DEPARTMENT OF ALCOHOL AND DRUG PROGRAMS
Title 9, California Code of Regulations, Division 4, Chapter 4

Subchapter 1:	**Amend Section 10000.**
Subchapter 2, Article 1:	**Amend Sections 10015, and 10020.**
Subchapter 2, Article 1:	**Adopt Sections 10021, 10023, and 10024.**
Subchapter 3, Article 2:	**Amend Section 10145.**
Subchapter 4, Article 3:	**Amend 10260.**
Subchapter 5, Article 3:	**Amend 10310, 10315, 10350, and 10355.**
Subchapter 5, Article 4:	**Amend 10365, 10370, 10375, 10380, 10385, 10390, 10400, and 10405.**

Office-Based and Mobile Narcotic Treatment Programs

Text of Proposed Regulations

Subchapter 1. General Administration.

AMEND:

§10000. Definitions.

(a) The following definitions shall apply to terminology contained in ~~Chapter 4, Division 4,~~ Title 9, California Code of Regulations, Division 4, Chapter 4.

(1) Amendment. "Amendment" means written changes in the protocol.

(2) CSAT. "CSAT" means the Center for Substance Abuse Treatment of the Substance Abuse and Mental Health Services Administration of the United States Department of Health and Human Services.

(3) DEA. "DEA" means the Drug Enforcement Administration of the United States Department of Justice.

~~(2)~~(4) Detoxification Treatment. "Detoxification treatment" means ~~the treatment modality whereby replacement narcotic therapy is used in decreasing, medically determined dosage levels for a period not more than 21 days, to reduce or eliminate opiate addiction, while the patient is provided treatment services.~~the dispensing or administering of a replacement narcotic therapy medication in decreasing doses to alleviate the adverse physical or psychological effects of-withdrawal from the continuous or sustained use of an opiate drug and as a method used to achieve a drug-free state within such period.

(A) Long-Term Detoxification. "Long-term Detoxification" means detoxification treatment for a period more than 21 days not to exceed 180 days.

2006 DRAFT

(B) Short-term Detoxification Treatment. "Short-term detoxification treatment" means detoxification treatment for a period not to exceed 21 days.

(~~3~~5) FDA. "FDA" means the United States Food and Drug Administration.

(6) Electronic Means or Transmission. "Electronic means or transmission" is a way of sending or transferring data or image information electronically. Electronic transmission may include, but is not limited to, email, fax, or a secured data system.

~~(4)~~(7) Illicit Drug. "Illicit drug" means any substance defined as a drug in Section 11014, Chapter 1, Division 10 of the Health and Safety Code, except:

(A) Drugs or medications prescribed by a physician or other person authorized to prescribe drugs, pursuant to Section 4040, Chapter 9, Division 2 of the Business and Professions Code, and used in the dosage and frequency prescribed; or

(B) Over-the-counter drugs or medications used in the dosage and frequency described on the box, bottle, or package insert.

~~(5)~~(8) Laboratory. "Laboratory" means a drug analysis laboratory approved and licensed by the State Department of Health Services to test or analyze samples of patient body specimens for the substances named in Section 10315 for a narcotic treatment program.

~~(6)~~(9) Levoalphacetylmethadol (LAAM). "Levoalphacetylmethadol (LAAM)," also known as Levo-Alpha-Acetyl-Methadol or levomethadyl acetate hydrochloride, means the substance that can be described chemically as levo-alpha-6-dimethylamino-4, 4-diphenyl-3-heptyl acetate hydrochloride.

~~(7)~~(10) Maintenance Treatment. "Maintenance treatment" means the ~~treatment modality whereby replacement narcotic therapy is used in sustained, stable, medically determined dosage levels for a period in excess of 21 days, to reduce or eliminate chronic opiate addiction, while the patient is provided a comprehensive range of treatment services.~~ Dispensing or adminisitering of a replacement narcotic therapy medication at medically determined dosage levels to reduce or eliminate opiate addiction while the patient is provided a comprehensive range of treatment services.

~~(8)~~(11) Medical Director. "Medical Director" means the physician licensed to practice medicine in California who is responsible for medical services provided by the program.

~~(9)~~(12) Medication. "Medication" means any opiate agonist medications that have been approved by the FDA for use in replacement narcotic therapy, including:

(A) Methadone, and

2006 DRAFT

(B) Levoalphacetylmethadol (LAAM)

~~(10)~~(13) Medication Unit. "Medication unit" means a narcotic treatment facility, established by a program sponsor as part of a maintenance treatment program, from which licensed private practitioners and community pharmacists are permitted to administer and dispense medications used in replacement narcotic therapy. These medication units may also collect patient body specimens for testing or analysis of samples for illicit drug use.

~~(11)~~(14) Methadone. "Methadone" means the substance that can be described as 6-dimenthylamino-4, 4-diphenyl-3-heptanone. Methadone doses are usually administered as methadone hydrochloride.

(15) Mobile Narcotic Treatment Program. "Mobile Narcotic Treatment Program" means a program in which interested and knowledgeable physicians and surgeons, counselors, and authorized licensed professionals provide addiction treatment services in a mobile facility, and through which medication may be obtained directly through the manufacturer or the licensed narcotic treatment program with which it is affiliated for distribution to patients and through direct administration and specified dispensing services. A Mobile NTP shall be affiliated with (i.e. operating under the license of) a licensed Office-Based NTP or NTP.

~~(12)~~(16) Narcotic Drug. "Narcotic drug" means any controlled substance which produces insensibility or stupor and applies especially to opium or any of its natural derivatives or synthetic substitutes.

~~(13)~~(17) Narcotic Treatment Program (NTP). "Narcotic treatment program" means any opiate addiction treatment modality, whether inpatient or outpatient, which offers replacement narcotic therapy for~~in~~ maintenance~~,~~ and detoxification, ~~or~~and provides other services in conjunction with that replacement narcotic therapy.

(18) Office-Based NTP. "Office-Based NTP" means a program in which interested and knowledgeable physicians and surgeons provide addiction treatment services, and in which community pharmacies supply necessary medication both to these physicians and surgeons for distribution to patients and through direct administration and specified dispensing services. An Office-Based NTP shall be either licensed or affiliated with (i.e. operating under the license of) a licensed NTP or licensed Office-Based NTP.

~~(14)~~(19) Opiate. "Opiate" means narcotic drug substances having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability~~;~~, including heroin, morphine, methadone, or any natural or synthetic opiate as set forth in the California Uniform Controlled Substances Act (Health and Safety Code sections 11000, et seq.).

2006 DRAFT

~~(15)~~(20) Opiate Addiction. “Opiate Addiction,” and the related term “addiction to opiates,” means a condition characterized by compulsion and lack of control that leads to illicit or inappropriate opiate-seeking behavior, including an opiate addiction that was acquired or supported by the misuse of a physician's legally prescribed narcotic medication.

~~(16)~~(21) Physical Dependence. “Physical Dependence,” and related terms “dependence,” “dependency,” “dependent,” and “physiological dependence,” means a condition resulting from repeated administration of a drug that necessitates its continued use to prevent withdrawal ~~syndrome~~symptoms that occur~~s~~ when the drug is abruptly discontinued.

~~(17)~~(22) Primary Metabolite of Methadone. “Primary metabolite of methadone” means 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine.

~~(18)~~(23) Program. “Program” means a narcotic treatment program, unless otherwise specified.

~~(19)~~(24) Program Director. “Program director” means the person who has primary administrative responsibility for operation of an approved and licensed program.

~~(20)~~(25) Program Sponsor. “Program sponsor” means the person or organization which has accepted final responsibility for operation of a narcotic treatment program. The program sponsor ~~also~~ may also be the program director or medical director or a licensed physician providing narcotic treatment services in a licensed Office-Based NTP.

