(1) Amend Section 10000 to read as follows:

§ 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) Buprenorphine. “Buprenorphine” means a semisynthetic narcotic analgesic that is derived from thebaine and is administered in the form of its hydrochloride $C_{29}H_{41}NO_4 \cdot HCl$ intravenously or intramuscularly to treat moderate to severe pain and sublingually to treat opioid dependence.

(3) Buprenorphine Products. “Buprenorphine products” means buprenorphine combination products approved by the United States Food and Drug Administration (FDA) for maintenance treatment or detoxification of opioid dependence.

(4) Department. “Department” means the Department of Health Care Services.

(~~2~~5) 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~~ opioid addiction, while the patient is provided treatment services.

(6) DEA. “DEA” means the United States Drug Enforcement Administration.

(~~3~~7) FDA. “FDA” means the United States Food and Drug Administration.

(~~4~~8) 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~~9) Laboratory. “Laboratory” means a drug analysis laboratory approved and licensed by the ~~State~~ California Department of Public Health ~~Services~~ to test or analyze samples of patient body specimens for the substances named in Section 10315 for a narcotic treatment program.

(~~6~~10) 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.

(11) License. “License” means a written permit issued by the Department to operate a narcotic treatment program in the State of California.

(12) Licensing Action. “Licensing action” means any administrative action taken by the Department which would adversely affect the license of a narcotic treatment program, including:

(A) Denial of an application for a license;

(B) Denial of a protocol amendment;

(C) Denial of a supplemental written protocol for a medication unit;

(D) Denial of a supplemental written protocol for an OBNTN;

(E) Denial of a request for license renewal;

(F) Denial of a request to relocate a narcotic treatment program outside of its current county;

(G) Assessment of a civil penalty; or

(H) Suspension or revocation of a license.

(~~7~~13) 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~~ opioid addiction, while the patient is provided a comprehensive range of treatment services.

(~~8~~14) Medical Director. “Medical director” means the physician licensed to practice medicine in California who is responsible for medical services provided by the program.

(~~9~~15) Medication. “Medication” means any ~~opiate~~opioid agonist medications that have been approved for use in replacement narcotic therapy, including:

(A) Methadone, ~~and~~

(B) Levoalphacetylmethadol (LAAM), and

(C) Buprenorphine and buprenorphine products.

(~~10~~16) Medication Unit. “Medication unit” means a ~~narcotic treatment~~ facility, established as part of, but geographically separate from, ~~by a program sponsor as part of~~ a ~~maintenance~~ narcotic treatment program, from which licensed private practitioners ~~and~~ or community pharmacists ~~are permitted to administer and~~ dispense or administer an opioid agonist treatment medication ~~medications used in replacement narcotic therapy. These medication units may also~~ or collect ~~patient body specimens for testing or analysis of~~ samples for ~~illicit drug use.~~ drug testing or analysis.

(~~11~~17) 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~~18) 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~~19) Narcotic Treatment Program (NTP). “Narcotic treatment program (NTP)” means a licensed ~~any opiate~~opioid addiction treatment ~~modality~~program, whether inpatient or outpatient, which offers all of the following: evaluation, ~~replacement narcotic therapy in~~ maintenance~~,~~ treatment and/or detoxification treatment, ~~or~~ and other services in conjunction with ~~that~~ replacement narcotic therapy.

(20) Office-Based Narcotic Treatment Network (OBNTN). “Office-Based Narcotic Treatment Network (OBNTN)” means a network of providers, that are affiliated and associated with a primary narcotic treatment program, offering one or more of the following: evaluation of medical, employment, alcohol, criminal, and psychological problems; screening for diseases that are disproportionately represented in the opioid-abusing population; counseling by addiction counselors that are evaluated through ongoing supervision; and professional medical, social work, and mental health services, on-site or by referral.

(~~14~~21) Opiate. “Opiate” ~~means narcotic drug substances having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability; including heroin, morphine, methadone, or any natural or synthetic opiate as set forth in the California Uniform Controlled Substances Act (Health and Safety Code sections 11000, et seq.).~~ means one of a group of alkaloids derived from the opium poppy (Papaver somniferum), with the ability to induce analgesia, euphoria, and, in higher doses, stupor, coma, and respiratory depression. The term excludes synthetic opioids.

(22) Opioid. “Opioid” means any psychoactive chemical that resembles morphine in pharmacological effects, including opiates and synthetic/semisynthetic agents that exert their effects by binding to highly selective receptors in the brain where morphine and endogenous opioids affect their actions.

(~~15~~23) ~~Opiate~~Opioid Addiction. "~~Opiate~~Opioid Addiction," and the related term "addiction to ~~opiates~~opioids," means a condition characterized by compulsion and lack of control that lead to illicit or inappropriate ~~opiate~~opioid-seeking behavior, including an ~~opiate~~ opioid addiction that was acquired or supported by the misuse of a physician's legally prescribed narcotic medication.

(~~16~~24) 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~~25) Primary Metabolite of Methadone. "Primary metabolite of methadone" means 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine.

(26) Primary Narcotic Treatment Program. "Primary Narcotic Treatment Program" means a program with an affiliated and associated medication unit and/or OBNTN.

(~~18~~27) Program. "Program" means a narcotic treatment program~~, unless otherwise specified~~.

(~~19~~28) Program Director. "Program director" means the person who has primary administrative responsibility for operation of an approved and licensed program.

(~~20~~29) 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.~~ named in the Initial Application Coversheet form DHCS 5014 (04/16), herein incorporated by reference, as responsible for the operation of the narcotic treatment program and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program or any of its medication units and

OBNTNs. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

(~~21~~30) Protocol. "Protocol" means a written document, including required forms, which sets forth a program's treatment concept, organization, and operational procedures ~~in the form required by the Department~~.

(~~22~~31) Rationale. "Rationale" means a rational statement of principles or the logical basis for a procedure.

(~~23~~32) Replacement Narcotic Therapy. "Replacement narcotic therapy" means ~~the medically supervised use of an opiate agonist medication that mimics the effects of endorphin, a naturally occurring compound, thus producing an opiate effect by interaction with the opioid receptor.~~ medication assisted treatment that uses agonist or partial agonist medication to normalize brain chemistry, block the euphoric effects of opioids and relieve physiological cravings and normalize body functions.

