

**CHAPTER 715. STANDARDS FOR APPROVAL OF NARCOTIC
TREATMENT PROGRAM**

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Authority

The provisions of this Chapter 715 issued under the Pennsylvania Drug and Alcohol Abuse Control Act (71 P. S. §§ 1690.101—1690.114), unless otherwise noted.

Source

The provisions of this Chapter 715 adopted November 15, 2002, effective November 16, 2002, 32 Pa.B. 5638, unless otherwise noted.

§ 715.1. General provisions.

(a) An entity within this Commonwealth which uses agents for maintenance or detoxification of persons shall obtain the approval of the Department to operate a narcotic treatment program.

(b) The Department's approval of a narcotic treatment program shall be contingent upon the narcotic treatment program's compliance with the standards and

conditions in this part. In addition, the program shall comply with applicable Federal laws and regulations.

§ 715.2. Relationship of Federal and State regulations.

(a) A narcotic treatment program shall comply with Federal regulations and requirements governing the administration, dispensing and storage of agents.

(b) This chapter is intended to supplement the Federal regulations governing narcotic treatment programs in 21 CFR Chapter II, 1300—1399 (relating to Drug Enforcement Administration, Department of Justice).

§ 715.3. Approval of narcotic treatment programs.

(a) An entity shall apply for and receive approval as required from the Department, DEA and CSAT or an organization designated by the Substance Abuse and Mental Health Services Administration (SAMHSA), under the authority of section 303 of the Controlled Substances Act (21 U.S.C.A. § 823) and sections 501(d), 509(a), 543, 1923, 1927(a) and 1976 of the Public Health Service Act (42 U.S.C.A. §§ 290aa(d), 290bb-2(a), 290dd-2, 300x-23, 300x-27(a) and 300y-11), prior to offering services within this Commonwealth as a narcotic treatment program. Application for approval shall be made simultaneously to the Department, DEA and CSAT or SAMHSA designee.

(1) The Department will forward a recommendation for approval to the Federal officials after a review of policies and procedures and an onsite inspection by an authorized representative of the Department and after a determination has been made that the requirements for approval under this chapter have been met.

(2) The decision of the Federal officials set forth in 21 CFR Chapter II (relating to Drug Enforcement Administration, Department of Justice) or other Federal statutes shall constitute the final determination on the application for approval by DEA and CSAT or SAMHSA designee.

(b) A narcotic treatment program shall be licensed under the Department's regulations for drug and alcohol facilities in Chapter 704, 705, 709, 710 or 711. When a licensee applies to operate a narcotic treatment program, the history component of the application of the licensee shall include the licensee's record of operation of any facility regulated by any State or Federal entity. A narcotic treatment program may not be recommended for approval unless licensure has been obtained under Chapters 704, 705, 709, 710 or 711.

(c) The Department will grant approval as a narcotic treatment program after an onsite inspection and review of narcotic treatment program policies, procedures and other material, when the Department determines that the requirements for approval have been met.

(d) The Department will inspect a narcotic treatment program at least annually to determine compliance with State narcotic treatment program regulations. This inspection shall consist of an onsite visit and shall include an examination

of patient records, reports, files, policies and procedures, and other similar items to enable the Department to make an evaluation of the status of the narcotic treatment program. The Department may inspect the narcotic treatment program without notice during any regular business hours of the narcotic treatment program.

(e) During the inspection process, a narcotic treatment program shall make available to the authorized staff of the Department full and free access to its premises, facilities, records, reports, files and other similar items necessary for a full and complete evaluation. The Department may make copies of materials it deems necessary under 42 CFR 2.53 (relating to audit and evaluation activities) and §§ 709.15 and 711.15 (relating to right to enter and inspect; and right to enter and inspect).

(f) The authorized Department representative may interview patients and staff as part of the inspection process.

(g) The Department may grant approval as a narcotic treatment program after an onsite inspection when the Department determines that a narcotic treatment program satisfies the following:

(1) It has substantially complied with applicable requirements for approval.

(2) It is complying with a plan of correction approved by the Department with regard to any outstanding deficiencies.

(3) Its existing deficiencies will not adversely alter the health, welfare or safety of the facility's patients.

(h) Notification of deficiencies involves the following:

(1) The authorized Department representative will provide the program director with a record of deficiencies with instructions to submit a plan of correction.

(2) The narcotic treatment program shall complete the plan of correction and submit it to the Department within 21 days after the last day of the onsite inspection.

(3) The Department will not grant approval as narcotic treatment program until the Department receives and approves a plan of correction.

§ 715.4. Denial, revocation or suspension of approval.

(a) The Department will deny, suspend or revoke approval of a narcotic treatment program if the applicant or program fails to comply with this chapter. Procedures for the revocation, suspension or denial of Department approval, and appeals from these actions, shall be the same as procedures in §§ 709.17, 709.18, 711.17 and 711.18.

(b) The Department may recommend to the DEA or CSAT or SAMHSA's designee to initiate proceedings to revoke or deny Federal approval.

