Department of Health Care Services
Behavioral Health Information Notice No. 25-008

Attachment 1
Narcotic Treatment Programs Regulation Text
Chapter 4, Division 4, Title 9, California Code of Regulations

The enclosed text is final regulation text for the sections in Chapter 4 that are superseded by this BHIN (see table of contents for sections amended). This BHIN adds new sections 10023, 10031, and 10306 to Chapter 4. Sections of Chapter 4 that are not present in this BHIN are still effective as shown in the California Code of Regulations, except this BHIN repeals sections 10400 and 10410.

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Subchapter 1. General Administration

§ 10000. Definitions

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

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

(2) Behavioral Health Services. “Behavioral health services” means any intervention carried out in a therapeutic context at an individual, family, or group level. Interventions may include structured, professionally administered clinical interventions (e.g., cognitive behavioral therapy or insight-oriented psychotherapy) that have been shown to facilitate treatment outcomes, or non-clinical interventions.

(3) 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 use disorder.

(4) Buprenorphine Products. “Buprenorphine products” means buprenorphine combination products approved by the FDA for maintenance treatment or detoxification of opioid use disorder.

(5) Care Plan. “Care plan” means an individualized treatment and/or recovery plan that outlines attainable treatment goals that have been identified and agreed upon between the patient and the patient’s counselor, that specifies the services to be provided and the proposed frequency and schedule for provision of services.

(6) Diversion Control Plan. “Diversion Control Plan” is a set of documented procedures that reduce the possibility that controlled medication for opioid use disorder will be transferred or otherwise shared with others to whom the medication was not prescribed or dispensed.

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

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

(9) Detoxification Treatment. “Detoxification treatment” means the treatment modality whereby medication for opioid use disorder is used in decreasing, individually determined dosage levels and provided in conjunction with an individualized range of harm reduction interventions and medical and behavioral health services.

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

(11) Harm Reduction. “Harm reduction” means evidence-based interventions to prevent harm, reduce risk, and promote health, including the following:

(A) Overdose education.

(B) Screening and referral for infectious diseases, including counseling and risk mitigation activities forming part of a comprehensive, integrated approach to address HIV, viral hepatitis, sexually transmitted infections, and bacterial and fungal infections.

(C) Opioid overdose reversal medications.

(D) Linkage to other public health services.

(E) Connecting patients who have expressed interest in additional support to peer services.

(12) 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.

(13) Interim Treatment. “Interim treatment” means that on a temporary basis, not to exceed 180 days in any 12-month period, a patient may receive medication for opioid use disorder from a narcotic treatment program while awaiting access to comprehensive treatment.

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

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

(16) 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 supplemental written protocol for interim treatment;

(F) Denial of a request for license renewal;

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

(H) Assessment of a civil penalty; or

(I) Suspension or revocation of a license.

(17) Maintenance Treatment. “Maintenance treatment” means the treatment modality whereby medication for opioid use disorder is used continuously and provided in conjunction with an individualized range of harm reduction interventions and medical and behavioral health services.

(18) Medical Director. “Medical director” means the physician licensed to practice medicine in California who is responsible for overseeing all medical and behavioral health services provided by the program and compliance with this chapter and all applicable federal and state laws.

(19) Medication for Opioid Use Disorder. “Medication for opioid use disorder” means any medications that have been approved by the FDA for use in treating opioid use disorder, including:

(A) Methadone;

(B) Naltrexone;

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

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

(20) Medication Unit. “Medication unit” means a DEA registered facility established as part of, but geographically separate from, a narcotic treatment program, from which appropriately licensed program staff, contractors working on behalf of the program, or community pharmacists dispense or administer controlled medication for opioid use disorder, and which may provide other treatment services. Medication units are a brick-and-mortar location and do not include mobile narcotic treatment programs.

(21) Methadone. “Methadone” means the substance that can be described as 6-dimenthylamino-4, 4-diphenyl-3-heptanone. Methadone doses are usually administered as methadone hydrochloride.

(22) 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.

(23) Narcotic Treatment Program (NTP). “Narcotic treatment program (NTP)” means a licensed opioid use disorder treatment program, whether inpatient or outpatient, which offers all of the following: evaluation, maintenance treatment and/or detoxification treatment, and other treatment services in conjunction with medication for opioid use disorder.

(24) 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 substance use disorder counselors who are evaluated through ongoing supervision; and professional medical and behavioral health services, on-site or by referral.

(25) Opiate. “Opiate” 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.

(26) 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.

(27) Opioid Use Disorder. “Opioid use disorder” means a cluster of cognitive, behavioral, and physiological symptoms associated with a problematic pattern of opioid use that continues despite clinically significant impairment or distress.

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

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

(30) Program. “Program” means a narcotic treatment program.

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

(32) Program Sponsor. “Program sponsor” means the person or organization named in the Initial Application Coversheet form DHCS 5014 (05/25), 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 or behavioral health 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.

(33) Protocol. “Protocol” means a written document, including required forms, which sets forth a program’s treatment concept, organization, and operational procedures.

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

(35) Replacement Narcotic Therapy. “Replacement narcotic therapy” means 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.

(36) SAMHSA. “SAMHSA” means the Substance Abuse and Mental Health Services Administration.

(37) Telehealth. “Telehealth” has the same meaning as defined in Section 2290.5(a) of the Business and Professions Code, except that references to telehealth in this chapter are only to synchronous interaction and do not include asynchronous store and forward transfer.

