INITIAL STATEMENT OF REASONS

INTRODUCTION

The California Department of Health Care Services' (Department) mission is to provide Californians with access to affordable, integrated, high-quality health care, including medical, dental, mental health, substance use treatment services and long-term care. In support of this mission, the Department administers many health care programs including Narcotic Treatment Programs (NTPs).

In California, NTPs, also known federally as Opioid Treatment Programs (OTPs), are licensed by the Department. California's NTPs provide replacement narcotic therapy (RNT) to those persons addicted to opiates. RNT combines behavioral therapy and medications to treat substance use disorders. NTPs also provide detoxification and/or maintenance treatment services, which include medical evaluations and rehabilitative services to help the patient become and/or remain a productive member of society.

Program History

NTPs are outpatient clinics that are permitted to use levoalphacetylmethadol (LAAM), methadone, buprenorphine or buprenorphine combination products, and any other federally controlled substance approved by the United States Food and Drug Administration (FDA) for the purpose of RNT. NTPs have been licensed in California since the early 1980's. In addition to complying with current law as provided in the Health and Safety Code (HSC), NTPs also must adhere to applicable laws in Titles 21 and 42 Code of Federal Regulations (CFR), Title 9 of the California Code of Regulations (CCR), and meet physical security requirements for storage and dispensing of controlled substances as administered by the United States Drug Enforcement Administration (DEA).

NTPs provide RNT in an outpatient, medically supervised setting to persons who are addicted to opioids. Services include, but are not limited to, replacement opioid medication and counseling. The Department has sole authority to license NTPs, which currently includes 161 licensed providers. When an NTP application is received, reviewed, and determined to be complete, an on-site review is conducted by the Department prior to licensure. An NTP applicant must demonstrate a need for NTP services in the county and receive the county Board of Supervisor's support in order to apply for an NTP license. Annual on-site reviews conducted by the Department are required to ensure ongoing compliance with Federal and State laws as well as regulatory requirements.

Related Existing Laws and Regulations

Assembly Bill (AB) 75 (Chapter 22, Statutes of 2013) added Section 11750 to the HSC, which transferred the administration of prevention, treatment, and recovery services for alcohol and drug abuse from the Department of Alcohol and Drug Programs (ADP) to the Department.

HSC Section 11839.2(c), provides for the controlled substances that are authorized for use in RNT by NTPs. Buprenorphine and buprenorphine combination products are approved medications to be used in NTPs for the treatment of opioid use disorder. This regulatory proposal includes amendments to include buprenorphine and buprenorphine combination products for use in RNT.

Senate Bill (SB) 973 (Hernandez, Chapter 484, Statutes of 2014) amended HSC Section 11839.3, to authorize NTPs to admit patients at the discretion of the medical director and requires changing the patient identifier from sequential numbers to unique identifiers. SB 973 also changed take-home medication requirements by allowing retired or disabled patients to be eligible for take-home medication, allowing programs to close on Sundays and provide take-home doses to eligible patients, and allowing the medical director the discretion to dilute take-home doses. Amendments throughout this regulatory proposal are intended to implement SB 973.

HSC Section 11839.3 authorizes the director of the Department to establish and enforce the criteria for the eligibility of patients to be included in the programs; program operation guidelines, such as dosage levels, record keeping and reporting, urinalysis requirements, take-home doses of controlled substances authorized for use pursuant to HSC Section 11839.2, and security against redistribution of narcotic replacement drugs; and any other regulations that are necessary to protect the safety and well-being of the patient, the local community, and the public. Title 42, CFR, Section 8.11, requires the Substance Abuse and Mental Health Services Administration (SAMHSA) to consult with the State authority prior to approving any application for an NTP.

HSC Section 11839.7 authorizes the Department to set a license fee at a level sufficient to cover all departmental costs associated with licensing incurred by the Department. This regulatory proposal includes amendments to NTP application fees and annual licensing fees consistent with HSC Section 11839.7.

Title 9, CCR, Division 4, Chapter 4, Subchapter 1 commencing with Section 10000 are the primary regulations for NTPs. These regulatory provisions address numerous topics including the program licensure, evaluation and administration, medication security and patient treatment. Many of these provisions will be updated and amended through this regulatory proposal. This regulatory proposal includes amendments to bring the regulations into compliance with recently enacted statutes in order to enhance the Department's oversight of the NTPs and improve the health and safety of NTP patients.

Statement of Purpose/Problem to be Addressed

SB 973, effective January 1, 2015, allows an NTP to admit a patient to narcotic maintenance or narcotic detoxification treatment at the discretion of the medical director by removing the requirement that a patient waits seven days in-between treatment episodes, enables patients to qualify for self-administered take-home medication under specified circumstances, requires a medical director to determine whether or not to dilute self-administered take-home medication, and requires a unique patient identifier for record keeping. The purpose of this regulation package is to implement, interpret

and make specific the NTP services defined in HSC, Division 10.5, Chapter 10 and to enact changes from SB 973 to remove barriers to access treatment and prevent unnecessary discomfort for patients in addiction recovery. Other changes are made to expand oversight of NTPs and improve the health and safety of NTP patients.

This regulation proposal addresses changes necessary to streamline the process for licensed patient capacity change requests with the primary focus being access to NTP treatment services. This regulation package amends the antiquated process currently in place for increasing and decreasing the licensed patient capacity of an NTP, including how fees are calculated and collected. When an NTP reaches the licensed patient capacity, the NTP is not able to intake additional patients until an application for a patient capacity increase is approved by the Department. With the streamlined process, the Department anticipates eliminating any unwarranted wait time, which can create barriers in access to necessary services. The changes are also expected to result in a clearly defined process including a shorter wait time for approval or denial of the request.

Currently, 28 out of 58 counties do not provide NTP services. This is a major hurdle to access for the people in need of services in many rural communities. Also, many of the counties with the highest rates of opioid overdose resulting in death do not have access to NTP services. One of the most prominent reasons this lack of access is occurring is the inability to set up a traditional NTP business model in a rural area where there is a relatively small number of patients. An evidence based solution to this problem, included in this regulation proposal, is to create Office-Based Narcotic Treatment Networks (OBNTNs) and to expand the availability of medication units. These OBNTNs and medication units are affiliated and associated with a licensed NTP and provide specified limited services. These smaller, limited facilities will be more feasible for expansion into rural areas; will reduce travel time to NTP services for many existing patients; and will increase access to NTP services in underserved areas.

In 2005, HSC Section 11839.2(c), established buprenorphine and buprenorphine combination products as approved medications to be used in NTPs for the treatment of opioid use disorders. Buprenorphine and buprenorphine combination products are another medication option for medication assisted treatment that is highly effective in treating opioid use disorders. This regulation package will further specify the requirements for NTPs treating patients with buprenorphine and buprenorphine combination products.

Anticipated Benefits of the Regulations

This regulatory proposal supports the intent of the initiating legislation under HSC Sections 11755 and 11839.3, which states that the Department shall establish and enforce any regulations that are necessary to protect the safety and well-being of the patient, the local community, and the public.

The amendments proposed through this regulatory action will promote the safety and well-being of the patient, the local community and the public through eliminating a

medically unnecessary seven-day waiting period between treatment episodes, adding retirement and medical disability to a list of qualifying factors for take-home medication doses, and leaving the decision to dilute take-home medication to the medical director. These amendments will directly benefit NTP patients by making it easier to transition from detoxification treatment to maintenance treatment, and by allowing patients who are retired or disabled to qualify for take-home medications. In addition to meeting the goals of the authorizing statutes, these proposed regulations support the proper and efficient administration of the NTPs (consistent with Chapter 10, Article 1 of the HSC) in accordance with the Federal and State laws that govern the program's rules of participation.

Additionally, this regulatory proposal and its inclusion of OBNTNs and medication units will help expand treatment services in more rural counties throughout California. HSC Section 11839.6 includes provisions for OBNTNs but regulations specifically detailing their approval and operation have yet to be implemented. Financial viability can be a major barrier in establishing and operating a free standing self-contained NTP in areas with small populations and even smaller populations of individuals in need of NTP services. OBNTNs and medication units provide a solution to that problem.

This regulation proposal adopts Sections 10021, 10036, 10037, 10056.5 and 10386, amends 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, and 10425 and repeals Sections 10015 and 10340 of Title 9 of the CCR.

Stakeholder Involvement in Preparation of the Regulations

The Department reviewed the proposed regulations with the Narcotic Treatment Programs Advisory Committee (NTPAC) throughout 2015 and 2016. The NTPAC is comprised of the following organizations:

- Small, Medium and Large Narcotic Treatment Programs
- California Society of Addiction Medicine
- California Alcohol and Drug Program Executives
- California Opioid Maintenance Providers
- California Behavioral Health Directors' Association
- Patient Advisory and Advocacy Group

These organizations are substance use disorder provider associations and county associations that have an interest in the proposed amendments.

Each date and topic that was discussed is listed below:

- March 18, 2015: Draft of entire regulation package was reviewed
- June 17, 2015: Medication Units were discussed with an opportunity for feedback
- September 30, 2015: Allowed time for stakeholder feedback
- January 7, 2016: Overview of regulation package and opportunity to comment

- May 9, 2016: Overview of next steps and opportunity for feedback
- June 1, 2016: Draft of entire regulation package was sent to stakeholders for informal feedback
- June 9, 2016: Conference call with walkthrough of all topics in the regulation package and opportunity to provide feedback
- September 7, 2016: Overview of next steps and opportunity to provide feedback

The Department received stakeholder comments and feedback throughout the process and made adjustments to the proposed amendments as needed.

FORMS

This regulatory action will update and expand definitions and program requirements. To assist the Department in verifying that program requirements are met, applicants/providers are required to complete specified forms to participate and continue to participate as a provider in the NTP. These forms allow the Department to effectively gather comprehensive and accurate information from applicants/providers that wish to participate as an NTP. These forms include criteria related to an applicant's/provider's: qualifications (i.e. licensing/certification), facilities/clinic locations, and services rendered. It is critical that the Department obtain all of this information, including documentation/verification (as applicable), as well as assurances that the applicant/provider is aware of the responsibilities for program participation. This information is necessary so that the Department can determine if an applicant/provider meets the standards to participate as an NTP and while participating that the provider is held to these standards. These forms will help clearly identify the information that shall be reported to the Department and will help streamline and standardize the application for licensure, application for protocol amendment and the annual licensure renewal processes. The following forms are incorporated by reference in this regulatory proposal.

1) Application for License Renewal form DHCS 4029 (04/16)
2) Initial Application Coversheet form DHCS 5014 (04/16)
3) Guarantor Agreement form DHCS 5020 (04/16)
4) Facility and Geographical Area form DHCS 5025 (04/16)
5) Staff Information form DHCS 5026 (04/16)
6) County Certification form DHCS 5027 (04/16)
7) Organizational Responsibility form DHCS 5031 (04/16)
8) Patient Death Report form DHCS 5048 (04/16)
9) Affiliated and Associated Acknowledgment form DHCS 5134 (04/16)
10) Application for Protocol Amendment form DHCS 5135 (04/16)

These forms are incorporated by reference because it would be too cumbersome to publish the forms directly in the CCR. The specific purpose and rationale for necessity of these forms is explained later in the document.

DETAILED STATEMENT OF REASONS: SUMMARY AND RATIONALE

Section 10000

Subsection (a)(2)
A definition for Buprenorphine is adopted to describe the medication approved in October 2002, by the FDA for use in the treatment of opioid use disorders. Pursuant to HSC Section 11839.2, buprenorphine is authorized as an allowable agonist treatment medication for use at an NTP. Buprenorphine is a semisynthetic narcotic analgesic that is derived from thebaine and is administered intravenously or intramuscularly to treat moderate to severe pain and sublingually to treat opioid dependence. Terms used within the definition describe the way the medication is administered; intravenously means into the vein, intramuscularly means into the muscle, and sublingual means under the tongue. Although buprenorphine is understood by the substance use disorder community, it is defined for clarity for the affected public and is consistent with the medical definition found in the Merriam-Webster's Dictionary: http://www.merriam-webster.com/medical/buprenorphine.

Subsection (a)(3)
A definition for Buprenorphine products is adopted to describe the medications approved in October 2002, by the FDA for use in the treatment of opioid use disorders. Buprenorphine products contain Buprenorphine but also contain an additional medication called Naloxone. Buprenorphine is the primary active ingredient and by attaching to the same receptors as other opioids, it can help to suppress withdrawal symptoms and reduce cravings. Naloxone is included to help prevent misuse. When the combination product is taken as directed, the naloxone component has virtually no effect on the patient. However, when the medication is misused and injected, the naloxone component will most likely induce withdrawal for the individual.

Pursuant to HSC Section 11839.2, Buprenorphine products are authorized as allowable agonist treatment medications for use at an NTP. Although the term is understood by the substance use disorder community, it is defined for clarity for the affected public. The definition is based on the description of Buprenorphine as described by SAMHSA at http://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine and is consistent with the definition of Buprenorphine as described above.

Subsection (a)(2) through (24)
Paragraphs 2 through 24 are re-designated as (5) through (34) to accommodate the addition of definitions to this section.

Subsection (a)(4)
A definition for Department is adopted to clearly indicate that any reference to the "Department" means the Department of Health Care Services. This clarification is necessary following the transfer of the administrative and programmatic functions for substance use disorder programs (including licensure of NTPs) from the ADP to the

Department, effective July 1, 2013, pursuant to HSC Section 11750. As a result, all references to ADP in the regulations are changed to refer to the Department.

Subsection (a)(5)
The definition for detoxification treatment is amended to replace the term opiate with opioid for reasons as discussed under subsection (a)(22).

Subsection (a)(6)
A definition for DEA is adopted to provide the meaning for this acronym. DEA is the United States Drug Enforcement Administration. This is necessary since this organization is referenced within the medication unit provisions using this acronym because a medication unit must be registered with the DEA in order to operate in California. Although the acronym is understood by the substance use disorder community, it is defined for clarity for the affected public.

Subsection (a)(9)
The definition of laboratory is amended to reference the California Department of Public Health (CDPH) as the State department with the statutory authority to license these laboratories. This change is necessary as result of SB 162 (Ortiz, Chapter 241, Statutes 2006), which amended HSC Section 20 and authorized the creation of CDPH and transitioned Public Health program authority from the former Department of Health Services to CDPH.

Subsection (a)(11)
A definition for license is adopted to distinguish a provider's ability to obtain licensure of an NTP in contrast to departmental approval to operate a medication unit and/or office-based narcotic treatment network, which are components of the license. A license is the document issued by the Department authorizing an NTP to operate in California. This distinction is necessary since a medication unit and/or office-based narcotic treatment network are not separately licensed and instead operate under a primary NTP license.

Subsection (a)(12)
The definition of licensing action was formerly located in Section 10057, Administrative Review of Licensing Actions, and is relocated to this subsection to provide all definitions in one central location for convenience. The phrase "but not limited to" is excluded from the definition because it is not necessary. The definition is further modified to expand the scope of adverse licensing action to include, denial of a protocol amendment, denial of a supplemental written protocol for a medication unit, denial of a supplemental written protocol for an OBNTN, and denial of a request to relocate outside of the current county. These additions are necessary to cover all types of administrative actions and to ensure that providers receive due process in the event of an adverse action.

Subsection (a)(13)
The definition for maintenance treatment is amended to replace the term opiate with opioid for reasons as discussed in subsection (a)(22).

Subsection (a)(15)
The definition for medication is amended to replace the term opiate with opioid for reasons as discussed in subsection (a)(22).

Subsection (a)(15)(C)
The definition of medication is amended to include Buprenorphine and Buprenorphine products. This is necessary to be consistent with the description of the medications found in HSC Section 11839.2(c), and to include all controlled substances approved by the FDA for use in replacement narcotic therapy.

Subsection (a)(16)
The definition of medication unit is amended to clarify its relationship as part of an NTP that is located at a separate location from the NTP. This is necessary to align with the federal definition of medication unit as provided in 42 CFR Section 8.2.

Subsection (a)(19)
The definition of NTP is amended to clarify the types of treatment services required to be provided at an NTP. The term “licensed” is included to clearly demonstrate that NTPs have received departmental approval to operate. The term “opiate” is amended to “opioid” and the term “modality” is amended to “program” to update to more currently used terminology in the substance use disorder community. Additionally, these amendments ensure consistency of terminology referencing evaluation, maintenance treatment and detoxification treatment as used throughout the regulation text. The phrase “all of the following” is added to clarify that the services listed are required elements of an NTP. The terms “evaluation,” “treatment and/or,” and “treatment” are added to be consistent with the definition of treatment, and the services that are required to be conducted at an NTP. The term “or” is amended to “and” because other services in conjunction with replacement narcotic therapy are required to be provided at NTPs. The word “that” is removed to use correct grammar. The acronym NTP is also added since it is commonly used within the substance use disorder community and is used frequently throughout the regulation text. These changes are necessary in order to differentiate between an NTP, medication unit and OBNTN.

Subsection (a)(20)
A definition for office-based narcotic treatment network (OBNTN) is adopted to describe an office-based program that is affiliated and associated with a primary NTP. This definition is necessary to implement HSC Section 11839.6, which authorizes the Department to establish a program for the provision of office-based narcotic treatment services. The phrase “affiliated and associated” as described in reference to the network providers is consistent with HSC Section 11839.6(a)(2). The treatment services to be provided at an OBNTN mirror the services included in the definition of “treatment” (under Section 10000(a)(34)) excluding “replacement narcotic therapy” and “monitoring for illicit drug use.” These two services are instead provided at a medication unit in accordance with 42 CFR Section 8.2, which clearly defines a medication unit as the facility where an opioid agonist treatment medication is dispensed or administered

or samples are collected for drug testing or analysis. This distinction is necessary to avoid an overlap of services being provided at a medication unit and OBNTN and distinguishes the programs for purposes of departmental approval.

Subsection (a)(21)
The term “Opiate” was added for formatting consistency. The definition of opiate is amended to include only the natural forms of the alkaloids derived from the opium poppy. This is necessary to be consistent with the American Society of Addiction Medicine, National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use, May 27, 2015, page 33.

Subsection (a)(22)
A definition for opioid is adopted to replace the antiquated term opiate, which is no longer commonly used in the substance use disorder community. The term opioid is more inclusive than the term opiate, which does not include synthetic opiates. This is necessary to be consistent with the American Society of Addiction Medicine, National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use, May 27, 2015, page 33. Throughout this proposal, the term opiate is replaced with opioid to update the regulations to the current terminology used within the substance use disorder community.