(c) The Department may seek an injunction for the closure of a narcotic treatment program in a court of competent jurisdiction.

§ 715.5. Patient capacity.

The Department may increase or decrease the number of patients a narcotic treatment program may treat. The Department may raise the patient capacity, upon the written request of the narcotic treatment program, based upon the Department's review of the narcotic treatment program. The factors the Department will consider include:

- (1) *Safety*. Considerations include dispensing time, internal patient flow and external traffic patterns.
- (2) *Physical facility*. Considerations include the number and size of counseling offices, waiting areas, restrooms, and dispensing and nursing windows.
- (3) *Staff size and composition*. Considerations include the number of narcotic treatment physicians, dispensing and counseling staff.
- (4) *Ability to provide required services*. Considerations include compliance with licensing and narcotic treatment program regulations as determined during licensing, monitoring and special visits to the narcotic treatment program.
- (5) *Availability and accessibility of service*. Considerations include the location of the narcotic treatment program and the hours of operation.

§ 715.6. Physician staffing.

(a) A narcotic treatment program shall designate a medical director to assume responsibility for administering all medical services performed by the narcotic treatment program.

- (1) A medical director shall be a physician and shall have obtained one of the following:
 - (i) Three years documented experience in the provision of services to persons who are addicted to alcohol or other drugs, including at least 1 year of experience in the treatment of narcotic addiction with a narcotic drug.
 - (ii) Certification in addiction medicine by the American Society of Addiction Medicine.
 - (iii) A certificate of added qualifications in addiction psychiatry by the American Board of Psychiatry and Neurology, Inc.
- (2) When a narcotic treatment program is unable to hire a medical director who meets the qualifications in paragraph (1), the narcotic treatment program may hire an interim medical director. The narcotic treatment program shall develop and submit to the Department for approval a training plan for the interim medical director, addressing the measures to be taken for the interim medical director to achieve minimal competencies and proficiencies until the interim medical director meets qualifications identified in paragraph (1)(i), (ii) or (iii). The interim medical director shall meet the qualifications within 36 months of being hired.
- (3) The medical director's responsibilities include the following:
 - (i) Supervision of narcotic treatment physicians.

- (ii) Supervision of licensed practical nurses if the narcotic treatment program does not employ a registered nurse to supervise the nursing staff. In addition, the medical director in these instances shall ensure that licensed practical nurses adhere to written protocols for dispensing and administration of medication.
- (b) A narcotic treatment program may employ narcotic treatment physicians to assist the medical director. A narcotic treatment physician's responsibilities include:
- (1) Performing a medical history and physical exam.
 - (2) Determining diagnosis and determining narcotic dependence.
 - (3) Reviewing treatment plans.
 - (4) Determining dosage and all changes in doses.
 - (5) Ordering take-home privileges.
 - (6) Discussing cases with the treatment team.
 - (7) Issuing verbal orders pertaining to patient care.
 - (8) Assessing coexisting medical and psychiatric disorders.
 - (9) Treating or making appropriate referrals for treatment of these disorders.
- (c) A narcotic treatment physician shall be otherwise available for consultation and verbal medication orders at all times when a narcotic treatment program is open and a narcotic treatment physician is not present.
- (d) A narcotic treatment program shall provide narcotic treatment physician services at least 1 hour per week onsite for every ten patients.
- (e) A physician assistant or certified registered nurse practitioner may perform functions of a narcotic treatment physician in a narcotic treatment program if authorized by Federal, State and local laws and regulations, and if these functions are delegated to the physician assistant or certified registered nurse practitioner by the medical director, and records are properly countersigned by the medical director or a narcotic treatment physician. One-third of all required narcotic treatment physician time shall be provided by a narcotic treatment physician. Time provided by a physician assistant or certified registered nurse practitioner may not exceed two-thirds of the required narcotic treatment physician time.

Cross References

This section cited in 28 Pa. Code § 701.1 (relating to definitions).

§ 715.7. Dispensing or administering staffing.

- (a) A narcotic treatment program shall be staffed as follows:
- (1) If it operates an automated dispensing system, one full-time nurse or other person authorized by law to administer or dispense a controlled substance shall be available for every 200 patients.

- (2) If it operates a manual or nonautomatic dispensing system, one full-time nurse or other person authorized by law to administer or dispense a controlled substance shall be available for every 150 patients.
- (b) Dispensing time shall be prorated for patient census. There shall be sufficient dispensing staff to ensure that all patients are medicated within 15 minutes of arrival at the dispensing area.

§ 715.8. Psychosocial staffing.

