

Revisions to Behavioral Health Care Requirements for Opioid Treatment Programs

The Joint Commission's **behavioral health care** program is approved by the Substance Abuse and Mental Health Services Administration (SAMHSA) to accredit **opioid treatment programs**. This designation indicates that The Joint Commission standards and survey process meet or exceed the federal regulations for opioid treatment programs and the accreditation guidelines set forth by SAMHSA's Center for Substance Abuse Treatment (CSAT).

Because CSAT accreditation guidelines were revised in July 2007, The Joint Commission has updated specific behavioral health care standards and elements of performance (EPs) that apply to only opioid treatment programs, to remain in compliance with these revised CSAT guidelines.

The revised behavioral health care opioid treatment program standards and EPs, which are **effective January 1, 2009**, are posted on The Joint Commission's Web site at <http://www.jointcommission.org/AccreditationPrograms/BehavioralHealthCare/>. These changes can also be found in the *2009 Comprehensive Accreditation Manual for Behavioral Health Care (CAMBHC)*.

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Standard EC.4.10

~~**B-23. For Opioid Treatment Programs:** The disaster plan includes links to community agencies and ensures emergency dosing.~~

~~**(M) A 24. 23. For Opioid Treatment Programs:** The program maintains a 24-hour telephone answering capability to respond to facility and patient emergencies. The program maintains a 24-hour telephone answering capability to respond to facility and patient emergencies.~~

~~**B-25. For Opioid Treatment Programs:** A roster of patients and a log of medication dosages are accessible to the staff person on call for verification purposes.~~

Standard EC.8.10

~~**B A 31. For Opioid Treatment Programs:** The use of physical space, including bathrooms reflects the special needs of female patients. The use of physical space, including bathrooms, reflects the special needs of female patients.~~

~~**A 32. For Opioid Treatment Programs:** The program has private, individual offices available for counseling.~~

Standard HR.1.10

~~**A. 8. For Opioid Treatment Programs:** Trained and qualified substance abuse counselors provide services to meet the needs of patients and are sufficient in number to ensure reasonable and prompt access by patients to counseling.~~

Standard HR.1.20

~~**A-20. For Opioid Treatment Programs:** Staff who are trained and proficient in cardiopulmonary resuscitation (CPR) through an evidence-based¹ training program; management of opiate overdose, and other appropriate techniques are available.~~

~~**B-21. For Opioid Treatment Programs:** Staff understands the benefits and limitations of urine screening and other toxicological testing.~~

~~**B-22. For Opioid Treatment Programs:** Staff is knowledgeable about strategies for treating alcohol, cocaine, and other drug abuse.~~

¹ Evidence-based: Based on empirical evidence or in the absence of empirical evidence, expert consensus (such as consensus statements promoted by professional societies – in the case of resuscitation training, examples include programs from the American Heart Association, American Red Cross, or Department of Defense).



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~~**B-23. For Opioid Treatment Programs:** Appropriately trained and qualified substance abuse counselors provide services to meet the needs of patients and are sufficient in number to ensure reasonable and prompt access by patients to counseling.~~

~~**B-24. For Opioid Treatment Programs:** Staff responsible for coordinating and linking medical and psychiatric care is knowledgeable about pharmacotherapy treatment.~~

Standard HR.2.10

~~**(M) C 13. For Opioid Treatment Programs:** All staff should receive initial education specific to the pharmacotherapies to be used and tailored to the patient population served. Before providing patient care, staff receive education specific to the medication-assisted treatment used in the program and tailored to the patient population.~~

~~**(M) C 17. For Opioid Treatment Programs:** Staff receive education about all forms of viral hepatitis and their effects on the health of the patient.~~

~~**(M) C 18. For Opioid Treatment Programs:** The program provides staff members with training in the specific characteristics and needs of women participating in their treatment program.~~

Standard HR.2.20

~~**(M) C 5. For Opioid Treatment Programs:** Procedures for handling physical or verbal threats, acts of violence, inappropriate behavior, or other escalating and potentially dangerous situations, including when security guards or police need to be summoned. Staff can describe or demonstrate procedures for handling physical or verbal threats, acts of violence, inappropriate behavior, or other escalating and potentially dangerous situations, including situations in which security guards or police need to be summoned.~~

Standard HR.2.30

~~**(M) C 12. For Opioid Treatment Programs:** Staff is trained to respond to medical emergencies.~~

~~**(M) C 13. For Opioid Treatment Programs:** Staff is trained in the specific characteristics and needs of women participating in the program.~~



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B 14. ~~(M) C 12.~~ For Opioid Treatment Programs: ~~Individual annual training programs are implemented.~~ The program implements an individual annual training plan for each staff member.

B 15. ~~A 13.~~ For Opioid Treatment Programs: ~~Staff has resources for problem solving and troubleshooting.~~ Staff has resources for problem solving and troubleshooting patient care issues.

Note: For example, vomiting medication, aggressive or disruptive behavior.

~~(M) C 16. For Opioid Treatment Programs:~~ ~~Records are maintained for staff training events.~~

Standard HR.5.10

~~(M) C 6. For Opioid Treatment Programs:~~ ~~The program physician(s) have knowledge about and experience in addiction medicine, including medication-assisted treatment.~~

~~(M) C 7. For Opioid Treatment Programs:~~ ~~Staff understands the benefits and limitations of toxicological testing procedures.~~

~~(M) C 8. For Opioid Treatment Programs:~~ ~~Staff is knowledgeable about strategies for treating alcohol, cocaine, and other drug abuse.~~

~~(M) C 9. For Opioid Treatment Programs:~~ ~~Staff responsible for coordinating medical and psychiatric care are knowledgeable about medication-assisted therapy.~~

~~(M) C 10. For Opioid Treatment Programs:~~ ~~The program maintains individualized personnel files as a record of employment.~~

~~(M) C 11. For Opioid Treatment Programs:~~ ~~The personnel files contain the following:~~

Employment and credentialing data

Employment application data

Date of employment

Up-to-date licensing and credentialing data

Detailed job descriptions

Performance evaluations

Training records



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Standard IM.2.10

~~A 11. For Opioid Treatment Programs only: The program adheres to all requirements of the federal confidentiality regulations (42 CFR Part 2).~~

~~A 12. For Opioid Treatment Programs only: Protection of confidentiality is ensured with the use of locked files.~~

Standard IM.3.10

~~(M) B 12. For Opioid Treatment Programs only: Programs should develop and implement procedures to avoid duplication of information gathering without compromising objectives of multiple agencies.~~

Standard MM.3.10

(M) C 2. For Opioid Treatment Programs: The program provides therapeutic doses of medications for each individual patient as determined by the program physician. Program-wide dosage caps or ceilings are not used.

(M) C 3. For Opioid Treatment Programs: Each dose of opioid medication is individually determined by the physician and based on the package insert. Deviations from the approved labeling are documented by the physician.

(M) C 4. For Opioid Treatment Programs: The initial full-day dose of methadone is based on current guidelines and the physician's evaluation of the patient's history and present condition and on knowledge of local conditions such as the relative purity of available street drugs.

Note: The initial dose needs be reflective of the patient's drug use history and should be the lowest dose possible. Current Center for Substance Abuse Treatment guidelines recommend that doses not exceed 30 mg initially or an additional 10 mg after the physician observes that symptoms are not adequately suppressed by the initial dose.

(M) C 5. For Opioid Treatment Programs: The initial methadone dose for a newly admitted pregnant patient and the subsequent induction and maintenance dosing strategy reflect the same dosing protocols used for all other patients.



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(M) C 6. For Opioid Treatment Programs: The duration or the dosage level of medication is based only on clinical indications.

Standard MM.4.40

Additional Rationale for Opioid Treatment Programs only

~~Methadone/LAAM treatment programs should have a diversion control plan that demonstrates accountability and efficient use of personnel and other resources to achieve the highest quality of patient care while reducing possibilities for diversion of controlled substances from legitimate treatment to illicit use.)~~ The potential for diversion is associated with opioid agonist treatment. Therefore, a diversion control plan is an important way to demonstrate accountability and efficient use of personnel and other resources to achieve the highest quality of patient care while reducing possibilities for diversion of controlled substances from legitimate treatment to illicit use. A diversion control plan helps the program determine whether or not there is a diversion problem. It may be helpful to assign diversion problem identification, correction, and prevention functions to one of the program's committees, such as the quality assurance committee of the management committee. When diversion problems are identified, several strategies may be helpful: investigate the alleged or actual source of diversion. If necessary, change the frequency of take-home reviews. Drug testing regimens may need to be reevaluated. Special group sessions or individual counseling may be helpful for groups or individuals at risk for diversion problems. Patient committees to advise on policies, procedures, and problem-solving may also help by giving patients a voice in keeping the treatment environment therapeutic and safe.