(33) SAMHSA. "SAMHSA" means the Substance Abuse and Mental Health Services Administration.

(~~24~~34) Treatment. "Treatment" means services which will habilitate and rehabilitate patients with an ~~opiate~~opioid 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~~opioid-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 11750, 11755, 11835, 11839.3, 11839.6 and 11839.20, Health and Safety Code. Reference: Sections ~~Division 10.5, Part 2, Chapter 10, Article 1 (commencing with Section 11839),~~11839.2, 11839.3, 11839.5, 11839.6, 11839.7 and 11839.19, Health and Safety Code.

(2) Amend Section 10010 to read as follows:

§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 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections ~~11217,~~ 11839.3 and 11839.5, Health and Safety Code.

(3) Repeal Section 10015:

§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.

(4) Amend Section 10020 to read as follows:

§10020. ~~Licensure of~~ Medication Units.

(a) ~~In order to~~ A medication unit may lawfully operate ~~a medication unit~~ if:

(1) The Department approves the primary NTP's supplemental written protocol as described in subsection (b); and

(2) The primary NTP has approval from SAMHSA to operate the medication unit; and

(3) The medication unit is registered with the DEA ~~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.~~

The primary NTP program sponsor shall submit an Initial Application Coversheet form DHCS 5014 (04/16) and supplemental written protocol to the Department to serve as an application to add a medication unit to the primary NTP license. The supplemental written protocol shall include all of the following information and the designated forms below:

(1) A description of the geographical surrounding areas to be served, as required by the Facility and Geographical Area form DHCS 5025 (04/16), herein incorporated by reference;

(2) The population of the area to be served, as required by the Facility and Geographical Area form DHCS 5025 (04/16);

(3) Each staff member's resume and the Staff Information form DHCS 5026 (04/16), herein incorporated by reference;

(4) A facility address including the geographic relationship of the medication unit to the primary NTP, as required by the Facility and Geographical Area form DHCS 5025 (04/16);

(5) The days and hours of medication dispensing, as required by the Facility and Geographical Area form DHCS 5025 (04/16);

(6) The days and hours for collection of samples for drug testing or analysis, if applicable, as required by the Facility and Geographical Area form DHCS 5025 (04/16);

(7) The type of services to be provided and the hours of use of the facility, if the facility is also used for purposes other than a medication unit, as required by the Facility and Geographical Area form DHCS 5025 (04/16);

(8) A facility description including a diagram showing dimensions of the facility housing the medication unit and an accompanying narrative that describes patient flow. The diagram

and narrative shall specify waiting areas, office space, medication administration area, patient body specimen collection locations for testing or analysis of samples for illicit drug use, record storage area, and parking or transportation access, as required by the Facility and Geographical Area form DHCS 5025 (04/16);

(9) The approximate number of patients to be served and a description of how every patient that is assigned to the medication unit will participate in the regular treatment provided by the primary NTP, as required by the Facility and Geographical Area form DHCS 5025 (04/16); and

(10) The written policies and procedures to be followed in the event of an emergency or disaster.

(c) In addition to the supplemental written protocol, the primary NTP shall submit to the Department an Affiliated and Associated Acknowledgement form DHCS 5134 (04/16), herein incorporated by reference.

(d) The Department shall notify the primary NTP, in writing, within 60 days of receipt of the Initial Application Coversheet form DHCS 5014 (04/16), supplemental written protocol, and the Affiliated and Associated Acknowledgement form DHCS 5134 (04/16), whether such documents are either:

(1) Complete, including all required documents specified in Section 10020(b) and (c), and accepted for review; or

(2) Incomplete, and the Department shall specify the missing or incomplete information or documentation. The primary NTP shall have 60 days from the date of the notification to provide the missing information or documentation. The Department shall terminate review of the application if the primary NTP does not provide the required information or documentation within 60 days. Upon termination of review, the incomplete application shall be returned to the

primary NTP. A primary NTP may reapply by submitting a new application to the Department. Termination of review of the application shall not constitute a licensing action.

(e) The proposed medication unit shall be subject to a site inspection by the Department prior to approval of the supplemental written protocol.

(f) The Department shall either approve or deny, in writing, a complete application for approval of a medication unit within 60 days after the application is accepted for review.

(g) The primary NTP shall notify the Department, in writing, at least 30 days prior to the closure of a medication unit. In the event that a medication unit ceases to provide services, the primary NTP shall be responsible for providing those services.

(h) The licensed patient capacity of the primary NTP and any of its medication unit(s) and/or OBNTN(s) shall not exceed the patient capacity set forth on the primary NTP license.

(i) A medication unit shall be subject to the same inspection and monitoring by the Department, as a narcotic treatment program, to ensure that operations are in accordance with the applicable laws and regulations.

(j) The primary NTP shall be responsible for submission and implementation of all required corrective action plans of its medication unit(s). The license of the primary NTP shall be subject to licensing action, as described in Section 10057, for any violation by its medication unit of these regulations or provisions under Article 1, Chapter 10, Part 2, Division 10.5 of the Health and Safety Code.

(k) A medication unit shall post the primary NTP license under which it is operating that identifies all the addresses of all facilities providing treatment services in a conspicuous place visible within the facility.

(l) The Department's approval to operate a medication unit shall automatically terminate if SAMHSA withdraws or revokes its approval of the medication unit, or if the DEA revokes the medication unit's registration.

(m) Treatment services at a medication unit are limited to the administering and dispensing of medications and/or the collection of patient body specimens for testing or analysis of samples for illicit drug use. The primary NTP shall be responsible for ensuring that patients have access to all other treatment services not provided at the medication unit.

NOTE: Authority cited: Sections 11750, 11755, 11835, 11839.3, 11839.6 and 11839.20, Health and Safety Code. Reference: Sections ~~11217,~~ 11839.3 and ~~11839.5~~ 11839.6, Health and Safety Code.

(5) Adopt Section 10021 to read as follows:

§10021. Office-Based Narcotic Treatment Network (OBNTN).

(a) An OBNTN may lawfully operate if:

(1) The Department approves the primary NTP's supplemental written protocol as described in this subsection (b); and

(2) The primary NTP has approval from SAMHSA, if required.

