

# Memo

**To:** Jennie Butler, FDA Dockets Management  
**From:** Nick Reuter, Deputy Director, Office of Pharmacological and Alternative Therapies  
**Date:** September 7, 1999  
**Subject:** Submission to Docket Number 98N-0617



Please add this matrix to Docket Number 98N-0617. The submission represents a matrix that compares the requirements proposed by the NPRM published July 22, 1999, to the existing FDA regulations along with CSAT Guidelines, as well as CARF and JCAHO Accreditation Standards.

Please contact me at 301-443-0457 if you would like to discuss further.

## Comparison of Guidelines/Regulations Applicable to Opioid Treatment Programs

<i>Issue</i>	<i>FDA Regulations</i>	<i>Proposed NPRM</i>	<i>CSAT Guidelines</i>	<i>CARF Standards</i>	<i>JCAHO Standards</i>
<b>Administrative Organization and Responsibilities</b>	<p><b>All references in this column are to 21 CFR</b></p> <p>291.505(a)(7): Defines the program sponsor as the person or organizational representative responsible for the operation of a narcotic treatment program</p> <p>291.505(b)(1)ii: Requires the program sponsor to submit to the FDA and the State authority a description of the organizational structure of the program, then name of the persons responsible for the program, the address, and the responsibilities of each facility or medication unit</p>	<p><b>All references in this column are to proposed changes to 42 CFR</b></p> <p>Section 8.11:(b): Specifies elements that must be included in the application package; among these are a description of the organizational structure and the names of the persons responsible for the program</p> <p>Section 8.12(a): Requires opioid treatment programs must provide treatment in accordance with Federal opioid treatment standards</p> <p>Section 8.12(b): Stipulates that programs structure must be adequate to ensure patient care and to meet the requirements of all pertinent government laws and regulations; each program must formally designate a formal program sponsor and medical director</p>	<p><b>All references in this column are to CSAT Guidelines for the Accreditation of Opioid Treatment Programs</b></p> <p>I.A Goals Program states goals for patient care</p> <p>I.B Human Resources Management Program has plan to ensure that staffing patterns are appropriate and adequate for patients served</p>	<p><b>All references in this column are to 1998 Draft Methadone/LAAM Treatment Program Accreditation Standards</b></p> <p>Section I, A: Program has written mission statement (includes purpose, patients served, and general service areas); purposes conveyed verbally and in writing; has written code of ethics and procedures for violating code of ethics; conducts or participates in activities that reduce stigma for persons served</p> <p>B: Organizational leaders are responsive to persons served. Are responsible for policies and procedures, written plans with input from person served, minutes of meetings, written plan for cultural diversity, organizational structure, management information system,, information systems and reports, administrative records, and client records.</p> <p>C. Program is managed fiscally in manner that is consistent with purpose and in accordance with responsible practices and legal requirements</p> <p>D. The organizations personnel provide services that meet the needs of persons served; personnel reflect mission of organization; personnel policies that contribute to effective employee performance are established and maintained</p> <p>Also see Section. 5A on program structure and staffing</p>	<p><b>All references in this column are to Comprehensive Accreditation Manual for Behavioral Health Care (CAMBHC) and Draft Methadone Accreditation Standards</b></p> <p>LD.1.7.: The scope of services provided by each program or service of the organization is defined in writing and approved by the organizations leaders.</p> <p>LD.1.1.3: The organization operates in accordance with applicable laws, rules, and regulations.</p> <p>HR.2: The organization provides an adequate number of staff members whose qualifications are consistent with job responsibilities. Appropriately trained, experienced, and qualified substance abuse counselors provide services of the intensity and duration required to meet the individual needs of a particular patient.</p>

<b>Definitions</b>	291.505 (a) Defines detoxification treatment (short and long term),	Section 8.2 part A: Defines accreditation body, accreditation body	None provided	Glossary Provided: Defines designated authority, extension, governance, mock	None provided
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<p><b>Definitions</b> (Continued)</p>	<p>maintenance treatment, medical director, medication unit, narcotic dependent, narcotic treatment program, program sponsor, services, and State authority</p>	<p>application, accreditation elements, accreditation survey, accredited opioid treatment program, certification, certification application, certified opioid treatment program, comprehensive maintenance treatment, detoxification treatment, Federal opioid treatment standards, for-cause inspections, interim maintenance treatment, maintenance treatment, medical director, medical and rehabilitative services, medication unit, opioid agonist treatment medication, opioid addiction, opioid drug, opioid treatment, opioid treatment program (OTP), patient, program sponsor, registered opioid treatment program, short-term detoxification, and treatment plan</p> <p>Note: ANarcotic@replaced by Aopiod@ throughout; refers to Opioid Treatment Programs (OTPs)</p>		<p>site visit, monitoring site visit, National Advisory Committee, international conference, National Leadership Panel, organization, person served, personnel, program sponsor, regional training, return visit, second visit, self-study questionnaire, staff member, standards manual and interpretive guidelines, and supplemental site visit</p>	
<p><b>Accreditation Body Approval and Related Requirements</b></p>	<p>Not Addressed</p>	<p>Note: Accreditation elements, which form basis of accreditation body standards, are expect to reflect the CSAT Guidelines.</p> <p>Section 8.3: Outlines application process to become SAMHSA-approved accreditation body</p> <p>Section 8.4: Establishes standards and responsibilities of approved accreditation bodies, including accreditation surveys and inspections, responses to non-compliant programs, record keeping, reporting, complaint responses, element modifications, conflicts of interest, accreditation teams, and accreditation fees</p> <p>Section 8.5: Permits periodic reviews by SAMHSA of performance of individual accreditation bodies</p> <p>Section 8.6: Allows SAMHSA to withdraw approval of approved accreditation body for major deficiencies and to require corrective action for minor deficiencies; provides procedures for reapplication and hearings</p>	<p>Not Applicable</p>	<p>Not Applicable</p>	<p>Not Applicable</p>
<p><b>Government</b></p>	<p>291.505(b)(1)(ii): Requires program to</p>	<p>Subpart B: Proposes process by which</p>	<p>I. Programs must comply with</p>	<p>Section 6C, 1 (f): Program maintains all</p>	<p>Intent of LD.1.1.3: The leaders provide</p>

<p><b>Approval/Licensure/Certification Requirements</b></p>	<p>submit description of organizational structure</p> <p>291.505(b)(2)(i): Requires program to submit application and receive approval to operate; prohibits dispensing of medication from location not previously approved for this purpose</p> <p>291.505(b)(2)(ii): Indicates that Federal agencies operating NTPs do not require approval or compliance with State laws</p> <p>291.505(b)(3): Establishes requirements for operation of a medication unit</p> <p>291.505(c)(3): Requires program to submit description of facilities</p> <p>291.505(c)(4): Requires program to submit proper applications simultaneously to FDA and the State authority</p> <p>291.505(c)(5)(i): Stipulates that FDA may approve a program only after notification from the State authority and DEA that the program conforms to all State and Federal requirements</p> <p>291.505(c)(5)(ii): Indicates that FDA will revoke license if requested by State authority or DEA</p> <p>291.505(d)(11): Indicates exemptions from specific program standards</p> <p>291.505(h)(5): FDA cannot consider a program appeal if denial of licensure is based upon State law or regulation</p>	<p>OTPs may obtain certification from SAMHSA, conditions necessary for maintaining certification, and suspension or revocation process; also proposes Secretary's Federal opioid treatment standards</p> <p>Section 8.11: Requires treatment programs to obtain certification from SAMHSA; certification period may not exceed 3 years, but may be extended if necessary to accommodate accreditation cycles. Program must obtain current, valid accreditation from SAMHSA-approved accreditation body to be eligible for certification; certification may be denied for specified reasons. Subsections provide for transitional or provisional certification; approval for the operation of interim methadone maintenance treatment, exemptions, medication units, long-term care facilities, and hospitals</p> <p>Section 8.12: Proposes Federal opioid treatment standards as enforceable regulatory requirements that treatment programs must follow as condition of certification</p> <p>Sections 8.13 and 8.14: Stipulate process SAMHSA will follow in revoking accreditation and accreditation body approval and suspending or revoking certification</p> <p>Section 8.15: Proposes 2 new application forms (SAMHSA-0001, Application for Certification to Use Opioid Agonist Medications in Opioid Treatment; and SAMHSA-0002, Application for Becoming an Accreditation Body under 42 CFR 8.3) and eliminates Form FDA-2632 Application for Approval of Use of Methadone in a Treatment Program, FDA-2633 Medical Responsibility Statement for Use of Methadone in a Treatment Program, and Form FDA-2635 Consent to Treatment with a Narcotic Drug</p>	<p>requirements of laws and regulations of DHHS, DEA, and States</p>	<p>necessary licenses and certifications in conformance with local, State, and Federal regulations</p>	<p>for compliance with applicable federal, state, and local law and regulation. The leaders ensure that the organization maintains current licensure or certification by appropriate agencies, as applicable. Other evidence of compliance includes certificates of ownership, articles of incorporation, stock certificates, corporate bylaws, and when applicable, state licensure or certification.</p> <p><i>EC.1: The organization establishes an environment of care that meets the needs of individuals served, encourages a positive self image, and respects their human dignity.</i></p>
<p><b>Program Oversight and Monitoring</b></p>	<p>291.505(d)(10): Requires programs to allow inspections by State and Federal authorities</p>	<p>Subpart C: Stipulates procedures for programs to seek review of denials, suspensions, or revocations of</p>	<p>Not addressed</p>	<p>Possible site visit outcomes are: (1) 3-year accreditation; (2) 1-year accreditation; (3) provisional</p>	<p>Not addressed.</p>