~~**B 7. For Opioid Treatment Programs:** The dose of methadone/LAAM maintenance medication is individually determined by a practitioner with prescribing privileges who is knowledgeable about and experienced in addiction medicine.~~

~~**A 8. For Opioid Treatment Programs:** Medication blood levels are obtained when clinically indicated.~~

~~**B 9. A 7. For Opioid Treatment Programs:** Doses of methadone and LAAM or 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.~~ Medication doses are adjusted as needed if the program switches from one generic formula to another and differences in effective dose cause clinically relevant complaints

~~**B 10. A 8. For Opioid Treatment Programs:** A procedure is established for calibrating medication dispensing instruments consistent with manufacturers'~~



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~~recommendations to ensure accurate patient dosing and substance tracking. There is a procedure for calibrating medication dispensing instruments consistent with manufacturers' recommendations to ensure accurate patient dosing and substance tracking.~~

~~**B 11. For Opioid Treatment Programs:** A diversion control plan has been established.~~

~~**B 12. For Opioid Treatment Programs:** The diversion control plan includes a mechanism for continuous monitoring of clinical and administrative activities.~~

~~**B 13. For Opioid Treatment Programs:** The diversion control plan includes a mechanism for problem identification and correction and prevention of related diversion problems.~~

~~**B 14. For Opioid Treatment Programs:** The diversion control plan includes a mechanism for demonstrating accountability to patients and the community.~~

~~**A 9. For Opioid Treatment Programs Only:** The program dispenses methadone only in an oral form that is formulated in such a way as to reduce its potential for parenteral abuse.~~

Standard MM.4.50

~~**B A 5. For Opioid Treatment Programs:** An up-to-date plan for emergency administration of medications is maintained in case the program must be closed temporarily, including how patients will be informed of these emergency arrangements. The program maintains an up-to-date written plan for emergency administration of medications in the event the program must be closed temporarily. The plan describes how patients will be informed of these emergency arrangements.~~

~~**A 6. For Opioid Treatment Programs:** Access to designated program staff is provided 24 hours per day, seven days per week, so that patient emergencies can be addressed and dosage levels can be verified. Medication dosages and other pertinent patient information are available on a 24-hour, 7 day a week basis in case of patient emergency.~~

Standard MM.5.10

~~**(M) C 5.** Before administering a medication, the licensed independent practitioner or qualified individual administering the medication does the following: Verifies that the~~



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medication is being administered at the proper time, in the prescribed dose, and by the correct route.

Note: For Opioid Treatment Programs: Medications that are also best administered by directly observed therapy (DOT) – such as tuberculosis and psychiatric medications – can be given at the same time as the opioid dose.

(M) C 9. For Opioid Treatment Programs: Every dose of medication is recorded on an administration sheet at the time the dose is administered or dispensed, and recorded on the patient's individual medication dose history.

Standard MM.5.20

Rationale for MM.5.20

For Opioid Treatment Programs:

~~Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and state or federal holidays. Programs consider the criteria outlined in the elements of performance in determining patient eligibility for take-home medications. The results of urine or other toxicological tests help clinical staff make informed decisions about take-home medication privileges; however, clinical decisions about take-home medications or discharge are not based solely on urine or other toxicology test reports. One-time or temporary (usually not to exceed three days) take-home medications may be approved for documented family or medical emergencies or other exceptional circumstances.~~

~~**B 4. For Opioid Treatment Programs:** A take-home medication plan has been developed.~~

~~**B 5. A 4. For Opioid Treatment Programs:** Programs consider cessation of illicit drug use in determining patient eligibility for take-home medication. The program's medical director authorizes procedures for determining the eligibility of patients in comprehensive maintenance treatment for unsupervised, or "take-home", doses of medication that include consideration of the following:~~

~~Absence of recent use of drugs, including alcohol~~

~~Regularity of clinic attendance~~

~~Absence of serious behavior problems at the clinic~~

~~Absence of recent known criminal activity, such as drug-dealing~~

~~Stability of the patient's home environment and social relationships~~

~~Length of time in maintenance treatment~~



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Assurance that the take-home medication can be safely stored within the patient's home

Whether the benefit the patient will derive from decreasing clinic attendance outweighs the potential risks of diversion

Note: Policies that prohibit take-home doses for all patients are unacceptable because they preclude individualized patient care.

~~**B-6. For Opioid Treatment Programs:** Programs consider regularity of program attendance in determining patient eligibility for take-home medication.~~

~~**B-7. For Opioid Treatment Programs:** Programs consider length of time and level of treatment in methadone/LAAM therapy in determining patient eligibility for take-home medication.~~

~~**B-8. For Opioid Treatment Programs:** Programs consider absence of known recent criminal activity in determining patient eligibility for take-home medication.~~

~~**B-9. For Opioid Treatment Programs:** Programs consider absence of serious behavioral problems in determining patient eligibility for take-home medication.~~

~~**B-10. For Opioid Treatment Programs:** Programs consider absence of abuse of drugs including excessive use of alcohol in determining patient eligibility for take-home medication.~~

~~**B-11. For Opioid Treatment Programs:** Programs consider other special needs of the patient, such as split dosing, physical health needs, and pain treatment in determining patient eligibility for take-home medication.~~

~~**B-12. For Opioid Treatment Programs:** Programs consider capacity to safely store take-home medication within the patient's home in determining patient eligibility for take-home medication.~~

~~**B-13. For Opioid Treatment Programs:** Programs consider stability of the patient's home environment and social relationships in determining patient eligibility for take-home medication.~~

~~**B-14. For Opioid Treatment Programs:** Programs consider patient's work, school, or other daily life activity schedule in determining patient eligibility for take-home medication.~~



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~~**B 15. For Opioid Treatment Programs:** Programs consider hardship experienced by the patient in traveling to and from the program in determining patient eligibility for take-home medication.~~

~~**B 16. A 5. For Opioid Treatment Programs:** Criteria for determining the number and quantity of take-home doses include the following: The number and quantity of take-home doses are restricted as follows:~~

~~First 90 days of treatment: maximum of 1 unsupervised dose per week~~

~~Second 90 days of treatment: maximum of 2 unsupervised doses per week~~

~~Third 90 days of treatment: maximum of 3 unsupervised doses per week~~

~~Remaining months of the first year: maximum of 6 unsupervised doses per week~~

~~After 1 year of continuous treatment: maximum of 14 unsupervised doses of medication~~

~~After 2 years of continuous treatment: maximum of 1-month supply; however, the patient must make monthly visits~~

~~**B 17. A 6. For Opioid Treatment Programs:** There are policies for one-time, temporary take-home medication. There are policies that guide decisions about one-time, temporary take-home medication in exceptional circumstances, such as documented family or medical emergencies.~~

~~**B 18. (M) C 7. For Opioid Treatment Programs:** A multidisciplinary team provides recommendations and input regarding approval for take-home medications. A multidisciplinary team provides recommendations and input for the physician's review for decisions allowing take-home medications.~~

~~**A 19. (M) C 8. For Opioid Treatment Programs:** A physician makes the final decision of approval for take-home medications. A physician makes the final decision of approval for take-home medications and documents the reasons for the decision (in accordance with the criteria outlined in EP 4) in the patient's record.~~

~~**(M) C 20. 9. For Opioid Treatment Programs:** Decisions regarding take-home medications are reviewed at least every 90 days and more frequently if indicated, and documented in the patient record. Decisions regarding take-home medications are reviewed periodically (according to the criteria outlined in EP 4 and any other clinically relevant factors), and documented in the patient record.~~



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A 24. 10. For Opioid Treatment Programs: ~~Take-home medications are stored in child-proof containers.~~ Take-home medications are packaged in child-proof containers.

(M) C 22. For Opioid Treatment Programs: ~~A physician evaluates patient stability and response to take-home medication and adjusts doses at regular intervals.~~

(M) C 23. 11. For Opioid Treatment Programs: ~~Patients are informed of their rights and responsibilities in ensuring the security of opioid medications.~~ Patients are informed of their responsibility to keep opioid medications secure.

(M) C 12. For Opioid Treatment Programs: The program records the chain of custody for transporting methadone when a patient is transferring to a different level of care or a new location and the program provides sufficient medication to cover the time until the patient arrives at the new location.

Standard MM.6.10

Additional Rationale for Opioid Treatment Programs only

~~Opioid addiction therapy has three desired clinical effects, which include the following in ascending importance:~~

- ~~— 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 illicitly acquired, self-administered opioids without inducing persistent euphoric or other undesirable effects that are experienced by the patient or noticed by other observers~~

~~Methadone is continued as long as benefit is derived from treatment and the patient desires the treatment. Methadone or LAAM maintenance medication doses are sufficient to produce the desired response in the patient for the desired duration of time, with allowance for a margin of effectiveness and safety.~~

~~Methadone is a medication: It should not be standard practice to manipulate doses to reinforce positive behavior or to punish negative behavior. However, there are exceptions to this rule. Sometimes the patient's need for acute or emergency medical care may be urgent and may take precedence over the need for a single day's dose at the program.)~~

Medication-assisted treatment has the following desired outcomes:



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Preventing the onset of subjective and/or objective signs of opioid abstinence syndrome for 24 hours or more
Reducing or eliminating the drug craving routinely experienced by the patient
Blocking the euphoric effects of any illicitly acquired, self-administered opioids without inducing undesirable effects that are experienced by the patient or noticed by other observers

Medication-assisted treatment should be continued as long as benefit is derived from treatment and the patient desires the treatment. That is, there should be no fixed length of time in treatment. In some cases, indefinite medication-assisted treatment may be clinically indicated.

The program should not adjust doses to reinforce positive behavior or to punish negative behavior. For example, the dose should not necessarily be reduced when a patient is not compliant with the treatment plan or has a positive toxicology screen.