(b) The primary NTP program sponsor shall submit an Initial Application Coversheet form DHCS 5014 (04/16) and supplemental written protocol to the Department to serve as an application to add an OBNTN to the primary NTP license. The supplemental written protocol shall include all of the following information and designated forms:

(1) A description of the geographical surrounding areas to be served, as required by the Facility and Geographical Area form DHCS 5025 (04/16);

(2) The population of the area to be served, as required by the Facility and Geographical Area form DHCS 5025 (04/16);

(3) Each staff member's resume and Staff Information form DHCS 5026 (04/16);

(4) A facility address, including the geographic relationship of the OBNTN to the primary NTP, as required by the Facility and Geographical Area form DHCS 5025 (04/16);

(5) The days and hours of operation, as required by the Facility and Geographical Area form DHCS 5025 (04/16);

(6) The type of services to be provided and the hours of use of the facility, if the facility is also used for purposes other than a OBNTN, as required by the Facility and Geographical Area form DHCS 5025 (04/16);

(7) A facility description including a diagram showing dimensions of the facility housing the OBNTN and an accompanying narrative that describes patient flow. The diagram and

narrative shall specify waiting areas, office space, record storage area, and parking or transportation access, as required by the Facility and Geographical Area form DHCS 5025 (04/16);

(8) The approximate number of patients to be served and a description of how every patient that is assigned to the OBNTN will participate in the regular treatment provided by the primary NTP, as required by the Facility and Geographical Area form DHCS 5025 (04/16); and

(9) The written policies and procedures to be followed in the event of an emergency or disaster.

(c) In addition to the supplemental written protocol, the primary NTP shall submit to the Department an Affiliated and Associated Acknowledgement form DHCS 5134 (04/16).

(d) The Department shall notify the primary NTP, in writing, within 60 days of receipt of the Initial Application Coversheet form DHCS 5014 (04/16), supplemental written protocol, and the Affiliated and Associated Acknowledgement form DHCS 5134 (04/16), whether such documents are either:

(1) Complete, including all required documents specified in Section 10021(b) and (c), and accepted for review; or

(2) Incomplete, and the Department shall specify the missing or incomplete information or documentation. The primary NTP shall have 60 days from the date of the notification to provide the missing information or documentation. The Department shall terminate review of the application if the primary NTP does not provide the required information or documentation within 60 days. Upon termination of review, the incomplete application shall be returned to the primary NTP. A primary NTP may reapply by submitting a new application to the Department. Termination of review of the application shall not constitute a licensing action.

(e) The proposed OBNTN shall be subject to a site inspection by the Department prior to approval of the supplemental written protocol.

(f) The Department shall either approve or deny, in writing, a complete application for approval of an OBNTN within 60 days after the application is accepted for review.

(g) The primary NTP shall notify the Department, in writing, at least 30 days prior to the closure of an OBNTN. In the event that an OBNTN ceases to provide services, the primary NTP shall be responsible for providing those services.

(h) The licensed patient capacity of the primary NTP and any of its medication unit(s) and/or OBNTN(s) shall not exceed the patient capacity set forth on the primary NTP license.

(i) An OBNTN shall be subject to the same inspection and monitoring by the Department, as a narcotic treatment program, to ensure that operations are in accordance with the applicable laws and regulations.

(j) The primary NTP shall be responsible for submission and implementation of all required corrective action plans for any of its OBNTNs. The license of the primary NTP shall be subject to licensing action, as described in Section 10057, for any violation by its OBNTNs of these regulations or provisions under Article 1, Chapter 10, Part 2, Division 10.5 of the Health and Safety Code.

(k) An OBNTN shall post the primary NTP license under which it is operating that identifies all the addresses of all facilities providing treatment services in a conspicuous place visible within the facility.

(l) The primary NTP shall be responsible for ensuring that patients have access to all other treatment services not provided at the OBNTN.

NOTE: Authority cited: Sections 11750, 11755, 11835, 11839.3, 11839.6 and 11839.20, Health and Safety code. Reference: Sections 11839.3 and 11839.6, Health and Safety Code.

(6) Amend Section 10025 to read as follows:

§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~~:~~ the Department.

~~Department of Alcohol and Drug Programs~~

~~1700 K Street~~

~~Sacramento, CA 95811-4037~~

NOTE: Authority cited: Sections 11750, 11755, 11835, 11839.3 and ~~11839.20~~ 11839.6, Health and Safety code. Reference: Sections 11839.3 and 11839.19, Health and Safety Code.

(7) Amend Section 10030 to read as follows:

§10030. Protocol for Proposed Programs.

(a) The program sponsor shall submit or cause to be submitted on its behalf to the Department an Initial Application Coversheet form DHCS 5014 (04/16) and 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 and designated forms:

(1) Plan of operation.

(2) A description of the geographical surrounding areas to be served by the program, as required by the Facility and Geographical Area form DHCS 5025 (04/16).

(3) Population and area to be served, as required by the Facility and Geographical Area form DHCS 5025 (04/16).

(4) The estimated number of persons in the described area having an addiction to ~~opiates~~ opioids and an explanation of the basis of such estimate, as required by the Facility and Geographical Area form DHCS 5025 (04/16).

(5) The estimated number of persons in the described area having an addiction to ~~opiates~~ opioids that are presently in a narcotic treatment program and other treatment programs, as required by the Facility and Geographical Area form DHCS 5025 (04/16).

(6) The number of patients in regular treatment, projected rate of intake, and factors controlling projected intake, as required by the Facility and Geographical Area form DHCS 5025 (04/16).

(7) Program goals.

(8) Research goals.

(9) Plan for evaluation.

(10) County Alcohol and Drug Program Administrator's certification, as required by the County Certification form DHCS 5027 (04/16), herein incorporated by reference.

(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, as required by the Organizational Responsibility form DHCS 5031 (04/16), herein incorporated by reference.

(16) ~~Persons responsible for program.~~ Program sponsor.

(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~~and Staff Information form DHCS 5026 (04/16).

(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, as required by the Facility and Geographical Area form DHCS 5025 (04/16).

(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) The written policies and ~~P~~procedures to be followed in the event of an 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, as required by the Facility and Geographical Area form DHCS 5025 (04/16).

(38) Amount of space devoted to narcotic treatment, including waiting, counseling, dispensing, and storage areas, as required by the Facility and Geographical Area form DHCS 5025 (04/16).

