisor. An OTP shall employ one of these identified clinicians for a minimum of one full−time equivalent of 40 hours per week for every 55 enrolled patients in the service. All counselors rostered to the service are subject to this ratio.

(f) *Supervision of counseling staff.* The service shall provide for ongoing clinical supervision of the counseling staff in accordance with s. SPS 162.01. The service shall employ one full−time clinical supervisor at an equivalent of 40 hours per week for every 10 counselors employed. The clinical supervisor shall not carry a caseload greater than 30 patients to ensure access to prompt and adequate care of those patients while balancing their clinical supervision responsibilities.

(g) *Physician assistants.* The service may employ physician assistants to practice in accordance with ch. Med 8 and carry out duties specifically allowed by regulation as required by SAMHSA under 42 CFR 8.11 (h).

(6) ADMISSION. (a) *Admission criteria.* For admission to the service, a person shall meet all of the following criteria as determined by the service physician:

1. 'Maintenance treatment for an adult.' The service shall maintain current procedures determined by the service physician to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria, such as those listed in the DSM, that the person is currently addicted to an opioid drug, and that the person became addicted at least one year before admission for treatment. In addition, a service physician shall ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the patient, and that each patient provides informed written consent to treatment.

2. 'Maintenance treatment for a minor.' A minor shall be eligible for maintenance treatment only if the minor has had at least 2 documented unsuccessful attempts at short−term detoxification or drug−free treatment within a 12−month period. No minor may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by the relevant state authority consents in writing to such treatment.

3. 'Maintenance treatment admission exceptions.' If clinically appropriate, the program physician may waive the requirement of a one−year history of addiction of subd. 1. for any of the following:

a. A patient released from penal institutions within 6 months of release.

b. A pregnant patient certified as pregnant by a service physician.

c. A previously treated patient who was discharged from the service less than 2 years prior.

4. 'Detoxification treatment.' An OTP shall maintain current procedures that are designed to ensure that patients are admitted to short− or long−term detoxification treatment by qualified personnel, such as a service physician, who determines that such treatment is appropriate for the specific patient by applying established diagnostic criteria. Patients with two or more unsuccessful detoxification episodes within a 12−month period must be assessed by the service physician for other forms of treatment. A service shall not admit a patient for more than 2 detoxification treatment episodes in one year.

5. 'Health care release of information.' When the patient receives health care services from outside the service, the patient shall provide names, addresses and written consents for release of information from each health care provider to allow the service to contact the providers, and shall update releases if changes occur.

6. 'Prohibition on reward for referral.' No service shall provide a bounty, free services, medication or other reward for referral of potential service recipients to the clinic.

(b) *Voluntary treatment.* Participation in an OTP shall be voluntary.

(c) *Explanation.* Clinical staff shall clearly and adequately explain to the patient being admitted all relevant facts concerning the use of medications used by the service, service rules, and expectations.

(d) *Consent.* The service shall require a patient to complete an informed medication consent form which clearly indicates which FDA−approved medication for opioid use disorder they will be receiving, the reason for the use of the medication, the expected benefits of the use of the medication, and the potential side effects of the medication.

(e) *Examination.* 1. For each patient eligible for admission, the service shall arrange for a comprehensive physical examination and clinically indicated laboratory work−up. The comprehensive physical examination shall be ordered by the service physician on the day of admission and shall include a complete blood count and liver function testing. The service shall test for Hepatitis A, B, C and HIV if the patient gives informed consent in writing. If the patient declines permission to test shall be documented in the patient's record. An updated comprehensive physical examination including lab work shall be completed annually.

2. The service shall complete a psychosocial assessment and initial treatment plan within 3 days of admission.

(f) *Initial dose.* If a person meets the admission criteria under par. (a), an initial dose of an FDA−approved medication may be administered to the patient on the day of admission. For each new patient enrolled in a service, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams, unless the service physician documents in the patient's record that 40 milligrams did not suppress opioid abstinence symptoms.

(g) *Central registry.* All facilities shall participate in the department's central registry, subject to all of the following requirements:

1. A patient shall be informed of the service's participation in the central registry, and prior to initiating a central registry inquiry the service shall obtain the patient's written consent.

2. To prevent simultaneous enrollment of a patient in more than one OTP, at the time of admission and prior to the dosing of a patient, the service shall initiate a clearance inquiry by submitting to the approved central registry the patient's name, date of birth, and relevant information as required for the clearance procedure. No patient who is reported by the central registry to be participating in another such service shall be admitted to an OTP. When a dual enrollment is found, the patient shall be discharged from one OTP in order to continue enrollment at another OTP. The SOTA shall be notified within 24 hours of any dual enrollment discovered.

3. A disclosure shall be made with the patient's written consent that meets the requirements of 42 CFR part 2, relating to alcohol and drug abuse patient records, except that the consent shall list the name and address of each central registry or acceptable alternative and each known OTP to which a disclosure will be made.

4. Reports received by the central registry shall be treated as confidential and shall not be released except to a licensed service or its designated legal representative, as required by law or as part of continuity of operations in the case of an emergency. Information made available by the central registry shall also be treated as confidential.

5. If a service operates not more than 200 miles away from an OTP in an adjoining state, the SOTA may direct the service to share service recipient information with the OTP in the other state to prevent simultaneous enrollment of persons in more than one OTP service.

6. A patient shall not be dosed prior to a central registry check being conducted.

7. Documentation of the central registry check shall be kept in the patient's file.

(h) *Information provided at admission.* A patient admitted to the OTP shall receive written copies of the following information at the time of admission:

1. The mission and goals of the OTP.

2. The hours during which services are provided.

3. The service must provide access to staff support 24 hours a day 7 days a week to ensure that the service provides a mechanism to address patient emergencies (which includes medication verification by any other OTP, Emergency Department, correctional institution, or jail) by establishing an emergency contact system. The purpose of the contact system is to obtain dosage levels and other pertinent patient information on a 24 hour, 7−day−a−week−basis, as appropriate under confidentiality regulations. This subdivision does not require staff to be on site at all times, but at least one designated staff member is available "on call" as the emergency contact.

4. Treatment costs.

5. Patient rights and responsibilities.

6. Federal confidentiality requirements.

(i) *Admissions protocol.* The service shall have a written admissions protocol that accomplishes all of the following:

1. Identifies the patient on the basis of appropriate substantiated documents that contain the patient's name and address, date of birth, sex and race or ethnic origin as evidenced by a valid driver's license or other suitable documentation such as a passport.

2. Determines the patient's current addiction, to the extent possible, the current degree of dependence on narcotics or opiates, or both, including route of administration, length of time of the patient's dependence, old and new needle marks, past treatment history and arrest record.

3. Determines and verifies the patient's age. If the patient is a minor, the policy shall require documentation as provided in par. (a) 2.

4. Identifies all substances being used. To the extent possible, service staff shall obtain information on all substances used, route of administration, length of time used and amount and frequency of use.

5. Obtains information about past treatment. To the extent possible, service staff shall obtain information on a patient's treatment history, use of secondary substances while in the treatment, dates and length of time in treatment and reasons for discharge.

6. Obtains personal information about the patient. Personal information includes history and current status regarding employment, education, legal status (including arrests and conviction history), military service, family and psychiatric and medical information.

7. Identifies the patient's reasons for seeking treatment. Reasons shall include why the patient chose the service and whether they fully understand the treatment options and the nature and requirements of medication assisted treatment are fully understood.

8. Completes an initial drug screening or analysis to detect the use of opiates, methadone, buprenorphine, synthetic opioids, amphetamines, methamphetamine, benzodiazepines, cocaine, alcohol, and THC. The analysis shall show positive for narcotics, or an adequate explanation for negative results shall be provided and noted in the prospective patient's record.

9. Refers a patient who also has a physical health problem that cannot be treated within the service to an appropriate agency for appropriate treatment.

10. Obtains the patient's written consent for the service to secure records from other agencies that may assist the service with treatment planning.

11. Refers prospective patients who are physiologically dependent on alcohol, sedatives, or to anxiolytics to hospital detoxification before initiating treatment. If prospective patient refuses hospital detoxification, the medical director shall determine if the risk of treating a patient with a history of use of alcohol, sedatives, or anxiolytics outweighs the risk of non−admission to the service.

(j) *First priority for services.* A service shall offer priority admission either through immediate admission or priority placement on a waiting list in the following order:

1. Pregnant women who inject drugs. Pregnant women are to be assessed for appropriateness for admission by a physician within 24 hours of contacting the service.

2. Pregnant women who are drug or alcohol dependent and need treatment.

3. Other individuals who inject drugs.

4. Others individuals who are drug or alcohol dependent and need treatment.

(k) *Capacity management and wait list.* 1. 'Capacity management.' An OTP must notify the SOTA within seven days of the program reaching both 90 and 100 percent of the program's capacity to care for clients. Each week, the service must report its capacity, currently enrolled dosing clients, and any waiting list. A service reporting 90 percent of capacity must also notify the SOTA when the program's census increases or decreases from the 90 percent level.

2. 'Waiting list.' If the service is at capacity, it shall immediately advise a prospective patient of the service's waiting list and provide that person with a referral to another treatment service that can serve the person's treatment needs. The OTP shall provide the SOTA documentation of any waiting list and where prospective patients were referred for treatment upon request. An OTP must have a waiting list system. If the prospective patient seeking admission cannot be admitted within 14 days of the date of application, each person seeking admission must be placed on the waiting list, unless the person seeking admission is assessed by the service and found ineligible for admission according to this chapter, 42 CFR parts 2 to 11, or 45 CFR parts 160 to 164. The waiting list must assign a unique client identifier for each person seeking treatment while awaiting admission.

