

State of California Office of Administrative Law

In re:
Department of Health Care Services

Regulatory Action:

Title 09, California Code of Regulations

Adopt sections: 10021, 10036, 10037,
10386

Amend sections: 10000, 10010, 10020,
10025, 10030, 10035,
10040, 10045, 10055,
10056, 10057, 10060,
10095, 10125, 10130,
10145, 10160, 10165,
10190, 10195, 10240,
10260, 10270, 10280,
10315, 10320, 10330,
10345, 10355, 10360,
10365, 10370, 10375,
10380, 10385, 10410,
10425

Repeal sections: 10015, 10340

NOTICE OF APPROVAL OF REGULATORY
ACTION

Government Code Section 11349.3

OAL Matter Number: 2020-0319-02

OAL Matter Type: Regular Resubmittal (SR)

This rulemaking action regarding narcotic treatment programs (NTPs) streamlines the process for licensed patient capacity change requests and calculating related license and application fees, creates Office-Based Narcotic Treatment Networks (OBNTNs) to expand NTP services and availability of medication units to rural communities, and establishes requirements for NTPs treating patients with buprenorphine and buprenorphine combination products.

OAL approves this regulatory action pursuant to section 11349.3 of the Government Code. This regulatory action becomes effective on 7/1/2020.

Date: May 7, 2020

Original Signed

Eric Partington
Senior Attorney

For: Kenneth J. Pogue
Director

Original: Jennifer Kent, Director

Copy: Kenneisha Moore

NOTICE PUBLICATION/REGULATIONS SUBMISSION

(See instructions on reverse)

STD. 400 (REV. 01-2013)

For use by Secretary of State only

OAL FILE NUMBERS	NOTICE FILE NUMBER Z-2018-0806-01	REGULATORY ACTION NUMBER 2020-0319-0252	EMERGENCY NUMBER
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For use by Office of Administrative Law (OAL) only

2020 MAR 19 P 4:44
OFFICE OF
ADMINISTRATIVE LAW

ENDORSED - FILED
in the office of the Secretary of State
of the State of California

MAY 07 2020

1:40 p.m.

NOTICE	REGULATIONS
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AGENCY WITH RULEMAKING AUTHORITY
Department of Health Care Services

AGENCY FILE NUMBER (if any)
DHCS-14-026

A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

1. SUBJECT OF NOTICE		TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE
3. NOTICE TYPE <input type="checkbox"/> Notice re Proposed Regulatory Action <input type="checkbox"/> Other		4. AGENCY CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)
OAL USE ONLY	ACTION ON PROPOSED NOTICE <input type="checkbox"/> Approved as Submitted <input type="checkbox"/> Approved as Modified <input type="checkbox"/> Disapproved/Withdrawn		NOTICE REGISTER NUMBER 2018-33-2	PUBLICATION DATE 8/17/2018

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

1a. SUBJECT OF REGULATION(S) Narcotic Treatment Program	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S) 2019-0813-02S
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2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (Including title 26, if toxics related)

SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)	ADOPT 10021, 10036, 10037 and 10386
	AMEND See attached sheet
TITLE(S) 9	REPEAL 10015 and 10340

3. TYPE OF FILING

<input type="checkbox"/> Regular Rulemaking (Gov. Code §11346)	<input type="checkbox"/> Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.	<input type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h))	<input type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
<input checked="" type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)	<input type="checkbox"/> Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)	<input type="checkbox"/> File & Print	<input type="checkbox"/> Print Only
<input type="checkbox"/> Emergency (Gov. Code, §11346.1(b))		<input type="checkbox"/> Other (Specify)	

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)

Dates of Availability: June 4, 2019 through June 19, 2019 and January 16, 2020 through January 30, 2020.

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)

<input checked="" type="checkbox"/> Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))	<input type="checkbox"/> Effective on filing with Secretary of State	<input type="checkbox"/> \$100 Changes Without Regulatory Effect	<input type="checkbox"/> Effective other (Specify)
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6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY

<input checked="" type="checkbox"/> Department of Finance (Form STD. 399) (SAM §6660)	<input type="checkbox"/> Fair Political Practices Commission	<input type="checkbox"/> State Fire Marshal
<input type="checkbox"/> Other (Specify)		

7. CONTACT PERSON Kenneisha Moore	TELEPHONE NUMBER (916) 345-8403	FAX NUMBER (Optional) (916) 440-5748	E-MAIL ADDRESS (Optional)
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8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE

Original Signed

DATE

3/19/20

TYPED NAME AND TITLE OF SIGNATORY

Bradley Gilbert Director

For use by Office of Administrative Law (OAL) only

ENDORSED APPROVED

MAY 07 2020

Office of Administrative Law

Notice Register File Number – Z-2018-0806-01

STD 400

B. Submission of Regulations – Sections Amended

10000, 10010, 10020, 10025, 10030, 10035, 10040, 10045, 10055, 10056, 10057, 10060, 10095, 10125, 10130, 10145, 10160, 10165, 10190, 10195, 10240, 10260, 10270, 10280, 10315, 10320, 10330, 10345, 10355, 10360, 10365, 10370, 10375, 10380, 10385, 10410, and 10425

(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 $C_{29}H_{41}NO_4 \cdot HCl$ to control moderate to severe pain and treat opioid dependence.

(3) Buprenorphine Products. "Buprenorphine products" means buprenorphine combination products approved by the FDA for maintenance treatment or detoxification of opioid dependence.

(4) DEA. "DEA" means the United States Drug Enforcement Administration.

(5) Department. "Department" means the Department of Health Care Services.

(26) 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 treat physical dependence ~~reduce or eliminate opiate addiction~~, while the patient is provided a comprehensive range of treatment services.

(37) FDA. "FDA" means the United States Food and Drug Administration.

(48) 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.

(59) 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.

(610) 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 that 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.

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

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

(915) 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);

(C) Buprenorphine and buprenorphine products approved by the FDA for maintenance treatment or detoxification treatment of opioid addiction; and

(D) Any other medication approved by the FDA for the purpose of narcotic replacement treatment or medication-assisted treatment of substance use disorders.

(4016) 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.

(1417) Methadone. "Methadone" means the substance that can be described as 6-dimethylamino-4, 4-diphenyl-3-heptanone. Methadone doses are usually administered as methadone hydrochloride.

(1418) 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.

(1419) 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 substance use disorder population; counseling by addiction counselors who are evaluated through ongoing supervision; and professional medical, social work, and mental health services, on-site or by referral.

(1421) 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.

(4523) OpiateOpioid Addiction. "OpiateOpioid Addiction," and the related term "addiction to opiatesopioids," mean a condition characterized by compulsion and lack of control that lead to illicit or inappropriate opiateopioid-seeking behavior, including an opiate opioid addiction that was acquired or supported by the misuse of a physician's legally prescribed narcotic medication.

(4624) 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.

(4725) 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.

(4827) Program. "Program" means a narcotic treatment program, unless otherwise specified.

(4928) Program Director. "Program director" means the person who has primary administrative responsibility for operation of an approved and licensed program.

(2029) 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 of 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.

(2130) 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.~~

(2231) Rationale. "Rationale" means a rational statement of principles or the logical basis for a procedure.

(2332) 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.

(2434) 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-abusing substance use disorder 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);

(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 who 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 the documents are:

(1) Complete, including all required documents specified in subsections (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 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 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 an 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 the documents are:

(1) Complete, including all required documents specified in subsections (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 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: Section 11839.3, 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 that~~ opioids who 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 (physical or electronic).

(13) Control and security of patient identification cards system.

(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 Pprocedures 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~~that 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.~~

(~~eb~~) 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 submitted 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 Amendments and changes in ~~or significant protocol changes~~ shall consist of a series of dated page revisions for insertion into the approved protocol.

~~(c) 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.~~

(ed) 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) 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 that 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 from 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 the application is:

(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) ~~that~~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 ~~an~~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~~es demonstrated need and support ~~of~~ received a recommendation from 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 ~~the~~such application is ~~either~~:

(1) Complete, including all required documents specified in Section 10030, and accepted for ~~file~~ing 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, an 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 an effective date 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. 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 the addition of a medication unit as described in Section 10020 or an OBNTN as described in Section 10021 ~~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 licensed ~~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 Sections 10035 and 10037.

(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 License 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 March 1st April 30 of each year, the Department shall calculate the annual license fee for the future 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 that year. The license fee shall be due and payable in the manner described in subsection (h) below.

(e) No later than March 1st April 30 of each year, following the effective date of this regulation, the Department shall give written notice to narcotic treatment program licensees of the license fees for the future fiscal year and the manner in which they were calculated, including data used in making the calculation.

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

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

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

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

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

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

(1) If the licensee pays the total annual license fees once annually, the licensee ~~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, the licensee ~~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 of the failure ~~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 the ~~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 of the right to ~~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 the ~~his/her~~ obligation to pay license fees and shall not entitle the licensee to renewal of the ~~his/her~~ license.

(i) 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 and issue a refund for the days remaining between the effective closure date through the June 30th expiration date of the license. 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 ~~and 11839.20~~, Health and Safety Code. Reference: Sections 11839.3 and 11839.7, Health and Safety Code.

(15) 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) 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.

(~~eb~~) 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 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 the 15- 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.

(~~32~~) 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 (~~eb~~)(1)(~~B~~) ~~or~~ (C).

(~~43~~) 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.

(~~54~~) 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.

(~~9~~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, Behavioral Health, 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 ~~(ed)~~(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.

~~(fe)~~ 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 ~~(ba)~~ and ~~(ed)~~ 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.

~~(gf)~~ 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.~~

(16) 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~~ treating 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.

(17) 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.

(18) 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.

(19) 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.

(20) 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 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 who 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.~~

(2d) ~~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.~~

(e) ~~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.~~

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

(e) The Department may issue 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~~that:

(A) Informs 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) Informs the licensee that as soon as the program is within its licensed patient capacity, the program ~~shall~~ is required to 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.

(21) 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.

(4b) Programs shall keep patient records in a secure location within the facility or in a secure electronic medical record database.

(~~b~~c) 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.

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

(e) Each program shall specify in its protocol the methods in place to safeguard physical and/or electronic patient records.

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.

(22) 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) ~~Known incidence of arrests, and convictions~~ 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~~ outcomes 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~~ outcomes.
- (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 one ~~year~~ ~~two years~~, the circumstances justifying such continued treatment as set forth in ~~s~~Section 10410.
- (4) Reasons for changes in dosage of levels and medications.
- (5) For patients who have terminated the program, a discharge summary and follow-up notations to allow determination of ~~success or failure of treatment~~ outcomes.

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 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, or opioid addiction, where treatment is available 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 ~~11245~~, 11839.3 and 11839.20, Health and Safety Code.

(24) 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 One (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 deaths, 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.

(25) Amend Section 10240 to read as follows:

§10240. Patient Identification Card System.

(a) Each program shall establish and maintain a patient identification system. ~~make known to each patient the availability of a completed identification card which shall be supplied by the program.~~

(b) ~~The patient identification system cards shall~~ assign unique identifiers to patients ~~be numbered consecutively.~~

(c) The patient identification system shall maintain the following information:

(1) The patient's name;

(2) The patient's unique identifier;

(3) The patient's physical description;

(4) The patient's signature; and

(5) A full-face photograph of the patient.

(d) The patient identification system may employ the use of patient identification cards.

(~~e~~1) ~~A patient identification cards shall contain~~ include the following items ~~information:~~

(~~A~~4) The patient's name;

(~~B~~2) The patient's unique identifier ~~record number;~~

(~~C~~3) The patient's physical description;

(~~D~~4) The patient's signature;

(~~E~~5) A full-face photograph of the patient;

(~~F~~6) The program's name, address, 24-hour phone number, and signature of the
program director or designee; and

(~~G~~7) The issuance and expiration dates of the patient identification card.

(d2) Patients shall not be required to carry the patient identification card when away from the program premises.

(e3) Patients may be required by the program to carry the patient identification card while on the program's premises.

(fe) Each program shall set forth in its protocol the system ~~the program will used~~ to ensure:

(1) Positive identification of the patient and a correct recording of attendance and/or medication.

(2) For programs that utilize patient identification cards:

(1A) ~~Accurate documentation of the voluntary use~~ The issuance and tracking of patient identification cards.

(2B) ~~Recovery of the voluntary patient~~ identification cards when the patient identification card has expired or when the patient has either completed or terminated treatment.

(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.

(26) Amend Section 10260 to read as follows:

§10260. Administering~~ration~~ 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 that~~ 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.

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

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

(56) Methadone shall be available seven days a~~p~~er 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 ~~11245~~, 11839.2 and 11839.3, Health and Safety Code.

(27) 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~~that includes the applicant's history of illicit drug use;

(2) An optional laboratory test for the determination of human immunodeficiency virus (HIV) in accordance with Division 105, Part 4, Chapter 7 of Health and Safety Code; and
~~L~~laboratory tests for determination of narcotic drug use, hepatitis C virus (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~~that 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, and 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~~that 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)(54)(A) and (d)(54)(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)(54)(A) and (d)(54)(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.~~

~~(64)~~ The applicant is not in the last trimester of pregnancy.

(d) Maintenance Treatment.

The program shall determine which applicants with an addiction to opiates opiods 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 of addiction to opiates opiods. 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~~outcomes, that which are used to confirm ~~two~~one years of addiction to opiates opiods. 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.~~

~~(32)~~ A minimum age of 18 years. For patients under the age of 18 years, a documented history of two unsuccessful attempts at short-term detoxification or drug-free treatment within a

12-month period. The methods to confirm this history and the types of documentation to be maintained in the patient's record shall be stated in the protocol. Patients under the age of 18 years shall also have the written consent of their parent(s) or guardian prior to the admission into maintenance treatment.

(43) 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, including linkages to care and treatment, where needed, for patients who test positive for HIV, HCV, tuberculosis or syphilis.

(54) 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.

(65) Pregnant patients who are currently physically dependent on ~~opiates~~ opioids and have had a documented history of ~~addiction~~ 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)(65) ~~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 ~~41835~~, 11839.2, 11839.3, and 11839.20 ~~and 11875~~, Health and Safety Code.