(39) Days and hours of medication program dispensing, as required by the Facility and Geographical Area form DHCS 5025 (04/16).

(40) Days and hours for other narcotic treatment program services, as required by the Facility and Geographical Area form DHCS 5025 (04/16).

(41) Type of services provided and the hours of use, if the facility is also used for purposes other than a narcotic treatment program, as required by the Facility and Geographical Area form DHCS 5025 (04/16).

(42) Diagram of the facility housing the narcotic treatment program and an accompanying narrative which describes patient flow, as required by the Facility and Geographical Area form DHCS 5025 (04/16). 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.

(43) Guarantor Agreement, as required by the Guarantor Agreement form DHCS 5020 (04/16), herein incorporated by reference.

~~(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~~b) 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 11750, 11755, 11835~~,~~ and 11839.3 ~~and 11839.20~~, Health and Safety Code. Reference: Sections ~~11215, 11217, 11839.2,~~ 11839.3, 11839.19, 11839.20 and 11839.22, Health and Safety Code.

(8) Amend Section 10035 to read as follows:

§10035. Protocol Amendments and Changes.

(a) The following changes in a program's protocol and supplemental written protocol require the prior approval of the Department. A program ~~and~~ shall ~~be~~ submit~~ted~~ these changes to the Department on an Application for Protocol Amendment form DHCS 5135 (04/16), herein incorporated by reference ~~as an amendment to the protocol~~:

(1) Any ~~change of location~~ relocation of the program within the county indicated on its license~~, or of any portion of the program, including any dispensing facility or other unit~~.

(2) Any change in the ~~number~~ licensed patient capacity ~~of authorized patients or facilities~~.

(3) Any addition, reduction or termination of services.

(4) Any change in program sponsor.

(5) Any change in partner, officer, director, 10 percent or greater shareholder, or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code.

(6) Any change to the physical structure or floor plan of the facility including expansions or modifications to dispensing stations.

(b) All other ~~significant~~ changes in the protocol and supplemental written protocol shall be reported to the Department on an Application for Protocol Amendment form DHCS 5135 (04/16) ~~in writing~~ within 30 days after the date such change becomes effective.

(c) ~~Each~~Every proposed amendment described in subsection (a) and changes in protocol described in subsection (b) 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 and supplemental written protocol affected by the proposed amendment or ~~significant~~ protocol change. The requested effective date of implementation of the proposed amendment ~~or significant change~~ shall be included. Approved ~~A~~amendments and changes in ~~or significant~~ protocol ~~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~~d) 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 11750, 11755, 11835, 11839.3 and 11839.6 ~~and 11839.20~~, Health and Safety Code. Reference: Sections ~~11215, 11217, 11839.2~~, 11839.3 and 11839.22, Health and Safety Code.

(9) Adopt Section 10036 to read as follows:

§10036. Approval of Protocol Amendments and Changes.

(a) If a program submits an Application for Protocol Amendment form DHCS 5135 (04/16) pursuant to Section 10035(a), the Department shall notify the program, in writing, within 30 days of receipt of the form, whether the documentation is:

(1) Complete and accepted for review; or

(2) Incomplete, and the Department shall specify the missing or incomplete information or documentation. The program shall have 30 days from the date of the notification to provide the missing information or documentation. The Department shall terminate review of the protocol amendment if the program does not provide all required information or documentation within 30 days. Upon termination of review, the incomplete protocol amendment shall be returned to the program. The program may reapply by submitting a new Application for Protocol Amendment form DHCS 5135 (04/16) to the Department. Termination of review of the protocol amendment shall not constitute a licensing action.

(b) The Department shall either approve or deny, in writing, the complete protocol amendment within 30 days after the amendment is accepted for review.

NOTE: Authority cited: Sections 11750, 11755, 11835 and 11839.3, Health and Safety Code. Reference: Sections 11839.3 and 11839.22, Health and Safety Code.

(10) Adopt Section 10037 to read as follows:

§10037. Relocation Outside of Current County.

(a) Relocation of a program outside of the county indicated on its license shall be prohibited except as authorized in this section.

(b) To relocate a program outside of the county indicated on the license, the licensee shall submit to the Department an Initial Application Coversheet form DHCS 5014 (04/16) and a written protocol as described in Section 10030(a)(1) – (43) at least 120 days prior to the proposed relocation date.

(c) The Department may issue a new license to a program requesting relocation pursuant to subsection (b) if such program is determined by the Department to have submitted a satisfactory protocol, be able to conform to all applicable statutory requirements and regulations, and have demonstrated need and received a recommendation by the County Alcohol and Drug Program Administrator.

(d) The Department shall notify the licensee, in writing, within 60 days of receipt of the application whether such application is either:

(1) Complete, including all required documents specified in Section 10030, and accepted for review; or

(2) Incomplete, and the Department shall specify the missing or incomplete information or documentation. The licensee shall have 60 days from the date of the notification to provide the missing information or documentation. The Department shall terminate review of the relocation request if the licensee does not provide all required information or documentation within 60 days. Upon termination of review, the incomplete relocation request shall be returned to the licensee. The licensee may reapply by submitting a new relocation request to the Department. Termination of review shall not constitute a licensing action.

(e) The Department shall either approve or deny, in writing, a complete relocation request within 60 days after the request is accepted for review.

NOTE: Authority cited: Sections 11750, 11755, 11835 and 11839.3, Health and Safety Code. Reference: Sections 11839.3 and 11839.22, Health and Safety Code.

(11) Amend Section 10040 to read as follows:

§10040. Certification by County Alcohol and Drug Program Administrator.

(a) A completed, original protocol shall be filed with the County Alcohol and 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 Alcohol and Drug Program Administrator on the County Certification form DHCS 5027 (04/16) 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 11750, 11755, 11835~~,~~ and 11839.3 ~~and 11839.20~~, Health and Safety Code. Reference: Sections 11839.3 and 11839.5, Health and Safety Code.

(12) Amend Section 10045 to read as follows:

§10045. Approval of License Application.

(a) The Department may license a~~n~~program applicant if ~~such program~~ the applicant 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~~ recommendation of the County Alcohol and Drug Program Administrator.

