TITLE 9. Rehabilitative And Developmental Services
Division 4. Department of Alcohol and Drug Programs
Chapter 4. Narcotic Treatment Programs
Subchapter 1. General Administration

§10000. Definitions.

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

(1) Amendment. “Amendment” means written changes in the protocol.

(2) 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.

(3) FDA. “FDA” means the United States Food and Drug Administration.

(4) 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) 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) 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) 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.

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

(9) Medication. “Medication” means any opiate agonist medications that have been approved for use in replacement narcotic therapy, including:

(A) Methadone, and

(B) Levoalphacetylmethadol (LAAM)

(10) 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) 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.

(12) 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) Narcotic Treatment Program. “Narcotic treatment program” means any opiate addiction treatment modality, whether inpatient or outpatient, which offers replacement narcotic therapy in maintenance, detoxification, or other services in conjunction with that replacement narcotic therapy.

(14) “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.).

(15) Opiate Addiction. “Opiate Addiction,” and the related term “addiction to opiates,” mean a condition characterized by compulsion and lack of control that lead 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) 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 that occurs when the drug is abruptly discontinued.

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

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

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

(20) 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 be the program director or medical director.

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

(23) 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.

(24) 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 that help them become productive, independent members of society; and will include:

(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 are evaluated through ongoing supervision; and

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

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), Health and Safety Code.

TITLE 9. Rehabilitative And Developmental Services
Division 4. Department of Alcohol and Drug Programs
Chapter 4. Narcotic Treatment Programs
Subchapter 2. Licensure of Narcotic Treatment Programs.
Article 1. Program Licensure

§10010. License Requirement.

All narcotic treatment programs operating in the State of California shall be licensed by the Department of Alcohol and Drug Programs in accordance with the provisions of this article.

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.

§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.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11217, 11839.2, 11839.3 and 11839.5, Health and Safety Code.

§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 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.

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.

§10025. Place to Obtain Forms and Submit Protocols.

All Department forms for narcotic treatment programs may be obtained from, and completed protocols and other forms shall be sent to:

Department of Alcohol and Drug Programs
1700 K Street
Sacramento, CA 95814

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

§10030. Protocol for Proposed Programs.

(a) The program sponsor shall submit or cause to be submitted on its behalf to the Department a written protocol which shall serve as an application for licensure by the Department. The protocol shall include, but not be shall not be limited to, the following information:

(1) Plan of operation.

(2) A description of the geographical area to be served by the program.

(3) Population and area to be served.

(4) The estimated number of persons in the described area having an addiction to opiates and an explanation of the basis of such estimate.

(5) The estimated number of persons in the described area having an addiction to opiates that are presently in a narcotic treatment program and other treatment programs.

(6) The number of patients in regular treatment, projected rate of intake, and factors controlling projected intake.

(7) Program goals.

(8) Research goals.

(9) Plan for evaluation.
(10) County Drug Program Administrator's certification.
(11) Letters of community support.
(12) Patient identification system.
(13) Control and security of identification cards.
(14) System to prevent patient's multiple program registration.
(15) Organizational responsibility.
(16) Persons responsible for program.
(17) First-year budget, listing available, pending, or projected funds. Copies of letters verifying funding shall also be submitted with the protocol. Subsequent years' budgets may be submitted as amendments to the original, approved protocol.
(18) Schedule of patient fees.
(19) Duties and responsibilities of each staff member and the relationship between the staffing pattern and the treatment goals.
(20) Each staff member's profile and resume of educational and professional experience.
(21) Duties and responsibilities of the medical director.
(22) Plan for delegation of the medical director's duties, if appropriate.
(23) Training and experience of counselors.
(24) Counselor caseload.
(25) Procedures and criteria for patient selection.
(26) Program rules and instructions.
(27) Facility description.
(28) Initial, medically determined dosage levels.
(29) Decreasing, medically determined dosage levels for patients in detoxification treatment and stable, medically determined dosage levels for patients in maintenance treatment.
(30) Operational procedures.
(31) Procedures, which provide for cooperation with local jails for either detoxification or maintenance treatment while in custody, in the event of patient hospitalization or incarceration.
(32) Procedures in the event of emergency or disaster.
(33) Testing or analysis procedures for illicit drug use which utilize random selection or unannounced collection.
(34) Procedures for scheduled termination, voluntary termination, and involuntary termination for cause, including reasons for termination for cause.
(35) Fair hearings.
(36) Copies of all forms developed and to be used by the proposed program.
(37) Facility address and dimensions.
(38) Amount of space devoted to narcotic treatment, including waiting, counseling, dispensing, and storage areas.
(39) Days and hours of medication program dispensing.
(40) Days and hours for other narcotic treatment program services.
(41) Type of services provided and the hours of use, if the facility is also used for purposes other than a narcotic treatment program.
(42) Diagram of the facility housing the narcotic treatment program and an accompanying narrative which describes patient flow. The diagram and narrative shall specify:
(A) Waiting areas.
(B) Office space.

(C) Medication administration area.

(D) Patient body specimen collection locations for testing or analysis of samples for illicit drug use.

(E) Record storage area.

(F) Parking or transportation access.

(G) The relation of the narcotic treatment program to the total facility.

(b) There shall be attached to the protocol a letter of cooperation from each agency which the protocol indicates will provide services or financial support to the program. Such letters shall be listed in the text of the protocol.

(c) A protocol proposing a new program or a complete revision of the protocol of an approved and licensed program shall be submitted to the Department on a form furnished by the Department.

(d) A protocol shall be current, detailed, specific, and complete to permit evaluation by the Department and to provide a basis for compliance inspections or surveys.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11215, 11217, 11839.2, 11839.3, 11839.20 and 11839.22, Health and Safety Code.

§10035. Protocol Amendments and Changes.

(a) The following changes in a program's protocol require the prior approval of the Department and shall be submitted to the Department as an amendment to the protocol:

(1) Any change of location of the program, or of any portion of the program, including any dispensing facility or other unit.

(2) Any change in the number of authorized patients or facilities.

(3) Any reduction or termination of services.

(4) Any change in program sponsor.

(b) All other significant changes in the protocol shall be reported to the Department in writing within 30 days after the date such change becomes effective.

(c) Each proposed amendment shall be accompanied by a written statement of the estimated impact of the proposed amendment or significant change upon the population and area served, funding and budget, staff, and facilities, and upon any other portion of the approved protocol affected by the proposed amendment or significant change. The effective date of implementation of the proposed amendment or significant change shall be included. Amendments or significant changes shall consist of a series of dated page revisions for insertion into the approved protocol.

(d) An amendment proposing multiple locations for administering medications shall contain a description of safeguards to prevent multiple administering to one patient from different facilities, a description of the security arrangements to be used in the transfer of medications to and from facilities, and a description of security arrangements to be used at the administering facility.

(e) An amendment proposing an increase in the licensed capacity for detoxification or maintenance treatment at a program shall be subject to the Department's determination that the program is currently in compliance with applicable state and federal laws and regulations.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11215, 11217, 11839.2, 11839.3 and 11839.22, Health and Safety Code.

§10040. Certification by County Drug Program Administrator.

(a) A completed, original protocol shall be filed with the County Drug Program Administrator, as the narcotic treatment program's application for original licensure.

(b) There shall be attached to the protocol a certification from the County Drug Program Administrator which shall include:

(1) A certification of need for the proposed narcotic treatment program services.

(2) A certification that all local ordinances, fire regulations, and local planning agency requirements have been complied with.

(3) A recommendation for program licensure.

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

§10045. Approval of License Application.

(a) The Department may license a program if such program is determined by the Department to have submitted a satisfactory protocol and to be able to conform to all applicable statutory requirements and regulations, and has demonstrated need and support of the County Drug Program Administrator.

(b) The Department shall notify the applicant, in writing, within 45 days of receipt of the application whether such application is either:

(1) Complete, and accepted for filing; or

(2) Incomplete, and the licensing process shall cease unless and until the applicant provides the specific material outlined in the notification.

(c) The Department shall either approve or disapprove, in writing, an application for licensure of a narcotic treatment program within 45 days after filing of a completed application.

(d) The Department shall process applications in a timely manner, consistent with the Department's responsibility to protect the health and safety of the patient and the public. As of April 1, 1983, the Department's experience in processing an application from initial submission of the application to the final determination is as follows:

(1) median time is 96 days.

(2) minimum time is 27 days.

(3) maximum time is 388 days.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code; and Section 15376, Government Code. Reference: Sections 11839.3, 11839.5 and 11839.19, Health and Safety Code; and Section 15376, Government Code.

§10050. Commencing Program Operation.

(a) Each program licensed by the Department shall become operational within six months after the date of licensure. Programs which fail to meet this time limit may reapply for a license by submitting to the Department a letter of explanation or a new protocol.

(b) Each program shall notify the Department in advance of the date the program plans to begin its operations. Each program shall also notify the Department of the date such operations actually commence.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.3, 11839.5, 11839.7 and 11839.19, Health and Safety Code.

§10055. Period of Licensure and Annual License Renewal.

(a) Narcotic treatment programs shall not be licensed for more than one year.

(b) The Department shall renew a program's license annually if:

(1) The Department determines that the program is in satisfactory compliance with the requirements of article 1, chapter 10, part 2, division 10.5, of the Health and Safety Code, and this article.

(2) The County Drug Program Administrator submits to the Department:

(A) A certification of need for continued services of the narcotic treatment program.

(B) A recommendation for renewal of the license.

(c) Within 30 days of receipt of a renewal application, the Department shall notify the licensee, in writing, whether the application is:

(1) Complete, and the renewal licensing process shall continue; or

(2) Incomplete, and specified materials must be submitted to complete the application.

(d) Within 60 days of receipt of a completed renewal application the Department shall either relicense the program or deny licensure.

(e) As of April 1, 1983, the Department's experience in processing a renewal application from initial submission of the application to the final determination is as follows:

(1) Median time is 60 days.

(2) Minimum time is 5 days.

(3) Maximum time is 90 days.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Section 15376, Government Code; and Sections 11839.3, 11839.5 and 11839.19, Health and Safety Code.

§ 10056. License Fees.

(a) The Department shall assess a license fee to cover the cost of licensing narcotic treatment programs required to pay a licensing fee pursuant to Section 11839.7 of the Health and Safety Code.

As used in this regulation, “license fee” means:

(1) A fee for initial application for licensure (including licensure of components such as medication units); and

(2) An annual license fee, which shall include:

(A) A base annual license fee;

(B) A patient slot fee, based on the narcotic treatment program's authorized patient capacity; and

(3) A relocation fee, to be paid when the narcotic treatment program requests approval to move to another location, pursuant to Section 10035.