		certification; also available to accreditation bodies that are denied approval or whose approval has been revoked by SAMHSA		accreditation - must be functioning at 3-year level at the next site visit; and (4) for organizations participating in the Methadone/LAAM Accreditation Project, a 3-month abeyance may be provided in lieu of non-accreditation; (5) non-accreditation. These outcomes are identified in CARF's site visit procedures rather than its standards.	
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<b>Program Administration</b>	<p>291.505(d)(5): Specifies that person responsible for program determines personnel requirements and develops staffing pattern based on number of patients, patients' needs, and existing community resources</p> <p>291.505(a)(3) and (d)(4)(ii): Stipulates that medical director /program physician is responsible for administration of all medical services and compliance with Federal, State, and local laws and regulations re: patients' medical treatment</p> <p>291.505(b)(1)(ii): Requires program sponsor to submit a description of the organizational structure, names of persons responsible for the program, address, source of funding, etc. to FDA and State agency</p> <p>291,505(b)(1)(iv): Requires statement documenting feasibility to be attached to application if physician assumes medical director responsibility for more than one program,</p> <p>291.505(d)(4)(iii): Does not prohibit using licensed or certified health professionals to record histories, perform physical exams, or administer certain medications. Requires records to be countersigned by medical director if functions are delegated</p> <p>291.505(c)(2)(ii): Requires program to notify FDA within 3 weeks of change in program sponsor 291.505(d)(3)(iii): Program counselors must be well</p>	<p>Section 8.3: Stipulates accreditation body's policies and procedures for conducting surveys</p> <p>Section 8.11(f): Proposes general conditions for certification (including State laws and regulations; agreement to allow SAMHSA, DEA, State, and authorized accreditation bodies access to conduct surveys and inspections and to access patient records</p> <p>DHHS Secretary retains right to conduct show-cause inspections, as defined in Section 8.2</p>	<p>I.B: Program has plan to ensure that staffing patterns are appropriate and adequate for the needs of the patients being served</p> <p>II. B: Program has established policies and procedures that address life safety and security issues</p> <p>II.C(3) : Program reviews and recertifies policies annually</p>	<p>Section. 6C 1: Program has a sponsor with specified responsibilities</p> <p>Section. 6C 6a-d: Program has qualified medical director; responsibilities specified (administer all medical services, admit each person served, ensure that program conforms with applicable local, State, and Federal regulations re: medical treatment of opioid addiction, ensures that all medical exams and laboratory studies have been performed). Also see Section 5A4</p> <p>Section. 6C: 2a-m: Program has implemented and consistently applies written policies and procedures that address responsibilities of program sponsor; screening, admission, assessment, and individual planning; medication management (including responsibility of medical director, program physician, and other health care professionals, role of physicians re: admission and dosage, establishing dosage, unsupervised doses, emergency administration of medications, diversion control plan, medicating traveling persons, safe storage practices); drug-screening procedures, other lab procedures, counseling and education, treatment and referral for coexisting health issues; needs of special populations; withdrawal procedures; emergency medical procedures; program contingency; critical incidents; and research activities. Also see Sections 1B1,4B,4C,5B1</p>	<p>EC.2.5.: A management plan addresses safety.</p> <p>LD.1.1: A written plan defines a mission, and value for the organization as well as strategic, operational, program-related, and other plans and policies to achieve them.</p> <p>HR.1.1: Staff qualifications are commensurate with anticipated job responsibilities and applicable licensure, law and regulation, registration, and/or certification.</p> <p>HR.4.1: The organization has a process designed to ensure the competence of licensed independent practitioners.</p>
<b>Program Administration (continued)</b>					

	trained and qualified to assess background of drug abusers and to determine appropriate treatment plans				
<b>Treatment Capacity</b>	291.505(c)(3): Requires programs to have adequate facilities to provide necessary services	Not addressed	Not addressed	Not addressed	<p>EC.1.1: Waiting or reception areas are comfortable; their design, location, and furnishings accommodate visitors and individuals served, the anticipated waiting time, the need for privacy and/or support from staff, and the organization's goals.</p> <p>EC.1.2: Enough restrooms are available for the number of individuals served.</p>
<b>Facilities and Clinical Environment Management</b>	291.505(c)(3): Requires programs to have access to adequate physical facilities to provide necessary services	Addressed by reference in Guidelines	<p>II. Requires sufficient space and adequate equipment; clean and well maintained facility; codes met and documented; confidentiality protections (including locked files and private counseling areas); warm and welcoming environment with staff and patients treated with dignity and trust; service hours address patient needs</p>	<p>Section 6C1a, 1b: Program sponsor provides clean and well-maintained facilities in convenient and accessible location, with private offices for counseling, ability to keep records safe and secure, and adequate facilities for medication dispensing and physical examinations. Sponsor also provides stable, therapeutic environment with friendly staff, consistently assigned personnel, and services and hours that address needs of person served.</p> <p>Also see Section 3 on Accessibility, Health and Safety, and Transportation</p>	<p>EC.1 <i>The organization establishes an environment of care that meets the needs of individuals served, encourages a positive self image and respects their human dignity.</i></p> <p>SEE ABOVE</p>
<b>Informed Consent and Risk Management Practices</b>	291.505(d)(1)(ii): Requires program sponsor to ensure that patient participates voluntarily and with informed consent; must sign Form FDA 2635, Consent to Treatment with an Approved Narcotic Drug; parent, legal guardian, or responsible adult must sign for patient under 18 years of age	Section 8.12(e)(1): Requires program physician to ensure that each patient voluntarily chooses maintenance treatment, all relevant facts concerning use of the opioid drug are clearly and adequately explained, and each patient provides informed written consent to treatment	<p>III.</p> <p>A. Legal/Program policies address informed consent for treatment; patient orientation with information provided throughout treatment; informed consent to medication; child abuse/neglect reporting requirements; adherence to 42CFR Part2; patient rights and responsibilities; due process/involuntary discharge; staff credentialing procedures</p> <p>B. Life safety processes and procedures address: correct dose; need for emergency medications; 24 hours/day, 7 days/week access by</p>	<p>Section 6D13(a-d): Program obtains written informed consent prior to initiating treatment; informed consent addresses voluntary nature of treatment, Federal confidentiality requirements, facts and risks of treatment, including those associated with use of methadone/LAAM, and specified expectations (i.e., natural history of addiction altered by time and history; goal is stabilization; and continuation of maintenance should be periodically discussed by patient and physician, with continuation only if medication indicated). Also see Section 4A1</p>	<p>RI.1.2.2: Informed consent is obtained from each individual served. Informed consent is obtained when emancipated minors are admitted to the program. No individual under 18 years of age, except an emancipated Minor may be admitted to a maintenance treatment program unless a parent, legal guardian, or responsible adult completes and signs consent form FDA2635"Consent to Methadone Treatment"</p> <p>TX.2.2: The preparation, dispensing, and storage of medications adhere to law, regulation, licensure, and professional standards of practice.</p>

**Comparison of Guidelines/Regulations Applicable to Opioid Treatment Programs**

<i>Issue</i>	<i>FDA Regulations</i>	<i>Proposed NPRM</i>	<i>CSAT Guidelines</i>	<i>CARF Standards</i>	<i>JCAHO Standards</i>
<b>Informed Consent and Risk Management Practices</b> (continued)			<p>phone to designated staff ; treatment for CPR, overdoses; disaster plan; patient and staff safety</p> <p>D. Adverse events procedures in place</p>	<p>Section 6C2j: Program has emergency medical procedures in place that describe steps to follow and persons to be contacted; staff are trained to provide CPR and first aid; procedures may include disaster plans and linkages for emergency dosing. Also see Section 3B</p> <p>Section 6C2k: Program has procedures in place to address contingencies such as program closure, inclement weather, etc.</p> <p>Section 6C2l: Program has written procedures to address critical incidents and threats, including physical and verbal threats, violence and other inappropriate behavior, dangerous situations, medication errors, deaths, sale of drugs on premises, harassment and abuse. Also see Section 3B4</p> <p>Section 6C5: Program makes staff available 7 days/r week, 24 hours/day. Also see Sections 1D1, 5A3</p>	<p>TX2.2.1 Medications are appropriately controlled during preparation and dispensing.</p> <p>TX2.2.2 If the organization prepares, dispenses, or stores medications, a medication-dose system is followed. Methadone/LAAM treatment programs have a diversion control plan.</p> <p>SEE SECTION TX FOR MORE INFORMATION ON CONTROL OF MEDICATIONS</p>
<b>Continuous Quality Improvement</b>	None	Section 8.12(c)(1) Requires that OTPs have a quality assurance plan and pursue continuous quality improvement activities; must address patient outcomes and improve quality of treatment provided	CQI policies including provisions for regular and continuous staff education, staff development plans, annual reviews and recertifications of program policies and procedures, patient input into program policies and procedures, patient satisfaction surveys, infection control precautions, treatment outcomes, and diversion control plans	See Section 2 for information on quality improvement systems that include requirements for organizational planning, quality and appropriateness of services, and outcomes management	<p>PI.1.: The leaders establish a planned, systematic, organization wide approach to process design and performance measurement, analysis, and improvement.</p> <p>PI.1.3.Data are collected to monitor the stability of existing processes, identify opportunities for improvement, identify changes that will lead to improvement, and sustain improvements. Outcomes and processes should be measured and monitored such as: reducing or eliminating the use of illicit opioids, illicit drugs, and the problematic use of licit drugs; reducing or eliminating associated criminal activities; reducing behaviors contributing to the spread of infectious diseases; and improving quality of life by restoration of physical and mental health status.</p>

<i>Issue</i>	<i>FDA Regulations</i>	<i>Proposed NPRM</i>	<i>CSAT Guidelines</i>	<i>CARF Standards</i>	<i>JCAHO Standards</i>
<b>Professional Staff Credentialing</b>	291.505(a)(3): Defines medical director as physician who is licensed to practice medicine in jurisdiction in which program is located	Section 8.12(d): Requires physicians, nurses, addiction counselors, and other licensed professionals to have sufficient education, training, and experience to enable them to perform assigned functions; licensed professional care providers must comply with credentialing requirements of their respective professions	IV. Programs ensure that professional licenses are maintained; counselors meet State and program requirements; staff receive education on pharmacology and patient population; continuing education is provided; annual individual training plans are prepared; job descriptions define qualifications and competencies; records of staff training events are kept; resources for problem-solving are available	Section 6C4a-c: Services are provided by an interdisciplinary team of qualified and experienced staff composed of at least a licensed physician, licensed nurse/pharmacist, and primary counselor (who is preferably licensed or certified in the State). Also see Section 5A12  Section 6C7a-d: Program provides staff training related to methadone/LAAM treatment to new staff; develops annual training plan for all direct service staff; maintains record of staff training events; provides regular training on clinical and pharmacological issues, behavior management, first aid, CPR, and other emergency procedures, needs of special populations (including women, adolescents, and seniors), resources for problem solving and trouble shooting, and infectious diseases. Also see Sections 1D10, 1D11, 3B23, 3B25	HR.2 The organization provides an adequate number of staff members whose qualifications are consistent with job responsibilities. Staff are knowledgeable about current, effective strategies for treating alcohol, cocaine, and other drug abuse. All staff receive initial education specific to the pharmacotherapies to be used and tailored to the population served.  HR.3.3: Ongoing education and training maintains and improves staff competence. Records are kept of staff training events, including the qualifications of educators, outline of content, description of methods, and attendees.  HR.4.1.1: The process to ensure competence of licensed independent practitioners reviews licensure, certification, or registration, relevant training or experience; current competence; and the ability to perform clinical responsibilities.