~~(21)~~(26) Protocol. “Protocol” means a written document which sets forth a program's treatment concept, organization, and operational procedures in the form required by the Department.

~~(22)~~(27) Rationale. “Rationale” means a rational statement of principles or the logical basis for a procedure.

~~(23)~~(28) Replacement Narcotic Therapy. “Replacement narcotic therapy” means ~~the medically supervised use of an opiate agonist medication that mimics the effects of endorphin, a naturally occurring compound, thus producing an opiate effect by interaction with the opioid receptor.~~ medication-assisted treatment that uses agonist or partial agonist medication, such as methadone or LAAM, to normalize brain chemistry, block the euphoric effects of opioids, relieve physiological cravings, and normalize body functions.

~~(24)~~(29) Treatment. “Treatment” means services which will habilitate and rehabilitate patients with an opiate addiction to a basic level of social, life, work, and health ~~capabilities~~capability ~~that~~to help them become productive, independent members of society~~;~~. Treatment services ~~and will~~ include but are not limited to:

2006 DRAFT

(A) Replacement narcotic therapy;

(B) Evaluation of medical, employment, alcohol, criminal, and psychological problems;

(C) Screening for diseases that are disproportionately represented in the opiate-abusing population;

(D) Monitoring for illicit drug use;

(E) Counseling by addiction counselors ~~that~~who are evaluated through ongoing supervision; and

(F) Professional medical, social work, and mental health services, on-site or by referral (through contracted interagency agreements).

Necessity: To add definitions and to amend existing definitions to align with current terminology for terms used and to align in relation to the new Office-Based NTP treatment modality, Mobile NTP treatment modality, and federal agency changes.

NOTE: Authority cited: Sections 11755, 11835, 11839.3, and 11839.20, Health and Safety Code. Reference: Division 10.5, Part 2, Chapter 10, Article 1 (commencing with Section 11839), 11215, and 11875, Health and Safety Code.

2006 DRAFT

Subchapter 2. Licensure of Narcotic Treatment Programs
Article 1. Program Licensure

AMEND:

§10015. Licensure of Separate Facilities.

~~If there is to be a centralized organizational structure, consisting of a primary program facility and other program facilities, whether inpatient or outpatient, all of which provide treatment services which exceed the administering or dispensing of medications and the collection of patient body specimens for testing or analysis of samples for illicit drug use, both the primary program and each other program facility must be licensed as separate programs, even though some services may be shared, such as the same hospital or treatment referral services.~~

(a) An NTP, whether inpatient or outpatient, may operate from separate facilities within a complex of buildings only if all of the separate facilities are operating under one license and in compliance with all the requirements of this Chapter, and all of the separate facilities are within close proximity of each other.

(1) Each separate facility within the complex of buildings may have different numerical street addresses or suite numbers.

(b) For purposes of this section the following definitions apply:

(1) "Complex of buildings" means a strip mall, or buildings adjacent to each other, such as buildings connected by a breezeway or courtyard.

(2) "Close proximity" means next door, or upstairs, or through a breezeway or courtyard.

Necessity: To clarify that primary NTPs can have facilities in close proximity that do not require separate licensure. Treatment modalities that require separate licensure such as medication units and Office-Based NTPs will also be able to operate from separate facilities to provide all treatment services.

NOTE: Authority cited: Sections 11755, 11835, 11839.1, 11839.3, and 11839.20, Health and Safety Code. Reference: Sections 11217, 11839.3, 11839.5, and 11839.6, Health and Safety Code.

2006 DRAFT

Subchapter 2. Licensure of Narcotic Treatment Programs
Article 1. Program Licensure

AMEND:

§10020. Licensure of Medication Units.

(a) In order to lawfully operate a medication unit in California for patients in maintenance treatment, the sponsoring program shall first receive approval of ~~the~~CSAT and DEA, ~~FDA~~ and licensure by the Department.

(b) The Department may license the operation of a medication unit when the Department determines that the sponsoring program has satisfactorily demonstrated in its protocol that the following conditions and requirements have been met:

(1) The proposed location of the medication unit and the area to be served by the proposed medication unit are geographically isolated to such an extent that regular patient travel to the sponsoring program facility is impractical and would cause the patient great hardship.

(2) Treatment services are limited to the administering and dispensing of medications and the collection of patient body specimens for testing or analysis of samples for illicit drug use.

(3) The program's protocol describes how every patient in maintenance treatment that is assigned to the medication unit will participate in the regular treatment provided by the sponsoring program.

(4) Patient enrollment is of reasonable size in relation to the space available for treatment and the size of the staff at the facility.

(5) Maximum enrollment in a medication unit does not exceed 30 patients.

Necessity: Clean up change. To amend reference from FDA to CSAT and DEA as the current agencies from whom approval must be obtained.

NOTE: Authority cited: Sections 11755, 11835, 11839.3, and 11839.20, Health and Safety Code. Reference: Sections 11217, 11839.3, and 11839.5, Health and Safety Code.

2006 DRAFT

Subchapter 2. Licensure of Narcotic Treatment Programs
Article 1. Program Licensure

ADOPT:

§10021. Office-Based Narcotic Treatment Program.

(a) An Office-Based NTP shall comply with all of the requirements of this Chapter except those provisions that apply specifically to a Mobile NTP facility.

(b) An Office-Based NTP shall be licensed by the Department to provide narcotic treatment services or be affiliated with a licensed NTP or a licensed Office-Based NTP.

(c) A licensed NTP or a licensed Office-Based NTP may sponsor one or more affiliated Office-Based NTPs. An affiliated Office-Based NTP sponsored by a licensed NTP or a licensed Office-Based NTP is not required to obtain a separate license.

(d) A licensed NTP or a licensed Office-Based NTP sponsoring an affiliated Office-Based NTP shall enter into a written agreement with the affiliated Office-Based NTP to ensure that all services required under this Chapter are provided.

(e) An Office-Based NTP shall enter into a written agreement with a local pharmacy. The agreement will establish that the pharmacy shall supply replacement narcotic therapy medication to the Office-Based NTP and/or dispense or administer replacement narcotic therapy medication to the Office-Based NTP patients. The written agreement shall include all the requirements specified in Section 10023.

(f) Patient capacity in an affiliated Office-Based NTP shall not exceed twenty (20) patients per physician.

(g) A medication order for replacement narcotic therapy medication shall be directed to the pharmacy from the Office-Based NTP physician by a means that will ensure medication security and prevent diversion.

(h) To operate an Office-Based NTP and/or an affiliated Office-Based NTP, the applicant shall apply to the Department for review and approval pursuant to the requirements of this Chapter, and shall also apply to CSAT. The applicant shall obtain DEA registration prior to dispensing or administering replacement narcotic therapy medication at the Office-Based NTP and/or affiliated Office-Based NTP. The Office-Based NTP shall ensure patient confidentiality in compliance with the requirements set forth in Part 2, commencing with Section 2.1, of Title 42, Code of Federal Regulations, and the requirements set forth in this Chapter. The following shall be included with the application:

(1) A copy of a written agreement with the pharmacy.

(2) A copy of a written agreement with an affiliated Office-Based NTP, if applicable.

2006 DRAFT

(i) The Department shall review the application to determine if the proposed Office-Based NTP meets the requirements of this Chapter and Section 11839.6 of the Health and Safety Code, and shall approve or deny the application based on its review. If the Department denies the application, the applicant may appeal the action pursuant to Section 10057.

Necessity: To implement, interpret, and make specific Section 11839.6 of the Health and Safety Code to establish the requirements for licensure and operation of Office-Based NTPs.

NOTE: Authority cited: Sections 11755, 11839.3, 11839.5, 11839.6, and 11839.20, Health and Safety Code. Reference: Sections 11839.3, and 11839.6, Health and Safety Code.

2006 DRAFT

Subchapter 2. Licensure of Narcotic Treatment Programs
Article 1. Program Licensure

ADOPT:

§ 10023. Office-Based NTP Pharmacy Agreement.