Subsection (a)(23)
The definition for opiate addiction is amended to replace the term opiate with opioid for reasons as discussed in subsection (a)(22).

Subsection (a)(26)
A definition for primary Narcotic Treatment Program is adopted to describe a licensed NTP that has affiliated and associated medication unit(s) and/or OBNTN(s). This is necessary to implement HSC Section 11839.6, which authorizes the Department to establish a program for the provision of office-based narcotic treatment services that is affiliated and associated with a primary NTP.

Subsection (a)(27)
The definition for program is amended to remove the phrase, “unless otherwise specified.” This is necessary for added clarity and removal of the phrase clearly establishes that a program means an NTP when used throughout the regulations.

Subsection (a)(29)
The definition of program sponsor is amended to describe the entity accepting responsibility for the operation of the NTP and who is identified in the application for licensure on the Initial Application Coversheet form DHCS 5014 (04/16.) The form is incorporated by reference and is described in detail in the Forms Section below. This is necessary to align with the federal definition of program sponsor as provided in 42 CFR Section 8.2. The change creates consistency between who the Department identifies as responsible for the NTP and who SAMHSA would identify in the same role. This

definition also solidifies who is authorized to sign various Department forms when applying for initial licensure, licensure renewal or protocol amendments

Subsection (a)(30)
The definition of protocol is amended to add the phrase “including required forms” and remove the phrase “in the form required by the Department.” This is necessary to clarify that multiple forms are required as a part of the protocol.

Subsection (a)(32)
The definition of replacement narcotic therapy is amended to incorporate terms of art including “medication assisted treatment,” which is used in the substance use disorder community when referring to the treatment of opioid use disorders with medication. The new language also clarifies that medication assisted treatment includes both agonist and partial agonist medication. This definition includes language from the Substance Abuse and Mental Health Services Administration (SAMHSA) (http://www.samhsa.gov/medication-assisted-treatment). This is necessary to update to the current terminology regarding medication assisted treatment.

Subsection (a)(33)
A definition for SAMHSA is adopted to provide the meaning for this acronym. SAMHSA is the Substance Abuse and Mental Health Services Administration of the federal government. This is necessary since this organization is referenced within these regulations using this acronym. Although the acronym is understood by the substance use disorder community, it is defined for clarity for the affected public.

Subsection (a)(34)
The definition for treatment is amended to replace the term opiate with opioid for reasons as discussed under subsection (a)(22).

Section 10010
This section is amended to reference the Department of Health Care Services as the State department with statutory authority to license NTPs in California. This is necessary to be consistent with HSC Section 11750, which transferred the administrative and programmatic functions of the former ADP to the Department, effective July 1, 2013.

Section 10015
This section is repealed to remove requirements that are in conflict with the newly proposed regulatory provisions. The current provision requires licensure of separate facilities that are under a centralized organizational structure consisting of a primary program facility and other program facilities. However, the Department has the authority to establish an office-based narcotic treatment program (HSC Section 11839.6) and/or a medication unit (42 CFR Section 8) that do not require separate licensure from its primary NTP. This repeal is necessary for consistency.

Section 10020

The title of this section is amended to remove the phrase “licensure of” because medication units are not independently licensed by the Department.

Subsection (a) is amended to include minor structural changes to provide a better lead-in to paragraphs (1)-(3). The Department requires the information set forth in subsection (a)(1)-(3) for purposes of review and approval to operate a medication unit in California. Paragraph (1) is necessary to clearly indicate that the provider is capable of offering necessary and appropriate medication unit services. Paragraph (2) is necessary to be in compliance with the federal requirement that SAMHSA approval has been obtained pursuant to 42 CFR Section 8.11. This notification and approval is explained in further detail in the Federal Guidelines for Opioid Treatment Programs. Paragraph (3) is necessary to be in compliance with the federal requirement that DEA registration has been obtained pursuant to 21 CFR Chapter II. In addition, the remaining phrase “in California for patients in maintenance treatment…” is removed because it is no longer necessary. Specifically, FDA approval is not a requirement for medication unit operation and as discussed above the Department does not separately license medication units.

The existing content of subsection (b) is either removed or relocated. The language under former subsection (b) is now specified in subsection (a)(1) related to the supplemental written protocol. The content of former paragraph (1) is removed to reduce barriers to establishing medication units thereby allowing greater patient access to services. The content of former paragraph (2) is re-designated to subsection (m) with further amendments as described in subsection (m) below. The content of former paragraph (3) is re-designated to subsection (b)(9) with further amendments as described in subsection (b)(9) below. Former paragraph (4) is re-designated and reworded in subsection (h) to tie the patient enrollment to the maximum licensed patient capacity of the primary NTP. See subsection (h) for further information. Paragraph (5) is removed because no federal limit exists on the licensed patient capacity for a medication unit and the removal of this limitation will also allow for greater access to treatment of patients.

The content of subsection (b) is proposed to include the requirements for a primary NTP to request Department approval to add a medication unit to its existing license. This subsection clearly specifies that the primary NTP must submit both the Initial Application Coversheet form DHCS 5014 (04/16) and the supplemental written protocol. The Initial Application Coversheet form DHCS 5014 (04/16) is necessary for the Department to distinguish between the different types of applications received from NTP providers. The requirements for the supplemental written protocol are discussed below.

Subsection (b)(1)-(10) lists all of the documents and forms that must be included as part of the supplemental written protocol for a medication unit.

Paragraph (1) requires a description of the geographical area to be served by the medication unit to ensure the medication unit is in an appropriate location that has a need for services and allows for reasonable access to the primary NTP. This information is required as part of the Facility and Geographical Area form DHCS 5025

(04/16), which is incorporated by reference and is described in detail in the Forms Section below.

Paragraph (2) requires information on the population to be served. The Department requires this information to clearly establish where services are needed and the populations that need access to the services.

Paragraph (3) requires each staff member's resume to verify the qualifications and credentials of administrative, medical and counseling staff. The Staff Information form DHCS 5026 (04/16) is incorporated by reference and is described in detail in the Forms Section below. The Department utilizes the form to verify appropriate staffing levels for hours of operation and that there is adequate staff to meet the patient service needs.

Paragraph (4) requires the medication unit's physical address including information regarding its proximity to the primary NTP. This is necessary for the Department to assess how far the medication unit is from the primary NTP to ensure that patients have access to the services provided at the primary NTP.

Paragraphs (5)-(6) require the medication unit's hours of operation. This information is necessary so the Department knows when patients can receive medication dispensing and urinalyses services at the medication unit. The Department also uses the information to ensure hours of operation are adequate to service the licensed patient capacity. For monitoring purposes, the Department will verify the stated days and hours of operation.

Paragraph (7) requires information regarding other businesses that are at the medication unit facility location. This is necessary for the Department to ensure that there are no security or patient privacy concerns, and to understand all activities being provided at that location.

Paragraph (8) requires a facility description including a diagram with dimensions and narrative of patient flow explaining how a medication unit plans to move a patient securely through the facility as the patient receives treatment. This is necessary to ensure the health, safety and confidentiality of patients and staff.

Paragraph (9) is a re-designation of former subsection (b)(3) and is updated to refer to a primary NTP. A primary NTP is distinguishable from an NTP because it has affiliated and associated facilities. This paragraph is also updated to require the approximate number of patients to be served at the medication unit. The Department will review this information to determine if the facility staff and physical characteristics of the building are reasonable for the number of patients to be served, which is necessary to support the health and safety of the patients. This requirement is also necessary so the Department can monitor the coordination and provision of services that are needed by patients.

Paragraph (10) requires a medication unit to have written policies and procedures in place addressing the health and safety of patients and staff in the event of an emergency or disaster. This is necessary to ensure that the medication unit is prepared to deal with these types of unexpected situations.

Subsection (c) is necessary to verify the relationship required between the primary NTP and the medication unit. The Affiliated and Associated Acknowledgment form DHCS 5134 (04/16), is incorporated by reference and is described in detail in the Forms Section below. This form will be utilized by the Department to ensure an agreement exists between the primary NTP and the medication unit, as well as account for the services being provided by the medication unit.

Subsection (d) is necessary to establish a process by which the Department will review the initial submission of the documentation for approval of a medication unit, which includes: an Initial Application Coversheet form DHCS 5014 (04/16), supplemental written protocol, and the Affiliated and Associated Acknowledgment form DHCS 5134 (04/16). Based on the amount of documentation that comprises a supplemental written protocol, 60 days is a reasonable review timeframe for the Department to determine if the submission is complete. The 60-day timeframe is also consistent with the review timeframe to determine if an application is complete for the approval of an OBNTN, licensure of an NTP and approval for the relocation outside of the current county.

Subsection (d)(1) requires the Department to provide the applicant notice that their application is complete and under further review. This notice is for the convenience of the applicant and is necessary to provide the applicant with a status of the application. A reference to the documents required in Section 10020 (b) and (c) is included to clarify that these documents are necessary to be considered a complete application.

Subsection (d)(2) requires the Department to provide the applicant notice that the submitted documents are incomplete specifying the additional information needed. This notice is for the convenience of the applicant and is necessary to support a timely and accurate submission of the missing information. The Department believes that 60 days is an adequate timeframe for the applicant to obtain the required documentation and respond. This 60-day window provides the applicant time to obtain additional information from external stakeholders such as the County Board of Supervisors or fire marshal. The Department has experienced applicants who submit incomplete applications that remain pending indefinitely. Therefore, the Department will terminate the application review (for incompleteness) if the applicant has not responded to the Department with the requested information within the 60-day timeframe. This process allows the Department to definitively close out the review process for incomplete applications. An incomplete application will be returned to the applicant for their records and convenience. The applicant is also notified of the option to reapply in the future. This is necessary to inform the applicant that the termination of the application review process due to an incomplete application is not an adverse action and does not preclude the applicant from applying again.

Subsection (e) is necessary to inform the applicant that the Department will conduct a physical inspection of the medication unit for purposes of verifying the information stated in the application prior to departmental approval. Site visits prior to approval are necessary to ensure the proposed site is suitable to provide services and for the health and safety of patients.

Subsection (f) is necessary to notify the applicant of the Department's decision to either approve or deny the complete application. This provision also establishes the timeframe within which the Department must render a decision. The Department believes 60 days is necessary and adequate to complete the site visit process and review the completed application.

Subsection (g) is necessary to ensure that patients receive continued services in the event that a medication unit closes. This provision also assigns responsibility to the primary NTP for the continuation of services to the patients. Prior notice of closure is also necessary in order for the Department to update the primary NTP license. The timeframe of 30 days has been determined by the Department to be adequate for this notification purpose.

Subsection (h) ensures that the Department retains authority as prescribed in HSC Section 11839.3(d) for establishing the licensed patient capacity of any license. Because a medication unit is not independently licensed, the maximum capacity must be incorporated into the licensed patient capacity authorized by the Department for the primary NTP. This is necessary to promote the provision of appropriate services.

Subsection (i) satisfies the Department's obligation under HSC Section 11839.3(a)(2) to inspect NTPs in the state and ensure that programs are operating in accordance with the applicable laws and regulations. Pursuant to HSC Section 11839.3(a)(2) the Department has the sole responsibility for compliance inspections of all programs in every county.

Subsection (j) establishes the responsibility of the primary NTP as being the license holder and therefore ultimately responsible for submission and implementation of corrective action plans. Given that the primary NTP is the license holder, any administrative action taken by the Department, for violation of a regulation or statute by an affiliated and associated medication unit, shall be against the primary NTP. The cross references to Section 10057, these regulations and the HSC are included for the convenience of the reader.

Subsection (k) is necessary to inform the public and patients of the Department's approval to operate the medication unit and the name and address of the primary NTP for contact and verification purposes.

Subsection (l) is consistent with the statutory provision in HSC Section 11839.11 related to the automatic termination of an NTP license upon withdrawal or revocation of SAMHSA or DEA approval. Medication units cannot lawfully operate under federal law

without SAMHSA approval per 42 CFR Section 8.11 and DEA registration per 21 CFR Chapter II.

Subsection (m) is re-designated from Section 10020(b)(2). The term “or” was added to align with the federal definition of a medication unit as stated in 42 CFR Section 8.2. The services provided at a medication unit are limited to dispensing or administering an opioid agonist treatment medication or collecting samples for drug testing or analysis. This provision clarifies that all remaining necessary treatment services must be provided by the primary NTP to ensure patients access to necessary services.

Section 10021

Pursuant to HSC Section 11839.6 the Department is authorized to establish a program for office-based narcotic treatment services. This section is necessary to outline the Department’s requirements for a newly established OBNTN.

The Department requires the information set forth in subsection (a)(1)-(2) for purposes of review and approval to operate an OBNTN in California. Paragraph (1) is necessary to clearly indicate that the provider is capable of offering necessary and appropriate OBNTN services. Paragraph (2) is necessary to notify the primary NTP that SAMHSA requirements may be applicable for approval of an OBNTN per 42 CFR Section 8.12(f)(1).

The content of subsection (b) is proposed to include the requirements for a primary NTP to request Department approval to add an OBNTN to its existing license. This subsection clearly specifies that the primary NTP must submit both the Initial Application Coversheet form DHCS 5014 (04/16) and the supplemental written protocol. The Initial Application Coversheet form DHCS 5014 (04/16) is necessary for the Department to distinguish between the different types of applications received from NTP providers. The requirements for the supplemental written protocol are discussed below.

Subsection (b)(1)-(9) lists all the documents and forms that must be included as part of the supplemental written protocol for an OBNTN.

Paragraph (1) requires a description of the geographical area to be served by the OBNTN to ensure the OBNTN is in an appropriate location that has a need for services and allows for reasonable access to the primary NTP. This information is required as part of the Facility and Geographical Area form DHCS 5025 (04/16), which is described in detail in the Forms Section below.

Paragraph (2) requires information on the population to be served. The Department requires this information to clearly establish where access to services are needed and the populations that need access to the services.

Paragraph (3) requires each staff member’s resume to verify the qualifications and credentials of administrative, medical and counseling staff. The Staff Information form DHCS 5026 (04/16) is described in detail in the Forms Section below. The Department

utilizes the form to verify appropriate staffing levels for hours of operation and that there is adequate staff to meet the patient service needs.

Paragraph (4) requires the OBNTN's physical address including information regarding its proximity to the primary NTP. This is necessary for the Department to assess how far the OBNTN is from the primary NTP to ensure that patients have access to the services provided at the primary NTP.

Paragraph (5) requires the OBNTN's hours of operation. This is necessary so the Department knows when patients can access care at the facility. The Department also uses the information to ensure hours of operation are adequate to service the patient capacity. For monitoring purposes, the Department will verify the stated days and hours of operation.

Paragraph (6) requires information regarding other businesses that are at the OBNTN facility location. This is necessary for the Department to ensure that there are no security or patient privacy concerns, and to understand all activities being provided at that location.

Paragraph (7) requires a facility description including a diagram with dimensions and narrative of patient flow explaining how an OBNTN plans to move a patient securely through the facility as the patient receives treatment. This is necessary to ensure the health, safety and confidentiality of patients and staff.

Paragraph (8) is necessary in order to require the approximate number of patients to be served at the OBNTN and a description of how a patient of an OBNTN will participate in regular treatment provided by the primary NTP. The Department will review this information to determine if the facility staff and physical characteristics of the building are reasonable for the number of patients to be served, which is necessary to support the health and safety of the patients. This requirement is also necessary so the Department can monitor the coordination and provision of services that are needed by patients.

Paragraph (9) requires an OBNTN to have written policies and procedures in place addressing the health and safety of patients and staff in the event of an emergency or disaster. This is necessary to ensure that the OBNTN is prepared to deal with these types of unexpected situations.

Subsection (c) is necessary to verify the relationship required between the primary NTP and the OBNTN. The Affiliated and Associated Acknowledgment form DHCS 5134 (04/16), will be utilized by the Department to ensure an agreement exists between the primary NTP and the OBNTN, as well as account for the services being provided by the OBNTN.

Subsection (d) is necessary to establish a process by which the Department will review the initial submission of documentation for approval of an OBNTN, which includes: an

Initial Application Coversheet form DHCS 5014 (04/16), supplemental written protocol and the Affiliated and Associated Acknowledgment form DHCS 5134 (04/16). Based on the amount of documentation that comprises a supplemental written protocol, 60 days is a reasonable review timeframe for the Department to determine if the submission is complete. The 60-day timeframe is also consistent with the review timeframe to determine if an application is complete for the approval of a medication unit, licensure of an NTP and approval for the relocation outside of the current county.

Subsection (d)(1) requires the Department to provide the applicant notice that their application is complete and under further review. This notice is for the convenience of the applicant and is necessary to provide the applicant with a status of the application. A reference to the documents required in Section 10021 (b) and (c) is included to clarify that these documents are necessary to be considered a complete application.

Subsection (d)(2) requires the Department to provide the applicant notice that the submitted documents are incomplete specifying the additional information needed. This notice is for the convenience of the applicant and is necessary to support a timely and accurate submission of the missing information. The Department believes that 60 days is an adequate timeframe for the applicant to obtain the required documentation and respond. This 60-day window provides the applicant time to obtain additional information from external stakeholders such as the County Board of Supervisors or fire marshal. The Department has experienced applicants who submit incomplete applications that remain pending indefinitely. Therefore, the Department will terminate application review (for incompleteness) if the applicant has not responded to the Department with the requested information within the 60-day timeframe. This process allows the Department to definitively close out the review process for incomplete applications. An incomplete application will be returned to the applicant for their records and convenience. The applicant is also notified of the option to reapply in the future. This is necessary to inform the applicant that the termination of the application review process due to an incomplete application is not an adverse action and does not preclude the applicant from applying again.

Subsection (e) is necessary to inform the applicant that the Department will conduct a physical inspection of the OBNTN for purposes of verifying the information stated in the application prior to departmental approval. Site visits prior to approval are necessary to ensure the proposed site is suitable to provide services and for the health and safety of patients.

Subsection (f) is necessary to notify the applicant of the Department’s decision to either approve or deny a complete application. This provision also establishes the timeframe within which the Department must render a decision. The Department believes 60 days is necessary and adequate to complete the site visit process and review the completed application.

Subsection (g) is necessary to ensure that patients receive continued services in the event that an OBNTN discontinues services. This provision also assigns responsibility

to the primary NTP for the continuation of services to the patients. Prior notice of closure is also necessary in order for the Department to update the primary NTP license. The timeframe of 30 days has been determined by the Department to be adequate for this notification purpose.