<b>Patient Admission Procedures and Criteria</b>	291.505(d)(1): Establishes minimum standards for admission, including history of addiction and current physiologic dependence with 1 year dependence on narcotic; exceptions to minimum criteria include person who has resided in penal or chronic care institution, pregnant woman with documented past narcotic history, and previously treated patients (voluntarily discharged, seeking readmission within 2 years). Limitation: person under 18 years of age must have 2 documented attempts at short-term detoxification or drug-free treatment plus consent of parent, legal guardian, or other responsible adult (unless legally an emancipated minor®)	Section 8.12(e): Requires programs to maintain current procedures to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria (e.g., those used in the Diagnostic and Statistical Manual for Mental Disorders [DSM-IV] that the person is currently addicted to an opioid drug, has been addicted for at least 1 year before admission, voluntarily chooses maintenance treatment, has all relevant facts related to this treatment, and has provided written consent to treatment; those under 18 must have two documented attempts at short-term detoxification or drug-free treatment and must have written consent of parent, legal	V. A (1-4): Addresses evidence of current opioid dependence/addiction; medical necessity documented by physician; admission criteria based on DSM IV definition of opioid dependence; diagnosis supported by behavior; current dependence not required for specified special populations  B. Procedures to avoid multiple enrollments are in place; central registry participation is encouraged	Section 6D8-10: Initial screening documents eligibility and medical necessity of methadone/LAAM treatment, including evidence of tolerance to an opioid, current or past physiological dependence for at least 1 year, and multiple and daily self-administration of an opioid. Interpretive guidelines indicate that programs should refer to DSM IV or ICD-9 to make and document diagnoses. Guidelines also permit program physician to waive criteria if person was recently released from penal or chronic care facility and is likely to relapse, person was previously treated by program and is at risk of relapse, or person is a pregnant woman with opiate addiction history. Also see	CC.1: The process of providing access to care, health professionals and services also includes: program physician documentation that treatment is medically necessary; criteria of admission are based on DSMIV definition of opioid dependence, (etc). There may be special populations where the absence of physiological dependence should not be an exclusion criteria and admission is clinical justified...persons recently released from a penal institution, persons discharged from a chronic care facility, pregnant patients, previously treated patients, and adolescents.  CC.2.1: criteria for determining an
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<p><b>Patient Admission Procedures and Criteria</b> (Continued)</p>	<p>291.505(d)(1)(i)(C): Requires physician to sign, date, and record statement determining addiction and history prior to administration of narcotic drug to patient</p> <p>291.505(e)(1): Prohibits provision of narcotic drugs to patients enrolled in other programs except under specified circumstances (e.g., travel, emergency closure of home clinic)</p> <p>291.505(e)(2): Stipulates that permission to receive treatment at alternative clinic occurs only under exceptional circumstances</p>	<p>guardian, or designated responsible adult; retains exceptions for pregnant patients, patients released from penal institutions, and previously treated patients. Current requirement for 7-day waiting period between each detoxification period is maintained</p>		<p>Section 4B3</p> <p>Section 6D14: Program demonstrates efforts to prevent individuals from being enrolled in more than one methadone/LAAM treatment program. Measures protect confidentiality; including checking with central registry or admission database, collecting previous and current treatment information at screening, State authority documentation, and informal arrangements with other programs</p>	<p>individuals eligibility for entry to the program also address the following: patients are generally not admitted...to receive opioids only for pain; measures are taken to prevent patients from enrolling in treatment provided by more than one clinic or individual practitioner;...individuals under 18 are required to have had two documented attempts at short-term maintenance treatment. The program physician shall document in the patients record that the patient continues to be or is again physiologically dependent in narcotic drugs.(etc)</p> <p>PE.1.5: An emotional and behavioral assessment of each individual is completed and entered in the clinical record. The assessment includes at least a history of emotional, behavioral, and substance-abuse problems, their co-occurrence or treatment, including: use of alcohol and other drugs by individuals or by family members, current emotional and behavioral functioning, maladaptive or problem behaviors, when indicated, a psychiatric evaluation. (etc). The assessment/evaluation should be conducted within approximately 30 days of initiation of treatment. A physical health assessment, including medical history and physical examination is complete with 7 days after admission.</p> <p>PE1.11.1The physical health assessment includes, at a minimum urine drug screens; TB skin test, and screening for syphilis...</p> <p>PE1.14.1 the medical laboratory analysis may included Complete Blood count, Routine chemistry profile and drug screening panel, chest x-ray; screening tests for infectious diseases, HIV and STDs, EKG, Pap smear, Screening test for sickle cell anemia; Hepatitis B antigen and surface antibody; and testing for other drugs based on individual medical indicators and community use patterns.</p>
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<p><b>Medical and Psychosocial Assessment</b></p>	<p>291.505(d)(3)(i): Specifies minimum contents of medical evaluation by program physician or authorized health care professional under supervision of program physician; requires medical history, evidence of current physiologic dependence unless exempted by regulations, and physical exam; required lab tests including syphilis, TB skin test, and test or analysis for drug determination</p> <p>291.505(d)(3)(ii): Requires findings to be recorded</p> <p>291.505(d)(3)(iii): Requires admission evaluation by well trained program counselor to assess psychological and sociological background to determine the most appropriate treatment plan</p>	<p>Section 8.12(f)(1): Requires OTPs to provide adequate medical, counseling, vocational, educational, and assessment services; retains provision from current regulations to provide these services on site unless sponsor has entered into agreement to provide them elsewhere; retains requirement for development and periodic evaluation of individualized treatment plan</p> <p>Section 8.12(f)(2): Stipulates that OTPs must require each patient to undergo a complete, fully documented medical evaluation by a program physician or primary care physician, or an authorized healthcare professional under the supervision of a program physician, within the first 30 days following admission</p>	<p>VI. A(1-5): Assessments including determination of current dependence and addiction, medical and family history, psychiatric history and mental status examination, information on children and drug use by other family members; are completed by multidisciplinary staff; conducted within 30 days; updated 4 times per year in Year 1 and 2 times per year thereafter</p> <p>B(1-4). Medication lab evaluation and diagnostic criteria. Required: Syphilis test, TB skin test, and chest x-ray if skin test is positive. Recommended: CBC, EKG, chest x-ray, Pap smear, sickle cell screening, Hep B surface antigen and Hep B surface antibody, HIV C&amp;T; analyze urine drug-screening tests for opiates, methadone, amphetamines, cocaine, and barbiturates; other drugs if used within community; may defer testing until stabilized, but within first 3 months</p>	<p>Section 6D12a-c: Multi-disciplinary psychosocial assessment is completed within 30 days of admission and includes determination of current physical dependence and addiction, assessment of medical and family history, psychiatric history, and mental status exam. Also see Section 4B9</p> <p>Section 6D11a-c: Physical exam includes medical history and examination of body system; is conducted by physician, doctor of osteopathy, physicians assistant, or nurse practitioner with knowledge and documented experience in addictions. Program conducts physical exam and related lab work within 7 days; exam includes (minimally) urine drug screen, TB skin test, and screening for other infectious diseases. Interpretative guidelines recommend same tests included in CSAT guidelines and provide for deferring tests until person is stabilized.</p> <p>Also see Section 4B on screening and assessment</p>	<p>PE1.21.1 Assess or reassessment of individuals receiving treatment for chemical dependency addresses history of alcohol, nicotine, and other drug use, including age of onset, duration, patterns of use, and consequences of use; history of physical problems associated with dependence, use of alcohol and other drugs by family members, religion and spiritual orientation, types of previous treatment and responses to that treatment, and any history of abuse. <i>Concurrent abuse of other drugs is managed.</i></p>
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<p><b>Dosage Guidelines</b></p>	<p>291.505(b)(2)(v): States that methadone and LAAM are approved medications</p> <p>291.505(d)(6)(i)(A): Stipulates that initial dose of methadone may not exceed 30 mg and total first day dose may not exceed 40 mg, unless medical director documents failure of 40 mg to suppress opiate abstinence symptoms</p> <p>291.505(d)(6)(iii): Stipulates that methadone is required to be administered or dispensed in liquid form.</p> <p>291.505(k)(1)(i)(A and B): Stipulates that initial dose of LAAM may not exceed 40 mg for new patients whose tolerance is unknown; initial dose for previously stabilized methadone</p>	<p>Section 8.12(h)(1): Stipulates that medications can be dispensed only by licensed practitioner</p> <p>Section 8.12(h)(2): Stipulates that programs can use only those drugs approved by FDA to treat opioid addiction; currently, approval has been given only for methadone and LAAM</p> <p>Section 8.12(h)(3): Requires programs to ensure that methadone is administered or dispensed only in oral form and is formulated to reduce its potential for parenteral abuse (liquid formulation is not required); the initial dose does not exceed 30 mg and the total first day dose does not exceed 40 mg unless the physician documents in the patients record that 40 mg does not suppress opiate abstinence symptoms;</p>	<p>VII. A(1-3): Dosage principles Dosages are individually determined, based on clinical judgment by knowledgeable and experienced physician; dose is sufficient to address desired clinical effects</p> <p>B(1-12): Decision to use pharmacological intervention based on physical exam; first day dose based on physician's evaluation of patient plus information about relative purity of drugs in community; usual first dose is 20-30 mg, usually not greater than 40 mg; initial LAAM dose based on patient insert; induction and maintenance dosages, as in TIP #1 (<i>State Methadone Treatment Guidelines</i>); maintenance dose individually</p>	<p>Section 6E23a-d: Program uses medications in the treatment of opiate addiction that are approved by the FDA for opioid treatment; provides dosage levels sufficient to produce desired response for desired length of time; dispenses according to program labeling, and in the case of methadone, in liquid form only; and manages medications to ensure secure storage, accurate dosage, and follow-up accounting for unsupervised doses in conformance with DEA regulations. Factors in setting dose include results of physical examination, history of narcotic dependence, current practice standards, dosage required for stable function, evaluation of continued unauthorized drug use, withdrawal, and use of prescribed medications. Total dose and intervals between doses is</p>	<p>TX.2.2: The dose of methadone/LAAM medication is individually determined on the basis of good clinical judgement after examination of the patient by a physician or other professional practitioner with prescribing privileges who is knowledgeable about and experienced in addiction medicine including methadone/LAAM therapy. Doses of methadone and LAAM and other approved medications are adjusted as needed if a program switches from one generic formulation to another and differences in effective dose cause clinically relevant complaints. <i>Note:</i> Form of methadone (e.g., oral, liquid, etc.) is not stipulated</p> <p>TX.2.4.1: Methadone/LAAM therapy</p>
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<p>continued</p>	<p>patient shall be less than or equal to 1.3 times the patient's daily dose of methadone but not more than 120 mg</p> <p>291.505(d)(6)(i)(C): Requires physician to justify dose of methadone greater than 100 mg in patient's record</p> <p>291.505(k)(1)(i)(D): Requires physician to justify single dose of LAAM &gt;140 g in patient's record</p> <p>291.505(d)(6)(i)(B): Stipulates that physician is responsible for medication level and must record, date, and sign in patient's record each change in dosage schedule</p>	<p>and the physician ensures a daily dose of more than 100 mg is justified in the patient's record</p> <p>Section 8.12(h)(4): Requires program to maintain procedures to ensure that each medication is administered and dispensed in accordance with approved product labeling; any deviations are justified in the patient's record</p>	<p>determined; document dose greater than 100 mg; total dose and dose intervals adjusted for metabolic patterns or effects of other drugs; not standard to manipulate dose to punish or reward behavior; continue treatment as long as it is beneficial and patient concurs; adjust dose as needed; obtain medical blood levels if clinically needed. <i>Note:</i> Form of methadone (e.g., oral, liquid, etc.) is not stipulated</p> <p>C(1-4). Voluntary withdrawal may be initiated by patient in partnership with physician; reduce at tolerable rate; for women of child-bearing age, test for pregnancy before withdrawing from LAAM; methadone/LAAM resumed if relapse appears likely</p> <p>D(1-2): Consult with pain specialist for addressing chronic pain; for acute pain, continue dose and prescribe additional medications (see also, Special Considerations, Part E)</p>	<p>adjusted based on individual metabolic patterns and the use of other medications. In prescribing LAAM, program conforms to regulatory requirements. Program physician justifies deviations from doses, frequencies, and conditions of usage described in approved product labeling. Also see Section 5B4</p> <p>Section 6E25a-b: Initial dose is individually determined by physician after initial evaluation and (for methadone) does not exceed 30 mg (with maximum total for first day not exceeding 40 mg, unless justified by failure of 40 mg to suppress abstinence symptoms); initial dose of LAAM follows product labeling. Interpretative guidelines reflect guidance provided by CSAT in its guidelines and in TIPs 1 and 22). Also see Section 5B3</p> <p>Section 6D26: Physician determines maintenance dose of each individual served, based on sound clinical judgment; dosage is not manipulated to reinforce or punish behavior; and dose is not changed with person's consent (unless person has waived right to know); medication continues as long as benefit is derived and person desires to continue; program has no limits on duration of treatment or dosage level unless clinically justified (dosages more than 100 mg are justified in the person's record). Also see Section 5B3</p>	<p>has three desired clinical effects...preventing the onset of subjective and/or objective signs of opioid abstinence syndrome for 24 hours or more; reducing or eliminating the drug hunger or craving routinely experienced by the opioid addicted individual when not in treatment; blocking the effects of any illicit acquired, self-administered opioids without inducing persistent euphoric or other undesirable effects that are experienced by the patient or noticed by other observers...The usual initial dose of methadone should be from 20-30 mgs. Reasons for exceeding an initial dose of 30 mg. need to be carefully documented in the clinical chart and should not exceed 40 mg, unless the physician documents in the patient's record that 40 mg. did not suppress opiate abstinence symptoms after a 3 hour period of observation. Addicted patients abusing diverted medical opioids may require lower initial dose of methadone, and should have the initial dose of methadone based on standard dose conversion tables and their recent amount of opioid intake. Initial dosing of LAAM and other approved medications should be based on the package insert (etc.)</p> <p>...The maintenance dose is individually determined with careful and caring attention to the essential information provided by the patient, the dose should be determined by a physician experienced in addiction treatment and should be adequate to achieve the desired effects for 24 hours or more with allowance for day-to-day fluctuations and elimination patterns. SEE TX SECTION FOR MORE INFORMATION</p>
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<i>Issue</i>	<i>FDA Regulations</i>	<i>Proposed NPRM</i>	<i>CSAT Guidelines</i>	<i>CARF Standards</i>	<i>JCAHO Standards</i>
<p><b>Treatment Planning, Patient Progress, and Continuous Clinical Assessment</b></p>	<p>291.505(a)(6): Requires NTPs to dispense a narcotic treatment drug and provide comprehensive range of medical and rehabilitation services</p> <p>291.505(b)(2)(vi): Allows for programs to provide :interim maintenance treatment@</p> <p>291.505(d)(3)(iv)(A) (1): Stipulates contents of initial treatment plan, including patient's requirements for education, vocational rehabilitation, and employment; medical, psychosocial, economic, legal, and other supportive services; outlines realistic short-term goals; indicates mutual acceptance of goals in initial treatment plan; specifies behavioral tasks patient must perform to reach each short-term goal</p> <p>291.505(d)(3)(iv)(C): Requires review and sign off by physician or supervising counselor</p> <p>291.505(d)(3)(v)(C): Requires treatment plan to include name and reasons for prescribing psychotropic drugs</p> <p>291.505(d)(3)(iv)(A) (2): Requires primary counselor to monitor patient's progress in treatment</p> <p>291.505(d)(13)(iii): Mandates inclusion in patient's record of treatment progress</p> <p>291.505(d)(3)(v)(A): Requires reviews and updates every 90 days during Year 1; requires reviews 2 times per year thereafter</p>	<p>Section 8.12(c): Requires OTPs to continuously assess patient outcomes</p> <p>Section 8.12(f)(4): Requires programs to ensure that each patient accepted for treatment is initially and periodically assessed by qualified personnel to determine the most appropriate combination of services and treatment; initial assessment must include preparation of treatment plan with short-term goals and tasks patient must perform to complete them; must also identify patient's requirements for education, vocational rehabilitation employment, medical, psychosocial, economic, legal, and other supportive services; must identify frequency with which these services are needed; must be reviewed and updated periodically to reflect progress and continued need for services</p>	<p>VIII.</p> <p>A. Intensity and duration Intensity greater at beginning of treatment; psycho-social services may be needed for extended period; long-term patients may need medication, but not other services (see TIP 20); no limits on dosage levels or duration (unless clinically contraindicated); no limits on psycho-social services</p> <p>B. Retention Retain as long as clinically appropriate; other problems addressed in treatment plan</p> <p>C. Relapse Prevention Provide psycho-social treatment even if no medications; track patients (if possible) and reinstitute medication with signs of relapse; re-emerging psycho-social needs should be addressed</p> <p>D. Involve family and significant others in treatment</p>	<p>Section 6D15a-m: Program provides comprehensive array of services directly or through contract or referral, with intensity typically greater in the early stages of treatment; program retains patient as long as clinically appropriate, medically necessary, and acceptable to the person being served; program ensures that services and space requirements adhere to State and DEA requirements</p> <p>Also see Sections 4B; 4C; 4D; 5A1,2; and 5B</p>	<p>CC.4: the organization provides for continuity of care and services over time among the assessment and diagnosis, planning, and treatment phases of the individual's services.</p> <p>CC.6.1: the discharge process provides for continuing care to meet the individual's assessed needs at the time of discharge. The discharge planning process also addresses relapse prevention...including procedures that address...physical and mental health problems following withdrawal...provisions for continuing care following the last dose of medication and for re-entry to maintenance...tracking of patients and reinstatement of pharmacotherapy.</p> <p>TX.1:Treatment planning identifies care and services appropriate to the individual's specific needs and the severity of condition, impairment, or disability.</p> <p>TX.1.5.4: Individuals are encouraged to participatr in developing their treatment plans, and their involvement is documented.</p> <p>TX1.5.5:The treatment plan addresses the involvement of the family, when indicated.</p> <p>TX1.9: The treatment plan specifies the frequency of treatment procedures TX1.15.1: The plan is reviewed upon admission, transfer, and discharge and is revised as necessary.( See TX section of CAMBHC)</p>