(L) *Appropriate and un−coerced treatment.* Service staff shall determine through a screening process that an OTP is the most appropriate treatment modality for the prospective patient and that treatment is not coerced.

(m) *Non−admissions.* The service shall maintain written logs that identify persons who were considered for admission or initially screened for admission but were not admitted. Such logs shall identify the reasons why the person was not admitted and what referrals were made for them by the service. These logs will be provided to the department upon request.

(7) ORIENTATION OF NEW PATIENTS. (a) *Orientation information.* Within 3 days of admission, a patient shall receive an orientation to OTP services providing information on the following:

1. The mission and goals of the OTP.

2. The hours during which services are provided.

3. Treatment costs.

4. Patient rights and responsibilities.

5. Counseling services.

6. Federal confidentiality requirements.

7. Attendance expectations.

8. The OTP's treatment philosophy and service structure.

9. How to attain self−administered dose privileges and requirements to maintain those privileges.

10. Referral to services not provided by the OTP.

11. Rules governing patient conduct and infractions that can lead to disciplinary action or discharge from the OTP.

12. Information about initiating a discontinuation of medication.

(b) *Written materials.* Information provided in the orientation shall be accompanied by the provision of written materials on all covered topics.

(c) *Proof of orientation.* The OTP shall require a new patient to acknowledge in writing that the patient has received a full orientation to all requirements and responsibilities associated with service enrollment.

(d) *Additional orientation requirements for pregnant patients.* For pregnant patients, the OTP shall explain the following:

1. The risks and benefits of opioid treatment medication during pregnancy.

2. The program requirement for prenatal medical care.

(e) *Documentation.* Documentation of the provision of the above information shall be included in the patient's record.

(8) HOURS OF OPERATION. (a) *Accommodation of all patients.* A service's hours of operation shall accommodate patients involved in activities such as school, homemaking, child care and employment.

(b) *Availability of dosing and counseling.* Dosing and counseling shall be available at a medically appropriate level to meet patient needs and shall offer non−traditional hours of operation that meet the majority of patient's schedule needs.

(c) *Daily operations.* All clinics must be open for dosing and counseling at least 6 days per week and shall be open 7 days a week if they have any patients that do not meet criteria for take home medication if those patients cannot be served via guest dosing at other nearby clinics. Facilities shall notify the SOTA and patients of the date of any holiday when the service will be closed at least 7 days in advance of the holiday. Clinics may only close for a holiday if all patients are eligible for take−home medication. In the event that all patients are not eligible for take−home medication, the service may request to offer modified hours for the holiday.

(d) *Training day.* Any service may also be closed for one mandatory training day, if required by the SOTA.

(e) *Comprehensive services.* Facilities shall offer comprehensive services, including individual and group counseling, and referral services, at least six days per week. Medical exams shall be provided on days when new admissions are scheduled and as needed for current patients.

(9) RESEARCH. (a) *Human subjects.* An OTP conducting or permitting research involving human subjects shall establish a research and human rights committee in accordance with s. 51.61 (4), Stats., and 45 CFR part 46.

(b) *Proposed research.* All proposed research involving patients shall meet the requirements of s. 51.61 (1) (j), Stats., 45 CFR part 46 and this subsection.

(c) *Written consent.* No patient may be subjected to any experimental diagnostic or treatment technique or to any other experimental intervention unless the patient gives written informed consent and the research and human rights committee established under s. 51.61 (4), Stats., has determined that adequate provisions are made to do all of the following:

1. Protect the privacy of the patient.

2. Protect the confidentiality of treatment records in accordance with s. 51.30, Stats., and ch. DHS 92.

3. Ensure that no patient may be approached to participate in the research unless the patient's participation is approved by the person responsible for the patient's treatment plan.

(10) MEDICAL SERVICES. (a) *Primary medical services.* An OTP may provide primary medical services for patients. The OTPs may use all FDA−approved medications and formulations for use in treating the patient with a substance use disorder.

(b) *Coordination with medical providers.* For medical needs of a patient that exceed the scope of the service under this chapter, the service shall coordinate with appropriate medical providers.

(c) *Medical director responsibilities.* The medical director of a service is responsible for all of the following:

1. Overseeing all medical services provided by the service.

2. Ensuring that the service complies with all federal, state, and local statutes, ordinances and regulations regarding medical treatment of an opioid use disorder.

3. Ensuring that evidence of current physiological or psychological dependence, length of history of addiction and exceptions as granted by the SOTA to criteria for admission are documented in the patient's case record before the initial dose is administered.

4. Ensuring that a medical evaluation including a medical history and a physical examination have been completed for a patient before the initial dose is administered.

5. Making a clinical judgment that treatment is medically justified for a person who has resided in a penal or chronic care institution for one month or longer, under the following conditions:

a. The patient is admitted to treatment within 14 days before release or discharge or within 6 months after release without documented evidence to support findings of physiological dependence.

b. The patient would be eligible for admission if he or she were not incarcerated or institutionalized before eligibility was established.

c. The admitting service physician or service personnel supervised by the service physician records in the patient's case record evidence of the person's prior residence in a penal or chronic care institution and evidence of all other findings of addiction.

d. The medical director signs and dates the recordings under subd. 5. c. before the initial dose is administered to the patient or within 48 hours after administration of the initial dose to the patient.

6. Ensuring that appropriate laboratory studies have been performed and reviewed.

7. Signing or countersigning all medical orders as required by federal or state law, including all of the following:

a. Initial medical orders and all subsequent medical order changes.

b. Approval of all take−home medications.

c. Approval of all changes in frequency of take−home medication.

d. Orders for additional take−home medication for an emergency situation.

8. Reviewing and countersigning each treatment plan 4 times annually.

9. Ensuring that justification is recorded in the patient's case record for reducing the frequency of service visits for observed drug ingesting and providing additional take−home medication under exceptional circumstances or when there is physical disability, as well as when any medication is prescribed for physical health or psychiatric problems.

10. Ensuring the correct amount of medication is administered or dispensed, and for recording, signing and dating each change in the dosage schedule in a patient's case record.

11. Ensuring that all physician orders are executed by the date given in the order or, if no date is specified, within 24 hours of the order being written.

12. Having a valid DEA registration for prescribing, administering, or dispensing controlled substances, and having a DEA

waiver if they or any other healthcare professional they supervise prescribes, administers, or dispenses partial opioid agonists.

(d) *Service physician responsibilities.* A service physician is responsible for all of the following:

1. Determining the amount of the medication to be administered or dispensed and recording, signing and dating each change in a patient's dosage schedule in the patient's case record.

2. Approving, by signature and date, any request for an exception to the requirements under sub. (13) relating to take−home medications.

3. Detoxification of a patient from narcotic drugs and administering the narcotic drug or authorizing an agent to administer it under physician supervision and physician orders in a manner that prevents the onset of withdrawal symptoms.

4. A history and physical examination of the patient determining that the patient is a suitable candidate for admission to an OTP.

(11) DOSAGE. (a) *Dose determination.* The dose determination for a patient is a matter of clinical judgment by a physician in consultation with the patient and appropriate clinical staff.

(b) *Verbal orders.* The service physician shall determine, on the basis of clinical judgment, the appropriate medication dose for the patient and may also use verbal orders pursuant to state, accreditation, and federal rules. Upon receiving the service physician's order, the receiver shall record the order in the patient's record, and then shall read back the written order to the issuing professional to assure that the order is understood clearly. Orders made orally or telephonically must be documented as such and staff recording must sign their name and title. Oral or telephone orders must be countersigned by the service physician no later than 72 hours after being given.

(c) *Patient sanctioning.* Any dose adjustment to sanction the patient, to reinforce the patient's behavior, or for purposes of treatment contracting, is prohibited.

(d) *Patients under the influence.* The service shall delay administration of an FDA−approved medication for the treatment of an opioid use disorder to a patient under the influence of illicit drugs or alcohol until diminution of intoxication symptoms can be observed and documented, or the patient shall be readmitted for observation for withdrawal symptoms while augmenting the patient's daily dose in a controlled, observable fashion.

(e) *Sufficient dosing.* The FDA−approved medication dose that a service provides to a patient shall be sufficient to produce the desired response in the patient for the desired duration of time.

(f) *Initial methadone dose.* A patient's initial dose shall be based on the service physician's evaluation of the history and present condition of the patient. The initial dose of methadone may not exceed 30 milligrams except that the total dose for the first day may not exceed 40 milligrams.

(g) *Withdrawal planning.* A service shall incorporate withdrawal planning as a goal in a patient's initial treatment plan and all subsequent treatment plans. A service physician shall determine the rate of withdrawal to prevent relapse or withdrawal symptoms.

(12) INVOLUNTARY TERMINATION FROM AN OTP. (a) *Emergency termination.* 1. The service may terminate a patient immediately, prior to a fair hearing and without provision for medically supervised withdrawal, when either of the following occurs:

a. The clinic director reasonably determines and documents that the patient's continuance in the service presents an immediate and substantial threat of physical harm to other clients, service personnel or property.

b. The program's medical director reasonably determines that continued treatment of a client presents a serious documented medical risk.