Subsection (h) ensures that the Department retains authority as prescribed in HSC Section 11839.3(d) for establishing the licensed patient capacity of any license. Because an OBNTN is not independently licensed, the maximum capacity must be incorporated into the licensed patient capacity authorized by the Department for the primary NTP. This is necessary to promote the provision of appropriate services.

Subsection (i) satisfies the Department's obligation under HSC Section 11839.3(a)(2) to inspect narcotic treatment programs in the state and ensure that programs are operating in accordance with the applicable laws and regulations. Pursuant to HSC Section 11839.3(a)(2) the Department has the sole responsibility for compliance inspections of all programs in every county.

Subsection (j) establishes the responsibility of the primary NTP as being the license holder and therefore ultimately responsible for submission and implementation of corrective action plans. Given that the primary NTP is the license holder, any administrative action taken by the Department for violation of regulation or statute by an affiliated and associated OBNTN shall be against the primary NTP. The cross references to Section 10057, these regulations and the HSC are included for the convenience of reader.

Subsection (k) is necessary to inform the public and patients of the Department's approval to operate the OBNTN and the name and address of the primary NTP for contact and verification purposes.

Subsection (l) is necessary because OBNTN services are limited and do not include replacement narcotic therapy or monitoring for illicit drug use. This provision is necessary to clarify that it is the primary NTP's responsibility to ensure patient access to all necessary services.

Section 10025

Administrative and programmatic functions for substance use disorder programs were transferred from the ADP to the Department, effective July 1, 2013, per HSC, Section 11750. This section is amended to clarify for the affected public where to obtain and submit NTP forms. The mailing address for ADP is being removed from regulation, because it no longer exists. Forms may be obtained from and protocols and other forms shall be submitted to the Department's address as specified on each form.

Section 10030

The Initial Application Coversheet form DHCS 5014 (04/16) is added to subsection (a) to specify the form that must be submitted with a written protocol. The necessity for the provisions on this form are described in detail in the Forms Section below. This form is

considered part of the application for licensure. The phrase “but not be shall not be limited to,” is being removed from subsection (a) for clarity as all required elements are specified in this section. The phrase “and designated forms” is included as a lead in to paragraphs (1)-(43), which includes references to required forms.

Subsections (a)(2)-(6), (27), (37)-(42) establish a reference to the Facility and Geographical Area form DHCS 5025 (04/16) to clarify for the applicant where this information shall be included and which form is to be submitted.

Subsection (a)(2) adds the term “surrounding” to clarify the geographical area that needs to be described and for consistency with required information for medication units and OBNTNs.

Subsection (a)(4) and (5) replace the term “opiates” with “opioids” for reasons as discussed in Section 10000(a)(22).

Subsection (a)(10) adds the phrase “Alcohol and” to be consistent with the use of this phrase as used in HSC Section 11800 et seq. and within these regulations. This subsection also establishes a reference to the County Certification form DHCS 5027 (04/16) to clarify for the applicant where this information shall be included and which form is to be submitted. The certification is required as part of the County Certification form DHCS 5027 (04/16), which is incorporated by reference and is described in detail in the Forms Section below.

Subsection (a)(15) establishes a reference to the Organizational Responsibility form DHCS 5031 (04/16) to clarify for the applicant where this information shall be included and which form is to be submitted. The Organizational Responsibility form DHCS 5031 (04/16) is incorporated by reference and is described in detail in the Forms Section below.

Subsection (a)(16) removes the phrase “Persons responsible for program” and replaces it with “Program sponsor” because the program sponsor is a defined term in the regulations referring to the person responsible for the program. This amendment adds clarity and is necessary for consistent use of terms.

Subsection (a)(20) removes the phrase “profile and” to clarify that applicant’s need only submit a resume, which is a commonly understood term. The phrase “of educational and professional experience” is removed because it is redundant and it is generally understood that a resume contains this information. This provision also requires a completed Staff Information form DHCS 5026 (04/16), which identifies each staff member of the facility. The necessity for the provisions on this form are described in detail in the Forms Section below.

Subsection (a)(32) is amended to read “The written policies and procedures to be followed in the event of an emergency or disaster.” This amendment is necessary to

clarify that the policies and procedures shall be in writing and to be consistent with the parallel requirements under Section 10020(b)(10) and Section 10021(b)(9).

Subsection (a)(43) establishes a reference to the Guarantor Agreement form DHCS 5020 (04/16) to clarify for the applicant where this information shall be included and which form is to be submitted. The Guarantor Agreement form DHCS 5020 (04/16) is incorporated by reference and is described in detail in the Forms Section below.

Subsection (b) is no longer necessary because proposed regulatory text establishes a process whereby the Department reviews applications for approval of medication units and OBNTNs. Any services contemplated under the former subsection (b) that would not be rendered at the primary NTP would be provided at a medication unit or OBNTN. Additionally, the requirement for letters regarding financial support is already currently addressed in paragraph (17) and is therefore redundant.

Subsection (c) is no longer necessary because subsection (a) requires a new program to submit a protocol to the Department. Additionally, a complete revision of a protocol is currently addressed in Section 10035 Protocol Amendments and Changes.

Subsection (d) is re-designated to (b) due to the removal of subsections (b) and (c).

Section 10035

Subsection (a) adds the phrase “and supplemental written protocol” to ensure that the Department receives requests for supplemental protocol amendments for medication units and OBNTNs, in addition to requests for protocol amendments for NTPs.

Non-substantive amendments including adding the phrases “A program” and “these changes,” are necessary to clarify that a program shall request prior approval of the Department for any changes to the protocol or supplemental written protocol as set forth in subsection (a)(1)-(6). Prior departmental approval allows the Department to assess if the changes are necessary and appropriate to support patient services.

Subsection (a) also establishes a reference to the Application for Protocol Amendment form DHCS 5135 (04/16), to clarify for the applicant where this information shall be included and which form is to be submitted. The Application for Protocol Amendment form DHCS 5135 (04/16) is herein incorporated by reference and is described in detail in the Forms Section below.

Subsection (a)(1) removes the phrase “change of location” and replaces it with the term “relocation” for purposes of clarity. The phrase “within the county indicated on its license” is added to clarify the type of relocation and differentiate it from relocation outside of the current county. (New Section 10037 Relocation Outside of Current County specifies a separate application process if relocating to a county different than the county indicated on the license.) Also the phrase “or of any portion of the program…” is removed and clarifying language regarding changes to the physical facility structure is now in subsection (a)(6).

Subsection (a)(2) removes the phrase “number of authorized patients or facilities” and replaces it with “licensed patient capacity”. This phrase adds clarity and consistency with the use of this phrase throughout the regulations.

Subsection (a)(3) adds the word “addition,” in order to require prior approval to add new treatment services to a program and not just when services are reduced or terminated. With the OBNTNs and medication units there is potential for services to be added that were not included in the initial application. The Department must approve these additions prior to services commencing to ensure the safety of patients receiving the new services.

Subsection (a)(5) is added to ensure that the Department receives notification of any changes to individuals who have administrative influence or financial interest in an NTP. The Department needs this information to be able to assess any potential conflicts or other issues. This language is consistent with the list of individuals whose criminal history is subject to review by the Department pursuant to HSC Sections 11839.8 and 11839.9.

Subsection (a)(6) is added to ensure that the Department receives notification and grants approval prior to any change in the physical structure or floor plan of an NTP, medication unit and OBNTN. The phrase “physical structure” is clarified to include expansions or modifications to dispensing stations. It is necessary for the Department to review and ensure that the physical structure maintains security requirements as set forth in 21 CFR Chapter II. This provision also maintains an environment that continues to ensure patient health and safety as well as confidentiality.

Subsection (b) removes the word “significant” because it is an ambiguous term, removes the phrase “in writing” and adds the phrase “and supplemental written protocol” and a reference to the Application for Protocol Amendment form DHCS 5135 (04/16) to be consistent with the language in subsection (a). This is necessary to clarify that a Primary NTP shall report all other changes including those regarding a supplemental written protocol using this form, within 30 days of the change. This ensures that the Department maintains a current, up-to-date protocol and supplemental written protocol on all NTPs, medication units, and OBNTNs.

Subsection (c) changes the word “each” to “every” and adds the phrase “described in subsection (a) and change in protocol described in subsection (b)” to clarify that every amendment identified in subsection (a) and (b) must be submitted with the information described in subsection (c). This information submitted with each proposed amendment will provide the Department with the ability to make appropriate decisions regarding the approval or denial of a protocol amendment. The phrase “of the proposed amendment or” is removed because it is not needed and is redundant because the term “amendment” is used earlier in the sentence. Subsection (c) removes the term “significant” throughout, to remove ambiguous terminology. The Department is required to maintain an up-to-date protocol for each NTP and only requiring “significant” changes

to be reported puts the Department at risk of having an out-of-date protocol on file. NTP's could interpret the term significant incorrectly and not report a change to their protocol that would affect the health and safety of the patients or the public. The word "requested" is added to clarify that the effective date of the amendment submitted on the Application Protocol Amendment form DHCS 5135 may or may not be approved based on the Department's review of the application. The last sentence adds the word "Approved" to further clarify that these amendments and changes to the program must undergo departmental review. The term "protocol" is added to clarify that the referred change is a protocol change.

Subsection (d) is removed because the only "multiple locations for administering medications" would be medication units and the requirements for medication units are all described in the revised language included in Section 10020. This language is no longer applicable so it is repealed.

Subsection (e) is re-designated to (d) due to the removal of existing subsection (d).

Section 10036

This section is necessary to clearly describe the review and approval process for protocol amendments and changes as identified in Section 10035.

Subsections (a) and (b) are necessary to establish a process by which the Department will review the submission of the Application for Protocol Amendment form DHCS 5135 (04/16) pursuant to Section 10035(a). The 30-day timeframe is necessary so the Department can accurately review the documentation submitted and determine if the application for a protocol amendment is complete. This timeframe is less than the review timeframe to determine if an initial application for licensure is complete because less documentation is required with a protocol amendment.

Subsection (a)(1) requires the Department to provide the applicant notice that their application is complete and under further review. This notice is for the convenience of the applicant and is necessary to provide the applicant with a status of the application.

Subsection (a)(2) requires the Department to provide the applicant notice that the submitted documents are incomplete specifying the additional information needed. This notice is for the convenience of the applicant and is necessary to support a timely and accurate submission of the missing information. The Department believes that 30 days is an adequate timeframe for the applicant to obtain the required documentation and respond. This 30-day window provides the applicant time to obtain additional information from external stakeholders such as the County Board of Supervisors or fire marshal. This timeframe is less than the applicant response timeframe for an initial application for licensure because less documentation is typically required with a protocol amendment. The Department has experienced applicants who submit incomplete applications that remain pending indefinitely. Therefore, the Department will terminate the review of an application (for incompleteness) if the applicant has not responded to the Department with the requested information within the 30-day timeframe. This

process allows the Department to definitively close out the review process for an incomplete application. An incomplete application will be returned to the applicant for their records and convenience. The applicant is also notified of the option to reapply in the future. This is necessary to inform the applicant that the termination of the application review process due to an incomplete application is not an adverse action and does not preclude the applicant from applying again.

Subsection (b) is necessary to notify the applicant of the Department's decision to either approve or deny a complete application. This provision also established the timeframe within which the Department must render a decision. The Department believes 30 days is necessary and adequate to complete a review of an application for protocol amendment. This timeframe is less than the review timeframe for an initial application for licensure because less documentation is required with a protocol amendment.

Section 10037

This section is added to differentiate relocation within the county identified on the NTP license with relocation outside of the current county identified on the NTP license. When relocating outside of the county, the NTP will be working with a new County Board of Supervisors, new geographical area, and a new patient population will be served. These extensive changes to a program's protocol are too substantial to be included in a protocol amendment and will therefore require a complete protocol to be submitted.

Subsection (a) prohibits a program from relocating outside of the county indicated on its license, except as specified in this Section. This is necessary to clarify that a relocation outside of its current county is not considered a protocol amendment.

Subsection (b) includes the requirements for a primary NTP to request Department approval to relocate outside of its current county. This subsection clearly specifies that an NTP must submit both the Initial Application Coversheet form DHCS 5014 (04/16) and the written protocol described in Section 10030(a)(1)-(43). Subsection (b) requires these forms to be submitted 120 days prior to the date of relocation to allow time for application review and correction by the applicant if needed. This also allows time for a site visit to be conducted by the Department, coordination with DEA and SAMHSA, as well as final approval processes to be completed.

Subsection (c) mirrors language in Section 10045(a) in order to consistently apply the same requirements for both an application for a new license and an application to relocate outside of the current county. This is also consistent with the requirement in HSC Section 11839.3(a)(6) for the Department to evaluate recommendations made by County Alcohol and Drug Program Administrators regarding licensing activity in their respective counties.

Subsection (d) is necessary to establish a process by which the Department will review the application for relocation outside of the current county, which includes: an Initial Application Coversheet form DHCS 5014 (04/16) and written protocol. Based on the amount of documentation that comprises a written protocol, 60 days is a reasonable

review timeframe for the Department to determine if the submission is complete. The 60-day timeframe is also consistent with the review timeframe to determine if an application is complete for the approval of a medication unit or an OBNTN and licensure of an NTP.

Subsection (d)(1) requires the Department to provide the applicant notice that their application is complete and under further review. This notice is for the convenience of the applicant and is necessary to provide the applicant with a status of the application. A reference to the documents required in Section 10030 is included to clarify that these documents are necessary to be considered a complete application.

Subsection (d)(2) requires the Department to provide the applicant notice that the submitted documents are incomplete specifying the additional information needed. This notice is for the convenience of the applicant and is necessary to support a timely and accurate submission of missing information. The Department believes that 60 days is an adequate timeframe for the applicant to obtain the required documentation and respond. This 60-day window provides the applicant time to obtain additional information from external stakeholders such as the County Board of Supervisors or fire marshal. The Department has experienced applicants who submit incomplete applications that remain pending indefinitely. Therefore, the Department will terminate the review of an application (for incompleteness) if the applicant has not responded to the Department with the requested information within the 60-day timeframe. This process allows the Department to definitively close out the review process for an incomplete application. An incomplete application will be returned to the applicant for their records and convenience. The applicant is also notified of the option to reapply in the future. This is necessary to inform the applicant that the termination of the application review process due to an incomplete application is not an adverse action and does not preclude the applicant from applying again.

Subsection (e) is necessary to notify the applicant of the Department's decision to either approve or deny the complete application. This provision also establishes the timeframe within which the Department must render a decision. The Department believes 60 days is necessary and adequate to review the voluminous protocol, which includes items such as employee handbooks, plan of operations, policies and procedures, emergency plans, and facility descriptions. During this 60-day time period, the Department must also coordinate the review and approval of the application with multiple federal agencies. This includes a physical site inspection, which may present deficiencies that must be cleared prior to an applicant's approval. Within this time period the Department must also conduct final administrative reviews and processing of licenses.

Section 10040

The phrase "Alcohol and" is added to the title and subsections (a) and (b) to be consistent with the use of this phrase as used in HSC Section 11800 et seq. and within these regulations.

Subsection (b) also includes a reference to the County Certification form DHCS 5027 (04/16) to clearly indicate that this form must be submitted with the application for licensure.

Section 10045

Subsection (a) removes the word “support” and replaces it with “recommendation” to be consistent with the requirement in HSC Section 11839.3(a)(6). Subsection (a) also adds the phrase “Alcohol and” to be consistent with the use of this phrase as used in HSC Section 11800 et seq. and within these regulations. The term “program” is replaced with the term “applicant” for consistency within this section. Other non-substantive changes in sentence structure and syntax are included to incorporate these changes.

Subsection (b) changes the timeframe to notify the applicant whether an application is complete or incomplete from 45 days to 60 days. This is necessary to ensure accurate review of all documentation to determine if the submission is complete.

Subsection (b)(1) includes a reference to the documents required in Section 10030 to clarify that these documents are necessary to be considered a complete application. The term “filing” is replaced with the term “review” to clearly specify that the Department will review the application once deemed complete.

Subsection (b)(2) is reworded to better clarify that the Department must specify within the notice the missing or incomplete information or documentation needed to make the application complete. This is necessary to support a timely and accurate submission of missing information. A timeframe to submit the missing information is also specified. The Department believes that 60 days is an adequate timeframe for the applicant to obtain the required documentation and respond. This 60-day window provides the applicant time to obtain additional information from external stakeholders such as the County Board of Supervisors or fire marshal. The Department has experienced applicants who submit incomplete applications that remain pending indefinitely. Therefore, the Department will terminate the review of an application (for incompleteness) if the applicant has not responded to the Department with the requested information within the 60-day timeframe. This process allows the Department to definitively close out the review process for an incomplete application. An incomplete application will be returned to the applicant for their records and convenience. The applicant is also notified of the option to reapply in the future. This is necessary to inform the applicant that the termination of the application review process due to an incomplete application is not an adverse action and does not preclude the applicant from applying again. The existing phrase “licensing process shall cease unless and until the applicant provides the specific material outlined in the notification” is replaced with the more detailed and specific information described above.

Subsection (c) replaces the word “disapprove” with the word “deny” for consistency throughout the regulations and for clarity. The term “complete” is added for consistent phrasing throughout the regulations and to emphasize that the Department will only review and consider applications that are complete. Subsection (c) changes the

timeframe allotted to the Department for approval or denial of a completed application from 45 days to 60 days. This amendment is necessary to provide the Department with adequate time to review the voluminous protocol, which includes items such as employee handbooks, plan of operations, policies and procedures, emergency plans, and facility descriptions. During this 60-day time period, the Department must also coordinate the review and approval of the application with multiple federal agencies. This includes a physical site inspection, which may present deficiencies that must be cleared prior to an applicant's approval. Within this time period the Department must also conduct final administrative reviews and processing of licenses. The phrase "filing of a completed application" is replaced with "the application is accepted for review" to be consistent with Sections 10020(f), 10021(f) and 10036(b).

Subsection (d) is removed because it is outdated and merely informational language that has no regulatory impact and the timeframe in which an application shall be reviewed by the Department is clearly specified in subsection (c).

Section 10055

Subsection (b)(1) includes a reference to any affiliated and associated medication unit(s) and/or OBNTN, to ensure that all components of the NTP maintain compliance with related statutes and regulations, ensuring the lawful provision of services and protection of patient health and safety. The term "is" is changed to "are" for purposes of grammar.