<p><b>Treatment Planning, Patient Progress, and Continuous Clinical Assessment</b> (Continued)</p>	<p>291.505(d)(3)(iv)(C): Requires review and sign-off by supervising counselor</p> <p>291.505(d)(3)(v)(C): Requires physician to review, countersign, and date treatment plan at least annually; physician ensures that primary counselor provides annual evaluation of progress</p> <p>291.505(b)(2)(iii): Medical and rehabilitation services should be provided on site, but can be provided elsewhere thru agreement</p>				
<p><b>Testing for Drug Use</b></p>	<p>291.505(d)(2)(i): Requires testing in manner that minimizes opportunity for falsification</p> <p>291.505(d)(2)(ii): Requires program to use test results as guide to change treatment approaches</p> <p>291.505(d)(2)(i) and (d)(3)(i): Requires initial drug-screening test at admission</p> <p>291.505(d)(2)(i): Requires at least 8 additional tests must be performed in year 1 and at least 4 times a year thereafter; patients receiving 6 take-home doses should be tested monthly</p> <p>291.505(d)(2)(i): Stipulates screening for opiates, methadone, amphetamines, cocaine, and barbiturates plus any other drugs abused in the program's locality; tests must be done in labs that are in compliance with State and Federal standards</p> <p>291.505(d)(2)(ii): Requires person responsible for program to ensure that test results are not used as sole criterion for discharge but to change treatment approaches</p> <p>291.505(d)(13)(iii): Requires entry of test results in patient record</p>		<p>IX.</p> <p>A. Use drug screens to help monitor</p> <p>B. Staff understand benefits and limits</p> <p>C. Urine collected with respect for patient</p> <p>D. Test minimally for opiates, methadone, amphetamines, cocaine, and barbiturates; others as determined by community use patterns and patient history;</p> <p>E. Results addressed promptly with patients</p> <p>F. Initial urine part of admission</p> <p>G. Test results enter into take-home decisions but are not sole factor</p> <p>H. Document urine results in record</p> <p>I. Address false positive and false negative urines (see TIP 1)</p>	<p>Section 6D15i: Program provides drug screening</p> <p>Section 6C2d: Drug screening procedures include frequency and individualized screening; procedures that ensure respect during sample collection; testing for opiates, methadone, amphetamines, cocaine, and barbiturates; interpretation of results and action taken; procedures for minimizing falsification; medically-oriented handling of specimens. Interpretative guidelines suggest more frequent urine collection earlier in treatment; results should be documented in persons record</p>	<p>PE1.14.1: Diagnostic testing is performed to determine individuals' health care needs and as part of care. Programs conduct an initial urine or other toxicology test as part of the admission process. Thereafter, the frequency of urine screens or other toxicology testing is determined by the clinical appropriateness of each...patient and related to the stage of treatment. All urine...specimens are collected in a context that suggests trust and respect...Program staff addresses results of urine screens promptly with patients to facilitate rapid intervention with any drug taking...(SEE PE 1.14 )</p> <p>PE1.21.6: Concurrent abuse of other drugs is managed.</p>