A narcotic treatment program shall comply with the following staffing ratios as established in Chapter 704 (relating to staffing requirements for drug and alcohol treatment activities.):

- (1) *General requirements.* A narcotic treatment program shall comply with the patient/staff and patient/counselor ratios in subparagraphs (i)—(vi) during primary care hours. These ratios refer to the total number of patients being treated, including patients with diagnoses other than drug and alcohol addiction served in other facets of the project. Family units may be counted as one patient.
- (i) *Inpatient nonhospital detoxification (residential detoxification).*
- (A) There shall be one full-time equivalent (FTE) primary care staff person available for every seven patients during primary care hours.
- (B) There shall be a narcotic treatment physician on-call at all times.
- (ii) *Inpatient hospital detoxification.* There shall be one FTE primary care staff person available for every five patients during primary care hours.
- (iii) *Inpatient nonhospital treatment and rehabilitation (residential treatment and rehabilitation).* A narcotic treatment program serving adult patients shall have one FTE counselor for every eight patients.
- (iv) *Inpatient hospital treatment and rehabilitation (general, psychiatric or specialty hospital).* A narcotic treatment program serving adult patients shall have one FTE counselor for every five patients.
- (v) *Partial hospitalization.* A partial hospitalization narcotic treatment program shall have a minimum of one FTE counselor who provides direct counseling services to every ten patients.
- (vi) *Outpatients.* The counseling caseload for one FTE counselor in an outpatient narcotic treatment program may not exceed 35 active patients.
- (2) *Counselor assistants.* A counselor assistant eligible for a counseling caseload may be included in determining FTE ratios.

§ 715.9. Intake.

- (a) Prior to administration of an agent, a narcotic treatment program shall screen each individual to determine eligibility for admission. The narcotic treatment program shall:
- (1) Verify that the individual has reached 18 years of age.

- (2) Verify the individual's identity, including name, address, date of birth, emergency contact and other identifying data.
 - (3) Obtain a drug use history and current drug use status of the individual.
 - (4) Have a narcotic treatment physician make a face- to-face determination of whether an individual is currently physiologically dependent upon a narcotic drug and has been physiologically dependent for at least 1 year prior to admission for maintenance treatment. The narcotic treatment physician shall document in the patient's record the basis for the determination of current dependency and evidence of a 1 year history of addiction.
- (b) Exceptions to the requirements in subsection (a) are:
- (1) A 1 year history of physiologic dependency is not required for detoxification or for pregnant patients.
 - (2) Upon readmitting a patient who has been out of a narcotic treatment program for 6 months or less after a voluntary termination, the narcotic treatment program shall update the information in and review the patient's file to show current opiate narcotic dependency, but need not conduct a physical examination and applicable laboratory tests. Privileges earned during the previous treatment may be reinstated at the discretion of the narcotic treatment physician.
 - (3) A patient who has been treated and later detoxified from comprehensive maintenance treatment may be readmitted to maintenance treatment, without evidence to support findings of current physiologic dependence, up to 2 years after discharge, if the following conditions are met:
 - (i) The narcotic treatment program attended is able to document prior narcotic drug comprehensive maintenance treatment of 6 months or more.
 - (ii) The admitting narcotic treatment physician, exercising reasonable clinical judgment, finds readmission to comprehensive maintenance treatment to be medically justified.
 - (c) If a patient was previously discharged from treatment at another narcotic treatment program, the admitting narcotic treatment program, with patient consent, shall contact the previous facility for the treatment history.
 - (d) A narcotic treatment program shall explain to each patient treatment options; pharmacology of methadone, LAAM and other agents, including signs and symptoms of overdose and when to seek emergency assistance; detoxification rights; grievance procedures; and clinic charges, including the fee agreement signed by the patient.
 - (e) A narcotic treatment program shall secure a personal history from the patient within the first week of admission. The personal history shall be made a part of the patient record.

§ 715.10. Pregnant patients.

(a) A narcotic treatment program may place a pregnant patient, regardless of age, who has had a documented narcotic dependency in the past and who may return to narcotic dependency, on a comprehensive maintenance regime.

(1) For these patients, evidence of current physiological dependence on narcotic drugs is not needed if a narcotic treatment physician certifies the pregnancy and, exercising reasonable clinical judgment, finds treatment to be medically justified.

(2) Evidence of all findings and the criteria used to determine the findings shall be recorded in the patient's record by the admitting narcotic treatment physician before the initial dose is administered to the patient.

(b) A narcotic treatment program shall give pregnant patients the opportunity for prenatal care either by the narcotic treatment program or by referral to appropriate health-care providers.

(c) Counseling records and other appropriate patients records shall reflect the nature of prenatal support provided by the narcotic treatment program.

(d) Within 3 months after termination of pregnancy, the narcotic treatment physician shall enter an evaluation of the patient's treatment status into her record and state whether she should remain in comprehensive maintenance treatment or receive detoxification treatment.

(e) A patient who is or becomes pregnant may not be started or continued on LAAM, except by the written order of a narcotic treatment physician who determines that LAAM is the best therapy for that patient.

(1) An initial pregnancy test shall be performed for each prospective female patient of childbearing potential before admission to LAAM comprehensive maintenance treatment.

(2) A monthly pregnancy test shall be performed thereafter on female patients on LAAM.