2. Upon termination under this paragraph, the service shall:

a. Immediately notify the patient of the decision and the reasons for the decision.

b. Schedule a hearing, to be held on the next business day and in accordance with par. (d), on the decision to terminate and provide notice of the hearing to the patient.

c. After a hearing is held in accordance with par. (d), notify the patient of the hearing officer's decision within one business day of the hearing.

d. Provide referrals to ensure a continuum of care for the client, including continued counseling, medication, withdrawal management, and other services, including risk reduction and outreach.

3. Facilities that are in the process of termination are not required to provide medically supervised withdrawal services to clients who are discharged involuntarily on an emergency basis, but referrals for assistance elsewhere must be provided in such circumstances.

(b) *Non−emergency termination.* In a non−emergency situation, the service must afford the client the following procedural rights in addition to the rights listed in s. 51.61, Stats., and ch. DHS 94:

1. Prior to initiating medically supervised withdrawal, the service shall provide the client with prompt written notice which shall contain:

a. A statement of the reasons for the proposed termination, such as violations of a specific rule or rules, non−compliance with treatment contract, and the particulars of the infraction including the date, time, and place.

b. Notification that the client has the right, within 2 business days following receipt of written notice, to submit a written request for a fair hearing on the proposed termination; if a fair hearing is requested the medically supervised withdrawal is stopped until the hearing occurs and a decision is rendered.

c. A copy of the service's hearing procedures.

2. If a timely request for a hearing is made, arrange with the patient or patient's advocate for a mutually convenient date and time for a hearing within 10 business days of receipt of the notice. Additional time to secure appropriate representation may be granted to the client under exceptional circumstances.

3. Afford the client the opportunity of medically supervised withdrawal. If the client chooses medically supervised withdrawal, the service shall provide medically supervised withdrawal, or make arrangements for appropriate medically supervised withdrawal in another OTP. The rate of dosage reduction shall be determined by the services medical director in accordance with the patient's medical condition and the dosage level at which the client was medicated before the decision was made to terminate or suspend. In determining an appropriate course of withdrawal, the medical director shall review the record, consider the patient's physical and mental health status, and, upon request of the client, may take into account the opinions of the patients other physicians and medical providers. If a hearing is requested by the patient, the medically supervised withdrawal shall cease until the hearing occurs and a decision is rendered.

4. If a patient is terminated for non−payment of fees, medically supervised withdrawal may begin immediately upon providing written notice of termination, and continue concurrent with client's appeal, if any.

(c) *Documentation of receipt of notice.* The service shall document provision of notice to the patient by obtaining the signature of the staff person providing notice and by obtaining a signed, dated receipt from the patient. If the patient refuses to sign a receipt, the service shall document that refusal on its record of notice.

(d) *Hearing procedures.* The service shall ensure that hearings are conducted in accordance with the following procedures:

1. An impartial hearing officer shall preside over the hearing. The hearing officer may be any staff or other person not directly involved in the facts of the incident giving rise to the disciplinary

proceedings or in the decision to commence the proceedings, provided that the persons involved in either the facts of the incident or in the decision to commence the proceedings shall not have authority over the hearing officer.

2. The patient may be represented at the hearing by any responsible adult of the client's choosing. If the patient chooses to be represented by legal counsel, the patient must give the service at least 72 hours' notice in advance of the hearing, so that the service may consult its own legal counsel prior to the hearing.

3. At a hearing, the service bears the burden of proving, by a preponderance of the evidence, that the alleged violation occurred.

4. The patient shall be entitled, upon request, to examine any documentary evidence in the possession of the service that pertains to the subject matter of the hearing.

5. The patient shall be entitled to call his or her own witnesses and to question any adverse witnesses.

6. The service shall make an audio recording of the hearing. The patient may also make an audio recording of the hearing at the patient's expense.

7. The hearing officer shall make a decision within 7 business days after the hearing and will base the decision solely upon the information presented at the hearing. The decision shall be based upon the services policy and procedures in effect and posted at the time of the violation.

8. The hearing officer shall issue the decision in writing, and shall provide the patient or and patient's representative, or both, with a copy of the decision. The decision shall include an explanation of the reasons for the decision, and instructions explaining how to file an appeal of an adverse decision to the department. The instructions shall inform the client that the client's written request for an appeal constitutes the client's consent to release information to the department.

(e) *Department review of program decisions to terminate.* 1. A patient has the right to appeal an adverse decision of a hearing officer to the department's client rights office. The patient must request this appeal in writing to the department within 3 business days following the receipt of the adverse decision. This request must be postmarked within the 3 business day time frame. The patient's written appeal shall contain the patient's argument in support of the appeal. The department will either affirm or reverse the hearing officer's decision, or remand the decision to a new hearing officer for a new hearing. The decision of the department shall be made as follows in writing:

a. In the case of an emergency termination, the department shall decide within one business day of receipt of the complete hearing record and written materials submitted by both parties.

b. In the case of a non−emergency termination, the department shall decide within 10 business days of the department's receipt of the complete hearing record and written materials submitted by both parties. A service's failure to submit the complete hearing record will result in a finding for the patient. The department shall deliver a written decision, outlining the reason(s) for the decision, to the patient, the patient's advocate, and the service. The decision of the department is final.

2. In the case of a non−emergency termination, if the patient timely appeals the hearing decision, the service may not terminate the client or begin medically supervised withdrawal without first receiving, and ensuring that the client also receives, the department's decision on appeal.

(f) *Humane taper.* The process of withdrawal from medication for administrative reasons shall be conducted in a humane manner as determined by the service physician, and referral shall be made to other treatment services.

(13) TAKE−HOME MEDICATION PRACTICES. (a) *Granting take−home privileges.* During treatment, a patient may benefit from less frequent required visits for dosing. This shall be based on an assessment by the treatment staff. Time in treatment is not the sole consideration for granting take−home privileges. After consideration of treatment progress, the service physician shall determine if take−home doses are appropriate or if approval to take−home doses should be rescinded. Federal and State requirements that shall be adhered to by the SOTA and the service are as follows:

1. Take−home doses are not allowed during the first 30 days of treatment. Patients are expected to attend the service daily. Exception requests may be submitted for review when extenuating circumstances (i.e. pandemic) arise and will be reviewed and a determination made by the SOTA.

2. Take−home doses shall not be granted if the patient continues to use illicit drugs and if the primary counselor and the treatment team determine that the patient is not making progress in treatment and has continued drug use or legal problems.

3. Take−home doses shall only be provided when the patient is clearly adhering to the requirements of the service. The patient shall be expected to show responsibility for security and handling of take−home doses.

4. Service staff shall go over the requirements for take−home privileges with a patient before the take−home practice for self−dosing is implemented. Clinical staff shall require the patient to provide written acknowledgment that all the rules for self−dosing have been provided and understood at the time the review occurs.

5. Service staff may not use the level of the daily dose to determine whether a patient receives take−home medication.

(b) *Treatment team recommendation.* A treatment team of appropriate staff in consultation with a patient shall collect and evaluate the necessary information regarding a decision about take−home medication for the patient and make the recommendation to grant take−home privileges to the service physician.

(c) *Service physician review.* The rationale for approving, denying or rescinding take−home privileges shall be recorded in the patient's case record and the documentation shall be reviewed, signed and dated by the service physician. Physician orders for take−home medication for substance use disorders shall expire every 90 days. The physician shall document how a patient meets all criteria in par. (d) 1. to 8. within the order for take−home medication and what phase level the patient is at for which medication.

(d) *Service physician determination.* The service physician shall determine whether, in the service physician's reasonable clinical judgment, the patient has made substantial progress in rehabilitation and can responsibly handle narcotic drugs. In order to make this determination in the affirmative and grant take home privileges, the service physician must consider and attest to all of the following:

1. The patient is not abusing substances, including alcohol.

2. The patient keeps scheduled service appointments.

3. The patient exhibits no serious behavioral problems at the service.

4. The patient is not involved in criminal activity, such as drug dealing and selling take−home doses.

5. The patient has a stable home environment and social relationships.

6. The patient has met the applicable criteria for length of time in treatment provided in pars. (e) and (h).

7. The patient provides assurance that take−home medication will be safely stored in a locked metal box within the home.

8. The rehabilitative benefit to the patient in decreasing the frequency of service attendance outweighs the potential risks of diversion.

(e) *Time in treatment criteria and exceptions.* The time in treatment criteria under par. (h) shall be the minimum time before take−home medications will be considered unless there are exceptional circumstances and the service applies for and receives approval from the designated federal agency and the SOTA for a particular patient.

(f) *Individual consideration of request.* A request for take–home privileges shall be considered on an individual basis. No request for take–home privileges may be granted automatically to any patient.

(g) *Additional criteria for 6–day take–home privilege.* When a patient is considered for 6–day take–homes, the patient shall meet the following additional criteria:

1. The patient is employed, attends school, is a homemaker, or is disabled.

2. The patient is not known to have used or abused substances, including alcohol, in the previous year.

3. The patient is not known to have engaged in criminal activity in the previous year.

(h) *Phases.* 1. Methadone shall be provided on a take–home basis as follows:

a. For patient time in treatment starting day 31 through day 90, the patient shall be allowed no more than one take–home dose of medication per week.

b. For patient time in treatment starting day 91 through 180, the patient shall be allowed no more than 2 take–home doses of medication per week.

c. For patient time in treatment starting day 181 through day 270, the patient shall be allowed no more than 3 take–home doses of medication per week.

d. For patient time in treatment starting day 271 through day 365, the patient shall be allowed no more than 4 take–home doses of medication per week.

e. For patient time in treatment starting day 366 through day 730, the patient shall be allowed no more than 6 take–home doses of medication per week.

f. For patient time in treatment starting day 731 through completion of treatment, the patient shall be allowed no more than 13 take–home doses every 2 weeks.