(28) 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.

(29) 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).

(bc) 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.

(30) 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 ~~California~~State Department of Health Services Public Health as a Methadone Drug Analysis Laboratory, pursuant to the provisions of group 5.5 (commencing with ~~§~~Section 1160), ~~§~~Subchapter 1, ~~§~~Chapter 2, ~~§~~Division 1, ~~§~~Title 17, of the California Code of Regulations, and is currently included on the list of licensed and certified laboratories ~~that~~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.

(31) 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 in compliance with 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 ~~41839.24~~ 11839.24, Health and Safety Code.

(32) 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.

(33) 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 fifty (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 ~~§~~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 ~~§~~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 fourteen (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.

(34) 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.

(fg) Dosage Schedule Following Patient Absence.

~~After~~ When 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. The new medication order shall be provided by the medical director or program physician, either in person, by verbal order, or through other electronic means, and shall be documented and justified in the patient's record.

~~(gh)~~ 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 ~~11248, 11249, 11839.2, 11839.3, and 11839.20 and 11875,~~ Health and Safety Code.

(35) 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, physician assistant, or nurse practitioner licensed by the State of California and trained in obstetrics and/or gynecology, or a licensed midwife or certified nurse midwife licensed by the State of California.

(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.

(10) Evidence-based practices for managing neonatal abstinence syndrome.

(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.

(36) 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 (d)(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.

(37) 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, is adhering to program requirements, 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, educational, ~~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)~~ 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.

(38) 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 – Day 1 through 90 of continuous maintenance treatment, the medical director or program physician may grant the patient a single dose of take-home supply of medication per week. The patient shall attend the program at least six times per week for observed ingestion.

(12) 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 per week. The patient shall attend the program at least six five times a per week for observed ingestion.

(23) 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 per week. The patient shall attend the program at least five four times a per week for observed ingestion.

(34) Step IIIV Level – ~~After nine months~~ Day 271 through one 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 per week. The patient shall attend the program at least four one times a per week for observed ingestion.

(45) Step IV 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 ~~aper~~ week-month for observed ingestion.

(56) Step VI 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 times ~~aper~~ 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~~that is more stringent than is specified in the schedule contained herein.

(c) In the case of a patient who transfers to the program from another program without a break in treatment, the new medical director or program physician may consider the time the patient has spent at the former program when considering the patient's eligibility for take-home medication privileges, as well as for advancement to a new step level. ~~But in~~ no case shall any patient be placed, upon admission, at a step level higher than that which was occupied in the former program immediately before transferring to the new program.

NOTE: Authority cited: Sections 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 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 ~~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
<u>Cesar Chavez Day</u>	<u>March 31</u>
Memorial Day	Last Monday in May
Independence Day	July 4
Labor Day	First Monday in September
California Admission Day	September 9
Columbus Day	Second Monday in October
Veterans Day	November 11
Thanksgiving Day	Fourth Thursday in November
Christmas Day	December 25

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

NOTE: Authority cited: Sections 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 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 than an increased dosage level.~~

(b) Prior to granting submitting an 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 submitted 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.

(ed) 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.

(41) 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 pursuant to Section 10375, a split dose shall be considered a one-day take-home supply.

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.

(42) 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 years ~~after such~~ of treatment is begun ~~unless he or she completes.~~ The medical director or program physician shall do the following:

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

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

(43) 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;~~

~~(64)~~ The program applicant shall comply with all Departmental requirements for maintaining appropriate records or otherwise documenting and reporting activity;

~~(65)~~ 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

~~(76)~~ 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.

Documents Incorporated by Reference (10)

Application for License Renewal
form DHCS 4029 (04/16)

APPLICATION FOR LICENSE RENEWAL

INSTRUCTIONS FOR COMPLETION OF THE APPLICATION FOR LICENSE RENEWAL FORM
DHCS 4029 (04/16)

Return completed form to the address designated in the header above.

DO NOT USE staples on this form or on any attachments.

DO NOT USE correction tape, white out, or highlighter pen or ink of a similar type on this form. If you must make corrections, please line through, date, and initial in ink.

DO NOT LEAVE any questions, boxes, lines, or fields blank. Enter N/A if not applicable to you.

PLEASE NOTE: Read all the instructions included on this form carefully and complete each item requested. For additional information, please review the California Code of Regulations (CCR), Title 9, Division 4, Chapter 4, Subchapter 1 commencing with Section 10000, which outlines the requirements and standards for Narcotic Treatment Programs.

A Medication Unit (MU) or Office-Based Narcotic Treatment Network (OBNTN) must fill out sections A and B. If you have more than one MU or OBNTN attach additional Section B information.

Section A

Applicant Information

This section must be completed by all applicants.

Application for Fiscal Year – Enter the fiscal year for which you are applying for renewal.

Original License Date – Enter the initial effective date of the Narcotic Treatment Program (NTP) license.

License Number – Enter the NTP license number issued by the Department.

National Provider Identifier (NPI) – Enter the 10 digit NPI number associated with the facility. If you need additional information or do not know the NPI number, please contact the National Plan and Provider Enumeration System at: <https://nppes.cms.hhs.gov/NPPES/Welcome.do>

Name of Legal Entity – Enter the legal entity name.

PLEASE NOTE: Any business operation under a fictitious name shall submit a copy of the county filing setting forth that name.

Corporation – For a corporation, enter the name exactly as it is filed with the Secretary of State (SOS) and as it appears on the entity's Articles of Incorporation. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

APPLICATION FOR LICENSE RENEWAL

Limited Liability Company (LLC) – For a LLC, enter the name exactly as it is filed with the SOS and as it appears on the entity's Articles of Organization. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Partnership/Limited Partnership – For a partnership or limited partnership, enter the name of the partnership exactly as it is filed with the SOS on the Statement of Partnership Authority or Certificate of Limited Partnership respectively. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Sole Proprietor – For a sole proprietor, enter the full legal name of the sole proprietor.

Governmental Agency – Enter the name of the governmental agency.

Name of Narcotic Treatment Program – If different from legal entity name, enter the name of the facility.

Tax Status – Check the box which applies to your business structure for tax purposes.

Facility Street Address – Enter the exact address of the facility. A post office box or commercial box is not acceptable. If applicable, enter the room/suite/unit number of the facility.

City – Enter the city of the facility.

County – Enter the county of the facility.

Zip Code – Enter the zip code of the facility.

An exact address can be verified at the United States Postal Service website at:
https://tools.usps.com/go/ZipLookupAction_input

Mailing Address – If different from facility street address, enter the exact mailing address. If applicable, enter the room/suite/unit number of the mailing address.

City – Enter the city of the mailing address.

County – Enter the county of the mailing address.

Zip Code – Enter the zip code of the mailing address.

An exact address can be verified at the United States Postal Service website:
https://tools.usps.com/go/ZipLookupAction_input

Telephone Number – Enter the contact person's telephone number, including an extension if applicable.

APPLICATION FOR LICENSE RENEWAL

Fax Number – Enter the fax number of the facility.

Name of Program Sponsor – Enter the person or organization responsible for the operation of the NTP 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.

Name of Program Director – Enter the name of the person who has primary administrative responsibility for operation of the NTP.

Name of Medical Director – Enter the name of the physician licensed to practice medicine in California who is responsible for medical services provided by the NTP.

Licensed Patient Capacity – Enter the Department approved licensed patient capacity for maintenance and detoxification treatment.

Operating Hours (M-F) – Enter the facility hours of operation from Monday through Friday.

Dispensing Hours (M-F) – Enter the facility hours of dispensing medication from Monday through Friday.

Weekend Operating Hours – Enter the facility hours of operation for Saturday and Sunday.

Weekend Dispensing Hours – Enter the facility hours of dispensing medication for Saturday and Sunday.

Section B

MU/OBNTN

This section must be completed for each MU or OBNTN that is operating under the license of the Primary NTP that is applying for license renewal.

NPI – Enter the 10 digit NPI number associated with the facility. If you need additional information or do not know the NPI number, please contact the National Plan and Provider Enumeration System at: <https://nppes.cms.hhs.gov/NPPES/Welcome.do>.

Name of Legal Entity – Enter the legal entity name.

PLEASE NOTE: Any business operation under a fictitious name shall submit a copy of the county filing setting forth that name.

Corporation – For a corporation, enter the name exactly as it is filed with the SOS and as it appears on the entity's Articles of Incorporation. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

APPLICATION FOR LICENSE RENEWAL

Limited Liability Company (LLC) – For a LLC, enter the name exactly as it is filed with the SOS and as it appears on the entity's Articles of Organization. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Partnership/Limited Partnership – For a partnership or limited partnership, enter the name of the partnership exactly as it is filed with the SOS on the Statement of Partnership Authority or Certificate of Limited Partnership respectively. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Sole Proprietor – For a sole proprietor, enter the full legal name of the sole proprietor.

Governmental Agency – Enter the name of the governmental agency.

Name of MU or OBNTN – If different from legal entity name, enter the name of the facility or provider.

Tax Status – Check the box which applies to your business structure for tax purposes.

Facility Street Address – Enter the exact address of the facility. A post office box or commercial box is not acceptable. If applicable, enter the room/suite/unit number of the facility.

City – Enter the city of the facility.

County – Enter the county of the facility.

Zip Code – Enter the zip code of the facility.

An exact address can be verified at the United States Postal Service website:

https://tools.usps.com/go/ZipLookupAction_input

Mailing Address – If different from facility street address, enter the exact mailing address. If applicable, enter the room/suite/unit number of the mailing address.

City – Enter the city of the mailing address.

County – Enter the county of the mailing address.

Zip Code – Enter the zip code of the mailing address.

An exact address can be verified at the United States Postal Service website:

https://tools.usps.com/go/ZipLookupAction_input

Telephone Number – Enter the contact person's telephone number, including an extension if applicable.

Fax Number – Enter the fax number of the facility.

APPLICATION FOR LICENSE RENEWAL

Name of Program Director – Enter the name of the person who has primary administrative responsibility for operation of the NTP.

Section C

Annual Maintenance Report

This section must be completed by all applicants.

Maintenance Treatment – Enter the total number of patients in methadone maintenance treatment on January 31st of the current year.

Maintenance Treatment – Enter the total number of patients in buprenorphine maintenance treatment on January 31st of the current year.

Detoxification Treatment – Enter the total number of patients in methadone detoxification treatment on January 31st of the current year.

Detoxification Treatment – Enter the total number of patients in buprenorphine detoxification treatment on January 31st of the current year.

Annual Maintenance Dosage Level and Take-Home Privileges for Methadone – Complete all fields based on program census data on January 31st of the current year for the annual maintenance dosage level and step level of patients in methadone treatment.

Annual Maintenance Dosage Level and Take-Home Privileges for Buprenorphine – Complete all fields based on program census data on January 31st of the current year for the annual maintenance dosage level and step level of patients in buprenorphine treatment.

Patients in Methadone Detoxification Treatment – Complete all fields based on program census data on January 31st of the current year for dosage levels of patients in methadone detoxification treatment.

Patients in Buprenorphine Detoxification Treatment – Complete all fields based on program census data on January 31st of the current year for dosage levels of patients in buprenorphine detoxification treatment.

Section D

Declaration

This section must be completed by all applicants.

Print Name – Enter the name of the program sponsor.

APPLICATION FOR LICENSE RENEWAL

Title – *This field has been pre-filled by the Department to reflect that the form must be signed by the program sponsor.*

Signature – Program sponsor's signature.

Date – Enter the date that the application is signed by the program sponsor.

APPLICATION FOR LICENSE RENEWAL

Section A			Applicant Information		
Application for Fiscal Year:			Original License Date:		
License Number:			National Provider Identifier (NPI):		
Name of Legal Entity:					
Name of Narcotic Treatment Program (if different than name of legal entity):					
Tax Status: <input type="checkbox"/> Corporation <input type="checkbox"/> Nonprofit Corporation <input type="checkbox"/> Limited Liability Company <input type="checkbox"/> Partnership/Limited Partnership <input type="checkbox"/> Sole Proprietor <input type="checkbox"/> Governmental Agency					
Facility Street Address (if applicable Room/Suite/Unit):					
City:		County:		Zip Code:	
Mailing Address (if applicable Room/Suite/Unit)/(if different than facility street address):					
City:		County:		Zip Code:	
Telephone Number:			Fax Number:		
Name of Program Sponsor:					
Name of Program Director:					
Name of Medical Director:					
Licensed Patient Capacity:					
Operating Hours (M-F):			Dispensing Hours (M-F):		
Weekend Operating Hours:			Weekend Dispensing Hours:		

APPLICATION FOR LICENSE RENEWAL

Section B		MU/OBNTN	
NPI:			
Name of Legal Entity:			
Name of MU or OBNTN (if different than name of legal entity):			
Tax Status: <input type="checkbox"/> Corporation <input type="checkbox"/> Nonprofit Corporation <input type="checkbox"/> Limited Liability Company <input type="checkbox"/> Partnership/Limited Partnership <input type="checkbox"/> Sole Proprietor <input type="checkbox"/> Governmental Agency			
Facility Street Address (if applicable Room/Suite/Unit):			
City:		County:	Zip Code:
Mailing Address (if applicable Room/Suite/Unit)/(if different than facility street address):			
City:		County:	Zip Code:
Telephone Number:		Fax Number:	
Name of Program Director:			
Section C		Annual Maintenance Report	
Maintenance Treatment			
Total Number of Patients in Methadone Maintenance Treatment as of January 31:			
Total Number of Patients in Buprenorphine Maintenance Treatment as of January 31:			
Detoxification Treatment			
Total Number of Patients in Methadone Detoxification Treatment as of January 31:			
Total Number of Patients in Buprenorphine Detoxification Treatment as of January 31:			