(b) The Department calculated license fees for FY 2006-2007 by multiplying the prior year's (FY 2004-2005) license fees by the annual increase (3.3%) in the Consumer Price Index (CPI), as published by the California Department of Finance and adding that amount to the prior year's fees.

License fees for fiscal year 2006-07 are shown below:

Type of License Fee	Prior Year License Fees	Percent of Increase (based on CPI)	New License Fees for FY 2006-2007	Number of Estimated Transactions for FY 2006-2007 (based on FY 2004-2005 actual)	Total Statewide License Fees for FY 2006-2007
Initial Application for Licensure Fee	$ 3,100	3.3%	$ 3,202	5 applications	$ 16,010
Base Annual Fee	$ 861	3.3%	$ 889	134 private NTPs	$ 119,126
Patient Slot Fee	$ 27	3.3%	$ 28	36,287 total patient slots	$ 1,016,036
Program Relocation Fee	$ 1,100	3.3%	$ 1,136	1 relocation	$ 1,136
Total Statewide License Fees – All Categories					$1,152,308
Cost of Licensing Narcotic Treatment Programs					$1,889,000

(c) For future years the Department shall calculate license fees by multiplying the prior year's license fees by the most recent annual increase in the Consumer Price Index and adding that amount to the prior year's fees.

For example, if the most recent CPI were four percent (4%) and costs were $1,889,000, license fees for the future fiscal year would be as shown below:

Type of License Fee	Prior Year License Fees	Percent of Increase (4% CPI	New License Fees for Future Fiscal Year	Number of Estimated Transactions	Total Statewide License Fees for Future Fiscal Year
Initial Application for Licensure Fee	$ 3,202	4%	$ 3,330	5 applications	$ 16,650
Base Annual Fee	$ 889	4%	$ 925	134 private NTPs	$ 123,950
Patient Slot Fee	$ 28	4%	$ 29	36,287 total patient slots	$ 1,052,323
Program Relocation Fee	$ 1,136	4%	$ 1,181	1 relocation	$ 1,181
Total Statewide License Fees – All Categories					$1,194,104
Cost of Licensing Narcotic Treatment Programs					$1,889,000

(d) No later than April 30 of each year, the Department shall calculate the annual license fee for the future fiscal year (July 1st through June 30th)

(e) No later than April 30 of each year, following the effective date of this regulation, the Department shall give written notice to narcotic treatment program licensees of the license fees for the future fiscal year and the manner in which they were calculated, including data used in making the calculation.

(f) Applicants for initial licensure or relocation shall include the required fee with their application for licensure or relocation.

(1) The Department shall terminate review of the application if the applicant fails to include the required fee.

(2) The Department shall not refund the fee if the Department denies the application.

(3) Upon approval of the application for initial licensure, the Department shall send the licensee an invoice stating the amount of the prorated base annual license fee and the slot fees due for the remainder of the fiscal year.

(g) In August of each year the Department shall send license renewal invoices to all licensees, stating the amount of the base annual license fee and slot fees due for the fiscal year.

(h) The licensee may pay annual license fees once annually or quarterly in arrears.

(1) If the licensee pays the total annual license fees once annually, he/she shall submit the amount of the total annual license fees in time to be received by the Department by September 30th of the same year.

(2) If the licensee pays the annual license fees quarterly in arrears, he/she shall submit one quarter of the total annual license fees in time to be received by the Department by September 30th, December 31st, March 31st, and May 31st of the same fiscal year.

(3) If the licensee fails to timely submit the annual license fees in accordance with the requirements of this subsection, the Department shall issue a written notice of deficiency within seven (7) calendar days of the date payment was due. The notice of deficiency shall:

(A) Notify the licensee that he/she has failed to pay license fees in accordance with the requirements of this regulation;

(B) Specify the amount of the license fees due;

(C) State the date by which the license fees were due;

(D) Notify the licensee that his/her license shall not be renewed unless all license fees have been paid by May 31st of the same fiscal year;

(E) Notify the licensee that the Department shall assess a civil penalty in the amount of $100 per day for each day from the date the license fees were due until the date the licensee pays the license fees; and

(F) Notify the licensee that he/she may appeal civil penalties in accordance with Section 10057.

(4) If the Department fails to issue a written notice of deficiency within seven (7) calendar days, the Department shall not assess the civil penalty until the date of the notice. Failure to issue a written notice of deficiency within seven (7) calendar days shall not relieve the licensee of his/her obligation to pay license fees and shall not entitle the licensee to renewal of his/her license.

NOTE: Authority cited: Sections 11755, 11835, 11839.3, and 11839.20, Health and Safety Code. Reference: Sections 11839.3 and 11839.7, Health and Safety Code.

§ 10057. Administrative Review of Licensing Actions.

(a) "Licensing action" means any administrative action taken by the Department which would adversely affect the license of a Narcotic Treatment Program (NTP), including, but not limited to:

(1) Denial of an application for a license;

(2) Denial of a request for renewal or relocation;

(3) Assessment of a civil penalty; or

(4) Suspension or revocation of a license.

(b) Applicants and licensees may appeal a notice of licensing action by submitting a written request for administrative review to: Director, Department of Alcohol and Drug Programs, 1700 K Street, Sacramento, CA 95814.

(1) The request for administrative review shall be received by the Department no later than 15 calendar days from the date of service of the notice of licensing action. The request for administrative review shall:

(A) Identify the statute(s) or regulation(s) at issue and the legal basis for the applicant's or licensee's appeal;

(B) State the facts supporting the applicant's or licensee's position; and

(C) State whether the applicant or licensee waives an informal conference and requests to proceed with an administrative hearing conducted pursuant to Chapter 5 (commencing with Section 11500) of Part 1, Division 3, Title 2 of the Government Code.

(2) Failure to submit a written request for administrative review pursuant to this subsection shall be deemed a waiver of administrative hearing and the licensing action shall be final.

(c) The first level of review for a licensing action shall be an informal conference. The Department need not conduct the informal conference in the manner of a judicial hearing pursuant to the Administrative Procedure Act (Chapter 5 (commencing with Section 11500), Part 1, Division 3, Title 2 of the Government Code). The Department need not conduct the informal conference according to the technical rules relating to evidence and witnesses.

(1) Within 15 calendar days of receipt of the request for administrative review, the Deputy Director in charge of the Licensing and Certification Division or the Deputy Director's designee shall schedule an informal conference with the applicant or licensee, and the informal conference shall be held within 45 working days of receipt of the request for administrative review, unless:

(A) The Department and the applicant or licensee agree to settle the matter; or

(B) The applicant or licensee waives the15– or 45–day requirements for setting and holding the informal conference; or

(C) The applicant or licensee, waives the informal conference; or

(D) The Department or the applicant or licensee provides to the other party written substantiation of the cause for a delay.

(3) Failure of the applicant or licensee to appear at the informal conference constitutes a withdrawal of the appeal and the licensing action shall be
final, unless the informal conference is waived in writing pursuant to (c)(1)(B) or (C).

(4) The representative(s) of the Department who issued the notice of licensing action may attend the informal conference and present oral or written information in substantiation of the alleged violation or the Department's position may be presented in the notice of licensing action.

(5) At the informal conference the applicant or licensee shall have the right to:

(A) Representation by legal counsel.
(B) Present oral and written information.
(C) Explain any mitigating circumstances.

(6) No party to the action shall have the right to discovery at the informal conference. However, witness(es) shall be allowed to attend and present testimony under oath.

(7) Either party may record the proceedings of the informal conference on audio tape.

(8) At the applicant or licensee's request, the informal conference may be held in person, at a location specified by the Department, by telephone, by submission of the applicant or licensee's written position statement, or in any other manner agreed to by both parties.

(d) No later than 15 calendar days from the date of the informal conference, the Department shall mail the decision to affirm, modify, or dismiss the notice of licensing action to the applicant or licensee.

(1) The decision shall give notice to the applicant or licensee of his/her right to an administrative hearing and the time period in which to make such a request.

(2) A copy of the decision shall be transmitted to each party.

(e) The second level of review for a licensing action shall be an administrative hearing conducted pursuant to Chapter 5 (commencing with Section 11500), Part 1, Division 3, Title 2 of the Government Code.

(1) An applicant or licensee may request an administrative hearing only if:

(A) The applicant or licensee waives the informal conference and requests an administrative hearing pursuant to the provisions set forth in subsection (b) of this regulation, or

(B) The applicant or licensee timely requests an administrative hearing as specified in subsection (e)(2)(A) of this regulation.

(2) The applicant or licensee may request an administrative hearing by submitting a request in writing to: Director, Department of Alcohol and Drug Programs, 1700 K Street, Sacramento, CA 95814.

(A) The request for administrative hearing shall be received by the Department no later than 15 calendar days from the date of service of the:

1. Decision of the informal conference or
2. Notice of licensing action if the applicant or licensee waives the informal conference.

(B) Failure of the applicant or licensee to request an administrative hearing pursuant to subsection (e)(2)(A) of this regulation shall be a waiver of the right to a hearing and the licensing action shall be final.

(3) Upon receipt of the request for administrative hearing, the Department shall issue an Accusation or Statement of Issues and request that the matter be set for hearing.

(f) A licensing action shall be final when:

(1) The applicant or licensee fails to appeal the licensing action in a timely manner, pursuant to subsections (b) and (e) of this regulation; or

(2) A final determination is made in accordance with Section 11517 of the Government Code; or

(3) The parties have agreed in writing to a resolution of the matter.

(g) In the event an applicant or licensee appeals the Department's assessment of a civil penalty, collection of any civil penalty shall be stayed until the final action on the licensing appeal. When the licensing action is final, the applicant or licensee shall pay all civil penalties to the Department within 60 calendar days of receipt of mailing of final adjudication. The civil penalties shall bear interest at the legal rate of interest from the date of notice of final

adjudication until paid in full. Failure to pay the civil penalty and accrued interest within 60 calendar days of the notice of final adjudication shall result in one or more of the following sanctions:

(1) Denial of an application for a license;
(2) Denial of an application for renewal of a license;
(3) Suspension or revocation of a license.

NOTE: Authority cited: Sections 11755, 11835, 11839.3, and 11839.20, Health and Safety Code. Reference: Section 11839.3 and 11839.12, Health and Safety Code; and Chapter 5 (commencing with Section 11500), Part 1, Division 3, Title 2, Government Code.

TITLE 9. Rehabilitative And Developmental Services
Division 4. Department of Alcohol and Drug Programs
Chapter 4. Narcotic Treatment Programs
Subchapter 2. Licensure of Narcotic Treatment Programs.
Article 2. Program Evaluation.

§10060. Departmental Study and Evaluation of Programs.