(38) Treatment. “Treatment” means services which will habilitate and rehabilitate patients with an opioid use disorder to a basic level of social, life, work, and health capabilities that help them become productive, independent members of society and includes:

(A) Replacement narcotic therapy or medication-assisted treatment of substance use disorders;

(B) Evaluation of patient needs and goals for harm reduction interventions, medical, employment, education, psychosocial, vocational training, economic, legal, housing, and other services;

(C) Screening and referral for infectious diseases that are disproportionately represented in the substance use disorder population;

(D) Monitoring for illicit drug use;

(E) Counseling by substance use disorder counselors that are evaluated through ongoing supervision; and

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

Subchapter 2. Licensure of Narcotic Treatment Programs

Article 1. Program Licensure

§ 10020. Medication Units

(a) A medication unit may lawfully operate under a primary NTP’s license 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.

(b) The primary NTP program sponsor shall submit an Initial Application Coversheet form DHCS 5014 (05/25) 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 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 (05/25), herein incorporated by reference;

(2) The population of the area to be served, as required by the Facility and Geographical Area form DHCS 5025 (05/25);

(3) Each staff member’s resume and the Staff Information form DHCS 5026 (05/25), 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 (05/25);

(5) The days and hours of medication dispensing, as required by the Facility and Geographical Area form DHCS 5025 (05/25);

(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 (05/25);

(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 (05/25);

(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, counseling space, physical examination and assessment 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 (05/25);

(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, if all services are not available at the medication unit, as required by the Facility and Geographical Area form DHCS 5025 (05/25);

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

(11) The services available via telehealth and the days and hours telehealth services are available, if applicable.

(c) In addition to the supplemental written protocol, the primary NTP shall submit to the Department an Affiliated and Associated Acknowledgement form DHCS 5134 (05/25), 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 (05/25), supplemental written protocol, and the Affiliated and Associated Acknowledgement form DHCS 5134 (05/25), 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) A medication unit may provide any services that are provided by the primary NTP, provided that the medication unit has adequate space to provide the services to patients in a confidential manner. The primary NTP shall be responsible for ensuring that patients have access to all other treatment services not provided at the medication unit.

§ 10023. Interim Treatment

(a)(1) If a NTP elects to provide interim treatment, it shall obtain prior approval from the Department and SAMHSA and comply with this section.

(2) To apply to the Department to provide interim treatment, a NTP shall submit an Application for Protocol Amendment form DHCS 5135 (05/25) and supplemental written protocol to the Department that includes the NTP's written policies and procedures for the provision of interim treatment, and which shall document compliance with the requirements set forth in this section.

(3) The protocol amendment and supplemental written protocol shall also include all the following:

(A) The components of a protocol amendment required by Section 10035(c);

(B) Criteria for establishing the priority of admitting patients into interim treatment and transferring patients from interim treatment into comprehensive treatment, which shall prioritize the admission and transfer of pregnant patients; and

(C) Evidence that the NTP's provision of interim treatment will not reduce the capacity of the NTP to admit patients into comprehensive treatment.

(b) A NTP shall not provide interim treatment until the Department approves its application for a protocol amendment in accordance with Section 10036.

(c) In providing interim treatment, a NTP shall do all the following:

(1) Provide interim treatment to a person eligible for admission under the criteria in Section 10270 only if comprehensive treatment is unavailable to that person within a reasonable geographic distance within fourteen (14) days of the date on which the person sought admission;

(2) Limit the duration of a patient's interim treatment to no longer than 180 days in any 12-month period;

(3) Arrange for each patient's transfer into comprehensive treatment, which may be provided by another geographically accessible NTP, no later than 180 days from the date a patient was admitted into interim treatment;

(4) Prepare a plan for complying with subsection (c)(3) of this section before the patient reaches 120 days in interim treatment, and document the plan in the patient's record;

(5) Collect at least two patient body specimens for testing or analysis of illicit drug use during the 180-day interim treatment period; and

(6) Prioritize admission of pregnant persons into interim treatment and transfer of pregnant patients into comprehensive treatment.

(d)(1) A NTP shall notify the Department when any of the following events occur by submitting the Interim Treatment Patient Notification form DHCS 4032 (04/25).

(A) Within 30 days of the date a patient was admitted to interim treatment.

(B) Within 30 days of the date a patient was transferred from interim treatment to comprehensive treatment or discharged from interim treatment.

(C) At least 60 days before the date on which a patient's 180-day period of interim treatment will end.

(2) A NTP shall submit its plan for continuing a patient's treatment to the Department with the notice required by subsection (d)(1)(C).

(e) All the requirements in this chapter for comprehensive treatment apply to interim treatment, except a NTP is not required to offer or provide the following services to patients in interim treatment.

(1) Development of a care plan as set forth in Section 10305. However, a NTP shall perform an initial behavioral health assessment of an admitted patient as required by subsections (g)(1) and (g)(2) of Section 10270.

(2) Assignment of a counselor or counseling services as set forth in Section 10345, except that a NTP shall provide crisis intervention services.

(f) A NTP shall not involuntarily discharge a patient from interim treatment while the patient is awaiting transfer to comprehensive treatment, except as provided by Section 10415.

(g) The Department may suspend or revoke a NTP's authorization to provide interim treatment for noncompliance with this section or Part 8 of Title 42 of the Code of Federal Regulations.

(h) For purposes of this section, "comprehensive treatment" means the provision of medication for opioid use disorder in conjunction with an individualized range of harm reduction interventions and medical and behavioral health services.

§ 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 (05/25) and written protocol, which shall serve as an application for licensure by the Department. The protocol shall include 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 (05/25).

(3) Population and area to be served, as required by the Facility and Geographical Area form DHCS 5025 (05/25).

(4) The estimated number of persons in the described area having an opioid use disorder and an explanation of the basis of such estimate, as required by the Facility and Geographical Area form DHCS 5025 (05/25).

(5) The estimated number of persons in the described area having an opioid use disorder who are presently in a narcotic treatment program and other treatment programs, as required by the Facility and Geographical Area form DHCS 5025 (05/25).

(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 (05/25).

(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 (05/25), herein incorporated by reference.

(11) Letters of community support.

(12) Patient identification system (physical or electronic).