(f) The narcotic treatment program shall ensure that each female patient is fully informed of the possible risk to her or her unborn child from continued use of illicit drugs and from use of, or withdrawal from a narcotic drug administered or dispensed by the program in comprehensive maintenance or detoxification treatment.

§ 715.11. Confidentiality of patient records.

A narcotic treatment program shall physically secure and maintain the confidentiality of all patient records in accordance with 42 CFR 2.22 (relating to notice to patients of Federal confidentiality requirements) and § 709.28 (relating to confidentiality).

Cross References

This section cited in 28 Pa. Code § 715.20 (relating to patient transfers).

§ 715.12. Informed patient consent.

A narcotic treatment program shall obtain an informed, voluntary, written consent before an agent may be administered to the patient for either maintenance or detoxification treatment. The following shall appear on the patient consent form:

- (1) That methadone and LAAM are narcotic drugs which can be harmful if taken without medical supervision.
- (2) That methadone and LAAM are addictive medications and may, like other drugs used in medical practices, produce adverse results.
- (3) That alternative methods of treatment exist.
- (4) That the possible risks and complications of treatment have been explained to the patient.
- (5) That methadone is transmitted to the unborn child and will cause physical dependence.

§ 715.13. Patient identification.

(a) A narcotic treatment program shall use a system for patient identification for the purpose of verifying the correct identity of a patient prior to administration of an agent.

(b) A narcotic treatment program shall maintain onsite a photograph of each patient which includes the patient's name and birth date. The narcotic treatment program shall update the photograph every 3 years.

§ 715.14. Urine testing.

(a) A narcotic treatment program shall complete an initial drug-screening urinalysis for each prospective patient and a random urinalysis at least monthly thereafter.

(1) Each test shall be for opiates, methadone, amphetamines, barbiturates, cocaine and benzodiazepines.

(2) If the narcotic treatment program determines that other drugs are abused in that narcotic treatment program's locality or have been identified in the patient's drug and alcohol history as being a drug of abuse or use, a narcotic treatment program may conduct a test or analysis for other drugs as well.

(b) A narcotic treatment program shall develop and implement policies and procedures to ensure that urine collected from patients is unadulterated. These policies and procedures shall include random observation which shall be conducted professionally, ethically and in a manner which respects patient privacy.

(c) A narcotic treatment program shall develop and implement policies and procedures to minimize misidentification of urine specimens and to ensure that the tested specimens can be traced to the donor.

(d) A narcotic treatment program shall ensure that a laboratory that performs the testing required under this section shall be in compliance with applicable Federal requirements, specifically the Clinical Laboratory Improvement Amend-

ments of 1998 (42 U.S.C.A. §§ 201 note, 263 and 263a notes), and State requirements, specifically the Pennsylvania Clinical Laboratory Act (35 P. S. §§ 2151—2165) and Chapter 5 (relating to clinical laboratories).

§ 715.15. Medication dosage.

(a) The narcotic treatment physician shall review the dosage levels at least twice a year, with each review occurring at least 2 months apart, to determine a patient's therapeutic dosage.

(b) The narcotic treatment physician shall determine the proper dosage level for a patient, except as otherwise provided in this section. If the narcotic treatment physician determining the initial dose is not the narcotic treatment physician who conducted the patient examination, the narcotic treatment physician shall consult with the narcotic treatment physician who performed the examination before determining the patient's initial dose and schedule.

(c) Methadone shall be administered or dispensed only in oral form and shall be formulated to reduce its potential for parenteral abuse.

(d) A narcotic treatment program shall label all take-home medication with the patient's name and the narcotic treatment program's name, address and telephone number and shall package all take-home medication as required by Federal regulation.

(e) LAAM shall be administered or dispensed only in oral form and shall be formulated to reduce its potential for parenteral abuse.

(f) The narcotic treatment program shall develop written policies and procedures relating to narcotic treatment medication dosage which includes the requirements of subsections (a)—(e).

§ 715.16. Take-home privileges.

(a) A narcotic treatment program shall determine whether a patient may be provided take-home medications.

(1) A narcotic treatment program may give take-home medications only to a patient who the narcotic treatment physician has determined is responsible and able to handle narcotic drugs outside the narcotic treatment program.

(2) The narcotic treatment physician shall make this determination after consultations with staff involved in the patient's care.

(3) The narcotic treatment physician shall document in the patient record the rationale for permitting take-home medication.

(4) A narcotic treatment physician may rescind take-home medication privileges.

(5) A narcotic treatment program shall develop written policies and procedures relating to granting and rescinding take-home medication privileges.