~~**B 7. For Opioid Treatment Programs:** Opioid addiction therapy produces the desired clinical effects.~~

~~**B 8. For Opioid Treatment Programs:** A documented history and physical examination supports the physician's judgment that the patient is a suitable candidate for opioid addiction therapy.~~

~~**A 9. For Opioid Treatment Programs:** The initial full-day dose of methadone is based on the physician's evaluation of the client's history and present condition, with added knowledge of such local conditions as the relative purity of available street drugs.~~

~~**(M) C 10. (BHC) For Opioid Treatment Programs:** The usual initial dose of methadone should be from 20 milligrams to 30 milligrams. Reasons for exceeding an initial dose of 30 milligrams are documented in the clinical chart and should not exceed 40 milligrams unless the physician documents in the patient's record that 40 milligrams did not suppress opioid abstinence symptoms after a three-hour period of observation. (Addicted patients abusing diverted medical opioids alone may require a 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.)~~

~~**(M) C 11. For Opioid Treatment Programs:** Initial dosing of LAAM and other approved medications should be based on the package insert; deviations from this must be documented by the physician.~~

~~**Note:** Clinics providing treatment with LAAM must advise all patients of childbearing potential of the risks of LAAM, and make a medical evaluation available to all~~



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~~patients who become pregnant while taking the drug. Clinics should also have a mechanism in place to ease the transition from LAAM to methadone.~~

~~**B-12. For Opioid Treatment Programs:** 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.~~

~~**B-13. (M) C 7. For Opioid Treatment Programs:** The maintenance dose is individually determined with careful and caring attention to the essential information provided by the patient. The maintenance dose is individually determined based on monitoring of the effects of the patient's treatment.~~

~~Note: The medication dose and the interval between doses may require adjustments for patients who have concurrent health conditions, atypical metabolic patterns, or if the patient takes other prescribed medications that alter rates of opioid medication metabolism.~~

~~**B-14. For Opioid Treatment Programs:** 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.~~

~~**Note:** *The total dose of methadone and the interval between doses may require adjustments for patients who have atypical metabolism patterns or are prescribed other concurrent medications that alter rates of methadone metabolism.*~~

~~**(M) C 45. 8. For Opioid Treatment Programs:** Programs maintain patients who become pregnant during treatment on the pre-pregnancy dosage, if effective, and apply the same dosing principles as used with any other non-pregnant patient. The program maintains patients who become pregnant during treatment on the pre-pregnancy dosage, if effective, and applies the same medication dosages as used with any other non-pregnant patient.~~

~~**B-16. (M) C 9. For Opioid Treatment Programs:** The methadone dose is carefully monitored for pregnant patients, especially during the third trimester when pregnancy-induced changes in the rate at which methadone is metabolized or eliminated from the system may necessitate either an increased or a split dose. The methadone dose is carefully monitored for pregnant patients. This is especially true during the third trimester when pregnancy-induced changes in the rate at which methadone is metabolized or eliminated from the system.~~

~~Note: In these cases, an increased or a split dose may be necessary.~~



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~~**B-17. (M) C 10. For Opioid Treatment Programs:** Treatment programs monitor patients' prescribed take-home medications in a manner that complies with federal regulations. The physician evaluates the patient's stability and response to take-home medication and adjusts the dosage at regular intervals.~~

~~**B18. For Opioid Treatment Programs:** Voluntary withdrawal from opioid addiction therapy—as distinct from involuntary withdrawal and administrative withdrawal and other types of withdrawal—is initiated only when desired by the rehabilitated patient, in partnership with the physician.~~

~~**B-19. For Opioid Treatment Programs:** When medical withdrawal is initiated, dosages of methadone or LAAM are reduced at a rate that is well tolerated by the patient and in accordance with sound medical practices.~~

~~**(M) C 20. 11. For Opioid Treatment Programs:** For women of childbearing potential, results of a pregnancy test are reviewed before initiating medical withdrawal of methadone or LAAM. For women of childbearing potential, the physician conducts an assessment for pregnancy before initiating medical supervised withdrawal.~~

~~**B-24. (M) C 12. For Opioid Treatment Programs:** If a pregnant patient elects to withdraw from methadone, a physician experienced in addiction medicine supervises the withdrawal process; regular fetal assessments as appropriate for gestational age are part of the withdrawal process; and withdrawal is not initiated before 14 weeks or after 32 weeks of gestation. If a pregnant patient elects to withdraw from methadone and stays in the program, a physician experienced in addiction medicine supervises the withdrawal process with regular fetal assessments as appropriate for gestational age as part of the withdrawal process. The withdrawal is not initiated before 14 weeks or after 32 weeks of gestation.~~

Standard MM.6.20

~~**(M) C 4. For Opioid Treatment Programs:** Medication blood levels are obtained when clinically indicated.~~

Standard MM.7.10

~~**A 4. For Opioid Treatment Programs:** The program creates an ongoing accurate inventory of all medications received, dispensed, and disposed of.~~

~~**A 5. For Opioid Treatment Programs:** The program has a written diversion control plan.~~

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A 6. For Opioid Treatment Programs: The diversion control plan includes specific activities for reducing diversion and identification of those responsible for managing these activities.

A 7. For Opioid Treatment Programs: The diversion control plan includes a mechanism for periodic monitoring of clinical and administrative activities to reduce the risk of medication diversion.

Note: One mechanism for monitoring might be to have security or staff regularly walk around the clinic's hallways, alleys, and parking lot to assess whether there is a loitering or diversion problem close to the treatment site. Another example is to examine both dosing and take-home dispensing practices to identify potential weaknesses that could lead to diversion problems. Additionally, the program could periodically consult with law enforcement in the community and in areas where patients live to discuss the perceived and actual problems encountered.

A 8. For Opioid Treatment Programs: On a daily basis, the program documents the total number of milligrams of medication dispensed. (See also MM.5.10 EP 9).

Standard PC.1.10

Rationale for PC.1.10

For Opioid Treatment Programs

~~There may be patients in special populations who have a history of opioid use but are not currently physiologically dependent. The absence of physiological dependence should not be an exclusion criterion because patients in these populations are susceptible to relapse to opioid addiction, leading to high-risk behaviors with potentially life-threatening consequences. These populations include the following:~~

- ~~—Persons recently released from a penal institution~~
- ~~—Persons recently discharged from a chronic care facility~~
- ~~—Pregnant patients~~
- ~~—Previously treated patients~~
- ~~—Youth²~~

There may be patients in special populations who have a history of opioid use but are not currently physiologically dependent. Federal regulations waive the 1-year history of addiction for these special populations, because these individuals are

²No patient 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 an appropriate consent form

susceptible to relapse to opioid addiction, leading to high-risk behaviors with potentially life-threatening consequences. These populations include the following:

Persons recently released from a penal institution

Persons recently discharged from a chronic care facility

Pregnant patients

Previously treated patients

~~**A (M) C 14. For Opioid Treatment Programs:** The process for providing access to care, treatment, health professionals, and services includes documentation by the program physician that treatment is medically necessary. Patients may have access to the program after the program physician documents a diagnosis of addiction or dependence and determines that maintenance or withdrawal treatment is medically necessary.~~

- ~~1. **B 15. For Opioid Treatment Programs:** The process for providing access to care, treatment, health professionals, and services addresses the following:~~
- ~~— Criteria for admission based on the DSM-IV definition of opioid dependence~~
 - ~~— Criteria for determining a diagnosis of addiction³ based on behavior~~
 - ~~— Special populations where the absence of physiological dependence should not be an exclusion criterion and admission is clinically justified~~
 - ~~— Patients are not generally admitted to opioid addiction therapy to receive opioids only for pain~~
 - ~~— Measures commensurate with the severity of the problem and its documented consequences are taken to prevent patients from enrolling in treatment provided by more than one clinic or individual practitioner~~
 - ~~— Opioid addiction treatment programs should be encouraged to participate in central registries designed and implemented by the state~~
 - ~~Patients under 18 are required to have had two documented attempts at short-term medically supervised withdrawal (detoxification) or drug-free treatment to be eligible for maintenance treatment~~

³Behavior supportive of a diagnosis of addiction might include the following:

- ~~— Continuing to use the opioid despite known adverse consequences to self, family, or society~~
- ~~— Obtaining illicit opioids~~
- ~~— Using prescribed opioids inappropriately~~
- ~~— One or more attempts at gradual removal of physical dependence on opioids (detoxification) using methadone. This is also called medically supervised withdrawal (MSW). An unsuccessful attempt at MSW is evidenced by uncontrollable drug craving (or actual use) caused by insufficient methadone dose during an admission for detoxification or MSW directly into the early phase of methadone/LAAM maintenance treatment.~~

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A 16. 15. For Opioid Treatment Programs: ~~Pregnant women who seek treatment are given priority. When denial of admission to any pregnant applicant occurs, it is documented on an intake log. The treatment program gives priority for admission to pregnant women who seek treatment and documents the reasons for denying admission to any pregnant applicant on an intake log or other accessible program records.~~

(M) C 17. For Opioid Treatment Programs: ~~For patients under 18, the program physician documents in the patient's record that the patient continues to be or is again physiologically dependent on narcotic drugs.~~

A 18. 16. For Opioid Treatment Programs: ~~Services are provided to meet patients' needs, including before and/or after the traditional 8:00 A.M. to 5:00 P.M. working day, and if services are closed on Saturday or Sunday and national holidays (federal/state/local), when possible. Services are provided during hours that meet the needs of the majority of patients, including before and/or after the traditional 8:00 A.M. to 5:00 P.M. working day, when possible.~~

A 17. For Opioid Treatment Programs: ~~Admission procedures use accepted medical criteria, such as those listed in the current Diagnostic and Statistical Manual for Mental Disorders (DSM-IV) to determine that the person is currently addicted to or dependent on an opioid drug and that the person became addicted or dependent at least 1 year before admission for treatment.~~

Note: In order to determine the 1-year history of addiction or dependence, the program may accept arrest records, medical records, information from significant others and relatives, and other information.