<i>Issue</i>	<i>FDA Regulations</i>	<i>Proposed NPRM</i>	<i>CSAT Guidelines</i>	<i>CARF Standards</i>	<i>JCAHO Standards</i>
<b>Approved Unsupervised Use (Take Homes)</b>	<p>291.505(k)(1)(iii): Stipulates that take-home doses of LAAM are not allowed</p> <p>291.505(d)(6)(v)(D): Requires prior FDA approval for more than 1 take-home per week &gt;100 mg</p> <p>291.505(d)(6)(iii): Stipulates that take-home bottles require special packaging as mandated by the Poison Prevention Packaging Act and State laws; bottles must be labeled with programs name, address, and phone no.</p> <p>291.505(d)(6)(iv)(A): Provides criteria for take-home medications; may be given only to patient who in judgment of program physician can handle them responsibly; rationale is documented in patients record</p> <p>291.505(d)(6)(iv)(B): Requires physician to consider the following in assessing ability to handle narcotic drugs responsibly: absence of abuse of drugs, including alcohol, regularity of clinic attendance; absence of serious behavioral problems at clinic; absence of known recent criminal activity; stability of home environment and social relationships; assurance that medication can be stored safely; and whether benefit of take-homes outweighs risks</p> <p>291.505(d)(6)(v)(A)(3): Requires patients eligible for 6 take-homes per week to be employed (or searching), in school, or involved as homemaker</p> <p>291.505(d)(6)(v)(A): Stipulates time lines for patient eligibility: At admission: 1 per week After 3 months: 3 per week (3 clinic visits) After 2 years : 5 per week (2 clinic</p>	<p>Proposes to accept the IOM recommendation that the same eight criteria be used as are currently required (see 291.505(d)(6)(iv)(A) but with new take-home schedules permitted with physician approval and documentation of patient progress.</p> <p>Section 8.12(i)(1-5): Proposes new schedule for unsupervised use: 1<sup>st</sup> month: 1 take-home per week for days clinic is closed, including Sundays and State and Federal holidays 2<sup>nd</sup> month: 2 per week 3<sup>rd</sup> month: 2 observed ingestions per week - rest unsupervised Rest of year: maximum of 3 take-homes following observed ingestion After year 1: up to 31-day supply and monthly visits. Monthly visits required. Programs must maintain procedures to identify theft or diversion of take-home medications, including labeling containers with program name, address, and telephone number; must be packaged to comply with Poison Prevention Packaging Act.</p> <p>Notes: (1) The prohibitions against LAAM take-homes have been eliminated in the proposed rule; and (2) the Secretary is specifically requesting comments about the proposed take-home schedule.</p> <p>Section 8.12(j)(4)(ii): Prohibits take-homes for patients in interim maintenance treatment</p>	<p>X. A(1-3): Criteria for approval include: cessation of drug use; program attendance; time in and level; absence of known criminal activity; absence of abused drugs, including excessive alcohol use; no serious behavioral problems; special needs; capacity to store safely; stability of home and social relationships; work, school, or other activity schedule; travel hardship.</p> <p>Number and quantity criteria: 1<sup>st</sup> 90 days: maximum of 1 per week 2<sup>nd</sup> 90 days: maximum of 2 per week 3<sup>rd</sup> 90 days: maximum of 3 per week rest of year 1 and all of year 2: maximum of 6 per week Year 3 and more: 30 take homes per month with documented exception: 3 days</p> <p>B(1-2): Monitoring requirements comply with Federal regulations; physician evaluates and adjusts dosage as necessary</p> <p>C(1-3): To ensure security of medication, child-proof containers must be used; patients need to be informed of rights and responsibilities; programs monitor medications to prevent diversion</p>	<p>Section 6E27a-i: Medical director determines if person is eligible for unsupervised take-home medications. Criteria reflect CSAT guidelines (absence of illicit opiate use, no abuse of illicit drugs or alcohol, regular program attendance, length of time and level of , no recent criminal activity, no serious behavioral problems, stability of home and social relationships, ability to store medications safely, daily activity schedule, and travel)</p> <p>Section 6E29a-e: Quantity of unsupervised medications does not exceed: 1<sup>st</sup> 90 days: maximum of 1 per week 2<sup>nd</sup> 90 days: max of 2 per week 3<sup>rd</sup> 90 days: maximum of 3 per week rest of year 1 and all of year 2: maximum of 6 per week Year 3 and more: 30 take homes per month With documented exception: 3 days Program may select more rigid schedule; take-home medications must be labeled in conformance with DEA regulations</p>	<p>TX.2.3.2: Systems are implemented to support self administration or alternative medication administration systems. Programs consider the following criteria in determining patient eligibility for take-home medication: Cessation of illicit drug use...regularity of program attendance; length of time and level of treatment in methadone/LAAM therapy; absence of known recent criminal activity (especially drug dealing); absence of serious behavioral problems; absence of abuse of drugs including excessive use of alcohol;...capacity to safely store take home medication with the patients home...etc.</p> <p>Criteria for determining the number and quantity of take-home doses per week include the following: first 90 days-maximum of one unsupervised dose per week; second 90 days-maximum of 2 unsupervised doses per week; third 90 days-maximum of 3 unsupervised doses per week; remainder of year one and year two-max of 6 unsupervised doses per week and year 3- max of 30 unsupervised doses per month CTemporary take home medication may be approved for documented emergencies...Decisions should be reviewed periodically, at least every 90 days...and the physicians conclusions should be noted in the noted in the record. Program policies enable a physician to evaluate a patients stability and response to take-home medication and to adjust doses at regular intervals, etc</p>