(b) The narcotic treatment physician shall consider the following in determining whether, in exercising reasonable clinical judgment, a patient is responsible in handling narcotic drugs:

- (1) Absence of recent abuse of drugs (narcotic or non-narcotic), including alcohol.
 - (2) Regular narcotic treatment program attendance.
 - (3) Absence of serious behavioral problems at the narcotic treatment program.
 - (4) Absence of known recent criminal activity.
 - (5) Stability of the patient's home environment and social relationships.
 - (6) Length of time in comprehensive maintenance treatment.
 - (7) Assurance that take-home medication can be safely stored within the patient's home.
 - (8) Whether the rehabilitative benefit to the patient derived from decreasing the frequency of attendance outweighs the potential risks of drug diversion.
- (c) A narcotic treatment program shall require a patient to come to the narcotic treatment program for observation daily or at least 6 days a week for comprehensive maintenance treatment, unless a patient is permitted to receive take-home medication as follows:
- (1) A narcotic treatment program may permit a patient to reduce attendance at the narcotic treatment program for observation to three times weekly and receive no more than a 2-day take-home supply of medication when, in the reasonable clinical judgment of the narcotic treatment physician, which is documented in the patient record:
 - (i) A patient demonstrates satisfactory adherence to narcotic treatment program rules for at least 3 months.
 - (ii) A patient demonstrates substantial progress in rehabilitation.
 - (iii) A patient demonstrates responsibility in handling narcotic drugs.
 - (iv) A patient demonstrates that rehabilitation progress would improve by decreasing the frequency of attendance for observation.
 - (2) A narcotic treatment program may permit a patient to reduce attendance at the narcotic treatment program for observation to two times weekly and receive no more than a 3-day take-home supply of medication when in the reasonable clinical judgment of the narcotic treatment physician, which is documented in the patient record:
 - (i) A patient demonstrates satisfactory adherence to narcotic treatment program rules for at least 2 years.
 - (ii) A patient demonstrates substantial progress in rehabilitation.
 - (iii) A patient demonstrates responsibility in handling narcotic drugs.
 - (iv) A patient demonstrates that rehabilitation progress would improve by decreasing the frequency of attendance for observation.
 - (3) A narcotic treatment program may permit a patient to reduce attendance at the narcotic treatment program for observation to one time weekly and receive no more than a 6-day take-home supply of medication when in the reasonable clinical judgment of the narcotic treatment physician, which is documented in the patient record:

- (i) A patient demonstrates satisfactory adherence to narcotic treatment program rules for at least 3 years.
 - (ii) A patient demonstrates substantial progress in rehabilitation.
 - (iii) A patient demonstrates responsibility in handling narcotic drugs.
 - (iv) A patient demonstrates that rehabilitation progress would improve by decreasing the frequency of attendance for observation.
 - (v) A patient demonstrates no major behavioral problems.
 - (vi) A patient is employed, is actively seeking employment, attends school, is a homemaker or is considered unemployable for mental or physical reasons.
 - (vii) A patient is not known to have abused alcohol or other drugs within the previous year.
 - (viii) A patient is not known to have engaged in any criminal activity within the previous year.
- (d) A narcotic treatment program may make exceptions to the requirements in subsection (c) relating to the length of time of satisfactory adherence to narcotic treatment program rules and number of days of take-home medication when, in the reasonable clinical judgment of the narcotic treatment physician, which is documented in the patient record:
- (1) A patient has a permanent physical disability.
 - (2) A patient has a temporary disability.
 - (3) A patient has an exceptional circumstance such as illness, personal or family crisis, or travel which interferes with the patient's ability to conform to the applicable mandatory attendance schedules. In all cases, the patient shall demonstrate an ability to responsibly handle narcotic drugs.
- (e) With an exception granted under subsection (d), a narcotic treatment program may not permit a patient to receive more than a 2-week take-home supply of medication.
- (f) An exception granted under subsection (d) shall continue only for as long as the temporary disability or exceptional circumstance exists. When a patient is permanently disabled, that case shall be reviewed at least annually to determine whether the need for the exception still exists.

§ 715.17. Medication control.

- (a) A narcotic treatment program shall comply with applicable Federal and State statutes and regulations regarding the storing, compounding, administering and dispensing of medication.
- (b) A narcotic treatment program shall develop policies and procedures regarding verbal medication orders, including the issuing and receiving of orders, identifying circumstances when orders are appropriate and documenting orders, in accordance with applicable Federal and State statutes and regulations.

(c) A narcotic treatment program shall develop and implement written policies and procedures regarding the medications used by patients which shall include, at a minimum:

(1) *Administration of medication.*

(i) A narcotic treatment physician shall determine the patient's initial and subsequent dose and schedule. The physician shall communicate the initial and subsequent dose and schedule to the person responsible for the administration of medication. Each medication order and dosage change shall be written and signed by the narcotic treatment physician.

(ii) An agent shall be administered or dispensed only by a practitioner licensed under the appropriate Federal and State laws to dispense agents to patients.

(iii) Only authorized staff and patients who are receiving medication shall be permitted in the dispensing area.

(iv) There shall be only one patient permitted at a dispensing station at any given time.

(v) Each patient shall be observed when ingesting the agent.

(vi) Administering and dispensing shall be conducted in a manner that protects the patient from disruption or annoyance from other individuals.

(2) *Drug storage areas.* A narcotic treatment program shall develop and implement written policies and procedures regarding storage of medications and access to the medication storage area. Agents shall be stored in a locked safe that has been approved by the DEA under 21 CFR 1301.72 and 1301.74 (relating to physical security controls; and other security controls).