The Department may study and evaluate all programs on an ongoing basis to determine the effectiveness of each program's effort to aid patients in altering their life styles and eventually to eliminate their opiate addiction. Each program shall furnish to the Department information and reports the Department may request to facilitate such study and evaluation.

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

§10065. Factors to Be Included in Evaluation of Programs.

(a) Each program shall measure progress by comparing before and after treatment changes including, but not limited to:

(1) Adherence to program rules.
(2) Illicit drug use.
(3) Other drug use including alcohol, prescribed medications, and over-the-counter medications used in accordance with related instructions.
(4) Employment status.
(5) Criminal activity.
(6) The continued active participation in ongoing treatment by patients no longer receiving replacement narcotic therapy.

(b) Such comparisons shall be made for each type of treatment or treatment combination that is to be evaluated.

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

§10070. Program Evaluation Procedures.

(a) Each program shall submit in its protocol a plan for evaluating the effectiveness of the program which:

(1) States realistic and clearly defined objectives.

(2) Shall outline in detail the methodology to be employed.

(3) Specifies all data to be collected.

(b) Each program shall insure that the necessary information is collected and recorded in a uniform manner before initiation of treatment and at predetermined intervals during and after termination of treatment.

(c) Each program shall verify required information supplied by the patient, when it is possible to do so.

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

§10080. Inspections.

(a) Each program shall be subject to inspection not less than annually by the Department or its authorized representatives with or without prior notice. Inspections may include:

(1) An examination of all records of the program which pertain to patient care and program management.

(2) Observation of the program's treatment procedures, interviews with staff and voluntary interviews with patients.

(3) Any other aspect of the program which is subject to Department regulations and upon which the Department's licensure is based.

(b) When possible, all inspections shall take place in such a way as not to interfere with delivery of treatment services.

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

§10085. Site Visits.

(a) The Department shall conduct site visits:

(1) Prior to the licensure of new programs.

(2) Prior to the approval of program facility relocation.

(3) At least annually and in such other cases as the Department deems necessary or desirable.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Section 11839.3 and 11839.7, Health and Safety Code.

TITLE 9. Rehabilitative And Developmental Services
Division 4. Department of Alcohol and Drug Programs
Chapter 4. Narcotic Treatment Programs
Subchapter 2. Licensure of Narcotic Treatment Programs.
Article 3. Corrective Action

§10090. Revocation of Program License.

The Department may revoke the license of any program which fails to comply with any statutory requirement or regulation of the Department.
NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.3, 11839.5, 11839.7 and 11839.19, Health and Safety Code.

TITLE 9. Rehabilitative And Developmental Services
Division 4. Department of Alcohol and Drug Programs
Chapter 4. Narcotic Treatment Programs
Subchapter 3. Program Administration
Article 1. Organizational Structure of Program and Staffing Requirements

§10095. Program Administration.

The protocol shall contain detailed information about the person(s), association(s), or other organization(s) administering or sponsoring the program. For profit making entities this shall include the owners' names, titles, addresses, telephone numbers, and percentages of ownership. For non-profit entities this shall include the board of directors' names, titles, addresses, and telephone numbers. The Department may require supplemental documentation demonstrating organizational stability and responsibility as it relates to continuity of program operation, including a description and documentation of the type of legal entity which administers or sponsors the program.

(a) Program Sponsors.

(1) The program shall submit to the Department the name of the program sponsor and any other individuals responsible to the Department or other governmental agencies for the operations of the program.

(2) The program sponsor or an authorized representative, if the program sponsor is other than an individual, shall sign the protocol.

(b) Guarantors of Continuity of Maintenance Treatment.

(1) Programs offering maintenance treatment shall provide a guarantee that program operation will continue at the license program location for up to 90 days following receipt by the Department of the program's notice of intent to close the program.

(2) The Department may require the program to provide a guarantor who will guarantee, in writing, the continued operation of the program as required by this section.

(c) Change of Entity.

The program's protocol shall be amended in the event of a change of the public or private entity responsible for administering or funding the program. The amendment shall contain a plan which ensures continuity of patient care.

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

§10105. Program Director.

Each program shall have a program director who shall be responsible for:
(a) Submitting protocols, protocol amendments, and reports to the Department.
(b) Operating the program.
(c) Integrating staff services as described in the program protocol.
(d) Complying with all regulations and responsibility for compliance and adjustments after inspections by the Department.
(e) Training and supervising of all staff.
(f) Notifying all patients of their obligations to safeguard take-home medications.
(g) Security of both medications and patient records.

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.

§10110. Medical Director.

(a) Each program shall have a medical director who is a licensed physician in the State of California. The medical director may also serve as the program director. The medical director shall assume the medical responsibility for all program patients by:
(1) Signing patient record notes.
(2) Placing patients in treatment.
(3) Initiating, altering and terminating replacement narcotic therapy medications and dosage amounts.
(4) Supervising the administration and dispensing of medications.
(5) Planning and supervising provision of treatment including regular review and notes in the patients' records.
(b) Other duties and responsibilities of the medical director shall be set forth in the protocol.
(c) The medical director may delegate duties as prescribed in the program protocol to another licensed program physician(s) but may not delegate his/her responsibility in (a) above to physician extenders.

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.

§10115. Program Physicians.

A program physician may delegate his/her duties under this subchapter to other appropriately licensed personnel who are members of the program staff. The nature and extent of such delegation of duties shall be set forth in the protocol.

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.

§10120. Physician Extenders.

(a) The term “physician extender” refers to registered nurse practitioners and physicians' assistants only.

(b) The protocol shall contain documentation satisfactory to the Department verifying that:

(1) Nurse practitioners are used as physician extenders in compliance with the licensing and scope of practice requirements listed in article 8 (commencing with section 2834), chapter 6, division 2, of the Business and Professions Code and corresponding regulations adopted by the Board of Registered Nurses, and

(2) Physicians' assistants are used as physician extenders in compliance with the licensing and scope of practice requirements listed in chapter 7.7 (commencing with section 3500), division 2, of the Business and Professions Code and corresponding regulations adopted by the Medical Board of California.

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.

§10125. Counselors.

(a) Counselors **may be** nurses, psychologists, social workers, psychiatric technicians, trained counselors, or others **as long as they have training or experience** in treating persons with an opiate addiction.

(b) Program staff who provide counseling services (as defined in Section 13005) shall be licensed, certified, or registered to obtain certification or licensure pursuant to Chapter 8 (commencing with Section 13000).

(c) Program staff who provide counseling services (as defined in Section 13005) shall comply with the code of conduct, pursuant to Section 13060, developed by the organization or entity by which they were registered, licensed, or certified.

(d) The licensee shall maintain personnel records for all staff containing:

(1) Name, address, telephone number, position, duties, and date of employment; and

(2) Resumes, applications, and/or transcripts documenting work experience and/or education used to meet the requirements of this regulation.

(3) Personnel records for staff who provide counseling services (as defined in Section 13005) shall also contain:

(A) Written documentation of licensure, certification, or registration to obtain certification pursuant to Chapter 8 (commencing with Section 13000); and

(B) A copy of the code of conduct of the registrant's or certified AOD counselor's certifying organization pursuant to Section 13060.

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.

§10130. Staff Member Profile.

(a) For each program director and medical director, the following information shall be submitted to the Department by the program sponsor:

(1) Professional or license status or vocational aptitude.

(2) Hours that the staff member will provide to the program.

(3) **Resume** showing professional education and practical experience, and training or experience in treating persons with an opiate addiction.

(4) The procedure for replacement of such staff member in the event of death, retirement, or prolonged sickness.

(5) The procedure to assure that appropriate staff time will be provided to the program in the event of short-term emergency, vacation, or sickness.

(b) For each physician (other than the medical director), nurse practitioner, physician's assistant, registered nurse, licensed vocational nurse, psychiatric technician, counselor, and pharmacist participating in the program, the information required in subsections (a)(1), (2), (3), (4), and (5) above **shall be on file** at the program facility and available for the Department's review.

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.

§10140. Staff Training.

Each program shall inform staff members of the purpose of testing or analysis for illicit drug use, the meaning of the results, and the importance of reliable procedures and reports.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.3, 11839.20 and 11839.21, Health and Safety Code.

TITLE 9. Rehabilitative And Developmental Services
Division 4. Department of Alcohol and Drug Programs
Chapter 4. Narcotic Treatment Programs
Subchapter 3. Program Administration
Article 2. Patient Capacity and Caseload

§10145. Licensed Patient Capacity.

(a) A single program shall be licensed to provide treatment services to a maximum of 750 patients.

(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., detoxification and maintenance), 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.

(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.

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

§10150. Counseling Caseloads.

(a) Each patient shall be assigned to a counselor.

(b) Patient caseloads may vary according to the particular problems of patients and the amount of supportive services used.

(c) The protocol shall set forth the patient caseload per counselor.

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.

TITLE 9. Rehabilitative And Developmental Services
Division 4. Department of Alcohol and Drug Programs
Chapter 4. Narcotic Treatment Programs
Subchapter 3. Program Administration
Article 3. Patient Records

§10155. Confidentiality of Patient Records.

(a) All information and records obtained in the course of providing services to patients in a program shall be subject to the confidentiality and disclosure provisions contained in article 7 (commencing with section 5325), chapter 2, part 1, division 5, Welfare and Institutions Code and Title 42 (commencing with section 2.1), Code of Federal Regulations.

Each program and the Department, and all officers and employees of each program or of the Department, shall keep strictly confidential all information, records, and any individual patient data which may be obtained or compiled in the operation of a system to detect multiple registration and shall be subject to the confidentiality and disclosure provisions contained in article 7 (commencing with section 5325) chapter 2, part 1, division 5, Welfare and Institutions Code.

(b) Each program **shall train** all staff members in the confidentiality requirements of subsection (a) of this section.

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

§10160. Procedures for Patient Records.

(a) Programs shall assign consecutive numbers to patients as admitted, and shall maintain an individual record for each patient.

(1) Programs shall keep patient records in a secure location within the facility.

(b) If the program keeps a separate record of the type and amount of medication administered or dispensed to a patient on a day-to-day basis, the program shall transfer this data to the patient's record at least monthly.

(c) Each program shall submit a sample patient record to the Department with its protocol.

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.

§10165. Content of Patient Records.

(a) Each program shall document the following information in the individual patient's records:

(1) The patient's birth date.

(2) Physical examination data, including laboratory results for required tests and analyses.

(3) Evidence of current use of heroin or other opiates.

(4) Date of admission to the program, plan of treatment, and medication orders signed by the physician.