(13) Control and security of patient identification 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) 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 resume and Staff Information form DHCS 5026 (05/25).

(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 admission.

(26) Program rules and instructions.

(27) Facility description, as required by the Facility and Geographical Area form DHCS 5025 (05/25).

(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 procedures to be followed in the event of an emergency or disaster.

(33) Testing or analysis procedures for illicit drug use which utilize random selection or unannounced collection.

(34) Procedures for 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 (05/25).

(38) Amount of space devoted to NTP services, including waiting, counseling, dispensing, and storage areas, as required by the Facility and Geographical Area form DHCS 5025 (05/25).

(39) Days and hours of medication program dispensing, as required by the Facility and Geographical Area form DHCS 5025 (05/25).

(40) Days and hours for other narcotic treatment program services, as required by the Facility and Geographical Area form DHCS 5025 (05/25).

(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 (05/25).

(42) Diagram of the facility housing the narcotic treatment program and an accompanying narrative that describes patient flow, as required by the Facility and Geographical Area form DHCS 5025 (05/25). The diagram and narrative shall specify:

(A) Waiting areas.

(B) Office, counseling, and physical examination and assessment 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.

(44) The program’s diversion control plan, as required by Section 10265.

(45) The services available via telehealth and the days and hours telehealth services are available, if applicable.

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

§ 10031. Other Providers of Narcotic Treatment Program Services

(a) All NTP treatment services required by this chapter shall be available at the primary NTP's location, except if the program sponsor enters into a written agreement with a private or public agency, organization, health care provider, or institution such as a hospital, correctional facility, or long-term care facility ("other provider"), to provide specified NTP services to patients enrolled in the NTP.

(b) The NTP's agreement with an other provider shall contain:

(1) The services the other provider will provide to patients enrolled in the NTP.

(2) The conditions under which a patient will receive the services set forth in the agreement.

(3) Policies and procedures for the other provider to provide the services set forth in the agreement, including but not limited to, requirements to comply with all applicable federal and state laws on patient confidentiality and security of controlled medication for opioid use disorder.

(4) Policies and procedures for the other provider to provide documentation to the NTP of the services it provides to the NTP's patients.

(c) A NTP shall obtain approval from the Department before permitting an other provider to provide specified NTP services to its patients. A NTP shall not permit an other provider to provide specified NTP services to its patients until the Department approves its application for a protocol amendment in accordance with Section 10036.

(d) To apply to the Department for approval to permit an other provider to provide specified NTP services to its patients, a NTP shall submit the following documents to the Department:

(1) An Application for Protocol Amendment form DHCS 5135 (05/25);

(2) The components of a protocol amendment required by Section 10035(c); and

(3) A copy of the agreement containing the signatures of all service providers.

(e) For each patient receiving services from an other provider, a NTP shall document the services the patient received in the patient's record.

Article 2. Program Evaluation

§ 10060. Departmental Study and Evaluation of Programs

The Department may study and evaluate all programs on an ongoing basis to determine the program's effectiveness in treating patients with opioid use disorder. Each program shall furnish to the Department information and reports the Department may request to facilitate such study and evaluation.

Subchapter 3. Program Administration

Article 1. Organizational Structure of Program and Staffing Requirements

§ 10110. Medical Director

(a) Each program shall have a medical director who is a licensed physician in the State of California with at least one year of experience in treating persons with opioid use disorder. The medical director may also serve as the program director. The medical director shall be responsible for overseeing all medical and behavioral health services provided by the program and compliance with this chapter and all applicable federal and state laws.

(b) The activities of the medical director shall include:

(1) Overseeing the hiring, evaluation, and management of medical and behavioral health staff.

(2) Engaging in continuous quality improvement, including developing, implementing, and conducting annual reviews of the program’s policies and procedures.

(3) Overseeing the medical and behavioral health care of the program’s patients, including assessing patient outcomes on an ongoing basis.

(c) Other duties and responsibilities of the medical director shall be set forth in the protocol.

(d) The medical director may delegate duties as prescribed in the program protocol to another licensed program physician(s) or physician extender(s) but may not delegate their oversight and compliance obligations set forth in subsection (a) or (b) of this section.

§ 10125. Counselors

(a) Program staff who provide counseling services (as defined in Section 13005) pursuant to Section 10345 shall be certified, registered to obtain certification pursuant to Chapter 8 (commencing with Section 13000), or exempt from certification in accordance with Health and Safety Code section 11833.

(b) 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.

(c) 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, Board of Behavioral Science registration, graduate school program enrollment, 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.

§ 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 opioid use disorder.

(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.

Article 3. Patient Records

§ 10165. Content of Patient Records

(a) Each program shall document the following information in each patient's record:

(1) The patient's birth date and date of admission to the program.

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

(3) Results of initial and periodic behavioral health assessments and the patient's care plan, as required by Section 10305.

(4) Medication orders signed by the medical director, program physician, or physician extender.

(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 or buprenorphine (when prescribed), and the presence of any illicit drugs, or misuse of other substances, including alcohol.

(6) Known behavioral problems or recent diversion activity.

(7) Any other patient information required to be documented by this chapter.

(b) In addition to the requirements set forth in subsection (a) above, patient records shall contain the following:

(1) Documentation of services and treatment provided, as well as progress notes, signed by the physician, nurse, physician extender, or counselor.

(2) Test or analysis results for illicit drug use and periodic review or evaluation by the medical director, program physician, or physician extender. Such review shall be made not less than annually.

(3) Reasons for changes in dosage levels and medications.

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

Subchapter 4. Medication Security and Diversion Prevention

Article 1. Detection of Multiple Registration

§ 10210. Detection of Multiple Registration Following Admission

(a) Before dispensing the initial dose of controlled medication for opioid use disorder to an admitted patient, the program shall:

(1) Notify the patient that it cannot provide controlled medication for opioid use disorder to a patient who is simultaneously receiving this medication from another program.