Subsection (b)(2) adds the phrase "Alcohol and" to be consistent with the use of this phrase as it is used in HSC Section 11800 et seq. and within these regulations. This subsection also adds reference to the County Certification form DHCS 5027 (04/16) to clearly indicate that this form must be submitted with a request for licensure renewal. This form is necessary to specify that both county certification of the program and recommendation for renewal is required to continue the provision of services.

Subsection (b)(3) requires the licensee to submit to the Department, by March 31st of each year, the Application for License Renewal form DHCS 4029 (04/16) herein incorporated by reference and described in detail in the Forms Section below. This form provides instructions for current programs regarding requirements for the license renewal process. This form is necessary to establish program eligibility for license renewal.

Subsections (b)(3)(A)-(C) describes information that is required on the Application for License Renewal form DHCS 4029 (04/16). Paragraph (A) is necessary for the Department to update and confirm business information of the program and any of its affiliated and associated medication units and OBNTNs. Paragraph (B) is necessary for the Department to assess whether the current patient capacity needs to be increased or decreased. Paragraph (C) is necessary to provide the Department with information regarding patient demographics, dosing levels, and utilization of capacity. The Department uses this information to fulfill its obligation under HSC Section 11839.3(a)(4) to study and evaluate NTPs.

Subsection (b)(4) requires the licensee to submit to the Department, by March 31st of each year, the Organizational Responsibility form DHCS 5031 (04/16) as a requirement for annual renewal. This form is required to ensure the Department receives notification of any changes to individuals who have administrative influence or financial interest in an NTP. This language is consistent with the list of individuals whose criminal history is subject to review by the Department pursuant to HSC Sections 11839.8 and 11839.9.

The forms under subsections (b)(3) and (4) are required to be submitted by March 31st of each year. The March 31st submission date allows adequate time for Department review of renewal applications prior to the July 1st renewal date. This timeline also provides counties additional time to prepare any contract amendments for the upcoming fiscal year.

Subsection (c) removes the term “renewal application” and replaces it with the Application for License Renewal form DHCS 4029 (04/16) and the Organizational Responsibility form DHCS 5031 (04/16). This is consistent with the requirement set forth in subsections (b)(3) and (4) that programs utilize these forms for license renewal.

Subsection (c)(2) is reworded to better clarify that the Department must specify within the notice the missing or incomplete information or documentation needed to make the application complete. This information is provided for the convenience of the licensee and is necessary to support a timely and accurate submission of missing information. A timeframe to submit the missing information is also specified. The information requested in the renewal application is not as extensive as the protocol and is an update to existing information, therefore missing or incomplete information should be easily obtainable within a 15-day timeframe. This timeframe also allows time for the Department to review resubmitted information prior to the statutorily mandated July 1st renewal date. The Department has experienced applicants who submit incomplete applications that remain pending indefinitely. Therefore, the Department will terminate the review of an application (for incompleteness) if the applicant has not responded to the Department with the requested information within the 15-day timeframe. This process allows the Department to definitively close out the review process for an incomplete application. An incomplete application will be returned to the applicant for their records and convenience. This is necessary to inform the applicant that the termination of the application review process due to an incomplete application is not an adverse action.

Subsection (d) removes the sentence, “Within 60 days of receipt of…licensure” and replaces it with a specific date of June 15th by which the Department must approve or deny an NTP license renewal. This provides a definitive date for licensees to receive notice of their application renewal and provides adequate time for the Department to review the application. This subsection also clarifies that if approved, the Department shall issue a new license with an effective date of July 1st. The time period between the license approval and effective date provides the Department time to process the new license.

Subsection (e) is removed because it is outdated and merely informational language that has no regulatory impact. The timeframe in which a renewal application shall be reviewed by the Department is clearly specified in revised subsection (d).

Section 10056

HSC Section 11839.7 (as revised June 27, 2013) provides very specific requirements for the calculation of licensing and application fees. This section of the regulations is extensively modified to bring the regulation into compliance with the governing statute.

The title is amended by replacing the term “License” with the term “Application”. This is necessary to clearly distinguish this section pertaining to application fees from Section 10056.5 pertaining to license fees.

Existing subsection (a) is removed and replaced with subsections (a)(1)-(3), which clearly specifies the requirements for when an application fee shall be paid. This language is consistent with the requirements of HSC Section 11839.7(b) and is included for purposes of clarity and convenience for the affected public.

Existing subsection (b) including the license fee table is removed and replaced with a new subsection (b) in order to clarify when an application fee is to be paid. This section makes clear that the application fee must be paid before an application can be processed to ensure that the Department is covered for the cost incurred for reviewing the application consistent with HSC Section 11839.7. Paragraph (1) requires an application fee upon submission of an application for initial licensure. Paragraph (2) is included to specify that an application fee is also required for the addition of a Medication Unit and OBNTN. The Department incurs costs for review of these applications comparable to the costs of reviewing an initial application for licensure of an NTP. Paragraph (3) requires an application fee for the relocation of an existing program. Paragraph (4) requires an application fee for the relocation of a program outside of its current county.

Subsection (c) replaces portions of the existing subsections (b) and (c) describing how the application fee is calculated. Paragraph (1) specifies costs, including staff salaries and benefits, related travel costs, and state operational and administrative costs, that are incurred by the Department in processing applications. Paragraph (2) describes the calculation to arrive at the application fee to recover the departmental costs. This calculation is used because it accurately reflects the types of departmental costs associated with processing each application. Paragraph (3) describes the frequency with which the application fee is to be recalculated. The Department has decided to perform this calculation every other year to minimize administrative costs and shall begin this process in Fiscal Year 2018-2019. This biennial process will present an accurate and consistent application fee.

Existing subsection (c) and the license fee table are removed. HSC Section 11839.7 authorizes the imposition of application and licensing fees. The existing fee table

exceeds the statutorily permitted fees and therefore is removed. The application fee as set forth in the proposed subsection (c) now reflects a more accurate description of the fee methodology for applications.

Subsection (d) is added to ensure that each program is aware of the prorated licensing fee for the fiscal year. The Department calculates the prorated licensing fee and provides notification of the calculation to the program. This notification is necessary to advise the program of the prorated licensing fee.

Existing subsection (d) is re-designated to Section 10056.5(f) and amended as described under Section 10056.5 (f) below.

Existing subsection (e) is re-designated to Section 10056.5(g) and amended as described under Section 10056.5 (g) below.

Existing subsection (f) is removed. The content of subsection (f) and (f)(1) is reworded and incorporated to fit with the new format of subsection (b). The content of subsection (f)(2) is reworded and is set forth in the new subsection (e) and Section 10056.5(d).

New subsection (e) clarifies that the application fee is nonrefundable since the Department will incur costs for the review of the application. It is also consistent with the statutory intent of assessing a fee that covers costs incurred by the Department. Subsection (e) also specifies the methods in which the application fee can be paid. Payment shall be remitted to the Department using a check or money order, which is Department policy for fee submissions. The Department does not have the capability to accept credit card or cash for this type of license.

The content of subsection (f)(3) is reworded and is set forth in the new Section 10056.5(e), as described below.

Existing subsection (g) is re-designated to Section 10056.5(h) and amended as described below.

Existing subsection (h) is re-designated to Section 10056.5(i).

Section 10056.5

Subsection (a) sets forth the requirement for an annual license fee that is separate and distinct from an application fee. The proposed language is now consistent with the separation of these fees as described in HSC Sections 11839.7(a)(3) and 11839.7(b). This section clearly sets forth which programs must pay an annual license fee to the Department.

Subsection (b) adds language describing how the license fee is calculated. This fee structure creates an equitable allocation of departmental costs associated with licensing activities.

Paragraph (1) describes the first step of the methodology to compute the total departmental costs for licensing activities per year. This paragraph specifies what is included as departmental costs, such as staff salaries and benefits, related travel costs, and state operational and administrative costs.

Paragraph (2) describes the calculation to arrive at the patient capacity amount. This calculation identifies the amount associated with each patient that is then utilized as a factor for determining the total license fee.

Paragraph (3) describes how the patient capacity amount is used in the calculation to arrive at the licensing fee. The patient capacity amount is multiplied by the licensed patient capacity of each program to arrive at the total licensing fee.

Subsection (c) describes the frequency with which the license fee is to be recalculated. The Department has decided to perform this calculation every other year to minimize administrative costs and shall begin this process in Fiscal Year 2018-2019. This biennial process will present an accurate and consistent license fee.

Subsection (d) clarifies that the license fee is nonrefundable since the Department will incur costs for licensing activities. It is also consistent with the statutory intent in HSC Section 11839.7(a)(3) of assessing a fee that covers costs incurred by the Department. This provision also clarifies how payment shall be remitted to the Department using a check or money order, which is Department policy for fee submissions. The Department does not have the capability to accept credit card or cash for this type of license.

Subsection (e) explains the methodology to recalculate the license fee in the event a program receives approval for an increase or decrease in licensed patient capacity. This methodology creates a prorated system whereby the license fee is a reflection of each program's licensed patient capacity. If a program receives departmental approval for a decrease or increase in capacity, the fee for the remaining portion of that fiscal year will be recalculated on a prorated basis. The Department will send an invoice to the program specifying the prorated license fee. The Department will adjust the remaining quarterly payments based upon the recalculated fee.

Subsection (f) previously existed as Section 10056(d). April 30 is removed and replaced with March 1st in order to coincide with the revised submission date for an annual license renewal. The revised renewal submission date is March 31st, accordingly the March 1st date is necessary to give adequate notice of the upcoming license fee. July 1st is the required renewal date pursuant to HSC Section 11839.7(a)(2), therefore all renewal licenses must be issued by that date.

Subsection (g) previously existed as Section 10056(e). April 30 is removed and replaced with March 1st in order to coincide with the revised submission date for an annual license renewal. The revised renewal submission date is March 31st, accordingly the March 1st date is necessary to give adequate notice of the upcoming license fee.

Subsection (h) previously existed as Section 10056(g). The word “all” is removed and replaced with “every” for clarity. The phrases “base annual” and “slot fees” are removed and replaced with “license fee” to be consistent with new terminology and fee calculations set forth in the regulations.

Subsection (i) previously existed as Section 10056(h). The “may” is changed to “shall” to indicate a mandatory action. The “s” is removed from the word “fees” because there is only one license fee. In Paragraphs (1)-(3) the “s” is removed from the word “fees” because there is only one license fee. The word “annual” is removed to be consistent with new terminology set forth in the regulations. The term “he/she” is removed and replaced with “the licensee” to avoid the use of gender pronouns. The phrases “of the same year” and “of the same fiscal year” are unnecessary and are removed. Paragraphs (A)-(E) include non-substantive changes for purposes of grammar and sentence structure. Paragraph (F) removes the phrase “that he/she may” and replaces it with “of the right to” to emphasize the right of the licensee to appeal civil penalties. Paragraph (4) removes the “s” from the word “fees” because there is only one license fee. The term “his/her” is removed to avoid the use of gender pronouns. It also includes non-substantive changes for purposes of grammar and sentence structure.

Subsection (j) specifies that a licensee is entitled to a refund of the license fee in the event of closure due to automatic termination, license revocation or voluntary closure. Providing a refund is consistent with the purpose of the license fee, which is to cover the Department’s costs related to licensing activities. Once a program closes there are no additional licensing expenditures or costs associated with the closed program. Effective closure date is defined to provide a consistent description of this phrase as it is used in this subsection. It also clearly describes the date upon which the program is deemed closed and the date upon which the calculation of any remaining refund is determined. The date of June 30th is used to calculate the remaining funds due because all programs are licensed through June 30th pursuant to HSC Section 11839.7(a)(2) and have been previously invoiced through that date.

Section 10057

Existing subsection (a) is removed and relocated with other definitions under Section 10000(a)(12). This amendment is necessary to provide all definitions in one central location for the convenience of the regulated public. The revised definition of “licensing action” is amended as described in Section 10000(a)(12) above.

Existing subsection (b) is re-designated to (a) due to the removal of existing subsection (a). A re-designated subsection (a) removes the reference to the former ADP including the address. The administrative and programmatic functions for substance use disorder services were transferred from ADP to the Department, effective July 1, 2013, pursuant to HSC Section 11750. The address is not necessary because information regarding the submission of an appeal is available on the notice; additional non-substantive changes are included for purposes of grammar.

Subsection (c) is re-designated to subsection (b).

Subsection (b)(1) removes the references to “Deputy Director(‘s)” and “Licensing and Certification Division” and replaces them with “Division Chief(‘s)” and “Substance Use Disorder Compliance Division” to align with changes made to the organizational structure when the former ADP merged into the Department.

Subsection (b)(3) is re-designated to subsection (b)(2). The term “subsection” is added for consistency with the use of the term in the regulation and the cross reference is updated for accuracy.

Subsections (b)(4)-(b)(8) are re-designated to subsections (b)(3)-(b)(7), respectively.

Subsection (d) is re-designated to subsection (c).

Subsection (e) is re-designated to subsection (d).

Subsection (d)(1)(A) updates the cross reference for subsection (b) to subsection (a).

Subsection (d)(1)(B) updates the cross reference for subsection (e) to subsection (d).

Subsection (d)(2) adds “Deputy” and “Mental Health and Substance Use Disorder Services” and the Department’s current address; and removes reference to the former ADP to align with changes that occurred when the former ADP merged into the Department. The administrative and programmatic functions for substance use disorder services were transferred from the former ADP to the Department, effective July 1, 2013, per HSC Section 11750. A semicolon is added under subsection (d)(2)(A)1. for punctuation.

Subsection (d)(2)(B) updates the cross reference for subsection (e)(2)(A) to subsection (d)(2)(A).

Subsection (f) is re-designated to subsection (e).

Subsection (e)(1) updates the cross references for subsections (b) and (e) to subsections (a) and (d).

Subsection (g) is re-designated to subsection (f). In subsection (f)(1) “and/or” is included to clarify that the sanction can be one or more.

Section 10060

The term “opiate” is replaced with “opioid” for reasons as discussed in Section 10000(a)(22).

Section 10095

Subsection (b) includes changes that are necessary to align with HSC Sections 11839.9(c) and 11839.16(b)(1), which allow for patients to transfer to another program under identified situations. Proposed subsection (b)(1)(A) replaces the term "program operation" with "treatment" because the term treatment is defined in Section 10000(a)(34) and provides a clear description of these services. The phrase "license program" is replaced with "existing" to clarify that this paragraph refers to a guarantor continuing services at the existing location without moving patients. Subsection (b)(1)(B) is added to provide the option for a guarantor to continue treatment through the transfer to another program, which is consistent with HSC Sections 11839.9(c) and 11839.16(b)(1). The term "or" was added to connect paragraph (B) with paragraph (A) and specify either provision related to continued treatment may apply. Additional non-substantive changes are included in this section for proper punctuation, grammar and consistency throughout the regulations.

Subsection (b)(2) is amended to replace the term "may" with "shall" to indicate a mandatory action, which is consistent with HSC Section 11839.16(b)(1).

Subsection (c) is removed because the requirement is not consistent with HSC Section 11839.7(a)(4) that does not allow licenses to be transferable to another entity.

Sections 10125 and 10130

The term "opiate" is replaced with "opioid" for reasons as discussed in Section 10000(a)(22).

Section 10145

Subsection (a) removes the term "single" as it is unnecessary following the addition of the phrase "narcotic treatment," which is a defined and understood phrase. The 750 patient maximum is removed to provide the Department flexibility in assessing and determining patient capacity. The term "number" as well as the phrase "as specified on the license" is added in accordance with the Department's responsibility pursuant to HSC Section 11839.3(d). This amendment also clarifies that the license will specify the maximum number of patients that can be treated at an NTP, which was previously stated under former subsection (b)(1). The term "a" is changed to "the" for purposes of grammar.

Subsection (b) removes "The Department shall determine…" because the Department reviews a program's request for capacity change upon submission of the Application for Protocol Amendment form DHCS 5135 (04/16) as set forth in Section 10035. The new language in subsection (b) clarifies that the licensed patient capacity applies to the combined number of patients at all components of an NTP. The remaining language "except for those patients…" is relocated from existing subsection (c).

Subsection (c) as proposed requires notification by the licensee to the County Alcohol and Drug Program Administrator prior to a change in licensed patient capacity. This provides critical information regarding treatment availability and access to County

officials. Pursuant to HSC Section 11800, the County Alcohol and Drug Program Administrator must coordinate and monitor the alcohol and drug program in their respective county.

Existing subsection (b)(1) is removed because subsection (a) includes the requirement that the licensed patient capacity be specified on the license.

Existing subsection (b)(2) is being re-designated to the new subsection (d). The phrase "with outstanding deficiencies…" is removed and replaced with the phrase "unless it determines…" to be consistent with the language pursuant HSC Section 11839.3(d). This language clarifies that the Department will not increase a program's licensed patient capacity unless a determination is made that the program is operating in compliance with applicable laws and regulations. This is necessary to ensure that increases in capacity are only approved for programs operating in compliance with law to ensure the health and safety of patients.

Subsection (c) is removed and the requirements for this subsection are re-designated to subsection (b) as described above.

Subsection (d) is re-designated to subsection (e).

Subsection (e) is re-designated to subsection (f). The phrase "temporary suspension" is removed because it is not an accurate description of the action authorized to be taken by the Director. Pursuant to HSC Section 11839.16, the Director shall issue an order when a program exceeds its licensed patient capacity. The word "patient" is added to complete the phrase "licensed patient capacity," which is consistent with this phrase as it is used throughout the regulations.

Subsection (f)(1) removes the phrase "notice of temporary suspension" and replaces it with "an order" for the reasons discussed in subsection (e) above.

Subsection (f)(1)(A) replaces the phrase "has been" with the word "is" for purposes of grammar and because the order is effective on the date of the notice.

Subsections (f)(2) and (3) remove the phrase "temporary suspension" for the reasons discussed in subsection (e) above. An "n" is added to "a" for purposes of grammar.

Section 10160

Subsection (a) removes the phrase "consecutive numbers" and replaces it with "a unique identifier." In accordance with HSC Section 11839.3 (a)(1), a program is required to assign a unique identifier for patient identification. Using a unique identifier for every patient ensures protection of each individual's confidentiality. The phrase "as admitted" is removed because it is redundant as the word "patient" implies admission to the program.

Sections 10165
The term “opiates” is replaced with “opioids” for reasons as discussed in Section 10000(a)(22). The word “subsection” is added in subsections (b) and (c) in order to use consistent terminology for references throughout the regulation text.