(5) The program's response to a test or analysis for illicit drug use which discloses the absence of both methadone and its primary metabolite (when prescribed by the medical director and program physician), the presence of any illicit drugs, or abuse of other substances, including alcohol.

(6) Incidence of arrest and conviction or any other signs of retrogression.

(7) Any other patient information which the program finds useful in treating the patient.

(b) In addition to the requirements set forth in (a) above, records for patients in detoxification shall contain the following:

(1) Documentation of services and treatment provided, as well as progress notes signed by the physician, nurse, or counselor, test or analysis results for illicit drug use; and periodic review or evaluation by the medical director.

(2) For patients who have completed the program, a discharge summary and follow-up notations to allow determination of success or failure of treatment and follow-up.

(c) In addition to the requirements set forth in (a) above, for patients in maintenance treatment records shall contain the following:

(1) Documentation of prior addiction and prior treatment failure.

(2) Documentation of services and treatment provided, as well as progress notes, signed by the physician, nurse, or counselor; test or analysis results for illicit drug use and periodic review or evaluation by the medical director. Such review shall be made not less than annually.

(3) For any patient who is to be continued on maintenance treatment beyond two years, the circumstances justifying such continued treatment as set forth in section 10410.

(4) Reasons for changes in dosage of levels and medications.

(5) For patients who have terminated the program, a discharge summary and follow-up notations to allow determination of success or failure of treatment.

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.

TITLE 9. Rehabilitative And Developmental Services
Division 4. Department of Alcohol and Drug Programs
Chapter 4. Narcotic Treatment Programs
Subchapter 3. Program Administration
Article 4. Program Rules and Procedures

§10170. Program Rules and Instructions.

(a) Each program shall develop a set of written rules and instructions which shall be provided to all patients receiving services and to applicants for services prior to the program accepting the applicant as a patient.

(b) Rules and instructions shall include but not be limited to:

(1) Requirements for take-home medication privileges.

(2) Patient body specimen collection requirements for testing or analysis for illicit drug use.

(3) Fees.

(4) Grounds for involuntary termination.

(5) Fair hearing procedures.

(6) Patient rights.

(7) Program hours.

(8) Provision for emergencies.

(9) Other rules and procedures directly affecting the patient.

(c) Provisions shall be made for patients' acknowledgement of having been provided a copy of the program rules and instructions.

(d) The rules and instructions shall be included in the program protocol.

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.

§10175. Program Procedure Manual.

(a) Each program shall have a current procedure manual.

(1) The protocol which is approved by the Department may serve as the working procedure manual.

(2) Each program may adopt a separate procedure manual.

(b) The procedure manual shall set forth detailed information about all facets of program operation.

(c) Each treatment staff member **shall be familiar** with the provisions of the program's protocol and procedure manual.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11215, 11217, 11839.3, 11839.20, 11839.22 and 11845.5, Health and Safety Code.

§10185. Procedures in the Event of a Patient's Hospitalization.

(a) If the program is aware that a patient has been hospitalized, the program physician shall attempt to cooperate with the attending physician and the hospital staff in order for the hospital to continue a patient's replacement narcotic therapy.

(b) The patient's record shall contain documentation of:

(1) The program physician's coordination efforts with the attending physician and the hospital staff; and

(2) The date(s) of hospitalization, reason(s), and circumstances involved.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11215, 11839.2, 11839.3, 11839.20 and 11875, Health and Safety Code.

§10190. Procedures in the Event of a Patient's Incarceration.

(a) If the program is aware that a patient has been incarcerated, the program physician shall attempt to cooperate with the jail's medical officer in order to ensure the necessary treatment for opiate withdrawal symptoms, whenever it is possible to do so.

(b) The patient's record shall contain documentation of:

(1) The program physician's coordination efforts with the jail; and

(2) The date(s) of incarceration, reason(s), and circumstances involved.

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

§10195. Report of Patient Death.

(a) The program shall notify the Department within one (1) working day if:
(1) A patient of the program dies at the program site; or
(2) Ingestion of the medication used in replacement narcotic therapy may have been the cause of the patient's death.
(b) For all other patient deaths the program shall submit to the Department, within 90 calendar days from the date of the death, the following:
(1) A death report which is signed and dated by the medical director to signify concurrence with the findings; and
(2) Any other documentation of the death.

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

TITLE 9. Rehabilitative And Developmental Services
Division 4. Department of Alcohol and Drug Programs
Chapter 4. Narcotic Treatment Programs
Subchapter 4. Medication Security and Diversion Prevention
Article 1. Detection of Multiple Registration

§10205. Prohibition Against Multiple Registration.

(a) Except as specified in Subsection (b) of this regulation, narcotic treatment programs shall not accept a patient for treatment if the patient is registered in another narcotic treatment program at the same time.
(b) Programs may provide replacement narcotic therapy to short term (less than 30 days) visiting patients approved to receive services on a temporary basis, in accordance with Section 10295, so long as the program complies with the requirements of Section 10210(d).

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Section 11839.22, Health and Safety Code.

§10210. Detection of Multiple Registration at Time of Application for Admission.

(a) Before a program admits a patient for treatment, the program shall:
(1) Notify the patient that it cannot provide replacement narcotic therapy to a patient who is simultaneously receiving this therapy from another program.
(2) Require the patient to sign a written statement documenting whether he/she is currently receiving replacement narcotic therapy from another program and retain the

statement in the patient record. If the patient refuses to sign this statement, the program shall not admit the patient for treatment.

(3) Require the patient to provide the following information:

(A) Full name and any aliases,

(B) Month, day, and year of birth,

(C) Mother's maiden name,

(D) Sex,

(E) Race,

(F) Height,

(G) Weight,

(H) Color of hair,

(I) Color of eyes,

(J) Distinguishing markings, such as scars or tattoos.

(4) Request the patient to voluntarily provide his/her Social Security number,

(5) Request the patient to sign an authorization for disclosure of confidential information, pursuant to Section 2.34, Part 2, Chapter 1, Title 42 of the Code of Federal Regulations for the limited purpose of authorizing the program to contact each narcotic treatment program within a radius of 50 statute miles to determine if the patient, as identified at Subsection (a)(3) and (a)(4) of this regulation, is simultaneously receiving replacement narcotic therapy from another program.

(6) Document in the patient record, in accordance with Section 10165, all information provided and authorizations of release of information signed pursuant to this subsection.

(b) Upon completion of the requirements of Subsection (a) of this regulation, the program shall proceed in accordance with Subsection (c) or Subsection (d) of this regulation, as appropriate.

(c) If the patient states that he/she is currently receiving replacement narcotic therapy from another program and the patient is not approved to receive services on a temporary basis in accordance with Sections 10205(b) and 10295, before admitting the patient for treatment, the program shall:

(1) Request the patient to sign an authorization of disclosure of confidential information, pursuant to Section 2.34, Part 2, Chapter 1, Title 42 of the Code of Federal Regulations for the limited purpose of authorizing the program to contact the previous program to notify it that the patient has applied for admission for replacement narcotic therapy;

(2) Contact the previous program by telephone and notify the program that the individual has applied for admission for replacement narcotic therapy;

(3) Request the program to cease providing replacement narcotic therapy if it has not already done so;

(4) Request the previous program to provide the new program with written documentation (letter or discharge summary) that it has discharged the patient; and

(A) The previous program shall provide such information within 72 hours of receiving the request.

(B) If the previous program states that it has already discharged the patient, the new program may admit the patient for treatment.

(5) Document the following information in writing in the patient's record:

(A) The name of the program contacted,

(B) The date and time of the contact,

(C) The name of the program staff member contacted, and

(D) The results of the contact.

(d) If the patient states that he/she is a visiting patient approved to receive services on a temporary basis in accordance with Sections 10205(b) and 10295, before providing replacement narcotic therapy to the patient the program shall:

(1) Contact the other program to determine that it has not already provided the patient with replacement narcotic therapy for the same time period and that it will not do so; and

(2) Document the following information in writing in the patient's medication orders:

(A) The name of the program contacted,

(B) The date and time of the contact,

(C) The name of the program staff member contacted, and

(D) The results of the contact.

(e) If the patient states that he/she is not currently receiving replacement narcotic therapy from another program, the program shall proceed in accordance with Section 10215.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Section 11839.22, Health and Safety Code.

§10215. Detection of Multiple Registration by Reviewing Results from the Initial Test or Analysis for Illicit Drug Use.

(a) If, at the time of admission, the patient documents that he/she is not currently receiving replacement narcotic therapy from another program, the program shall review the results of the patient's initial test or analysis for illicit drug use to determine the presence of methadone or its primary metabolite. The program may admit the patient prior to receipt of these results.

(b) If the results of the test or analysis for illicit drug use indicate the presence of methadone or its primary metabolite, the program shall ask the patient if, during the preceding 72 hours, he/she received the medication while hospitalized or if he/she was discharged from an inpatient our outpatient narcotic treatment program. If the patient states that he/she was hospitalized or discharged during the preceding 72 hours, the program shall proceed in accordance with Subsection 10210(c). If the patient states that he/she was not hospitalized or discharged during the preceding 72 hours, the program shall proceed in accordance with Subsections (c), (d), and (e) of this regulation.

(c) If the results of the test or analysis for illicit drug use indicate the presence of methadone or its primary metabolite and the patient has signed an authorization for disclosure of confidential information as requested in Subsection 10210(a)(5), the program shall take the following action within 15 days of admitting the patient to the program:

(1) Contact each narcotic treatment program within a radius of 50 statute miles to determine if the patient is simultaneously receiving replacement narcotic therapy from another program, and

(2) Provide to each program the information provided by the patient in Subsection 10210(a)(3) and (a)(4).

(d) Each program receiving information provided in accordance with Subsection (c) of this regulation shall review its records to determine if it has provided replacement narcotic therapy to the patient.

(1) If the program has never provided replacement narcotic therapy to the patient or if it is no longer providing this therapy to the patient, the program shall so notify the inquiring program in writing within 72 hours of receipt of the notification.

(2) If the program is still providing replacement narcotic therapy to the patient, the program shall proceed in accordance with the requirements of Section 10225.

(e) The inquiring program shall document the following information in writing in the patient record:

(1) The name of each program contacted,
(2) The date,
(3) The time of the contact, if made by telephone,
(4) The name of the program staff member contacted, and
(5) The results of the contact.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.2, 11839.22 and 11875, Health and Safety Code.

§10220. Ongoing Detection of Multiple Registration Using Automated Patient Data System.