(2) Request the patient to sign a written statement documenting whether they are currently receiving controlled medication for opioid use disorder from another program and retain the statement in the patient record. If the patient declines to sign this statement, the program shall document the declination in the patient's record and proceed in accordance with Section 10215.

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

(A) Full legal name and any aliases,

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

(C) Mother's maiden name,

(D) Sex,

(E) Race,

(F) Height,

(G) Weight,

(H) Color of hair,

(I) Color of eyes,

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

(4) Request the patient to voluntarily provide their Social Security number;

(5) Request the patient to sign an authorization for disclosure of confidential information, pursuant to Section 2.34, Part 2, Chapter 1, Title 42 of the Code of Federal Regulations for the limited purpose of authorizing the program to contact each narcotic treatment program within a radius of 50 statute miles to determine if the patient, as identified at

Subsection (a)(3) and (a)(4) of this regulation, is simultaneously receiving controlled medication for opioid use disorder from another program.

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

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

(c) If the patient states that they are currently receiving controlled medication for opioid use disorder from another program and the patient is not approved to receive services on a temporary basis in accordance with Sections 10205(b) and 10295, before providing controlled medication for opioid use disorder to the patient, the program shall:

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

(2) Contact the previous program and notify the program that the patient was admitted;

(3) Request the program to cease providing controlled medication for opioid use disorder if it has not already done so;

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

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

(A) The name of the program contacted,

(B) The date and time of the contact,

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

(D) The results of the contact.

(d) If the patient states that they are a visiting patient approved to receive services on a temporary basis in accordance with Sections 10205(b) and 10295, before providing controlled medication for opioid use disorder to the patient the program shall:

(1) Contact the other program to determine whether it provided the patient with controlled medication for opioid use disorder for the same time period; and

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

(A) The name of the program contacted,

(B) The date and time of the contact,

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

(D) The results of the contact.

(e) If the patient states that they are not currently receiving controlled medication for opioid use disorder from another program, the program shall proceed in accordance with Section 10215.

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

(a) If the patient documents pursuant to Section 10210 that they are not currently receiving controlled medication for opioid use disorder from another program, or declines to sign the written statement documenting whether they are currently receiving controlled medication for opioid use disorder from another program, the program shall review the results of the patient's initial test or analysis for illicit drug use to determine the presence of methadone or its primary metabolite or buprenorphine. The program may provide controlled medication for opioid use disorder to the patient prior to receipt of these results.

(b) If the results of the test or analysis for illicit drug use indicate the presence of methadone or its primary metabolite or buprenorphine, the program shall ask the patient if, during the preceding 72 hours, they received the medication from a registered health care provider with prescriptive authority or while hospitalized or if they were discharged from another narcotic treatment program. If the patient states that they received the medication from a registered health care provider with prescriptive authority or were discharged from the hospital or another program during the preceding 72 hours, the program shall proceed in accordance with Subsection 10210(c). If the patient states that they did not receive the medication from a registered health care provider with prescriptive authority or were not discharged from the hospital or another program during the preceding 72 hours, the program shall proceed in accordance with Subsections (c), (d), and (e) of this regulation.

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

(1) Contact each narcotic treatment program within a radius of 50 statute miles to determine if the patient is simultaneously receiving controlled medication for opioid use disorder from another program, and

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

(d) Each program receiving information provided in accordance with Subsection (c) of this regulation shall review its records to determine if it has provided controlled medication for opioid use disorder to the patient within the past 90 days.

(1) If the program has not provided controlled medication for opioid use disorder to the patient or if it is no longer providing this medication to the patient, the program shall so notify the inquiring program in writing within 72 hours of receipt of the notification.

(2) If the program is still providing controlled medication for opioid use disorder to the patient, the programs shall proceed in accordance with the requirements of Section 10225.

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

(1) The name of each program contacted,

(2) The date and time of the contact,

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

(4) The results of the contact.

§ 10225. Resolution of Multiple Registration

(a) When a program determines that it is providing controlled medication for opioid use disorder to a patient who is simultaneously receiving this medication from one or more other programs, all the involved programs shall immediately:

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

(2) Revoke the patient’s take-home medication; and

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

(b) The program which agrees to accept sole responsibility for the patient shall continue to provide controlled medication for opioid use disorder to the patient.

(c) Each of the other programs involved shall:

(1) Immediately discharge the patient from the program;

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

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

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

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

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

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

Article 3. Medication Handling and Security

§ 10265. Security of Medication Stocks

(a) Each program shall maintain adequate security over controlled medication for opioid use disorder, over the manner in which controlled medications are administered or dispensed, over the manner in which they are distributed, and over the manner in which they are stored to guard against theft and diversion.

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

(c) Each program shall maintain a diversion control plan that contains specific measures to reduce the possibility of diversion of controlled medication for opioid use disorder. The diversion control plan shall assign specific responsibilities to program staff for carrying out the diversion control measures and functions described in the plan.

Subchapter 5. Patient Treatment

Article 1. Patient Admission and Orientation

§ 10270. Criteria for Patient Admission and Admission Procedure

(a)(1) Before admitting an applicant to detoxification or maintenance treatment, the medical director, program physician, or physician extender shall do all the following:

(A) Conduct a screening evaluation of the applicant in accordance with subsection (b) or review a screening evaluation that was performed by an appropriately licensed health care provider no more than seven days prior to admission;

(B) Explain all relevant facts concerning the use of medication for opioid use disorder;

(C) Obtain voluntary informed consent for treatment. A patient may consent verbally if the NTP obtains written consent following admission; and

(D) Document the narrative and results of the screening evaluation, or their review and concurrence with the screening evaluation, and patient consent in the patient's file.

(2) A NTP shall not admit an applicant who is under the age of 16 years without the consent of the applicant's parent or legal guardian.