A 18. For Opioid Treatment Programs only: ~~Admission procedures use criteria for determining a diagnosis of addiction or dependence based on behavior.~~

Note: behavior indicative of opioid addiction includes:

Continuing use of the opiate despite known adverse consequences to self, family, or society

Obtaining illicit opiates

Using prescribed opiates inappropriately

Previous attempts at tapering methadone or other drugs

(M) C 19. For Opioid Treatment Programs only: ~~An individual younger than 18 years is not eligible for maintenance treatment unless he or she has two documented, unsuccessful short term withdrawal or drug free treatment attempts within a 12-month period.~~



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A 20. For Opioid Treatment Programs only: The program physician waives the admission criteria requiring a 1 year history of addiction or dependence only in the following circumstances:

The patient has been released from a penal institution in the last six months

The patient is pregnant

The patient was treated with an opioid agonist treatment medication within the last two years

A 21. For Opioid Treatment Programs only: Admission procedures do not exclude patients that are not currently physiological dependent.

A 22. For Opioid Treatment Programs: Admission procedures include use of a central registry system (if applicable) or an alternative mechanism to avoid prevent patients from enrolling in treatment provided by more than one clinic or individual practitioner.

Note: In some cases, the program may, after obtaining the patient's consent, contact other opioid treatment programs within a reasonable geographic distance (100 miles) to verify that the patient is not enrolled in another program.

(M) C 23. For Opioid Treatment Programs: Patients are limited to two withdrawal treatment episodes in one year.

(M) C 24. For Opioid Treatment Programs: When a physician makes a diagnosis and admits a patient after reviewing by telephone or fax the medical examination performed by another qualified health professional, the physician reviews and countersigns the patient record within 72 hours.

Note: Standing orders for admitting patients are not acceptable.

A 25. For Opioid Treatment Programs: Patients who are diagnosed with physical dependence and a pain disorder are eligible to receive medication-assisted treatment for maintenance or for medically supervised withdrawal in a program setting.

A 26. For Opioid Treatment Programs: Patients in medication-assisted treatment are eligible to receive both medication-assisted treatment and adequate doses of opioid analgesics for pain.



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(M) C 27. For Opioid Treatment Programs: If a patient is denied admission based on the results of the initial assessment, the program provides a full explanation to the patient and a referral to another program

Standard PC.2.30

~~(M) C 3. For Opioid Treatment Programs: A physical health assessment, including a medical history and a physical examination, is completed within 14 days after admission. The program completes a medical evaluation within 14 days after treatment is initiated.~~

~~(M) C 4. For Opioid Treatment Programs: The physical health assessment includes urine drug screens.~~

~~(M) C 5. For Opioid Treatment Programs: The physical health assessment includes a tuberculosis skin test.~~

~~(M) C 6. For Opioid Treatment Programs: The physical health assessment includes screening for syphilis.~~

~~B-7. (M) C 4. For Opioid Treatment Programs: The physical examination must also focus on the following:~~

- ~~—Clinical signs~~
- ~~—Complications of addiction (liver problems, multiple traumas)~~
- ~~—Symptoms of addiction (such as needle marks, constricted or dilated pupils, eroded or perforated nasal septum, and the state of sedation or withdrawal characterized by yawning, restlessness, irritability, chills, perspiration, nausea, or diarrhea)~~

The physical assessment includes an examination of the following:

Clinical signs of addiction, such as old and fresh needle marks, constricted or dilated pupils, and/or an eroded or perforated nasal septum, Observable and reported presence of withdrawal signs and symptoms, such as yawning, rhinorrhea, lacrimation, chills, restlessness, irritability, perspiration, piloerection, nausea, and diarrhea.

Note: Onsite "point of collection" devices may be useful in screening a patient's current physiological dependence.



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(M) C 8. 5. For Opioid Treatment Programs: ~~A documented medical and family history includes current information to determine chronic or acute medical conditions, such as diabetes; renal diseases; hepatitis B, C, and delta; HIV exposure; tuberculosis; sexually transmitted diseases; other infectious diseases; sickle-cell trait or anemia; pregnancy (including past history of pregnancy and current involvement in prenatal care); and chronic cardiopulmonary disease. The program documents the patient's medical and family history to determine current chronic or acute medical conditions, such as diabetes; renal diseases; hepatitis A, B, C, and D; HIV exposure; tuberculosis; sexually transmitted diseases; other infectious diseases; sickle-cell trait or anemia; pregnancy (including past history of pregnancy and current involvement in prenatal care); and chronic cardiopulmonary disease.~~

(M) C 6. For Opioid Treatment Programs: ~~Based on the patient's history and physical examination, the program evaluates the possibility of various conditions (such as infectious disease, liver or pulmonary conditions, cardiac abnormalities, psychiatric problems, dermatologic sequelae of addiction, and concurrent surgical problems).~~

~~Note: This may be accomplished within the program itself, or by referring the patient to a cooperating agencies or a consultant clinician.~~

(M) C 7. For Opioid Treatment Programs: ~~Patients who test positive for viral hepatitis receive a referral for further evaluation and treatment, if necessary.~~

A 8. For Opioid Treatment Programs: ~~The program immunizes the patient, or refers the patient for immunization, against hepatitis A and B, and against other viral hepatitis strains as those vaccines become available.~~

Standard PC.2.50

~~Rationale for Opioid Treatment Programs~~

~~A medical laboratory analysis may include the following:~~

- ~~— Complete blood count (CBC)~~
- ~~— Routine chemistry profile and drug screening panel~~
- ~~— Chest X-ray~~
- ~~— Screening tests for infectious diseases, HIV, and sexually transmitted diseases~~
- ~~— EKG~~
- ~~— Pap smear~~
- ~~— Screening test for sickle-cell anemia~~

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- ~~Hepatitis B antigen and surface antibody~~
- ~~Testing for other drugs based on individual medical indicators and community drug use patterns~~

(M) C 3. For Opioid Treatment Programs: ~~Initial urine or other toxicology tests are conducted as part of the admission process.~~ The program conducts initial toxicology tests as part of the admission process.

Note: The recommended medical laboratory analysis and diagnostic evaluation may include the following as medically appropriate for the patient:

- Vital signs, including blood pressure, pulse, respirations, and temperature
- TB skin test, and chest x-ray if the skin test is positive (including consideration for anergy)
- Screening test for syphilis
- Complete blood count (CBC) and lipid panel
- Liver function tests and viral hepatitis marker tests
- HIV testing and counseling
- Tests appropriate for the screening or confirmation of illnesses or conditions based on concerns specific to the patient regarding renal function, electrolyte imbalance, metabolic syndromes, pain, and so forth
- Pregnancy test
- Neurological or psychological testing and assessment
- Chest X-ray
- Electrocardiogram (EKG)
- Pap smear
- Screening test for sickle-cell disease
- Additional diagnostic testing based on the results of baseline screening tests, especially when those results have the potential to affect treatment decisions

(M) C 4. For Opioid Treatment Programs: On admission, the program tests the patient for opiates, methadone, amphetamines, cocaine, marijuana, and benzodiazepines. The need for testing for additional substances is determined by individual patient circumstances and local drug use patterns.

B.4. (M) C 5. For Opioid Treatment Programs: ~~Urine and toxicological specimens are collected in a manner that suggests trust and respect while taking reasonable steps to prevent falsification of samples.~~⁴ The program collects toxicological

⁴ ~~Reliance on direct observation, one-way mirrors, and video cameras to minimize falsification of samples, although necessary for some patients, is neither necessary nor appropriate for all patients.~~



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specimens in a manner that demonstrates trust and respect while taking reasonable steps to prevent falsification of samples.

Note: Direct observation, although necessary for some patients, is neither necessary nor appropriate for all patients.

~~B 5. (M) C 6.~~ For Opioid Treatment Programs: Urine drug screening is used as an aid to monitor and evaluate a patient's progress in treatment. The program uses drug and alcohol screening as aids to monitor and evaluate a patient's progress in treatment.

(M) C 6. 7. For Opioid Treatment Programs: Urine drug screening tests are analyzed for opioids, methadone, amphetamines, cocaine, and barbiturates a minimum of 8 times per year. (Urine testing for other drug use should be determined by community drug use patterns or individual medical indications). The program performs drug tests for each patient on an ongoing basis as frequently as required by law and regulation.

(M) C 8. For Opioid Treatment Programs: The program's clinicians determine the ongoing drug-testing regime by analyzing individual circumstances and community drug use patterns.

Note: testing might include, but is not limited to, opiates, benzodiazepines, barbiturates, cocaine, marijuana, methadone and its metabolites, amphetamines, and alcohol.

