

**COMMUNITY SUBSTANCE ABUSE SERVICE (CSAS)
NARCOTIC TREATMENT SERVICE FOR OPIATE ADDICTION
INITIAL CERTIFICATION APPLICATION**

Chapter DHS 75.15

Initial Certification

- **Initial certification must meet all requirements, including staffing requirements (hired and in place) before services begin.**
- **This document paraphrases the rule language for application purposes.**
- **Applicants for a new narcotic treatment service for opiate addiction must demonstrate preparedness to comply with all Chapter DHS 75.15 standards.**

Applicants will have completed all required policies, including Chapter DHS 94 (Patient Rights). Use the check boxes () to affirm readiness to meet standards.

- **ATTENTION: The clinic must contact the regional Health Services Specialist to arrange a site visit following the submission of fee and this application.**

Chapter DHS 75.01(1) Authority and Purpose

This application is promulgated under the authority of ss. 46.973(2)(c), 51.42(7)(b), and 51.45(8) and (9), Wis. Stats., to establish standards for community substance abuse prevention and treatment services under ss. 51.42 and 51.45, Wis. Stats. Sections 51.42(1) and 51.45(1) and (7) provide that a full continuum of substance abuse services be available to Wisconsin citizens from county departments of community programs, either directly or through written agreements or contracts that document the availability of services. This application provides that service recommendations for initial placement, continued stay, level of care transfer, and discharge of a patient be made through the use of Wisconsin uniform placement criteria (WI-UPC), American Society of Addiction Medicine (ASAM) placement criteria, or similar placement criteria that may be approved by the department.

Use of approved placement criteria services as a contributor to the process of obtaining prior authorization from the treatment services funding source. It does not establish funding eligibility regardless of the funding source. The results yielded by application of these criteria serve as a starting point for further consultations among the provider, patient, and payer as to an initial recommendation for the type and amount of services that may be medically necessary and appropriate in the particular case. Use of WI-UPS or any other department-approved placement criteria does not replace and need to do a complete assessment and diagnosis of a patient in accordance with DSM-IV.

Chapter DHS 75.01(2) Applicability

This application applies to each substance abuse service that receives funds under Chapter DHS 51, Wis. Stats., is approved by the state methadone authority, is funded through the department as the federally designated single state agency for substance abuse services, receives substance abuse prevention and treatment funding or other funding specifically designated for providing services under ch. 75.04 or 75.16, or is a service operated by a private agency that requests certification.

**COMMUNITY SUBSTANCE ABUSE SERVICE (CSAS)
GENERAL REQUIREMENTS
INITIAL CERTIFICATION APPLICATION**

Chapter DHS 75.15

**By completing and submitting this form, the clinic indicates that
it is in compliance with the program standards as required by state statutes.**

Name – Facility					
Address – Physical		City	State	Zip Code	County
Telephone Number		E-mail Address <input type="checkbox"/> <i>May be published in Provider Directory</i>			
Fax Number		Internet Address <input type="checkbox"/> <i>May be published in Provider Directory</i>			
Name – Contact Person	Telephone Number	E-mail Address <input type="checkbox"/> <i>May be published in Provider Directory</i>			
Name – Person Who Completed this Form	Telephone Number	E-mail Address <input type="checkbox"/> <i>May be published in Provider Directory</i>			

**I hereby attest that all statements made in this application and any attachments are correct to the best of my knowledge and
that I will comply with all laws, rules, and regulations governing alcohol and other drug abuse intervention services.**

FULL SIGNATURE – Director	Date Signed	Full Name – Director (<i>Print or type.</i>)
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Checkboxes indicate a required response. To avoid delays in certification, ensure that you respond to each checkbox.

Yes No

Chapter DHS 75.15(1) Service Description

This service is equivalent to the service description as listed below and in ch. DHS 75.14(1).

A narcotic treatment service for opiate addiction provides for the management and rehabilitation of selected narcotic addicts through the use of methadone or other FDA-approved narcotics and a broad range of medical and psychological services, substance abuse counseling and social services. Methadone and other FDA-approved narcotics are used to prevent the onset of withdrawal symptoms for 24 hours or more, reduce or eliminate drug hunger or craving and block the euphoric effects of any illicitly self-administered narcotics while the patient is undergoing rehabilitation.

Yes No

Chapter DHS 75.15(2) Requirements

This narcotic treatment service for opiate addiction complies with all requirements included in ch. DHS 75.03 and all requirements included in ch. DHS 75.13 that apply to a narcotic treatment service for opiate addiction, as shown in Table Chapter DHS 75.03 and, in addition, a narcotic treatment service for opiate addiction complies with the requirements of this section. If a requirement in this section conflicts with an applicable requirement in ch. DHS 75.03, the requirement in this section shall be followed.