(3)(A) A NTP shall prioritize the admission of pregnant applicants. If possible, pregnancy should be confirmed before priority admission.

(B) If a patient declines a pregnancy test, the NTP shall obtain the patient's signature on a waiver, or if unable to obtain the patient's signature, document the declination in the patient's record.

(b) The screening evaluation shall confirm, based on accepted medical criteria, that the applicant does not have contraindications to treatment with medication for opioid use disorder and meets one of the following admission criteria:

(1) If the applicant will enter detoxification treatment, the applicant:

(A) Meets diagnostic criteria for an opioid use disorder; or

(B) Has an active opioid use disorder.

(2) If the applicant will enter maintenance treatment, the applicant:

(A) Meets diagnostic criteria for a moderate to severe opioid use disorder;

(B) Has an active moderate to severe opioid use disorder;

(C) Is in remission for opioid use disorder; or

(D) Is at high risk for recurrence or overdose.

(c) The screening evaluation may be conducted via telehealth if the medical director, program physician, or physician extender determines that an adequate evaluation of the patient can be accomplished via telehealth. The medical director, program physician, or physician extender shall review the evaluation results and order medication for opioid use disorder as indicated.

(1) For patients initiating buprenorphine treatment via telehealth, the screening evaluation may be conducted on an “audio-visual” or “audio-only” telehealth platform.

(2) For patients initiating methadone treatment via telehealth, the screening evaluation shall be conducted as follows:

(A) On an “audio-visual” telehealth platform only if the medical director, program physician, or physician extender determines and documents that an adequate evaluation of the patient has been, or can be, accomplished via an “audio-visual” platform; or

(B) On an “audio-only” telehealth platform only if the patient is in the presence of a licensed health care provider who is registered to prescribe and dispense controlled substances.

(d) Before dispensing the initial dose of controlled medication for opioid use disorder to an admitted patient, a NTP shall do the following:

(1) Perform a test or analysis for illicit drug use; and

(2) Complete the actions set forth in Section 10210.

(e) Within fourteen (14) calendar days following admission, a NTP shall do all the following:

(1) Perform a full medical history and physical examination of an admitted patient in accordance with subsection (f) or review a full medical history and physical examination that was performed by an appropriately licensed health care provider no later than fourteen (14) calendar days following admission;

(2) Complete a behavioral health assessment of an admitted patient in accordance with subsection (g); and

(3) Document the full medical history and physical examination, or the NTP’s review and concurrence of the full medical history and physical examination, and behavioral health assessment in the patient’s file.

(f)(1) A full medical history and physical examination shall include all the following:

(A) A review of the patient's medical and psychiatric history that includes the patient's history of substance use;

(B) An in-person physical examination, which includes serology and other laboratory testing considered clinically appropriate by the health care provider performing the examination. Serology and other lab testing collected within 30 days prior to admission may be included in the physical examination;

(C) Counseling on preventing exposure to, and the transmission of, tuberculosis, HIV, viral hepatitis, and sexually transmitted infections, including syphilis; and

(D) Optional screening for infectious diseases, including tuberculosis, HIV, viral hepatitis, and sexually transmitted infections.

(2)(A) A patient may decline to undergo laboratory testing for co-occurring physical health conditions. A NTP shall not exclude a patient from treatment with medication for opioid use disorder because the patient declined laboratory testing for co-occurring physical health conditions unless the declination will negatively impact the patient's treatment with medication for opioid use disorder.

(B) If a patient declines laboratory testing for co-occurring physical health conditions, the NTP shall obtain the patient's signature on a waiver, or if unable to obtain the patient's signature, document the declination and that risks and benefits were discussed with the patient in the patient's record.

(3) If an admitted patient tests positive for tuberculosis, HIV, viral hepatitis, or a sexually transmitted infection, a NTP shall connect the patient to a heath care provider who can provide treatment for the infection.

(g) A behavioral health assessment shall include all the following:

(1) Screening for imminent risk of harm to self or others;

(2) Assessment of the need for and/or response to treatment, including adjusting medication for opioid use disorder and other treatment interventions as appropriate; and

(3) Preparation of an individualized care plan, as required by Section 10305, that is developed by engaging in shared decision-making with the patient.

(h) A NTP's protocol shall set forth all procedures and criteria used to satisfy the requirements of this section.

Article 2. Patient Attendance and Absence

§ 10295. Patient Attendance Requirements

(a) A patient shall report to the same program to which they were admitted, except as provided by this section.

(b)(1) A patient may temporarily receive medication for opioid use disorder from a NTP in which the patient is not registered when the patient is unable to access treatment at the patient's NTP of record. Such circumstances include, but are not limited to, travel for work or family events, temporary relocation, temporary closure of the NTP of record, incarceration, or hospitalization.

(2) A NTP may provide medication for opioid use disorder on a temporary basis to a patient who is incarcerated, hospitalized, or a resident in a residential or long-term care facility for the duration of the patient's stay.

(c) A patient shall obtain prior approval from the program in which they are registered to receive services on a temporary basis from another narcotic treatment program. The approval shall be noted in the patient's record and shall include the following documentation:

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

(2) A medication change order by the referring medical director, program physician, or physician extender permitting the patient to receive services on a temporary basis from the other program for a length of time not to exceed 30 days, except as provided by subsection (b)(2); and

(3) Evidence that the program contacted to provide services on a temporary basis has accepted responsibility to treat the visiting patient, concurs with the patient's dosage schedule, and supervises the administration of the medication, subject to Section 10210(d).

§ 10300. Patient Absence

(a) Patient in Detoxification Treatment

(1) If a patient in detoxification treatment misses medication for more than seven (7) consecutive calendar days without notifying the program, the patient's episode of treatment may be terminated by the medical director or program physician and the discharge shall be noted in the record.

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

(b) Patient in Maintenance Treatment.