(M) C 9. For Opioid Treatment Programs: Program staff discusses results of toxicology testing promptly with patients. The program documents both the results of toxicology tests and the follow-up therapeutic interventions in the patient record.

~~B 8 A 10. For Opioid Treatment Programs: Programs establish procedures for addressing potentially false positive and false negative urine or toxicology test results following principles outlined in TIP 1, *State Methadone Guidelines*. The program establishes and implements procedures for addressing potentially false positive and false negative toxicology test results.~~

Note: TIP 43 outlines principles for handling potentially false positive and negative test results. See TIP 43, "Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs" (CSAT 2005, chapter 9).



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(M) C 11. For Opioid Treatment Programs: Clinicians determine the frequency of ongoing toxicological testing by evaluating the need for testing in relation to the patient's stage in treatment.

~~**B 7 (M) C 12. For Opioid Treatment Programs:** Program staff addresses results of urine screens promptly with patients to facilitate rapid intervention with any drug taking that was disclosed or possible diversion of methadone as evidenced by lack of methadone or its metabolites in the urine. Clinicians intervene when the patient discloses illicit drug use, has a positive drug test, or is suspected of diversion of opioid medication as evidenced by a lack of opioids or related metabolites in drug toxicology tests~~

Standard PC.2.140

(M) C 6. For Opioid Treatment Programs: Patients receive a comprehensive evaluation that covers the following, based on the patient's condition and needs: medical, psychosocial, vocational, educational, behavioral, family, financial, legal, health, and self care needs.

~~**(M) C 6.7. For Opioid Treatment Programs:** The emotional and behavioral assessment/evaluation is conducted within approximately 30 days of initiation of treatment. The comprehensive evaluation is conducted by one or more disciplines within approximately 30 days of admission or earlier when necessary.~~

Standard PC.2.150

~~**(M) C 3. For Opioid Treatment Programs:** Assessment updates should be conducted quarterly for the first year of continuous treatment and semiannually for subsequent years. Assessments are updated quarterly during the patient's first year of continuous treatment and semiannually during subsequent years.~~

Standard PC.3.80

~~Rationale for Opioid Treatment Programs~~

~~Careful diagnostic distinctions are made between the physical dependence associated with chronic administration of opioids to relieve pain and the disease of opioid addiction. Apparent drug-seeking behaviors, typically associated with chronic opioid addiction, may occur as a response to inadequately treated or prolonged pain ("pseudo-addiction"). The physical dependence and tolerance to opioids seen in~~

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~~some chronic pain patients are expected physiological responses to opioid addiction therapy and do not support a diagnosis of active opioid addiction.~~

~~**B 2. For Opioid Treatment Programs:** The process used to differentiate⁵ between the physical dependence associated with chronic administration of opioids for pain relief and the disease of opioid addiction includes the assessment of unsuccessful efforts to control use (loss of control).~~

~~**B 3. For Opioid Treatment Programs:** The process used to differentiate between the physical dependence associated with chronic administration of opioids for pain relief and the disease of opioid addiction includes the assessment of large amounts of time spent in activities to obtain or recover from effects; that is, compulsion (except as necessary to obtain pain relief).~~

~~**B 4. For Opioid Treatment Programs:** The process used to differentiate between the physical dependence associated with chronic administration of opioids for pain relief and the disease of opioid addiction includes the assessment of giving up or reducing important social, occupational, or recreational activities.~~

~~**B 5. For Opioid Treatment Programs:** The process used to differentiate between the physical dependence associated with chronic administration of opioids for pain relief and the disease of opioid addiction includes the assessment of continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.~~

~~**B 6. For Opioid Treatment Programs:** The process used to differentiate between the physical dependence associated with chronic administration of opioids for pain relief and the disease of opioid addiction includes the assessment of patients with both a chronic pain disorder and active opioid addiction are managed by multidisciplinary teams that include addiction medicine specialists and pain medicine specialists, as appropriate.~~

Standard PC.4.20

Rationale for Opioid Treatment Programs

Methadone has well-documented effects on several organ systems, including the respiratory, nervous, liver, and cardiac systems. Therefore, it is important for the program physician to consider whether the treatment drug will be methadone.

⁵ Patients who are dually diagnosed with addiction and a pain disorder may receive treatment in an opioid addiction program if such a program provides expertise or is the only source of treatment.



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buprenorphine, or another medication and whether the treatment indicated for the patient is induction, detoxification, or maintenance.

(M) C 6. For Opioid Treatment Programs: The program manages concurrent abuse of other drugs within the context of the medication-assisted treatment.

Note: Principles for managing concurrent abuse of other drugs are described in TIP 43, "Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs" (CSAT 2005).

(M) C 7. For Opioid Treatment Programs: For patients with two or more unsuccessful withdrawal episodes within a 12-month period, the program physician assesses the patient to determine what other forms of treatment should be considered.

(M) C 8. For Opioid Treatment Programs: The program includes smoking and tobacco cessation as an integral part of the treatment of patients who use tobacco.

A 9. For Opioid Treatment Programs: Patients diagnosed with diseases that must be reported to the public health department (such as tuberculosis or sexually transmitted diseases) are either treated by the program or are referred for further evaluation and treatment elsewhere.

A 10. For Opioid Treatment Programs: Provides patients with free or low cost access to the immunizations recommended by the CDC either on-site or through referral.

A 11. For Opioid Treatment Programs: The program establishes linkages with community HIV/AIDS treatment programs, prevention programs, and social support services to continue opioid medication when AIDS becomes the patient's primary health concern.

Standard PC.4.40

(M) C 5. For Opioid Treatment Programs: ~~Treatment plan updates are conducted quarterly for the first year of continuous treatment.~~ Treatment plans are updated when there are changes in the patient's problems, needs or response to treatment or, if no changes occur, at least quarterly during the patient's first year of continuous treatment and semiannually during subsequent years.

(M) C 6. For Opioid Treatment Programs: ~~Treatment plan updates are conducted semiannually for subsequent years of continuous treatment.~~



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A 6. For Opioid Treatment Programs: The program offers people living with HIV/AIDS medication-assisted treatment that addresses medication side effects and toxicity.

(M) C 7. For Opioid Treatment Programs: The program supports a patient's decision to breast-feed during methadone treatment, unless medically contraindicated, such as by the presence of HIV or HTLV I or II infection in the mother.

(M) C 8. For Opioid Treatment Programs: Voluntary withdrawal from medication-assisted treatment is medically supervised and occurs at a rate well tolerated by the patient and in accordance with sound clinical judgment.

Note: Voluntary withdrawal can occur when the physician and patient agree to the process or when the patient requests withdrawal against medical advice. Voluntary supervised withdrawal is distinct from involuntary tapering or administrative withdrawal. (See also, PC.15.10)

A 9. For Opioid Treatment Programs: The program offers a variety of options to promote successful medically supervised withdrawal, including increased counseling prior to discharge and encouraging attendance at a 12-step or other mutual help program that accepts individuals receiving medication-assisted treatment.

(M) C 10. For Opioid Treatment Programs: For medically supervised withdrawal against medical advice: The program explains the risks of leaving treatment and provides information about or referral to alternate treatment options.

(M) C 11. For Opioid Treatment Programs: For medically supervised withdrawal against medical advice: When a patient leaves the program abruptly, the program allows the patient to be readmitted without repeating the initial assessment procedures if the readmission is within 30 days.

(M) C 12. For Opioid Treatment Programs: For medically supervised withdrawal against medical advice: The program documents the reasons given by the patient for seeking medically supervised withdrawal against medical advice and documents all steps taken to avoid discharging the patient.

(M) C 13. For Opioid Treatment Programs: For medically supervised withdrawal against medical advice: If medically supervised withdrawal fails, the physician evaluates the appropriateness of resuming maintenance treatment.



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(M) C 14. For Opioid Treatment Programs: For medically supervised withdrawal against medical advice: For a pregnant patient, the program informs the physician or agency providing prenatal care that the patient is undergoing medically supervised withdrawal, consistent with Federal privacy standards.

Standard PC.4.90

(M) C 5. For Opioid Treatment Programs: The program helps female patients with infants that may be susceptible to neonatal abstinence syndrome to obtain a comprehensive evaluation and treatment for the infant.

A 6. For Opioid Treatment Programs: The program offers referrals to parenting support groups or other services to patients in medication-assisted treatment who have children.

Note: Children of patients in medication-assisted treatment may also need a referral for services because they may have special mental health and cognitive needs, especially if abuse or neglect has occurred.

A 7. For Opioid Treatment Programs: The program offers or provides referrals for child care services to patients in medication-assisted treatment who have children.

(M) C 8. For Opioid Treatment Programs only: If the program refers the patient elsewhere for prenatal care, it seeks reciprocity in the exchange of pertinent clinical information about compliance with the recommended course of medical care, in accordance with Federal privacy regulations. (See also NPSG.08.02.01)

(M) C 9. For Opioid Treatment Programs: If a pregnant woman refuses direct prenatal services or appropriate referral for such care, the program's treating physician or designee has the patient formally acknowledge in writing that the program offered these services but the patient refused them.

(M) C 10. For Opioid Treatment Programs: The program refers the patient for appropriate treatment if the assessment identifies mental health needs.

Standard PC.5.10

B 3. For Opioid Treatment Programs Only: Concurrent abuse of other drugs is managed.