(b) The Department shall notify the applicant, in writing, within ~~45~~ 60 days of receipt of the application whether such application is either:

(1) Complete, including all required documents specified in Section 10030, and accepted for ~~filing~~ review; or

(2) Incomplete, and the Department shall specify the missing or incomplete information or documentation. The applicant shall have 60 days from the date of the notification to provide the missing information or documentation~~licensing process shall cease unless and until the applicant provides the specific material outlined in the notification~~. The Department shall terminate review of the application if the applicant does not provide all required information or documentation within 60 days. Upon termination of review, the incomplete application shall be returned to the applicant. An applicant may reapply by submitting a new application to the Department. Termination of review shall not constitute a licensing action.

(c) The Department shall either approve or ~~disapprove~~deny, in writing, a~~n~~ complete application for licensure of a narcotic treatment program within ~~45~~ 60 days after ~~filing of a completed application~~ the application is accepted for review.

~~(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 11750, 11755, 11835~~,~~ and 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~~.

(13) Amend Section 10055 to read as follows:

§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, and any affiliated and associated medication unit(s) and/or OBNTNs, ~~is~~ are 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 Alcohol and Drug Program Administrator submits to the Department the County Certification form DHCS 5027 (04/16) that includes:

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

(B) A recommendation for renewal of the license.

(3) The Department receives, by March 31st of each year, an Application for License Renewal form DHCS 4029 (04/16), herein incorporated by reference, that includes:

(A) Program information, including any affiliated and associated medication unit(s) and/or OBNTNs;

(B) Projected patient capacity of the program; and

(C) An annual maintenance report.

(4) The Department receives, by March 31st of each year, an Organizational Responsibility form DHCS 5031 (04/16) that includes a current list of any partner, officer, director, 10 percent or greater shareholder, and person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code.

(c) Within 30 days of receipt of an Application for License Renewal form DHCS 4029 (04/16) and Organizational Responsibility form DHCS 5031 (04/16) ~~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.~~ and the Department shall specify the missing or incomplete information or documentation. The licensee shall have 15 days from the date of the notification to provide the missing information or documentation. The Department shall terminate review of the license renewal if the licensee does not provide all required information or documentation within 15 days. Upon termination of review, the incomplete license renewal application shall be returned to the licensee. Termination of review shall not constitute a licensing action.

(d) ~~Within 60 days of receipt of a completed renewal application the Department shall either relicense the program or deny licensure.~~The Department shall either approve or deny, in writing, the Application for License Renewal by June 15th of each fiscal year. If approved, the Department shall issue a new license to the program with a date effective of July 1st.

~~(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 11750, 11755, 11835~~,~~ and 11839.3 ~~and 11839.20~~, Health and Safety Code. Reference: ~~Section 15376, Government Code; and~~ Sections 11839.3, 11839.5, 11839.7, 11839.10 and 11839.19, Health and Safety Code.

(14) Amend Section 10056 to read as follows:

§ 10056. Application ~~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.~~

An application fee shall:

(1) Be paid by an applicant seeking licensure; or

(2) Be paid by a program seeking to relocate; and

(3) Not be paid by an applicant or a program owned and operated by the state, county, city, or city and county.

(b) The Department shall commence review of the information and documentation specified in subsections (b)(1)-(4) only after receipt of the application fee. An application fee shall be submitted with:

(1) An application for licensure as described in Section 10030; and

(2) An application to add a medication unit as described in Section 10020; or a OBNTN as described in Section 10021; and

(3) A request for a relocation of a program as described in Section 10035(a)(1); and

(4) A request for a relocation of a program outside of current county as described in Section 10037.

(c) An application fee shall be determined as follows:

(1) The Department shall compute the total cost to the Department for processing the applications identified in subsections (b)(1)-(4) during the previous fiscal year. The cost to the Department shall include staff salaries and benefits, related travel costs, and state operational and administrative costs.

(2) The Department shall divide the cost calculated in paragraph (1) above by the total number of applications identified in subsections (b)(1)-(4) received during the previous fiscal year. The amount resulting from this division shall be the application fee.

(3) The Department shall compute the application fee in the manner described in this subsection, every other year, beginning with the fiscal year 2018-2019.

(d) Upon approval of an application for licensure described in subsection (b)(1), the Department shall notify the applicant in writing of the prorated license fee described in Section 10056.5.

(e) The application fee described in this section is nonrefundable and shall be paid by check or money order made payable to the Department.

~~(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 the 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 11750, 11755, 11835~~,~~ and 11839.3 ~~and 11839.20~~, Health and Safety Code. Reference: Sections 11839.3 and 11839.7, Health and Safety Code.

(15) Adopt Section 10056.5 to read as follows:

§ 10056.5 License Fees.

(a) The Department shall annually assess a license fee that is sufficient to cover all departmental costs associated with licensing. Every program, except a program owned and operated by the state, county, city, or city and county, shall pay the license fee described in subsection (b).

(b) The license fee shall be determined as follows:

(1) The Department shall compute the total cost to the Department for licensing activities during the previous fiscal year. The cost to the Department shall include staff salaries and benefits, related travel costs, and state operational and administrative costs. Costs associated with licensing narcotic treatment programs shall not include any costs incurred by the Department in processing applications as identified in Section 10056.

(2) The Department shall divide the total cost calculated in paragraph (1) above, by the total licensed patient capacity of all narcotic treatment programs on July 1st of the current fiscal year. The amount resulting from this calculation shall be the patient capacity amount.

(3) The patient capacity amount shall be multiplied by the licensed patient capacity for each narcotic treatment program and the resulting amount shall be the narcotic treatment program's annual license fee.

(c) The Department shall compute the license fee in the manner described in subsection (b) every other year, beginning with the fiscal year 2018-2019.

(d) The license fee described in this section is nonrefundable and shall be paid by check or money order made payable to the Department.

(e) In the event that a program is approved, in accordance with Section 10036, to increase or decrease licensed patient capacity at any time other than at annual renewal, the

Department shall recalculate the license fee. The license fee shall be recalculated by taking the difference between the existing licensed patient capacity and the proposed licensed patient capacity, multiplied by the patient capacity amount as determined under subsection (b)(2). Upon approval of an increase or decrease to a licensed patient capacity, the Department shall send an invoice to the program setting forth the amount of the prorated license fee due for the remainder of the fiscal year.