(1) If a patient in maintenance treatment misses medication for 30 consecutive calendar days or more without notifying the program, the patient's episode of treatment shall be terminated by the medical director or program physician and the discharge shall be noted in the patient's record.

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

Article 3. Treatment Services

§ 10305. Patient Care Plans

(a) Programs shall develop an individualized care plan for each patient by engaging in shared decision-making with the patient. Each patient's care plan shall include harm reduction interventions as needed.

(b) The counselor shall record the patient's name and the date the patient was assigned to the counselor in the patient's record.

(c) Prior to developing a patient's initial care plan, the counselor shall complete and document in the patient's record a needs assessment for the patient which shall include:

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

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

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

(B) Employment;

(C) Education;

(D) Psychosocial, vocational training, economic, legal, housing, and other services.

(d)(1) Within fourteen (14) calendar days following admission, the counselor shall develop the patient's initial care plan, which shall include the patient's short-term and long-term goals and mutually agreed-upon actions for the patient to meet those goals in the following areas, as applicable:

(A) Education;

(B) Vocational training;

(C) Employment;

(D) Medical and psychiatric services; and

(E) Psychosocial, economic, legal, housing, and other services.

(2) A patient's care plan shall include a description of the recommended type and frequency of counseling services to be offered to the patient as set forth in Section 10345.

(3) The effective date of the initial care plan is the day the counselor signed the initial care plan.

(e) The counselor shall evaluate and update the patient's care plan whenever necessary or at least once every three months from the effective date of the initial care plan. This updated care plan shall include:

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

(2) New goals and mutually agreed-upon actions for any newly identified needs in the following areas, as applicable:

(A) Education;

(B) Vocational training;

(C) Employment;

(D) Medical and psychiatric services; and

(E) Psychosocial, economic, legal, housing, or other services.

(3) Any changes in the recommended type or frequency of counseling services to be offered to the patient as set forth in Section 10345.

(4) Documentation of patient responses to treatment.

(5) The effective date of the updated care plan is the day the counselor signed the updated care plan.

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

(g) A NTP may provide vocational training, education, and employment services to its patients. In the absence of providing such services, a NTP shall provide patients with referrals to accessible community resources for vocational training, education, and employment services.

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

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

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

§ 10306. Annual Physical Examination

(a) The medical director, program physician, or physician extender shall perform an in-person physical examination of a patient at least annually from the date of the patient's initial or last physical examination.

(b) The annual physical examination shall include:

(1) The elements of a physical examination listed in Section 10270(f)(1).

(2) Review and evaluation of:

(A) The results of the patient's last physical examination;

(B) The patient's care plan;

(C) Medication dosing and response to treatment;

(D) Other substance use disorder treatment needs and responses, and patient-identified goals; and

(E) Any other relevant physical and psychiatric treatment needs and goals.

(c)(1) A patient may decline to undergo the physical examination or laboratory testing for co-occurring physical health conditions. A NTP shall not exclude a patient from treatment with medication for opioid use disorder because the patient declined the physical examination or laboratory testing for co-occurring physical health conditions unless the declination will negatively impact the patient's treatment with medication for opioid use disorder.

(2) If a patient declines the physical examination or laboratory testing for co-occurring physical health conditions, the NTP shall obtain the patient's signature on a waiver, or if unable to obtain the patient's signature, document the declination in the patient's record.

(d) If a patient tests positive for tuberculosis, HIV, viral hepatitis, or a sexually transmitted infection, a NTP shall connect the patient to a heath care provider who can provide treatment for the infection.

(e) The medical director, program physician, or physician extender shall document the date and results of the annual physical examination in the patient's file.

§ 10310. Procedures for Collection of Patient Body Specimens

(a) Each program shall set forth in its protocol a plan for collection of patient body specimens for testing or analysis of samples for illicit drug use that describes the procedures to be used for:

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

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

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

(4) Usage of test or analysis results in patient evaluation and treatment.

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

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

(d) Each program shall describe in its protocol a plan for collection of patient body specimens which incorporates the elements of randomness and surprise.

(e)(1) A program shall perform a random test or analysis for illicit drug use of each patient no fewer than eight times per year, except if a patient experiences extenuating circumstances which the program documents in the patient's record.

(2) A program may perform a test or analysis for illicit drug use at any other time deemed clinically necessary by the medical director, program physician, or physician extender.

(f)(1) A program shall not discharge a patient because the patient declined to take a test for illicit drug use or tests positive for illicit drugs, unless the positive or presumed positive test will negatively impact the patient's treatment with medication for opioid use disorder or the program has documented evidence of increasing clinical risk to the patient's health and safety.

(2) If a patient declines a test for illicit drug use, the program shall obtain the patient's signature on a waiver, or if unable to obtain the patient's signature, document the declination in the patient's record.

(g) The requirement in subsection (e)(1) does not prohibit distribution of legal harm reduction supplies that allow a person to test their personal drug supply for the presence of substances that increase the risk of overdose.

§ 10345. Counseling Services

(a) Upon completion of the initial care plan, the program shall provide the patient with a minimum of 45 minutes of counseling services per calendar month, which shall include harm reduction interventions, psychoeducation, and recovery-oriented counseling.

(b) A counseling session shall qualify for the requirement in subsection (a) 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, on a one-on-one basis with the patient, on issues identified in the patient's care plan. An individual session may include additional individuals whose participation supports the patient's treatment goals.

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

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

(c) The following shall not qualify as a counseling session for the requirement in subsection (a):

(1) Interactions conducted with program staff solely 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) The 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) 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; 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 care plan.

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

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

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

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

(F) Results of screenings and assessments.

(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 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 care plan as specified in Section 10305(h).

(f) A NTP shall not exclude a patient from treatment with medication for opioid use disorder because the patient declined counseling. If a patient declines counseling, the NTP shall obtain the patient's signature on a waiver, or if unable to obtain the patient's signature, document the declination in the patient's record.