(a) The pharmacy shall obtain DEA registration prior to dispensing or administering replacement narcotic therapy medication.

(b) The written agreement between the Office-Based NTP and the pharmacy shall include, but not be limited to, the following:

(1) The name of the pharmacy.

(2) A copy of the state license issued by the Board of Pharmacy.

(3) The name of the pharmacist(s) and the pharmacist's license number.

(4) The days and hours the pharmacy will dispense and administer the replacement narcotic therapy medication.

(5) The manner in which the medication order will be directed to the pharmacy from the Office-Based NTP physician that will ensure medication security and prevent diversion.

(6) A description of the procedures to be used to ensure the security of replacement narcotic therapy medication both at the pharmacy and when the medication is supplied by the pharmacy to the Office-Based NTP (refer to Article 3 of this Chapter – *Medication Handling and Security*).

(7) A procedure for verification of patient identity prior to administering or dispensing replacement narcotic therapy medication.

(8) A procedure to ensure patient confidentiality in compliance with the requirements set forth in Part 2, commencing with Section 2.1, of Title 42, Code of Federal Regulations, and the requirements set forth in this Chapter.

(9) A procedure to ensure the participating pharmacist(s) is familiar with replacement narcotic therapy medication treatment and requirements.

(10) A procedure for maintaining and transferring patient dosing records. The pharmacy shall keep patient dosing records in a secure location within the facility. Dosing records shall include the type and amount of medication administered or dispensed to a patient on a day-to-day basis. The pharmacy shall provide a copy of this data to the Office-Based NTP at least monthly.

2006 DRAFT

(11) A procedure describing the manner and content of communication between the Office-Based NTP physician and the pharmacy. The procedure shall include, but not be limited to, the following:

(A) The Office-Based NTP physician and the pharmacist shall maintain contact to communicate all necessary information concerning the patient.

(B) The Office-Based NTP physician shall provide the pharmacy with a 24-hour emergency contact number.

(C) The pharmacy shall communicate and disclose to the Office-Based NTP physician if any of the following occurs:

1, Patient appears intoxicated or otherwise incapacitated at the pharmacy, or

2, Patient fails to maintain regularly scheduled appointments.

(12) The pharmacist shall observe ingestion of each medication dose administered at the pharmacy.

Necessity: To implement, interpret, and make specific Section 11839.6 of the Health and Safety Code to establish requirements for local pharmacies which supply replacement narcotic therapy medication to Office-Based NTP and administer the medication to the OB-NTP patients.

NOTE: Authority cited: Sections 11755, 11839.5, 11839.6, and 11839.20, Health and Safety Code. Reference: Sections 11839.6, Health and Safety Code.

2006 DRAFT

Subchapter 2. Licensure of Narcotic Treatment Programs
Article 1. Program Licensure

ADOPT:

§ 10024. Mobile Narcotic Treatment Programs.

(a) To operate a Mobile NTP, the applicant shall apply to the Department for review and approval and shall also apply to CSAT. The applicant shall obtain DEA registration prior to dispensing or administering replacement narcotic therapy medication at the Mobile NTP. Mobile NTPs shall be located at predetermined site(s) that shall be approved by the Department.

(b) A Mobile NTP shall be affiliated with (i.e. operating under the license of) a licensed NTP or a licensed Office-Based NTP. An affiliated Mobile NTP sponsored by a licensed NTP or a licensed Office-Based NTP is not required to obtain a separate license. A licensed NTP or a licensed Office-Based NTP may sponsor one or more Mobile NTPs.

(c) Replacement narcotic therapy medication shall be supplied to the Mobile NTP by the licensed NTP. Only authorized staff, pursuant to Section 11215 of the Health and Safety Code, may dispense or administer replacement narcotic therapy medication.

(d) Both the licensed NTP and the Mobile NTP shall ensure the operation of the Mobile NTP complies with the following:

(1) All the requirements of this Chapter, except the requirements in Sections 10021 and 10023 that pertain specifically to Office-Based NTPs.

(2) The requirements regarding patient confidentiality as set forth in Part 2, commencing with Section 2.1, of Title 42, Code of Federal Regulations.

(e) Each Mobile NTP patient must be registered with the licensed NTP. The admission process shall occur at the licensed NTP. The licensed NTP shall maintain all patient and personnel records for the Mobile NTP. The Mobile NTP shall have dosing records on site.

(f) The licensed NTP and the Mobile NTP shall have a written agreement to ensure that all treatment services required pursuant to this Chapter are provided to the Mobile NTP patients. A copy of the written agreement between the licensed NTP and the Mobile NTP shall be included with the application. Treatment services may be provided as follows:

(1) The Mobile NTP may provide all services in the mobile facility.

(2) The licensed NTP and the Mobile NTP may share responsibility for the provision of services.

2006 DRAFT

(3) Services other than dispensing or administering of replacement narcotic therapy medication may be provided at a facility adjacent to where the Mobile NTP is located. A written agreement shall be executed between all parties to ensure all treatment services are provided.

(g) A Mobile NTP facility that is providing all treatment services shall be of a sufficient size to contain the following:

(1) A secure dispensing area with a window.

(2) A restroom for body specimen collection.

(3) A counseling room.

(4) A physical examination room with an examination table.

(5) A sink with running water.

(h) Both the licensed NTP and the Mobile NTP shall set forth in the protocol procedures for the continuum of care, including, but not limited to, providing replacement narcotic therapy to the Mobile NTP patients in the event that the mobile vehicle is inoperable.

(i) The Mobile NTP vehicle shall comply with the applicable requirements of the Vehicle Code (VC). Both the licensed NTP and the Mobile NTP shall ensure that the mobile vehicle driver complies with the driver's licensing requirements specified in VC Section 12804.9. The applicant shall provide the vehicle identification number to the Department with the application.

(j) To ensure staff safety and medication security, the Mobile NTP shall comply with the following:

(1) The vehicle shall have a 24-hour security system connected to a security company or local law enforcement.

(2) Panic buttons shall be placed in specified locations on the vehicle.

(3) The vehicle shall be equipped with a Global Positioning System receiver.

(4) A telecommunications device and/or a secure method to transmit information to the licensed NTP by electronic means or transmission shall be on the vehicle.

(5) An armed security guard shall operate the vehicle and remain with the vehicle while treatment services are being provided. The security guard shall also be present when the medication is transferred to and from the vehicle.

(6) All interior doors (e.g., doors into the driving cab, dispensing area, and restroom) shall be equipped with bolt locks.

2006 DRAFT

(7) The driving cab area shall be secured.

(8) The vehicle shall contain a safe for storage of the narcotic replacement therapy medication.

(9) The vehicle shall be parked inside a secured, e.g., fenced, area when administering or dispensing replacement narcotic therapy medication.

(10) When the vehicle is not in use, it shall be parked in a secure location.

(k) The Mobile NTP shall comply with the provisions of the Americans with Disabilities Act (ADA) of 1990 and shall contain, at a minimum, the following:

(1) A wheelchair lift.

(2) Handrails at the dispensing window entrance and the rear entrance of the vehicle.

(3) Safeguards to prevent head injury for substandard height doorways.

(l) The vehicle shall comply with the fire safety provisions specified in Health and Safety Code Section 1765.170(c) and shall contain smoke alarms sufficient for the size of the vehicle.

(m) The vehicle shall be maintained in good repair and in a clean, safe, and sanitary manner and shall have documented evidence of preventive maintenance as specified in Health and Safety Code Section 1765.170(d).

(n) Mobile NTPs may be deployed at the Department's discretion in the event of an emergency.

Necessity: To implement, interpret, and make specific Section 11839.65 of the Health and Safety Code to establish the requirements for licensure and operation of Mobile NTPs.