Section 10190
Subsections (a) and (b)(1) add the program director as an eligible person who can coordinate care with a jail. This is necessary to allow the program director, in addition to the medical director, the authority to coordinate necessary care. Additionally, the term “opiate” is replaced with “opioid” for reasons as discussed in Section 10000(a)(22).

Section 10195
The first sentence is added to clarify that programs must utilize the Patient Death Report form DHCS 5048 (04/16) as described in detail in the Forms Section below, when reporting a patient death to the Department. Subsection (a) is reworded for parallel grammatical construction. The phrase “from the date the program is notified of death” is added to clarify the timeframe in which notification shall take place. Subsection (b) is reworded for parallel grammatical construction. Subsections (b)(1)-(2) are removed because these requirements are set forth on the Patient Death Report form DHCS 5048 (04/16).

Section 10240
Subsection (c)(2) removes the phrase “record number” and replaces it with “unique identifier.” Pursuant to HSC Section 11839.3 (a)(1), the program is to assign unique identifiers for patient identification. Using a unique identifier for every patient ensures protection of each individual’s confidentiality.

Section 10260
Subsection (c)(1) removes the phrase “these medications” and replaces it with “Methadone” to clarify that Methadone is currently the only narcotic replacement therapy medication dispensed in liquid form. Methadone must be dispensed in liquid form pursuant to 42 CFR Section 8.12(h)(3)(i).

Subsection (c)(2) removes the word “medication” and replaces it with “Methadone” to clarify that Methadone is currently the only narcotic replacement therapy medication that may be diluted due to its liquid form as required in 42 CFR Section 8.12(h)(3)(i). The phrase “The medical director…dilute” is added as a result of changes to HSC Section 11839.3(b). The phrase “shall be diluted…ounce” is removed, because the dilution of take-home medication is at the discretion of the medical director.

A new subsection (c)(3) is added to clearly delineate the requirement that the medical director documents his/her determination not to dilute take-home medication. Documentation can then be reviewed by the Department during compliance inspections.

Subsection (c)(3) is re-designated to subsection (c)(4).

Subsection (c)(4) is re-designated to the new subsection (c)(5). The word “these” is replaced with “all” and the phrase “used in replacement narcotic therapy” is added to clarify that this subsection applies to all medications used in replacement narcotic therapy and not solely Methadone.

Subsection (c)(6) is re-designated to subsection (c)(7).

Section 10270

Subsection (a)(2) adds the words “HIV” and “HCV” as required tests to be conducted as part of the patient selection process. According to http://www.samhsa.gov/medication-assisted-treatment/treatment/common-comorbidities people with substance use disorders are at particular risk for HIV, AIDS and viral hepatitis. Therefore, HIV and HCV are included in the laboratory tests that are evaluated.

Subsections (b)(1) and (2) remove the word “paragraphs” and replaces it with “subsections” in order to use consistent terminology for references throughout the regulation text. The term “opiates” is replaced with “opioids” for reasons discussed in Section 10000(a)(22). Additionally, the cross references to (the exceptions previously specified under) subsections (d)(5)(A) and (d)(5)(B) are updated to subsections (d)(4)(A) and (d)(4)(B), respectively.

In subsections (c) and (c)(2) the term “opiates” is replaced with “opioids” for reasons discussed in Section 10000(a)(22).

Subsections (c)(4)-(5) are removed in accordance with HSC Section 11839.3(a)(1), which removed the seven-day waiting period between withdrawal treatment episodes. A program may admit a patient to narcotic maintenance or narcotic detoxification treatment at the discretion of the medical director. This allows patients immediate access to treatment that is critical to their recovery from an opioid use disorder. A waiting period is contrary to current medical and evidence-based practices. Forced time in-between treatment episodes may lead to drug seeking-behavior, illicit drug use, exposure to infectious diseases (e.g. HIV, Hepatitis C), drug overdose, and/or death of patients seeking access to treatment.

Subsection (c)(6) is re-designated to subsection (c)(4).

Subsection (d)(1) reduces the timeframe from a “two” to a “one” year history of addiction to opioids. This is necessary to align with the federal requirements for maintenance treatment admission provided in 42 CFR Section 8.12(e)(1).

Subsection (d)(2) removes the sentences, “Confirmed history of…in the protocol.” This is necessary since the federal requirements for maintenance treatment admission, provided in 42 CFR Section 8.12(e)(1), for a person who is 18 years or older, do not include a confirmed history of unsuccessful attempts in detoxification (withdrawal) treatment. The phrase “At least seven days…subsection” is removed for reasons as discussed in subsections (c)(4)-(5) above.

Subsections (d)(3) through (d)(6) are re-designated to subsections (d)(2) through (d)(5) respectively, to accommodate for the deletion of the original subsection (d)(2) as explained above.

Throughout subsection (d) the term “opiates” is replaced with the term “opioids” for reasons as discussed in Section 10000(a)(22).

Subsection (d)(4)(A) increases the timeframe for an applicant from a penal institution or chronic care institution to be admitted into maintenance treatment from within one month to within six months of release without documented evidence of physical dependence. This is necessary to align with the federal requirements for maintenance treatment admission of patients from a penal institution, provided in 42 CFR Section 8.12(e)(3). This provision also extends to chronic care institutions. Patients who have been in a penal institution or chronic care institution may present at a NTP with no physical signs of dependence because they did not have access to opioids while in those institutions, forcing them through withdrawal. Physician’s conducting the intake process at a NTP are assured that a patient had a previous dependence issue without the physical signs being present because the patient was previously in maintenance treatment.

Subsection (d)(4)(B) increases the timeframe for an applicant, who was previously treated and voluntarily detoxed from maintenance treatment, to be admitted to maintenance treatment from within six months to within two years of discharge without documented evidence of physical dependence. This is necessary to align with the federal requirements for maintenance treatment admission provided in 42 CFR Section 8.12(e)(3). Patients who have voluntarily detoxed from maintenance treatment are uniquely aware of their potential to relapse and misuse opioids. It is critical that these patients have immediate access to return to maintenance treatment, potentially without physical signs of dependence. Physician’s conducting the intake process at a NTP are assured that a patient had a previous dependence issue without the physical signs being present because the patient was previously in maintenance treatment.

Subsection (d)(5) reduces the timeframe from a “two” to a “one” year history of addiction to opioids. This is necessary to align with the federal requirements for maintenance treatment admission provided in 42 CFR Section 8.12(e)(3). The phrase “or two prior treatment failures” is deleted. This is necessary since the federal requirements for maintenance treatment, for a person who is 18 years or older, do not include a confirmed history of unsuccessful attempts in treatment. Additionally, a non-substantive change is made to correct a grammatical error by removing the word “addition” and replacing it with the proper term “addiction.”

Subsection (e) includes the addition of the term “subsection” to clearly identify (d)(5) as a subsection and to be consistent throughout the regulation. The cross reference to subsection (d)(6) is updated to subsection (d)(5).

Sections 10280
In subsection (a)(6), the term “opiates” is replaced with “opioids” for reasons as discussed in Section 10000(a)(22).

Section 10315
Subsection (a)(2) replaces the term “Opiates” with “Opioids” for reasons as discussed in Section 10000(a)(22).

Subsection (a)(6) adds “Benzodiazepines” to the list of substances to be analyzed or tested in patient body specimens. Benzodiazepines are now commonly abused and are contraindicated with methadone use. Testing for the use of Benzodiazepines is anticipated to improve the health and safety of NTP patients. Some of the more commonly known Benzodiazepines include Librium, Valium, and Diazepam.

Subsection (b) adds “Buprenorphine” to the list of substances to be analyzed or tested in patient body specimens for those patients receiving buprenorphine or buprenorphine products as part of their replacement narcotic therapy. This is necessary to ensure that the patients receiving buprenorphine as part of their narcotic replacement therapy are taking the medication as ordered.

Subsection (b) is re-designated to subsection (c) and the term “the” is added for purposes of grammar.

Section 10320
This phrase “Health Services” is removed and replaced with “Public Health” for reasons as discussed in Section 10000(a)(9) above. In addition to identifying the proper department with the statutory authority to license these laboratories, the Food and Drug Laboratory Branch is specified as the branch responsible for licensing the laboratories. Information about this Branch is available on the California Department of Public Health website.

Section 10330
Subsection (a) adds the phrase “in every patient’s file” and removes the phrases “test or analysis...which contain” and “for each patient” to improve clarity for the effected public. Subsection (b) is added to address the Department’s current concern that program’s do not include adequate laboratory results in patient files. This language requires that the official laboratory documentation be maintained by the program and is available in patient files for inspection and review by the Department. This documentation is needed to verify that a licensed and certified laboratory conducted the test or analysis, which is necessary for the health and safety of patients.

Section 10340
This section is repealed based on informal stakeholder feedback. The requirement to have an agreement with a hospital official to provide general medical care does not align with the current health care landscape. For general medical care, program patients will be directed to contact their primary care physician. In the event an emergency

should arise at a program, ambulatory services will transport the patient to the nearest hospital.

Section 10345
Subsection (a) removes the incorrect reference to paragraph (4), which does not exist.

For subsections (a) and (e), the word “paragraph” is changed to “subsection” for consistency throughout the regulation. Subsections (b), (c) and (d)(3) change the capital “s” in “subsection” to lower case for consistency throughout the regulation.

Subsection (b)(3)(B) changes the group size from a minimum of four patients to a minimum of two patients and the maximum of ten patients to a maximum of twelve patients to conform with State Plan Amendment CA-15-012 approved June 9, 2015. State Plan Amendment CA-15-012 can be found at: http://www.dhcs.ca.gov/formsandpubs/laws/Documents/15-012_Approved_Package.pdf.

Section 10355
Subsection (b) includes a period for accurate punctuation.

For subsections (b)(2) and (d)(2), the term “opiate” is replaced with the term “opioid” for reasons as discussed in Section 10000(a)(22).

Subsection (f) is added because buprenorphine and buprenorphine products have been added to the regulation text as an authorized replacement narcotic therapy medication pursuant to HSC Section 11839.2. The language in subsection (f)(1) and (2) requiring programs to maintain current procedures and physicians making dosing decisions is consistent with 42 CFR 8.12 (h)(4). The documentation requirements are necessary so the Department can review this justification during inspections and compare it against the program’s procedures to ensure compliance. This is necessary for quality assurance and patient health and safety.

Subsection (f) is re-designated to subsection (g).

Subsection (g) is re-designated to subsection (h) and a period is added for accurate punctuation.

Section 10360
In subsection (c)(1) a semi-colon was replaced with a period “.” for consistency within this provision.

Subsections (c)(3) and (f)(2) change the term “paragraph” to “subsection” for consistent use throughout the regulation.

Throughout subsection (d) the term “opiate(s)” is replaced with “opioid(s)” for reasons as discussed in Section 10000(a)(22).

Section 10365
Subsection (d)(3), (5) and (8) are changed for consistency of terms, parallel construction and sentence flow.

Subsection (e) is amended to remove the phrase "The program should…so" because prior to SB 973 all take-home medication was diluted. SB 973 amended HSC Section 11839.3(b) to allow the medical director discretion to determine whether to dilute take-home medication. Accordingly, the requirement to provide diluted take-home medication in a non-sweetened liquid is no longer universally applicable. It is the responsibility of the medical director to determine whether and how to appropriately dilute take-home medication. Additionally, grammatical and structural edits are made to clarify that all patients receiving take-home medication whether diluted or not shall be instructed to keep the medication out of the refrigerator. This is necessary for the safety and welfare of children and to prevent fermentation of the liquid.

Section 10370
Subsection (a) removes the phrase "self administered take-home medication" and replaces it with the phrase "Methadone, buprenorphine and buprenorphine products" to clarify that all patients receiving these specific types of take-home medication shall meet the criteria set forth in Section 10370.

Subsection (b) adds the term "methadone" because the six take-home medication levels only apply to patients receiving methadone.

Subsection (b)(1) removes existing language and adds new language to be consistent with terminology used in HSC Section 11839.3(b). Furthermore, grammatical revisions are made for sentence structure, clarity and ease of reading.

Subsection (c) is removed because program attendance is not tied to the dosage level prescribed to a patient. Program attendance is based on other factors as specified in subsection (a)(1)-(8) and the step-levels identified in Section 10375.

Subsection (d) is re-designated to subsection (c).

Section 10375
Pursuant to the SAMHSA letter (http://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/dear_colleague_letters/2012-colleague-letter-final-rule-42-cfr-part-8.pdf), the time in treatment requirements for patients receiving buprenorphine do not apply. This change in the treatment standards requires this section to be amended to apply only to methadone.

The word "methadone" is added to the title to specify that this section only applies to patients receiving methadone.

Subsection (a) adds the word “methadone” to specify that this subsection only applies to patients receiving methadone.

Currently, subsection (a)(1)-(6) does not align with federal requirements for take-home medications under 42 CFR Section 8.12. Subsection (a)(1) is added to specify that the Department does not allow take-home medication during the first 90 days of treatment except for holiday or Sunday closure (pursuant to Section 10380). This 90-day timeframe will allow the NTP to establish a relationship with the patient to better ensure adherence to the criteria for take-home medication as specified in Section 10370. This deviates from 42 CFR Section 8.12, which establishes the minimum standard, however the Department has chosen to establish a more stringent standard as explained above.

The amendments in subsection (a)(2)-(6) are all necessary to be consistent with the time in treatment requirements for take-home medication as specified in 42 CFR Section 8.12.

Following the description of each step level, there is an express statement informing the patient of the number of days that the patient must be present at the program for observed ingestion. This number is derived from a seven-day week minus the number of permitted take-home doses. For example, Step Level II permits not more than 2 (two) take-home doses per week. Accordingly, the patient must attend the program at least 5 times during that week.

Subsection (a)(1) is re-designated to subsection (a)(2) and changed to step II.

Subsection (a)(2) is re-designated to subsection (a)(3) and changed to step III.

Subsection (a)(3) is re-designated to subsection (a)(4) and changed to step IV.

Subsection (a)(4) is re-designated to subsection (a)(5) and changed to step V.

Subsection (a)(5) is re-designated to subsection (a)(6) and changed to step VI.

Subsection (a)(6) is removed. This provision is no longer necessary because the requirements specified do not align with 42 CFR Section 8.12.

Subsection (a)(2) through (a)(4) also changes the timeframe in months to days for clarity and consistency with the take-home requirements in 42 CFR Section 8.12.

Subsection (a)(5) includes the term “Level”, which is mistakenly missing.

In subsection (c), the word “But” is removed because it is not necessary for the meaning of the sentence.

Section 10380

The phrase “or Sunday closure” is added to the title to specify that requirements related to a program closure on a Sunday will be included in this Section. SB 973 amended HSC Section 11839.3(b) to allow NTPs to close on Sundays. The requirements for take-home medication when a program observes a Sunday closure are set forth in this section. The phrase referencing subsection (c) is removed because a reference within this section is not necessary.

Throughout subsection (a) the phrase “or Sunday closure” is added. The reference to program closure on a Sunday is necessary in order to be consistent with HSC Section 11839.3(b). Paragraphs (1) and (2) add the phrase “or Sunday closure” to clarify that these requirements now apply to Sunday closure.

Subsection (b)(1) is removed because the requirements for the supply of take-home medication allowed are described in Section 10375 and allow for more than a six day supply of medication under the specified circumstances.

Subsection (b)(2) is removed because the dosage level is not linked to the amount of take-home medication allowed. The requirements for take-home medication are clearly described in Section 10370 (a)(1)-(8) and the step-levels are identified in Section 10375.

Existing subsection (b)(3) is now incorporated as part of subsection (b). The word “the” is replaced with the word “a” for purposes of grammar. The phrase “or Sunday closure” is added to clarify that these requirements now apply to Sunday closure as indicated throughout the section.

Subsection (c) sets forth the official state holidays as found in Government Code Section 6700. Cesar Chavez Day is added to the list of holidays because at the time the regulation was adopted, Cesar Chavez Day was not an official state holiday. While California Admission Day is a legally observed holiday, it is removed from the list of holidays because most public offices do not close for business on this day, including the Department.

Subsection (d) is revised for purposes of grammar and for consistency with language used throughout the regulations.

Section 10385

A period “.” was removed from the section title for proper grammar and formatting.

Subsection (a) removes the word “grant” and replaces it with the phrase “request from the Department” to reflect the federal requirement in 42 CFR Section 8.12 for approval of a deviation to take-home medication criteria and dosage schedules. This modification is also consistent with HSC Section 11839.3(a)(7) wherein the Department must be consistent with federal law when granting exceptions.

Subsection (a)(1) replaces the term “physical” with “medical” to be consistent with the requirements set forth in HSC Section 11839.3(b).

Subsections (a)(1) and (2) remove the sentence “The patient shall not…medication.” because the purpose of this section is to allow the medical director or program physician independent judgment in determining the appropriate take-home dosage and duration when requesting an exception to the take-home dosing schedule set forth in Section 10375.

Subsection (a)(3) is removed because the requirements for split doses are now addressed and expanded upon in the new Section 10386 (see explanation below). This is done for purposes of clarity for the regulated public.

Subsection (b) removes the term “granting” and replaces it with “submitting” and removes the term “exception” and replaces it with “request for exception” because the approval for exceptions to take-home medications must be given by the Department and SAMHSA pursuant to 42 CFR Section 8.11(h).

Subsection (c) is proposed to require that all documentation submitted to SAMHSA for an exception request, pursuant to 42 CFR Section 8.11(h), shall also be submitted to the Department. This is already current practice and will ensure consistency and accuracy in the requirements for submitting an exception request. This requirement that the Department is provided a copy of submission documentation is also consistent with the requirement under 42 CFR Section 8.11 (h) that SAMHSA consult with the state authority about the exemption requirement. This ensures that the Department has timely access to this information.

Subsection (c) is re-designated to subsection (d) and removes the phrases “the granting of,” “exception and,” and “exception” and replaces these phrases with the phrases “request for an exception…10375” and “request, and the…request.” This is necessary to reference the sections where a request for an exception request would be submitted and to specify that documentation related to the exception and the decision regarding the exception must be kept in the patient’s record. This documentation is necessary to verify that the information provided to the Department and to SAMHSA is consistent and to confirm that the program complies with the terms of an exception, if one is granted.

Subsection (d) is re-designated to subsection (e).

Section 10386

Subsection (a) is adopted to address a commonly utilized practice in NTPs whereby a daily dose of medication is split, in order to more effectively block opioid abstinence symptoms. This language authorizes the medical director or program physician to order a split dose upon a determination of medical necessity. The necessity of split dosing is discussed in detail in the American Society of Addiction Medicine, National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use, May 27, 2015, pages 22, 78, 110, 112 and 116.