(3) *Inspection of storage areas.* A narcotic treatment program shall inspect all drug storage areas and the dispensing station at least quarterly to ensure that the areas are maintained in compliance with Federal, State and local laws and regulations. A narcotic treatment program shall develop and implement written policies and procedures regarding who performs the inspections, how often, and in what manner the inspections are to be documented. The policies and procedures shall include the following:

(i) Disinfectants and drugs for external use shall be stored separately from oral and injectable drugs.

(ii) Drugs requiring special conditions for storage to insure stability shall be properly stored.

(iii) Outdated and contaminated drugs shall be removed and destroyed according to Federal and State regulations.

(iv) Administration of controlled substances shall be documented.

(v) Controlled substances and other abusable drugs shall be stored in accordance with Federal and State regulations.

(4) *Method for control and accountability of drugs.* A narcotic treatment program shall develop and implement written policies and procedures regarding who is authorized to remove drugs from the storage area and the method

for accounting for all stored drugs. An agent or other drug prescribed or administered shall be documented on an individual medication record or sheet in a manner sufficient to maintain an accurate accounting of medication at all times and shall include:

- (i) The name of the medication.
- (ii) The date prescribed.
- (iii) The dosage.
- (iv) The frequency.
- (v) The route of administration.
- (vi) The date and time administered.
- (vii) The name of the person administering the medication.
- (viii) The take-home schedule, if applicable.

(5) *Security of all substances.* A narcotic treatment program shall develop and implement written policies and procedures to minimize the likelihood of loss, theft or misuse of an agent or another controlled substance as well as a plan of action if a loss, theft or misuse does occur. In the event of loss, theft or misuse, the Federal and State statutes and regulations regarding reporting shall be followed.

(6) *Inventories.* A narcotic treatment program shall conduct monthly inventories of agents and other controlled substances stored. Each inventory record shall include:

- (i) The date the inventory was conducted.
- (ii) The time of day it was conducted.
- (iii) The name and amount of each product on hand at the time of the inventory.
- (iv) The name of the individual conducting the inventory.

(7) *Drug reactions and medication errors.* A narcotic treatment program shall report any adverse drug reaction or medication error to a narcotic treatment physician immediately and initiate corrective action. The narcotic treatment program shall record the reaction or error in the drug administration record and the clinical chart, and shall inform each person who is authorized to administer medication or supervise self-medication of the reaction or error.

§ 715.18. Rehabilitative services.

(a) A narcotic treatment program shall provide, either onsite or through referral agreements, a full range of rehabilitative services. Rehabilitative services shall include:

- (1) HIV education services.
- (2) Employment services.
- (3) Adult educational services.
- (4) Behavioral health services.

(b) A patient shall also have the opportunity to access legal services.

§ 715.19. Psychotherapy services.

A narcotic treatment program shall provide individualized psychotherapy services and shall meet the following requirements:

- (1) A narcotic treatment program shall provide each patient an average of 2.5 hours of psychotherapy per month during the patient's first 2 years, 1 hour of which shall be individual psychotherapy. Additional psychotherapy shall be provided as dictated by ongoing assessment of the patient.
- (2) A narcotic treatment program shall provide each patient at least 1 hour per month of group or individual psychotherapy during the third and fourth year of treatment. Additional psychotherapy shall be provided as dictated by ongoing assessment of the patient.
- (3) After 4 years of treatment, a narcotic treatment program shall provide each patient with at least 1 hour of group or individual psychotherapy every 2 months. Additional psychotherapy shall be provided as dictated by ongoing assessment of the patient.

§ 715.20. Patient transfers.

A narcotic treatment program shall develop written transfer policies and procedures which shall require that the narcotic treatment program transfer a patient to another narcotic treatment program for continued maintenance, detoxification or another treatment activity within 7 days of the request of the patient.

- (1) The transferring narcotic treatment program shall transfer patient files which include admission date, medical and psychosocial summaries, dosage level, urinalysis reports or summary, exception requests, and current status of the patient, and shall contain the written consent of the patient.
- (2) A narcotic treatment program shall maintain the confidentiality of patient records remaining in its possession after the transfer under § 715.11 (relating to confidentiality of patient records).
- (3) The transferring narcotic treatment program shall document what materials were sent to the receiving narcotic treatment program.
- (4) The receiving narcotic treatment program shall document in writing that it notified the transferring narcotic treatment program of the admission of the patient and the date of the initial dose given to the patient by the receiving narcotic treatment program.

§ 715.21. Patient termination.

A narcotic treatment program shall develop and implement policies and procedures regarding involuntary terminations. Involuntary terminations shall be initiated only when all other efforts to retain the patient in the program have failed.

- (1) A narcotic treatment program may involuntarily terminate a patient from the narcotic treatment program if it deems that the termination would be

in the best interests of the health or safety of the patient and others, or the program finds any of the following conditions to exist:

(i) The patient has committed or threatened to commit acts of physical violence in or around the narcotic treatment program premises.