(f) No later than March 1st of each year, the Department shall calculate the license fee for the next fiscal year (July 1st through June 30th). If the Department determines all conditions required in Section 10055 have been met, the license of a program shall be renewed on July 1st of each year. The license fee shall be due and payable in the manner described in subsection (i) below.

(g) No later than March 1st of each year the Department shall give written notice to programs of the license fee for the next fiscal year.

(h) In August of each year the Department shall send license renewal invoices to every licensee stating the amount of the license fee for the fiscal year.

(i) The licensee shall pay the license fee either once annually or quarterly in arrears.

(1) If the licensee pays the total license fee once annually, the licensee shall submit the amount of the total license fee in time to be received by the Department by September 30th.

(2) If the licensee pays the license fee quarterly in arrears, the licensee shall submit one quarter of the total license fee in time to be received by the Department by September 30th, December 31st, March 31st, and May 31st.

(3) If the licensee fails to timely submit the license fee 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 of the failure to pay the license fee in accordance with the requirements of this section;

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

(C) State the date that the license fee was due;

(D) Notify the licensee that the license shall not be renewed unless the license fee is 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 fee was due until the date the licensee pays the license fee; and

(F) Notify the licensee of the right to 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 the obligation to pay the license fee and shall not entitle the licensee to renewal of the license.

(j) In the event that a program closes as a result of automatic termination, license revocation, or voluntary closure, the Department shall determine the license fee refund amount, if any. The Department shall calculate a refund for the days remaining between the effective closure date through June 30th. For purposes of this subsection "effective closure date" means the date that the automatic termination or license revocation becomes effective or the date of voluntary closure.

NOTE: Authority cited: Sections 11750, 11755, 11835 and 11839.3, Health and Safety Code. Reference: Sections 11839.3 and 11839.7, Health and Safety Code.

(16) Amend Section 10057 to read as follows:

§ 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~~a) Applicants and licensees may appeal a notice of licensing action by submitting a written request for administrative review to~~:~~ the Director~~,~~ of the Department. ~~of Alcohol and Drug Programs, 1700 K Street, Sacramento, CA 95811-4037.~~

(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~~b) 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~~ Division Chief in charge of the ~~Licensing and Certification Division~~ Substance Use Disorder Compliance Division or the ~~Deputy Director's~~Division Chief'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~~2) 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 subsection (~~c~~b)(1)~~(B) or~~ (C).

(~~4~~3) 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~~4) 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~~5) 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~~6) Either party may record the proceedings of the informal conference on audio tape.

(~~8~~7) 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~~c) 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~~d) 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~~a) of this regulation, or

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

(2) The applicant or licensee may request an administrative hearing by submitting a request in writing to: Deputy Director, Mental Health and Substance Use Disorder Services, Department of Health Care Services, P.O. Box 997413, MS 2603, Sacramento, CA 95899-7413 ~~Alcohol and Drug Programs, 1700 K Street, Sacramento, CA 95811-4037~~.

(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~~d)(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~~e) 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~~a) and (~~e~~d) 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~~f) 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; and/or

(3) Suspension or revocation of a license.

NOTE: Authority cited: Sections 11750, 11755, 11835~~,~~ and 11839.3 ~~and 11839.20~~, Health and Safety Code. Reference: Sections 11839.3, 11839.4, 11839.9 and 11839.12, Health and Safety Code; and Chapter 5 (commencing with Section 11500), Part 1, Division 3, Title 2, Government Code.

(17) Amend Section 10060 to read as follows:

§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~~ opioid 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 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Section 11839.3, Health and Safety Code.

(18) Amend Section 10095 to read as follows:

§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:

(A) ~~program operation~~Treatment will continue to be provided at the ~~license program~~ existing location for up to 90 days following receipt by the Department of the program's notice of intent to close the program~~.~~; or

(B) Treatment will continue to be provided through the transfer of patients to another program.

(2) The Department ~~may~~shall 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 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Section 11839.3, Health and Safety Code.

(19) Amend Section 10125 to read as follows:

§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~~ opioid 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 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.3 and 11839.20, Health and Safety Code.

(20) Amend Section 10130 to read as follows:

§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~~ opioid 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 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.3 and 11839.20, Health and Safety Code.

(21) Amend Section 10145 to read as follows:

§10145. Licensed Patient Capacity.

(a) A ~~single~~ narcotic treatment program shall be licensed to provide treatment services to ~~a~~ the maximum number of ~~750~~ patients, as specified on the license.

(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.~~ The licensed patient capacity applies to the combined number of patients receiving treatment at the narcotic treatment program, medication unit and/or OBNTN, except for those patients from another program that are receiving dosing services at the narcotic treatment program on a temporary basis as specified in Section 10295.

(c) A licensee shall notify the County Alcohol and Drug Program Administrator in writing prior to any change in the licensed patient capacity.

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

(~~2~~d) 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~~ unless it determines that the licensee is operating in full compliance with applicable laws and regulations.

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

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

(A) Inform the licensee that the program is ~~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 an ~~temporary suspension~~ order.

NOTE: Authority cited: Sections 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.3, 11839.16 and 11839.20, Health and Safety Code.

(22) Amend Section 10160 to read as follows:

§10160. Procedures for Patient Records.

(a) Programs shall assign a unique identifier ~~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 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections ~~11839.2,~~ 11839.3~~,~~ and 11839.20 ~~and 11875~~, Health and Safety Code.

(23) Amend Section 10165 to read as follows:

§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~~ opioids.

(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 subsection (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 subsection (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 sSection 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 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.2, 11839.3, and 11839.20 and 11875, Health and Safety Code.

(24) Amend Section 10190 to read as follows:

§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 or program director shall attempt to cooperate with the jail's medical officer in order to ensure the necessary treatment for ~~opiate~~ opioid withdrawal symptoms, whenever it is possible to do so.

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

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

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

NOTE: Authority cited: Sections 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections ~~11215,~~ 11839.3 and 11839.20, Health and Safety Code.

(25) Amend Section 10195 to read as follows:

§10195. Report of Patient Death.

A program shall notify the Department of a patient death using the Patient Death Report form DHCS 5048 (04/16), herein incorporated by reference, within:

(a) ~~The program shall notify the Department within~~ O~~o~~ne (1) working day from the date the program is notified of the death 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, for all other patient death~~s, 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 11750, 11755, 11835~~,~~ and 11839.3 ~~and 11839.20~~, Health and Safety Code. Reference: Section 11839.3, Health and Safety Code.