(a) Consistent with the provision of Section 2.53, Part 2, Chapter 1, Title 42 of the Code of Federal Regulations, by the sixth working day of the month following the month in which the program admits or discharges a patient the program shall report to the Department in writing for purposes of evaluation, patient admission and discharge data which shall include:

(1) Provider identification, including program name, county, and address;
(2) Patient identification, including:
(A) Patient name or initials,
(B) Sex,
(C) Month, day, and year of birth;
(D) Race,
(3) The month, day, and year of admission,
(4) The month, day, and year of discharge,
(5) The type of admission (e.g. initial admission, transfer from another program, change in treatment service, etc.)
(6) The type of treatment provided (e.g. detoxification or maintenance), and
(7) The type of medication prescribed.

(b) The Department shall include patient data reported by each program in its automated patient data collection system.

(c) If the Department's analysis of the automated patient data indicates that a patient is registered in more than one program, the Department shall send written notification of multiple registration to each program in which the patient is registered. The notification shall list all narcotic treatment programs in which the patient is simultaneously registered.

(d) When a program receives notification from the Department that a patient is registered in another narcotic treatment program, the notified program shall determine if it is currently providing replacement narcotic therapy to the patient.

(1) If the program is no longer providing this therapy to the patient, the program shall so notify the Department in writing within 72 hours of receipt of the notification.

(2) If the program is still providing this therapy to the patient, the program shall proceed in accordance with the provisions of Section 10225.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11755 and 11839.22, Health and Safety Code.

§10225. Resolution of Multiple Registration.

(a) When a program determines that it is providing replacement narcotic therapy to a patient who is simultaneously receiving this therapy from one or more other programs, all of the involved programs shall immediately:

(1) Confer to determine which program will accept sole responsibility for the patient.

(2) Revoke the patient's take-home medication privileges in accordance with the provisions of Section 10390(b) and (c), and

(3) Notify the Department's Narcotic Treatment Program Licensing Branch by telephone within 72 hours of such determination;

(b) The program which agrees to accept sole responsibility for the patient shall continue to provide replacement narcotic therapy.

(c) Each of the other programs involved shall:

(1) Immediately discharge the patient from the program;

(2) Document in the patient's record why the patient was discharged from the program;

(3) Provide to the new program, within 72 hours of the discharge, written documentation (letter or discharge summary) that it has discharged the patient.

(4) Send written notification of the discharge to the Department within 72 hours of the discharge.

(d) If the Department determines that neither program has accepted sole responsibility for the patient, the Department shall:

(1) Designate one program which shall accept sole responsibility for the patient, and

(2) Order the remaining programs to proceed in accordance with the provisions of Subsections (a)(2) and (c) of this regulation.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.2, 11839.22 and 11875, Health and Safety Code.

TITLE 9. Rehabilitative And Developmental Services
Division 4. Department of Alcohol and Drug Programs
Chapter 4. Narcotic Treatment Programs
Subchapter 4. Medication Security and Diversion Prevention
Article 2. Patient Identification

§10235. Patient Identification.

Each program shall describe in its protocol and use a system of patient identification which shall insure that each patient is properly identified and that his/her medication dose is not administered or dispensed to another person.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.2, 11839.22 and 11875, Health and Safety Code.

§10240. Patient Identification Card.

(a) Each program shall make known to each patient the availability of a completed identification card which shall be supplied by the program.
(b) Identification cards shall be numbered consecutively.
(c) Identification cards shall contain the following items:
(1) The patient's name.
(2) The patient's record number.
(3) The patient's physical description.
(4) The patient's signature.
(5) A full-face photograph of the patient.
(6) The program's name, address, 24-hour phone number, and signature of the program director or designee.
(7) The issuance and expiration dates of the card.
(d) Patients shall not be required to carry the identification card when away from the program premises.
(e) Patients may be required by the program to carry the identification card while on the program's premises.
(f) Each program shall set forth in its protocol the system the program will use to insure:
(1) Accurate documentation of the voluntary use of identification cards.
(2) Recovery of the voluntary identification cards.
(3) That a means of identification is used to assure positive identification of the patient and a correct recording of attendance and/or medication.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Section 11839.22, Health and Safety Code.

§10245. Duties of Program in Issuing Identification Card.

Each program shall complete all the following steps when issuing an identification card to each patient:
(a) Complete the card by entering the required patient and program information on the card.
(b) Determine that the patient information entered on the card is accurate and consistent with the information in the patient's records.
(c) Require the patient to sign the card under the direct observation of a member of the program staff. The staff member shall compare the signature with at least one other document signed by the patient to determine that the signature is valid. A valid driver's license may be used for this purpose.
(d) Attach to the card a full-face photograph of the patient, which provides sufficient detail for clear identification. A second full-face photograph shall be retained by the program for patient identification purposes.
(e) Laminate the card in clear plastic to prevent alteration.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Section 11839.22, Health and Safety Code.

§10250. Control and Security of Identification Cards.

Each program shall set forth in its protocol its system of control and security for the maintenance of its supply of identification card forms. Each program shall make an attempt to reclaim and retain a patient's identification card whenever a patient is discharged from a program or whenever he/she receives a replacement card.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Section 11839.22, Health and Safety Code.

TITLE 9. Rehabilitative And Developmental Services
Division 4. Department of Alcohol and Drug Programs
Chapter 4. Narcotic Treatment Programs
Subchapter 4. Medication Security and Diversion Prevention
Article 3. Medication Handling and Security

§10255. Medications Record Keeping.

(a) Each program shall maintain accurate records of medications used in replacement narcotic therapy traceable to specific patients, showing dates, quantity, and batch code marks of the medications.

(1) These records shall be maintained by a physician, pharmacist, or health professional authorized to compound, administer or dispense medications used in replacement narcotic therapy.

(2) These records shall be retained for a period of three years.

(b) Each program shall describe in its protocol all of the following information for medications used in replacement narcotic therapy:

(1) The records which will be kept to reconcile on a daily basis, the amount of medications received, on hand, and administered or dispensed to patients.

(2) The names of individuals who will actually compound medications used in replacement narcotic therapy and who administer or dispense the patient medication.

(3) The source or supplier of these medications and the form of medications to be purchased for the program.

(4) The name of the person who will purchase these medications and documentation of the federal authorization to do so.

(5) The name and function of anyone, other than a staff member, who handles these medications.

(6) The method used to transfer of these medications within and between facilities.

(7) Security provisions at every location in which these medications will be stored or diluted, and the names of individuals who have access to keys and safe combinations where these medications are stored.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11215, 11217, 11839.2, 11839.3 and 11875, Health and Safety Code.

§10260. Administration or Dispensing of Medications.

(a) The program physician shall be responsible for administering or dispensing to patients all medications used in replacement narcotic therapy.

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

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

(1) These medications shall be administered or dispensed to patients orally in liquid formulation.

(2) Medication doses ingested at the program facility 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 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.

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

§10265. Security of Medication Stocks.

(a) Each program shall maintain adequate security over stocks of medications used in replacement narcotic therapy, over the manner in which they are administered or dispensed, over the manner in which they are distributed, and over the manner in which they are stored to guard against theft and diversion.

(b) Programs shall ensure compliance with the security standards for the distribution and storage of controlled substances as set forth in sections 1301.71 through 1301.76, Title 21, Code of Federal Regulations.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11215, 11835, 11839.2, 11839.3, 11839.20 and 11875, Health and Safety Code; and Sections 1301.71 through 1301.76, Title 21, Code of Federal Regulations.

TITLE 9. Rehabilitative And Developmental Services
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Chapter 4. Narcotic Treatment Programs
Subchapter 5. Patient Treatment
Article 1. Patient Selection and Orientation

§10270. Criteria for Patient Selection.

(a) **Before admitting an applicant to detoxification or maintenance** treatment, the medical director shall either conduct a medical evaluation or document his or her review and concurrence of a medical evaluation conducted by the physician extender. At a minimum this evaluation shall consist of:

(1) A medical history which includes the applicant's history of illicit drug use;

(2) Laboratory tests for determination of narcotic drug use, tuberculosis, and syphilis (unless the medical director has determined the applicant's subcutaneous veins are severely damaged to the extent that a blood specimen cannot be obtained); and

(3) A physical examination which includes:

(A) An evaluation of the applicant's organ systems for possibility of infectious diseases; pulmonary, liver, or cardiac abnormalities; and dermatologic sequelae of addiction;

(B) A record of the applicant's vital signs (temperature, pulse, blood pressure, and respiratory rate);

(C) An examination of the applicant's head, ears, eyes, nose, throat (thyroid), chest (including heart, lungs, and breasts), abdomen, extremities, skin, and general appearance;

(D) An assessment of the applicant's neurological system; and

(E) A record of an overall impression which identifies any medical condition or health problem for which treatment is warranted.

(b) Before admitting an applicant to either detoxification or maintenance treatment, the medical director shall:

(1) Document the evidence, or review and concur with the physician extender's documentation of evidence, used from the medical evaluation to determine physical dependence (except as specified in paragraphs (d)(5)(A) and (d)(5)(B) of this section) and addiction to opiates; and

(2) Document his or her final determination concerning physical dependence (except as specified in paragraphs (d)(5)(A) and (d)(5)(B) of this section) and addiction to opiates.

(c) **Detoxification Treatment**.

The program shall determine which applicants with an addiction to opiates are accepted as patients for detoxification treatment subject to the following minimum criteria which shall be documented in the patient records:

(1) Certification of fitness for replacement narcotic therapy by a physician.

(2) Determination by a program physician that the patient is currently **physically dependent on opiates**. Evidence of current physical dependence shall include:

(A) **Observed signs of physical dependence**, which shall be clearly and +specifically noted in the patient's record.

(B) Results of an initial test or analysis for illicit drug use shall be used to aid in determining current physical dependence, and shall be noted in the patient's record. Results of the initial test or analysis may be obtained after commencement of detoxification treatment.

(3) Patients under the age of 18 years shall have the written consent of their parent(s) or guardian prior to the administration of the first medication dose.

(4) At least seven days shall have elapsed since termination of the immediately preceding episode of detoxification treatment. A program may not knowingly admit a patient who does not satisfy this requirement.

(5) The patient's signed statement that at least seven days have elapsed since termination of the immediately preceding episode of detoxification treatment may, if reliable, be acceptable evidence of compliance with the requirements of subsection (c)(4) above.

(6) The applicant is not in the last trimester of pregnancy.

(d) **Maintenance Treatment**.

The program shall determine which applicants with an addiction to opiates are accepted as patients for maintenance treatment subject to the following minimum criteria which shall be entered in the patient records:

(1) Confirmed documented history of at least **two years of addiction** to opiates. The method to be used to make confirmations shall be stated in the protocol. The program shall maintain in the patient record documents, such as records of arrest or **treatment failures**, which are used to confirm two years of addiction to opiates. Statements of personal friends or family shall not be sufficient to establish a history of addiction. With prior Department approval, the program may make an exception to this requirement only if the program physician determines, based on his or her medical training and expertise, that withholding treatment constitutes a life- or health-endangering situation. The program physician shall document the reason for this determination in the patient record.