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Standard PC.5.60

BA 8. For Opioid Treatment Programs: ~~Services are coordinated with agents of the criminal justice system on the patients' behalf and in a way that advocates for continuous treatment of incarcerated opioid addiction therapy patients as well as those on probation or parole. The program works with the criminal justice system to provide continuous treatment to patients who are incarcerated, on probation, or on parole.~~

A 9. For Opioid Treatment Programs: The program develops referral and consultative relationships with other agencies and providers that can provide services to treat patients for any psychiatric co-morbid conditions, medical complications, and communicable diseases.

(M) C 10. For Opioid Treatment Programs: When a patient is being treated for mental health issues, the program and the mental health provider jointly review the prescribed medications.

(M) C 11. For Opioid Treatment Programs: When a patient has hepatitis C, the program coordinates its treatment with the agency responsible for medical treatment. Attention is paid to the patient's adherence to the medication regimen and adverse events.

Standard PC.6.10

(M)C 4. For opioid treatment programs: The program provides each patient with an orientation and ongoing education that includes: The nature of addictive disorders

(M)C 5. For opioid treatment programs: The program provides each patient with an orientation and ongoing education that includes: The benefits of treatment and nature of the recovery process, including the phases of treatment

(M)C 6. For opioid treatment programs: The program provides each patient with an orientation and ongoing education that includes: Clinic guidelines, rules, and regulations, including the requirement to sign a formal agreement of consent, and fees and billing procedures

(M)C 7. For opioid treatment programs: The program provides each patient with an orientation and ongoing education that includes: Noncompliance and discharge procedures, including administrative withdrawal from medication



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(M)C 8. For opioid treatment programs: The program provides each patient with an orientation and ongoing education that includes: Toxicology testing procedures

(M)C 9. For opioid treatment programs: The program provides each patient with an orientation and ongoing education that includes: Dispensing medication

(M)C 10. For opioid treatment programs: The program provides each patient with an orientation and ongoing education that includes: Potential drug interactions

(M)C 11. For opioid treatment programs: The program provides each patient with an orientation and ongoing education that includes: Any agreements needed in order to exchange appropriate information within the network of consultants and referral agencies (in accordance with HIPAA regulations)

(M)C 12. For opioid treatment programs: The program provides each patient with an orientation and ongoing education that includes: The availability of any 12-step or other mutual help group that is accepting of medication-assisted treatment and of the benefits of peer support.

(M)C 13. For opioid treatment programs: The program documents that in informed and counseled the pregnant patient about the latest patient information sheets and product inserts for methadone.

~~(M) C 4. 14. For Opioid Treatment Programs: Education includes the following: Basic prenatal instruction for pregnant women, which includes, at a minimum, maternal, physical, and dietary care. If prenatal care is not available on site or by referral, or if the pregnant patient refuses prenatal care, the treatment program offers basic prenatal instruction on maternal, physical, and dietary care. Provision of the education is documented in the clinical record.~~

~~(M)C 5. A 15. For Opioid Treatment Programs: Education includes the following: Training for all male and female parenting patients or referral of patients to appropriate parenting skills services. The program offers or refers the patient education and training for all patients who are parents or refers patients to parenting skills.~~

~~(M)C 6. A 16. For Opioid Treatment Programs: Education includes the following: Reproductive health and referral for contraceptive services for patients, if indicated. The program offers reproductive health education and referrals for contraceptive services.~~



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(M)C 7. 17. For Opioid Treatment Programs: ~~Education includes the following: HIV/AIDS, testing procedures, confidentiality, reporting, follow-up care, counseling, safer sex, social responsibilities, and sharing of intravenous equipment. The program educates patients about HIV/AIDS, including testing procedures, confidentiality, reporting, follow-up care, counseling, safer sex, social responsibilities, universal precautions, and sharing of intravenous injection equipment.~~

(M)C 18. For opioid treatment programs: The program provides education to patients about viral hepatitis and its effects on physical and mental health, including prevention, treatment, and the effects of treatment on dosage levels of opioid medications.

(M)C 19. For opioid treatment programs: The program provides education to patients about preventing HIV infection and other prevalent infectious diseases, such as hepatitis, sexually transmitted infections, and tuberculosis.

Standard PC.8.10

A 8. For opioid treatment programs: The program employs a multidisciplinary approach for treating patients with both chronic pain disorder and addiction, including both addiction medicine specialists and pain medicine specialists.

Note: The site of such treatment may be either a medical clinic or an opioid treatment program, depending on the patient's needs and the best utilization of available resources.

Standard PC.9.20

A 4. For opioid treatment programs: The program's offices and waiting areas display the names and telephone numbers of who to contact in case of emergency or 911 or similar local emergency resources.

A 5. For Opioid Treatment Programs: The program has staff on duty who are trained and proficient in the following: cardiopulmonary resuscitation (CPR) through an evidence-based training program; management of opiate overdose; management of medical emergencies; and other appropriate techniques.

Standard PC.15.10



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~~**B 7. For Opioid Treatment Programs:** The process for transfer, referral, and discharge address linkages with HIV/AIDS treatment programs in the community.~~

~~**B (M) C 9. For Opioid Treatment Programs:** Relapse prevention addresses the following: Physical and mental health problems after withdrawal from opioid addiction therapy, including the need for counseling and appropriate medication to help with sleep disorders, depression, and other problems. The discharge planning process addresses any physical and mental health problems following medically supervised withdrawal.~~

~~Note: For example, the program might address the need for counseling or appropriate medication to help with sleep disorders, depression, and other problems.~~

~~**B (M) C 10. For Opioid Treatment Programs:** Relapse prevention addresses the following: Provisions for continuing care after the last dose of medications and for re-entry to maintenance treatment if relapse occurs. The discharge planning process addresses referrals for continuing outpatient care after the last dose of medication and planning for re-entry to maintenance treatment if relapse occurs.~~

~~**(M) C 11. For Opioid Treatment Programs:** Psychosocial treatment is continued for patients electing to discontinue pharmacotherapy. Psychosocial treatment is continued for patients electing to discontinue medication-assisted therapy.~~

~~**(M) C A 12 For Opioid Treatment Programs:** Patients are tracked and pharmacotherapy is reinstated at the first sign of relapse or impending relapse, when possible. The program has a process for tracking patients and reinstating medication-assisted therapy at the first sign of relapse or impending relapse.~~

~~Note: It may not be possible for the program to track each patient, especially patients that leave the program, but it is important for the program to have processes in place in order to reinstate medication-assisted therapy when possible.~~

~~**B A 13. For Opioid Treatment Programs:** Opportunities are provided for patients receiving long-term pharmacotherapy services only to receive psychosocial services again if the need emerges. The program provides the opportunity for patients receiving only long-term medication-assisted therapy to receive psychosocial services again if the need emerges.~~

~~**A 14. For Opioid Treatment Programs:** The discharge planning process addresses administrative withdrawal.⁶ The program's process for administrative~~

⁶Administrative withdrawal may result from the following:

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withdrawal is implemented on an individual basis and follows the principles involved in medically supervised withdrawal from medication.

Note: Administrative withdrawal is usually involuntary and might be initiated based on nonpayment of fees, disruptive behavior, or incarceration. The principles followed for any medically supervised withdrawal also apply for administrative withdrawal; namely, that sound clinical judgment is followed; the time frame is generally 30 days but is adjusted by the physician depending on clinical factors; and a variety of supportive options are available to the patient.

A 15. For Opioid Treatment Programs: ~~The discharge planning process addresses medical withdrawal,⁷ including against medical advice.~~

-
- ~~— Nonpayment of fees. Remedies may include referral to a more affordable treatment program. As a last resort, programs provide a humane schedule of withdrawal.~~
 - ~~— Disruptive conduct or behavior considered to have an adverse effect on the program, staff, or patient population of such gravity to justify the involuntary withdrawal and discharge of a patient despite an extremely poor prognosis. Such behaviors include violence, threat of violence, dealing drugs, repeated loitering, and flagrant noncompliance resulting in an observable, negative impact on the program, staff, and other patients.~~
- ~~Incarceration or other confinement.~~

⁷ ~~Medical withdrawal occurs as follows:~~

- ~~— As a voluntary and therapeutic withdrawal agreed upon by staff and patient~~
- ~~or~~
- ~~— In response to the patient's request over the objections of the physician, counselor, and other staff; that is against medical advice (AMA)~~

~~The following policies and procedures promote successful medical withdrawal whether conducted with or against medical advice:~~

- ~~— Dose reduction occurs at a rate well tolerated by the patient.~~
- ~~— A variety of supportive options are available to improve chances of a successful withdrawal.~~
- ~~— Increased counseling is available before discharge.~~
- ~~— Participants are encouraged to attend a self-help program sensitive to the needs of opioid-addiction therapy patients.~~
- ~~— The patient cannot be voluntarily withdrawn more than twice within a 12-month period.~~
- ~~— The third time within the 12-month period, a patient must be evaluated by a physician for an alternative treatment to a detox program.~~

~~Additional considerations for medical withdrawal against medical advice are as follows:~~

- ~~— The patient has the right to leave treatment when he or she chooses to do so. The program explains the risks of leaving treatment.~~
- ~~— The physician, in consultation with the patient, determines the schedule for withdrawal from opioid addiction therapy.~~
- ~~— 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.~~
~~The program documents the issue that caused the patient to seek discharge and provides full documentation of steps taken to avoid discharge.~~



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(M) C 15. For opioid treatment programs: When a pregnant patient is discharged, the program refers her for prenatal care and documents the name, address, and telephone number of the physician who will be caring for the patient after discharge.