<p><b>Approved Unsupervised Use (Take Homes), continued</b></p>	<p>visits) After 3 years: 6 per week (1 visit)</p> <p>291.505(d)(6)(vii): Permits 1 extra take-home and 1 fewer clinic visit per week for official State holidays</p> <p>291.505(d)(6)(vi)(B): Permits up to a 2-week supply in exceptional cases and in instances of disability</p> <p>291.505(d)(6)(v)(B) (1-3): Requires increased attendance for missed visit after receiving take-home until submission of specified number of consecutive monthly negative urines</p>				
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<p><b>Withdrawal and Discharge</b></p>	<p>291.505(d)(13)(iii): Requires program to note patient termination in record</p> <p>291.505(d)(13)(iii): Allows program to terminate patient who has missed appointments for 2 weeks or more without notifying program (does not differentiate between detoxification patients and maintenance patients)</p> <p>291.505(d)(6): Specifies standards for short-term detoxification, to be conducted over not more than 30 days; not recommended for pregnant patient</p> <p>291.505(d)(7): Specifies standards for long-term detoxification; designed to reach drug-free state in 180 days or less; not recommended for pregnant patient</p>		<p>XI</p> <p>A(1-3): Administrative withdrawal may result from nonpayment of fees; disruptive behavior or behavior that adversely affects program, staff, or patients; incarceration or other confinement; usually less than 30 days; poor prognosis but attempt to refer</p> <p>B(1-2): Medical withdrawal is voluntary and either done in agreement with staff assessment or against medical advice</p> <p>C(1-4): Provide support Withdraw at rate that is well tolerated; make supportive options available; make available increased counseling; encourage patient to attend self-help program</p> <p>D(1-4): Considerations for withdrawal against medical advice: Patient has right to leave; staff explain risks; physician determines schedule with patient input; may readmit within 30 days with out formal reassessment; document issue that resulted in patient desire to leave and programs attempts to avoid discharge</p> <p>E(1-3): Continuing care essential part of treatment and includes discharge planning and relapse</p>	<p>Section6D13d: Natural history of opioid addiction is altered by time and history. Goal of methadone/LAAM treatment is stabilization of functioning. At periodical intervals, in full consultation with person served, provider will discuss present level of functioning, course of treatment, and future goals. Discussions are in no way intended to place unfair burden or pressure on person served to withdraw from or continue maintenance unless medically indicated.</p> <p>Section. 6E29a-e: Medical withdrawal procedures include reduction schedule that is well tolerated by person; assurance that voluntary withdrawal can be discontinued and maintenance resume in event of pending relapse; reviews of recent pregnancy test (for women); increase in counseling and other support service with continuation after withdrawal has been completed; provisions for continuing care</p> <p>Section. 6E30a-b: When withdrawal is conducted against medical advice, program documents efforts by staff to avoid discharge and reasons person is seeking discharge; keeps record active for 30 days</p> <p>Section 6E31a-b: Before beginning</p>	<p>RI.1.2.2: Informed consent iterates that termination of opioid therapy or continued maintenance decisions would be patient focused and clinically justified. Patients advised that: (1) Natural history of opioid addiction is altered by time and history; (2) Goal of methadone/LAAM treatment is stabilization of functioning; (3) at periodical intervals, in full consultation with the patient, the provider will discuss present level of functioning, course of treatment, and future goals. Discussions are in no way intended to place unfair burden or pressure on patient to withdraw from or be maintained unless medically indicated. Involuntary withdrawal is only used as a sanction of last resort that is accomplished in the most humane manner consistent with the safety and well-being of staff, other patients, and the program</p> <p>CC6.1: Additional considerations for medical withdrawal AMA are as follows: The patient has the right to leave treatment when he chooses to do so...in the case of a patient who leaves the program abruptly, the program may readmit the patient within 30 days without a formal reassessment procedure...(etc)</p>
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<p><b>Withdrawal and Discharge</b> (Continued)</p>			<p>prevention ; addresses physical and mental health problems; provisions made and re-entry permitted if relapse occurs</p> <p>F:Natural history of opioid addiction is altered by time and hisotry. Goal of methadone/LAAM medication therapy is stabilization of functioning. Aat periodic intervals, in full consultation with patient, the provider discusses present level of functioning, course of treatment, and future goals. Discussions are in no way intended to place unfair burden or pressure on patient to withdraw from or maintain on medication unless medically indicated</p>	<p>administrative withdrawal, program documents efforts to refer or transfer person to alternative program and implements due process provisions for appeals or grievances. Used only when all other retention efforts have failed; Withdrawal typically does not go beyond 30 days. Also see Section 4A2</p> <p>Section. 6E32a-d: Program documents each person-s condition during withdrawal, including symptoms of medical and emotional distress, significant signs, actions taken, progress of person served</p> <p>Section 6E33: Program provides counseling designed to motivate person to continue services following medical withdrawal</p>	<p>TX.2.4:Medical withdrawal refers to a medically supervised, gradual reduction or tapering of dose over time to achieve the elimination of tolerance and physical dependence tp methadone or LAAM. Withdrawal from methadone/LAAM therapy is initiated only when strongly desired by the rehabilitated patient. If medical withdrawal is initiated, dosages of methadone or LAAM are reduced at a rate that is well tolerated by the patient and also in accordance with sound medical practices. For women of childbearing potential, the results of a pregnancy test are reviewed before initiating medical withdrawal of methadone or LAAM. (Etc)</p>
<p><b>Management of Concurrent Alcohol and Polysubstance Abuse</b></p>	<p>Not addressed</p>	<p>Addressed by reference in Guidelines</p>	<p>XII</p> <p>A. Follow principles described in TIP 10 (<i>Assessment and Treatment of Cocaine-Abusing Methadone Patients</i> and TAP 7 (<i>Treatment of Opiate Addiction with Methadone</i>)</p> <p>B. Program staff knowledgeable about how to address</p> <p>C. Ongoing multiple drug use is not necessarily a reason for discharge; take other factors into account</p> <p>D. When possible, manage co-morbidities on site</p>	<p>Section 6C2g: Program has procedures in place for addressing use/abuse of other licit and illicit drugs and/or alcohol</p> <p>Section 6D15(d): Program provides counseling that addresses concurrent alcohol and drug abuse. Also see Section 4C5</p> <p>Section 6D17: Program screens for and provides services, either directly or through contract or referral, for persons who use/abuse multiple drugs and /or alcohol. Also see Section 4B12, 4C5</p>	<p>LD1.3.1:Services should be provided or referrals made for individuals who have co-existing health and psychosocial issues. Co-existing health and social issues or needs may include:medical problems, other addiction problems...mental health and family problems...When possible, comorbidities are concurrently managed on site...</p>
<p><b>Rehabilitation-Related Services</b></p>	<p>291.505(d)(4)(i)(A): Requires programs to provide access to comprehensive range of medical and rehabilitation services</p> <p>291.505(d)(4)(i)(D): Requires programs to list in application any services not provided on site, and to notify FDA immediately if previously offered services are modified or deleted</p>	<p>Section 8.12(f)(1): Requires programs to provide adequate medical, counseling, vocational, educational, and vocational services on site, or through formal, documented agreement with a private or public agency, organization, practitioner, or institution; must document that these services are fully and reasonably available</p>	<p>XIII</p> <p>A(1-12: Orientation to patient addresses overdoses, meds and side effects, addictive disorders, benefits of patient, guidelines, discharge procedures, patient rights, confidentiality, drug screening, dispensing, HIV, drug interactions</p> <p>B. Provide substance abuse counseling in accordance with intensity and duration needed; determine staffing patterns based on patient characteristics; establish staff:patient ratios that are sufficient to ensure</p>	<p>Section. 6D15a-n: Program provides directly or through contract or referral screening and assessment; individual patient plan; orientation; individual, group, and family counseling; education for addictions and mental health issues; medical care; vocational and employment services; HIV, Hepatitis B, TB, and other STD testing, counseling, and education services; observed medication dispensing; drug screening; emergency medical services; crisis intervention; continuing care; advocacy and self-help groups; follow-up and outcome. Interpretative guidelines parallel access</p>	<p>CC.4 and CC.5: The coordination of services should also include the establishment of agreements...with agents of the criminal justice system.</p> <p>CC.6...the establishment and use of linkages with HIV/AIDS treatment programs in the community.</p> <p>LD.1.3.4 Services should be provided or referrals made, for individuals who have co-existing health and psychosociak issues, including medical problems; other addiction problems; chronic pain disorder; ...mental health and family</p>

			reasonable and prompt frequency and intensity of services required	to counselors, and to provide concurrent services identified in the	problems...; HIV;...Infectious diseases,(etc) (SEE LD. Section)
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<i>Issue</i>	<i>FDA Regulations</i>	<i>Proposed NPRM</i>	<i>CSAT Guidelines</i>	<i>CARF Standards</i>	<i>JCAHO Standards</i>
<b>Rehabilitation-Related Services</b> (Continued)	291.505(d)(4)(ii): Mandates minimum medical services provided by physicians licensed to practice medicine; responsible for ensuring compliance with all Federal, State, and local laws regarding medical patient of opiate addiction.	Section 8.12(f)(5)(i): Requires program to provide adequate substance abuse counseling to each patient as necessary; counseling is to be provided by counselor who is qualified by education, training, or experience to assess the psychological and sociological background of drug abusers, to contribute to appropriate treatment plan, and to monitor patient progress  Section 8.12(f)(5)(iii): Requires program to provide directly, or through referral, vocational rehabilitation, education, and employment services	C. Encourage self-help group participation  D. Provide HIV counseling and testing and risk reduction education  E. Medical services Providing on-site primary care is recommended, but not required; can provide through referral; coordinate care; train staff to respond to medical emergencies and provide necessary equipment and supplies	CSAT guidelines. Also see Sections 4B; 4C; 4D; 5A1,2; 5B  Section. 6C2g: Program has procedures in place to provide services for co-existing problems  Section 6D17: Program provides services directly or through referral for individuals with coexisting health and psychosocial issues. Also see Sections 4B12, 4C5  Section 6D18: Community resource file has been developed and is maintained and used for proper referral and placement of person served; file includes information on services, fees, hours of operation, contact person, and material to be provided.  Also see Section 5A2,3	LD1.7-LD1.7.2: Policies for each program or service describe the kinds of care and services provided by staff to individuals served...Policies for methadone/LAAM treatment programs address...specific needs of female patients;...patients who are dually-diagnosed with addiction and a pain disorder are not prohibited from receiving methadone/LAAM therapy;... encouragement of breast feeding, etc.  HR.2: The organization provides an adequate number of staff members whose qualifications are consistent with job responsibilities. Patient to staff ratios are sufficient to ensure reasonable and prompt access to counselors and to provide the frequency and intensity of counseling services needed.