(2) Confirmed history of **two or more unsuccessful attempts** in withdrawal treatment with subsequent relapse to illicit opiate use. The methods used to make confirmations and the types of documentation to be maintained in the patient's record shall be stated in the protocol. At least seven days shall have elapsed since completion of the immediately preceding episode of withdrawal treatment if it is to be used to satisfy this subsection.

(3) A minimum age of 18 years.

(4) Certification by a physician of fitness for replacement narcotic therapy based upon physical examination, medical history, and indicated laboratory findings. Plans for correction of existing medical problems should be indicated.

(5) Evidence of observed signs of physical dependence.

(A) An applicant who has **resided** in a penal or chronic care institution for one month or longer may be admitted to maintenance treatment within one month of release **without documented evidence to support findings of physical dependence**, provided the person would have been eligible for admission before he or she was incarcerated or institutionalized and, in the clinical judgment of the medical director or program physician, treatment is medically justified.

(B) Previously treated patients who voluntarily detoxified from maintenance treatment may be admitted to maintenance treatment without documentation of current physical dependence **within six months after discharge**, if the program is able to document prior maintenance treatment of six months or more and, in the clinical judgment of the medical director or program physician, treatment is medically justified. Patients admitted pursuant to this subsection may, at the discretion of **the medical director or program physician, be granted the same take-home step level they were on at the time of discharge**.

(6) Pregnant patients who are currently physically dependent on opiates and have had a documented history of addition to opiates in the past may be admitted to maintenance treatment without documentation of a two-year addiction history or two prior treatment failures, provided the medical director or program physician, in his or her clinical judgment, finds treatment to be medically justified.

(e) Pregnant patients admitted pursuant to (d)(6) immediately above shall be reevaluated by the program physician not later than 60 days following termination of the pregnancy in order to determine whether continued maintenance treatment is appropriate.

(f) All information used in patient selections shall be documented in the patients' records.

(g) The protocol for each program shall set forth all procedures and criteria used to satisfy the requirements of this section.

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

§10280. Patient Orientation.

(a) Programs shall advise patients of the nature and purpose of treatment which shall include but shall not be limited to the following information.

(1) The addicting nature of medications used in replacement narcotic therapy.

(2) The hazards and risks involved in replacement narcotic therapy.

(3) The patient's responsibility to the program.

(4) The program's responsibility to the patient.

(5) The patient's participation in the program is wholly voluntary and the patient may terminate his/her participation in the program at any time without penalty.

(6) The patient will be tested for evidence of use of opiates and other illicit drugs.

(7) The patient's medically determined dosage level may be adjusted without the patient's knowledge, and at some later point the patient's dose may contain no medications used in replacement narcotic therapy.

(8) Take-home medication which may be dispensed to the patient is only for the patient's personal use.

(9) Misuse of medications will result in specified penalties within the program and may also result in criminal prosecution.

(10) The patient has a right to a humane procedure of withdrawal from medications used in replacement narcotic therapy and a procedure for gradual withdrawal is available.

(11) Possible adverse effects of abrupt withdrawal from medications used in replacement narcotic therapy.

(12) Protection under the confidentiality requirements.

(b) Provisions for patient acknowledgement of orientation shall be made in the patient records.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11217, 11839.2, 11839.3, 11839.20, 11839.22 and 11875, Health and Safety Code.

§10285. Patient Orientation for Female Patients of Childbearing Age.

(a) Each program shall provide the following orientation to female patients of childbearing age:

(1) Knowledge of the effects of medications used in replacement narcotic therapy on pregnant women and their unborn children is presently inadequate to guarantee that these medications may not produce significant or serious side effects.

(2) These medications are transmitted to the unborn child and may cause physical dependence.

(3) Abrupt withdrawal from these medications may adversely affect the unborn child.

(4) The use of other medications or illicit drugs in addition to medications used in replacement narcotic therapy may harm the patient and/or unborn child.

(5) The patient should consult with a physician before nursing.

(6) The child may show irritability or other ill effects from the patient's use of these medications for a brief period following birth.

(b) Provisions for patient acknowledgement of orientation shall be a part of the patient records.

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.

§10290. Patient Consent Form.

(a) Each patient shall attest to voluntary participation in a program by providing written documentation of his/her informed consent.

(b) The program shall ensure that the patient reads and understands the consent form, explain program rules, and supply the patient with copies of the consent form and program rules.

(c) If a patient is admitted to a new treatment episode after a previous episode of treatment was terminated by the program physician and the discharge was noted in the patient's record, the program shall reissue rules and instructions to the patient and require that the patient resign the consent form.

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;

TITLE 9. Rehabilitative And Developmental Services
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Chapter 4. Narcotic Treatment Programs
Subchapter 5. Patient Treatment
Article 2. Patient Attendance and Absence

§10295. Patient Attendance Requirements. (Courtesy Dose)

A patient shall report to the same program to which he or she was admitted unless prior approval is obtained from the patient's medical director or program physician to receive services on a temporary basis from another narcotic treatment program. The approval shall be noted in the patient's record and shall include the following documentation:

(a) The patient's signed and dated consent for disclosing identifying information to the program which will provide services on a temporary basis;

(b) A medication change order by the referring medical director or program physician permitting the patient to receive services on a temporary basis from the other program for a length of time not to exceed 30 days; and

(c) Evidence that the medical director or program physician for the program contacted to provide services on a temporary basis has accepted responsibility to treat the visiting patient, concurs with his or her dosage schedule, and supervises the administration of the medication, subject to Section 10210(d).

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.

§10300. Patient Absence.

(a) Patient in Detoxification Treatment

(1) If a patient in detoxification treatment misses appointments for three consecutive days or more without notifying the program, the patient's episode of treatment may be terminated by the medical director or program physician and the discharge shall be noted in the record.

(2) A patient in detoxification treatment that is discharged pursuant to Subsection (a)(1) of this regulation may be continued in treatment by the program physician if medically indicated, based upon establishment of a legitimate reason for absence. The reasons for continuation of treatment shall be documented in the patient's record.

(b) Patient in Maintenance Treatment.

(1) If a patient in maintenance treatment misses appointments for two weeks or more without notifying the program, the patient's episode of treatment shall be terminated by the medical director or program physician and the discharge shall be noted in the patient's record.

(2) If the discharged patient returns for care and is accepted into the program, the patient shall be readmitted as a new patient and documentation for the new readmission shall be noted in the patient's record.

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.

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Article 3. Treatment Services

§10305. Patient Treatment Plans.

(a) The primary counselor shall enter in the patient's record his or her name and the date the patient was assigned to the counselor.

(b) **Detoxification Treatment Plan Requirements.**
Programs shall develop an individualized treatment plan for each patient which shall include:

(1) Provisions to assist the patient to understand illicit drug addictions and how to deal with them.

(2) Provisions for furnishing services to the patient as needed when the period of detoxification treatment is completed.

(3) The treatment services required and a description of the role they play in achieving the stated goals.

(4) The type and frequency of scheduled counseling services.

(c) **Maintenance Treatment Plan Requirements.**
Programs shall develop an individualized treatment plan for each patient.

(d) Prior to developing a patient's initial maintenance treatment plan, as required in paragraph (e) of this section, the primary counselor shall complete and document in the patient's record a needs assessment for the patient which shall include:

(1) A summary of the patient's psychological and sociological background, including his or her educational and vocational experience.

(2) An assessment of the patient's needs for:

(A) Health care as recorded within the overall impression portion of the physical examination;

(B) Employment;

(C) Education;

(D) Psychosocial, vocational rehabilitation, economic, and legal services.

(e) Within 28 calendar days after initiation of maintenance treatment the primary counselor shall develop the patient's initial maintenance treatment plan which shall include:

(1) Goals to be achieved by the patient based on the needs identified in paragraph (d) of this section and with estimated target dates for attainment in accordance with the following:

(A) Short-term goals are those which are estimated to require ninety (90) days or less for the patient to achieve; and

(B) Long-term goals are those which are estimated to require a specified time exceeding ninety (90) days for the patient to achieve.

(2) Specific behavioral tasks the patient must accomplish to complete each short-term and long-term goal.

(3) A description of the type and frequency of counseling services to be provided to the patient as required in Section 10345.

(4) An effective date based on the day the primary counselor signed the initial treatment plan.

(f) The primary counselor shall evaluate and update the patient's maintenance treatment plan whenever necessary or at least once every three months from the date of admission. This updated treatment plan shall include:

(1) A summary of the patient's progress or lack of progress toward each goal identified on the previous treatment plan.

(2) New goals and behavioral tasks for any newly identified needs, and related changes in the type and frequency of counseling services as required in Section 10345.

(3) An effective date based on the day the primary counselor signed the updated treatment plan.

(g) The **supervising counselor** shall review the initial maintenance treatment plan, along with the corresponding needs assessment, and all updated maintenance treatment plans within **fourteen (14) calendar days from the effective dates** and shall countersign these documents to signify concurrence with the findings.

(h) The **medical director** shall review the initial maintenance treatment plan, along with the corresponding needs assessment, and all updated maintenance treatment plans within fourteen **(14) calendar days from the effective dates** and shall record the following:

(1) Countersignature to signify concurrence with the findings; and

(2) Amendments to the plan where medically deemed appropriate.

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.

§10310. Procedures for Collection of Patient Body Specimens.

(a) Each program shall set forth in its protocol a plan for collection of patient body

(b) specimens for testing or analysis of samples for illicit drug use that describes the procedures to be used for:

(1) Assuring the reliability of its body patient specimen collection procedure.

(2) Storage of body patient specimens in a secure place to avoid substitution.

(3) The substances for which samples of patient body specimens are to be analyzed pursuant to section 10315.

(4) Usage of test or analysis results in 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 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) A test or analysis for illicit drug use shall be performed at least monthly for every patient in maintenance treatment.

(f) In programs providing detoxification treatment, 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 physician.

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.

§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.

(b) Programs may have samples collected from each patient body specimen tested or analyzed for evidence of other illicit drugs if those drugs are commonly used in the area served by program.

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.

§10320. Use of Approved and Licensed Laboratories for Testing or Analyzing Samples Collected from Patient Body Specimens.