A 16. For opioid treatment programs: The program makes decisions about administrative withdrawal on a case-by-case basis.

(M) C 17. For opioid treatment programs: When the program makes an administrative decision to discharge a patient from medication-assisted treatment, the program offers a schedule of medically supervised withdrawal that is well-tolerated by the patient and based on clinical judgment. The offer is documented.

(M) C 18. For opioid treatment programs: During medically supervised administrative withdrawal, the program documents the patient's condition in the clinical/case record.

(M) C 19. For opioid treatment programs: Upon discharge following medically supervised administrative withdrawal, the program provides the patient with referrals to an alternate treatment program. These referrals are documented.

Standard PI.1.10

~~**B A 26. (BHC) For opiate addiction treatment programs: 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~~
- ~~—Improving quality of life by restoration of physical and mental health and functional status.~~

The program collects data about treatment outcomes and processes.

Note: Examples of measures include:

- Use of illicit opioids, illegal drugs, and the problematic use of alcohol and prescription medicines
- Criminal activities and entry into the criminal justice system
- Behaviors contributing to the spread of infectious diseases
- Restoration of physical and mental health and functional status
- Retention in treatment



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Number of patients who are employed
Abstinence from drugs of abuse

Ethics, Rights, and Responsibilities

Overview

~~The goal of the ethics, rights, and responsibilities function is to improve care, treatment, services, and outcomes by recognizing and respecting the rights of each [patient] and by conducting business in an ethical manner. Care, treatment, and services are provided in a way that respects and fosters dignity, autonomy, positive self-regard, civil rights, and involvement of [patients]. Care, treatment, and services consider the [patient]'s abilities and resources; the relevant demands of his or her environment; and the requirements and expectations of the providers and those they serve. The family is involved in care, treatment, and service decisions with the [patient]'s approval.~~

The goal of the rights and responsibilities function is to improve care, treatment, services, and outcomes by recognizing and respecting the rights of each [patient]. Care, treatment, and services are provided in a way that respects and fosters dignity, autonomy, positive self-regard, civil rights, and involvement of [patients]. Care, treatment, and services reflect the [patient]'s abilities and resources and the relevant demands of his or her environment. The family is involved in care, treatment, and service decisions with the [patient]'s approval.

~~[An organization]'s adherence to ethical care and business practices significantly affects the [patient]'s experience of and response to care, treatment, and services. The standards in this chapter address the following processes and activities related to ethical care and business practices:~~

- ~~— Managing the [organization]'s relationships with [patients] and the public in an ethical manner~~
- ~~— Considering the values and preferences of [patients], including the decision to discontinue care, treatment, and services~~
- ~~— Helping [patients] understand and exercise their rights~~
- ~~— Informing [patients] of their responsibilities in care, treatment, and services~~
- ~~— Recognizing the [organization]'s responsibilities under law~~



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[Patients] deserve care, treatment, and services that safeguard their personal dignity and respect their cultural, psychosocial, and spiritual values. These values often influence the [patient]'s perceptions and needs. By understanding and respecting these values, providers can meet care, treatment, and service needs and preferences.

(Note to PUBS: RI.1.10, RI.1.20, RI.1.30, and RI.1.40 have been moved to the Leadership chapter so the following heading and introduction related to Organization Ethics should be removed for BHC, LTC, and LT2.)

~~Organization Ethics (BHC, LTC, LT2)~~

~~Introduction (BHC, LTC, LT2)~~

~~[An organization] has an ethical responsibility to the [patients] and community it serves. To fulfill this responsibility, ethical care, treatment, and service practices and ethical business practices must go hand in hand. Furthermore, the [organization] provides care, treatment, and services within its scope, stated mission and philosophy, and applicable law and regulation.~~

~~The [organization]'s system of ethics supports honest and appropriate interactions with [patients]. The system of ethics also includes [patients] whenever possible in decisions about their care, treatment, and services, including ethical issues.~~

Standard RI.2.10

~~**A 5. For Opioid Treatment Programs: The program treats women respectfully and safely.**~~

~~**A 6. For Opioid Treatment Programs: The medication schedule (dosing times/program hours) is the least intrusive and disruptive schedule for the majority of patients.**~~

~~**A 7. For Opioid Treatment Programs: Satisfaction surveys allow patients to provide feedback on program policies and services. (See also PI.1.10, EP 3)**~~

Standard RI.2.20



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~~(M) C 14.12. For Opioid Treatment Programs: The [organization] obtains written acknowledgement from patients as evidence that they received a copy of their rights governing the conduct of patients, and that these rights were discussed with them. The program obtains written acknowledgement from patients that they received a copy of their rights and that these rights were discussed with them.~~

~~B 15. For Opioid Treatment Programs: Programs support patient choice in seeking alternative therapies while providing appropriate guidance in the process. Programs may provide culturally appropriate or popular and non-harmful alternative therapies as indicated (such as acupuncture or providing a space for sweat lodge ceremonies in a rural clinic serving Native Americans).~~

~~B 16. For Opioid Treatment Programs: Programs ensure that youth are not harassed or exploited by older patients or staff.~~

~~B 17. For Opioid Treatment Programs: Programs make provisions to provide for respectful and safe treatment of women.~~

~~(M) C 18. For Opioid Treatment Programs: Patients have a right to a medication schedule (dosing hours/schedule) that is most accommodating and least intrusive and disruptive for most patients.~~

~~(M) C 19. For Opioid Treatment Programs: Patients have the right to be informed about potential interactions with and adverse reactions to other substances, including those reactions that might result from interactions and adverse reactions to alcohol, other prescribed or over-the-counter pharmacological agents, other medical procedures, and food.~~

~~(M) C 20. For Opioid Treatment Programs: Patients have the right to review their own record with clinical staff supervision and obtain a timely response to the request for copies of the record.~~

~~(M) C 21. For Opioid Treatment Programs: Patients have the right to input into program policies and services through patient satisfaction surveys.~~

~~(M) C 22.13. For Opioid Treatment Programs: Patients have the right to be informed regarding patients about the financial aspects of treatment, including the consequence of nonpayment of required fees. The program informs patients about the financial aspects of treatment, including the consequence of nonpayment of required fees.~~



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~~(M) C 23. For Opioid Treatment Programs: Programs ensure that patients are made aware of the Consumer Bill of Rights and Responsibilities developed by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. (A complete, detailed copy of the Consumer Bill of Rights can be obtained at www.hcqualitycommission.gov).~~

A 14. For Opioid Treatment Programs: The program posts patients' rights and responsibilities at the treatment site in a manner that makes the posting visible to patients.

(M) C 15. For Opioid Treatment Programs: The program reviews rights and responsibilities with the patient following admission, at the end of the stabilization period, and when any changes have been made to the list of rights and responsibilities.

Standard RI.2.30

~~B 14. For Opioid Treatment Programs: The conflict resolution process requires the following:~~

- ~~— Patients receive a decision in writing with the reason stated~~
- ~~— Patients have the right to appeal the decision to a final, unbiased source~~
- ~~— The program makes every attempt, before a patient is discharged, to accommodate his or her desire to remain in some type of opioid therapy at an alternative treatment program~~
~~Involuntary withdrawal is used only as a last resort and is done in the most humane manner consistent with the safety and well-being of staff, other patients, and the program~~

~~(M) C 15. For Opioid Treatment Programs: The methadone dose of a patient should not be changed without his or her knowledge unless he or she signs a document waiving such consent.~~

A 14. For Opioid Treatment Programs: The program allows for patient choice in seeking alternative therapies and provides support to patients who choose to explore these alternatives.

Note: Programs may provide culturally appropriate or popular and non-harmful alternative therapies, such as acupuncture or providing a space for sweat lodge.