NOTE: Authority cited: Sections 11755, 11839.3, 11839.5, ~~11839.65~~, and 11839.20, Health and Safety Code. Reference: Sections 11839.3, and 11839.65, Health and Safety Code.

2006 DRAFT

Subchapter 3. Program Administration
Article 2. Patient Capacity and Caseload

AMEND:

§10145. Licensed Patient Capacity.

(a) A single narcotic treatment program shall be licensed to provide treatment services to a maximum number of~~750~~ patients as determined by the Department.

(b) The Department shall determine a program's maximum patient capacity based on its review of the licensee's application or written request for either an increase or decrease.

(1) The Department shall specify on the license the patient capacity in licensed slots.

(2) The Department shall not increase the licensed patient capacity of a program with outstanding deficiencies where the Department has not accepted the program's corrective action plan.

(c) The maximum patient capacity shall apply to a combined total of patients in all treatment modalities ~~(e.g.~~, including detoxification, ~~and~~ maintenance, affiliated Office-Based NTPs, Mobile NTPs, and medication units, ~~),~~ except for those patients from another program that are receiving dosing services on a temporary basis as specified in Section 10295.

(d) The program may adjust the ratio of patients in each treatment modality in response to need, but shall not treat more patients at any one time than the maximum patient capacity specified on the license.

(e) The Department may issue a temporary suspension order that prohibits the program from admitting new patients if the program is over its maximum licensed capacity.

(1) The Department shall deliver to the licensee, in person or by certified mail, a notice of temporary suspension, which shall:

(A) Inform the licensee that the program has been prohibited from admitting any new patients, effective as of the date of receipt of the order; and

(B) Inform the licensee that as soon as the program is within its licensed patient capacity, the program shall submit a written notification to the Department.

(2) The temporary suspension order shall be automatically vacated as soon as the Department receives the program's written notification that it is within its licensed patient capacity.

2006 DRAFT

(3) The Department shall assess a civil penalty of five hundred dollars ($500) a day for each day a program violates a temporary suspension order.

Necessity: Amended to remove the cap on patient slots to allow expanded access to treatment to more patients with the addition of Office-Based NTPs, affiliated Office-Based NTPs, and Mobile NTPs.

NOTE: Authority cited: Sections 11755, 11835, 11839.3, 11839.5, and 11839.20, Health and Safety Code. Reference: Sections 11839.3, 11839.16, and 11839.20, Health and Safety Code.

2006 DRAFT

Subchapter 4. Medication Security and Diversion Prevention
Article 3. Medication Handling and Security

AMEND:

§10260. Administration or Dispensing of Medications.

(a) The medical director or program physician shall be responsible for administering or dispensing ~~to patients~~, or supervising the administration or dispensing of, ~~all medications used in~~ replacement narcotic therapy medication to patients. A pharmacist, when acting under the direction of an Office-Based NTP physician, may administer or dispense replacement narcotic therapy medication to patients.

(b) Under the medical director or program physician's direction, appropriately licensed program personnel authorized by Section 11215 of the Health and Safety Code may administer or dispense ~~these~~ replacement narcotic therapy medication~~s~~ to patients ~~as authorized by Section 11215 of the Health and Safety Code~~.

(c) Replacement narcotic therapy medication shall be available seven days a week.

~~(c)~~(d) Each program shall use the following procedures when administering or dispensing ~~medications used for~~ replacement narcotic therapy medication at the facility~~or furnishing methadone~~:

(1) ~~These~~Replacement narcotic therapy medication~~s~~ shall be administered or dispensed to patients orally in liquid formulation.

(2) Medication doses ~~ingested at the program facility~~in liquid formulation shall be diluted in a solution which has a volume of not less than two ounces. ~~Take-home medication doses given to patients in maintenance treatment shall be diluted in a solution which has a volume of not less than one ounce.~~

(3) A program staff member qualified pursuant to subdivision (b) above, or an Office-Based NTP pharmacist acting under the direction of an Office-Based NTP physician, shall observe ingestion of each ~~medication~~ dose ~~administered at the program facility~~.

~~(4) Each program shall devise precautions to prevent diversion of these medications.~~

~~(5) Methadone shall be available seven days a week.~~

~~(6) No patient shall be allowed to access a program's supply of medications, act as an observer in the collection of patient body specimens used for testing or analysis of samples for illicit drug use, or handle these specimens.~~

(e) Each program shall use the following procedures when administering or dispensing replacement narcotic therapy medication to patients for take-home privileges:

2006 DRAFT

(1) Each program shall ensure that a patient receiving take-home medication has been determined eligible for take-home privileges as specified in Section 10370.

(2) A program staff member shall observe ingestion of the medication dose administered to a patient on any day the patient is present at the facility except for those patients who the medical director or program physician has determined, in his or her clinical judgment, qualify to receive take-home medication for an extended period (i.e., thirteen or more days) on a continuous basis.

(3) Take-home medication doses shall be dispensed in liquid formulation. No more than a 14-day supply of take-home medication shall be given in liquid formulation. If liquid take-home medication doses are diluted by the program, each dose shall be diluted in a solution which has a volume of not less than one ounce. If liquid take-home medication doses are not diluted by the program, written instructions for dilution of liquid take-home doses shall be provided to the patient with the liquid take-home medication.

(4) For take-home periods exceeding a 14-day supply of take-home medication, take-home medication doses may be dispensed in solid formulation upon approval by the Department.

(f) No patient shall be allowed to access a program's supply of medications, act as an observer in the collection of patient body specimens, or handle patient body specimens.

(g) Each program shall develop and set forth in its protocol a plan to prevent diversion of replacement narcotic therapy medications.

Necessity: Amended to clarify and make specific responsibility and procedures for administering and dispensing medications at the facility and for take-homes including new allowance for medication in solid form upon approval by the department; and allowance for Office-Based NTP pharmacist to dispense under direction of Office-Based NTP physician. Observed ingestion is eliminated for patients who receive extended take-homes; as well as supplying diluted liquid formulation for more than 14 days of take-homes.

Changes allowing take-home medication to be dispensed or administered in solid form upon approval and clarifying procedures for administering or dispensing medication both at the program and for take-homes would apply to all NTPs including Office-Based NTPs and Office-Based NTP pharmacies.

NOTE: Authority cited: Sections 11755, 11835, 11839.3, and 11839.20, Health and Safety Code. Reference: Sections 11215, 11839.2, ~~and~~ 11839.3, and 11839.6, Health and Safety Code.

2006 DRAFT

Subchapter 5. Patient Treatment
Article 3. Treatment Services

AMEND:

§10310. Procedures for Collection of Patient Body Specimens.

(a) Each program shall set forth in its protocol a plan for collection of patient body specimens for testing or analysis of samples for illicit drug use and abuse of any substance. The plan shall establish procedures that will~~describes the procedures to be used for~~:

(1) Assure~~ing~~ the reliability of its ~~body~~ patient body specimen collection procedures.

(2) Ensure that~~Storage of~~ ~~body~~ patient body specimens are stored in a secure place to avoid substitution.

(3) Determine ~~T~~the substances for which samples of patient body specimens are to be analyzed pursuant to ~~s~~Section 10315.

(4) Describe how~~Usage of~~ test or analysis results ~~in~~will be used for patient evaluation and treatment.

(b) Each program shall ensure that patient body specimens are collected in sufficient quantity to permit retesting or analysis of samples, if necessary.

(c) Each program shall describe in its protocol the method to be used to validate collection of patient body specimens and sample testing or analysis procedures.

(d) Each program providing detoxification and/or maintenance treatment shall describe in its protocol a plan for collection of patient body specimens which incorporates the elements of randomness and surprise and/or requires daily collection.

(e) For patients in maintenance treatment, each program shall collect a patient body specimen and perform a~~A~~ test or analysis for illicit drug use ~~shall be performed~~ at the time of admission and randomly thereafter at least eight (8) times per year ~~least monthly~~ ~~for every patient in maintenance treatment~~.