Chapter DHS 75.15(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 from two or more methadone programs patient identifying information 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.
- (d) "Initial dosing" means the first administration of methadone or other FDA-approved narcotic to relieve a degree of withdrawal and drug craving of the patient.
- (e) "Mandatory schedule" means the required dosing schedule for a patient and the established frequency that the patient must attend the service.
- (f) "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.
- (g) "Objectively intoxicated person" means a person who is determined through a breathalyzer test to be under the influence of alcohol.
- (h) "Opioid addiction" means psychological and physiological dependence on an opiate substance, either natural or synthetic, that is beyond voluntary control.
- (i) "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.
- (j) "Phase" means a patient's level of dosing frequency.
- (k) "Service physician" means a physician licensed to practice medicine in the jurisdiction in which the program is located, who assumes responsibility for the administration of all medical services performed by the narcotic treatment service, including ensuring that the service is in compliance with all federal, state, and local laws relating to medical treatment of narcotic addiction with a narcotic drug.
- (l) "Service sponsor" means a person or a representative of an organization who is responsible for the operation of a narcotic treatment service and for all service employees including any practitioners, agents, or other persons providing services at the service or at a medication unit.
- (m) "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 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.
- (n) "Treatment contracting" means an agreement developed between the primary counselor or the program director and the patient in an effort to allow the patient to remain in treatment on condition that the patient adheres to service rules.

- (o) "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 program director.

Chapter DHS 75.03(4) Required Personnel

- Yes No (a) This narcotic treatment service for opiate addiction designates a physician licensed under ch. 448, Wis. Stats., as its medical director. The physician is readily accessible and able to respond in person in a reasonable period of time not to exceed 45 minutes.
- Yes No (b) This service has a registered nurse on staff to supervise the dosing process and perform other functions delegated by the physician.
- Yes No (c) This service may employ nursing assistants and related medical ancillary personnel to perform functions permitted under state medical and nursing practice statutes and administrative rules.
- Yes No (d) This service employs substance abuse counselors, substance abuse counselors-in-training, or clinical substance abuse counselors who are under the supervision of a clinical supervisor on a ratio of at least one to 50 patients in the service or fraction thereof.

This narcotic treatment service for opiate addiction provides for ongoing clinical supervision of the counseling staff. Ongoing clinical supervision is provided as required in s. RL 162.01.

A clinical supervisor at this service provides a minimum of the following, as required by s. RL 162.01.

- Yes No 1. Two hours of clinical supervision for every 40 hours of work performed by a substance abuse counselor-in-training.
- Yes No 2. Two hours of clinical supervision for every 40 hours of counseling provided by a substance abuse counselor.
- Yes No 3. One hour of clinical supervision for every 40 hours of counseling provided by a clinical substance abuse counselor.
- Yes No 4. One in person meeting each calendar month with a substance abuse counselor-in-training, substance abuse counselor, or clinical substance abuse counselor. This meeting may fulfill a part of the requirements above.
- Yes No (e) A clinical supervisor at this service provides supervision to substance abuse counselors in the areas identified in s. RL 162.01(5) as listed below.

The goals of clinical supervision are to provide the opportunity to develop competency in the transdisciplinary foundations, practice dimensions and care functions, provide a context for professional growth and development, and ensure a continuance of quality patient care.

Chapter DHS 75.03(5) Admission

- Yes No (a) *Admission criteria*
- Admission to this narcotic addiction treatment service for opiate addiction only occurs when a person meets all of the following criteria as determined by the service physician:
1. The person is physiologically and psychologically dependent upon a narcotic drug that may be a synthetic narcotic.
 2. The person has been physiologically and psychologically dependent upon the narcotic drug not less than one year before admission.
 3. In instances where the presenting drug history is inadequate to substantiate such a diagnosis, the material submitted by other health care professionals indicates a high degree of probability of such a diagnosis, based on further evaluation.
 4. When the person receives health care services from outside this service, the person has provided names, addresses, and written consents for release of information from each health care provider to allow the service to contact the providers, and agrees to update releases if changes occur.
- Yes No (b) *Voluntary treatment*
- Participation in this narcotic addiction treatment is voluntary.
- Yes No (c) *Explanation*
- Service staff clearly and adequately explain to the person being admitted all relevant facts concerning the use of the narcotic drug used by this service.
- Yes No (d) *Consent*
- This service requires a person being admitted to complete the most current version of FDA form 2635, Consent to Narcotic Addiction Treatment.