<b>Special Considerations</b>	291.505(d)(4)(i)(C): Mandates counseling on HIV disease	Section 8.12(h)(5)(ii): Requires programs to provide counseling on preventing exposure to, and transmission of HIV disease for each patient admitted or readmitted to maintenance or detoxification treatment	XIV A(1-5): Develop and implement written, nondiscrimination policies; ensure that staff are sensitive to culture and values of person treated; persons in positions of authority need to be professional and culturally competent; use unbiased language in materials; offer patient in groups according to special needs, as appropriate  B(1-4): Identify and refer patients with mh needs; monitor patients during withdrawal for re-emergence of symptoms; establish linkages with mental health providers; evaluate medication in conjunction with mental health provider  C(1-3): Provide HIV education; balance drug patient with HIV care; establish linkages with HIV service providers  D. Provide or encourage alternative	See Section 4A on the rights of persons served, which addresses policies and procedures safeguarding rights and prohibiting discrimination; and delivery of services that are culturally sensitive  Section 6D17: Services are provided directly or through contract or referral for patient with mental health and family problems. Also see Sections 4B12, 4C5  Section 6D17: Services are provided directly or through contract or referral for HIV or other STDs. Also see Sections 4B12, 4C5  Section 6D18: Program has developed community resource file, which includes programs offering alternative therapies; provides support and guidance to persons seeking these alternatives	RI.1: Using a framework that reflects the interdependence of care and service delivery and organization ethical issues, the organization addresses the rights of individuals served and ethical issues in the delivery of care and services. (See RI section)
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<p><b>Special Considerations</b> (Continued)</p>			<p>therapies if appropriate, popular, and not harmful E(1-5): Distinguish between patient for pain and patient for addiction; use criteria in DSM IV to make distinctions; pain patients generally not admitted; patients with chronic pain and addiction managed by pain and addiction specialists; patients with chronic pain and dependence may be admitted if program is sole source for pain patient</p> <p>F(1-2): Develop and regularly update disaster plan; maintain 24-hr phone answering capability</p> <p>G(1-2): In the event of voluntary or involuntary closure, ensure continuity of care, working with State and other levels of gov; secure patient records</p> <p>H(1-3): If &lt;18, need 2 documented attempts at detox or drug-free patient; parent or legal guardian must give consent if not emancipated minor; tailor assessment to developmental stage; ensure adolescents are not harassed by older patients</p> <p>I(1-2): Coordinate with agents of criminal justice system in regard to patients; advocate for continuous treatment of incarcerated patients</p>	<p>Section 6D10: Individuals requiring opioids solely for pain are generally not admitted for patient; interdisciplinary teams of pain and addiction specialists serve persons with both a chronic pain disorder and active opioid addiction. Also see Section 4B3</p> <p>Section 6D17: Individuals with chronic pain disorders and no concurrent addiction problems may be treated if the program is the only available source of patient. Also see Sections 4B12, 4C5</p> <p>Section 6C2j: Program has procedures in place to address emergencies, including closures</p> <p>Section 6D21a-d: In providing services to adolescents, program provides developmentally appropriate assessment, instructional, and counseling services; ensures safety of the person served, identifies cases of abuse and neglect, and provides referral for special needs; program follows State regulations regarding: treatment of individuals &lt; 18 years of age; documents eligibility (2 attempts at short-term detox or drug-free patient plus physician documentation of physical dependence on narcotic drug). Also see Sections 4A1, 4B7, 4B9, 4C4, 4D2</p> <p>Section 6C2h(4): Program has cooperative agreements with criminal justice system to encourage continuous patient of incarcerated individuals or those on parole or probation</p>	
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<p><b>Care of Women in Treatment</b></p>	<p>291.505(d)(1)(iii)(B)(1): Permits treatment of pregnant applicant regardless of age or evidence of current physical dependence; only documented past narcotic dependency required</p> <p>291.505(d)(8)(iii) and (d)(9)(iii): Recommends against admitting pregnant patients for detoxification</p>		<p>XV A(106): Policies and procedures reflect needs of women; provide respectful and safe treatment; physical space reflects women's needs; staff are trained to address women's needs; assign patients to counselors sensitive to women's needs; single-sex counseling groups are available</p>	<p>Section 6D19a-c: In providing services to women, program provides counseling on women's issues, violence, sexual abuse, and pregnancy; provides appropriate physical space; and assigns counselors and specialized groups based on needs and desires of person served. Interpretative guidelines reflect need to provide safe</p>	<p>RI.1-The right to reasonable access to care, regardless of race, religion, gender, sexual orientation, ethnicity, age or disability...Programs make provisions to provide for respectful and safe treatment of women;</p> <p>RI.1.2.2- Informed consent is obtained from pregnant patients referred for</p>
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<p><b>Care of Women in Treatment, continued</b></p>	<p>291.505(d)(1)(iii)(B)(1) and (d)(4)(i)(B)(1): Requires programs to offer pregnant patients prenatal care directly or by referral; if refused or cannot afford prenatal care, basic prenatal instruction must be offered during counseling</p> <p>291.505(d)(4)(i)(B): Mandates documentation of prenatal support in patient record</p> <p>291.505(d)(1)(iii)(B)(4): Mandates re-evaluation of pregnant patient 3 months after delivery or termination of pregnant to determine if continued maintenance is warranted</p> <p>291.505(d)(1)(iii)(B)(6): Prohibits patients who are or may become pregnant from being started or continued on LAAM except by written order of the physician; patients must be advised of risks of LAAM; women of child-bearing age who are placed on LAAM must have initial and monthly pregnancy tests</p>		<p>B (1-8): Give priority for treatment admission to pregnant and post-partum women; provide prenatal care on site or through referral; provide basic instruction if prenatal care not available; document refusal for prenatal care; maintain and monitor dose; encourage breastfeeding unless contraindicated; establish policies and procedures for followup primary care</p> <p>C.(1-3): Offer same services to HIV-positive women as are offered to other pregnant patients; provide information about AZT to reduce perinatal transmission and provide with referrals for this treatment</p> <p>D(1-2) Offer parenting education to all male and female parenting patients; provide reproductive health education with referrals for contraception as needed.</p>	<p>environment that is respectful of women and ensures the maintenance of their dignity. Program ensures that staff receive training on women's treatment needs; staff are qualified to counsel women regarding violence, neglect, and sexual abuse are available. Also see Sections 4A1, 4A4, 5A12</p> <p>Section 6D20a-c: In providing services to pregnant women, the program addresses accepted medical practices and dosing strategies during pregnancy, provides priority access to treatment, and provides prenatal care, education, and post-partum follow up.</p> <p>Section 6D17: Coexisting health issues, including pregnancy, may be addressed through services provided on site or by referral; these include prenatal care for pregnant women, post-partum followup directly or through referral; referral for treatment and case management are provided. Also see Sections 4B12, 4C5</p> <p>Section 6D17: Pregnant women with HIV infection receive the same services as other pregnant patients; information about AZT is provided; refers women for treatment and case management</p>	<p>prenatal care to ensure reciprocity in the exchange of pertinent clinical information regarding compliance with the recommended course of medical care; If a pregnant patient refuses direct prenatal services or appropriate referral for such care, the treating physician may use informed consent procedures to have the patient formally acknowledge in writing that these services were offered but refused; Informed consent policies are established and implemented to ensure appropriate follow-up primary care of new mothers and well baby care for their infants;</p> <p>CC.1B There may be individuals in special populations who have a history of opioid use but who are not currently physiologically dependent...admission is clinically justified. These populations include the following:...pregnant patients...Priority is given to pregnant women who seek treatment...</p> <p>TX2.4.1B The initial methadone dose for a newly admitted pregnant patient and the subsequent induction and maintenance dosing strategy reflect the same effective dosing protocols used for all other patients...Programs maintain patients who become pregnant during treatment on the pre-pregnancy dose, etc...</p> <p>PF 2.2.7B Education also includes the following...basic prenatal instruction for pregnant women...education and training for male and female parenting patients..</p> <p>LD 1.7- Policies for methadone/LAAM treatment programs address...clinical flexibility in assigning female patients to counselors who are sensitive to..their needs...etc</p> <p>EC.1.2-The use of physical space, including bathrooms, reflects the special needs of female patients.</p>
<p><b>Patient Rights</b></p>	<p>Not addressed</p>	<p>Addressed by reference through Guidelines</p>	<p>XVI. A(1-5): Patients have right to treatment</p>	<p>See Section 4A(1-6) on the rights of persons served, which addresses policies and procedures safeguarding</p>	<p>RI.1 B Programs support patient choice in seeking alternative therapies while providing appropriate guidance in the</p>

			<p>that is given with informed consent, is individualized and participatory, addresses needs, promotes dignity and is humane, promotes autonomy and responsibility, protects confidentiality, promotes health and well being; administration is responsive to patient feedback; policies and procedures exist to protect patient rights; inform patients verbally and in writing about rules, regulations, patients rights and responsibilities; cooperate in medicating patients who are traveling</p> <p>B(1-14): Patients rights and responsibilities include fair treatment; treatment in accordance with accepted practice; complete information about rights and responsibilities; adequate and humane services; least restrictive treatment; individualized treatment plan; adequate number of competent staff; information about alternative meds and treatment; information about potential interactions; encouragement to exercise rights as patient; information regarding: financial requirements of treatment and consequences of non payment; admission based on assessment, or referral, with explanation; referral to alternative treatment. Include all items within Consumer Bill of Rights and Responsibilities</p> <p>C. Privacy within and outside program setting</p> <p>D(1-2): Ensures confidentiality in accordance with 42CFR Part 2; informed of extent and limits of confidentiality</p> <p>E(1-2): Requires Informed consent prior to involvement in research projects; information about treatment and medications in language patients understand</p>	<p>rights and prohibiting discrimination; delivery of services that are culturally sensitive; obtaining and retaining informed consent; prohibiting physical abuse (including sexual abuse); mechanisms for facilitating access and referral; mechanisms for communicating policies to persons served; right of persons served to be provided with information to facilitate decision making; use of crisis procedures; and procedures for staff training. Also requires written grievance procedure; frequent re-evaluation of restrictions; appropriate arrangements for meeting privacy needs; assurance of human subjects protections in human subjects research; and adherence to confidentiality regulations</p> <p>Section 6C1c: Programs must also ensure that rights of person served address services provided in least restrictive environment, adequate and human service, information about alternative treatments (including medication, modalities, and scientific evidence regarding treatment), access to one's own record with clinical supervision, timely response to requests for copies of records, protection from behavioral disruptions from other patients, equal access regardless of race, ethnicity, gender, age (specific policies for minors), source of payment, and sexual preference. Also have right to be informed of appeal procedures, to initiate appeals, be informed about grievance procedures, received decisions in writing, and appeal decision to unbiased source. Also see Section 4A16</p> <p>Section 6D22: Program adheres to Consumer Bill of Rights</p>	<p>process...Programs ensure that adolescents are not harassed or exploited by older patients or staff..Patients have right to a medication schedule which is most accommodating and least intrusive and disruptive for most patients...Patients have the right to review their own record with clinical supervision and to obtain a timely response to the request for copies of the record...Patients have the right to input into program policies and services through patient satisfaction surveys...Patients have the right to be informed regarding the financial aspects of treatment, including consequences of nonpayment ...Programs ensure that patients are made aware of the Consumer Bill of Rights and Responsibilities...etc.</p> <p>RI.1.2.2 Informed consent is obtained from each individual. .. Information provided includes: (1) nature of opioid addiction is altered by time and history; (2) goal of methadone/LAAM treatment is stabilization; (3) at periodic intervals, in full consultation with patient, provider will discuss present level of functioning, course of treatment, and future goals; not intended to place unfair burden or pressure on patient to withdraw from or maintain on medication unless medically indicated.</p> <p>RI.1.2.5BThe conflict resolution process should also require that: patients have the right to receive a decision in writing with reasoning articulated;...involuntary withdrawal is only used as a sanction of last resort that is accomplished in the most humane manner...The patient's methadone dose not be changed without the patient's knowledge, etc...</p>
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<i>Issue</i>	<i>FDA Regulations</i>	<i>Proposed NPRM</i>	<i>CSAT Guidelines</i>	<i>CARF Standards</i>	<i>JCAHO Standards</i>
<b>Patient Rights (continued)</b>	Not addressed	Addressed by reference through Guidelines	<p>F(1-8): Patients have right to express dissatisfaction; right to initiate grievance procedures; right to be informed of grievance procedures; right to receive decision in writing; right to appeal; responsibility of program to identify alternative treatment for patient who is being discharged; involuntary w/drawal as last resort; no change in dose without consent</p> <p>XI. F:Natural history of opioid treatment is altered by time and history. Goal of methadone/LAAM medication therapy is stabilization of functioning. At periodic intervals, in full consultation with patient, the provider discusses present level of functioning, course of treatment, and goals of future treatment. These discussions are not intended to place unfair burden or pressure on patient to withdraw from or continue with medication unless medically indicated.</p>	Also see SectionD13(a-d): Program obtains written informed consent of person served prior to initiating treatment; informed consent addresses voluntary nature of participation in treatment, Federal confidentiality regulations, facts and risks concerning all treatment procedures including use of methadone/ LAAM, and specified expectations (including expectation that natural history of opioid addiction is altered by time and history; goal is stabilization; and that at periodic intervals, provider and patient will discuss present level of functioning, course of treatment, and future goals; discussions are not intended to place undue pressure on patient to either continue on methadone/LAAM or withdraw from it).	