(f) ~~In programs providing~~For patients in short-term detoxification treatment, each program shall collect a patient body specimen and perform a test or analysis for illicit drug use ~~shall be performed~~ at the time of admission and any other time deemed necessary by the ~~attending~~medical director or program physician.

(g) For patients in long-term detoxification treatment, a test or analysis for illicit drug use shall be performed at the time of admission and randomly every month the patient remains in long-term detoxification treatment.

2006 DRAFT

NECESSITY: To align with federal regulations for testing requirements for patients in short- and long-term detoxification and maintenance. Clarification needed for all NTPs including Office-Based NTPs, affiliated Office-Based NTPs, and Mobile NTPs who treat patients in detox and maintenance.

NOTE: Authority cited: Sections 11755, 11835, 11839.3, and 11839.20, Health and Safety Code. Reference: Sections 11839.3, and 11839.20, Health and Safety Code.

2006 DRAFT

Subchapter 5. Patient Treatment
Article 3. Treatment Services

AMEND:

§10315. Substances To Be Tested or Analyzed for in Samples Collected from Patient Body Specimens.

(a) Programs shall have samples collected from each patient body specimen tested or analyzed for evidence of the following~~ substances in a patient's system~~:

(1) Methadone and its primary metabolite.

(2) Opiates.

(3) Cocaine.

(4) Amphetamines.

(5) ~~Barbiturates~~Other.

(b) At the discretion of the medical director or program physician, ~~P~~programs may have samples collected from each patient body specimen tested or analyzed for evidence of any other ~~illicit~~ drug~~s~~ or substance if abuse of such ~~those~~ drug~~s~~ or substance is prevalent in the ~~are commonly used in the area~~community served by the program.

NECESSITY: Barbiturates are currently not an abused drug. This change will eliminate the requirement to test for barbiturates and will make clearer that providers can screen for *any* drug, such as barbiturates or benzodiazepines, if abuse of such drug is prevalent in the community served by the program. Providers are charged an amount per drug being tested. The cost of testing will remain the same unless the program discretionarily chooses to add additional drugs to the list of those being analyzed.

NOTE: Authority cited: Sections 11755, 11835, 11839.3, and 11839.20, Health and Safety Code. Reference: Sections 11839.2, 11839.3, 11839.20, and 11875, Health and Safety Code.

2006 DRAFT

Subchapter 5. Patient Treatment
Article 3. Treatment Services

AMEND:
§10350. Administration of Initial Dose~~s~~ of Medication to New Patients.

(a) The medical director or program physician shall administer to new patients, or supervise the administration of, the initial dos~~age~~e of ~~a~~ medication used in replacement narcotic therapy. An Office-Based NTP pharmacist, when acting under the direction of an Office-Based NTP physician, may administer the initial dose of medication.

(b) The medical director or program physician or Office-Based NTP pharmacist shall ensure by observation that the new patient has ingested the initial dose. The new patient ~~shall be observed to ingest the initial dose and~~ shall continue to be observed for a period of time ~~prescribed~~specified by the medical director or program physician for evidence of any adverse effects.

(c) If the requirement contained in Sub~~section~~division (b) of this regulation ~~are~~is delegated to appropriately~~staff member as~~ licensed program personnel authorized by Section 11215(a) of the Health and Safety Code to administer or dispense medications, that licensed individual ~~staff member~~ shall notify the medical director or program physician immediately of any adverse effects~~,~~ and document in the patient's record the length of time he/she observed the new patient, ~~and~~as well as the outcome of the observation.

(d) The initial dosage shall be sufficient to control symptoms of withdrawal but shall not be so ~~great~~excessive as to cause sedation, respiratory depression, or other effects of acute intoxication.

(e) Programs shall specify in their protocols details of planned initial doses.

(f) If a program admits a patient who ~~was~~ receiv~~ing~~ed replacement narcotic therapy medication from another program the previous day, the initial dosage level requirement provided in Section 10355 and the observation requirement contained in Sub~~sections~~divisions (b) and (c) of this regulation ~~do~~shall not apply.

NECESSITY: To allow the Office-Based NTP pharmacist to administer the initial dose of replacement narcotic therapy medication when the Office-Based NTP has a written agreement with a local pharmacy to administer narcotic therapy medication to its patients. Other clarifying changes to align with the same or similar changes made to Section 10260.

NOTE: Authority cited: Sections 11755, 11835, 11839.3, and 11839.20, Health and Safety Code. Reference: Sections 11839.2, 11839.3, 11839.20, and 11875, Health and Safety Code.

2006 DRAFT

Subchapter 5. Patient Treatment
Article 3. Treatment Services

AMEND:

§10355. Medication Dosage Levels.

(a) Detoxification Dosage Levels.

(1) The medical director or program physician shall ~~individually determine~~establish an individualized dosage schedule for each patient~~'s medication schedule based on the following criteria:~~ in detoxification treatment. The schedule shall include initial, stabilizing, and reducing dosage amounts for a period not less than 21 days but not to exceed 180 days. Detoxification dosage levels shall not exceed that which is necessary to suppress withdrawal symptoms.

(A) Medications shall be administered daily under observation for a minimum of 30 continuous treatment days.~~;~~

~~(B) Dosage levels shall not exceed that which is necessary to suppress withdrawal symptoms; and~~

~~(C) Schedules shall include initial, stabilizing, and reducing dosage amounts for a period of not more than 21 days.~~

(2) The medical director or program physician shall record, date, and sign in the patient's record ~~each~~any change in the dosage schedule and shall document the~~with~~ reason~~s~~ for such ~~deviations~~change.

(b) Detoxification Dosage Levels Specific to Methadone.

(1) The first-day dose of methadone shall not exceed 30 milligrams unless:

(A) The dose is divided and the initial portion of the dose does not exceed~~is not above~~ 30 milligrams; and

(B) The subsequent portion is administered to the patient separately after ~~the~~a period of observation ~~period prescribed~~specified by the medical director or program physician.

(2) The total dose of methadone for the first day shall not exceed 40 milligrams unless the medical director or program physician determines that 40 milligrams is not sufficient to suppress the patient's opiate abstinence symptoms, and documents in the patient's record the basis for his/her determination.

(c) Maintenance Dosage Levels.

2006 DRAFT

(1) Each program ~~furnishing~~providing maintenance treatment shall set forth in its protocol the medical director or program physician's procedures for medically determining a ~~stable~~ dosage level that:

(A) Minimizes sedation~~.~~;

(B) Decreases withdrawal symptoms~~.~~; and

(C) Reduces the potential for diversion of take-home medication.

~~(2) Deviations from these planned procedures shall be noted by the medical director or program physician with reason for such deviations, in the patient's record.~~

(2) The medical director or program physician shall record, date, and sign in the patient's record any change in the dosage schedule and shall document the reason for such change.

(3) The medical director or program physician shall review the most recent approved product labeling for up-to-date information on important treatment parameters for each medication. Deviation from doses, frequencies, and conditions of usage described in the approved labeling shall be justified in the patient's record.

(4) The medical director or program physician shall review each patient's dosage level at least every three months.

(d) Maintenance Dosage Levels Specific to Methadone.

(1) The medical director or program physician shall ensure that the first-day dose of methadone shall not exceed 30 milligrams unless:

(A) The dose is divided and the initial portion of the dose does not exceed~~is not above~~ 30 milligrams; and

(B) The subsequent portion is administered to the patient separately after ~~the~~a period of observation ~~period prescribed~~specified by the medical director or program physician.

(2) The total dose of methadone for the first day shall not exceed 40 milligrams unless the medical director or program physician determines that 40 milligrams is not sufficient to suppress the patient's opiate abstinence symptoms, and documents in the patient's record the basis for his/her determination.