Programs shall utilize the services of a laboratory that is licensed and certified by the State Department of Health Services as a Methadone Drug Analysis Laboratory, pursuant to the provisions of group 5.5 (commencing with section 1160), subchapter 1, chapter 2, division 1, title 17, of the California Code of Regulations, and is currently included on the list of licensed and certified laboratories which is available from:

FOOD AND DRUG LABORATORY BRANCH
DIVISION OF FOOD, DRUG, AND RADIATION SAFETY
DEPARTMENT OF HEALTH SERVICES
850 MARINA BAY PARKWAY, G-365
RICHMOND, CA 94804

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.3, 11839.20 and 11839.21, Health and Safety Code.

§10325. Reliability of Tests or Analyses for Illicit Drug Use.

Each program shall participate in and maintain records pursuant to a quality control program, prescribed by the State Department of Health Services pursuant to section 1192, title 17, California Code of Regulations, to examine the reliability of test or analyses for illicit drug use and their results.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.3, 11839.20 and 11839.21, Health and Safety Code.

§10330. Test or Analysis Records for Illicit Drug Use.

(a) Each program shall maintain test or analysis records for illicit drug use which contain the following information for each patient:

(1) The date the patient body specimen was collected;

(2) The test or analysis results; and

(3) The date the program received the results of the test or analysis.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.3, 11839.20 and 11839.21, Health and Safety Code.

§10335. Failure of Patients to Provide a Body Specimen.

When a patient fails to provide a body specimen when required, the program shall proceed as though the patient's sample from his or her body specimen disclosed the presence of an illicit drug(s). Such failures shall be noted in the patient's records.

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.3, 11839.20 and 11839.21, Health and Safety Code.

§10340. Medical Care.

(a) If a program is not physically located in a hospital that has agreed to provide any needed care for opiate addiction-related problems for the program's patients, the program sponsor shall enter into an agreement with a hospital official to provide general medical care for both inpatients and outpatients who may require such care.

(b) Neither the program sponsor nor the hospital shall be required to assume financial responsibility for the patient's medical care.

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

§10345. Counseling Services in Maintenance Treatment.

(a) Upon completion of the initial treatment plan, the primary counselor shall arrange for the patient to receive at the licensed program a minimum of 50 (fifty) minutes of counseling services per calendar month, except as allowed in paragraph (e)(4) of this section, and shall be in accordance with the following:

(b) A counseling session shall qualify for the requirement in Subsection (a) of this regulation if:

(1) The program staff member conducting the session meets minimum counselor qualifications, as specified in Section 10125.

(2) The session is conducted in a private setting in accordance with all applicable federal and state regulations regarding confidentiality.

(3) The format of the counseling session shall be one of the following:

(A) Individual session, with face-to-face discussion with the patient, on a one-on-one basis, on issues identified in the patient's treatment plan.

(B) Group session, with a minimum of four patients and no more than ten patients and having a clear goal and/or purpose that is a common issue identified in the treatment plans of all participating patients.

(C) Medical psychotherapy session, with face-to-face discussion conducted by the medical director on a one-on-one basis with the patient, on issues identified in the patient's treatment plan.

(c) The following shall not qualify as a counseling session for the requirement in Subsection (a) of this regulation:

(1) Interactions conducted with program staff in conjunction with dosage administration.

(2) Self-help meetings, including the 12-step programs of Narcotics Anonymous, Methadone Anonymous, Cocaine Anonymous, and Alcoholics Anonymous.

(3) Educational sessions, including patient orientation sessions specified in Sections 10280 and 10285.

(4) Administrative intervention regarding payment of fees.

(d) The counselor conducting the counseling session shall document in the patient's record within 14 (fourteen) calendar days of the session the following information:

(1) Date of the counseling session;

(2) Type of counseling format (i.e., individual, group, or medical psychotherapy);

(3) The duration of the counseling session in ten-minute intervals, excluding the time required to document the session as required in Subsection (d)(4) of this regulation; and

(4) Summary of the session, including one or more of the following:

(A) Patient's progress towards one or more goals in the patient's treatment plan.

(B) Response to a drug-screening specimen which is positive for illicit drugs or is negative for the replacement narcotic therapy medication dispensed by the program.

(C) New issue or problem that affects the patient's treatment.

(D) Nature of prenatal support provided by the program or other appropriate health care provider.

(E) Goal and/or purpose of the group session, the subjects discussed, and a brief summary of the patient's participation.

(e) The medical director may adjust or waive at any time after admission, by medical order, the minimum number of minutes of counseling services per calendar month as specified in paragraph (a) of this section. The medical director shall document the rationale for the medical order to adjust or waive counseling services in the patient's treatment plan as specified in Section 10305(h).

NOTE: Authority cited: Sections 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11758.42, 11839.3 and 11839.20, Health and Safety Code.

§10350. Administration of Initial Doses of Medication to New Patients.

(a) The program physician shall administer or supervise the initial dosage of a medication used in replacement narcotic therapy.

(b) The new patient shall be observed to ingest the initial dose and shall continue to be observed for a period of time prescribed by the medical director or program physician.

(c) If the requirement contained in Subsection (b) of this regulation are delegated to a staff member as authorized by Section 11215 of the Health and Safety Code to administer or dispense medications, that 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 the outcome of the observation.

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

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

(f) If a program admits a patient who was receiving replacement narcotic therapy from another program the previous day, the initial dosage level requirement provided in Section 10355 and the observation requirement contained in Subsections (b) and (c) of this regulation do not apply.

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.

§10355. Medication Dosage Levels.

(a) Detoxification Dosage Levels.

(1) The medical director or program physician shall individually determine each patient's medication schedule based on the following criteria:

(A) Medications shall be administered daily under observation;

(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 change in the dosage schedule with reasons for such deviations.

(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 is not above 30 milligrams; and

(B) The subsequent portion is administered to the patient separately after the observation period prescribed 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.

(1) Each program furnishing 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.

(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.

(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 is not above 30 milligrams; and

(B) The subsequent portion is administered to the patient separately after the observation period prescribed 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.

(f) Dosage Schedule Following Patient Absence.

After a patient has missed three (3) or more consecutive doses of replacement narcotic therapy, 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.

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.

§10360. Additional Requirements for Pregnant Patients.

(a) Within fourteen (14) calendar days from the date of the primary counselor's knowledge that the patient may be pregnant, as documented in the patient's record, the medical director shall review, sign, and date a confirmation of pregnancy. Also within this time frame, the medical director shall document his or her:

(1) Acceptance of medical responsibility for the patient's prenatal care; or

(2) Verification that the patient is under the care of a physician licensed by the State of California and trained in obstetrics and/or gynecology.

(b) The medical director shall document a medical order and his or her rationale for determining LAAM to be the best choice of therapy for the patient prior to:

(1) Placing a pregnant applicant on LAAM therapy; or

(2) Continuing LAAM therapy after confirmation of a patient's pregnancy. The medical director shall conduct a physical examination of this patient, as specified in Section 10270(a)(3), prior to documenting a medical order to continue LAAM therapy.

(c) Within fourteen (14) calendar days from the date the medical director confirmed the pregnancy, the primary counselor shall update the patient's treatment plan in accordance with Section 10305. The nature of prenatal support reflected in subsequent updated treatment plans shall include at least the following services:

(1) Periodic face-to-face consultation at least monthly with the medical director or physician extender designated by the medical director;

(2) Collection of patient body specimens at least once each calendar week in accordance with collection procedures specified in Section 10310.

(3) Prenatal instruction as specified in paragraph (d) of this section.

(d) The medical director or licensed health personnel designated by the medical director shall document completion of instruction on each of the following prenatal topics:

(1) Risks to the patient and unborn child from continued use of both illicit and legal drugs, including premature birth.

(2) Benefits of replacement narcotic therapy and risks of abrupt withdrawal from opiates, including premature birth.

(3) Importance of attending all prenatal care visits.

(4) Need for evaluation for the opiate addiction-related care of both the patient and the newborn following the birth.

(5) Signs and symptoms of opiate withdrawal in the newborn child and warning that the patient not share take-home medication with the newborn child who appears to be in withdrawal.

(6) Current understanding related to the risks and benefits of breast-feeding while on medications used in replacement narcotic therapy.

(7) Phenomenon of postpartum depression.

(8) Family planning and contraception.

(9) Basic prenatal care for those patients not referred to another health care provider, which shall include instruction on at least the following:

(A) Nutrition and prenatal vitamins.

(B) Child pediatric care, immunization, handling, health, and safety.

(e) If a patient repeatedly refuses referrals offered by the program for prenatal care or refuses direct prenatal services offered by the program, the medical director shall document in the patient's record these repeated refusals and have the patient acknowledge in writing that she has refused these treatment services.

(f) Within fourteen (14) calendar days after the date of birth and/or termination of the pregnancy, the medical director shall document in the patient's record the following information:

(1) The hospital's or attending physician's summary of the delivery and treatment outcome for the patient and offspring; or

(2) Evidence that a request for information as specified in paragraph (f)(1) of this section was made, but no response was received.

(g) Within fourteen (14) calendar days from the date of the birth and/or termination of the pregnancy, the primary counselor shall update the patient's treatment plan in accordance with Section 10305. The nature of pediatric care and child immunization shall be reflected in subsequent updated treatment plans until the child is at least three (3) years of age.

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.

TITLE 9. Rehabilitative And Developmental Services
Division 4. Department of Alcohol and Drug Programs
Chapter 4. Narcotic Treatment Programs
Subchapter 5. Patient Treatment
Article 4. Take-Home Medication Privileges

§10365. Take-Home Medication Procedures.

Each program shall ensure compliance with the following procedures when granting take-home medication privileges to a patient in maintenance treatment:

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

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

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

(d) The program shall label each take-home 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.

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

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

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.

§10370. Criteria for Take-Home Medication Privileges.

(a) Self-administered take-home medication shall only be provided to a patient if the medical director or program physician has determined, in his or her clinical judgment, that the patient is responsible in handling narcotic medications, and **has documented his or her rationale in the patient's record. The rationale shall be based on consideration of the following criteria:**

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

(2) Regularity of program attendance for replacement narcotic therapy and counseling services;

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

(4) Absence of known 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 the patient's home; and

(8) Whether 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) Documentation in the patient's record that the patient is participating in gainful vocational, educational, or responsible homemaking (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 activity;

(2) Documentation in the patient's record that the current 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; 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) 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.

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.

§10375. Step Level Schedules for Take-Home Medication Privileges.

The following take-home medication step levels identify the maximum number of take-homes that will be allowed by this exception to Title 9, CCR, §10375(a)(1-6) (Exhibit 2):

Step I Level –Admission a single take home if determined responsible for State approved Holidays §10380.

Step II Level –After 90 days 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. *Plus one (1) if State holiday.

Step III Level –After 180 days of continuous maintenance 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 four times a week for observed ingestion. *Plus one (1) if State holiday.

Step IV Level –After 270 days 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 one (1) time a week for observed ingestion. *Plus one (1) if State holiday.