(ii) The patient possessed a controlled substance without a prescription or sold or distributed a controlled substance, in or around the narcotic treatment program premises.

(iii) The patient has been absent from the narcotic treatment program for 3 consecutive days or longer without cause.

(iv) The patient has failed to follow treatment plan objectives.

(2) A patient terminated involuntarily, except a patient who commits or threatens to commit acts of physical violence, shall be afforded the opportunity to receive detoxification of at least 7 days. The detoxification may take place at the facility or the patient may be referred to another narcotic treatment program or hospital licensed and approved by the Department for detoxification.

§ 715.22. Patient grievance procedures.

(a) A narcotic treatment program shall develop and utilize a patient grievance procedure.

(b) The procedure shall permit aggrieved patients a full and fair opportunity to be heard, to question and confront persons and evidence used against them and to have a fair review of their grievances by the narcotic treatment program director. If the grievance is filed against the narcotic treatment program director, the review of the case shall be conducted by either a multi-representative group of the narcotic treatment program or a subcommittee of the governing body instituted for the express purposes of grievance adjudication.

(c) Penalties may not be initiated prior to final resolution with the exception that penalties may be initiated against patients who have committed acts of physical violence or who have threatened to commit acts of physical violence in or around the narcotic treatment program premises.

§ 715.23. Patient records.

(a) A narcotic treatment program shall maintain patient records in conformance with 42 CFR 2.16 and 2.22 (relating to security for written records; and notice to patients of Federal confidentiality requirements) and State statutes and regulations. A narcotic treatment program shall maintain a complete file on the premises for each present and former patient of the narcotic treatment program for at least 4 years after the patient has completed treatment or treatment has been terminated. Files shall be updated regularly so that the information is current.

(b) Each patient file shall include the following information:

(1) A complete personal history.

(2) A complete drug and alcohol history.

(3) A complete medical history.

- (4) The results of an initial intake physical examination.
 - (5) The results of all annual physical examinations given by the narcotic treatment program which includes an annual reevaluation by the narcotic treatment physician.
 - (6) Results of laboratory tests or other special examinations given by the narcotic treatment program.
 - (7) Documentation of a 1-year history of narcotic dependency, if applicable.
 - (8) The patient's current and past narcotic dosage level.
 - (9) Other drugs prescribed by the narcotic treatment physician and the reasons therefore.
 - (10) Urine testing results.
 - (11) Counselor notes regarding patient progress and status.
 - (12) Applicable consent forms.
 - (13) Patient record of services.
 - (14) Case consultation notes regarding the patient.
 - (15) Psychosocial evaluations of the patient.
 - (16) Any psychiatric, psychological or other evaluations, if available.
 - (17) Treatment plans and applicable periodic treatment plan updates.
 - (18) Federal and State exceptions to the regulations granted to the project on behalf of the patient.
 - (19) Referrals to other projects or services.
 - (20) Take-home privileges granted to the patient.
 - (21) Annual evaluation by the counselor.
 - (22) Aftercare plan, if applicable.
 - (23) Discharge summary.
 - (24) Follow-up information regarding the patient.
 - (25) Documentation of patient grievances.
- (c) An annual evaluation of each patient's status shall be completed by the patient's counselor and shall be reviewed, dated and signed by the medical director. The annual evaluation period shall start on the date of the patient's admission to a narcotic treatment program and shall address the following areas:
- (1) Employment, education and training.
 - (2) Legal standing.
 - (3) Substance abuse.
 - (4) Financial management abilities.
 - (5) Physical and emotional health.
 - (6) Fulfillment of treatment objectives.
 - (7) Family and community supports.
- (d) A narcotic treatment program shall prepare a treatment plan that outlines realistic short and long-term treatment goals which are mutually acceptable to the patient and the narcotic treatment program.

- (1) The treatment plan shall identify the behavioral tasks a patient shall perform to complete each short-term goal.
- (2) The narcotic treatment physician or the patient's counselor shall review, reevaluate, modify and update each patient's treatment plan as required by Chapters 709, 710 and 711 (relating to standards for licensure of freestanding treatment activities; drug and alcohol services; and standards for certification of treatment activities which are a part of a health care facility).
- (e) Patient file records, information and documentation shall be legible, accurate, complete, written in English and maintained on standardized forms or electronically.
- (f) If a narcotic treatment program keeps patient information in more than one file or location, it is the responsibility of the narcotic treatment program to provide the entire patient record to authorized persons conducting narcotic treatment program approval activities at the narcotic treatment program, upon request.

§ 715.24. Narcotic detoxification.