~~(3) A daily dose above 100 milligrams shall be justified by the medical director or program physician in the patient's record.~~

(e) Maintenance Dosage Levels Specific to LAAM.

2006 DRAFT

(1) The medical director or program physician shall ensure that the initial dose of LAAM to a new patient whose tolerance for the drug is unknown does not exceed 40 milligrams, unless:

(A) The dose is divided, ~~with~~and the initial portion of the dose does not ~~above~~exceed 40 milligrams, and the subsequent portion is administered to the patient separately after ~~the~~a period of observation ~~period prescribed~~specified by the medical director or program physician; or

(B) The patient's tolerance for the medication is known by the medical director or program physician and he~~/~~ or she documents the basis for this determination in the patient's record ~~the basis for this determination~~.

(2) The medical director or program physician shall ensure that the initial dose of LAAM to a patient stabilized on replacement narcotic therapy and administered methadone on the previous day is less than or equal to 1.3 times the patient's daily methadone dose, not to exceed 120 milligrams.

(3) After a patient's tolerance to LAAM is established, LAAM shall not be administered to the patient more frequently than every other day.

(4) A dose above 140 milligrams shall be justified by the medical director or program physician in the patient's record.

(f) Dosage Schedule Following Patient Absence.

After a patient has missed three (3) or more consecutive doses of replacement narcotic therapy medication, the medical director or program physician shall provide a new medication order before continuation of treatment.

(g) Changes in the Dosage Schedule.

Only the medical director or program physician is authorized to change the patient's medication dosage schedule, either in person, by verbal order, or through other electronic means.

(h) Confirmation of Verbal Orders.

Confirmation of verbal orders for medication dosage changes and verbal orders for any other aspect of a patient's treatment shall be documented in writing in the patient's record by the medical director or program physician within three days from the date of the verbal order.

NECESSITY: To clarify that detoxification can be up to 180 days. Subsection (a)(1)(A) is revised because patients in long-term detoxification may qualify for take-home privileges after thirty days in treatment. Added language to specify verbal

2006 DRAFT

orders must be confirmed within three days. Other grammatical changes for cleanup.

NOTE: Authority cited: Sections 11755, 11835, 11839.3, and 11839.20, Health and Safety Code. Reference: Sections 11218, 11219, 11839.2, 11839.3, 11839.20, and 11875, Health and Safety Code.

2006 DRAFT

Subchapter 5. Patient Treatment
Article 4. Take-Home Medication Privileges

AMEND:

§10365. Take-Home Medication Procedures.

(a) Each program shall ensure compliance with the following procedures when granting take-home medication privileges to ~~a~~ patients ~~in maintenance treatment~~who qualify pursuant to the criteria set forth in Section 10370.

~~(a)~~(1) The medical director or program physician shall determine the quantity of take-home medication dispensed to a patient.

~~(b)~~(2) The program shall instruct each patient of his/her obligation to safeguard the take-home medication.

~~(c)~~(3) The program shall utilize containers for take-home medication doses which comply with the special packaging requirements as set forth in section 1700.14, Title 16, Code of Federal Regulations.

~~(d)~~(b) The program shall label each take-home medication dosage container indicating:

(1) The facility's name and address;

(2) The telephone number of the program;

(3) The 24-hour emergency telephone number if different from subsection (2);

(4) The name of the medication;

(5) Name of the prescribing medical director or program physician;

(6) The name of the patient;

(7) The date issued; and

(8) A warning: Poison—May Be Fatal to Adult or Child; Keep Out of Reach of Children.

(c) The program may put other information on the label provided it does not obscure the required information.

~~(e)~~(d) ~~The program should provide take-home medication in a non-sweetened liquid containing a preservative so p~~Patients ~~can~~shall be instructed to keep the take-home medication out of the reach of children~~refrigerator~~ to prevent accidental ~~overdoses~~ingestion ~~by children and fermentation of the liquid~~.

2006 DRAFT

NECESSITY: To align with federal regulations regarding take-homes and the implementation of HSC §11839.6 regarding Office-Based NTPS.

NOTE: Authority cited: Sections 11755, 11835, 11839.3, and 11839.20, Health and Safety Code. Reference: Sections 11839.2, 11839.3, 11839.20, and 11875, Health and Safety Code.

2006 DRAFT

Subchapter 5. Patient Treatment
Article 4. Take-Home Medication Privileges

AMEND:

§10370. Criteria for Determining Patient Eligibility for Take-home Medication Privileges.

(a) Self-administered take-home medication shall only be provided to ~~a~~ patients ~~if~~whom the medical director or program physician ~~has~~ determines~~d~~, in his or her clinical judgment, ~~that the patient is responsible in handling~~can responsibly handle replacement narcotic therapy medications without daily supervision. The medical director or program physician shall use the following criteria when considering granting a patient eligibility for take-home medication privileges and shall document his or her rationale in the patient's record.~~, and has documented his or her rationale in the patient's record rationale shall be based on consideration of the following criteria:~~

(1) Absence of recent use of illicit drugs and abuse of other substances, including alcohol;

(2) Regularity of program attendance ~~for replacement narcotic therapy~~ and compliance with all other treatment~~counseling~~ services;

(3) Absence of serious behavioral problems while at the program;

(4) Absence of known recent criminal activity, including the selling or distributing of ~~illicit~~ drugs;

(5) Stability of the patient's home environment and social relationships;

(6) Length of time in ~~maintenance~~ treatment;

(7) Assurance that take-home medication can be safely stored ~~within~~at the patient's home; ~~and~~

(8) ~~Whether~~Determination that the rehabilitative benefit to the patient derived from decreasing the frequency of program attendance outweighs the potential risks of diversion~~.~~;

~~(b) The medical director or program physician may place a patient on one of the six take-home medication schedules, as specified in Section 10375, only when at least the additional following criteria have been met:~~

(~~1~~9) ~~Documentation in the patient's record that the patient is p~~Participation~~g~~ in gainful employment, vocational rehabilitation training, education~~al~~, or a responsible homemaking activity, (i.e., primary care giver, retiree with household responsibilities, or volunteer helping others), ~~activity~~ and the patient's daily attendance at the program would be incompatible with such

2006 DRAFT

activity~~;~~. However, a patient who is permanently disabled or otherwise unable to participate in any of the activities listed above may, at the discretion of the medical director or program physician, be considered for take-home privilege; and,

(~~2~~10) ~~Documentation in the patient's record that t~~The current monthly body specimen collected from the patient is both negative for illicit drugs and abuse of other substances and positive for the narcotic medication administered or dispensed by the program.~~; and~~

~~(3) No other evidence in the patient's record that he or she has used illicit drugs, abused alcohol, or engaged in criminal activity within:~~

~~(A) The last 30 days for those patients being placed on step level schedules I through V, as specified in Section 10375(a)(1), (2), (3), (4) and (5); and~~

~~(B) The last year for those patients being placed on step level schedule VI, as specified in Section 10375(a)(6).~~

~~(c) Patients on a daily dose of methadone above 100 milligrams are required to attend the program at least six days per week for observed ingestion irrespective of provisions specified in Section 10375 (a)(2), (3), (4), (5) and (6), unless the program has received prior written approval from the Department.~~

~~(d)~~(b) Take-home doses of LAAM are not permitted under any circumstances, including any of the provisions for take-home medication as specified in Sections 10365, 10370, 10375, 10380, 10385, and 10400.

NECESSITY: To align with federal regulations regarding take-homes and the implementation of HSC §11839.6 regarding Office-Based NTPs.

NOTE: Authority cited: Sections 11755, 11835, 11839.3, and 11839.20, Health and Safety Code. Reference: Sections 11839.2, 11839.3, 11839.20, and 11875, Health and Safety Code.

2006 DRAFT

Subchapter 5. Patient Treatment
Article 4. Take-Home Medication Privileges

AMEND:

§10375. ~~Step Level Schedules for~~ Take-home Medication Privileges.