- Yes No (e) *Examination*
For each applicant eligible for narcotic addiction treatment, this service arranges for completion of a comprehensive physical examination, clinically indicated laboratory work-up prescribed by the physician, psycho-social assessment, initial treatment plan and patient orientation during the admission process.
- Yes No (f) *Initial dose.*
This service understands that if a person meets the admission criteria under par.(a), an initial dose of narcotic medication may be administered to the patient on the day of application.
- Yes No (g) *Distance of service from residence*
This service acknowledges that a person shall receive treatment at a service located in the same county or at the nearest location to the person's residence, except that if a service is unavailable within a radius of 50 miles from the patient's residence, the patient may, in writing, request the state methadone authority to approve an exception. In no case may a patient be allowed to attend a service at a greater distance to obtain take-home doses.
- Yes No (h) *Non-residents*
This service acknowledges that a self-pay person who is not a resident of Wisconsin may be accepted for treatment only after written notification to the Wisconsin state methadone authority. Permission shall be obtained before initial dosing.
- Yes No (i) *Central registry*
- Yes No 1. This service participates in a central registry or an alternative acceptable to the state methadone authority in order to prevent multiple enrollments in detoxification and narcotic addiction treatment services for opiate addiction. The central registry may include services and programs.
 - Yes No 2. This service makes a disclosure to the central registry whenever any of the following occurs:
 - a. A person is accepted for treatment.
 - b. The person is dis-enrolled in the service.
 - Yes No 3. The disclosure is limited to:
 - a. Patient-identifying information.
 - b. Dates of admission, transfer, or discharge from treatment.
- Yes No (j) *Admissions protocol*
This service has a written admissions protocol that accomplishes all of the following:
- Yes No 1. Identifies the person on the basis of appropriate substantiated documents that contain the individual'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.
 - Yes No 2. Determines the person'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.
 - Yes No 3. Determines the person's age. The patient shall verify that he or she is 18 years or older.
 - Yes No 4. Identifies the 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.
 - Yes No 5. Obtains information about past treatment. To the extent possible, service staff shall obtain information on a person's treatment history, use of secondary substances while in the treatment, dates and length of time in treatment, and reasons for discharge.
 - Yes No 6. Obtains personal information about the person. Personal information includes history and current status regarding employment, education, legal status, military service, family and psychiatric and medical information.
 - Yes No 7. Identifies the person's reasons for seeking treatment. Reasons shall include why the person chose the service and whether the person fully understands the treatment options and the nature and requirements of narcotic addiction treatment.
 - Yes No 8. Completes an initial drug screening or analysis of the person's urine to detect use of opiates, methadone, amphetamines, benzodiazepines, cocaine, or barbiturates. The analysis shall show positive for narcotics or an adequate explanation for negative results shall be provided and noted in the applicant's record. The primary counselor shall enter into the patient's case record the counselor's name, the content of a patient's initial assessment and the initial treatment plan. The primary counselor shall make these entries immediately after the patient is stabilized on a dose or within 4 weeks of admission, whichever is sooner.
 - Yes No 9. If the service is at capacity, immediately advises the applicant of the existence of a waiting list and providing that person with a referral to another treatment service that can serve the person's treatment needs.
 - Yes No 10. Refers a person who also has a physical health or mental health problem that cannot be treated within the service to an appropriate agency for appropriate treatment.

- Yes No 11. Obtains the person's written consent for the service to secure records from other agencies that may assist the service with treatment planning.
- Yes No 12. Arranges for hospital detoxification for patients seriously addicted to alcohol or sedatives or to anxiolytics before initiating outpatient treatment.
- Yes No (k) *Priority admissions*
This service offers priority admission either through immediate admission or priority placement on a waiting list in the following order:
 1. Pregnant women.
 2. Persons with serious medical or psychiatric problems
 3. Persons identified by the service through screening as having an infectious or communicable disease, including screening for risk behaviors related to human immunodeficiency virus infection, sexually transmitted diseases and tuberculosis.
- Yes No (l) *Appropriate and uncoerced treatment*
Service staff determine, through a screening process, that narcotic addiction treatment is the most appropriate treatment modality for the applicant and that treatment is not coerced.
- Yes No (m) *Correctional supervision notification*
This service requires a person who is under correctional supervision to provide written information releases that are necessary for the service to notify and communicate with the patient's probation and parole officer and any other correctional authority regarding the patient's participation in the service.

Chapter DHS 75.015(6) Orientation of New Patients

This service provides new patients with an orientation to the service, which includes all of the following:

- Yes No (a) A description of treatment policies and procedures.
- Yes No (b) A description of patient rights and responsibilities.
- Yes No (c) Provisions of a copy of a patient handbook that covers treatment policies and procedures and patient rights and responsibilities. The service shall require a new patient to acknowledge, in writing, receipt of the handbook.

Chapter DHS 75.15(7) Research and Human Rights Committee

If this narcotic treatment service is conducting or permitting research involving human subjects, it has established a research and human rights committee in accordance with s. 51.61, Wis. Stats., and 45 CFR Part 46.