APPLICATION FOR LICENSE RENEWAL

Section C (Continued)				Patients in Detoxification Treatment			
Patients in Methadone Detoxification Treatment		Patients in Buprenorphine Detoxification Treatment					
Dosage	No.	Dosage	No.				
(mg.)	Take-Homes	(mg.)	Take-Homes				
	M		M				
	F		F				
0		0					
1-19		2-4					
20-39		6-8					
40-59		10-12					
60-79		14-16					
80-99		18-20					
100-119		22-24					
120-139		26-28					
140-159		30-32					
160-179		34-36					
180-199		38-40					
200-219		42+					
220-239		TOTALS					
240-259				GRAND TOTAL:			
260-279							
280-300+							
TOTALS:							
	GRAND TOTAL:						

APPLICATION FOR LICENSE RENEWAL

Section D	Declaration
<p>I declare under penalty of perjury under the laws of the State of California that the foregoing information and any attachment is true, accurate and complete to the best of my knowledge and belief. I hereby further declare that I will abide by all State and federal laws and regulations governing narcotic treatment programs.</p> <p>I declare that I am authorized to sign this application.</p>	
Print Name:	Title: Program Sponsor
Signature:	Date:
Privacy Statement	
<p style="text-align: center;">PRIVACY STATEMENT (Civil Code Section 1798 et seq.)</p> <p>All information requested in this form is mandatory. This information is required by the Department of Health Care Services (Department) by the authority of Health and Safety Code, Section 11839.3 and California Code of Regulations, Title 9, Section 10055. The consequences of not supplying the mandatory information requested is that review of the application shall be terminated, which may result in lapse of licensure and/or imposition of fines. The Department may share or provide any of the information provided in or with this form to the California Health and Human Services Agency, the California State Controller's Office, the California Department of Justice, the California Department of Consumer Affairs, the Department of Corporations, or other state or local agencies as appropriate, the Federal Bureau of Investigation, the Internal Revenue Service, the U.S. Justice Department, the United States Drug Enforcement Administration, the United States Department of Health and Human Services, and the United States Substance Abuse and Mental Health Services Administration. For more information or access to records containing your personal information maintained by the Department, contact the Counselor & Medication Assisted Treatment Section Officer of the Day at (916) 322-6682.</p>	

INITIAL APPLICATION COVERSHEET

INSTRUCTIONS FOR COMPLETION OF THE INITIAL APPLICATION COVERSHEET FORM
DHCS 5014 (04/16)

Return completed form to the address designated in the header above.

DO NOT USE staples on this form or on any attachments.

DO NOT USE correction tape, white out, or highlighter pen or ink of a similar type on this form. If you must make corrections, please line through, date, and initial in ink.

DO NOT LEAVE any questions, boxes, lines, or fields blank. Enter N/A if not applicable to you.

PLEASE NOTE: Read all the instructions included on this form carefully and complete each item requested. For additional information, please review the California Code of Regulations (CCR), Title 9, Division 4, Chapter 4, Subchapter 1 commencing with Section 10000, which outlines the requirements and standards for Narcotic Treatment Programs.

Section A	Application Type
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This section must be completed by all applicants.

Check the appropriate box(es) for the type of facility for which you are applying. If applying for a narcotic treatment program, please check the appropriate box(es) for services that will be provided.

Narcotic Treatment Program (NTP) – A licensed opioid addiction treatment program, whether inpatient or outpatient, which offers all of the following: evaluation, maintenance treatment and/or detoxification treatment, and other services in conjunction with replacement narcotic therapy.

Detoxification Treatment – 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 opioid addiction, while the patient is provided treatment services.

Maintenance Treatment – 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 opioid addiction, while the patient is provided a comprehensive range of treatment services.

Medication Unit (MU) – A facility established as part of, but geographically separate from an NTP, from which licensed private practitioners or community pharmacists dispense or administer an opioid agonist treatment medication and/or collect samples for drug testing or analysis.

INITIAL APPLICATION COVERSHEET

Office-Based Narcotic Treatment Network (OBNTN) – A network of providers, that are affiliated and associated with a primary NTP, 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.

Section B

Applicant Information

This section must be completed by all applicants.

License Number – If the applicant currently holds an active NTP license issued by the Department, enter the license number. If the applicant does not currently hold an NTP license issued by the Department, please enter “N/A”.

National Provider Identifier (NPI) – Enter the 10 digit NPI number associated with the facility. If you need additional information or do not know the NPI number, please contact the National Plan and Provider Enumeration System at: <https://nppes.cms.hhs.gov/NPPES/Welcome.do>

Name of Legal Entity – Enter the legal entity name.

PLEASE NOTE: Any business operation under a fictitious name shall submit a copy of the county filing setting forth that name.

Corporation – For a corporation, enter the name exactly as it is filed with the Secretary of State (SOS) and as it appears on the entity’s Articles of Incorporation. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Limited Liability Company (LLC) – For a LLC, enter the name exactly as it is filed with the SOS and as it appears on the entity’s Articles of Organization. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Partnership/Limited Partnership – For a partnership or limited partnership, enter the name of the partnership exactly as it is filed with the SOS on the Statement of Partnership Authority or Certificate of Limited Partnership respectively. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Sole Proprietor – For a sole proprietor, enter the full legal name of the sole proprietor.

Governmental Agency – Enter the name of the governmental agency.

INITIAL APPLICATION COVERSHEET

Name of Narcotic Treatment Program – If different from legal entity name, enter the name of the facility.

Tax Status – Check the box which applies to your business structure for tax purposes.

Facility Street Address – Enter the exact address of the facility. A post office box or commercial box is not acceptable. If applicable, enter the room/suite/unit number of the facility.

City – Enter the city of the facility.

County – Enter the county of the facility.

Zip Code – Enter the zip code of the facility.

An exact address can be verified at the United States Postal Service website:

https://tools.usps.com/go/ZipLookupAction_input

Mailing Address – If different from facility street address, enter the exact mailing address. If applicable, enter the room/suite/unit number of the mailing address.

City – Enter the city of the mailing address.

County – Enter the county of the mailing address.

Zip Code – Enter the zip code of the mailing address.

An exact address can be verified at the United States Postal Service website:

https://tools.usps.com/go/ZipLookupAction_input

Telephone Number – Enter the contact person's telephone number, including an extension if applicable.

Fax Number – Enter the fax number assigned to the facility.

Name of Program Sponsor – Enter the person or organization responsible for the operation of the NTP 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.

Name of Program Director – Enter the name of the person who has primary administrative responsibility for operation of the NTP.

INITIAL APPLICATION COVERSHEET

Name of Medical Director – Enter the name of the physician licensed to practice medicine in California who is responsible for medical services provided by the NTP.

Proposed Capacity – Enter the proposed patient capacity for the NTP.

Section C

MU/OBNTN

This section must be completed by MU and OBNTN applicants only.

NPI – Enter the 10 digit NPI number associated with the facility. If you need additional information or do not know the NPI number, please contact the National Plan and Provider Enumeration System at: <https://nppes.cms.hhs.gov/NPPES/Welcome.do>

Name of Legal Entity – Enter the legal entity name.

PLEASE NOTE: Any business operation under a fictitious name shall submit a copy of the county filing setting forth that name.

Corporation – For a corporation, enter the name exactly as it is filed with the SOS and as it appears on the entity's Articles of Incorporation. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Limited Liability Company (LLC) – For a LLC, enter the name exactly as it is filed with the SOS and as it appears on the entity's Articles of Organization. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Partnership/Limited Partnership – For a partnership or limited partnership, enter the name of the partnership exactly as it is filed with the SOS on the Statement of Partnership Authority or Certificate of Limited Partnership respectively. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Sole Proprietor – For a sole proprietor, enter the full legal name of the sole proprietor.

Governmental Agency – Enter the name of the governmental agency.

Name of MU or OBNTN – If different from legal entity name, enter the name of the facility or provider.

Tax Status – Check the box which applies to your business structure for tax purposes.

Facility Street Address – Enter the exact address of the facility. A post office box or commercial box is not acceptable. If applicable, enter the room/suite/unit number of the facility.

City – Enter the city of the facility.

INITIAL APPLICATION COVERSHEET

County – Enter the county of the facility.

Zip Code – Enter the zip code of the facility.

An exact address can be verified at the United States Postal Service website:

https://tools.usps.com/go/ZipLookupAction_input

Mailing Address – If different from facility street address, enter the exact mailing address. If applicable, enter the room/suite/unit number of the mailing address.

City – Enter the city of the mailing address.

County – Enter the county of the mailing address.

Zip Code – Enter the zip code of the mailing address.

An exact address can be verified at the United States Postal Service website:

https://tools.usps.com/go/ZipLookupAction_input

Telephone Number – Enter the contact person's telephone number, including an extension if applicable.

Fax Number – Enter the fax number of the facility.

Name of Program Director – Enter the name of the person who has primary administrative responsibility for operation of the facility.

Section D	Declaration
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This section must be completed by all applicants.

Print Name – Enter the name of the program sponsor.

Title – *This field has been pre-filled by the Department to reflect that the form must be signed by the program sponsor.*

Signature – Program sponsor's signature.

Date – Enter the date that the application is signed by the program sponsor.

INITIAL APPLICATION COVERSHEET

Section A	Application Type	
<input type="checkbox"/> Narcotic Treatment Program (NTP) CCR, Title 9, §10030 (Complete Sections B & D) <input type="checkbox"/> Detoxification Treatment <input type="checkbox"/> Maintenance Treatment		
<input type="checkbox"/> Medication Unit (MU) CCR, Title 9, §10020 (Complete Sections B, C, & D)		
<input type="checkbox"/> Office-Based Narcotic Treatment Network (OBNTN) CCR, Title 9, §10021 (Complete Sections B, C, & D)		
License Number (if applicable):		
National Provider Identifier (NPI):		
Name of Legal Entity:		
Name of Narcotic Treatment Program (if different than name of legal entity):		
Tax Status: <input type="checkbox"/> Corporation <input type="checkbox"/> Nonprofit Corporation <input type="checkbox"/> Limited Liability Company <input type="checkbox"/> Partnership/Limited Partnership <input type="checkbox"/> Sole Proprietor <input type="checkbox"/> Governmental Agency		
Facility Street Address (if applicable Room/Suite/Unit):		
City:	County:	Zip Code:
Mailing Address (if applicable Room/Suite/Unit)/(if different than facility street address):		

INITIAL APPLICATION COVERSHEET

City:	County:	Zip Code:
Section B (Continued) Applicant Information		
Telephone Number:	Fax Number:	
Name of Program Sponsor:		
Name of Program Director:		
Name of Medical Director:		
Proposed Capacity:		
Section C MU/OBNTN (Complete section C only if application is for MU or OBNTN.)		
NPI:		
Name of Legal Entity:		
Name of MU or OBNTN (if different than name of legal entity):		
Tax Status: <input type="checkbox"/> Corporation <input type="checkbox"/> Nonprofit Corporation <input type="checkbox"/> Limited Liability Company <input type="checkbox"/> Partnership/Limited Partnership <input type="checkbox"/> Sole Proprietor <input type="checkbox"/> Governmental Agency		
Facility Street Address (if applicable Room/Suite/Unit):		
City:	County:	Zip Code:
Mailing Address (if applicable Room/Suite/Unit)/(if different than facility street address):		
City:	County:	Zip Code:
Telephone Number:	Fax Number:	

INITIAL APPLICATION COVERSHEET

Name of Program Director:	
Section D Declaration	
I declare under penalty of perjury under the laws of the State of California that the foregoing information and any attachment is true, accurate and complete to the best of my knowledge and belief. I hereby further declare that I will abide by all State and federal laws and regulations governing narcotic treatment programs.	
I declare that I am authorized to sign this application.	
Print Name:	Title: Program Sponsor
Signature:	Date:
Privacy Statement	
PRIVACY STATEMENT (Civil Code Section 1798 et seq.)	
All information requested in this form is mandatory. This information is required by the Department of Health Care Services (Department) by the authority of Health and Safety Code, Section 11839.3 and California Code of Regulations, Title 9, Section 10055. The consequences of not supplying the mandatory information requested is that review of the application shall be terminated, which may result in lapse of licensure and/or imposition of fines. The Department may share or provide any of the information provided in or with this form to the California Health and Human Services Agency, the California State Controller's Office, the California Department of Justice, the California Department of Consumer Affairs, the Department of Corporations, or other state or local agencies as appropriate, the Federal Bureau of Investigation, the Internal Revenue Service, the U.S. Justice Department, the United States Drug Enforcement Administration, the United States Department of Health and Human Services, and the United States Substance Abuse and Mental Health Services Administration. For more information or access to records containing your personal information maintained by the Department, contact the Counselor & Medication Assisted Treatment Section Officer of the Day at (916) 322-6682.	

GUARANTOR AGREEMENT

INSTRUCTIONS FOR COMPLETION OF THE GUARANTOR AGREEMENT FORM
DHCS 5020 (04/16)

Return completed form to the address designated in the header above.

DO NOT USE staples on this form or on any attachments.

DO NOT USE correction tape, white out, or highlighter pen or ink of a similar type on this form. If you must make corrections, please line through, date, and initial in ink.

DO NOT LEAVE any questions, boxes, lines, or fields blank. Enter N/A if not applicable to you.

PLEASE NOTE: Read all the instructions included on this form carefully and complete each item requested. For additional information, please review the California Code of Regulations (CCR), Title 9, Division 4, Chapter 4, Subchapter 1 commencing with Section 10000, which outlines the requirements and standards for Narcotic Treatment Programs.

SECTION A

Applicant Information

License Number – If the applicant currently holds an active Narcotic Treatment Program (NTP) license issued by the Department, enter the license number. If the applicant does not currently hold an NTP license issued by the Department, please enter “N/A”.

National Provider Identifier (NPI) – Enter the 10 digit NPI number associated with the facility. If you need additional information or do not know the NPI number, please contact the National Plan and Provider Enumeration System at <https://nppes.cms.hhs.gov/NPPES/Welcome.do>

Name of Legal Entity – Enter the legal entity name.

PLEASE NOTE: Any business operation under a fictitious name shall submit a copy of the county filing setting forth that name.