<b>Record keeping and Documentation</b>	<p>291.505(d)(13)(i): Requires program to establish record system to document and monitor patient care; must comply with all Federal and State reporting requirements relevant to narcotic drugs approved for use in treatment of narcotic addiction</p> <p>291.505(g): Requires programs to comply with confidentiality requirements stipulated in 42 CFR Part2</p> <p>291.505(c)(2)(i): Requires programs to train staff about confidentiality requirements</p> <p>291.505(d)(13)(iii): Specifies contents of adequate patient record, including copy of signed consent forms, date of each visit, amount of drug dispensed or administered, results of each drug test, any significant physical or psychological disability, type of</p>	Section 8.12(g)(1-2): Requires OTPs to maintain patient record system that is adequate to document and monitor patient care and outcomes, and comply with relevant Federal and State requirements; required to keep patient records confidential in accordance with applicable Federal and State requirements; also requires treatment programs to determine that patients at admission are not enrolled in any other OTP	<p>XVII. A(1-14): Patient records contain basic demographic data and results of screening process; documentation of compliance with Federal regulations if applicable; initial assessment; bio-psycho-social history within 30 days; medical reports; dated case entries include counseling notes; dates and results of case conferences; treatment plan and amendments (4x/yr in Year 1, 2x/yr in following years plus semiannual progress repts by counselor); documentation of services; report of process and factors considered in decision making; record of correspondence regarding; patient; documentation that patient was given program rules and regulations, statement of rights and responsibilities, and discussion of same; consent forms, releases, prescription documentation, etc.; closing summary</p>	<p>Section 6d12: Program completes assessment w/in 30 days and is included in the record of the person served. Also see Section 4B9</p> <p>Section 6D15b:: Program records contain individual treatment plan, which is reviewed and updated 4x/yr in Year 1 and 2x/yr thereafter. Also see Sections 4c, 4D</p> <p>Section 6D16a-g: Patient record contains documentation of orientation that includes nature or addictive disorders and recovery, information about methadone/LAAM, program rules (including noncompliance, discharge procedures, and withdrawal), persons rights and responsibilities, confidentiality, signs and symptoms of overdose and when to seek emergency care, characteristics of prescribed medications, HIV and other infectious</p>	<p>CC.1.BThe process for providing access to care, health professionals and services also includes: program physician documentation that treatment is medically necessary...Priority is given to pregnant women...; the reason for denying admission to any pregnant applicant is documented on an intake log</p> <p>PE.1.5BAn emotional and behavioral assessment of each individual is completed and entered in the clinical record. The assessment includes at least a history of emotional, behavioral and substance-abuse problems, their co-occurrence or treatment, etc...The assessment/ evaluation should be conducted within approximately 30 days of initiation of patient treatment...A medical and family history must be documented, including ...diabetes, renal diseases, hepatitis B,</p>
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<p><b>Record keeping and Documentation (continued)</b></p>	<p>rehabilitation and counseling efforts employed, account of patients progress, and other relevant aspects of treatment.</p>		<p>with reasons for discharge and any referral, or death certificate.</p> <p>B(1-3). Storage, Dispensing, and Administering of Methadone/LAAM Policies and procedures consistent with DEA regulations; each medication order and change written on order sheet signed by physician with signed notation, administration sheet and patient record notation, initialed by administering person, signature at end of each page initials used, mg totaled daily for each substance; procedure for calibrating med dispensing instruments.</p> <p>C(1-2) Maintain individual personnel records; avoid duplication of information gathering</p>	<p>diseases, and drug safety issues. Also see Sections 3B23, 4B6, 5B5</p> <p>Section 6E24a-c: Program ensures that each medication and/or dosage change is ordered and signed by program physician; ensures that each dose is recorded in patient record and medication sheet to maintain accurate inventory at all times (with signature or initials of qualified person administering medication and exact mgs of substance dispensed with daily totals); and has procedure in place for calibrating medication dispensing instruments. Also see Sections 5B2, 5B7</p> <p>Also see Section 4E16</p>	<p>C,...other infectious diseases, etc.</p> <p>PE.3- Assessment updates should be conducted quarterly for the first year of continuous treatment and semi-annually for subsequent years.</p> <p>SEE TX.1 THROUGH TX.1.12 WHERE THERE IS A DESCRIPTION OF THE TREATMENT PLAN, ITS REASSESSMENT AND ITS CONTENTS.</p> <p>TX.2.3.2BTake-home...The physicians conclusions on this review should be noted in the record.</p> <p>SEE HUMAN RESOURCES (HR) FOR DOCUMENTATION IN EMPLOYEE RECORDS.</p>
<p><b>Community Relations and Education</b></p>	<p>Not addressed</p>	<p>Not addressed</p>	<p>XVIII (1-8)</p> <p>Consider community need and impact; elicit input; clean and orderly facility; establish relationships with community leaders, including elected officials, local health and social service providers, business leaders, community and health planning agency directors, grassroots community leaders, local police and law enforcement, religious and spiritual leaders; develop community relations plan with liaison, staff who function as community relations coordinators; serve as community resource on substance abuse; solicit community input; develop policies and procedures to address and resolve community problems; document efforts and contacts; devise communication mechanism; develop plans that address poor weather, emergencies, closure etc.</p>	<p>Section 6C3a-e: Program has written community relations plan that solicits community input, educates groups about substance abuse and use of methadone/LAAM in treatment, identifies staff to serve in community relations activities, and addresses and resolves community relations problems; program prominently displays all licenses and certifications. Also see Section 1A4, 1B2</p>	<p>LD. 1.3.1BCommunity relations also includes input from the community on the programs impact in the neighborhood; a process for ensuring that the facility's physical appearance is clean and orderly... establishment of a liaison with the community representatives to share information about the program...development of program policies and procedures to effectively address or resolve community problems; documentation of community relations efforts and community contacts, etc. development of a communication mechanism to that interested parties and potential patients may obtain general information about the program outside regular operating hours.</p>
<p><b>Diversion Control</b></p>	<p>291.505(d)(14): Requires program to meet security standards for distribution and storage of controlled substances as stated in 21 CFR 1301.72-1301.76</p> <p>291.505(e): Prohibits provision of medication to patient who is known to be receiving treatment from another program; requires attendance at same treatment facility except under</p>	<p>Section 8.12(c)(2): Requires treatment programs to include a Diversion Control Plan</p> <p>Section 8.12(g)(2): Requires programs to document upon admission that patient is not enrolled in another treatment program</p>	<p>XIX.</p> <p>A. Develop mechanism for continuous monitoring</p> <p>B. Develop mechanism for identifying, correcting, and preventing problems regarding diversion</p>	<p>Section 6C2c(6): Program has diversion control plan in place that includes continuous monitoring; problem identification, correction, and prevention, and accountability to person and community</p>	<p>SEE TX.2.2 THROUGH 2.2.3 FOR DISPENSING, ADMINISTRATION, AND STORAGE Methadone/LAAM treatment programs have a diversion control plan...demonstrates accountability and efficient use of personal and other resources...The plan includes a mechanism for continuous monitoring of clinical and administrative activities...a mechanism</p>

	exceptional circumstances that are noted in the patient's record				for problem identification and correction and for prevention of related diversion problems, etc.
<b>Participation in OAT Research Activities</b>	Not addressed	Addressed by reference to Guidelines	<p>XX. (Note: Full Federal human subject protection standards apply; 45 CFR, Part. 46)</p> <p>A. Programs encouraged to participate</p> <p>B. Research does not compromise treatment</p> <p>C. Treatment program manager/director has authority to ensure research is based on sound scientific principles</p> <p>D. Conducted in accordance with 45 CFR, Part. 46</p> <p>E. Patients may refuse to participate without jeopardizing treatment</p>	Section 6C2m: Programs are encouraged to participate in research activities as long as treatment is not compromised; full Federal human subject protections apply; persons served can refuse to participate without jeopardizing treatment	<p>RI.1 B The federal human subject protection standards generally assume that 1. All participation in new interventions is voluntary, 2. Confidentiality of patient records and research data is assured, 3. Written, informed consent is obtained, 4. The risk/benefits of participation are explained to participants; 5 participation does not jeopardize ongoing treatment; and 6. The research does not impose an undue burden on participants.</p>