- Yes No

Chapter DHS 75.15(8) Research

- Yes No (a) All proposed research involving patients meets the requirements of s. 51.61(1)(j), Wis. Stats., and 45 CFR Part 46 and this subsection.
- Yes No (b) No patient is 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), Wis. 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, Wis. 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 patient's treatment plan.

Chapter DHS 75.15(9) Medical Services

- Yes No (a) This service is not to provide any medical services not directly related to narcotic treatment. If a patient has medical service needs that are not directly related to narcotic treatment, this service refers the patient for appropriate health care.
- Yes No (b) The medical director of this service is responsible for all of the following:
 - Yes No 1. Administering all medical services provided by the service.
 - Yes No 2. Ensuring that the service complies with all federal, state, and local statutes, ordinances, and regulations regarding medical treatment of narcotic addiction.
 - Yes No 3. Ensuring that evidence of current physiological or psychological dependence, length of history of addiction and exceptions as granted by the state methadone authority to criteria for admission are documented in the patient's case record before the initial dose is administered.

- Yes No 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.
- Yes No 5. Ensuring that appropriate laboratory studies have been performed and reviewed.
- Yes No 6. 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. Prescriptions for additional take-home medication for an emergency situation.
- Yes No 7. Reviewing and countersigning each treatment plan four times annually.
- Yes No 8. 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.
- Yes No 9. The amount of narcotic drug administered or dispensed and for recording, signing, and dating each change in the dosage schedule in a patient's case record.
- (c) The service physician is responsible for all of the following:
- Yes No 1. Determining the amount of the narcotic drug to be administered or dispensed and recording, signing, and dating each change in a patient's dosage schedule in the patient's case record.
- Yes No 2. Ensuring that written justification is included in a patient's case record for a daily dose greater than 100 milligrams.
- Yes No 3. Approving, by signature and date, any request for an exception to the requirements under sub. (11) relating to take-home medications.
- Yes No 4. 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.
- Yes No 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 person is admitted to treatment with 14 days before release or discharge or within 6 months after release without documented evidence to support findings of physiological dependence.
 - b. The person 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 new 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 service physician 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.
- Yes No (d) A patient's history and physical examination supports a judgment on the part of the service physician that the patient is a suitable candidate for narcotic addiction treatment.
- Yes No (e) This service provides narcotic addiction treatment to a patient for a maximum of two years from the date of the person's admission to the service, unless clear justification for longer service provision is documented in the treatment plan and progress notes.
- Yes No Clear justification for longer service is included in documentation for all of the following:
1. The patient continues to benefit from the treatment
 2. The risk of relapse is no longer present.
 3. The patient exhibits no side effects from the treatment.
 4. Continued treatment is medically necessary in the professional judgment of the service physician.

Chapter DHS 75.15(10) Dosage

- Yes No (a) Because methadone and other FDA-approved narcotics are medications, the dose determination for a patient is a matter of clinical judgment by a physician in consultation with the patient and appropriate staff of this service. This service complies.

- Yes No (b) The service physician who has examined a patient determines, on the basis of clinical judgment, the appropriate narcotic dose for the patient.
- Yes No (c) This service acknowledges that any dose adjustment, either up or down, to sanction the patient is sufficient to produce the desired response in the patient for the desired duration of time.
- Yes No (d) This service delays administration of methadone to an objectively intoxicated patient until diminution of intoxication symptoms can be documented, or the patient is readmitted for observation for withdrawal symptoms while augmenting the patient's daily dose in a controlled, observable fashion.
- Yes No (e) The narcotic dose that this service provides to a patient is sufficient to produce the desired response in the patient for the desired duration of time.
- Yes No (f) A patient's initial dose is based on the service physician's evaluation of the history and present condition of the patient.
- Yes No The evaluation includes knowledge of local conditions, such as the relative purity of available street drugs.
- Yes No The initial dose may not exceed 30 milligrams except that the total dose for the first day may not exceed 40 milligrams.
- Yes No (g) This service incorporates withdrawal planning as a goal in a patient's treatment plan and begins to address it once the patient is stabilized.
- Yes No A service physician determines the rate of withdrawal to prevent relapse or withdrawal symptoms.
- Yes No (h) 1. A service physician may order the withdrawal of a patient from medication for administrative reasons, such as extreme antisocial behavior or noncompliance with minimal service standards.
2. The process of withdrawal from medication for administrative reasons is conducted in a humane manner as determined by the service physician, and referral is made to other treatment services.