(26) Amend Section 10240 to read as follows:

§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 unique identifier ~~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 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11893.3 and 11839.22, Health and Safety Code.

(27) Amend Section 10260 to read as follows:

§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~~ Methadone shall be administered or dispensed to patients orally in liquid formulation.

(2) ~~Medication~~ Methadone doses ingested at the program facility shall be diluted in a solution which has a volume of not less than two ounces. The medical director shall determine whether to dilute ~~T~~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) If the medical director determines not to dilute take-home medication, the reason for that decision shall be documented in the patient record.

(~~3~~4) A program staff member shall observe ingestion of each medication dose administered at the program facility.

(~~4~~5) Each program shall devise precautions to prevent diversion of ~~these~~ all medications used in replacement narcotic therapy.

(~~5~~6) Methadone shall be available seven days a week.

(~~6~~7) 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 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections ~~11215,~~ 11839.2 and 11839.3, Health and Safety Code.

(28) Amend Section 10270 to read as follows:

§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, HIV, HCV, 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~~ subsections (d)(~~5~~4)(A) and (d)(~~5~~4)(B) of this section) and addiction to ~~opiates~~ opioids; and

(2) Document his or her final determination concerning physical dependence (except as specified in ~~paragraphs~~ subsections (d)(~~5~~4)(A) and (d)(~~5~~4)(B) of this section) and addiction to ~~opiates~~ opioids.

(c) Detoxification Treatment.

The program shall determine which applicants with an addiction to ~~opiates~~ opioids 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~~ opioids. 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~~4) The applicant is not in the last trimester of pregnancy.

(d) Maintenance Treatment.

The program shall determine which applicants with an addiction to ~~opiates~~ opioids 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~~one years~~s~~ of addiction to ~~opiates~~ opioids. 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~~one years~~s~~ of addiction to ~~opiates~~ opioids. 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~~2) A minimum age of 18 years.

(~~4~~3) 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~~4) 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~~six months 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~~two years 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~~5) Pregnant patients who are currently physically dependent on ~~opiates~~ opioids and have had a documented history of ~~addition~~ addiction to ~~opiates~~ opioids in the past may be admitted to maintenance treatment without documentation of a ~~two~~one-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 subsection (d)(~~6~~5) 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 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections ~~11835,~~ 11839.2, 11839.3~~,~~ and 11839.20 ~~and 11875~~, Health and Safety Code.

(29) Amend Section 10280 to read as follows:

§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~~ opioids 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 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections ~~11217,~~ 11839.2, 11839.3~~,~~ and 11839.20, ~~11839.22 and 11875,~~ Health and Safety Code.

(30) Amend Section 10315 to read as follows:

§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~~Opioids.

(3) Cocaine.

(4) Amphetamines.

(5) Barbiturates.

(6) Benzodiazepines.

(b) For every patient receiving buprenorphine or buprenorphine products, programs shall have samples collected from each patient body specimen tested or analyzed for evidence of buprenorphine in addition to the substances specified in subsections (a)(1)-(6).

(~~b~~c) 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 the program.

NOTE: Authority cited: Sections 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.2, 11839.3~~,~~ and 11839.20 ~~and 11875~~, Health and Safety Code.

(31) Amend Section 10320 to read as follows:

§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~~ Public Health as a Methadone Drug Analysis Laboratory, pursuant to the provisions of group 5.5 (commencing with ~~s~~Section 1160), ~~s~~Subchapter 1, ~~c~~Chapter 2, ~~d~~Division 1, ~~t~~Title 17, of the California Code of Regulations, and is currently included on the list of licensed and certified laboratories which is available from~~:~~ the California Department of Public Health Food and Drug Laboratory Branch.

~~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 20, 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.3, 11839.20 and ~~11839.21~~ 11839.24, Health and Safety Code.

(32) Amend Section 10330 to read as follows:

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

(a) Each program shall maintain in every patient's file~~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.

(b) All test or analysis records for illicit drug use shall be from a laboratory licensed and certified pursuant to Section 10320.

NOTE: Authority cited: Sections 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.3, 11839.20 and ~~11839.21~~ 11839.24, Health and Safety Code.

(33) Repeal Section 10340 as follows:

§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.

(34) Amend Section 10345 to read as follows:

§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~~ subsection (e)~~(4)~~ of this section, and shall be in accordance with the following:

(b) A counseling session shall qualify for the requirement in ~~S~~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~~ two patients and no more than ~~ten~~ twelve 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 ~~S~~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 ~~S~~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~~ subsection (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 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections ~~11758.42,~~ 11839.3 and 11839.20, Health and Safety Code.

(35) Amend Section 10355 to read as follows:

§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~~ opioid 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~~ opioid abstinence symptoms, and documents in the patient's record the basis for his/her determination.

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

(e) Maintenance Dosage Levels Specific to LAAM.

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

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

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

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

(3) After a patient's tolerance to LAAM is established, LAAM shall be administered to more frequently than every other day.

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

(f) Maintenance Dosage Levels Specific to buprenorphine and buprenorphine products.

(1) Each program shall develop and maintain current procedures that require administering and dispensing buprenorphine and buprenorphine product treatment medication in accordance with the medication's approved product labeling. These procedures shall include the requirement that any deviation from approved product labeling, including deviations regarding dose, frequency, or the conditions of use described on the approved product label, shall be documented and justified in the patient's record.

(2) Dosing decisions shall be made by the medical director or a program physician, who shall be knowledgeable about the most current and approved product labeling.

(~~f~~g) 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~~h) 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 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections ~~11218, 11219,~~ 11839.2, 11839.3~~,~~ and 11839.20 ~~and 11875~~, Health and Safety Code.

(36) Amend Section 10360 to read as follows:

§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~~subsection (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~~ opioids, including premature birth.

(3) Importance of attending all prenatal care visits.

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

(5) Signs and symptoms of ~~opiate~~opioid 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~~subsection (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 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.3 and 11839.20, Health and Safety Code.

(37) Amend Section 10365 to read as follows:

§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 ~~s~~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~~ paragraph (2);

(4) The name of the medication;

(5) The ~~N~~name of the prescribing medical director or program physician;

(6) The name of the patient;

(7) The date issued; and

(8) The following~~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~~ The program shall instruct all patients ~~can be instructed~~ to keep ~~the~~ all take-home medication out of the refrigerator to prevent accidental overdoses by children and fermentation of the liquid.