Corporation – For a corporation, enter the name exactly as it is filed with the Secretary of State (SOS) and as it appears on the entity's Articles of Incorporation. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Limited Liability Company (LLC) – For a LLC, enter the name exactly as it is filed with the SOS and as it appears on the entity's Articles of Organization. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

GUARANTOR AGREEMENT

Partnership/Limited Partnership – For a partnership or limited partnership, enter the name of the partnership exactly as it is filed with the SOS on the Statement of Partnership Authority or Certificate of Limited Partnership respectively. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>.

Sole Proprietor – For a sole proprietor, enter the full legal name of the sole proprietor.

Governmental Agency – Enter the name of the governmental agency.

Name of Narcotic Treatment Program – If different from legal entity name, enter the name of the facility.

Facility Street Address – Enter the exact address of the facility. A post office box or a commercial box is not acceptable. If applicable, enter the room/suite/unit number of the facility.

City – Enter the city of the facility.

County – Enter the county of the facility.

Zip Code – Enter the zip code of the facility.

An exact address can be verified at the United States Postal Service website:

https://tools.usps.com/go/ZipLookupAction_input

Mailing Address – If different from facility street address, enter the exact mailing address. If applicable, enter the room/suite/unit number of the mailing address.

City – Enter the city of the mailing address.

County – Enter the county of the mailing address.

Zip Code – Enter the zip code of the mailing address.

An exact address can be verified at the United States Postal Service website:

https://tools.usps.com/go/ZipLookupAction_input

SECTION B

Guarantor Selection

PLEASE NOTE: Pursuant to CCR, Title 9, §10095(b)(1)(A)-(B), programs offering treatment shall provide a guarantee that treatment will continue at the existing location for up to 90 days following receipt by the Department of the program's notice of intent to close the program or shall guarantee that treatment will be provided through the transfer of patients at another program.

GUARANTOR AGREEMENT

Check the appropriate box for the continued operation of the program as required by this section.

SECTION C

Guarantor Information

Name of Guarantor – Enter the name of the individual or entity who will guarantee that treatment will continue at the existing location for up to 90 days following receipt by the Department of the program's notice of intent to close the program.

Mailing Address – Enter the mailing address of the Guarantor. If applicable, enter the room/suite/unit number of the Guarantor.

City – Enter the city of the mailing address of the Guarantor.

County – Enter the county of the mailing address of the Guarantor.

Zip Code – Enter the zip code of the mailing address of the Guarantor.

An exact address can be verified at the United States Postal Service website:

https://tools.usps.com/go/ZipLookupAction_input

Telephone Number – Enter the Guarantor's telephone number, including an extension if applicable.

Fax Number – Enter the Guarantor's fax number.

SECTION D

Guarantor Program Information

License Number – Enter the license number of the NTP that will guarantee that treatment will be provided through the transfer of patients to the NTP location.

NPI – Enter the 10 digit NPI number associated with the facility. If you need additional information or do not know the NPI number, please contact the National Plan and Provider Enumeration System at <https://nppes.cms.hhs.gov/NPPES/Welcome.do>

Name of Legal Entity – Enter the legal entity name.

PLEASE NOTE: Any business operation under a fictitious name shall submit a copy of the county filing setting forth that name.

GUARANTOR AGREEMENT

Corporation – For a corporation, enter the name exactly as it is filed with the SOS and as it appears on the entity's Articles of Incorporation. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Limited Liability Company (LLC) – For a LLC, enter the name exactly as it is filed with the SOS and as it appears on the entity's Articles of Organization. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Partnership/Limited Partnership – For a partnership or limited partnership, enter the name of the partnership exactly as it is filed with the SOS on the Statement of Partnership Authority or Certificate of Limited Partnership respectively. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Sole Proprietor – For a sole proprietor, enter the full legal name of the sole proprietor.

Governmental Agency – Enter the name of the governmental agency.

Name of NTP – If different from legal entity name, enter the name of the NTP that will guarantee that treatment will be provided through the transfer of patients to the NTP location.

Facility Street Address – Enter the exact address of the facility. A post office box or commercial box is not acceptable. If applicable, enter the room/suite/unit number of the facility.

City – Enter the city of the facility.

County – Enter the county of the facility.

Zip Code – Enter the zip code of the facility.

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Mailing Address – If different from facility street address, enter the exact mailing address. If applicable, enter the room/suite/unit number of the mailing address.

City – Enter the city of the mailing address.

County – Enter the county of the mailing address.

Zip Code – Enter the zip code of the mailing address.

GUARANTOR AGREEMENT

An exact address can be verified at the United States Postal Service website:

https://tools.usps.com/go/ZipLookupAction_input

Telephone Number – Enter the contact person's telephone number, including an extension if applicable.

Fax Number – Enter the fax number of the NTP.

Section E	Declaration
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Print Name – Enter the name of the program sponsor.

Title – *This field has been pre-filled by the Department to reflect that the form must be signed by the program sponsor.*

Signature – Program sponsor's signature.

Date – Enter the date that the application is signed by the program sponsor.

Print Name – Enter the name of the legal representative for the Guarantor.

Title – This field has been pre-filled by the Department to reflect that the form must be signed by the legal representative for the Guarantor.

Signature – Legal representative's signature.

Date – Enter the date that the application is signed by the legal representative for the Guarantor.

GUARANTOR AGREEMENT

Section A		Applicant Information	
License Number (if applicable):		National Provider Identifier (NPI):	
Name of Legal Entity:			
Name of Narcotic Treatment Program (if different than name of legal entity):			
Facility Street Address (if applicable Room/Suite/Unit):			
City:	County:	Zip Code:	
Mailing Address (if applicable Room/Suite/Unit)/(if different than above):			
City:	County:	Zip Code:	
Section B		Guarantor Selection (Check one box)	
Pursuant to CCR, Title 9, §10095 the Guarantor agrees as follows:			
<input type="checkbox"/> Treatment will continue at the NTP location specified in Section A for up to 90 days following receipt by the Department of the program's notice of intent to close the program. CCR, Title 9, §10095(b)(1)(A) (complete Sections C & E)			
<input type="checkbox"/> Treatment will be provided through the transfer of patients at another program. CCR, Title 9, §10095(b)(1)(B) (complete Sections D & E)			
Section C		Guarantor Information	
Name of Guarantor:			
Mailing Address (if applicable Room/Suite/Unit):			
City:	County:	Zip Code:	
Telephone Number:		Fax Number:	
Section D		Guarantor Program Information	
License Number:		NPI:	
Name of Legal Entity:			
Name of Narcotic Treatment Program:			

GUARANTOR AGREEMENT

Section D (Continued) Guarantor Program Information		
Facility Street Address (if applicable Room/Suite/Unit):		
City:	County:	Zip Code:
Mailing Address (if applicable Room/Suite/Unit)/(if different than facility street address):		
City:	County:	Zip Code:
Telephone Number:		Fax Number:
Section E Declaration		
I declare under penalty of perjury under the laws of the State of California that the foregoing information and any attachment is true, accurate, and complete to the best of my knowledge and belief. By signing below, each party warrants that he/she has read this document and understands its content.		
I declare that I have the authority to legally bind the NTP.		
Print Name:		Title: Program Sponsor
Signature:		Date:
I declare that I have the authority to legally bind the guarantor.		
Print Name:		Title: Legal Representative
Signature:		Date:
PRIVACY STATEMENT		
<p align="center">PRIVACY STATEMENT (Civil Code Section 1798 et seq.)</p> <p>All information requested in this form is mandatory. This information is required by the Department of Health Care Services (Department) by the authority of Health and Safety Code, Section 11839.3 and California Code of Regulations, Title 9, Section 10055. The consequences of not supplying the mandatory information requested is that review of the application shall be terminated, which may result in lapse of licensure and/or imposition of fines. The Department may share or provide any of the information provided in or with this form to the California Health and Human Services Agency, the California State Controller's Office, the California Department of</p>		

GUARANTOR AGREEMENT

PRIVACY STATEMENT (Continued)

Justice, the California Department of Consumer Affairs, the Department of Corporations, or other state or local agencies as appropriate, the Federal Bureau of Investigation, the Internal Revenue Service, the U.S. Justice Department, the United States Drug Enforcement Administration, the United States Department of Health and Human Services, and the United States Substance Abuse and Mental Health Services Administration. For more information or access to records containing your personal information maintained by the Department, contact the Counselor & Medication Assisted Treatment Section Officer of the Day at (916) 322-6682.

FACILITY AND GEOGRAPHICAL AREA

INSTRUCTIONS FOR COMPLETION OF THE FACILITY AND GEOGRAPHICAL AREA FORM
DHCS 5025 (04/16)

Return completed form to the address designated in the header above.

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DO NOT LEAVE any questions, boxes, lines, or fields blank. Enter N/A if not applicable to you.

PLEASE NOTE: Read all the instructions included on this form carefully and complete each item requested. For additional information, please review the California Code of Regulations (CCR), Title 9, Division 4, Chapter 4, Subchapter 1 commencing with Section 10000, which outlines the requirements and standards for Narcotic Treatment Programs.

SECTION A	FACILITY TYPE
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Check the appropriate box for the type of facility.

Narcotic Treatment Program (NTP) – A licensed opioid addiction treatment program, whether inpatient or outpatient, which offers all of the following: evaluation, maintenance treatment and/or detoxification treatment, and other services in conjunction with replacement narcotic therapy.

Medication Unit (MU) – A facility established as part of, but geographically separate from a NTP, from which licensed private practitioners or community pharmacists dispense or administer an opioid agonist treatment medication and/or collect samples for drug testing or analysis.

Office-Based Narcotic Treatment Network (OBNTN) – A network of providers, that are affiliated and associated with a primary NTP, 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.

SECTION B	APPLICANT INFORMATION
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License Number – If the applicant currently holds an active NTP license issued by the Department, enter the license number. If the applicant does not currently hold a NTP license issued by the Department, please enter "N/A".

FACILITY AND GEOGRAPHICAL AREA

National Provider Identifier (NPI) – Enter the 10 digit NPI number associated with the facility. If you need additional information or do not know the NPI number, please contact the National Plan and Provider Enumeration System at <https://nppes.cms.hhs.gov/NPPES/Welcome.do>

Name of Legal Entity – Enter the legal entity name.

PLEASE NOTE: Any business operation under a fictitious name shall submit a copy of the county filing setting forth that name.

Corporation – For a corporation, enter the name exactly as it is filed with the Secretary of State (SOS) and as it appears on the entity's Articles of Incorporation. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Limited Liability Company (LLC) – For a LLC, enter the name exactly as it is filed with the SOS and as it appears on the entity's Articles of Organization. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Partnership/Limited Partnership – For a partnership or limited partnership, enter the name of the partnership exactly as it is filed with the SOS on the Statement of Partnership Authority or Certificate of Limited Partnership respectively. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Sole Proprietor – For a sole proprietor, enter the full legal name of the sole proprietor.

Governmental Agency – Enter the name of the governmental agency.

Name of NTP, MU or OBNTN – If different from legal entity name, enter the name of the facility or provider.

Facility Street Address – Enter the exact address of the facility. A post office box or commercial box is not acceptable. If applicable, enter the room/suite/unit number of the facility.

City – Enter the city of the facility.

County – Enter the county of the facility.

Zip Code – Enter the zip code of the facility.

Exact address can be verified at the United States Postal Service website:

https://tools.usps.com/go/ZipLookupAction_input

FACILITY AND GEOGRAPHICAL AREA

Mailing Address – If different from facility street address, enter the exact mailing address. If applicable, enter the room/suite/unit number of the mailing address.

City – Enter the city of the mailing address.

County – Enter the county of the mailing address.

Zip Code – Enter the zip code of the mailing address.

Exact address can be verified at the United States Postal Service website:

https://tools.usps.com/go/ZipLookupAction_input

List the Days and Hours of Medication Dispensing Services – Enter the schedule of hours, per day, that medication used in replacement narcotic therapy is dispensed at the facility.

Example:

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
5:00am-11:00am	5:00am-11:00am	5:00am-11:00am	5:00am-11:00am	5:00am-11:00am	5:00am-11:00am	5:00am-11:00am

List the Days and Hours for Other NTP Services – Enter the schedule of hours, per day, that other NTP services are provided at the facility.