(a) A patient, whether in long-term detoxification or maintenance treatment, shall not be ~~placed on a~~granted take-home medication privileges~~schedule or granted a step level increase~~ until the medical director or program physician~~he or she~~ has ~~been~~ determined ~~responsible in handling narcotic medications~~that the patient has met the criteria for eligibility for take-home medication privileges as specified in Section 10370(a). ~~Each program shall adhere to the following schedules with respect to providing a patient with take-home medication privileges permitted under Section 10370(b):~~

~~(1) Step I Level--After three months of continuous maintenance treatment, the medical director or program physician may grant the patient not more than a one-day take-home supply of medication. The patient shall attend the program at least six times a week for observed ingestion.~~

~~(2) Step II Level--After six months of continuous maintenance treatment, the medical director or program physician may grant the patient not more than a two-day take-home supply of medication. The patient shall attend the program at least five times a week for observed ingestion.~~

~~(3) Step III Level--After nine months of continuous treatment, the medical director or program physician may grant the patient not more than a two-day take-home supply of medication. The patient shall attend the program at least four times a week for observed ingestion.~~

~~(4) Step IV --After one year of continuous treatment, the medical director or program physician may grant the patient not more than a two-day supply of medication. The patient shall attend the program at least three times a week for observed ingestion.~~

~~(5) Step V Level--After two years of continuous treatment, the medical director or program physician may grant the patient not more than a three-day take-home supply of medication. The patient shall attend the program at least two times a week for observed ingestion.~~

~~(6) Step VI Level--After three years of continuous treatment, the medical director or program physician may grant the patient not more than a six-day take-home supply of medication. The patient shall attend the program at least once each week for observed ingestion.~~

(b) A take-home medication dose is defined as a patient's entire daily dose of medication.

2006 DRAFT

(1) If the medical director or program physician has determined that the patient would benefit from splitting the daily dose, each split portion shall be placed in a separate take-home container.

(d) Patients in detoxification or maintenance treatment may receive a single dose of take-home medication for a day that the clinic is closed for business, including Sundays and State and Federal holidays, except for the following:

(1) Any patient in detoxification treatment who has not completed more than thirty continuous days of treatment from his or her date of admission to detoxification treatment.

(2) Any patient in detoxification or maintenance treatment who the medical director or program physician has included on a list of patients that, in his or her clinical judgment based on consideration of the criteria specified in Section 10370, cannot responsibly handle replacement narcotic therapy medications without daily supervision. This list shall be maintained with the daily reconciliation dispensing record.

(e) In addition to the provision allowed in Subdivision (d) above, replacement narcotic therapy medication may be dispensed to eligible detoxification and maintenance patients for unsupervised take-home use subject to the following restrictions:

(1) Within the first 90 days of treatment, take-home medication is limited to one dose per week.

(2) Within the second 90 days of treatment, take-home medication is limited to two doses per week.

(3) Within the third 90 days of treatment, take-home medication is limited to three doses per week.

(4) In the remaining three months of the first year of treatment, take-home medication is limited to six take-home doses per week.

(5) After one year of continuous treatment, a patient may be given a maximum 14-day supply of take-home medication.

(6) After two years of continuous treatment, a patient may be given a maximum 30-day supply of take-home medication but shall be required to attend the clinic at least once per month.

~~(b)~~(f) Nothing in this section shall prevent any program from establishing in its individual protocol any take-home medication requirement which is more stringent than is specified in ~~the schedule contained herein~~this regulation.

~~(c)~~(g) In the case of a patient who transfers to the program from another program without a break in treatment, the new medical director or program physician may consider the time the patient has spent at the former program when considering the patient's

2006 DRAFT

eligibility for take-home medication privileges~~, as well as for advancement to a new step level. But in no case shall any patient be placed, upon admission, at a step level higher than that which was occupied in the former program immediately before transferring to the new program~~.

NECESSITY: To align with federal regulations regarding take-homes and the implementation of HSC §11839.6 regarding Office-Based NTPS

NOTE: Authority cited: Sections 11755, 11835, 11839.3, and 11839.20, Health and Safety Code. Reference: Sections 11839.2, 11839.3, 11839.20, and 11875, Health and Safety Code.

2006 DRAFT

Subchapter 5. Patient Treatment
Article 4. Take-Home Medication Privileges

AMEND:

§10380. Take-home Medication Procedures for Holidays.

(a) A program that is closed for observance of any of the official State holidays specified in Subdivision (b) of this regulation may allow take-home medication privileges to patients for each State holiday subject to the following requirements~~whose maintenance treatment modality is not in operation due to the program's observance of an official State holiday, as specified in Subsection (c) of this regulation, may provide take-home medication according to the following procedures~~:

(1) Patients currently granted~~receiving~~ take-home medication privileges who are scheduled to attend the program on the holiday may be provided one ~~(1)~~ additional ~~day's supply~~take-home medication dose on the last day the patient is dosed~~of dosing~~ at the program facility before the holiday, unless the additional dose would result in the patient receiving more than a 30-day supply of take-home medication; and

(2) Patients who do not ~~receiving~~ have take-home medication privileges may be provided ~~a~~ one ~~(1) day supply~~take-home medication dose on the day before the holiday~~.~~ unless:

(A) The patient has not been in continuous detoxification treatment for at least 30 days, or

(B) The medical director or program physician has included the patient on a list of patients that, in his or her clinical judgment based on consideration of the criteria specified in Section 10370, cannot responsibly handle replacement narcotic therapy medications without daily supervision. This list shall be maintained with the daily reconciliation dispensing record for the holiday.

~~(b) A patient shall not receive a take-home medication dose for the holiday, under the provisions of Subsection (a) of this regulation and shall be continued on the same dosage schedule if:~~

~~(1) The additional dose would result in the patient receiving more than a six-day supply of medication.~~

~~(2) The additional dose would result in the patient receiving more than one take-home dose per week at a dosage level above 100 milligrams, except as provided in Section 10370(c); or~~

~~(3) The medical director or program physician has included the patient within a list of all patients that, in his or her clinical judgment, have been determined currently not responsible in handling narcotic medications, based on~~

2006 DRAFT

~~consideration of the criteria specified in Section 10370(a). This list shall be maintained with the daily reconciliation dispensing record for the holiday.~~

~~(c)~~(b) The official State holidays are:

New Year's Day	January 1
Martin Luther King Jr. ~~Birthd~~Day	Third Monday in January
~~Lincoln's Birthday~~	~~February 12~~
Washington's Birthday	Third Monday in February
Cesar Chavez Day	March 31
Memorial Day	Last Monday in May
Independence Day	July 4
Labor Day	First Monday in September
~~California Admission Day~~	~~September 9~~
~~Columbus Day~~	~~Second Monday in October~~
Veterans Day	November 11
Thanksgiving Day	Fourth Thursday in November
Christmas Day	December 25

~~(d)~~(c) With prior written approval of the Department, a program may exchange other days of special local or ethnic significance on a one-for-one basis with the holidays listed in Subsection (~~c~~b) of this regulation.

NECESSITY: To align with federal regulations regarding take-homes and the implementation of HSC §11839.6 regarding Office-Based NTPS

NOTE: Authority cited: Sections 11755, 11835, 11839.3, and 11839.20, Health and Safety Code. Reference: Sections 11839.2, 11839.3, 11839.20, and 11875, Health and Safety Code.

2006 DRAFT

Subchapter 5. Patient Treatment
Article 4. Take-Home Medication Privileges

AMEND:

§10385. Exceptions to Take-Home Medication Criteria~~. and Dosage Schedules~~.