NOTE: Authority cited: Sections 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections ~~11839.2,~~ 11839.3~~,~~ and 11839.20 ~~and 11875~~, Health and Safety Code.

(38) Amend Section 10370 to read as follows:

§10370. Criteria for Take-Home Medication Privileges

(a) ~~Self-administered take-home medication~~ Methadone, buprenorphine and buprenorphine products shall only be provided to a patient as take-home medication 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 methadone 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~~ employment, educationa~~l, or~~ responsible homemaking (i.e., primary care giver,

retiree with household responsibilities, or volunteer helping others), or that the patient is retired or medically disabled ~~activity~~ and if 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~~c) 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 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections ~~11839.2,~~ 11839.3~~,~~ and 11839.20 ~~and 11875~~, Health and Safety Code.

(39) Amend Section 10375 to read as follows:

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

(a) A methadone 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—During the first 90 days of continuous maintenance treatment, take-home medication is not permitted, except as provided in Section 10380.

(~~1~~2) Step II Level--~~After three months~~ Day 91 through 180 of continuous maintenance treatment, the medical director or program physician may grant the patient not more than a ~~one~~ two-day take-home supply of medication. The patient shall attend the program at least ~~six~~ five times a week for observed ingestion.

(~~2~~3) Step III Level--~~After six months~~ Day 181 through 270 of continuous maintenance treatment, the medical director or program physician may grant the patient not more than a ~~two~~ three-day take-home supply of medication. The patient shall attend the program at least ~~five~~ four times a week for observed ingestion.

(~~3~~4) Step ~~II~~IV Level--~~After nine months~~ Day 271 through a year of continuous treatment, the medical director or program physician may grant the patient not more than a ~~two~~ six-day take-home supply of medication. The patient shall attend the program at least ~~four~~ one time~~s~~ a week for observed ingestion.

(~~4~~5) Step ~~I~~V Level--After one year of continuous treatment, the medical director or program physician may grant the patient not more than a two-~~day~~ week supply of medication.

The patient shall attend the program at least ~~three~~ two times a ~~week~~ month for observed ingestion.

(~~5~~6) Step V~~I~~ Level--After two years of continuous treatment, the medical director or program physician may grant the patient not more than a ~~three-day~~ one-month take-home supply of medication. The patient shall attend the program at least ~~two~~ one time~~s~~ a ~~week~~ month 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 i~~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 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections ~~11839.2,~~ 11839.3~~,~~ and 11839.20 ~~and 11875~~, Health and Safety Code.

(40) Amend Section 10380 to read as follows:

§10380. Take-Home Medication Procedures for Holidays or Sunday Closure.

(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,~~ or Sunday closure, 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 or Sunday closure may be provided one (1) additional day's supply on the last day of dosing at the program before the holiday or Sunday closure; and

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

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

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

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

~~(3) The~~a 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 or Sunday closure.

(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
Cesar Chavez Day	March 31
Memorial Day	Last Monday in May
Independence Day	July 4
Labor Day	First Monday in September
~~California Admission Day~~	~~September 9~~
Columbus Day	Second Monday in October
Veterans Day	November 11
Thanksgiving Day	Fourth Thursday in November
Christmas Day	December 25

(d) 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~~a holiday~~s~~ listed in ~~S~~subsection (c) of this regulation.

NOTE: Authority cited: Sections 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections ~~11839.2,~~ 11839.3~~,~~ and 11839.20 ~~and 11875~~, Health and Safety Code.

(41) Amend Section 10385 to read as follows:

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

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

(1) The patient has a ~~physical~~medical disability or chronic, acute, or terminal illness that makes daily attendance at the program a hardship. The program must verify the patient's ~~physical~~medical 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~~ submitting a~~n exception~~ request for 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) A request to the Department for an exception to take-home medication criteria and dosage schedules shall be accompanied by copies of all documents provided by the program to the Substance Abuse and Mental Health Services Administration pursuant to Section 8.11(h) of Title 42 of the Code of Federal Regulations.

(dc) The medical director or program physician shall document in the patient's record ~~the granting of~~ any request for an exception to Sections 10370(b) and 10375, ~~exception and~~ the facts justifying the ~~exception~~ request, and the approval or denial of the request.

(de) 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 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections ~~11839.2,~~ 11839.3~~,~~ and 11839.20 ~~and 11875~~, Health and Safety Code.
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(42) Adopt Section 10386 to read as follows:

§10386. Split Doses.

(a)The medical director or program physician may, upon determining that a split dose is medically necessary, order that a patient receive his or her daily dose of medication split in two doses.

(b) Prior to ordering a split dose, 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 immediately upon the decision of medical necessity, document in the patient's record the medical necessity for split doses, the dosage amounts and the ingestion times of the doses.

(d) Any portion of a split dose removed from the program or medication unit shall be considered take-home medication.

(e) The medical director or program physician shall adhere to the step levels set forth in Section 10375 for patients receiving methadone as take-home medication in a split dose.

(f) For purposes of calculating the take-home supply of medication, a split dose shall be considered a one day take-home supply, pursuant to Section 10375.

NOTE: Authority cited: Sections 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.3 and 11839.20, Health and Safety Code.

(43) Amend Section 10410 to read as follows:

§10410. Scheduled ~~Termination~~ Evaluation of Maintenance Treatment.

(a) The medical director or program physician shall ~~discontinue~~ evaluate a patient's maintenance treatment ~~within two~~ after one continuous year~~s~~ ~~after such~~ of treatment ~~is begun unless he or she completes~~. The medical director or program physician shall do the following:

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

(2) Determine~~s~~, 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~~ opioid addiction.

(b) Patient status relative to continued maintenance treatment as specified in ~~paragraph~~subsection (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 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Sections 11839.3 and 11839.20, Health and Safety Code.

(44) Amend Section 10425 to read as follows:

§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~~4) The program applicant shall comply with all Departmental requirements for maintaining appropriate records or otherwise documenting and reporting activity;

(~~6~~5) 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~~6) 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 11750, 11755, 11835, 11839.3 and 11839.20, Health and Safety Code. Reference: Section 11839.3, Health and Safety Code.