Step V Level –After one year of continuous treatment, the medical director or program physician may grant the patient not more than a two-week supply of medication. The patient shall attend the program at least two times a month for observed ingestion. *Plus one (1) if State holiday.

Step VI Level –After two years of continuous treatment, the medical director or program physician may grant the patient not more than a one month take-home supply of medication. The patient shall attend the program at least one time a month for observed ingestion per CCR Title 9 §10380(b)(1).

~~(a) A patient shall not be placed on a take-home medication schedule or granted a step level increase until he or she has been determined responsible in handling narcotic medications 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) 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.

(c) 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 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.

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.

§10380. Take-Home Medication Procedures for Holidays.

(a) A program 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 receiving take-home medication who are scheduled to attend the program on the holiday may be provided one (1) additional day's supply on the last day of dosing at the program before the holiday; and

(2) Patients not receiving take-home medication may be provided a one (1) day supply on the day before the holiday.

(b) A patient shall not receive a take-home medication 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. (unless it falls on state holiday).

~~(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 consideration of the criteria specified in Section

10370(a). This list shall be maintained with the daily reconciliation dispensing record for the holiday.

(c) The official State holidays are:

New Year's Day	January 1
Martin Luther King's Birthday	Third Monday in January
Lincoln's Birthday	February 12
Washington's Birthday	Third Monday in February
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) 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) of this regulation.

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.

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

Title 9, CCR, §10385(a)(1-2) gives physicians the authority to make exceptions to take-homes for patients with medical or exceptional circumstance which make daily attendance a hardship is **eliminated**. This section does not comply with H&S §11839(a)(7). No exception may be granted if it is contrary to, or less stringent than, the federal laws and regulations which govern narcotic treatment programs. May 18, 2001, 42 Code of Federal Regulations (CFR) Part 8 replaced 21 CFR Part 291 §291.505; 42 CFR Part 8 does not allow the medical director or program physician to make this exception and requires submission of the SMA 168 form.

The Physician Request for a Temporary Exception to Regulations (ADP 8045 form) has been **discontinued**. Effective the date of this bulletin all providers (ADP Bulletin 12-10 June 6, 2012) shall submit requests electronically for exceptions to Title 9, CCR utilizing the SAMHSA, Exception Request and Record of Justification (SMA 168 form), http://otp-extranet.samhsa.gov/REQUEST.

~~(a) The **medical director** or program physician may grant an exception to take-home medication criteria and dosage schedules as set forth in sections 10370(b) and 10375 for any of the following reasons:~~

~~(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. **The patient shall not be given at any one time, more than a two-week 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.~~ **~~The patient shall not be given at any one time, more than a one-week 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.

(b) Prior to granting an exception to Sections 10370(b) and 10375, the medical director or program physician shall determine that the patient 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.

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

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.

§10390. Restricting 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, 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 a patient's take-home medication privileges for any of the reasons specified in Subsection (a) of this regulation, or for any other reasons, including:

(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 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.

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.

§10400. Restoring Restricted Take-Home Medication Privileges.

(a) The medical director or program physician, when restoring each step of a patient's restricted take-home medication privileges, shall:

(1) Determine that the patient is responsible for handling narcotic medications, as specified in Section 10370(a).

(2) Ensure that the patient has completed at least a 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.

(3) Ensure that at least the previous 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:

(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) This section shall not be used to circumvent the requirements of section 10375. No patient shall be advanced to a step level pursuant to this section unless he/she has previously been at such step level after having satisfied the requirements of section 10375(a).

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.

§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. Suspension may occur only when a program fails to comply with any

applicable regulation or statute regarding treatment requirements, medication handling, security of medications, or take-home medication procedures.

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.

TITLE 9. Rehabilitative And Developmental Services
Division 4. Department of Alcohol and Drug Programs
Chapter 4. Narcotic Treatment Programs
Subchapter 5. Patient Treatment
Article 5. Termination of Treatment

§10410. Scheduled Termination of Maintenance Treatment.

(a) The medical director or program physician shall discontinue a patient's maintenance treatment within two continuous years after such treatment is begun unless he or she completes the following:

(1) Evaluates the patient's progress, or lack of progress in achieving treatment goals as specified in Section 10305(f)(1); and

(2) Determines, in his or her clinical judgment, that the patient's status indicates that such treatment should be continued for a longer period of time because discontinuance from treatment would lead to a return to opiate addiction.

(b) Patient status relative to continued maintenance treatment as specified in paragraph (a) of this section shall be re-evaluated at least annually after two continuous years of maintenance treatment.

(c) The medical director or program physician shall document in the patient's record the facts justifying his or her decision to continue the patient's maintenance treatment as required by subsections (a) and (b).

(d) Each program shall submit in its protocol a specific plan for scheduled termination of maintenance treatment indicating an average period for a maintenance treatment episode before such scheduled termination. This termination plan shall include information on counseling, and any other patient support which will be provided during withdrawal.

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.

§10415. Treatment Termination Procedures.

(a) A patient may voluntarily terminate participation in a program even though termination may be against the advice of the medical director or program physician.

(b) If the medical director or program director determines that the patient's continued participation in the program creates a physically threatening situation for staff or other patients, the patient's participation may be terminated immediately.

(c) A patient's participation in a program may be involuntarily terminated by the medical director or program physician for cause.

(d) If a program utilizes disciplinary proceedings which include involuntary termination for cause, the program shall include in its protocol reasons and procedures for involuntarily terminating a patient's participation in the program. The procedures shall provide for:

(1) Explanation to the patient of when participation may be terminated for cause.

(2) Patient notification of termination.

(3) Patient's right to hearing.

(4) Patients right to representation.

(e) If the program elects not to terminate for cause, the protocol shall state that patients shall not be involuntarily terminated for cause except as provided in (b) above.

(f) Except as noted in (b) above, either voluntary or involuntary termination shall be individualized, under the direction of the medical director or program physician, and take place over a period of time not less than 15 days, unless:

(1) The medical director or program physician deems it clinically necessary to terminate participation sooner and documents why in the patient's record;

(2) The patient requests in writing a shorter termination period; or

(3) The patient is currently within a 21-day detoxification treatment episode.

(g) The program shall complete a discharge summary for each patient who is terminated from treatment, either voluntarily or involuntarily. The discharge summary shall include at least the following:

(1) The patient's name and date of discharge;

(2) The reason for the discharge; and

(3) A summary of the patient's progress during treatment.

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.

TITLE 9. Rehabilitative And Developmental Services
Division 4. Department of Alcohol and Drug Programs
Chapter 4. Narcotic Treatment Programs
Subchapter 5. Patient Treatment
Article 6. Fair Hearings

§10420. Patient Fair Hearings.

(a) The protocol for each program shall contain a detailed description of the pre-termination fair hearing procedures. The protocol shall provide that a patient has a right to a pre-termination fair hearing in all cases of involuntary termination from the program for cause where continued participation in the program does not create a physically threatening situation for staff or other patients. The procedures shall include but not be limited to:

(1) Identification of reasons for termination, as stated in program rules, which may include:

(A) Diversion of medications used in replacement narcotic therapy.

(B) Violence or threat of violence to program staff or other patients in the program.

(C) Multiple registration.

(2) Written notification to the patient of pending termination, containing:

(A) Reasons for termination.

(B) Explanation of right to pre-termination fair hearing, which shall explain to the patient that such rights must be exercised within 48 hours of written notice.

(3) Provision for continuance of patient's treatment status pending decision upon the hearing.

(4) Explanation of the patient's rights during the hearing to:

(A) Be represented at the hearing by a person or attorney of their choice.

(B) Call witnesses on their behalf, who need not be under oath.

(C) Examine witnesses presented by the program.

(5) Release of medical information in the patient's file to the patient or to the patient's representative at least 48 hours prior to the hearing.

(A) Medical information requests by the patient shall be in the form of a signed consent to release of information.

(B) Medical information to be released to the patient or patient's representative shall be approved by the physician in charge of the patient.

(b) The protocol shall state whether the patient is entitled to a hearing before a panel or before a single hearing officer. If the protocol states that the patient is entitled to a hearing before a panel, a single hearing officer may not be substituted for the panel without the consent of the patient. In the case of a hearing before a panel, a majority vote of the panel is necessary to terminate a person from the program.

(c) The program shall select the hearing officer or panel from impartial persons not directly involved with the patient's care.

(d) A hearing shall be scheduled within seven working days from the time the patient requests a hearing.

(e) Unless the program protocol requires a higher standard of proof, a patient's participation in a program shall be terminated for cause only after the hearing officer or panel finds by a preponderance of the evidence presented that the reason stated in the notice justifies termination.

(f) The hearing officer or panel shall render a decision not later than the first working day following the hearing. The program shall keep a permanent record of the proceedings. The permanent record of the proceedings may be a tape recording. The decision shall be in writing and shall be based solely on the evidence presented at the hearing. The decision shall include a summary of the proceedings and the formal findings and conclusions of the hearing officer or panel.

(1) A copy of the record of the proceedings and/or the decision shall be provided to the patient upon request.

(2) Copies of all written materials, including all evidence introduced at the hearing, shall be retained for one year.

(g) A patient may appeal an adverse decision of a hearing officer or panel by means of a writ of mandate pursuant to section 1094.5, Code of Civil Procedure.

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

TITLE 9. Rehabilitative And Developmental Services

Division 4. Department of Alcohol and Drug Programs

Chapter 4. Narcotic Treatment Programs

Subchapter 6. Temporary Exceptions

§10425. Temporary Exceptions to Regulations.

(a) The Department may grant temporary exceptions to the regulations adopted under this chapter if it determines that such action is justified and would improve treatment services or afford greater protections to the health, safety or welfare of patients, the community, or the general public. No exception may be granted if it is contrary to or less stringent than the federal laws and regulations which govern narcotic treatment programs. Any exception(s) shall be subject to all of the following requirements:

(1) Such exceptions shall be limited to program licensees operating in compliance with applicable laws and regulations;

(2) Requests for exceptions shall be formally submitted in writing to the Department;

(3) Exceptions shall be limited to a one-year period unless an extension is formally granted by the Department;

(4) No exception may be granted until the Department has requested and evaluated a recommendation from the applicable County Drug Program Administrator and all applicable fees have been received;

(5) The program applicant shall comply with all Departmental requirements for maintaining appropriate records or otherwise documenting and reporting activity;

(6) The formal approval of the Department shall contain an accurate description of the exception(s) granted and the terms and conditions to be observed by the licensee; and

(7) Exception(s) shall be voided if the licensee fails to maintain compliance with this section or other applicable laws and regulations that govern narcotic treatment programs.

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