(g) A NTP may provide counseling services via telehealth. However, a patient has the right to request and receive in-person counseling.

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

(a) The program physician or physician extender shall administer or supervise the initial dosage of controlled medication for opioid use disorder provided to a patient.

(b) The new patient shall be observed to ingest the initial dose and shall continue to be observed for a period of time prescribed by the medical director, program physician, or physician extender to monitor the patient for signs of sedation, respiratory depression, or other effects of acute intoxication.

(c) If the observation requirement contained in Subsection (b) of this regulation is delegated to a staff member who is authorized by Section 11215 of the Health and Safety Code to administer or dispense medications, that staff member shall notify the medical director, program physician, or physician extender immediately of any adverse effects, and document in the patient's record the length of time the staff member observed the new patient and the outcome of the observation.

(d) The initial dosage shall be sufficient to control symptoms of withdrawal.

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

(f) If a program admits a patient who was receiving controlled medication for opioid use disorder from another program or a registered health care provider with prescriptive authority the previous day, the initial dosage level guideline provided in Section 10355 and the observation requirement contained in Subsections (b) and (c) of this regulation do not apply.

§ 10355. Medication Dosage Levels

(a) Detoxification Dosage Levels.

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

(A) In accordance with the medication's FDA approved product label, subject to deviation therefrom upon documentation of the clinical rationale in the patient's record; and

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

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

(3) The medication tapering rate in detoxification treatment shall be mutually agreed-upon based on shared decision-making with the patient.

(b) Maintenance Dosage Levels.

(1) Each program furnishing maintenance treatment shall set forth in its protocol the program'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.

(D) Includes the patient's report of medication effects and dosage level preference, including the following:

1. Changes in health status that can affect medications;

2. Changes in medications;

3. Pregnancy status; and

4. Concurrent drug or alcohol use.

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

(3) The medical director, program physician, or physician extender shall review the most recent FDA 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, program physician, or physician extender shall document their review of each patient's dosage level at least once every three months.

(c) Dosage Levels Specific to Methadone.

(1) The medical director, program physician, or physician extender shall determine, on an individual patient basis, the initial dose of methadone considering the types of opioids involved in the patient's opioid use disorder, other medications or substances being taken, medical history, and severity of opioid withdrawal, and prescribe an observation period to ensure the initial dose does not exceed a patient's tolerance.

(2) The total dose of methadone for the first day shall not exceed 50 milligrams unless the medical director, program physician, or physician extender finds sufficient rationale for a higher dose and documents in the patient's record that a higher dose was clinically indicated.

(d) 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 FDA 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, program physician, or physician extender, who shall be knowledgeable about the most current and approved product labeling.

(e) Dosage Schedule Following Patient Absence.

When a patient has missed more than four (4) consecutive doses of controlled medication for opioid use disorder, the medical director, program physician, or physician extender shall provide a new medication order before continuation of treatment. The new medication order shall be provided either in person, by verbal order, or through other electronic means, and shall be documented and justified in the patient's record.

(f) Changes in the Dosage Schedule.

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

§ 10360. Additional Requirements for Pregnant Patients

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

(1) Acceptance of medical responsibility for the patient's prenatal and postpartum care, including providing reproductive health services; 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) If a patient declines a pregnancy test, the program shall obtain the patient's signature on a waiver, or if unable to obtain the patient's signature, document the declination in the patient's record.

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

(1) Periodic consultation at least monthly with the medical director, program physician, or physician extender.

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

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

(d) The medical director, program physician, or physician extender 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 medication for opioid use disorder and risks of abrupt withdrawal from opioids, including premature birth.

(3) Importance of attending all prenatal care visits.

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

(5) Signs and symptoms of 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 medication for opioid use disorder.

(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 split-dosing regimens and managing neonatal opioid withdrawal syndrome.

(e) If a patient declines prenatal care offered by the program or by referral, the program shall document the declination in the patient’s record.

(f) Within fourteen (14) calendar days after the date of birth, the program shall document in the patient’s record the following information:

(1) The hospital’s or attending physician’s summary of the delivery and outcome for the patient and newborn child; or

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

(g) Within fourteen (14) calendar days after the date of the birth, the counselor shall update the patient’s care plan in accordance with Section 10305. The nature of postpartum and pediatric care shall be reflected in subsequent updated care plans until the child is at least three (3) years of age.

Article 4. Take-Home Medication

§ 10365. Take-Home Medication Procedures

Each program shall maintain current procedures adequate to identify the theft or diversion of unsupervised or take-home medication for opioid use disorder and ensure compliance with the following procedures when providing take-home methadone or buprenorphine to a patient in maintenance or detoxification treatment:

(a) The medical director, program physician, or physician extender shall determine the quantity of take-home medication dispensed to a patient based on the criteria listed in Section 10370(a). Unsupervised or take-home methadone is subject to the supply limits set forth in Section 10375.

(b) The program shall instruct each patient of their obligation to safely transport and store the take-home medication, including on child and household safety precautions. The provision of this education shall be documented in the patient’s record.

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

(d) The program shall label each take-home medication 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 name of the prescribing medical director or program physician;

(6) The name of the patient;

(7) The date issued; and

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

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

(e) The program shall instruct all patients to keep all take-home medication out of the refrigerator to prevent accidental overdoses by children and fermentation of the liquid.

§ 10370. Criteria for Take-Home Medication

(a) Methadone, buprenorphine, and buprenorphine products shall only be provided to a patient as unsupervised or take-home medication if the medical director, program physician, or physician extender has determined, in their clinical judgment, that the patient is safely able to manage take-home medication for opioid use disorder, and has documented their rationale in the patient's record. The rationale shall be based on consideration of the following criteria, among other pertinent factors indicating the therapeutic benefits of unsupervised medication outweigh the risks.