2. Buprenorphine Oral Products shall be provided on a take–home basis as follows:

a. For patient time in treatment starting day 31 through day 60, the patient shall be allowed no more than 1 take–home dose of medication per week.

b. For patient time in treatment starting day 61 through day 90, the patient shall be allowed no more than 2 take–home doses of medication per week.

c. For patient time in treatment starting day 91 through day 120, the patient shall be allowed no more than 3 take–home doses of medication per week.

d. For patient time in treatment starting day 121 through day 240, the patient shall be allowed no more than 4 take–home doses of medication per week.

e. For patient time in treatment starting day 241 through day 365, the patient shall be allowed no more than 6 take–home doses of medication per week.

f. For patient time in treatment starting day 366 through completion of treatment, the patient shall be allowed no more than 13 take–home doses every 2 weeks.

(i) *Denial or rescinding of approval.* A service shall deny or rescind approval for take–home privileges for any of the following reasons:

1. Signs or symptoms of withdrawal.

2. Continued illicit substance use.

3. The absence of laboratory evidence of FDA–approved narcotic treatment in test samples, including serum levels.

4. Potential complications from concurrent disorders.

5. Ongoing or renewed criminal behavior.

6. An unstable home environment.

(j) *Review.* 1. The service physician shall review the status of every patient provided with take–home medication at least every 90 days and more frequently if clinically indicated.

2. The service treatment team shall review the merits and detriments of continuing a patient's take–home privilege and shall make appropriate recommendations to the service physician as part of the service physician's 90–day review.

3. Service staff shall use biochemical monitoring to ensure that a patient with take–home privileges is not using illicit substances and is consuming the FDA–approved narcotic provided.

4. Service staff may not recommend denial or rescinding of a patient's take–home privilege to punish the patient for an action not related to meeting requirements for take–home privileges.

(k) *Reduction of take–home privileges or requirement of more frequent visits to the service.* 1. A service may reduce a patient's take–home privileges or may require more frequent visits to the service if the patient inexcusably misses a scheduled appointment with the service, including an appointment for dosing, counseling, a medical review or a psychosocial review or for an annual physical or an evaluation.

2. A service shall reduce a patient's take–home privileges or may require more frequent visits to the service if the patient shows positive results in drug test analysis for morphine–like substances or substances of abuse or if the patient tests negative for the narcotic drug administered or dispensed by the service.

(L) *Reinstatement.* A service shall not reinstate take–home privileges that have been revoked until:

1. The patient has had at least 3 consecutive tests or analyses that are neither positive for morphine–like substances or substances of abuse, or negative for the narcotic drug administered or dispensed by the service. The tests must be at least one week apart.

2. The service physician determines that the patient can responsibly handle narcotic drugs.

(m) *Clinical probation.* 1. A patient receiving a 6–day supply of take–home medication or more who has a test or analysis that is confirmed to be positive for a substance of abuse or negative for the narcotic drug dispensed by the service shall be placed on clinical probation for 3 months.

2. A patient on 3–month clinical probation who has a test or analysis that is confirmed to be positive for a substance of abuse or negative for the narcotic drug administered or dispensed by the service shall be required to attend the service at least twice weekly for observation of the ingestion of medication, and may receive no more than a 3–day take–home supply of medication.

(n) *Employment–related exception to 6–day supply.* A patient who is employed and working on Saturdays may apply for an exception to the dosing requirements if dosing schedules of the service conflict with working hours of the patient. A service may give the patient an additional take–home dose after verification of work hours through pay slips or other reliable means, and following approval for the exception from the SOTA and the designated federal agency.

(14) EXCEPTIONS TO TAKE–HOME REQUIREMENTS. (a) *Exception requests.* A service may submit a request to the designated federal authority and the SOTA for an exception to certain take–home requirements for a particular patient if, in the reasonable clinical judgment of the service physician, any of the following conditions is met:

1. The patient has a physical disability that interferes with his or her ability to conform to the applicable mandatory schedule. The patient may be permitted a temporarily or permanently reduced schedule provided that she or he is found under par. (c) to be responsible in handling narcotic drugs.

2. The patient, because of an exceptional circumstance such as illness, personal or family crisis, travel or other hardship, is

unable to conform to the applicable mandatory schedule. The patient may be permitted a temporarily reduced schedule, provided that she or he is found under par. (c) to be responsible in handling narcotic drugs.

(b) *Rationale for exception.* The program physician or program personnel supervised by the program physician shall record the rationale for an exception to an applicable mandatory schedule in the patient's case record. A patient may not be given more than a 14−day supply of narcotic drugs at one time.

(c) *Exception criteria.* The service physician's judgment that a patient is responsible in handling narcotic drugs shall be supported by information in the patient's case file that the patient meets all of the following criteria:

1. Absence of recent abuse of narcotic or non−narcotic drugs including alcohol.

2. Regularity of service attendance.

3. Absence of serious behavior problems in the service.

4. Absence of known recent criminal activity such as drug dealing.

5. Stability of the patient's home environment and social relationships.

6. Length of time in maintenance treatment.

7. Assurance that take−home medication can be safely stored within the patient's home.

8. The rehabilitative benefit to the patient derived from decreasing the frequency attendance outweighs the potential risks of diversion.

(d) *Exception outcome.* 1. Any exception to the take−home requirements is subject to approval of the designated federal agency and the SOTA. Both the designated federal agency and the SOTA must approve the exception. If one does not approve then the exception is considered denied.

2. Service staff on receipt of notices of approval or denial of a request for an exception from the SOTA and the designated federal agency shall place the notices in the patient's case record.

(e) *Exception review.* Service staff shall review an exception when the conditions of the request change or at the time of review of the treatment plan, whichever occurs first.

(f) *Exception duration.* An exception shall remain in effect only as long as the conditions establishing the exception remain in effect.

(15) TESTING AND ANALYSIS FOR DRUGS. (a) *Use.* 1. A service shall use drug tests and analyses to determine the presence of opiates, methadone, fentanyl, buprenorphine, amphetamines, benzodiazepines, methamphetamine, cocaine, and THC. Alcohol testing will occur for individuals with a history of alcohol use disorders and when concerns exist. Alcohol testing may occur via breathalyzer, urinalysis or blood testing. If any other drug has been determined by a service or the SOTA to be abused in that service's locality, a specimen shall also be analyzed for that drug. A service shall receive a 30−day notice and opportunity to provide input before it must begin analyzing for any additional substances other than those listed above. Any laboratory that performs the testing shall comply with 42 CFR part 493. A patient's specimen shall be tested for the medication they are receiving for their opioid use disorder as well as the appropriate metabolite for that medication.

2. A service shall use the results of a drug test or analysis on a patient as a guide to review and modify treatment approaches and not as the sole criterion to discharge the patient from treatment. If a patient tests positive for any illicit substance or alcohol, that substance must be specifically addressed in the patient's treatment plan.

3. A service's policies and procedures shall integrate testing and analysis into treatment planning and clinical practice.

(b) *Drawing blood for testing.* A service shall determine a patient's methadone levels in plasma or serum via a peak and trough when medically indicated but no less frequently than annually for patients who receive methadone or whenever split dosing is requested. The trough blood level should be drawn immediately prior to that day's dose and the peak blood level should be drawn 3−4 hours after the dose is administered.

(c) *Obtaining urine specimens.* A service shall obtain urine specimens for testing from a patient, unless a patient is medically unable to provide a urine specimen, in which case an exception to use another testing device may be requested from the Division of Quality Assurance and the SOTA. Specimens shall be collected in a clinical atmosphere that respects the patient's confidentiality, as follows:

1. A urine specimen shall be collected on a random basis. During the first 90 days of treatment urine drug screens shall occur weekly. After that time period, urine drug screens shall occur at least once a month.

2. The patient shall be informed about how test specimens are collected and the responsibility of the patient to provide a specimen when asked.

3. The bathroom used for collection shall be clean and always supplied with soap, paper towels, and toilet articles.

4. Specimens shall be collected in a manner that minimizes the possibility of falsification.

5. When service staff must directly observe the collection of a urine sample, this task shall be done with respect for patient privacy.

(d) *Response to positive test results.* 1. Service staff shall discuss positive test results with the patient within one week of the sample being taken by the service and shall document them in the patient's case record with the patient's response noted.

2. The service shall provide counseling, casework, medical review and other interventions when continued use of substances is identified.

3. When there is a positive test result, service staff shall allow sufficient time before re−testing to prevent a second positive test result from the same substance use.

4. Service staff confronted with a patient's denial of substance use shall consider the possibility of a false positive test. Patients shall be given the opportunity to challenge a test result by having the sample given retested.

5. Service staff shall review a patient's dosage and shall counsel the patient regarding their use when test reports are positive for morphine−like substances and negative for the FDA−approved treatment.

(e) *Frequency of drug screens.* 1. The frequency that a service shall require drug screening shall be clinically appropriate for each patient, allow for a rapid response to the possibility of relapse, and occur at least on a monthly basis.

2. A service shall arrange for drug screens with sufficient frequency so that they can be used to assist in making informed decisions about take−home privileges.

(16) TREATMENT DURATION AND RETENTION. (a) *Patient retention.* Patient retention shall be a major objective of treatment. The service shall do all of the following to retain patients for the planned course of treatment:

1. Render treatment in a way that is least disruptive to the patient's travel, work, educational activities, ability to use supportive services, and family life.