Standard RI.2.40



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~~(M) C 4. For Opioid Treatment Programs: Each patient must give informed consent for prescribed pharmacotherapy before dosing begins. Before administering medication, the program obtains voluntary, written, informed consent from the patient for the prescribed medication-assisted therapy.~~

~~(M) C 5. For Opioid Treatment Programs: Patients are informed upon admission that the natural history of opioid addiction is altered by time and history.~~

~~(M) C 6.5. For Opioid Treatment Programs: Patients are informed upon admission that the goal of medication therapy is to stabilize functioning. The program informs patients that the goal of medication-assisted treatment is to stabilize functioning.~~

~~(M) C 7.6. For Opioid Treatment Programs: Patients are informed upon admission that, in full consultation with them, the provider will periodically discuss present level of functioning, course of treatment, and future goals. The program informs patients that the provider will periodically discuss with them their present level of functioning, course of treatment, and future goals.~~

~~Note: These discussions are not intended to place pressure on the patient to either withdraw from medication or remain on medication maintenance.~~

~~(M) C 8. For Opioid Treatment Programs: Patients are informed upon admission about state-specific requirements and program policies and procedures for reporting suspected child abuse and neglect and other forms of abuse.~~

~~(M) C 9.7. For Opioid Treatment Programs: Patients are informed about their disease's natural progression, including statistics about success after withdrawing from methadone.~~

~~(M) C 10. For Opioid Treatment Programs: Informed consent is obtained when emancipated minors are admitted to the program.~~

~~(M) C 11. For Opioid Treatment Programs: Pregnant women referred for prenatal care must give informed consent to ensure that pertinent clinical information about complying with the recommended course of medical care is exchanged.~~

~~(M) C 12. For Opioid Treatment Programs: If a pregnant woman refuses direct prenatal services or appropriate referral, the treating physician uses informed consent procedures to have her formally acknowledge that these services were offered but refused, as appropriate.~~



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~~(M) C 13. For Opioid Treatment Programs: Informed consent policies are established and implemented to ensure appropriate follow-up primary care for new mothers and well baby care for their infants.~~

~~(M) C 8. For Opioid Treatment Programs: The program informs patients about potential interactions with and adverse reactions to other substances, including those related to the use of alcohol, other prescribed or over-the-counter pharmacological agents, other medical procedures, and food.~~

~~(M) C 9. For Opioid Treatment Programs: The program informs all pregnant patients with concurrent HIV infection that HIV medication treatment is currently recommended to reduce perinatal transmission and it provides pregnant patients with appropriate referrals and case management for this treatment.~~

Standard RI.2.120

~~A 10. For Opioid Treatment Programs: The program develops and makes available policies and procedures addressing patient grievances.~~

~~A 11. For Opioid Treatment Programs: The policies and procedures specify the minimum elements of due process applicable based on the program's setting and resources, and includes the following:~~

~~Providing the patient with a written decision which includes the reason for the decision~~

~~The right of patients to appeal the decision to a final, unbiased source~~

~~Making every attempt, before a patient is discharged, to accommodate his or her desire to remain in opioid therapy at an alternative treatment program.~~

~~Use of involuntary withdrawal only as a last resort and applied in the most humane manner possible, consistent with the safety and well-being of the patient, staff, other patients,~~

~~As a result of the patient filing a grievance, the program will not change the patient's dose of opioids or other medications without his or her knowledge, unless the patient has signed a document waiving such consent.~~

Standard RI.2.130

~~(M) C 13. For Opioid Treatment Programs: The program informs patients upon admission about its obligation under state-specific requirements and its own policies~~



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and procedures to report suspected child abuse and neglect and other forms of abuse (such as violence against women).

Standard RI.2.150

A 3. For Opioid Treatment Programs: The program takes steps to prevent patients from being harassed or exploited by other patients or staff.

Standard RI.3.10

~~(M) C 5. For Opioid Treatment Programs only: The [organization] obtains written acknowledgement from patients as evidence that they received a copy of their responsibilities governing the conduct of patients, and that the responsibilities were discussed with the patients. The program obtains written acknowledgement from patients that the patient's responsibilities were explained.~~

Standard LD.01.04.01

A chief executive manages the [organization].

~~B-A 4. 12.~~ For opioid treatment programs: Individuals in positions of authority are professionally and culturally competent.

Note: These individuals are able to work effectively with the local community and/or receive input from members of minority groups or advisors who are knowledgeable about gender, ethnicity, and language issues.

A 13. For opioid treatment programs: The program formally designates a program sponsor and a medical director.

A 14. For opioid treatment programs: The medical director is responsible for all medical services performed by the program.

A 15. For opioid treatment programs: All medical care is the responsibility of the program's physician(s).

A 16. For opioid treatment programs: The program's medical director is a physician licensed in the jurisdiction where the program is located.

Standard LD.04.01.09



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Policies and procedures guide the provision of program services and define the goals and scope of services offered.

~~B A~~ 1. For opioid treatment programs: Procedures are in place to ensure continuity of care for patients in the event of the voluntary or involuntary closure of the program. The procedures provide for orderly transfer of patients, records, and assets to other programs or practitioners.

~~B A 6. 2.~~ For opioid treatment programs: The program's written policies provide for assigning female patients to counselors who are sensitive to and trained to address their individual needs, such as domestic violence, or sexual abuse.

~~B A 9. 3.~~ For opioid treatment programs: The program establishes written policies and procedures for follow-up primary care of new mothers and well baby care for their infants.

~~B A 10. 4.~~ For opioid treatment programs: Written policies and procedures apply equally to women with concurrent HIV infection or HIV diagnosis, regardless of whether they are pregnant. These women receive the same services and treatment opportunities.

~~B A 12. 5.~~ For opioid treatment programs: The program offers treatment for groups organized with their special needs in mind, such as gender, sexual minority, seniors, and language.

~~A 6. For opioid treatment programs: The option of participation in groups comprised of the same sex is available to all patients.~~

~~A 7. For opioid treatment programs: The program does not limit the psychosocial services offered to patients receiving "0" dose levels.~~

~~A 8. For opioid treatment programs: The program establishes procedures for admitting patients to short or long term withdrawal treatment.~~

14. 9. For opioid treatment programs: Policies and procedures are reviewed and recertified at least annually.

~~2. For Opioid Treatment Programs only: Policies for opioid treatment programs address the provision that HIV-positive [patient]s are offered options to balance opioid addiction therapy and HIV/AIDS care, treatment, and services.~~



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~~3. For Opioid Treatment Programs only: Policies for opioid treatment programs address the provision that [patient]s who are dually diagnosed with addiction and a pain disorder are not prohibited from receiving opioid addiction therapy for either maintenance or withdrawal in a program setting if such a setting provides expertise or is the only source of treatment.~~

~~4. For Opioid Treatment Programs only: Policies for opioid treatment programs address the provision that addiction [patient]s maintained on opioid addiction therapy are not prohibited from receiving needed pain treatment including, when appropriate, adequate doses of opioid analgesics.~~

~~5. For Opioid Treatment Programs only: Policies for opioid treatment programs address the specific needs of female [patient]s.~~

~~7. For Opioid Treatment Programs only: Policies for opioid treatment programs address the availability of appropriate child care services to male and female [patient]s who are parents.~~

~~8. For Opioid Treatment Programs only: Policies for opioid treatment programs address the assessment of the appropriateness of breast-feeding during opioid addiction therapy.~~

~~11. For Opioid Treatment Programs only: Policies for opioid treatment programs address the provision that all pregnant [patient]s with concurrent HIV infection are provided with appropriate referrals and case management to determine which medication can be used to reduce prenatal transmission.~~

Standard LD.04.03.05

Services are defined through the collaboration of the [organization]'s leaders with leaders of the various communities served by the [organization] and other external [organization]s.

A 1. For opioid treatment programs: The program selects its location based on community need and impact.

~~B~~ A 4. 2. For opioid treatment programs: The program solicits input from the community and uses both solicited and unsolicited input from the community to determine the program's impact in the neighborhood.



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A 3. For opioid treatment programs: The program establishes a liaison with community leaders in order to foster good relations.

Note: Examples of community leaders include publicly elected representatives; local health, substance abuse, social and/or human service agency directors; business organization leaders; community and health planning agency directors; grassroots community organization leaders; local police and law enforcement officials; and religious and spiritual leaders.

A 4. For opioid treatment programs: The program has a written community relations plan that is specific to the configuration and needs of the program within its community.

~~B A 4. 5.~~ For opioid treatment programs: The community relations plan includes goals and procedures and identifies the program staff who will function as community relations coordinators.

~~B A 3. 6.~~ For opioid treatment programs: The community relations plan addresses how the program will establish a liaison with the community representatives to share information about the program, the community, and mutual issues.

A 7. For opioid treatment programs: The community relations plan addresses how the program will serve as a community resource on substance abuse and related health and social issues as well as how it will promote the benefit of medication-assisted treatment in preserving public health.

~~B A 6. 9.~~ For opioid treatment programs: The program documents its community relations efforts and community contacts.

~~B A 6. 10.~~ For opioid treatment programs: The program evaluates its community relations efforts over time and addresses any outstanding problems.

~~B A 7. 11.~~ For opioid treatment programs: The program has a communication mechanism so that interested parties and potential patients can obtain general information about the program outside regular operating hours.

~~B A 5. 14.~~ For opioid treatment programs: The program has written policies and procedures that address community problems (such as patient loitering and medication diversion). Program operations do not adversely affect community life.

~~B A 2. 15.~~ For opioid treatment programs: The program's building is clean and orderly and the physical setting does not impede pedestrian or traffic flow.



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~~11. For Opioid Treatment Programs only: Services are provided, or referrals made, for [patient]s who have coexisting health and psychosocial issues.~~

~~12. For Opioid Treatment Programs only: Treatment programs ensure that every pregnant [patient] has the opportunity for prenatal care, provided either on site or by referral to appropriate health care providers.~~

~~13. For Opioid Treatment Programs only: If referred, the treatment program has agreements, including informed consent procedures, that ensure reciprocity in the exchange of pertinent clinical information about compliance with the recommended course of medical~~

Standard LD.04.04.05

The [organization] has an organization-wide, integrated [patient] safety program.

5. As part of the safety program, the organization creates procedures for responding to system or process failures.

Note 1: Responses might include continuing to provide care, treatment, or services to those affected, containing the risk to others, and preserving factual information for subsequent analysis.

Note 2: For Opioid treatment programs: Examples of reportable patient deaths include:

- Drug-related deaths.

- Methadone or buprenorphine deaths.

- Unexpected or suspicious deaths.

- Treatment-context deaths that raise individual, family, community, or public concern.