Examples of other NTP services:

- Evaluation of medical, employment, alcohol, criminal, and psychological problems
- Screening for diseases that are disproportionately represented in the opioid-abusing population
- Monitoring for illicit drug use
- Counseling by addiction counselors that are evaluated through ongoing supervision; and professional medical, social work, and mental health services, on-site or by referral (through contracted interagency agreements)

Example:

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
5:00am-1:00pm	5:00am-1:00pm	5:00am-1:00pm	5:00am-1:00pm	5:00am-1:00pm	5:00am-1:00pm	5:00am-1:00pm

FACILITY AND GEOGRAPHICAL AREA

SECTION C

REQUIRED DOCUMENTATION

Attach the following:

Written Statement Explaining Geographical Area and Facility – Complete a written statement explaining the following:

- A description of the geographical surrounding areas to be served by the program CCR, Title 9, §10020(b)(1), §10021(b)(1), §10030(a)(2)
- A description of the facility CCR, Title 9, §10020(b)(8), §10021(b)(7), §10030(a)(27)
- Facility address and dimensions CCR, Title 9, §10020(b)(4) and (8), §10021(b)(4) and (7), §10030(a)(37)
- A description of the amount of space devoted to narcotic treatment including waiting, counseling, dispensing and storage areas CCR, Title 9, §10020(b)(8), §10021(b)(7), §10030(a)(38)
- A description of 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 NTP, OBNTN or MU CCR, Title 9, §10020(b)(7), §10021(b)(6), §10030(a)(41)
- If MU or OBNTN include a description of geographic relationship between the MU or OBNTN and primary NTP CCR, Title 9, §10020(b)(4), §10021(b)(4)

Facility Diagram – Complete a diagram of the facility location that identifies the following:

- Waiting areas
- Office space
- Medication administration area (if applicable)
- Patient body specimen collection locations for testing or analysis of samples for illicit drug use (if applicable)
- Record storage area
- Parking or transportation access
- The relation of the narcotic treatment program to the total facility

Narrative of Patient Flow – Complete a written narrative describing the flow of patients in relation to the following:

- Waiting areas
- Office space

FACILITY AND GEOGRAPHICAL AREA

- Medication administration area (if applicable)
- Patient body specimen collection locations for testing or analysis of samples for illicit drug use (if applicable)
- Record storage area
- Parking or transportation access
- The relation of the narcotic treatment program to the total facility

Written Statement Explaining Facility Population Demographics – Complete a written statement explaining the following:

- Population and area to be served by the facility CCR, Title 9, §10020(b)(2), §10021(b)(2), §10030(a)(3)
- The estimated number of persons in the described area that have an addiction to opioids and an explanation of the basis of such estimate CCR, Title 9, §10030(a)(4)
- The estimated number of persons in the described area that have an addiction to opioids that are presently in a narcotic treatment program and other treatment programs CCR, Title 9, §10030(a)(5)
- The number of patients in regular treatment, projected rate of intake and factors controlling projected intake CCR, Title 9, §10030(a)(6)
- If MU or OBNTN include the approximate number of patients to be served and a description of how every patient that is assigned to the MU or OBNTN will participate in the regular treatment provided by the primary NTP CCR, Title 9, §10020(b)(9), §10021(b)(8)

FACILITY AND GEOGRAPHICAL AREA

Section A		Facility Type				
<p>Check one box:</p> <p><input type="checkbox"/> Narcotic Treatment Program (NTP) CCR, Title 9, §10030</p> <p><input type="checkbox"/> Medication Unit (MU) CCR, Title 9, §10020</p> <p><input type="checkbox"/> Office-Based Narcotic Treatment Network (OBNTN) CCR, Title 9, §10021</p>						
Section B		Applicant Information				
License Number (if applicable):			National Provider Identifier (NPI):			
Name of Legal Entity:						
Name of NTP, MU or OBNTN (if different than name of legal entity):						
Facility Street Address (if applicable Room/Suite/Unit):						
City:		County:		Zip Code:		
Mailing Address (if applicable Room/Suite/Unit)/(if different than facility street address):						
City:		County:		Zip Code:		
List the Days and Hours of Medication Dispensing Services (if applicable) CCR, Title 9, §10020(b)(5), §10030(a)(39)						
Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday

FACILITY AND GEOGRAPHICAL AREA

Section B						
Applicant Information (Continued)						
List the days and hours for other NTP services (if applicable) CCR, Title 9, §10020(b)(6), §10021(b)(5), §10030(a)(40)						
Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Section C						
Required Documentation						
<input type="checkbox"/> Written Statement Explaining Geographical Area and Facility						
<input type="checkbox"/> Facility Diagram						
<input type="checkbox"/> Narrative of Patient Flow						
<input type="checkbox"/> Written Statement Explaining Facility Population Demographics						
Privacy Statement						
PRIVACY STATEMENT (Civil Code Section 1798 et seq.)						
<p>All information requested in this form is mandatory. This information is required by the Department of Health Care Services (Department) by the authority of Health and Safety Code, Section 11839.3 and California Code of Regulations, Title 9, Section 10055. The consequences of not supplying the mandatory information requested is that review of the application shall be terminated, which may result in lapse of licensure and/or imposition of fines. The Department may share or provide any of the information provided in or with this form to the California Health and Human Services Agency, the California State Controller's Office, the California Department of Justice, the California Department of Consumer Affairs, the Department of Corporations, or other state or local agencies as appropriate, the Federal Bureau of Investigation, the Internal Revenue Service, the U.S. Justice Department, the United States Drug Enforcement Administration, the United States Department of Health and Human Services, and the United States Substance Abuse and Mental Health Services Administration. For more information or access to records containing your personal information maintained by the Department, contact the Counselor & Medication Assisted Treatment Section Officer of the Day at (916) 322-6682.</p>						

Staff Information form DHCS 5026 (04/16)

STAFF INFORMATION

INSTRUCTIONS FOR COMPLETION OF THE STAFF INFORMATION FORM
DHCS 5026 (04/16)

Return completed form to the address designated in the header above.

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DO NOT LEAVE any questions, boxes, lines, or fields blank. Enter N/A if not applicable to you.

PLEASE NOTE: Read all the instructions included on this form carefully and complete each item requested. For additional information, please review the California Code of Regulations (CCR), Title 9, Division 4, Chapter 4, Subchapter 1 commencing with Section 10000, which outlines the requirements and standards for Narcotic Treatment Programs.

SECTION A	Facility Type
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This section must be completed by all applicants.

Check the appropriate box for the type of facility.

Narcotic Treatment Program (NTP) – A licensed opioid addiction treatment program, whether inpatient or outpatient, which offers all of the following: evaluation, maintenance treatment and/or detoxification treatment, and other services in conjunction with replacement narcotic therapy.

Medication Unit (MU) – A facility established as part of, but geographically separate from an NTP, from which licensed private practitioners or community pharmacists dispense or administer an opioid agonist treatment medication and/or collect samples for drug testing or analysis.

Office-Based Narcotic Treatment Network (OBNTN) – A network of providers, that are affiliated and associated with a primary NTP, 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.

STAFF INFORMATION**SECTION B Staff Hours**

PLEASE NOTE: If a staff member performs more than one role, specify the number of hours spent in each role. For Example: A staff member serves as both a dispensing nurse and counselor. Under medical services, list the staff member and the number of hours spent dispensing medication. Under counseling services, list the staff member and the number of hours spent providing counseling services.

Example:

Medical					Scheduled Hours						
Name	Function	License Number	Total Hours Per Week		Mon	Tue	Wed	Thu	Fri	Sat	Sun
Jane Doe	Nurse	VN12345	20		5am-9am	5am-9am	5am-9am	5am-9am	5am-9am		
Counseling					Scheduled Hours						
Name	Certifying Organization /Licensing Body	Certification /License Number	Case load	Total Hours Per Week	Mon	Tue	Wed	Thu	Fri	Sat	Sun
Jane Doe	CCAPP	CN12345	10	20	10am-2pm	10am-2pm	10am-2pm	10am-2pm	10am-2pm		

Administration

Name – Enter the name of the staff member.

Function – Enter the function of the staff member.

License Number – If applicable, enter the professional license number of the staff member.

Total hours per week – Enter the number of hours, per week, that the staff member works at the facility.

Scheduled Hours – Enter the schedule of hours, per day, that the staff member works at the facility.

Medical

PLEASE NOTE: Pursuant to CCR, Title 9, §10260 (a)-(b), the program physician shall be responsible for administering or dispensing to patients all medications used in replacement narcotic therapy. Under

STAFF INFORMATION

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

Name – Enter the name of the staff member.

Function – Enter the function of the staff member.

License Number – Enter the professional license number of the staff member.

Total hours per week – Enter the number of hours, per week, that the staff member works at the facility.

Scheduled Hours – Enter the schedule of hours, per day, that the staff member works at the facility.

Counseling

PLEASE NOTE: Pursuant to CCR, Title 9, §10125(b), program staff who provide counseling services (as defined in §13005) shall be licensed, certified, or registered to obtain certification or licensure pursuant to Chapter 8 (commencing with §13000).

Name – Enter the name of the staff member.

Certifying Organization/Licensing Body – Enter the name of the counselor certifying organization or licensing body.

Certification/License Number – If applicable, enter the counselor license number of the staff member.

Registration Number – If applicable, enter the counselor registration number of the staff member.

Caseload – Enter the number of patients assigned to the counselor.

Total hours per week – Enter the number of hours, per week, that the counselor works at the facility.

Scheduled Hours – Enter the schedule of hours, per day, that the counselor works at the facility.

STAFF INFORMATION

Section A		Facility Type								
Check one box:										
<input type="checkbox"/> Narcotic Treatment Program CCR, Title 9, §10030		<input type="checkbox"/> Medication Unit CCR, Title 9, §10020								
<input type="checkbox"/> Office-Based Narcotic Treatment Network CCR, Title 9, §10021										
Section B		Staff Hours								
Administration		Scheduled Hours								
Name	Function	License Number	Total Hours Per Week	Mon	Tue	Wed	Thu	Fri	Sat	Sun
Medical		Scheduled Hours								
Name	Function	License Number	Total Hours Per Week	Mon	Tue	Wed	Thu	Fri	Sat	Sun

Counselor & Medication Assisted
Treatment Section, MS 2603
PO Box 997413
Sacramento, CA 95899-7413

STAFF INFORMATION

Counseling						Scheduled Hours						
Name	Certifying Organization/ Licensing Body	Certification/License Number	Registration Number	Caseload	Total Hours Per Week	Mon	Tue	Wed	Thu	Fri	Sat	Sun

STAFF INFORMATION

Privacy Statement

PRIVACY STATEMENT (Civil Code Section 1798 et seq.)

All information requested in this form is mandatory. This information is required by the Department of Health Care Services (Department) by the authority of Health and Safety Code, Section 11839.3 and California Code of Regulations, Title 9, Section 10055. The consequences of not supplying the mandatory information requested is that review of the application shall be terminated, which may result in lapse of licensure and/or imposition of fines. The Department may share or provide any of the information provided in or with this form to the California Health and Human Services Agency, the California State Controller's Office, the California Department of Justice, the California Department of Consumer Affairs, the Department of Corporations, or other state or local agencies as appropriate, the Federal Bureau of Investigation, the Internal Revenue Service, the U.S. Justice Department, the United States Drug Enforcement Administration, the United States Department of Health and Human Services, and the United States Substance Abuse and Mental Health Services Administration. For more information or access to records containing your personal information maintained by the Department, contact the Counselor & Medication Assisted Treatment Section Officer of the Day at (916) 322-6682.

COUNTY CERTIFICATION

INSTRUCTIONS FOR COMPLETION OF THE COUNTY CERTIFICATION FORM
DHCS 5027 (04/16)

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PLEASE NOTE: Read all the instructions included on this form carefully and complete each item requested. For additional information, please review the California Code of Regulations (CCR), Title 9, Division 4, Chapter 4, Subchapter 1 commencing with Section 10000, which outlines the requirements and standards for Narcotic Treatment Programs.

SECTION A

Program Information

This section must be completed by applicant.

License Number – If the applicant currently holds an active Narcotic Treatment Program (NTP) license issued by the Department, enter the license number. If the applicant does not currently hold an NTP license issued by the Department, please enter “N/A”.

National Provider Identifier (NPI) – Enter the 10 digit NPI number associated with the facility. If you need additional information or do not know the NPI number, please contact the National Plan and Provider Enumeration System at: <https://nppes.cms.hhs.gov/NPPES/Welcome.do>

Name of Legal Entity – Enter the legal entity name.

PLEASE NOTE: Any business operation under a fictitious name shall submit a copy of the county filing setting forth that name.

Corporation – For a corporation, enter the name exactly as it is filed with the Secretary of State (SOS) and as it appears on the entity's Articles of Incorporation. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Limited Liability Company (LLC) – For a LLC, enter the name exactly as it is filed with the SOS and as it appears on the entity's Articles of Organization. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Partnership/Limited Partnership – For a partnership or limited partnership, enter the name of the partnership exactly as it is filed with the SOS on the Statement of Partnership Authority or

COUNTY CERTIFICATION

Certificate of Limited Partnership respectively. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Sole Proprietor – For a sole proprietor, enter the full legal name of the sole proprietor.

Governmental Agency – Enter the name of the governmental agency.

Name of Narcotic Treatment Program – If different from legal entity name, enter the name of the facility.

Facility Street Address – Enter the exact address of the facility. A post office box or commercial box is not acceptable. If applicable, enter the room/suite/unit number of the facility.

City – Enter the city of the facility.

County – Enter the county of the facility.

Zip Code – Enter the zip code of the facility.

An exact address can be verified at the United States Postal Service website:

https://tools.usps.com/go/ZipLookupAction_input

Mailing Address – If different from facility street address, enter the exact mailing address. If applicable, enter the room/suite/unit number of the mailing address.

City – Enter the city of the mailing address.

County – Enter the county of the mailing address.

Zip Code – Enter the zip code of the mailing address.

An exact address can be verified at the United States Postal Service website:

https://tools.usps.com/go/ZipLookupAction_input

SECTION B

Type of Program Request

This section must be completed by applicant.

Check the appropriate box for the type of program request.

Initial Application – If requesting county certification for initial licensure, enter the maximum number of patients that will be served at the facility.

COUNTY CERTIFICATION

License Renewal – Enter the Department approved licensed patient capacity for maintenance and detoxification services.

Relocation – A change of location of a facility or of any portion of the facility.

SECTION C Regulation Authority

PLEASE NOTE: Pursuant to CCR, Title 9, §10040 a complete protocol must include a statement from the County Alcohol and Drug Program Administrator certifying that:

- 1) There is need for the NTP services described in the program's protocol in the community in which it is located, and
- 2) All local ordinances, fire regulations, and local planning agency requirements have been complied with.

Pursuant to CCR, Title 9, §10055(b)(2), the renewal of a NTP license requires the County Alcohol and Drug Program Administrators to submit to the Department a certification for continued services of the NTP and a recommendation for renewal of the license.

SECTION D County Information

This section must be completed by the County Alcohol and Drug Program Administrator.

County – Enter the county.

Address – Enter the business address of the County Alcohol and Drug Program Administrator.

Telephone Number – Enter the telephone number of the County Alcohol and Drug Program Administrator.

Fax Number – Enter the fax number of the County Alcohol and Drug Program Administrator.

SECTION E County Recommendation

This section must be completed by the County Alcohol and Drug Program Administrator.

Check the appropriate box for recommendation.

PLEASE NOTE: A county's recommendation for denial may not be based on funding. If the county does not recommend initial program licensure, renewal or relocation additional documentation to support the recommendation must be attached to the County Certification Form DHCS 5027 (04/16) such as:

COUNTY CERTIFICATION

- Evidence of a substantial decline in medically qualified NTP patients,
- Program compliance issues, and/or
- Evidence showing other licensees within the area that can provide more efficient, cost effective NTP services.