2. Determine hours based on patient needs.

3. Ensure that a patient has ready access to clinical staff, particularly to the patient's primary counselor.

4. Ensure that clinical staff are adequately trained and are sensitive to gender− and culture−specific issues.

5. Provide services that incorporate evidence based practice standards for substance use treatment.

6. Ensure that patients receive adequate doses of medication based on their individual needs.

7. Ensure that all clinical staff are accepting of medication−assisted treatment.

8. Ensure that patients understand that they are responsible for complying with all aspects of their treatment, including participating in counseling sessions.

(b) *Effort to retain patients.* Since treatment duration and retention are directly correlated to rehabilitation success, a service shall make a concerted effort to retain patients within the first year following admission. Evidence of this concerted effort shall include written documentation of all of the following:

1. Whether the patient continues to benefit from the treatment.

2. Whether the risk of relapse is discontinued.

3. Whether the patient exhibits no side effects from the treatment.

4. Whether continued treatment is medically necessary in the professional judgement of the service physician.

(c) *Referral for further treatment.* A service shall refer a patient discharged from the service to a more suitable treatment modality when further treatment is required or is requested by the patient and cannot be provided by the service.

(17) MULTIPLE SUBSTANCE USE AND CO−OCCURRING TREATMENT. (a) *Assessment.* A service shall assess a prospective patient for admission during the admission process to distinguish substance use, abuse and dependence, and determine patterns of other substance use and self−reported etiologies, including non−prescription, non−therapeutic and prescribed therapeutic use and mental health problems.

(b) *Multiple substance use patients.* 1. A service shall provide a variety of services that support cessation by a patient of alcohol and prescription and non−prescription substance use as the desired goal.

2. Service objectives shall indicate that abstinence by a patient from alcohol and prescription and non−prescription substance use should extend for increasing periods, progress toward long−term abstinence and be associated with improved life functioning and well−being.

3. Service staff shall instruct multiple substance use patients about their vulnerabilities to cross−tolerance, drug−to−drug interaction and potentiation and the risk of dependency substitution associated with self−medication.

(c) *Patients with co−occurring disorders.* 1. A service shall have the ability to provide concurrent treatment for a patient diagnosed with both a mental health disorder and a substance use disorder. The service shall arrange for coordination of treatment options and for provision of a continuum of care across the boundaries of physical sites, services and outside treatment referral sources.

2. When a co−occurring disorder exists, a service shall develop with the patient a treatment plan that integrates measures for treating all alcohol, drug and mental health problems. For the treatment of a patient with co−occurring disorders, the service shall arrange for a mental health professional to help develop the treatment plan and provide ongoing treatment services. The mental health professional shall be available either as an employee of the service or through a written agreement. The mental health professional shall complete a mental health assessment within 3 business days of admission.

(18) PREGNANCY. Each OTP shall have written procedures for pregnant patients including the following minimum standards:

(a) *Risks.* A requirement that each patient admitted to the OTP be informed of the possible risks to herself or to her unborn child from the use of medication−assisted treatment, and be informed that abrupt withdrawal from these medications may adversely affect the unborn child.

(b) *Medication−assisted treatment.* A requirement that a pregnant patient who has a documented past opioid dependency and who may be in direct jeopardy of returning to opioid dependency with all of its attendant dangers during pregnancy, be informed that they may be placed on a medication−assisted treatment regimen. The service shall also provide a statement that for such pregnant women, evidence of current physiological dependence on opioid drugs is not needed if the medical director or other authorized program physician certifies the pregnancy, determines and documents that the woman may resort to the use of opioid drugs, and determines that medication−assisted treatment is justified in their clinical opinion.

(c) *Approval of admission.* A requirement that the admission of each pregnant patient to an OTP be approved by the medical director or other authorized program physician prior to admitting the patient to the program.

(d) *Coordination of care.* A requirement that OTPs develop a form for release of information between themselves and the healthcare provider in care of obstetrical care. This voluntary form should be offered to all pregnant patients for coordination of medical care.

(e) *Education.* A requirement that each pregnant patient be given education on recognizing the symptoms of neonatal abstinence syndrome near the time of delivery.

(f) *Prenatal care.* Procedures for prenatal care that include:

1. Providing prenatal care by the service or by referral to an appropriate health care provider. If appropriate prenatal care is neither available on−site or by referral, or if the pregnant patient cannot afford care or refuses prenatal care services on−site or by referral, an OTP, at a minimum, should offer basic prenatal instruction on maternal, physical, and dietary care as part of its counseling services. If a pregnant patient refuses the offered on−site or referred prenatal services, the medical director or treating physician must use informed consent procedures to have the patient formally acknowledge, in writing, refusal of these services.

2. A requirement that if a patient is referred to prenatal care outside the agency, the name, address and telephone number of the health care provider shall be recorded in the patient's clinical record.

3. A requirement that if prenatal care is provided by the OTP, the clinical record shall include documentation to reflect services provided.

4. A requirement that if a patient is referred outside of the agency for prenatal services, the provider to whom she has been referred shall be notified that she is on medication−assisted treatment; however, such notice shall only be given after the patient has signed a release of information.

5. A requirement that any changes in medication−assisted treatment be communicated to the appropriate healthcare provider if the woman has prenatal care outside the agency if the patient allows communication among providers.

6. A requirement that the service monitor the medication dose carefully throughout the pregnancy, moving rapidly to supply increased or split dose if it becomes necessary.

7. A recommendation that blood serum levels for methadone agonist be monitored once a trimester, and every three days for two weeks after delivery to ensure appropriate level of medication before and after delivery by the appropriate healthcare professional. The medical director shall request and review serum levels to determine whether any changes to treatment need to be made.

8. A requirement that the service shall offer on−site parenting education and training to all patients who are parents or shall refer interested patients to appropriate alternative services for the training; and,

(g) *Pregnant patients that refuse prenatal services.* Procedures for a patient who refuses prenatal service by the OTP or an outside provider, including that

1. The medical director or other authorized program physician shall note this in the clinical record.

2. Requiring that the patient be asked to sign a statement that says "I have been offered the opportunity for prenatal care by the opioid treatment program or by a referral to a prenatal clinic or by a referral to the physician of my choice. I refuse prenatal counseling by the opioid treatment program. I refuse to permit the opioid treatment program to refer me to a physician or prenatal clinic for prenatal services." If the patient refuses to sign the statement, the medical director or other authorized program physician shall indicate in the signature block that "patient refused to sign" and affix their signature and the date on the statement.

(19) COMMUNICABLE DISEASE. (a) *Tuberculosis − patients.* An OTP shall screen patients for tuberculosis in a manner and frequency consistent with current CDC standard of practice. Tuberculosis treatment may be provided by referral to an appropriate public health agency or community medical service.

(b) *Tuberculosis − staff.* A service shall screen prospective new staff and ongoing staff for tuberculosis in a manner and frequency consistent with current CDC standard of practice.

(c) *Screening.* A service shall screen all patients via a risk factor assessment at admission and annually thereafter for viral hepatitis and sexually transmitted diseases and shall ensure that any necessary medical follow−up occurs, either on site or through referral to community medical services. Positive screening results or disease risks must have a management plan that is seen through to completion regardless of whether this is accomplished via services provided directly on−site or by referral and care coordination.

(d) *Hepatitis B.* A service shall ensure that all clinical staff have been immunized against hepatitis B. Documentation of refusal to be immunized shall be entered in the staff member's personnel record.

(20) FACILITY. A service shall provide a setting that is conducive to rehabilitation of the patients and that meets all of the following requirements:

(a) *Cleanliness.* The waiting area, restrooms, dosing areas, and counseling offices shall be clean.

(b) *Ventilation and lighting.* Waiting areas, dosing stations and all other areas for patients shall be provided with adequate ventilation and lighting.

(c) *Confidentiality.* Dosing stations and adjacent areas shall be kept sanitary and ensure privacy and confidentiality.

(d) *Sound proofing.* Patient counseling rooms, physical examination rooms and other rooms or areas in the facility that are used to meet with patients shall have adequate sound proofing so that normal conversations will be confidential.

(e) *Security.* Adequate security shall be provided inside and outside the facility for the safety of the patients and to prevent loitering and illegal activities.

(f) *Restrooms.* Separate toilet facilities shall be provided for patient and staff use.

(g) *Accessibility.* The facility and areas within the facility shall be accessible to persons with physical disabilities.

(h) *Physical environment.* The physical environment within the facility shall be conducive to promoting improved functioning and a drug−free lifestyle.

(i) *Facility regulations.* Meet all local, state, and federal requirements.

(j) *Annual inspection.* Post an annual inspection report from appropriate officials.

(k) *First aid kit.* The facility shall maintain stocked first aid kits for emergency use including naloxone.

(L) *Disaster plan.* Have a disaster plan and facility evacuation plan that is updated annually and posted in an area accessible to staff and patients.

(m) *Accreditation body.* The facility shall meet physical facility standards established by the services accreditation body.

(21) DIVERSION CONTROL. (a) *Staff member responsibility.* Each staff member of the OTP is responsible for being alert to potential diversion of medication by patients and staff.

(b) *Minimize diversion.* Service staff shall take all of the following measures to minimize diversion:

1. Require that doses of Methadone shall be dispensed only in liquid form. Other FDA approved medications are allowable in their FDA−approved formats as determined by the medical staff.