If a narcotic treatment program provides narcotic detoxification services, the narcotic treatment program shall develop and implement narcotic detoxification policies and procedures which include the following:

- (1) For narcotic detoxification from methadone or any other narcotic, the detoxification service may not exceed 180 days.
- (2) For calculating the 1-year narcotic dependency history required for admission to maintenance treatment, the narcotic detoxification period may not be included.
- (3) A 1-year physiologic dependence is not required for narcotic detoxification although documentation of current dependency is required.
- (4) Minimum requirements for short-term narcotic detoxification treatment are as follows:
 - (i) Take-home medication is not allowed during a 30-day narcotic detoxification treatment. A narcotic treatment program shall observe the patient ingesting the medication 7 days per week.
 - (ii) The narcotic treatment program shall perform an initial drug screening test or analysis.
 - (iii) The narcotic treatment program shall develop a treatment plan. The patient's counselor shall monitor the patient's progress toward the goal of short-term narcotic detoxification and possible drug-free treatment referral.
 - (iv) No narcotic treatment program may provide short-term narcotic detoxification treatment to an individual until at least 7 days after the conclusion of any previous short-term narcotic detoxification treatment.
- (5) Minimum requirements for long-term detoxification treatment are as follows:

(i) A narcotic treatment program shall administer medication to allow a patient to attain drug-free status and to make progress in rehabilitation within 180 days or less.

(ii) A narcotic treatment program shall perform an initial drug screening test or analysis. A narcotic treatment program shall perform at least one additional random test or analysis monthly on each patient during long-term narcotic detoxification.

(iii) The narcotic treatment program shall develop an initial treatment plan, and update the plan monthly.

(iv) A narcotic treatment program shall observe the patient while ingesting the medication at least 6 days a week.

(v) No narcotic treatment program may provide long-term narcotic detoxification treatment to an individual until at least 7 days after the conclusion of any previous narcotic detoxification treatment.

§ 715.25. Prohibition of medication units.

Narcotic treatment medication units are prohibited.

§ 715.26. Security.

(a) A narcotic treatment program shall meet the security standards for the distribution and storage of controlled substances as required by Federal regulations, including 21 CFR 1301.72 and 1301.74 (relating to physical security controls; and other security controls) and State statutes and regulations.

(b) Each narcotic treatment program shall provide the Department with a specific plan describing the efforts it will make to avoid disruption of the community by its patients and the actions it will take to assure responsiveness to the community. This plan shall designate a staff member to act as community liaison.

§ 715.27. Readmission.

If a patient requests readmission to a narcotic treatment program after voluntary termination from that narcotic treatment program, that narcotic treatment program shall provide that patient with an evaluation interview and shall give that patient priority consideration for readmission.

§ 715.28. Unusual incidents.

(a) A narcotic treatment program shall develop and implement policies and procedures to respond to the following unusual incidents:

- (1) Physical assault by a patient.
- (2) Inappropriate behavior by a patient causing disruption to the narcotic treatment program.
- (3) Selling of drugs on the premises.
- (4) Complaints of patient abuse (physical, verbal, sexual and emotional).

- (5) Death or serious injury due to trauma, suicide, medication error or unusual circumstances.
 - (6) Significant disruption of services due to disaster such as fire, storm, flood or other occurrence.
 - (7) Incident with potential for negative community reaction or which the facility director believes may lead to community concern.
 - (8) Theft, burglary, break-in or similar incident at the facility.
 - (9) Drug related hospitalization of a patient.
 - (10) Other unusual incidents the narcotic treatment program believes should be documented.
- (b) These policies and procedures shall include the following:
- (1) Documentation of the unusual incident.
 - (2) Prompt review and investigation.
 - (3) Implementation of a timely and appropriate corrective action plan, when indicated.
 - (4) Ongoing monitoring of the corrective action plan.
- (c) A narcotic treatment program shall file a written Unusual Incident Report with the Department within 48 hours following an unusual incident including the following:
- (1) Complaints of patient abuse (physical, verbal, sexual and emotional).
 - (2) Death or serious injury due to trauma, suicide, medication error or unusual circumstances.
 - (3) Significant disruption of services due to a disaster such as a fire, storm, flood or other occurrence.
 - (4) Incidents with potential for negative community reaction or which the facility director believes may lead to community concern.
 - (5) Drug related hospitalization of a patient.

§ 715.29. Exceptions.

A narcotic treatment program is permitted, at the time of application or any time thereafter, to request an exception from a specific regulation.

- (1) The request for an exception from a specific regulation shall be in writing, with governing body approval, and shall state how the narcotic treatment program will meet the intent of the regulation.
- (2) The Department may withhold the granting of an exception and may require a narcotic treatment program to be in actual operation to assess if the exception is appropriate.
- (3) The Department will reserve the right to revoke any exception previously granted.
- (4) The narcotic treatment program shall maintain documentation of the Department's approval of an exception.
- (5) If the exception relates to a specific patient, the narcotic treatment program shall maintain documentation of the exception in the patient's record.

§ 715.30. Applicability.

This chapter applies to the use of any agent which may be approved by the Department for use in narcotic or opioid dependency medication therapy. This chapter applies to the administration of any agent which may be approved by the Department for use in the treatment of opioid dependency.

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(407514) No. 568 Mar. 22

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