Chapter DHS 75.15(11) Take-Home Medication Practices

- Yes No (a) *Granting take-home privileges*
- During treatment, a patient may benefit from less frequent required visits for dosing. This is based on an assessment by the treatment staff.
- Yes No Time in treatment is not the sole consideration for granting take-home privileges.
- Yes No After consideration of treatment progress, the service physician determines if take-home doses are appropriate or if approval to take home doses should be rescinded.
- This service complies with federal requirements as follows:
- Yes No 1. Take-home doses are not allowed during the first 90 days of treatment. Patients shall be expected to attend the service daily, except Sundays, during the initial 90-day period with no exceptions granted.
- Yes No 2. Take-home doses may 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.
- Yes No 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.
- Yes No 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. The service 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.
- Yes No 5. Service staff may not use the level of the daily dose to determine whether a patient receives take-home medication.
- Yes No (b) *Treatment team recommendation*
- This service has a treatment team of appropriate staff in consultation with a patient to collect and evaluate the necessary information regarding a decision about take-home medication for the patient and to make the recommendation to grant take-home privileges to the service physician.
- Yes No (c) *Service physician review*
- The rationale for approving, denying, or rescinding take-home privileges is recorded in the patient's case record and the documentation is reviewed, signed, and dated by the service physician.

(d) Service physician determination

The service physician considers and attests to all of the following in determining whether, in this service physician's reasonable clinical judgment, a patient is responsible in handling narcotic drugs and has made substantial progress in rehabilitation:

- Yes No 1. The patient is not abusing substances, including alcohol
- Yes No 2. The patient keeps scheduled service appointments.
- Yes No 3. The patient exhibits no serious behavioral problems at the service.
- Yes No 4. The patient is not involved in criminal activity, such as drug dealing and selling take-home doses.
- Yes No 5. The patient has a stable home environment and social relationships.
- Yes No 6. The patient has met the following criteria for length of time in treatment starting from the date of admission:
- a. Three months in treatment before being allowed to take home doses for two days.
 - b. Two years in treatment before being allowed to take home doses for three days.
 - c. Three years in treatment before being allowed to take home doses for six days.
- Yes No 7. The patient provides assurance that take-home medication will be safely stored in a locked metal box within the home.
- Yes No 8. The rehabilitative benefit to the patient in decreasing the frequency of service attendance outweighs the potential risks of diversion.

 Yes No *(e) Time in treatment criteria*

The time in treatment criteria under par. (d) 6. is the minimum time before take-home medications will be considered unless there are exceptional circumstances and this service applies for and receives approval from the FDA and the state methadone authority for a particular patient for longer period of time.

 Yes No *(f) Individual consideration of request*

A request for take-home privileges is considered on an individual basis. No request for take-home privileges are granted automatically to any patient.

(g) Additional criteria for 6-day take-homes

When a patient is considered for 6-day take-homes, the patient meets the following additional criteria:

- Yes No 1. The patient is employed, attends school, is a homemaker, or is disabled.
- Yes No 2. The patient is not known to have used or abused substances, including alcohol, in the previous year.
- Yes No 3. The patient is not known to have engaged in criminal activity in the previous year.

 Yes No *(h) Observation requirement*

A patient receiving a daily dose of a narcotic medication above 100 milligrams is required to be under observation while ingesting the drug at least 6 days per week, irrespective of the length of time in treatment, unless the service has received prior approval from the designated federal agency, with concurrence by the state methadone authority, to waive this requirement. This service is in compliance.

 Yes No *(i) Denial or rescinding of approval*

This service denies or rescinds 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

- Yes No 1. The service physician reviews the status of every patient provided with take-home medication at least every 90 days and more frequently if clinically indicated.
- Yes No 2. The service treatment team reviews the merits and detriments of continuing a patient's take-home privilege and makes appropriate recommendations to the service physician as part of the service physician's 90-day review.

- Yes No 3. Service staff 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.
- Yes No 4. Service staff does 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*
- Yes No 1. This service understands that it 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.
- Yes No 2. This service understands that it may 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.
- Yes No (l) *Reinstatement*
- This service does not reinstate take-home privileges that have been revoked until the patient has had at least three consecutive months of 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, and the service physician determines that the patient is responsible in handling narcotic drugs.
- (m) *Clinical probation*
- Yes No 1. A patient receiving a six-day supply of take-home medication 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 is placed on clinical probation for three months.
- Yes No 2. A patient on three-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 is required to attend the service at least twice weekly for observation of the ingestion of medication, and may receive no more than a three-day take-home supply of medication.
- Yes No (n) *Employment-related exception to 6-day supply*
- This service understands that a patient who is employed and working on Saturdays may apply for an exception to the dosing requirements if dosing schedules of this service conflict with working hours of the patient. This 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 state methadone authority.