Subsection (b) is necessary because the medical director or program physician must evaluate the patient's ability to handle narcotic medication taken from the facility according to the criteria in Section 10370(a). This provision is necessary to protect the health and safety of the patient, family members and the general public.

Subsection (c) is necessary for the Department to review patient records during site inspections. The records must be up to date with all relevant patient information pertaining to the medical director's decision to split doses. All decisions related to dosing specifically related to medical necessity, dosage amounts, and ingestion time must be timely documented in the patient file. Medical necessity must be documented to ensure that each patient is receiving appropriate treatment services. Medical personnel must document that an assessment and diagnosis is consistent with the decision to provide split doses. The dosage amount and ingestion time of the split dose is important to document as it defines the patient's treatment regimen. It is important for the Department to review patient records during inspections to verify dosing orders against dispensing records. This is also a key component in the Department's efforts to minimize the potential of diversion. This oversight component and the availability of this information to the Department is critical for the monitoring of program services and for the overall health and welfare of the patients as well as the protection of family members and the general public.

Subsection (d) clearly states that any medication, including a portion of a split dose, removed from the facility by a patient is considered take-home medication under these regulations. This provision is necessary because any medication that is removed from the facility, even if it is due to a split dose, has the same diversion potential. A patient that is taking any medication home must be eligible to do so and meet the criteria as specified in Section 10370 (a)(1)-(8) in order to minimize diversion.

Subsection (e) includes the requirement for adhering to the step levels for take-home medication and is necessary to reiterate that medical directors and program physicians must comply with Section 10375 and the cross reference to this section is included for the convenience of the reader.

Subsection (f) explains how the Department calculates split doses for purposes of take-home medication step levels in Section 10375. Patients who receive split doses as take-home medication will receive two bottles of medication per day. This is necessary to clarify that the two bottles are considered a single take-home dose under the take-home schedule in Section 10375.

Section 10410

The word "termination" is replaced with the word "evaluation" in the title because a patient's maintenance treatment will no longer be subject to automatically ending after the passage of two years.

Subsection (a) removes the word “discontinue” and replaces it with “evaluate” to eliminate the automatic termination of maintenance treatment to patients. According to the Federal Guidelines for Opioid Treatment Programs, http://store.samhsa.gov/shin/content//PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf, treatment should not be automatically terminated for patients deriving a benefit from the services. The phrase “within two” is removed and replaced with “after one” to ensure that patients are reaching their treatment plan goals and receiving adequate care and support to maximize their recovery. The phrases “after such” and “is begun unless he or she completes” are removed and the term “of” is included to correct the grammatical construction of the sentence following its revision. The phrase “The medical director…shall do” is also included to be a lead into paragraphs (1) and (2) that describes the activities to be completed by the medical director or program physician after the one continuous year of treatment. Under paragraphs (1) and (2) the “s” is removed from the first words for purposes of parallel construction.

In subsection (a)(2), the term “opiate” is replaced with “opioid” for reasons as discussed in Section 10000(a)(22).

Subsection (b) removes the word “paragraph” and replaces it with “subsection” in order to use consistent terminology for references throughout the regulation text. The phrase “after two continuous…treatment” is removed because the timeframe for a patient evaluation has changed to be consistent with subsection (a).

Section 10425

Subsection (a)(4) removes the requirement that the Department obtains a recommendation from the County Drug Program Administrator prior to granting requests for exceptions to the regulations. HSC Section 11839.3(a)(7) specifically grants the Director authority to make exceptions to the regulations when he or she determines that the “action would improve treatment services or achieve greater protection to the health and safety of patients, the local community, or the general public.” This authority is vested only in the Director; the regulation is amended accordingly.

Subsections (a)(5)-(a)(7) are re-designated to subsections (a)(4)-(a)(6), respectively.

REPEATING NON-SUBSTANTIVE CHANGES

Capitalization, grammar and punctuation amendments are included throughout the sections for clarity and to incorporate proposed amendments.

Subsections and paragraphs are re-designated where appropriate to incorporate proposed amendments.

The term “opioid” is added throughout the regulations wherever “opiate” appears, to update the regulations to reflect the appropriate medical terminology. The term is added and replaced in the following sections: 10000, 10030, 10060, 10125, 10130, 10165, 10190, 10270, 10280, 10355, 10360, and 10410.

FORMS INCORPORATED BY REFERENCE

In the discussion of the forms below, medication unit(s) are also referred to as MU(s.)

Application for License Renewal Form DHCS 4029 (04/16)
The Department proposes to amend Section 10055 to incorporate the Application for License Renewal form DHCS 4029 (04/16) by reference. This form is incorporated by reference because it would be too cumbersome to print it directly in the CCR. The NTP forms are available on the Department's internet website at http://www.dhcs.ca.gov/individuals/Pages/NTP-Applications-and-Forms-.aspx.

The adoption of this form is necessary to set forth the requirements for license renewal. The applicant must submit the Application for License Renewal form DHCS 4029 (04/16), as part of an application package for licensure renewal of an NTP.

The following standardized information is included in the header and footer portions of each form that is incorporated by reference throughout this regulatory action.

Header
- The name of the State Agency, Department, and program. This information is necessary to identify the entity responsible for the form.

- The mailing address for the Department's Narcotic Treatment Program. This information is necessary for the applicant to submit the form and/or any additional required protocols or information to the correct address.

Footer
- The form number and revision date. This information is necessary for the applicant to identify the correct type and version of a form.

- The page number formatted to show the current page number and the total number of pages of the form. This information is necessary for the applicant to ensure that all pages are completed and included with submission.

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

The instructions that accompany this form are necessary to provide supporting guidance to the applicant on how to correctly fill out and submit the form. The instructions highlight the type of information that must be included in order for the form to be considered complete and accurate and to ensure the integrity of the form. The directive to read all of the instructions on the form is included as a reminder for the applicant. A cross reference to the location in the CCR that includes the requirements

and standards for the Narcotic Treatment Programs is included for the applicant's convenience.

The instructions also provide additional information to support a clear understanding of the requirement of each field on the form and the submission of correct information including:

- Cross references to additional information including links to the CMS National Plan and Provider Enumeration System for information on National Provider Identifiers (NPIs), the California Secretary of State for information on legal entities, and the United States Postal Service for information on how to obtain the exact zip code for the mailing address or physical address of a facility.
- Instructions to submit a copy of the county filing if operating the business under a fictitious name.

APPLICATION FOR LICENSE RENEWAL FORM DHCS 4029 (04/16)

Section A, Applicant Information

The "Applicant Information" section instructs the applicant to supply pertinent information regarding the applicant. This information is necessary during the application process for identification and verification purposes and includes the following:

- The "Application for Fiscal Year" section instructs the applicant to enter the fiscal year for which the applicant is applying. This information is necessary so the Department knows for which fiscal year the applicant is requesting licensure renewal.

- The "Original License Date" section instructs the applicant to list the initial effective date of the NTP license. Pursuant to Section 10055, NTPs shall not be licensed for more than one year. This information is necessary for the Department to confirm that the applicant has not been licensed for more than one year.

- The "License Number" section instructs the applicant to enter their license number. This information is necessary to inform the Department if the applicant is already a licensed NTP.

- The "National Provider Identifier (NPI)" section instructs the applicant to enter their assigned NPI. Section 162.410 of the CFR, Title 45, Part 162, requires all covered healthcare providers to obtain NPI numbers. Federal entities overseeing the operation of NTPs commonly utilize the NPI as a program identifier. The Department is required to utilize the NPI as a program identifier when electronically transmitting health information in connection with Health Insurance Portability and Accountability Act (HIPAA) standard transactions and also uses the NPI as a program identifier in communications with federal administrative entities.

- The “Name of Legal Entity” section instructs the applicant to provide the legal name of the entity. This information is necessary for the Department to identify who is applying for licensure.

- The “Name of Narcotic Treatment Program” section instructs the applicant to provide the name of the NTP if it is different from the name of the legal entity. This information is necessary for the Department to correlate the legal name with the business name of the NTP.

- The “Tax Status” section instructs the applicant to check the applicable box indicating the tax status of the applicant’s entity. This information is necessary to inform the Department of the applicant’s legal business structure.

- The “Facility Street Address” section instructs the applicant to list the exact physical address of the NTP location including room, suite, unit number, city, county and zip code of the actual location where services are rendered. The physical street address is necessary in order for the Department to conduct site reviews and determine whether the applicant meets established requirements pursuant to Section 10030.

- The “Mailing Address” section instructs the applicant to list the mailing address if different from the facility street address of the NTP. The mailing address, including room, suite, unit number, city, county and zip code, is necessary in order for the Department to mail pertinent information to the applicant and to maintain current files.

- The “Telephone Number” section instructs the applicant to enter the telephone number and if applicable, the extension number of the applicant. This information is necessary in order for the Department to contact the applicant by phone and to maintain current files.

- The “Fax Number” section instructs the applicant to provide the fax number. This information is necessary in order for the Department to contact or communicate with the applicant via fax and to maintain current files.

- The “Name of Program Sponsor” section instructs the applicant to enter the name of the program sponsor. This information is necessary in order for the Department to confirm the identity of the person or organization responsible for the operation of the NTP and who assumes responsibility for all its employees.

- The “Name of Program Director” section instructs the applicant to enter the name of the program director. This information is necessary in order for the Department to confirm the name of the person who has primary administrative responsibly for operation of the NTP.

- The “Name of Medical Director” section instructs the applicant to enter the name of the medical director. This information is necessary in order for the Department to confirm the identity of the physician licensed to practice medicine in California, and who is responsible for medical services provided by the NTP.

- The “Licensed Patient Capacity” section instructs the applicant to enter the maximum number of patients served at the NTP location. This information is necessary pursuant to Section 10145, to determine if the applicant has reached the maximum treatment capacity. This information is necessary to maintain current files.

- The “Operating Hours (M-F)” section instructs the applicant to list the NTP’s hours of operation for Monday through Friday. This information is necessary to inform the Department of the days and hours treatment services are provided, to update the NTP provider directory and to schedule site inspections.

- The “Dispensing Hours (M-F)” section instructs the applicant to list the hours of medication dispensing for Monday through Friday at the NTP. This information is necessary to inform the Department of the days and hours medication will be dispensed.

- The “Weekend Operating Hours” section instructs the applicant to list the hours of operation for Saturday and Sunday. This information is necessary to inform the Department of the days and hours treatment services are offered on the weekend. In addition, this information is necessary to update the NTP provider directory and schedule site inspections.

- The “Weekend Dispensing Hours” section instructs the applicant to list the hours of medication dispensing on Saturday and Sunday. This information is necessary to inform the Department of the days and hours medication will be dispensed on the weekend.

<u>Section B, MU/OBNTN</u>
The “MU/OBNTN” section instructs the applicant to supply pertinent information pertaining to the MU/OBNTN applicant. This information is necessary during the application process for identification and verification purposes. To mitigate fraud and abuse and assist the Department in verifying the identity of the licensed NTP with a supplemental MU/OBNTN, the following fields are included:

- The “National Provider Identifier (NPI)” section instructs the applicant to enter their assigned NPI. Section 162.410 of the CFR, Title 45, Part 162, requires all covered healthcare providers to obtain NPI numbers. Federal entities overseeing the operation of NTPs commonly utilize the NPI as a program identifier. The Department is required to utilize the NPI as a program identifier when electronically transmitting health information in connection with HIPAA standard

transactions and also uses the NPI as a program identifier in communications with federal administrative entities.

- The “Name of Legal Entity” section instructs the applicant to provide the legal name of the entity for the MU/OBNTN. This information is necessary for the Department to identify who is applying for licensure.

- The “Name of MU or OBNTN” section instructs the applicant to provide the name of the MU or OBNTN if it is different from the legal entity name. This information is necessary for the Department to correlate the legal name with the business name of the MU/OBNTN.

- The “Tax Status” section instructs the applicant to check the applicable box indicating the tax status of the MU/OBNTN’s entity. This information is necessary to inform the Department of the MU/OBNTN’s legal business structure.

- The “Facility Street Address” section instructs the applicant to list the physical address of the MU/OBNTN’s location including room, suite, unit number, city, county and zip code of the actual location where services will be rendered. The physical street address is necessary in order for the Department to conduct site reviews and determine whether the MU/OBNTN meets established requirements pursuant to Sections 10020 and 10021. The Department needs to know the MU or OBNTN location for which the applicant is including in the NTP’s request for renewal of licensure.

- The “Mailing Address” section instructs the applicant to list the mailing address of the MU/OBNTN, including room, suite, unit number, city, county and zip code. The mailing address of the MU/OBNTN is necessary in order for the Department to mail pertinent information to the provider and to maintain current files.

- The “Telephone Number” section instructs the applicant to enter the telephone number of the MU/OBNTN. This information is necessary in order for the Department to contact the MU/OBNTN by phone and to maintain current files.

- The “Fax Number” section instructs the applicant to provide the fax number for the MU/OBNTN. This information is necessary in order for the Department to contact or communicate with the MU/OBNTN via fax and to maintain current files.

- The “Name of Program Director” section instructs the applicant to enter the name of the program director for the MU/OBNTN. This information is necessary in order for the Department to confirm the name of the person who has primary administrative responsibly for operation of the MU/OBNTN.

Section C, Annual Maintenance Report

- The “Maintenance Treatment” section instructs the applicant to enter the total number of patients in methadone maintenance treatment as of January 31st of the current year. This information is required for the Department to fulfill its obligation to study and evaluate NTPs pursuant to HSC Section 11839.3(a)(4).

- The “Maintenance Treatment” section instructs the applicant to enter the total number of patients in buprenorphine maintenance treatment as of January 31st of the current year. This information is required for the Department to fulfill its obligation to study and evaluate NTPs pursuant to HSC Section 11839.3(a)(4).

- The “Detoxification Treatment” section instructs the applicant to enter the total number of patients in methadone detoxification treatment as of January 31st of the current year. This information is required for the Department to fulfill its obligation to study and evaluate NTPs pursuant to HSC Section 11839.3(a)(4).

- The “Detoxification Treatment” section instructs the applicant to enter the total number of patients in buprenorphine detoxification treatment as of January 31st of the current year. This information is required for the Department to fulfill its obligation to study and evaluate NTPs pursuant to HSC Section 11839.3(a)(4).

- The “Annual Maintenance Dosage Level and Take-Home Privileges for Methadone” section instructs the applicant to complete all fields based on NTP census data as of January 31st of the current year for the annual maintenance dosage level and step level of patients in methadone treatment. The required information in the Annual Maintenance Report provides the Department with information regarding patient demographics, dosing levels and utilization of capacity. The Department uses this information to fulfill its obligation under HSC Section 11839.3(a)(4) to study and evaluate NTPs.

- The “Annual Maintenance Dosage Level and Take-Home Privileges for Buprenorphine” section instructs the applicant to complete all fields based on NTP census data as of January 31st of the current year for the annual maintenance dosage level and step level of patients in buprenorphine treatment. The required information in the Annual Maintenance Report provides the Department with information regarding patient demographics, dosing levels and utilization of capacity. The Department uses this information to fulfill its obligation under HSC Section 11839.3(a)(4) to study and evaluate NTPs.

- The “Patients in Methadone Detoxification Treatment” section instructs the applicant to complete all fields based on NTP census data as of January 31st of the current year for dosage levels of patients in methadone detoxification treatment. The required information in the Annual Maintenance Report provides the Department with information regarding patient demographics, dosing levels and utilization of capacity. The Department uses this information to fulfill its obligation under HSC Section 11839.3(a)(4) to study and evaluate NTPs.

- The “Patients in Buprenorphine Detoxification Treatment” section instructs the applicant to complete all fields based on NTP census data as of January 31st of the current year for dosage levels of patients in buprenorphine detoxification treatment. The required information in the Annual Maintenance Report provides the Department with information regarding patient demographics, dosing levels and utilization of capacity. The Department uses this information to fulfill its obligation under HSC Section 11839.3(a)(4) to study and evaluate NTPs.

Section D, Declaration

This information is necessary to ensure that the authorized individual signing the application is aware of and acknowledges the requirements and stipulations within this application.

The Declaration section instructs the applicant to attest to the following:

> 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.

The section provides the following information:

- The “Print Name” section instructs the applicant to print the name of the Program Sponsor who will sign the Declaration section. This information is needed to confirm the identity of the individual signing and to ensure that the individual is authorized to sign on behalf of the NTP, MU, or OBNTN.

- The “Title” section is pre-filled by the Department with the title “Program Sponsor.” This information is necessary to specify the individual that is authorized to sign the form.

- The “Signature” section instructs the applicant to provide an original signature of the Program Sponsor. This information is necessary to ensure that the authorized individual signing the application is aware of and acknowledges the requirements and stipulations within this application.

- The “Date” section instructs the applicant to enter the date the application is signed by the Program Sponsor. This field is standard information that is requested across all Department applications and assists the Department in determining when the application was completed.

Privacy Statement
A privacy statement is adopted in order to comply with Civil Code Section 1798.17. The privacy statement is included on each form that is incorporated by reference through this regulatory action. This privacy statement is necessary to inform the applicant that all information requested is mandatory and includes references to the bodies of law that authorize NTPs. The Department gives its due diligence by advising the applicant of the consequences of not providing the required information. This privacy statement also advises the applicant that information may be shared with additional entities, as required or permitted by law. Lastly, the applicant is given the Narcotic Treatment Programs Section's telephone number for more information or to access records.

Initial Application Coversheet Form DHCS 5014 (04/16)

The Department proposes to amend Section 10030 to incorporate the Initial Application Coversheet form DHCS 5014 (04/16) by reference. This form is incorporated by reference because it would be too cumbersome to print it directly in the CCR. The NTP forms are made available on the Department's internet website at http://www.dhcs.ca.gov/individuals/Pages/NTP-Applications-and-Forms-.aspx.

The adoption of this form is necessary to make a distinction between the different types of applications received from NTP providers. The Initial Application Coversheet form DHCS 5014 (04/16), when submitted with a protocol is part of an application package for licensure of an NTP. The Initial Application Coversheet form DHCS 5014 (04/16) shall be submitted as follows:

- With a supplemental written protocol, as part of an application package to add a medication unit to the primary NTP license, in accordance with Section 10020.
- With a supplemental written protocol, as part of an application to add an OBNTN to the primary NTP license, in accordance with Section 10021.
- With a written protocol, as part of an application package for licensure or relocation outside of current county of a narcotic treatment program, in accordance with Sections 10030 and 10037, respectively.