(1) Absence of active substance use disorders or other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose or the ability to function safely.

(2) Regularity of program attendance for supervised medication administration.

(3) Absence of serious behavioral problems that endanger the patient or the public.

(4) Absence of known recent diversion activity.

(5) Whether the patient can safety transport and store take-home medication.

(6) Any other criteria the medical director, program physician, or physician extender considers relevant to the patient's safety and the public's health.

(b) Unsupervised or take-home methadone is subject to the supply limits set forth in Section 10375.

§ 10375. Take-Home Methadone Supply Limits

(a) If a patient is safely able to manage take-home medication for opioid use disorder as set forth in Section 10370(a), then the supply limits in this section apply to take-home methadone. Each program shall adhere to the following supply limits with respect to providing a patient with take-home methadone:

(1) During the first fourteen (14) days of treatment, the take-home supply shall not exceed seven (7) days.

(2) From fifteen (15) days of treatment, the take-home supply shall not exceed fourteen (14) days.

(3) From 31 days of treatment, the take-home supply shall not exceed 28 days.

(b) The medical director, program physician, or physician extender shall determine the supply of take-home methadone that is provided to a patient, up to the supply limits set forth in subsection (a), based on the criteria listed in Section 10370(a).

(c) If a patient transfers to another program without a break in treatment, the new program may provide the patient with take-home methadone up to the applicable supply limit set forth in subsection (a) based on the number of days the patient was in treatment at the former program.

(d) Methadone that is provided for unsupervised use in accordance with Section 10380 does not count towards the supply limits set forth in subsection (a).

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

(a) A program that is not in operation due to the program's observance of an official State holiday or weekend day 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 days the program is not operating, including one weekend day and official State holidays, no matter their length of time in treatment, may be provided one (1) additional day's supply on the last day of dosing at the program before the closure; and

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

(b)(1) The medical director, program physician, or physician extender shall determine whether a patient is safely able to manage take-home medication for opioid use disorder during holiday or weekend day closures based on the criteria listed in Section 10370(a). A patient shall not receive take-home medication under the provisions of subsection (a) and shall be continued on the same dosage schedule if the medical director, program physician, or physician extender has included the patient within a list of all patients that, in their clinical judgment, have been determined currently not safely able to manage take-home medication, 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 weekend day closure.

(2) If a program has patients who are not approved for take-home medication during holiday or weekend day closures, the program shall maintain limited dispensing hours to provide medication to these patients during the closure or arrange for courtesy dosing at another program.

(c) The official State holidays are:

New Year's Day	January 1
Martin Luther King's Birthday	Third Monday in January
Lincoln's Birthday	February 12
Washington's Birthday	Third Monday in February
Cesar Chavez Day	March 31
Memorial Day	Last Monday in May
Juneteenth	June 19
Independence Day	July 4
Labor Day	First Monday in September
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).

§ 10385. Exceptions to Take-Home Medication Criteria and Take-Home Methadone Supply Limits

(a) A NTP shall submit to the Department in writing a request for an exception to the take-home medication criteria set forth in Section 10370(a) or the take-home methadone supply limits set forth in Section 10375(a). Prior to submitting a request for an exception, the medical director, program physician, or physician extender shall determine the patient is safely able to manage take-home medication for opioid use disorder as specified in Section 10370(a).

(b) A request submitted to the Department for an exception to take-home medication criteria or take-home methadone supply limits 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(g) of Title 42 of the Code of Federal Regulations.

(c) The medical director, program physician, or physician extender shall document in the patient's record any request for an exception, the facts justifying the request, and the approval or denial of the request.

(d) Upon SAMHSA approval, the Department may grant additional exceptions to the take-home medication requirements contained in sections 10370(a) or 10375(a) in the case of an emergency or natural disaster, such as fire, flood, or earthquake.

§ 10386. Split Doses

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

(b) The medical director, program physician, or physician extender 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.

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

(d) The program shall adhere to the take-home methadone supply limits set forth in Section 10375 for patients receiving methadone as take-home medication in a split dose.

(e) 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.

§ 10390. Revoking, Reducing, and Restoring a Patient's Take-Home Medication

(a)(1) The medical director, program physician, or physician extender may revoke, reduce, or restore a patient's take-home medication for opioid use disorder by increasing or decreasing the take-home supply, within the limits for methadone set forth in section 10375(a), as often as is necessary based on the criteria listed in Section 10370(a) and their clinical judgment.

(2) The medical director, program physician, or physician extender shall document in the patient's record the rationale for their decision to revoke, reduce, or restore a patient's take-home supply of medication for opioid use disorder.

(b) In addition to the criteria listed in Section 10370(a), the medical director, program physician, or physician extender may reduce a patient's supply of take-home medication for opioid use disorder for the following reasons.

(1) Patients who have submitted a body specimen that tested positive for illicit drugs and/or negative for the controlled medication for opioid use disorder administered or dispensed by the program, unless the program physician or physician extender invalidates the accuracy of the test results.

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

(c) In addition to the criteria listed in Section 10370(a), the medical director, program physician, or physician extender may revoke a patient's take-home medication for any of the reasons specified in Subsection (b) of this regulation, or for any other clinically appropriate reasons, including but not limited to:

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

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

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

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

(d) As part of its protocol, a program shall maintain a policy and procedure that includes its criteria and process for revoking, reducing, and restoring a patient's take-home medication for opioid use disorder.

§ 10400. Repealed.

§ 10405. Suspension of Take-Home Medication by the Department

The Department may order a program to suspend immediately all or any part of its take-home medication orders, or to revoke, reduce, or restore the take-home medication of any individual patient. Suspension may occur only when a program fails to comply with any applicable regulation or statute regarding treatment requirements, medication handling, security of medications, or take-home medication procedures.

Article 5. Termination of Treatment

§ 10410. Repealed.