2. Require that each take−home bottle or other form of medication packaging used for medication−assisted treatment dispensed have a label that contains the following information:

a. The OTPs name, address and telephone number.

b. The name of the patient.

c. The name of service physician prescribing the medication.

d. The name of the medication.

e. The dosing instructions and schedule.

f. The date that the take−home dose was prepared.

g. A warning that reads "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

h. Any other requirements pursuant to rules adopted by the department.

3. Require a patient to return all empty take−home bottles on the patient's next day of service attendance following take−home dosing. Clinical staff shall examine the bottles to ensure that the bottles are received from the appropriate patient and in an intact state.

4. The service may discontinue take−home medications for patients who fail to return empty take−home bottles in the prescribed manner. If upon review of take home medication it is determined that medication is missing and cannot reasonably be accounted for the service shall discontinue take home medication.

(c) *Counselor responsibility.* If a service receives reliable information that a patient is diverting medication, the patient's primary counselor shall immediately discuss the problem with the patient.

(d) *Revocation of take homes.* Based on information provided by the patient or continuing reports of diversion, a service may revoke take−home privileges of the patient.

(e) *State revocation of take−homes.* The SOTA may, based on reports of diversion, revoke take−home privileges, exceptions or exemptions granted to or by the service for all patients. If a service agency disagrees with the SOTA's decision, it may provide additional relevant information to the SOTA, request that SOTA review the revocation decision, or file a request for review and reconsideration of the revocation decision with the Department's Division of Care and Treatment Services.

(f) *State revocation of a services ability to grant take−homes.* The SOTA may revoke the authority of an OTP to grant take−home privileges when the service cannot demonstrate that all requirements have been met in granting take−home privileges to patients. If a service agency disagrees with the SOTA's decision, it may provide additional relevant information to the SOTA, request that SOTA review the revocation decision, or file a request for review and reconsideration of the revocation decision with the Department's Division of Care and Treatment Services.

(g) *Loitering.* An OTP shall have a written policy to discourage the congregation of patients at a location inside or outside the service facility for non−programmatic reasons, and shall post that policy in the facility.

(h) *Callbacks.* The diversion control plan shall contain, at a minimum, a random call−back program with mandatory compliance that includes:

1. Call−backs shall be in addition to the regular schedule of clinic visits.

2. Each patient receiving two or more take−home medications shall be called back randomly but no less frequently than on a quarterly basis.

3. Upon call back a service recipient shall report to the clinic the next day within dosing hours, with all take−home medications. The quantity and integrity of packaging shall be verified for all doses. If a take−home dose shows evidence of tampering, the clinic shall impose uniform sanctions for violating take−home policies, including sanctions for a patient's tampering with a take−home dose.

4. Patients shall be informed of consequences for violating the take−home policy.

5. The service shall maintain individual call−back results in the patient record.

(22) SERVICE APPROVAL. (a) *Approval of primary service.* An applicant for approval to operate an OTP in Wisconsin with the intent of administering or dispensing medication for the treatment of an opioid use disorder shall submit all of the following to the SOTA:

1. Copies of all completed designated federal agency applications.

2. A copy of the request for registration with the DEA for the use of narcotic medications in the treatment of opiate addiction.

3. A narrative description of the treatment services that will be provided in addition to medication.

4. Documentation of the need for the service.

5. Criteria for admitting a patient.

6. A copy of the policy and procedures manual for the service, detailing the operation of the service as follows:

a. A description of the intake process.

b. A description of the treatment process.

c. A description of the expectations the service has for a patient.

d. A description of any service privileges or sanctions.

e. A description of the service's use of testing or analysis to detect substances and the purposes for which the results of testing or analysis are used as well as the frequency of use.

7. Documentation that there are adequate physical facilities to provide all necessary services.

8. Documentation that the service will have ready access to a comprehensive range of medical and rehabilitative services that will be available if needed, including the name, address, and a description of each hospital, institution, clinical laboratory or other facility available to provide the necessary services.

9. A list of persons working in the service who are licensed to administer or dispense narcotic drugs even if they are not responsible for administering or dispensing narcotic drugs.

(b) *Approval of service sites.* Only service sites approved by SAMHSA, the DEA and the SOTA may be used for treating persons with an opioid use disorder with a narcotic drug.

(c) *Approval of medication units.* 1. To operate a medication unit, a service shall apply to the department for approval to operate the medication unit. A separate approval is required for each medication unit to be operated by the service. A medication unit is established to facilitate the needs of patients who are stabilized on an optimal dosage level. The department shall approve a medication unit before it may begin operation.

2. Approval of a medication unit shall take into consideration the distribution of patients and other medication units in a geographic area.

3. If a service has its approval revoked, the approval of each medication unit operated by the service is automatically revoked. Revocation of the approval of a medication unit does not automatically affect the approval of the primary service.

(23) ASSENT TO REGULATION. (a) *Service sponsor.* A person who sponsors an OTP and any personnel responsible for a particular service shall agree in writing to adhere to all applicable requirements of this chapter and 21 CFR part 291 and 42 CFR part 2.

(b) *Responsibilities.* The service sponsor is responsible for all service staff and for all other service providers who work in the service at the primary facility or at other facilities or medication units.

(c) *Written agreement.* The service sponsor shall agree in writing to inform all service staff and all contracted service providers of the provisions of all pertinent state rules and federal regulations and shall monitor their activities to ensure that they comply with those rules and regulations.

(d) *Replacement.* The service shall notify the designated federal agency and SOTA within 5 business days after replacement of the service sponsor or medical director.

(e) *Required services.* OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients. This documentation must be provided to the department upon request.

(24) DEATH REPORTING. An OTP shall report the death of a patient and deaths related to a patient's medication to the SOTA within 5 business days after learning of the death.

(25) PRESCRIPTION DRUG MONITORING PROGRAM. (a) *Policy and procedure.* The service must develop and maintain a policy and procedure that requires the ongoing monitoring of the data from the prescription drug monitoring program (PDMP) for each patient. The policy and procedure must include how the service meets the requirements in par. (b).

(b) *Requirements.* If a medication used for the treatment of substance use disorder is administered or dispensed to a patient, the OTP shall be subject to the following requirements:

1. Upon admission a patient must be notified in writing that the medical director must monitor the PDMP to review the prescribed controlled drugs a client received.

2. The medical director or the medical director's delegate must review the data from the PDMP before the patient is ordered any controlled substance including medications for maintenance therapy, and subsequent reviews of the PDMP data must occur at least every 90 days.

3. A copy of the PDMP data reviewed must be maintained in the client's file.

4. When the PDMP data contains a recent history of multiple prescribers or multiple prescriptions for controlled substances, the physician's review of the data and subsequent actions must be documented in the patient's file within 72 hours and must contain the medical director's determination of whether the prescriptions place the patient at risk of harm and the actions to be taken in response to the PDMP findings. The provider must conduct subsequent reviews of the PDMP in these circumstances on a monthly basis.

5. If at any time the medical director believes the use of the controlled substances places the patient at risk of harm, the service must seek the patient's consent to discuss the patient's opioid treatment with other prescribers and for other prescribers to disclose to the OTP's medical director of the client's condition that formed the basis of the other prescriptions. If the information is

not obtained within 7 days, the medical director must document whether or not changes to the client's medication dose or number of unsupervised use doses are necessary until the information is obtained.

(25m) GUEST DOSING. (a) *Approval.* To receive a guest dose, the patient must be enrolled in an OTP elsewhere in the state or country and be receiving the medication on a temporary basis because the client is not able to receive the medication at the program in which the client is enrolled. A patient may guest dose at a different OTP if prior approval is obtained from the patient's medical director or program physician to receive services on a temporary basis from another OTP certified under this rule or by SAMHSA. The approval shall be noted in the patient's record and shall include the following documentation:

1. The patient's signed and dated consent for disclosing identifying information to the program which will provide services on a temporary basis.

2. A medication change order by the referring medical director or program physician permitting the patient to receive services on a temporary basis from the other program for a length of time not to exceed 30 days.

3. Evidence that the medical director or program physician for the program contacted to provide services on a temporary basis has accepted responsibility to treat the visiting patient, concurs with his or her dosage schedule, and supervises the administration of the medication.

(b) *Maximum number of days.* Guest dosing shall be provided for a maximum of 30 days.

(c) *Patient requirement.* Patients receiving guest dosing shall have been enrolled at the home clinic for a minimum of 30 days before being eligible for a guest dose. Patients enrolled less than 30 days at the home clinic shall be eligible for guest dosing only if approved by the SOTA.

(d) *Drug screen requirement.* Patients shall have two consecutive urine drug screens free of illicit substances or substances of abuse before being eligible for a guest dose, unless the medical director determines that the benefits of guest dosing outweigh the risks and documents the justification for granting guest dosing privileges in the patient's record.

(26) OVERDOSE PREVENTION. (a) *Naloxone.* An OTP shall provide a patient with a naloxone kit or a prescription for naloxone at admission. The OTP shall provide instruction on the kits use including recognizing the signs and symptoms of overdose and calling 911 in overdose situations.

(b) *Use or expiration of Naloxone.* The OTP shall provide a new naloxone kit or prescription upon expiration or use of the old kit.

(c) *Exemption.* The OTP shall be exempt from this requirement for one year if the client refuses the naloxone kit or already has a naloxone kit.

(d) *Orientation training.* Documentation that the patient has completed the orientation training on recognizing an overdose and how to use naloxone and received written information shall be completed and signed by service staff and the patient and maintained in the patient's record.

(27) INTERIM MAINTENANCE TREATMENT. (a) The provision of interim maintenance with medication assisted treatment is prohibited under this rule unless the opioid treatment program has a waiver from the department in addition to authorization from SAMHSA in accordance with 42 CFR 8.11 (g).