The following standardized information is included in the header and footer portions of each form that is incorporated by reference throughout this regulatory action.

Header

- The name of the State Agency, Department, and program. This information is necessary to identify the entity responsible for the form.

- The mailing address for the Department's Narcotic Treatment Program. This information is necessary for the applicant to submit the form and/or any additional required protocols or information to the correct address.

Footer

- The form number and revision date. This information is necessary for the applicant to identify the correct type and version of a form.

- The page number formatted to show the current page number and the total number of pages of the form. This information is necessary for the applicant to ensure that all pages are completed and included with submission.

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

The instructions that accompany this form are necessary to provide supporting guidance to the applicant on how to correctly fill out and submit the form. The instructions highlight the type of information that must be included in order for the form to be considered complete and accurate and to ensure the integrity of the form. The directive to read all of the instructions on the form is included as a reminder for the applicant. A cross reference to the location in the CCR that includes the requirements and standards for the Narcotic Treatment Programs is included for the applicant's convenience.

The instructions also provide additional information to support a clear understanding of the requirement of each field on the form and the submission of correct information including:

- The definitions of specific terms that are referenced in the form, specifically for NTPs, MUs, OBNTNs, detoxification and maintenance treatment.
- Cross references to additional information including links to the CMS National Plan and Provider Enumeration System for information on NPIs, the California Secretary of State for information on legal entities, and the United States Postal Service for information on how to obtain the exact zip code for the mailing address or physical address of a facility.
- Instructions to submit a copy of the county filing if operating the business under a fictitious name.
- A description of the program sponsor.
- A description of the NTP, which must have an address that matches the facility address.

INITIAL APPLICATION COVERSHEET FORM DHCS 5014 (04/16)

Section A, Application Type

The "Application Type" section instructs the applicant to specify the type of licensure it is requesting by checking the appropriate box(es) within a type of licensure category. This information is necessary and will assist the Department during the application review period.

Section B, Applicant Information

The "Applicant Information" section instructs the applicant to supply pertinent information regarding the applicant. This information is necessary during the application process for identification and verification purposes and includes the following:

- The “License Number” section instructs the applicant to enter their license number, or to enter N/A if not applicable. This information is necessary to inform the Department if the applicant is already a licensed NTP.

- The “National Provider Identifier (NPI)” section instructs the applicant to enter their assigned NPI. Section 162.410 of the CFR, Title 45, Part 162, requires all covered healthcare providers to obtain NPI numbers. Federal entities overseeing the operation of NTPs commonly utilize the NPI as a program identifier. The Department is required to utilize the NPI as a program identifier when electronically transmitting health information in connection with HIPAA standard transactions and also uses the NPI as a program identifier in communications with federal administrative entities.

- The “Name of Legal Entity” section instructs the applicant to provide the legal name of the entity. This information is necessary for the Department to identify who is applying for licensure.

- The “Name of Narcotic Treatment Program” section instructs the applicant to provide the name of the NTP if it is different from the name of the legal entity. This information is necessary for the Department to correlate the legal name with the business name of the NTP.

- The “Tax Status” section instructs the applicant to check the applicable box indicating the tax status of the applicant’s entity. This information is necessary to inform the Department of the applicant’s legal business structure.

- The “Facility Street Address” section instructs the applicant to list the exact physical address of the NTP location including room, suite, unit number, city, county and zip code of the actual location where services are rendered. The physical street address is necessary in order for the Department to conduct site reviews and determine whether the applicant meets established requirements pursuant to Section 10030.

- The “Mailing Address” section instructs the applicant to list the mailing address if different from the facility street address of the NTP. The mailing address, including room, suite, unit number, city, county and zip code, is necessary in order for the Department to mail pertinent information to the applicant and to maintain current files.

- The “Telephone Number” section instructs the applicant to enter the telephone number and if applicable, the extension number. This information is necessary in order for the Department to contact the applicant by phone and to maintain current files.

- The “Fax Number” section instructs the applicant to provide the fax number. This information is necessary in order for the Department to contact or communicate with the applicant via fax and to maintain current files.

- The “Name of Program Sponsor” section instructs the applicant to enter the name of the program sponsor. This information is necessary in order for the Department to confirm the identity of the person or organization responsible for the operation of the NTP and who assumes responsibility for all its employees.

- The “Name of Program Director” section instructs the applicant to enter the name of the program director. This information is necessary in order for the Department to confirm the name of the person who has primary administrative responsibly for operation of the NTP.

- The “Name of Medical Director” section instructs the applicant to enter the name of the medical director. This information is necessary in order for the Department to confirm the identity of the physician licensed to practice medicine in California, and who is responsible for medical services provided by the NTP.

- The “Proposed Capacity” section instructs the applicant to enter the proposed number of patients served at the NTP location. This information is necessary to specify for the Department how many patients are projected to receive treatment services. This is necessary for the Department to determine adequate staffing requirements and if the facility is able to accommodate the proposed patient capacity safely.

Section C, MU/OBNTN

The “MU/OBNTN” section instructs the applicant to supply pertinent information pertaining to the MU/OBNTN applicant. The applicant is advised that “Section C” must be completed by all MU/OBNTN applicants only. This information is necessary during the application process for identification and verification purposes and to ensure that the MU/OBNTN applicant(s) are eligible to participate as a MU/OBNTN. To mitigate fraud and abuse and to assist the Department in verifying the identity of the NTP as a licensed MU/OBNTN, the following fields are included:

- The “National Provider Identifier (NPI)” section instructs the applicant to enter their assigned NPI. Section 162.410 of the CFR, Title 45, Part 162, requires all covered healthcare providers to obtain NPI numbers. Federal entities overseeing the operation of NTPs commonly utilize the NPI as a program identifier. The Department is required to utilize the NPI as a program identifier when electronically transmitting health information in connection with HIPAA standard transactions and also uses the NPI as a program identifier in communications with federal administrative entities.

- The “Name of Legal Entity” section instructs the applicant to provide the legal name of the entity for the MU/OBNTN. This information is necessary for the Department to identify who is applying for licensure.

- The “Name of MU or OBNTN” section instructs the applicant to provide the name of the MU or OBNTN if it is different from the legal entity name. This information is necessary for the Department to correlate the legal name with the business name of the MU/OBNTN.

- The “Tax Status” section instructs the applicant to check the applicable box indicating the tax status of the MU/OBNTN’s entity. This information is necessary to inform the Department of the MU/OBNTN’s legal business structure.

- The “Facility Street Address” section instructs the applicant to list the physical address of the MU/OBNTN’s location including room, suite, unit number, city, county and zip code of the actual location where services will be rendered. The physical street address is necessary in order for the Department to conduct site reviews and determine whether the MU/OBNTN meets established requirements pursuant to Sections 10020 and 10021. The Department needs to know the MU or OBNTN location for which the applicant is including in the NTP’s request for renewal of licensure.

- The “Mailing Address” section instructs the applicant to list the mailing address of the MU/OBNTN, including room, suite, unit number, city, county and zip code. The mailing address of the MU/OBNTN is necessary in order for the Department to mail pertinent information to the provider and to maintain current files.

- The “Telephone Number” section instructs the applicant to enter the telephone number of the MU/OBNTN. This information is necessary in order for the Department to contact the MU/OBNTN by phone and to maintain current files.

- The “Fax Number” section instructs the applicant to provide the fax number for the MU/OBNTN. This information is necessary in order for the Department to contact or communicate with the MU/OBNTN via fax and to maintain current files.

- The “Name of Program Director” section instructs the applicant to enter the name of the program director for the MU/OBNTN. This information is necessary in order for the Department to confirm the name of the person who has primary administrative responsibly for operation of the MU/OBNTN.

<u>Section D, Declaration</u>
This section is necessary to ensure that the authorized individual signing the application is aware of and acknowledges the requirements and stipulations within this form.

The Declaration section instructs the applicant to attest to the following:

> 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.

This section provides the following information:

- The “Print Name” section instructs the program sponsor to print his/her name. This information is needed to confirm the identity of the individual signing and to ensure the individual is authorized to sign on behalf of the NTP, MU, or OBNTN.

- The “Title” section is pre-filled by the Department with the title “Program Sponsor.” This information is necessary to specify the individual that is authorized to sign the form.

- The “Signature” section instructs the applicant to provide an original signature of the Program Sponsor. This information is necessary to ensure that the authorized individual signing the application is aware of and acknowledges the requirements and stipulations within this application.

- The “Date” section instructs the applicant to enter the date the application is signed by the Program Sponsor. This field is standard information that is requested across all Department applications and assists the Department in determining when the application was completed.

Privacy Statement

A privacy statement is adopted in order to comply with Civil Code Section 1798.17. The privacy statement is included on each form that is incorporated by reference through this regulatory action. This privacy statement is necessary to inform the applicant that all information requested is mandatory and includes references to the bodies of law that authorize NTPs. The Department gives its due diligence by advising the applicant of the consequences of not providing the required information. This privacy statement also advises the applicant that information may be shared with additional entities, as required or permitted by law. Lastly, the applicant is given the Narcotic Treatment Programs Section’s telephone number for more information or to access records.

Guarantor Agreement Form DHCS 5020 (04/16)

The Department proposes to amend Section 10030 to incorporate the Guarantor Agreement form DHCS 5020 (04/16) by reference. This form is incorporated by reference because it would be too cumbersome to print it directly in the CCR. The NTP

forms are available on the Department's internet website at http://www.dhcs.ca.gov/individuals/Pages/NTP-Applications-and-Forms-.aspx.

The adoption of this form is necessary for the Department to obtain the name of the individual or entity who will guarantee that maintenance treatment will continue at the existing program location for up to 90 days following receipt by the Department of the program's notice of intent to close the program or guarantee continuity of maintenance treatment through the transfer of patients to another program. The Guarantor Agreement form DHCS 5020 (04/16) shall be submitted with a written protocol, as part of an application package for licensure of a narcotic treatment program, in accordance with Section 10030.

The following standardized information is included in the header and footer portions of each form that is incorporated by reference throughout this regulatory action.

Header

- The name of the State Agency, Department, and program. This information is necessary to identify the entity responsible for the form.

- The mailing address for the Department's Narcotic Treatment Program. This information is necessary for the applicant to submit the form and/or any additional required protocols or information to the correct address.

Footer

- The form number and revision date. This information is necessary for the applicant to identify the correct type and version of a form.

- The page number formatted to show the current page number and the total number of pages of the form. This information is necessary for the applicant to ensure that all pages are completed and included with submission.

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

The instructions that accompany this form are necessary to provide supporting guidance to the applicant on how to correctly fill out and submit the form. The instructions highlight the type of information that must be included in order for the form to be considered complete and accurate and to ensure the integrity of the form. The directive to read all of the instructions on the form is included as a reminder for the applicant. A cross reference to the location in the CCR that includes the requirements and standards for the Narcotic Treatment Programs is included for the applicant's convenience.

The instructions also provide additional information to support a clear understanding of the requirement of each field on the form and the submission of correct information including:

- Instructions to submit a copy of the county filing if operating the business under a fictitious name.

- Cross references to additional information including links to the CMS National Plan and Provider Enumeration System for information on NPIs, the California Secretary of State for information on legal entities, and the United States Postal Service for information on how to obtain the exact zip code for the mailing address or physical address of a facility.

GUARANTOR AGREEMENT FORM DHCS 5020 (04/16)

Section A, Applicant Information

The "Applicant Information" section instructs the applicant to supply pertinent information regarding the applicant. This information is necessary during the application process for identification and verification purposes and includes the following:

- The "License Number" section instructs the applicant to enter their license number, or to enter N/A if not applicable. This information is necessary to inform the Department if the applicant is already a licensed NTP.

- The "National Provider Identifier (NPI)" section instructs the applicant to enter their assigned NPI. Section 162.410 of the CFR, Title 45, Part 162, requires all covered healthcare providers to obtain NPI numbers. Federal entities overseeing the operation of NTPs commonly utilize the NPI as a program identifier. The Department is required to utilize the NPI as a program identifier when electronically transmitting health information in connection with HIPAA standard transactions and also uses the NPI as a program identifier in communications with federal administrative entities.

- The "Name of Legal Entity" section instructs the applicant to provide the legal name of the entity. This information is necessary for the Department to identify who is applying for licensure.

- The "Name of Narcotic Treatment Program" section instructs the applicant to provide the name of the NTP if it is different from the name of the legal entity. This information is necessary for the Department to correlate the legal name with the business name of the NTP.

- The "Facility Street Address" section instructs the applicant to list the exact physical address of the NTP location including room, suite, unit number, city, county and zip code of the actual location where services are rendered. The physical street address is necessary in order for the Department to conduct site reviews and determine whether the applicant meets established requirements pursuant to Section 10030.

- The “Mailing Address” section instructs the applicant to list the mailing address if different from the facility street address of the NTP. The mailing address, including room, suite, unit number, city, county and zip code, is necessary in order for the Department to mail pertinent information to the applicant and to maintain current files.

Section B, Guarantor Selection

- The “Guarantor Selection” section instructs the applicant to check the applicable box. The options are, “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),” and “Treatment will be provided through the transfer of patients to another program. CCR, Title 9, §10095(b)(1)(B).” This information informs the Department of how the guarantor intends to continue providing maintenance treatment to program participants should the NTP decide to close, which is necessary to ensure continuity of care.

Section C, Guarantor Information

- The “Name of Guarantor” section instructs the applicant to enter the name of the guarantor. This information is required pursuant to Section 10095(b)(2) and is necessary to confirm the identity of the guarantor.

- The “Mailing Address” section instructs the applicant to list the mailing address of the guarantor, including room, suite, unit number, city, county and zip code. The mailing address of the guarantor is necessary in order for the Department to mail pertinent information to the guarantor and to maintain current files.

- The “Telephone Number” section instructs the applicant to enter the telephone number and if applicable, the extension number of the guarantor. This information is necessary in order for the Department to contact the guarantor by phone and to maintain current files.

- The “Fax Number” section instructs the applicant to provide the fax number for the guarantor. This information is necessary in order for the Department to communicate with the guarantor via fax and to maintain current files.

Section D, Guarantor Program Information

- The “License Number” section instructs the applicant to enter the license number of the NTP that will guarantee that maintenance treatment will continue to be provided through the transfer of patients to the NTP location. This information is necessary to ensure that patients are transferred to a currently licensed program that has the capacity to accept new patients.

- The “National Provider Identifier (NPI)” section instructs the applicant to enter their assigned NPI. Section 162.410 of the CFR, Title 45, Part 162, requires all covered healthcare providers to obtain NPI numbers. Federal entities overseeing

the operation of NTPs commonly utilize the NPI as a program identifier. The Department is required to utilize the NPI as a program identifier when electronically transmitting health information in connection with HIPAA standard transactions and also uses the NPI as a program identifier in communications with federal administrative entities.

- The “Name of Legal Entity” section instructs the applicant to provide the legal name of the entity acting as guarantor. This information is necessary for the Department to identify the NTP that is accepting responsibility as the guarantor.

- The “Name of Narcotic Treatment Program” section instructs the applicant to provide the name of the NTP acting as guarantor if it is different from the name of the legal entity acting as guarantor. This information is necessary for the Department to correlate the legal name with the business name of the NTP acting as guarantor.

- The “Facility Street Address” section instructs the applicant to list the physical address of the NTP location including room, suite, unit number, city, county and zip code of the actual location where services will be rendered by the NTP acting as guarantor. The physical street address is necessary in order for the Department to conduct site reviews and determine whether the NTP acting as guarantor meets established requirements pursuant to Section 10030.

- The “Mailing Address” section instructs the applicant to list the mailing address of the NTP acting as guarantor, including room, suite, unit number, city, county and zip code. The mailing address of the guarantor is necessary in order for the Department to mail pertinent information to the guarantor and to maintain current files.

- The “Telephone Number” section instructs the applicant to enter the telephone number and if applicable, the extension number of the individual at the NTP acting as guarantor. This information is necessary in order for the Department to contact the individual at the NTP acting as guarantor by phone and to maintain current files.

- The “Fax Number” section instructs the applicant to provide the fax number for the NTP acting as guarantor. This information is necessary in order for the Department to communicate with the individual at the NTP acting as guarantor via fax and to maintain current files.

<u>Section E, Declaration</u>
This section is necessary and required pursuant to Sections 10030 and 10095 to ensure that the authorized individual signing the Guarantor Agreement form DHCS 5020 (04/16) is aware of and acknowledges the requirements and stipulations within this form.

The Declaration section instructs the applicant to attest to the following:

> 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.
>
> There is an additional line reading “I declare that I have the authority to legally bind the NTP.” This line delineates the portion of Section E to be completed by the NTP using this form to enter into an agreement with a guarantor.

This section provides the following information:

- The “Print Name” section instructs the applicant to print the name of the legal representative of the NTP. This information is needed to confirm the identity of the individual signing the document and to ensure that the individual is authorized to sign on behalf of the NTP pursuant to Section 10030.

- The “Title” section is pre-filled by the Department with the title “Program Sponsor.” This information is necessary to specify the individual that is authorized to sign the form.

- The “Signature” section instructs the applicant to provide an original signature of the Program Sponsor. This information is necessary to ensure that the authorized individual signing the application is aware of and acknowledges the requirements and stipulations within this application.

- The “Date” section instructs the applicant to enter the date the application is signed by the Program Sponsor. This field is standard information that is requested across all Department applications and assists the Department in determining when the application was completed.

  There is an additional line reading “I declare that I have the authority to legally bind the guarantor.” This line delineates the portion of Section E to be completed by the guarantor using this form to enter into an agreement with an NTP.

- The “Print Name” section instructs the applicant to print the name of the legal representative of the guarantor who will sign this agreement. This information is needed to confirm the identity of the individual signing the document and to ensure that the individual is authorized to sign on behalf of the guarantor pursuant to Section 10030.

- The “Title” section is pre-filled by the Department with the title “Legal Representative.” This information is necessary to specify the individual that is authorized to sign the form.

- The “Signature” section instructs the applicant to provide an original signature of the Legal Representative of the Guarantor. This information is necessary to ensure that the authorized individual signing the application is aware of and acknowledges the requirements and stipulations within this application.

- The “Date” section instructs the applicant to enter the date the application is signed by the Legal Representative of the Guarantor. This field is standard information that is requested across all Department applications and assists the Department in determining when the application was completed.