Chapter DHS 75.15(12) Exceptions to Take-Home Requirements

- Yes No (a) This service may grant an exception to certain take-home requirements for a particular patient, but only does so if, in the reasonable clinical judgment of the program 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.
- Yes No (b) The program physician or program personnel supervised by the program physician records the rationale for an exception to an applicable mandatory schedule in the patient's case record. If program personnel record the rationale, the physician reviews, countersigns, and dates the rationale in the patient's record.
- Yes No A patient is not to be given more than a 14-day supply of narcotic drugs at one time.
- Yes No The service physician's judgment that a patient is responsible in handling narcotic drugs is 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 of attendance outweighs the potential risks of diversion.

- Yes No (d) 1. This service understands that any exception to the take-home requirements exceeding two times the amount in that phase is subject to approval of the designated federal agency and the state methadone authority. The following is the amount of additional take-home doses needing approval: Phase 1 = 2 additional (excluding Sunday); Phase 2 = 4 additional; Phase 3 = 6 additional; Phase 4 = 12 take-home doses required for approval.
- Yes No 2. Service staff on receipt of notices of approval or denial of a request for an extension from the state methadone authority and the designated federal agency place the notices in the patient's case record.
- Yes No (e) Service staff review an exception when the conditions of the request change or at the time of review of the treatment plan, whichever occurs first.
- Yes No (f) An exception remains in effect only as long as the conditions establishing the exception remain in effect.

Chapter DHS 75.15(13) Testing and Analysis for Drugs

(a) Use

- Yes No 1. This service uses drug tests and analyses to determine the presence in a patient of opiates, methadone, amphetamines, cocaine, or barbiturates.
- Yes No If any other drug has been determined by this service or the state methadone authority to be abused in that service's locality, a specimen is also analyzed for that drug.
- Yes No The laboratory used by this service to perform the testing complies with 42 CFR Part 493.
- Yes No 2. This service uses 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.
- Yes No 3. This service's policies and procedures integrate testing and analysis into treatment planning and clinical practice.

(b) Drawing blood for testing

- Yes No This service determines a patient's drug levels in plasma or serum at the time the person is admitted to this service to determine a baseline.
- Yes No The determinations are made at three months, six months, and annually subsequently
- Yes No If a patient requests and receives doses above 100 milligrams, serum levels are drawn to evaluate peak and through determinations after the patient's dose is stabilized.

(c) Obtaining urine specimens

- Yes No This service obtains urine specimens for testing from a patient in a clinical atmosphere that respects the patient's confidentiality, as follows:
1. A urine specimen shall be collected upon each patient's service visit and specimens shall be tested on a random basis.
 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 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

- Yes No 1. Service staff discuss positive test results with the patient within one week after receipt of results and document them in the patient's case record with the patient's response noted.
- Yes No 2. This service provides counseling, casework, medical review, and other interventions when continued use of substances is identified. Punishment is not appropriate.
- Yes No 3. When there is a positive test result, service staff allow sufficient time before retesting to prevent a second positive test result from the same substance use.
- Yes No 4. Service staff confronted with a patient's denial of substance use consider the possibility of a false positive test.
- Yes No 5. Service staff review a patient's dosage and counsel the patient when test reports are positive for morphine-like substances and negative for the FDA-approved narcotic treatment.

Chapter DHS 75.15(14) Treatment Duration and Retention

- (a) Patient retention is a major objective of treatment. This service does all of the following to retain patients for the planned course of treatment:

- Yes No 1. Make the service physically accessible.
- Yes No 2. 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.
- Yes No 3. Determine hours based on patient needs.
- Yes No 4. Provide affordable treatment to all needing it.
- Yes No 5. Ensure that a patient has ready access to staff, particularly to the patient's primary counselor.
- Yes No 6. Ensure that staff are adequately trained and are sensitive to gender-specific and culture-specific issues.
- Yes No 7. Provide services that incorporate good practice standards for substance abuse treatment.
- Yes No 8. Ensure that patients receive adequate doses of narcotic medication based on their individual needs.
- Yes No 9. Ensure that the attitude of staff is accepting of narcotic addiction treatment.
- Yes No 10. Ensure that patients understand that they are responsible for complying with all aspects of their treatment, including participating in counseling sessions.
- Yes No (b) Since treatment duration and retention are directly correlated to rehabilitation success, this service makes a concerted effort to retain patients within the first year following admission. Evidence of this concerted effort includes written documentation of all of the following:
 - 1. The patient continues to benefit from the treatment
 - 2. The risk of relapse is discontinued.
 - 3. The patient exhibits no side effects from the treatment.
 - 4. Continued treatment is medically necessary in the professional judgment
- Yes No (c) This service refers an individual discharged from the service to a more suitable treatment modality when further treatment is required or is requested by that person and cannot be provided by this service.
- Yes No (d) For services needed by a patient but not provided by this service, this service refers the individual to an appropriate service provider.