(b) All of the requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions for patients receiving methadone: no take–home doses are permitted except on federal holidays if the program is closed on those days; an initial and periodic treatment plan are not required; a primary counselor is not required; and the rehabilitative and other services described in 42 CFR. 8.12 (f) (4), (f) (5) (i), and (f) (5) (iii) are not required.

(c) Interim maintenance cannot be provided to an individual for more than 120 days in any 12–month period.

(d) To receive interim maintenance, a patient must be fully eligible for admission to comprehensive maintenance.

(e) Interim maintenance treatment is for those patients who cannot be enrolled in comprehensive maintenance treatment in a reasonable geographic area within fourteen days of application for admission.

(f) During interim maintenance, the initial toxicology and at least two additional toxicology screening tests should be obtained.

(g) Programs offering interim maintenance must develop clear policies and procedures governing the admission to interim maintenance and transfer of patients to comprehensive maintenance.

(28) DISASTER PLANNING. (a) *Emergency situations.* Each OTP shall maintain an up–to–date disaster plan that addresses emergency situations including fire emergencies, tornadoes, earth quakes, flooding, winter storms, pandemics, and involuntary temporary or permanent facility closure.

(b) *Committee.* OTPs shall establish a health and safety committee that initiates planning actions for disaster scenarios. This committee shall:

1. Identify internal resources and areas of need that shall include, at minimum, considerations of:

a. Personnel training.

b. Equipment needs.

c. Evacuation plans.

d. Backup systems for payroll, billing records, and patient records.

e. Communications with staff, patients and local, state, and federal partners.

2. Identify external resources and areas of need that shall include, at minimum:

a. Suppliers of medication used for treatment of substance use disorder.

b. Other OTPs; and

c. Alternative dosing locations.

3. Develop a communication plan for the disaster scenario to inform patients, the SOTA, SAMHSA, the DEA, and any other parties deemed necessary.

4. Develop disaster documentation procedures for guest patients that shall include at minimum:

a. A temporary chart and client identification number.

b. Identity verification.

c. Medication verification.

(c) *Emergency contact.* Each OTP shall provide the SOTA with the emergency contact information for at least one member of the service.

(d) *Medication supply.* Each OTP shall keep at least a 10–day supply based on average caseload of methadone and buprenorphine products on site to prepare to receive clients from other facilities in disaster scenarios.

History: CR 20–047: cr. Register October 2021 No. 790, eff. 10–1–22; correction in (5) (b), (g) , (6) (a) 3. a., 4., (h), (k) 2., (7) (a) (intro.), (9) (a), (10) (c) 12., (12) (b) 2., (d) 2., 7., (h) 1. d. to f., 2. a. to e., (15) (a) 1., (21) (e), (f), (23) (a) made under s. 35.17, Stats., correction in numbering in (25m) made under s. 13.92 (4) (b) 1., Stats., correction in (6) (i) 3. made under s. 13.92 (4) (b) 4., Stats., and (10) (b) (title) created under s. 13.92 (4) (b) 2., Stats., Register October 2021 No. 790.

DHS 75.60 Office–based opioid treatment.

(1) APPLICABILITY. This section shall not apply to office–based opioid treatment occurring in any of the following settings:

(a) A treatment service in which all patients receiving medication for addiction are enrolled in a service otherwise certified under this chapter.

(b) A state or local correctional facility.

(c) A hospital as defined under s. 50.33 (2), Stats., and their affiliates.

(d) A primary care service.

(e) A service providing medication for addiction to less than 30 patients.

(2) SERVICE DESCRIPTION. In this section, "office−based opioid treatment," or "OBOT" service means pharmacotherapy for opioid use disorder, delivered in a stand−alone office−based opioid treatment clinic, a private office, or public sector clinic setting, excluding certified settings exempted in s. DHS 75.60 (1) or otherwise certified under this chapter, by practitioners authorized to prescribe outpatient supplies of medications approved by the FDA for the treatment of opioid addiction or dependence, prevention of relapse of opioid addiction or dependence, or both. An OBOT is subject to the oversight of the state opioid treatment authority. OBOT includes treatment with all medications approved by the FDA for such treatment.

(3) RELATIONSHIP TO TREATMENT SERVICE GENERAL REQUIREMENTS. A service that provides OBOT under this section shall be exempt from the treatment service general requirements in subchapter IV, unless otherwise indicated in this section.

(4) DEFINITIONS. In this section:

(a) "Drug Addiction Treatment Act of 2000" (DATA 2000) means Title XXXV, Section 3502 of the Children's Health Act, permits physicians who meet certain qualifications to treat opioid addiction with Schedule III, IV, and V narcotic medications that have been specifically approved by the FDA for that indication.

(b) "DATA 2000 waiver" means an authorization conveyed by SAMHSA and the DEA to a practitioner that permits them to prescribe or administer buprenorphine products to an individual with an opioid use disorder.

(c) "Primary care service" means outpatient general health care services provided by a clinic for regular health care services, preventive care, or for a specific health concern, and includes all of the following:

1. Care that promotes and maintains mental and physical health and wellness.

2. Care that prevents disease.

3. Screening, diagnosing, and treating acute or chronic conditions caused by disease, injury, or illness.

4. Patient counseling and education.

5. Provision of a broad spectrum of preventive and curative health care over a period of time.

6. Coordination of care.

(5) STATE OPIOID TREATMENT AUTHORITY. The powers and duties of the SOTA include:

(a) Facilitating the development and implementation of rules, regulations, standards, and evidence−based practices, emerging best practices, or promising practices, to ensure the quality of services delivered by OBOT services.

(b) Acting as a liaison between relevant state and federal agencies.

(c) Reviewing opioid treatment guidelines and regulations developed by the federal government.

(d) Delivering technical assistance and informational materials to OBOT services as needed.

(e) Performing both scheduled and unscheduled site visits OBOTs in cooperation with department certification office or other oversight agencies, or as designated by the SOTA, when necessary and appropriate, and preparing reports as appropriate.

(f) Consulting with the federal government regarding approval or disapproval of requests for exceptions to federal regulations, where appropriate.

(g) Receiving and addressing service recipient appeals and grievances in partnership with the department's client rights office.

(h) Issuing a list of required evidence−based practices, emerging best practices, and promising practices to be delivered by OBOT services, so long as the required practices are recognized by SAMHSA, Centers for Disease Control, or National Institute of Health. The SOTA may also provide a list of recommended evidence−based practices, emerging best practices, and promising practices. The SOTA may update the required practices list and the recommended practices list as needed to reflect advances in outcomes research and medical services for persons living with opioid use disorders. The SOTA shall take into consideration the adequacy of evidence to support the efficacy of the practice, the quality of workforce available, and the current availability of the practice in the state when updating the lists. At least 120 days before issuing the initial required practices list and any revisions to the required practices list, the SOTA shall provide stakeholders with an opportunity to comment and shall take those comments into consideration when updating the required practices list.

(6) GENERAL REQUIREMENTS. (a) *Governing authority or entity owner.* The governing authority or entity owner of an OBOT service shall do all of the following:

1. Designate a member or representative of the governing body that is legally responsible for the operation of a service that has the authority to conduct the policy, actions, and affairs of the service, to complete the entity owner background check and to be the entity owner responsible for a service.

2. Appoint a service director whose qualifications, authority, and duties are defined in writing.

3. Establish written policies and procedures for the operation of the service and exercise general direction over the service, to ensure the following:

a. Compliance with local, state and federal laws.

b. That no person will be denied service or discriminated against on the basis of sex, race, color, creed, sexual orientation, disability, or age, in accordance with 45 CFR part 92 and Title VI of the Civil Rights Act of 1964, as amended, 42 USC. 2000d, Title XI of the Education Amendments of 1972, 20 USC 1681−1686 and s. 504 of the Rehabilitation Act of 1973, as amended, 29 USC 794, and the Americans with Disabilities Act of 1990, as amended, 42 USC 12101−12213.

(b) *Caregiver background check.* At the time of hire, employment, or contract, and every 4 years after, the service shall conduct and document a caregiver background check following the procedures in s. 50.065, Stats., and ch. DHS 12. A service shall not employ or contract with a person who has been convicted of a crime or offense, or has a governmental finding of misconduct, found in s. 50.065, Stats., and ch. DHS 12, Appendix A, unless the person has been approved under the department's rehabilitation process as defined in ch. DHS 12.

(c) *Personnel records.* Employee records shall be available upon request at the service for review by the department. A separate record for each employee shall be maintained, kept current, and at a minimum, include:

1. A written job description including duties, responsibilities and qualifications required for the employee.

2. Beginning date of employment.

3. Qualifications based on education or experience.

4. A completed caregiver background check following procedures under s. 50.065, Stats., and ch. DHS 12.

5. A copy of a signed statement regarding confidentiality of client information.

6. Documentation of any required training.

7. A copy of any required licenses or certifications.

(d) *Confidentiality.* A service shall have written policies, procedures, and staff training to ensure compliance with confidentiality provisions of 42 CFR part 2, 45 CFR parts 164 and 170, s. 51.30, Stats., and ch. DHS 92. Each staff member shall sign a statement acknowledging responsibility to maintain confidentiality of personal information about persons served.