(a) The medical director or program physician may grant an exception to the required criteria and amount of take-home medication doses allowed based on a patient's time in continuous treatment ~~dosage schedules~~ (as set forth in S~~s~~ections 10370 and 10375) for any of the following ~~reasons~~circumstances:

(1) The patient has a physical disability or chronic, acute, or terminal illness that makes daily attendance at the program a hardship. The program must verify the patient's physical disability or illness, and include medical documentation of the disability or illness in the patient's record. Notwithstanding, t~~T~~he patient shall not be given at any one time more than a ~~two-week~~14-day supply of take-home ~~supply of~~ medication.

(2) The patient has an exceptional circumstance, such as a personal or family crisis, that makes daily attendance at the program a hardship. When the patient must travel out of the program area, the program shall attempt to arrange for the patient to receive his or her medication at a program in the patient's travel area. The program shall document such attempts in the patient's record. Notwithstanding, t~~T~~he patient shall not be given at any one time~~,~~ more than a ~~one-week~~7-day supply of take-home ~~supply of~~ medication.

~~(3) The patient would benefit, as determined by the medical director or program physician, from receiving his or her medication in two split doses, with one portion dispensed as a take-home dose, when the medical director or program physician has determined that split doses would be more effective in blocking opiate abstinence symptoms that an increased dosage level.~~

(3) The patient would benefit from receiving his or her medication as a split dose when the medical director or program physician has determined that a split dose would be more effective in blocking opiate abstinence symptoms than an increased dosage level. At least one portion of the split dose shall be administered at the facility.

(b) Prior to granting an exception to Sections 10370~~(b)~~ and 10375 pursuant to Subdivision (a)(1-3) of this regulation, the medical director or program physician shall determine, based on the criteria specified in Section 10370(a) if ~~that~~ the patient can responsibly handle replacement narcotic therapy medications without supervision. ~~is responsible in handling narcotic medications as specified in Section 10370(a).~~

(c) The medical director or program physician shall document in the patient's record the granting of any exception and the facts justifying the exception.

2006 DRAFT

(d) The Department may grant additional exceptions to the take-home medication requirements contained in this ~~S~~section in the case of an emergency, or natural disaster, such as fire, flood, or earthquake.

NECESSITY: To align with federal regulations regarding take-homes and the implementation of HSC §11839.6 regarding Office-Based NTPS.

NOTE: Authority cited: Sections 11755, 11835, 11839.3, and 11839.20, Health and Safety Code. Reference: Sections 11839.2, 11839.3, 11839.20, and 11875, Health and Safety Code.

2006 DRAFT

Subchapter 5. Patient Treatment
Article 4. Take-Home Medication Privileges

AMEND:

§10390. Restricting or Revoking a Patient's Take-home Medication Privileges.

(a) The medical director or program physician shall restrict a patient's take-home medication privileges ~~by moving the patient back at least one step level on the take-home medication schedule~~ for any of the following reasons:

(1) Patients ~~on step level schedules I through V~~ who have submitted at least two consecutive monthly body specimens which have tested positive for illicit drugs and/or negative for the narcotic medication administered or dispensed by the program, unless the program physician invalidates the accuracy of the test results.

(2) Patients ~~on step level schedule VI~~ who have submitted at least two monthly body specimens within the last four consecutive months which have tested positive for illicit drugs and/or negative for the narcotic medication administered or dispensed by the program, unless the program physician invalidates the accuracy of the test results.

(3) Patients who, after receiving a supply of take-home medication, are inexcusably absent from or miss a scheduled appointment with the program without authorization from the program staff.

(4) The patient is no longer a suitable candidate for take-home medication privileges ~~as presently scheduled,~~ based on consideration of the criteria specified in Section 10370(a).

(b) Nothing in this regulation shall prevent a medical director or program physician from ~~ordering a revocation of~~revoking a patient's take-home medication privilege~~s~~ for any of the reasons specified in Subsection (a) of this regulation, or for any other reason~~s~~, including, but not limited to, the following:

(1) The patient is sharing, giving away, selling, or trading the medication administered or dispensed by the program.

(2) The patient attempts to register in another narcotic treatment program.

(3) The patient alters or attempts to alter a test or analysis for illicit drug use.

(c) The medical director or program physician shall order the restriction or revocation of a patient's take-home medication privilege within fifteen (15) days from the date the program has obtained evidence for any of the reasons identified in Subsections (a) and (b) of this regulation.

2006 DRAFT

NECESSITY: To align with federal regulations regarding take-homes and the implementation of HSC §11839.6 regarding Office-Based NTPS

NOTE: Authority cited: Sections 11755, 11839.2, 11835, 11839.3, 11839.20, and 11875, Health and Safety Code. Reference: Sections 11839.3, and 11839.20, Health and Safety Code.

2006 DRAFT

Subchapter 5. Patient Treatment
Article 4. Take-Home Medication Privileges

AMEND:

§10400. Restoring Restricted or Revoked Take-home Medication Privileges.

(a) The medical director or program physician~~, when restoring each step of~~ may restore a patient's ~~restricted~~ take-home medication privilege~~s, shall~~ if it was restricted for any of the reasons specified in Section 10390(a) after determining that the following conditions have been met:

(1) ~~Determine that t~~The patient is again deemed responsible enough ~~for~~to handle~~ing~~ narcotic medications, as based on the criteria specified in Section 10370(a).

(2) ~~Ensure that t~~The patient has completed ~~at least~~ a minimum 30-day restriction, and the most recent monthly body specimen collected from the patient is both negative for illicit drugs and positive for the narcotic medication administered or dispensed by the program. ~~when restoring the following:~~

~~(A) Step level schedules I through V which were restricted due to drug-screening test or analysis results.~~

(b) The medical director or program physician may restore a patient's take-home medication privilege if it was revoked for any of the reasons specified in Section 10390(b), after determining that the following conditions have been met:

(1) The patient is no longer committing any of the acts described in Section 10390(b), and has not committed any of those acts for a minimum of three months, and

~~(3)~~(2) ~~Ensure that at least the previous~~ The most recent three (3) consecutive monthly body specimens collected from the patient are both negative for illicit drugs and positive for the narcotic medication administered or dispensed by the program. ~~when restoring the following:~~

(3) The patient is again deemed responsible enough to handle narcotic medications, as based on the criteria specified in Section 10370(a).

~~(A) Step level schedule VI which was restricted due to drug-screening test or analysis results.~~

~~(B) Any step which was restricted due to an unexcused absence after receiving a supply of take-home medication.~~

~~(b)~~(c) This section shall not be used to circumvent the requirements of ~~s~~Section 10375. ~~No patient shall be advanced to a step level pursuant to this section unless he/she~~

2006 DRAFT

~~has previously been at such step level after having satisfied the requirements of section 10375(a).~~

(d) Nothing in this section shall prevent any program from establishing in its protocol more stringent requirements for the restoration of take-home medication privileges.

NECESSITY: To align with federal regulations regarding take-homes and the implementation of HSC §11839.6 regarding Office-Based NTPS

NOTE: Authority cited: Sections 11755, 11835, 11839.3, and 11839.20, Health and Safety Code. Reference: Sections 11839.2, 11839.3, 11839.20, and 11875, Health and Safety Code.

2006 DRAFT

Subchapter 5. Patient Treatment
Article 4. Take-Home Medication Privileges

AMEND:

§10405. Suspension of Take-home Medication Privileges by the Department.

The Department may order a program to suspend immediately all or any part of its take-home medication orders or to revoke or restrict the take-home medication privileges of any individual patient. Departmental s~~S~~uspension of a program's take-home medication authority may occur ~~only~~ when ~~a~~the program fails to comply with any applicable regulation or statute regarding treatment requirements, medication handling, security of medications, or take-home medication procedures.

NECESSITY: To align with federal regulations regarding take-homes and the implementation of HSC §11839.6 regarding Office-Based NTPS

NOTE: Authority cited: Sections 11755, 11835, 11839.3, and 11839.20, Health and Safety Code. Reference: Sections 11839.2, 11839.3, 11839.20, and 11875, Health and Safety Code.

2006 DRAFT