Chapter DHS 75.15(15) Multiple Substance Use and Dual Diagnosis Treatment

- Yes No (a) *Assessment*
This service assesses an applicant for admission during the admission process and a patient, as appropriate, to distinguish substance use, abuse and dependence, and determines patterns of othe substance use and self-reported etiologies, including non-prescription, non-therapeutic and prescribed therapeutic use and mental health problems.
- Yes No (b) *Multiple substance use patients*
 - Yes No 1. This service provides a variety of services that support cessation by a patient of alcohol and prescription and non-prescription substance abuse as the desired goal.
 - Yes No 2. Service objectives indicate that abstinence by a patient from alcohol and prescription and non-prescription substance abuse should extend for increasing periods, progress toward long-term abstinence and be associated with improved life functioning and well-being.
 - Yes No 3. Service staff 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.
- Yes No (c) *Dually diagnosed patients*
 - Yes No 1. This service has the ability to provide concurrent treatment for a patient diagnosed with both a mental health disorder and a substance use disorder.
This service arranges 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.
 - Yes No 2. When a dual diagnosis exists, this service develops with the patient a treatment plan that integrates measures for treating all alcohol, drug, and mental health problems.
 - Yes No 3. For the treatment of a dually diagnosed patient, this service arranges for a mental health professional to help develop the treatment plan and provides ongoing treatment services.
 - Yes No The mental health professional is available either as an employee of this service or through a written agreement.

Chapter DHS 75.15(16) Pregnancy

- Yes No (a) When this service provides narcotic addiction treatment to pregnant women, it provides that treatment within a comprehensive treatment service that addresses medical, perinatal, obstetrical, psychosocial, and addiction issues.
- Yes No (b) A diagnosis of opioid addiction and need of the patient to avoid use of narcotic antagonists is based on the same factors, such as medical and substance abuse history, psychosocial history, physical examination, test toxicology, and signs and symptoms of withdrawal, that are used in diagnosing opiate addiction in non-pregnant opioid-dependent women. In this paragraph, "narcotic antagonist" means a drug primarily used to counter narcotic-induced respiratory depression.
- Yes No (c) A pregnant woman seeking narcotic addiction treatment is referred to a prenatal specialist or obstetrician as soon as possible after initiating narcotic addiction treatment with follow up contact, to coordinate care of the woman's prenatal health status, evaluate fetal growth, and document physiologic dependence.
- Yes No (d) 1. When withdrawal from narcotic medication is the selected treatment option, withdrawal is conducted under the supervision of a service physician experienced in perinatal addiction, ideally in a perinatal unit equipped with fetal monitoring equipment.
- Yes No 2. Withdrawal is not to be initiated before the 14th week of pregnancy or after the 32nd week of pregnancy.
- Yes No (e) Pregnant women are monitored and their dosages individualized, as needed.
- Yes No (f) This service does not change the methadone dose that a pregnant woman was receiving before her pregnancy unless necessary to avoid withdrawal.
- Yes No (g) This service increases the methadone dose for a patient, if needed, during the later stages of the patient's pregnancy to maintain the same plasma level and avoid withdrawal.
- Yes No (h) This service arranges for appropriate assistance for pregnant patient, including education and parent support groups, to improve mother-infant interaction after birth and to lessen the behavioral consequences of poor mother-infant bonding.

Chapter DHS 75.15(17) Communicable Disease

- Yes No (a) This narcotic treatment service for opiate addiction screens patients immediately following admission and annually thereafter for tuberculosis (TB). Tuberculosis treatment may be provided by referral to an appropriate public health agency or community medical service.
- Yes No (b) This service screens prospective new staff for TB and annually tests all service staff for TB.
- Yes No (c) This service screens all patients at admission and annually thereafter for viral hepatitis and sexually transmitted diseases (STDs) and ensures that any necessary medical follow-up occurs, either on-site or through referral to community medical services.
- Yes No (d) This service ensures that all service staff have been immunized against hepatitis B. Documentation of refusal to be immunized is entered in the staff member's case record.

Chapter DHS 75.15(18) Facility

This service provides a setting that is conducive to rehabilitation of the patients and that meets all of the following requirements:

- Yes No (a) The waiting area for dosing shall be clean.
- Yes No (b) Waiting areas, dosing stations, and all other areas for patients shall be provided with adequate ventilation and lighting.
- Yes No (c) Dosing stations and adjacent areas shall be kept sanitary and ensure privacy and confidentiality.
- Yes No (d) 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.
- Yes No (e) Adequate security shall be provided inside and outside the facility for the safety of the patients and to prevent loitering and illegal activities.
- Yes No (f) Separate toilet facilities shall be provided for patient and staff use.
- Yes No (g) The facility and areas within the facility shall be accessible to persons with physical disabilities.
- Yes No (h) The physical environment within the facility shall be conducive to promoting improved functioning and a drug free lifestyle.