(7) ASSESSMENT. (a) An OBOT service shall perform and document an assessment of each patient. The assessment shall include all of the following:

1. A comprehensive medical and psychiatric history.

2. A brief mental status exam.

3. Substance abuse history.

4. Family history and psychosocial supports.

5. Clinically appropriate physical examination at the time of admission and annually thereafter.

6. Urine drug screen or oral fluid drug testing.

7. Pregnancy test for patients of childbearing age and ability.

8. Review of the patient's prescription information in the PDMP.

9. Testing for human immunodeficiency virus.

10. Testing for hepatitis B.

11. Testing for hepatitis C.

12. Consideration of screening for tuberculosis and sexually transmitted diseases in patients with known risk factors.

(b) A prescriber may satisfy the assessment requirements, other than toxicology testing, by reviewing records from a physical examination and laboratory testing of the patient that was conducted within a reasonable period of time prior to the visit.

(c) If any part of the assessment cannot be completed prior to the initiation of medication for opioid use disorder, the prescriber shall document the reasons in the patient's record.

(d) For medical needs of a patient that exceed the scope of the service under this chapter, the service shall coordinate with appropriate medical providers.

(8) INTAKE. An OBOT service shall comply with all of the following requirements:

(a) Before initiating a medication for opioid use disorder, an approved DATA 2000−waived prescriber shall give the patient or the patient's representative information about all drugs approved by the FDA for use in medication−assisted treatment. The information must be provided both orally and in writing. The prescriber or the prescriber's delegate shall note in the patient's medical record when this information was provided and make the record available to employees of the department upon request.

(b) Comply with all federal and state laws and regulations governing the prescribing of the medication.

(9) TREATMENT PLAN. (a) An OBOT service shall establish and document a treatment plan that includes all of the following:

1. The prescriber's rationale for selection of the specific drug to be used in the medication−assisted treatment.

2. Patient education regarding the medication and the services to be provided.

3. The patient's written, informed consent to treatment and for the medication they will be receiving.

4. Random urine−drug screens or oral swabs.

5. A signed treatment agreement that outlines the responsibilities of the patient and the prescriber.

6. A plan for psychosocial treatment, pursuant to par. (c).

(b) The prescriber shall only provide medication for opioid use disorder in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering. Acceptable protocols include any of the following:

1. SAMHSA treatment improvement protocol publications for medication assisted treatment.

Note: SAMSHA treatment improvement protocols are available at: https://store.samhsa.gov.

2. ASAM national practice guidelines for the use of medications in the treatment of addiction involving opioid use.

Note: ASAM national practice guidelines are available at https://www.asam.org/.

(c) Unless the prescriber providing OBOT services is a board−certified addictionologist, board certified addiction psychiatrist, or psychiatrist, the prescriber shall refer and work jointly with a qualified behavioral healthcare provider, community mental health services provider, or community addiction services provider, to determine the optimal type and intensity of psychosocial treatment for the patient and document the treatment plan in the patient record. The treatment provided shall, at minimum, include:

1. A psychosocial needs assessment, substance abuse counseling, links to existing family supports, and referral to community services.

2. Substance use treatment services addressing the patient's needs identified during the assessment.

3. Procedures for revising the treatment plan if the patient does not adhere to the original plan.

4. When clinically appropriate, and if the patient refuses treatment from a qualified behavioral healthcare provider, community mental health services provider, or community addiction services provider, the prescriber shall document the reason for the refusal in the patient's medical record.

5. Additional requirements related to the provision of behavioral health services, including:

a. If the prescriber who prescribes the medication for opioid use disorder is also a board−certified addictionologist, psychiatrist, or board certified psychiatrist, the prescriber may personally provide behavioral health services for addiction.

b. If the prescriber refers the patient to a qualified behavioral healthcare provider, community addiction services provider, or community mental health services provider, the prescriber shall document the referral and the maintenance of meaningful interactions with the provider in the patient record.

(10) PRESCRIBING REQUIREMENTS. (a) The OBOT service shall ensure that all of its patients receive the following:

1. A prescription for naloxone.

2. Instructions for naloxone including recognizing the signs and symptoms of overdose and calling 911 in an overdose situation.

3. An offer for a new prescription for naloxone upon expiration or use of the old kit.

4. If the patient refuses the prescription for naloxone the prescriber shall provide the patient with information on where to obtain naloxone without a prescription.

(b) The OBOT service shall ensure that all prescriptions for buprenorphine products shall comply with all of the following requirements:

1. The provision shall be in compliance with the FDA−approved risk evaluation and mitigation strategy" for buprenorphine products.

Note: The FDA−approved risk evaluation and mitigation strategy for buprenorphine products can be found at https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.

2. With the exception of those conditions listed in subd. 3. a. to e., a prescriber who treats opioid use disorder with a buprenorphine product shall only prescribe buprenorphine and naloxone combination products for use in the OBOT service.

3. The prescriber shall prescribe buprenorphine without naloxone (buprenorphine mono−product) at the OBOT service only in the following situations, and shall fully document the evidence for the decision to use buprenorphine mono−product in the patient's record when any of the following apply:

a. A patient is pregnant or breast−feeding.

b. Converting a patient from buprenorphine mono−product to buprenorphine and naloxone combination product.

c. Formulations other than tablet or film form approved by the FDA are administered.

d. A buprenorphine and naloxone combination product is contraindicated for withdrawal management and the contraindication documented in the patient record.

e. The patient, after an explanation by the service of the difference between an allergic reaction and symptoms of opioid withdrawal precipitated by buprenorphine or naloxone, has an allergy to or intolerance of a buprenorphine and naloxone combination product. This information shall be included in the patient's record.

4. Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, or tramadol, the prescriber shall only co−prescribe these substances when it is medically necessary and the following requirements are met:

a. The prescriber shall verify the diagnosis for which the patient is receiving the other drug and coordinate care with the prescriber for the other drug, including whether it is possible to taper the drug to discontinuation. If the prescriber prescribing buprenorphine is the prescriber of the other drug, the prescriber shall taper the other drug to discontinuation, if it is safe to do so. The prescriber shall educate the patient about the serious risks of the combined use.

b. The prescriber shall document progress with achieving the tapering plan.

5. During the induction phase the prescriber shall not prescribe a dosage that exceeds the recommendation in the United States FDA−approved labeling, except for medically indicated circumstances as documented in the patient record. The prescriber shall see the patient at least once per week during this phase.

6. During the stabilization phase, when using any oral formulation of buprenorphine, the prescriber shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.

7. During the first 90 days of treatment, no more than a 2−week supply of the buprenorphine and naloxone combination product may be prescribed.

8. Starting with the 91st day of treatment and until the completion of 12 months of treatment, no more than a 30−day supply of the buprenorphine and naloxone combination product may be prescribed.

8m. The prescriber shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill or film counts, and checks of the PDMP. The prescriber shall require urine drug screens, serum medication levels, or oral fluid testing at least twice per quarter for the first year of treatment and at least once per quarter thereafter.

9. When using any oral formulation of buprenorphine, the prescriber shall document in the medical record the rationale for prescribed doses exceeding 16 milligrams of buprenorphine per day.

10. Relapse prevention strategies shall be incorporated into counseling or assure that they are addressed by a qualified behavioral healthcare provider who has the education and experience to provide substance abuse counseling.

11. Extended−release, injectable, or implanted buprenorphine product may be used. In using these formulations, the prescriber shall:

a. Strictly comply with any required risk evaluation and mitigation strategy program for the drug.

b. Prescribe an extended−release buprenorphine product strictly in accordance with the FDA's approved labeling for the drug's use.

c. Document in the patient record the rationale for the use of the extended−release buprenorphine product.

d. Require the extended−release, injectable, or implanted buprenorphine product to be administered by a licensed health care professional acting in accordance with the scope of the professional license.

(c) The OBOT service that utilizes naltrexone to treat opioid use disorder shall comply with all of the following requirements:

1. Prior to treating a patient with naltrexone, the patient shall be informed about the risk of opioid overdose if the patient ceases naltrexone and then uses opioids.

2. The prescriber shall take measures to ensure that the patient is adequately detoxified from opioids prior to treatment with naltrexone.

3. The prescriber shall use oral naltrexone only for treatment of patients who can be closely supervised and who are highly motivated and:

a. The dosage regime shall strictly comply with FDA−approved labeling for naltrexone hydrochloride tablets.

b. The patient shall be encouraged to have a support person administer and supervise the medication. Examples of a support person are a family member, close friend, or employer.

c. The OBOT service shall require urine drug screens, serum medication levels, or oral fluid drug testing at least every 3 months for the first year of treatment and at least every 6 months thereafter.

d. The OBOT service shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider who has the education and experience to provide substance abuse counseling.

4. The OBOT service may treat a patient with extended−release naltrexone for opioid dependence or for co−occurring opioid and alcohol use disorders.

a. Treatment with extended−release naltrexone for patients who have issues with treatment adherence should be considered.

b. The injections dosage shall strictly comply with FDA−approved labeling for extended−release naltrexone.

c. Relapse prevention strategies shall be incorporated into counseling or assure that they are addressed by a qualified behavioral healthcare provider who has the education and experience to provide substance abuse counseling.

History: CR 20−047: cr. Register October 2021 No. 790, eff. 10−1−22; correction in (1) (c), (2), (6) (a) 3. b., (d) made under s. 35.17, Stats., correction in numbering of (4) (c) 1. to 6., (10) (b) 8m. made under s. 13.92 (4) (b) 1., Stats., and correction in (10) (b) 2. made under s. 13.92 (4) (b) 7., Stats., Register October 2021 No. 790; correction in (11) (b) made under s. 35.17, Stats., Register November 2021 No. 791.