SECTION F

Declaration

This section must be completed by the County Alcohol and Drug Program Administrator.

Print Name – Enter the name of the County Alcohol and Drug Program Administrator.

Title – *This field has been pre-filled by the Department to reflect that the form must be signed by the County Alcohol and Drug Program Administrator.*

Signature – County Alcohol and Drug Program Administrator's signature.

Date – Enter the date that this form is signed by the County Alcohol and Drug Program Administrator.

COUNTY CERTIFICATION

Section A			Program Information
License Number (if applicable):		National Provider Identifier (NPI):	
Name of Legal Entity:			
Name of Narcotic Treatment Program (if different from legal entity name):			
Facility Street Address (if applicable Room/Suite/Unit):			
City:	County:	Zip Code:	
Mailing Address (if applicable Room/Suite/Unit)/(if different than facility street address):			
City:	County:	Zip Code:	
Section B		Type of Program Request	
Check one box:			
<input type="checkbox"/> Initial Application – Proposed Capacity: _____			
<input type="checkbox"/> License Renewal – Current Licensed Capacity: _____			
<input type="checkbox"/> Relocation			
Section C		Regulation Authority	
Pursuant to CCR, Title 9, § 10040 a complete protocol must include a statement from the County Alcohol and Drug Program Administrator certifying that:			
1) There is need for the narcotic treatment program services described in the program's protocol in the community in which it is located, and			
2) All local ordinances, fire regulations, and local planning agency requirements have been complied with.			
Pursuant to CCR, Title 9, § 10055(b)(2), the renewal of a narcotic treatment program license requires the County Alcohol and Drug Program Administrator to submit to the Department a certification for continued treatment services of the narcotic treatment program and a recommendation for renewal of the license.			

COUNTY CERTIFICATION

Section D		County Information	
County:			
Address:			
Telephone Number:		Fax Number:	
Section E		County Recommendation	
Check one box:			
<input type="checkbox"/> County recommends the program's initial licensure, renewal or relocation.			
<input type="checkbox"/> County does not recommend initial program licensure, renewal or relocation. Documentation attached to support the county's recommendation.			
Section F		Declaration	
I declare that I am the County Alcohol and Drug Program Administrator responsible for issuing the county recommendation.			
Print Name:		Title: County Alcohol and Drug Program Administrator	
Signature:		Date:	
PRIVACY STATEMENT			
PRIVACY STATEMENT (Civil Code Section 1798 et seq.)			
<p>All information requested in this form is mandatory. This information is required by the Department of Health Care Services (Department) by the authority of Health and Safety Code, Section 11839.3 and California Code of Regulations, Title 9, Section 10055. The consequences of not supplying the mandatory information requested is that review of the application shall be terminated, which may result in lapse of licensure and/or imposition of fines. The Department may share or provide any of the information provided in or with this form to the California Health and Human Services Agency, the California State Controller's Office, the California Department of Justice, the California Department of Consumer Affairs, the Department of Corporations, or other state or local agencies as appropriate, the Federal Bureau of Investigation, the Internal Revenue Service, the U.S. Justice Department, the United States Drug Enforcement Administration, the United States Department of Health and Human Services, and the United States Substance Abuse and Mental Health Services Administration. For more information or access to records containing your personal information maintained by the Department, contact the Counselor & Medication Assisted Treatment Section Officer of the Day at (916) 322-6682.</p>			

Organizational Responsibility
form DHCS 5031 (04/16)

ORGANIZATIONAL RESPONSIBILITY

INSTRUCTIONS FOR COMPLETION OF THE ORGANIZATIONAL RESPONSIBILITY FORM
DHCS 5031 (04/16)

Return completed form to the address designated in the header above.

DO NOT USE staples on this form or on any attachments.

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DO NOT LEAVE any questions, boxes, lines, or fields blank. Enter N/A if not applicable to you.

PLEASE NOTE: Read all the instructions included on this form carefully and complete each item requested. For additional information, please review the California Code of Regulations (CCR), Title 9, Division 4, Chapter 4, Subchapter 1 commencing with Section 10000, which outlines the requirements and standards for Narcotic Treatment Programs.

Section A

Type of Organization

Tax Status – Check the box which applies to your organization's business structure for tax purposes.

Section B

Organizational Information

License Number – If the applicant currently holds an active Narcotic Treatment Program (NTP) license issued by the Department, enter the license number. If the applicant does not currently hold a NTP license issued by the Department, please enter "N/A".

Federal Tax ID Number – Enter the federal tax identification number assigned to the organization.

Name of Organization – Enter the name of the organization.

PLEASE NOTE: Any business operation under a fictitious name shall submit a copy of the county filing setting forth that name.

Corporation – For a corporation, enter the name exactly as it is filed with the Secretary of State (SOS) and as it appears on the entity's Articles of Incorporation. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Limited Liability Company (LLC) – For a LLC, enter the name exactly as it is filed with the SOS and as it appears on the entity's Articles of Organization. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

ORGANIZATIONAL RESPONSIBILITY

Partnership/Limited Partnership – For a partnership or limited partnership, enter the name of the partnership exactly as it is filled with the SOS on the Statement of Partnership Authority or Certificate of Limited Partnership respectively. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Sole Proprietor – For a sole proprietor, enter the full legal name of the sole proprietor.

Governmental Agency – Enter the name of the governmental agency.

Facility Street Address – Enter the exact address of the facility. A post office box or commercial box is not acceptable. If applicable, enter the room/suite/unit number of the facility.

City – Enter the city of the facility.

County – Enter the county of the facility.

Zip Code – Enter the zip code of the facility.

An exact address can be verified at the United States Postal Service website:

https://tools.usps.com/go/ZipLookupAction_input

Section C

Individual Information

Name – Enter the name of the partner, officer, director or 10 percent or greater shareholder of the organization.

Title – Enter the title of the partner, officer, director or 10 percent or greater shareholder of the organization.

Address – Enter the address of the partner, officer, director or 10 percent or greater shareholder of the organization.

Telephone Number – Enter the telephone number of the partner, officer, director or 10 percent or greater shareholder of the organization.

Percentage of Ownership – If applicable, for a for-profit organization enter the percentage of the organization owned by the partner, officer, director or 10 percent or greater shareholder.

Term Began – If applicable, for a non-profit organization enter the date that the term of the partner, officer, director or 10 percent or greater shareholder of the organization began.

ORGANIZATIONAL RESPONSIBILITY

Term Expire – If applicable, for a non-profit organization enter the date that the term of the partner, officer, director or 10 percent or greater shareholder of the organization will expire.

Section D

Declaration

Print Name – Enter the name of the program sponsor.

Title – *This field has been pre-filled by the Department to reflect that the form must be signed by the program sponsor.*

Signature – Program sponsor's signature.

Date – Enter the date that the form is signed by the program sponsor.

ORGANIZATIONAL RESPONSIBILITY

Section A		Type of Organization
Tax Status:		
<input type="checkbox"/>	Corporation	
<input type="checkbox"/>	Nonprofit Corporation	
<input type="checkbox"/>	Limited Liability Company	
<input type="checkbox"/>	Partnership/Limited Partnership	
<input type="checkbox"/>	Sole Proprietor	
<input type="checkbox"/>	Governmental Agency	
Section B		Organization Information
License Number (if applicable):		Federal Tax ID Number:
Name of Organization:		
Facility Street Address (if applicable Room/Suite/Unit):		
City:	County:	Zip Code:

ORGANIZATIONAL RESPONSIBILITY

Section D		Declaration
I declare under penalty of perjury under the laws of the State of California that the foregoing information and any attachment is true, accurate, and complete to the best of my knowledge and belief.		
Print Name:		Title: Program Sponsor
Signature:		Date:
Privacy Statement		
<p>PRIVACY STATEMENT (Civil Code Section 1798 et seq.)</p> <p>All information requested in this form is mandatory. This information is required by the Department of Health Care Services (Department) by the authority of Health and Safety Code, Section 11839.3 and California Code of Regulations, Title 9, Section 10055. The consequences of not supplying the mandatory information requested is that review of the application shall be terminated, which may result in lapse of licensure and/or imposition of fines. The Department may share or provide any of the information provided in or with this form to the California Health and Human Services Agency, the California State Controller's Office, the California Department of Justice, the California Department of Consumer Affairs, the Department of Corporations, or other state or local agencies as appropriate, the Federal Bureau of Investigation, the Internal Revenue Service, the U.S. Justice Department, the United States Drug Enforcement Administration, the United States Department of Health and Human Services, and the United States Substance Abuse and Mental Health Services Administration. For more information or access to records containing your personal information maintained by the Department, contact the Counselor & Medication Assisted Treatment Section Officer of the Day at (916) 322-6682.</p>		

PATIENT DEATH REPORT

INSTRUCTIONS FOR COMPLETION OF THE PATIENT DEATH REPORT FORM
DHCS 5048 (04/16)

DO NOT USE staples on this form or on any attachments.

DO NOT USE correction tape, white out, or highlighter pen or ink of a similar type on this form. If you must make corrections, please line through, date, and initial in ink.

DO NOT LEAVE any questions, boxes, lines, or fields blank. Enter N/A if not applicable to you.

PLEASE NOTE: Read all the instructions included on this form carefully and complete each item requested. For additional information, please review the California Code of Regulations (CCR), Title 9, Division 4, Chapter 4, Subchapter 1 commencing with Section 10000, which outlines the requirements and standards for Narcotic Treatment Programs.

SECTION A

Regulation Authority

PLEASE NOTE: Pursuant to CCR, Title 9, §10195, a program shall notify the Department of a patient's death within one (1) working day from the date the program is notified, if a patient of the program dies at the program site, or if ingestion of medication used in replacement narcotic therapy may have been the cause of the patient's death; and within ninety (90) calendar days from the date of death for all other patients.

Patient Death Report Form DHCS 5048 (04/16) should be mailed to:

Department of Health Care Services
Counselor & Medication Assisted Treatment Section, Unit 2 MS 2603
PO Box 997413
Sacramento, CA 95899-7413

Sent via email to: DHCSNTP@dhcs.ca.gov **Sent via Fax to:** (916) 440-5230

Please confirm receipt by calling: (916) 322-6682

SECTION B

Program Information

License Number – Enter the Narcotic Treatment Program (NTP) license number issued by the Department.

PATIENT DEATH REPORT

National Provider Identifier (NPI) – Enter the 10 digit NPI number associated with the facility. If you need additional information or do not know the NPI number, please contact the National Plan and Provider Enumeration System at <https://nppes.cms.hhs.gov/NPPES/Welcome.do>

Name of Legal Entity – Enter the legal entity name.

PLEASE NOTE: Any business operation under a fictitious name shall submit a copy of the county filing setting forth that name.

Corporation – For a corporation, enter the name exactly as it is filed with the Secretary of State (SOS) and as it appears on the entity's Articles of Incorporation. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Limited Liability Company (LLC) – For a LLC, enter the name exactly as it is filed with the SOS and as it appears on the entity's Articles of Organization. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Partnership/Limited Partnership – For a partnership or limited partnership, enter the name of the partnership exactly as it is filed with the SOS on the Statement of Partnership Authority or Certificate of Limited Partnership respectively. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Sole Proprietor – For a sole proprietor, enter the full legal name of the sole proprietor.

Governmental Agency – Enter the name of the governmental agency.

Name of Narcotic Treatment Program – If different from legal entity name, enter the name of the facility.

Facility Street Address – Enter the exact address of the facility. A post office box or commercial box is not acceptable. If applicable, enter the room/suite/unit number of the facility.

City – Enter the city of the facility.

County – Enter the county of the facility.

Zip Code – Enter the zip code of the facility.

An exact address can be verified at the United States Postal Service website:
https://tools.usps.com/go/ZipLookupAction_input

Mailing Address – If different from facility street address, enter the exact mailing address. If applicable, enter the room/suite/unit number of the mailing address.

PATIENT DEATH REPORT

City – Enter the city of the mailing address.

County – Enter the county of the mailing address.

Zip Code – Enter the zip code of the mailing address.

An exact address can be verified at the United States Postal Service website:

https://tools.usps.com/go/ZipLookupAction_input

Telephone Number – Enter the contact person's telephone number, including an extension if applicable.

Fax Number – Enter the fax number of the facility.

SECTION C

Patient Information

Name – Enter the first and last name of the patient.

Patient Record Number – Enter the record number assigned to the patient by the NTP.

Gender – Enter the patient's gender.

Dose level – Enter the patient's dose level at the time of the patient's death.

Take-home Status – Enter the patient's take-home status at the time of the patient's death.

Date of Patient Death – Enter the date of the patient's death.

Age of Patient at Death – Enter the patient's age at the time of the patient's death.

Date Death Information was Received by Program – Enter the date that the program was notified of the patient's death.

Cause of Death – Enter the cause of the patient's death. Please be sure to include all relevant details known about the cause of the patient's death.

SECTION D

Declaration

Print Name – Enter the name of the authorized program representative.

Title – Enter the title of the authorized program representative.

Signature – Authorized program representative signature.

Date – Enter the date that the form is signed by the authorized program representative.