Chapter DHS 75.15(19) Diversion Control

- Yes No (a) Each staff member of this narcotic treatment service for opiate addiction is responsible for being alert to potential diversion of narcotic medication by patients and staff.
- Yes No (b) Service staff take all of the following measures to minimize diversion:
- Yes No 1. Doses of narcotic medication shall be dispensed only in liquid form.
- Yes No 2. Bottles of narcotic medication shall be labeled with the patient's name, the dose, the source service, the prescribing physician, and the date by which the dose is to be consumed.
- Yes No 3. The service shall require a patient to return all empty take-home bottles on the patient's next day of service attendance following take-home dosing. Service staff shall examine the bottles to ensure that the bottles are received from the appropriate patient and in an intact state.
- Yes No 4. The service shall discontinue take-home medications for patients who fail to return empty take-home bottles in the prescribed manner.
- Yes No (c) If this service receives reliable information that a patient is diverting narcotic medication, the patient's primary counselor is immediately discuss the problem with the patient.
- Yes No (d) This service understands that based on information provided by the patient or continuing reports of diversion, this service may revoke take-home privileges of the patient.
- Yes No (e) This service understands that the state methadone authority may, based on reports of diversion, revoke take-home privileges, exceptions, or exemptions granted to or by this service for all patients.
- Yes No (f) This service acknowledges that the state methadone authority may revoke the authority of this narcotic treatment service for opiate addiction to grant take-home privileges when this service cannot demonstrate that all requirements have been met in granting take-home privileges.
- Yes No (g) This narcotic treatment service for opiate addiction has a written policy to discourage the congregation of patients at a location inside or outside the service facility for non-programmatic reasons, and posts that policy in the facility.

Chapter DHS 75.15(20) Service Approval*(a) Approval of primary service*

As an applicant for approval to operate a narcotic treatment service for opiate addiction in Wisconsin with the intent of administering or dispensing of narcotic drug to narcotic addicts for maintenance or with the intent of administering or dispensing of narcotic drug to narcotic addicts for maintenance or detoxification treatment, this service has submitted all of the following to the state methadone authority:

- Yes No 1. Copies of all completed designated federal agency applications.
- Yes No 2. A copy of the request for registration with the U.S. drug enforcement administration for the use of narcotic medications in the treatment of opiate addiction.
- Yes No 3. A narrative description of the treatment services that will be provided in addition to chemotherapy.
- Yes No 4. Documentation of the need for the service.
- Yes No 5. Criteria for admitting a patient.
- Yes No 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. Descriptions 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.
- Yes No 7. Documentation that there are adequate physical facilities to provide all necessary services.
- Yes No 8. a. Documentation that this service will have ready access to a comprehensive range of medical and rehabilitative services will be available if needed.
- b. The name, address, and a description of each hospital, institution, clinical laboratory or other facility available to provide the necessary services.
- Yes No 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.

- Yes No (b) *Approval of service sites*
This service site is approved by the FDA, the U.S. drug enforcement administration and the state methadone authority for treating narcotic addicts with a narcotic drug.
- Yes No (c) *Approval of medication units*
- Yes No 1. To operate a medication unit, this service applied to the department for approval to operate the medication unit.
- Yes No This service understands that a separate approval is required for each medication unit to be operated by the service.
- Yes No 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.
- Yes No 2. Approval of a medication unit takes into consideration the distribution of patients and other medication units in a geographic area.
- Yes No 3. This service acknowledges that if this service has its approval revoked, the approval of each medication unit operated by this service is automatically revoked. Revocation of the approval of medication unit does not automatically affect the approval of the primary service.
- Yes No **NOTE:** To apply for approval to operate a medication unit, contact the **State Methadone Authority** at:
Bureau of Prevention, Treatment and Recovery
P.O. Box 7851
Madison, WI 53707-7851
- Approvals of the Center for Substance Abuse Treatment and the U.S. Drug Enforcement Administration to operate a medication unit are also required. The State Methadone Authority will facilitate the application consideration by the Center for Substance Abuse Treatment and the U.S. Drug Enforcement Administration.

Chapter DHS 75.15(21) Assent to Regulation

Verify that this service is in compliance of these regulations by checking the checkbox.

- Yes No (a) A person who sponsors a narcotic treatment service for opiate addiction 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. **THIS SERVICE IS IN COMPLIANCE.**
- Yes No (b) 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. **THIS SERVICE IS IN COMPLIANCE.**
- Yes No (c) 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 regulations. **THIS SERVICE IS IN COMPLIANCE.**
- Yes No (d) The service shall notify the designated federal agency and state methadone authority within three weeks after replacement of the service sponsor or medical director.

 Yes No **Chapter DHS 75.15(22) Death Reporting**

This narcotic treatment service for opiate addiction will and does report the death of any of its patients to the state methadone authority within one week after learning of the patient's death.