PATIENT DEATH REPORT

Section A		Regulation Authority	
Pursuant to CCR, Title 9, §10195, a program shall notify the Department of a patient's death within one (1) working day from the date the program is notified, if a patient of the program dies at the program site; or if ingestion of the medication used in replacement narcotic therapy may have been the cause of the patient's death; and within ninety (90) calendar days from the date of death for all other patients.			
Mail to: Department of Health Care Services Counselor & Medication Assisted Treatment Section, Unit 2 MS 2603 PO Box 997413 Sacramento, CA 95899-7413		Email: DHCSNTP@dhcs.ca.gov Fax: (916) 440-5230 Please confirm receipt by calling: (916) 322-6682	
Section B		Program Information	
License Number:		National Provider Identifier (NPI):	
Name of Legal Entity:			
Name of Narcotic Treatment Program (If different than legal entity name):			
Facility Street Address (if applicable Room/Suite/Unit):			
City:		County:	Zip Code:
Mailing Address (if applicable Room/Suite/Unit)/(if different than facility street address):			
City:		County:	Zip Code:
Telephone Number:		Fax Number:	
Section C		Patient Information	
Name:			
Patient Record Number:		Gender:	
Dose Level:		Take-home Status:	
Date of Patient Death:		Age of Patient at Death:	
Date Death Information was Received by Program:			

PATIENT DEATH REPORT**Section C (Continued)****Patient Information**

Cause of Death (describe the cause of death and all relevant details known about the death of the patient):

Section D**Declaration**

I declare under penalty of perjury under the laws of the State of California that the foregoing information and any attachment is true, accurate, and complete to the best of my knowledge and belief.

Print Name:

Title:

Signature:

Date:

Privacy Statement**PRIVACY STATEMENT (Civil Code Section 1798 et seq.)**

All information requested in this form is mandatory. This information is required by the Department of Health Care Services (Department) by the authority of Health and Safety Code, Section 11839.3 and California Code of Regulations, Title 9, Section 10055. The consequences of not supplying the mandatory information requested is that review of the application shall be terminated, which may result in lapse of licensure and/or imposition of fines. The Department may share or provide any of the information provided in or with this form to the California Health and Human Services Agency, the California State Controller's Office, the California Department of Justice, the California Department of Consumer Affairs, the Department of Corporations, or other state or local agencies as appropriate, the Federal Bureau of Investigation, the Internal Revenue Service, the U.S. Justice Department, the United States Drug Enforcement Administration, the United States Department of Health and Human Services, and the United States Substance Abuse and Mental Health Services Administration. For more information or access to records containing your personal information maintained by the Department, contact the Counselor & Medication Assisted Treatment Section Officer of the Day at (916) 322-6682.

Affiliated and Associated Acknowledgment
form DHCS 5134 (04/16)

AFFILIATED AND ASSOCIATED ACKNOWLEDGMENT

INSTRUCTIONS FOR COMPLETION OF THE
AFFILIATED AND ASSOCIATED ACKNOWLEDGMENT FORM
DHCS 5134 (04/16)

Return completed form to the address designated in the header above.

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DO NOT LEAVE any questions, boxes, lines, or fields blank. Enter N/A if not applicable to you.

PLEASE NOTE: Read all the instructions included on this form carefully and complete each item requested. For additional information, please review the California Code of Regulations (CCR), Title 9, Division 4, Chapter 4, Subchapter 1 commencing with Section 10000, which outlines the requirements and standards for Narcotic Treatment Programs.

SECTION A

Narcotic Treatment Program (NTP) Information

License Number – Enter the NTP license number issued by the Department.

National Provider Identifier (NPI) – Enter the 10 digit NPI number associated with the facility. If you need additional information or do not know the NPI number, please contact the National Plan and Provider Enumeration System at: <https://nppes.cms.hhs.gov/NPPES/Welcome.do>

Name of Legal Entity – Enter the legal entity name.

PLEASE NOTE: Any business operation under a fictitious name shall submit a copy of the county filing setting forth that name.

Corporation – For a corporation, enter the name exactly as it is filed with the Secretary of State (SOS) and as it appears on the entity's Articles of Incorporation. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Limited Liability Company (LLC) – For a LLC, enter the name exactly as it is filed with the SOS and as it appears on the entity's Articles of Organization. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Partnership/Limited Partnership – For a partnership or limited partnership, enter the name of the partnership exactly as it is filed with the SOS on the Statement of Partnership Authority or Certificate of Limited Partnership respectively. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

AFFILIATED AND ASSOCIATED ACKNOWLEDGMENT

Sole Proprietor – For a sole proprietor, enter the full legal name of the sole proprietor.

Governmental Agency – Enter the name of the governmental agency.

Name of Narcotic Treatment Program – If different from legal entity name, enter the name of the facility.

Facility Street Address – Enter the exact address of the facility. A post office box or commercial box is not acceptable. If applicable, enter the room/suite/unit number of the facility.

City – Enter the city of the facility.

County – Enter the county of the facility.

Zip Code – Enter the zip code of the facility.

An exact address can be verified at the United States Postal Service website:

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Mailing Address – If different from facility street address, enter the exact mailing address. If applicable, enter the room/suite/unit number of the mailing address.

City – Enter the city of the mailing address.

County – Enter the county of the mailing address.

Zip Code – Enter the zip code of the mailing address.

An exact address can be verified at the United States Postal Service website:

https://tools.usps.com/go/ZipLookupAction_input

Telephone Number – Enter the contact person's telephone number, including an extension if applicable.

Fax Number – Enter the fax number assigned to the facility.

AFFILIATED AND ASSOCIATED ACKNOWLEDGMENT

**SECTION B Office-Based Narcotic Treatment Network (OBNTN) /
Medication Unit (MU) Information**

Name of Provider – Enter the name of the provider that will be affiliated and associated with the primary NTP.

Professional License or Certification Number – If applicable, enter the professional license or certification number of the provider.

NPI – Enter the 10 digit NPI number associated with the provider. If you need additional information or do not know the NPI number, please contact the National Plan and Provider Enumeration System at: <https://nppes.cms.hhs.gov/NPPES/Welcome.do>

Facility Street Address – Enter the exact address of the facility. A post office box or commercial box is not acceptable. If applicable, enter the room/suite/unit number of the facility.

City – Enter the city of the facility.

County – Enter the county of the facility.

Zip Code – Enter the zip code of the facility.

An exact address can be verified at the United States Postal Service website:
https://tools.usps.com/go/ZipLookupAction_input

Mailing Address – If different from facility street address, enter the exact mailing address. If applicable, enter the room/suite/unit number of the mailing address.

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County – Enter the county of the mailing address.

Zip Code – Enter the zip code of the mailing address.

An exact address can be verified at the United States Postal Service website:
https://tools.usps.com/go/ZipLookupAction_input

Telephone Number – Enter the contact person's telephone number, including an extension if applicable.

Fax Number – Enter the fax number of the provider.

AFFILIATED AND ASSOCIATED ACKNOWLEDGMENT

Describe Services – Provide a description of the services that the provider affiliated and associated with the primary NTP will offer. If necessary, attach additional pages to this form.

SECTION C Acknowledgment of Agreement

This section must be read and agreed upon by the primary NTP and affiliated and associated OBNTN /MU.

SECTION D Declaration

Print Name – Enter the name of the program sponsor.

Title – *This field has been pre-filled by the Department to reflect that the form must be signed by the program sponsor.*

Signature – Program sponsor's signature.

Date – Enter the date that this form is signed by the program sponsor.

Print Name – Enter the name of the legal representative for the provider.

Title – *This field has been pre-filled by the Department to reflect that the form must be signed by the legal representative for the provider.*

Signature – Legal representative's signature.

Date – Enter the date that this form is signed by the legal representative for the provider.

AFFILIATED AND ASSOCIATED ACKNOWLEDGMENT

Section A Narcotic Treatment Program (NTP) Information		
License Number:		National Provider Identifier (NPI):
Name of Legal Entity:		
Name of NTP (if different than name of legal entity):		
Facility Street Address (if applicable Room/Suite/Unit):		
City:	County:	Zip Code:
Mailing Address (if different than facility street address)/(if applicable Room/Suite/Unit):		
City:	County:	Zip Code:
Telephone Number:		Fax Number:
Section B Office-Based Narcotic Treatment Network (OBNTN)/ Medication Unit (MU) Information		
Name of Provider:		
Professional License or Certification Number (if applicable):		
NPI:		
Facility Street Address (if applicable Room/Suite/Unit):		
City:	County:	Zip Code:
Mailing Address (if different than facility street address)/(if applicable Room/Suite/Unit):		
City:	County:	Zip Code:
Telephone Number:		Fax Number:
Describe services the OBNTN or MU will provide:		

AFFILIATED AND ASSOCIATED ACKNOWLEDGMENT

Section C Acknowledgment of Agreement	
<p>NTP named in Section A, hereinafter "NTP", and provider named in Section B, hereinafter "Provider", hereby acknowledge that the named parties have entered into a formal, documented agreement whereby the Provider shall render services described in Section B to patients enrolled at the NTP. This agreement shall be made available for verification by the Department upon written request.</p> <p>NTP and Provider agree as follows:</p> <ol style="list-style-type: none">1. Provider is affiliated and associated with the NTP.2. Provider shall operate under the license of the NTP.3. Provider shall adhere to the protocol of the NTP and the supplemental written protocol approved by the Department.4. Provider shall immediately cease the provision of services in the event the license of the NTP is suspended or revoked.5. NTP shall notify the Department in writing if the Provider intends to discontinue any service(s) described in Section B. Written notice shall be given at least 30 days prior to cessation of service(s) and shall be mailed to the Department.6. This Affiliated and Associated Acknowledgment form DHCS 5134 (04/16) shall become effective on the date the Department approves the supplemental written protocol for the Provider. It shall remain effective until:<ol style="list-style-type: none">a. Service(s) are discontinued pursuant to paragraph 5 of this Agreement; orb. The license of the NTP is revoked or expires.	
Section D Declaration	
<p>I declare under penalty of perjury under the laws of the State of California that the foregoing information and any attachment is true, accurate, and complete to the best of my knowledge and belief. By signing below, each party warrants that he/she has read this document and understands its content.</p> <p>I declare that I have the authority to legally bind the NTP.</p>	
Print Name:	Title: Program Sponsor
Signature:	Date:
I declare that I have the authority to legally bind the Provider.	
Print Name:	Title: Legal Representative
Signature:	Date:

AFFILIATED AND ASSOCIATED ACKNOWLEDGMENT

Privacy Statement

PRIVACY STATEMENT (Civil Code Section 1798 et seq.)

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Application for Protocol Amendment
form DHCS 5135 (04/16)

APPLICATION FOR PROTOCOL AMENDMENT

INSTRUCTIONS FOR COMPLETION OF THE
APPLICATION FOR PROTOCOL AMENDMENT FORM
DHCS 5135 (04/16)

Return completed form to the address designated in the header above.

DO NOT USE staples on this form or on any attachments.

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DO NOT LEAVE any questions, boxes, lines, or fields blank. Enter N/A if not applicable to you.

PLEASE NOTE: Read all the instructions included on this form carefully and complete each item requested. For additional information, please review the California Code of Regulations (CCR), Title 9, Division 4, Chapter 4, Subchapter 1 commencing with Section 10000, which outlines the requirements and standards for Narcotic Treatment Programs.

SECTION A

Facility Type

This section must be completed by all applicants.

Check the appropriate box for the type of facility.

Narcotic Treatment Program (NTP) – A licensed opioid addiction treatment program, whether inpatient or outpatient, which offers all of the following: evaluation, maintenance treatment and/or detoxification treatment, and other services in conjunction with replacement narcotic therapy.

Medication Unit (MU) – A facility established as part of, but geographically separate from an NTP, from which licensed private practitioners or community pharmacists dispense or administer an opioid agonist treatment medication or collect samples for drug testing or analysis.

Office-Based Narcotic Treatment Network (OBNTN) – A network of providers, that are affiliated and associated with a primary NTP, 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.

SECTION B

Type of Amendment

This section must be completed by all applicants.

APPLICATION FOR PROTOCOL AMENDMENT

Check the appropriate box(es) for the type(s) of protocol amendment for which you are applying and complete the corresponding sections for each protocol amendment.

Relocation – A change of location of a facility or of any portion of the facility.

Change in Licensed Patient Capacity – An increase or decrease in the licensed capacity for detoxification or maintenance treatment.

Addition, Reduction or Termination of Services – Any addition, reduction or termination of services.

Name of Program Sponsor – Any change in the person or organization responsible for the operation of the NTP 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. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

Change in Individual Pursuant to CCR, Title 9 §10035(a)(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.

Change in Physical Structure – Any change to the physical structure or floor plan of the facility including expansions or modifications to dispensing stations.

Other – All other changes in the protocol and supplemental written protocol.

SECTION C

Existing Licensee Information

This section must be completed by all applicants.

License Number – Enter the NTP license number issued by the Department for the facility with the proposed protocol amendment(s).

National Provider Identifier (NPI) – Enter the 10 digit NPI number associated with the facility. If you need additional information or do not know the NPI number, please contact the National Plan and Provider Enumeration System at <https://nppes.cms.hhs.gov/NPPES/Welcome.do>

Name of Legal Entity – Enter the legal entity name.

PLEASE NOTE: Any business operation under a fictitious name shall submit a copy of the county filing setting forth that name.

APPLICATION FOR PROTOCOL AMENDMENT

Corporation – For a corporation, enter the name exactly as it is filed with the Secretary of State (SOS) and as it appears on the entity's Articles of Incorporation. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Limited Liability Company (LLC) – For a LLC, enter the name exactly as it is filed with the SOS and as it appears on the entity's Articles of Organization. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Partnership/Limited Partnership – For a partnership or limited partnership, enter the name of the partnership exactly as it is filed with the SOS on the Statement of Partnership Authority or Certificate of Limited Partnership respectively. If you need additional information, please contact the SOS at: <http://kepler.sos.ca.gov/>

Sole Proprietor – For a sole proprietor, enter the full legal name of the sole proprietor.

Governmental Agency – Enter the name of the governmental agency.

Name of NTP, MU or OBNTN – If different from legal entity name, enter the name of the facility or provider.

Tax Status – Check the box which applies to your business structure for tax purposes.

Facility Street Address – Enter the exact address of the facility. A post office box or commercial box is not acceptable. If applicable, enter the room/suite/unit number of the facility.

City – Enter the city of the facility.

County – Enter the county of the facility.

Zip Code – Enter the zip code of the facility.

An exact address can be verified at the United States Postal Service website:

https://tools.usps.com/go/ZipLookupAction_input

Mailing Address – If different from facility street address, enter the exact mailing address. If applicable, enter the room/suite/unit number of the mailing address.

City – Enter the city of the mailing address.

County – Enter the county of the mailing address.

Zip Code – Enter the zip code of the mailing address.

APPLICATION FOR PROTOCOL AMENDMENT

An exact address can be verified at the United States Postal Service website:

https://tools.usps.com/go/ZipLookupAction_input

Telephone Number – Enter the contact person's telephone number, including an extension if applicable.

Fax Number – Enter the fax number assigned to the facility.

Name of Program Sponsor – Enter the person or organization responsible for the operation of the NTP 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. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

Name of Program Director – Enter the name of the person who has primary administrative responsibility for operation of the NTP.

Name of Medical Director – Enter the name of the physician licensed to practice medicine in California who is responsible for medical services provided by the NTP.

SECTION D

Relocation

This section must be completed by applicants applying for program relocation.

PLEASE NOTE: Pursuant to CCR, Title 9, §10085(a)(2), the Department shall conduct a site visit prior to the approval of program facility relocation.

For relocation of a Department approved NTP location, additional documentation is required.

Written Statement Explaining Relocation – Check box to indicate that a written statement is attached to this form.

Statement must include:

- The proposed effective date of the relocation of the program to the new location.
- The estimated impact that the relocation will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the relocation.

Facility and Geographical Area Form DHCS 5025 (04/16) – Complete the Facility and Geographical Area form DHCS 5025 (04/16) for the new NTP location and attach to this form.

APPLICATION FOR PROTOCOL AMENDMENT

County Certification Form DHCS 5027 (04/16) – Complete the County Certification form DHCS 5027 (04/16) for the new NTP location and attach to this form.

Letters of Community Support – Obtain written verification of support from the community for the new NTP location and attach to this form.

SECTION E

Change in Licensed Patient Capacity

This section must be completed by applicants applying for a change in licensed patient capacity.

PLEASE NOTE: Pursuant to CCR, Title 9, §10035(d), an amendment proposing an increase in the licensed patient 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.

For a change in the Department approved maximum licensed patient capacity, additional documentation is required.

Written Statement Explaining Change in Licensed Patient Capacity – Check box to indicate that a written statement is attached to this form.

Statement must include:

- The proposed effective date of the change in licensed patient capacity.
- The estimated impact that the change in licensed patient capacity will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the change in licensed patient capacity.

Current Licensed Patient Capacity – Enter the Department approved maximum licensed patient capacity for maintenance and detoxification treatment.

Amount of Licensed Patient Capacity Increase or Decrease – Enter the amount of licensed patient capacity increase or decrease for maintenance and detoxification treatment.

Requested Licensed Patient Capacity – Enter the requested total licensed patient capacity for maintenance and detoxification treatment.

APPLICATION FOR PROTOCOL AMENDMENT

Number of Deaths Reported – Enter the number of patient deaths reported in the last 90 days as required by CCR, Title 9, §10195. This information will be verified against Department records for purposes of verifying compliance.

Current Program Census – Enter the total number of patients currently receiving maintenance or detoxification treatment at the NTP.

Proposed Counselor to Patient Ratio – Enter the number of counselors per patient with the additional capacity.

Example: If the program has a current total capacity of 100 patients and 10 counselors. The ratio would be 1:10.

Updated Facility Map – If any change has been made to the facility map previously provided to the Department in the protocol, attach an updated map of the NTP location.

Section F

Addition, Reduction or Termination of Services

This section must be completed by applicants applying for an addition, reduction or termination of services.

PLEASE NOTE: This section must be completed for a change in hours of operation.

For a change in Department approved services including the addition, reduction or termination of services additional documentation is required.

Written Statement Explaining Addition, Reduction or Termination of Services – Check box to indicate that a written statement is attached to this form.

Statement must include:

- The proposed effective date of the addition, reduction or termination of services.
- The estimated impact that the addition, reduction or termination of services will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the addition, reduction or termination of services.

Section G

Change in Program Sponsor

This section must be completed by applicants applying for change in Program Sponsor.

APPLICATION FOR PROTOCOL AMENDMENT

Name of Current Program Sponsor – Enter the person or organization currently responsible for the operation of the NTP 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. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

Name of New Program Sponsor – Enter the person or organization that, if approved by the Department, will be responsible for the operation of the NTP 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 new program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

Business Address of New Program Sponsor – Enter the business address of the new program sponsor.

Telephone Number of New Program Sponsor – Enter the telephone number of the new program sponsor, include an extension if applicable.

Email Address of New Program Sponsor – Enter the email address of the new program sponsor.

PLEASE NOTE: For a change in program sponsor additional documentation is required.

Written Statement Explaining Change in Program Sponsor – Check box to indicate that a written statement is attached to this form.

Statement must include:

- The proposed effective date of the change in program sponsor.
- The estimated impact that the change in program sponsor will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the change in program sponsor.

New Program Sponsor Resume – Check box to indicate that the proposed program sponsor's resume is attached to this form.

Section H: Change in Individual Pursuant to CCR, Title 9, §10035(a)(5)

This section must be completed by applicants applying for change in individual pursuant to CCR, Title 9, §10035(a)(5).

APPLICATION FOR PROTOCOL AMENDMENT

Name of Individual – Enter the name of the 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.

Telephone Number – Enter the telephone number and extension if applicable of the 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.

Email Address – Enter the email address of the 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.

Individual Live Scan Fingerprinting Date – Enter the date that the 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, had individual live scan fingerprinting.

PLEASE NOTE: For any change in personnel pursuant to CCR, Title 9, §10035(a)(5), *additional documentation is needed.*

Written Statement Explaining Change in Individual – If applying for a change in partner, officer, board of director's member, or 10 percent or greater shareholder, check box to indicate that a written statement is attached to this form.

Statement must include:

- The proposed effective date of the change in individual.
- The estimated impact that the change in individual), will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the change in individual.

Organizational Responsibility Form DHCS 5031 (04/16) – If applying for a change in partner, officer, board of director's member, or 10 percent or greater shareholder, complete the Organizational Responsibility form DHCS 5031 (04/16) and attach to this form.

Written Statement Explaining Change in Individual – If applying for a change in program director, medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, check box to indicate that a written statement is attached to this form.

Statement must include:

- The proposed effective date of the change in individual.

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- The estimated impact that the change in individual will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the change in individual.

Staff Information Form DHCS 5026 (04/16) – If applying for a change in program director, medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, complete the Staff Information form DHCS 5026 (04/16) and attach to this form.

Written Documentation of Medical Licensure – If applying for a change in medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, obtain written documentation of medical licensure and attach to this form.

Procedure for Replacement – If applying for a change in medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, complete a written statement describing the procedure of replacement of such staff member in the event of death, retirement, or prolonged sickness and attach to this form.

Procedure to Assure Appropriate Staff Time – If applying for a change in medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, complete a written statement describing the procedure to assure that appropriate staff time will be provided to the program in the event of a short-term emergency, vacation, or sickness and attach to this form.

Resume – If applying for a change in program director, medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, attach a resume to this form.

Section I Change in Physical Structure

This section must be completed by applicants applying for change in physical structure.

For a change in physical structure, additional documentation is required.

Written Statement Explaining Change in Physical Structure – Check box to indicate that a written statement is attached to this form.

Statement must include:

- The proposed effective date of the change in physical structure.

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- A narrative describing the changes in physical structure.
- The estimated impact that the change in physical structure will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the change in physical structure.

Facility and Geographical Area Form 5025 (04/16) – Complete the Facility and Geographical Area form DHCS 5025 (04/16) to include the change in physical structure and attach to this form.

Updated Facility Map – Complete an updated facility map that includes the change in physical structure for which you are applying for and attach to this form.

Section J

Declaration

This section must be completed by all applicants.

Print Name – Enter the name of the program sponsor.

Title – *This field has been pre-filled by the Department to reflect that the form must be signed by the program sponsor.*

Signature – Program sponsor's signature.

Date – Enter the date that the application is signed by the program sponsor.

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Section A Facility Type	
Check one box:	
<input type="checkbox"/> Narcotic Treatment Program (NTP) CCR, Title 9, §10030	
<input type="checkbox"/> Medication Unit (MU) CCR, Title 9, §10020	
<input type="checkbox"/> Office-Based Narcotic Treatment Network (OBNTN) CCR, Title 9, §10021	
Section B Type of Amendment	
Check all that apply:	
<input type="checkbox"/> Relocation CCR, Title 9, §10035(a)(1)	
<input type="checkbox"/> Change in Licensed Patient Capacity CCR, Title 9, §10035(a)(2)	
<input type="checkbox"/> Addition, Reduction or Termination of Services CCR, Title 9, §10035(a)(3)	
<input type="checkbox"/> Program Sponsor CCR, Title 9, §10035(a)(4)	
<input type="checkbox"/> 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 CCR, Title 9, §10035(a)(5)	
<input type="checkbox"/> Any change to the physical structure of the facility or floor plan including expansions or modifications to dispensing stations CCR, Title 9, §10035(a)(6)	
<input type="checkbox"/> Other CCR, Title 9, §10035(b) _____	
Section C Existing Licensee Information	
License Number:	National Provider Identifier (NPI):
Name of Legal Entity:	
Name of NTP, MU or OBNTN (if different than name of legal entity):	

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Section C (Continued)		Existing Licensee Information	
Tax Status:			
<input type="checkbox"/> Corporation			
<input type="checkbox"/> Nonprofit Corporation			
<input type="checkbox"/> Limited Liability Company			
<input type="checkbox"/> Partnership/Limited Partnership			
<input type="checkbox"/> Sole Proprietor			
<input type="checkbox"/> Governmental Agency			
Facility Street Address (if applicable Room/Suite/Unit):			
City:		County:	Zip Code:
Mailing Address (if applicable Room/Suite/Unit)/(if different than facility street address):			
City:		County:	Zip Code:
Telephone Number:		Fax Number:	
Name of Program Sponsor:			
Name of Program Director:			
Name of Medical Director:			

APPLICATION FOR PROTOCOL AMENDMENT

Section D Relocation	
Attach the following:	
<input type="checkbox"/> Written Statement Explaining Relocation	
<input type="checkbox"/> Facility and Geographical Area Form DHCS 5025 (04/16)	
<input type="checkbox"/> County Certification Form DHCS 5027 (04/16)	
<input type="checkbox"/> Letters of Community Support	
Section E Change in Licensed Patient Capacity (Complete section E if application is for increase or decrease in capacity)	
Attach the following:	
<input type="checkbox"/> Written Statement Explaining Change in Licensed Patient Capacity	
Current Licensed Patient Capacity:	
Amount of Licensed Patient Capacity Increase or Decrease:	
Requested Licensed Patient Capacity:	
Number of Deaths Reported in the last 90 days as required by CCR, Title 9, §10195:	
Current Program Census:	Proposed Counselor to Patient Ratio:
Updated Facility Map Attached: <input type="checkbox"/> Yes <input type="checkbox"/> N/A	
Section F Addition, Reduction or Termination of Services	
Attach the following:	
<input type="checkbox"/> Written Statement Explaining Addition, Reduction or Termination of Services	
Section G Change in Program Sponsor	
Name of Current Program Sponsor:	
Name of New Program Sponsor:	
Business Address of New Program Sponsor:	

APPLICATION FOR PROTOCOL AMENDMENT

Section G (Continued) Change in Program Sponsor	
Telephone Number of New Program Sponsor:	Email Address of New Program Sponsor:
Attach the following: <input type="checkbox"/> Written Statement Explaining Change in Program Sponsor <input type="checkbox"/> New Program Sponsor Resume	
Section H Change in Individual Pursuant to CCR, Title 9, §10035(a)(5)	
Name of Individual:	
Telephone Number:	Email Address:
Individual Live Scan Fingerprinting Date:	
Attach the following for a change in partner, officer, board of director's member, or 10 percent or greater shareholder: <input type="checkbox"/> Written Statement Explaining Change in Individual <input type="checkbox"/> Organizational Responsibility Form DHCS 5031 (04/16)	
Attach the following for a change in program director, medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code: <input type="checkbox"/> Written Statement Explaining Change in Individual <input type="checkbox"/> Staff Information Form DHCS 5026 (04/16) <input type="checkbox"/> Written Documentation of Medical Licensure <input type="checkbox"/> Procedure for Replacement <input type="checkbox"/> Procedure to Assure Appropriate Staff Time <input type="checkbox"/> Resume	

APPLICATION FOR PROTOCOL AMENDMENT

Section I Change in Physical Structure	
Attach the following documents:	
<input type="checkbox"/> Written Statement Explaining Change in Physical Structure Facility Geographical Area Form DHCS 5025 (04/16)	
<input type="checkbox"/> Updated Facility Map	
Section J Declaration	
I declare under penalty of perjury under the laws of the State of California that the foregoing information and any attachment is true, accurate, and complete to the best of my knowledge and belief. I hereby further declare that I will abide by all State and federal laws and regulations governing narcotic treatment programs. I declare that I am authorized to sign this application.	
Print Name:	Title: Program Sponsor
Signature:	Date:
Privacy Statement	
<p>PRIVACY STATEMENT (Civil Code Section 1798 et seq.)</p> <p>All information requested in this form is mandatory. This information is required by the Department of Health Care Services (Department) by the authority of Health and Safety Code, Section 11839.3 and California Code of Regulations, Title 9, Section 10055. The consequences of not supplying the mandatory information requested is that review of the application shall be terminated, which may result in lapse of licensure and/or imposition of fines. The Department may share or provide any of the information provided in or with this form to the California Health and Human Services Agency, the California State Controller's Office, the California Department of Justice, the California Department of Consumer Affairs, the Department of Corporations, or other state or local agencies as appropriate, the Federal Bureau of Investigation, the Internal Revenue Service, the U.S. Justice Department, the United States Drug Enforcement Administration, the United States Department of Health and Human Services, and the United States Substance Abuse and Mental Health Services Administration. For more information or access to records containing your personal information maintained by the Department, contact the Counselor & Medication Assisted Treatment Section Officer of the Day at (916) 322-6682.</p>	