Privacy Statement

A privacy statement is adopted in order to comply with Civil Code Section 1798.17. The privacy statement is included on each form that is incorporated by reference through this regulatory action. This privacy statement is necessary to inform the applicant that all information requested is mandatory and includes references to the bodies of law that authorize NTPs. The Department gives its due diligence by advising the applicant of the consequences of not providing the required information. This privacy statement also advises the applicant that information may be shared with additional entities, as required or permitted by law. Lastly, the applicant is given the Narcotic Treatment Programs Section’s telephone number for more information or to access records.

Facility and Geographical Area Form DHCS 5025 (04/16)

The Department proposes to amend Section 10020(b)(1) to incorporate the Facility and Geographical Area form DHCS 5025 (04/16) by reference. This form is incorporated by reference because it would be too cumbersome to print it directly in the CCR. The NTP forms are made available on the Department’s internet website at http://www.dhcs.ca.gov/individuals/Pages/NTP-Applications-and-Forms-.aspx.

The adoption of this form is necessary for the Department to ensure that the facility provides appropriate physical treatment space and availability for patient services. The Department also uses the form to assess the distance of the medication unit from the primary NTP to ensure that patients have access to the services provided at the primary NTP. The Facility and Geographical Area form DHCS 5025 (04/16) shall be submitted as follows:

- With a supplemental written protocol, as part of an application package to add a medication unit to the primary NTP license, in accordance with Section 10020.

- With a supplemental written protocol, as part of an application to add an OBNTN to the primary NTP license, in accordance with Section 10021.

- With a written protocol, as part of an application package for licensure of a narcotic treatment program, in accordance with Section 10030.

- With a written protocol, as part of an application package for relocation of a narcotic treatment program outside of its current county, in accordance with Section 10037.

The following standardized information is included in the header and footer portions of each form that is incorporated by reference throughout this regulatory action.

Header

- The name of the State, Agency, Department, and program. This information is necessary to identify the entity responsible for the form.

- The mailing address for the Department's Narcotic Treatment Program. This information is necessary for the applicant to submit the form and/or any additional required protocols or information to the correct address.

Footer

- The form number and revision date. This information is necessary for the applicant to identify the correct type and version of a form.

- The page number formatted to show the current page number and the total number of pages of the form. This information is necessary for the applicant to ensure that all pages are completed and included with submission.

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

The instructions that accompany this form are necessary to provide supporting guidance to the applicant on how to correctly fill out and submit the form. The instructions highlight the type of information that must be included in order for the form to be considered complete and accurate and to ensure the integrity of the form. The directive to read all of the instructions on the form is included as a reminder for the applicant. A cross reference to the location in the CCR that includes the requirements and standards for the Narcotic Treatment Programs is included for the applicant's convenience.

The instructions also provide additional information to support a clear understanding of the requirement of each field on the form and the submission of correct information including:

- The definitions of specific terms that are referenced in the form, specifically for Narcotic Treatment Program (NTP), Medication Unit (MU) and Office-Based Narcotic Treatment Network (OBNTN).

- Instructions to submit a copy of the county filing if operating the business under a fictitious name.

- Cross references to additional information including links to the CMS National Plan and Provider Enumeration System for information on NPIs, the California Secretary of State for information on legal entities, and the United States Postal Service for information on how to obtain the exact zip code for the mailing address or physical address of a facility.

- Examples on how the form should be completed when listing the days and hours of medication dispensing and other NTP services, as well as examples of what are considered other NTP services.

- A description of what is included in the: Written Statement Explaining Geographical Area and Facility, Facility Diagram, Narrative of Patient Flow, and Written Statement Explaining Facility Population Demographics.

FACILITY AND GEOGRAPHICAL AREA FORM DHCS 5025 (04/16)

Section A, Facility Type

- The “Facility Type” section instructs the applicant to check the appropriate box for the following facility types: “Narcotic Treatment Program,” “Medication Unit,” (MU) or “Office-Based Narcotic Treatment Network” (OBNTN). This field is necessary to identify the specific type of facility in which the staff work.

Section B, Applicant Information

The “Applicant Information” section instructs the applicant to supply pertinent information regarding the applicant. This information is necessary during the application process for identification and verification purposes and includes the following:

- The “License Number” section instructs the applicant to enter their license number, or to enter N/A if not applicable. This information is necessary to inform the Department if the applicant is already a licensed NTP.

- The “National Provider Identifier (NPI)” section instructs the applicant to enter their assigned NPI. Section 162.410 of the CFR, Title 45, Part 162, requires all covered healthcare providers to obtain NPI numbers. Federal entities overseeing the operation of NTPs commonly utilize the NPI as a program identifier. The Department is required to utilize the NPI as a program identifier when electronically transmitting health information in connection with HIPAA standard transactions and also uses the NPI as a program identifier in communications with federal administrative entities.

- The “Name of NTP, MU or OBNTN” section instructs the applicant to provide the name of the NTP, MU or OBNTN if it is different from the name of the legal entity. This information is necessary for the Department to correlate the legal name with the business name of the NTP, MU or OBNTN.

- The “Facility Street Address” section instructs the applicant to list the physical address of the NTP, MU or OBNTN location including room, suite, unit number, city, county and zip code of the actual location where services will be rendered by the NTP, MU or OBNTN. The facility street address is necessary in order for the Department to conduct site reviews and determine whether the NTP, MU or OBNTN meets established requirements pursuant to Section 10030.

- The “Mailing Address” section instructs the applicant to list the mailing address if different from the facility street address of the NTP, MU or OBNTN. The mailing address, including room, suite, unit number, city, county and zip code, is necessary in order for the Department to mail pertinent information to the NTP, MU or OBNTN and to maintain current files.

- The “List the Days and Hours of Medication Dispensing Services” section instructs the applicant to enter the schedule of hours, per day, that medication used in replacement narcotic therapy is dispensed at the facility. The Department uses the information to ensure hours of operation are adequate to service the licensed patient capacity. For monitoring purposes, the Department will verify the stated days and hours of operation.

- The “List the Days and Hours for other NTP services” section instructs the applicant to enter the schedule of hours, per day, that other NTP services are provided at the facility. This information is necessary to inform the Department the days and hours other treatment services are provided, to update the online NTP provider directory and schedule on-site inspections and interviews.

Section C, Required Documentation

- The applicant is instructed to check the box to indicate that the applicant has completed and attached a “Written Statement Explaining Geographical Area and Facility”, “Facility Diagram,” “Narrative of Patient Flow,” and “Written Statement Explaining Facility Population Demographics,” as required documentation for this form.

- The written statement explaining geographical area and facility requires a description of the geographical surrounding areas to be served by the program because this information establishes where access to services are needed and the populations that need the services. A description of the facility is required for verification of an adequate amount of space dedicated to provide narcotic treatment services. The facility address is necessary to verify the location of the facility. A description of the space devoted to the facility is necessary to ensure adequate space is dedicated for each component of narcotic treatment services. The Department must be aware if services other than narcotic treatment services are provided at the physical location of the facility to ensure patient confidentiality and security of medications. The geographic relationship between a MU or OBNTN to the primary NTP is necessary to ensure patients can access all required narcotic treatment services.

- Facility diagram is required to ensure that the facility can safely manage the licensed patient capacity and store medication in a manner that complies with federal requirements.

- Narrative of patient flow is necessary to determine if the facility can accommodate the requested patient capacity for initial licensure, capacity change, relocation or modification to the building. The narrative of patient flow shows how the facility plans to move a patient securely through the facility as the patient receives treatment. This is necessary to ensure the health, safety and confidentiality of patients and staff.

- The written statement explaining facility population demographics is required to establish the need for narcotic treatment services at the location where services will be provided. This information is also necessary for data collection by the Department to conduct studies and analyze population demographics. The approximate number of patients to be served and how they will participate in the primary NTP services is necessary to ensure patients have access to all required narcotic treatment services.

Privacy Statement
A privacy statement is adopted in order to comply with Civil Code Section 1798.17. The privacy statement is included on each form that is incorporated by reference through this regulatory action. This privacy statement is necessary to inform the applicant that all information requested is mandatory and includes references to the bodies of law that authorize NTPs. The Department gives its due diligence by advising the applicant of the consequences of not providing the required information. This privacy statement also advises the applicant that information may be shared with additional entities, as required or permitted by law. Lastly, the applicant is given the Narcotic Treatment Programs Section's telephone number for more information or to access records.

Staff Information Form DHCS 5026 (04/16)

The Department proposes to amend Section 10020 to incorporate the Staff Information form DHCS 5026 (04/16) by reference. This form is incorporated by reference because it would be too cumbersome to print it directly in the CCR. NTP forms are available on the Department's internet website http://www.dhcs.ca.gov/individuals/Pages/NTP-Applications-and-Forms-.aspx.

The adoption of this form is necessary for the Department to verify that program staff members hold appropriate licenses and/or certifications required for duties they will perform and that the program has sufficient staff to ensure the health and welfare of program participants. The Staff Information form DHCS 5026 (04/16) shall be submitted as follows:

- With a supplemental written protocol, as part of an application package to add a medication unit to the primary NTP license, in accordance with Section 10020.

- With a supplemental written protocol, as part of an application to add an OBNTN to the primary NTP license, in accordance with Section 10021.

- With a written protocol, as part of an application package for licensure of a narcotic treatment program, in accordance with Section 10030.

The following standardized information is included in the header and footer portions of each form that is incorporated by reference throughout this regulatory action.

Header

- The name of the State, Agency, Department, and program. This information is necessary to identify the entity responsible for the form.

- The mailing address for the Department's Narcotic Treatment Program. This information is necessary for the applicant to submit the form and/or any additional required protocols or information to the correct address.

Footer

- The form number and revision date. This information is necessary for the applicant to identify the correct type and version of a form.

- The page number formatted to show the current page number and the total number of pages of the form. This information is necessary for the applicant to ensure that all pages are completed and included with submission.

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

The instructions that accompany this form are necessary to provide supporting guidance to the applicant on how to correctly fill out and submit the form. The instructions highlight the type of information that must be included in order for the form to be considered complete and accurate and to ensure the integrity of the form. The directive to read all of the instructions on the form is included as a reminder for the applicant. A cross reference to the location in the CCR that includes the requirements and standards for the Narcotic Treatment Programs is included for the applicant's convenience.

The instructions also provide additional information to support a clear understanding of the requirement of each field on the form and the submission of correct information including:

- The definitions of specific terms that are referenced in the form, specifically for NTPs, MUs and OBNTNs.

- An example of how the form should be completed when a staff member performs more than one role (administration, medical, counseling) at the facility.

STAFF INFORMATION FORM DHCS 5026 (04/16)

Section A, Facility Type

- The "Facility Type" section instructs the applicant to check the appropriate box for the following facility types: "Narcotic Treatment Program," "Medication Unit," (MU) or "Office-Based Narcotic Treatment Network" (OBNTN). This field is necessary to identify the specific type of facility in which the staff work.

Section B, Staff Hours

- The staff hours for the "Administration" and "Medical" categories include these fields, which are necessary for the following reasons:
  - Name - To identify the staff person.
  - Function - To identify the type of work performed by the staff person.
  - License Number - To verify that the staff person holds the appropriate license that is required for that person's job functions.
  - Total hours per week – To verify that staff persons are working within maximum allowable hours.
  - Scheduled Hours (Monday through Sunday) - To verify that the facility has sufficient staff to ensure the health and welfare of program participants.

- The staff hours for the "Counseling" category includes these fields, which are necessary for the following reasons:
  - Name - To identify the staff person.
  - Certifying Organization/Licensing Body – To identify the entity that certified/licensed/registered the staff person.
  - License/Certification Number - To verify that the staff person holds the appropriate license/certification that is required for that person's job functions.
  - Registration Number – To verify with the certifying organizations if the counselor is registered, the valid dates of registration or if registration is suspended or revoked.
  - Caseload – To identify the number of program participants that are assigned to each staff person to ensure that the facility has sufficient staffing levels.
  - Total hours per week – To verify that staff persons are working within maximum allowable hours.
  - Scheduled Hours (Monday through Sunday) - To verify that the facility has sufficient staff to ensure the health and welfare of program participants.

Privacy Statement

A privacy statement is adopted in order to comply with Civil Code Section 1798.17. The privacy statement is included on each form that is incorporated by reference through this regulatory action. This privacy statement is necessary to inform the applicant that all

information requested is mandatory and includes references to the bodies of law that authorize NTPs. The Department gives its due diligence by advising the applicant of the consequences of not providing the required information. This privacy statement also advises the applicant that information may be shared with additional entities, as required or permitted by law. Lastly, the applicant is given the Narcotic Treatment Programs Section's telephone number for more information or to access records.

County Certification Form DHCS 5027 (04/16)

The Department proposes to amend Section 10030 to incorporate the County Certification form DHCS 5027 (04/16) by reference. This form is incorporated by reference because it would be too cumbersome to print it directly in the CCR. The NTP forms are made available on the Department's internet website at http://www.dhcs.ca.gov/individuals/Pages/NTP-Applications-and-Forms-.aspx.

The adoption of this form is necessary for the Department to ensure that the facility applying for an initial or a renewal of an NTP license or a relocation outside of its current county obtains a county certification. The applicant must obtain certification from the County Alcohol and Drug Program Administrator. The County Certification form DHCS 5027 (04/16) shall be submitted with a written protocol as part of an application for or renewal of an NTP license.

The following standardized information is included in the header and footer portions of each form that is incorporated by reference throughout this regulatory action.

Header

- The name of the State, Agency, Department, and program. This information is necessary to identify the entity responsible for the form.

- The mailing address for the Department's Narcotic Treatment Program. This information is necessary for the applicant to submit the form and/or any additional required protocols or information to the correct address.

Footer

- The form number and revision date. This information is necessary for the applicant to identify the correct type and version of a form.

- The page number formatted to show the current page number and the total number of pages of the form. This information is necessary for the applicant to ensure that all pages are completed and included with submission.

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

The instructions that accompany this form are necessary to provide supporting guidance to the applicant on how to correctly fill out and submit the form. The

instructions highlight the type of information that must be included in order for the form to be considered complete and accurate and to ensure the integrity of the form. The directive to read all of the instructions on the form is included as a reminder for the applicant. A cross reference to the location in the CCR that includes the requirements and standards for the Narcotic Treatment Programs is included for the applicant's convenience.

The instructions also provide additional information to support a clear understanding of the requirement of each field on the form and the submission of correct information including:

- Instructions to submit a copy of the county filing if operating the business under a fictitious name.

- Instructions that the "Type of Program Request" section must be completed by the applicant; and that the "County Information," "County Recommendation," and Declaration" sections must be completed by the County Alcohol and Drug Program Administrator.

- Cross references to additional information including links to the CMS National Plan and Provider Enumeration System for information on NPIs, the California Secretary of State for information on legal entities, and the United States Postal Service for information on how to obtain the exact zip code for the mailing address or physical address of a facility.

COUNTY CERTIFICATION FORM DHCS 5027 (04/16)

Section A, Program Information

The "Program Information" section instructs the applicant to supply pertinent information regarding the program. This information is necessary during the application process for identification and verification purposes and includes the following:

- The "License Number" section instructs the program to enter its license number, or to enter N/A if not applicable. This information is necessary to inform the Department if the applicant is already a licensed NTP.

- The "National Provider Identifier (NPI)" section instructs the program to enter their assigned NPI. Section 162.410 of the CFR, Title 45, Part 162, requires all covered healthcare providers to obtain NPI numbers. Federal entities overseeing the operation of NTPs commonly utilize the NPI as a program identifier. The Department is required to utilize the NPI as a program identifier when electronically transmitting health information in connection with HIPAA standard transactions and also uses the NPI as a program identifier in communications with federal administrative entities.

- The “Name of Legal Entity” section instructs the program to provide the legal name of the entity. This information is necessary for the Department and county to identify the NTP that is requesting county certification.

- The “Name of Narcotic Treatment Program” section instructs the program to provide the name of the NTP program if it is different from the name of the legal entity. This information is necessary for the Department to correlate the legal name with the business name of the NTP program requesting county certification.

- The “Facility Street Address” section instructs the program to list the physical address of the NTP program location including room, suite, unit number, city, county and zip code of the actual location where services will be rendered by the program. The facility street address is necessary in order for the Department to conduct site reviews and determine whether the NTP program meets established requirements pursuant to Section 10030.

- The “Mailing Address” section instructs the program to list the mailing address if different from the facility street address of the program. The mailing address, including room, suite, unit number, city, county and zip code, is necessary in order for the Department to mail pertinent information to the program and to maintain current files.

Section B, Type of Program Request

The “Type of Program Request” section instructs the applicant to check one box to specify which category applies: “Initial Application,” License Renewal,” or “Relocation.” For “Initial Application,” the program is required to provide a figure for proposed capacity and for “License Renewal,” the program is required to provide a figure for current licensed capacity. This information is necessary for the Department to identify what type of program request the applicant is applying for. Initial applicants are required to provide a figure of proposed capacity for fee purposes and to determine if the program will be adequately staffed. License Renewal applicants are required to provide a figure of current licensed capacity for the Department to ensure the program can still maintain the existing patient capacity.

Section C, Regulation Authority

The “Regulation Authority” section advises the applicant that a complete protocol must include a statement from the County Alcohol and Drug Program Administrator that certifies the need for NTP services in the community and that all local requirements have been met. This is consistent with the requirements of Section 10055(b) and is necessary to ensure that the NTP is capable of providing safe and appropriate care to patients.

The cross reference to Section 10040 Certification by County Alcohol and Drug Program Administrator is provided for the convenience of the program.

Section D, County Information

- The “County” section instructs the County Alcohol and Drug Program Administrator to provide the name of the county in which the NTP services are to be rendered. This information is necessary in order to determine whether the applicant meets requirements pursuant to Sections 10030 and 10040.

- The “Address” section instructs the County Alcohol and Drug Program Administrator to enter the business address of the County Alcohol and Drug Program Administrator. This information assists the Department to mail pertinent information to the County Alcohol and Drug Program Administrator.

- The “Telephone Number” section instructs the County Alcohol and Drug Program Administrator to provide the telephone number for the County Alcohol and Drug Program Administrator. This information is necessary in order for the Department to contact the County Alcohol and Drug Program Administrator during the review period to ask questions or remediate deficiencies.

- The “Fax Number” section instructs the County Alcohol and Drug Program Administrator to provide the fax number used for the County Alcohol and Drug Program Administrator. This information is necessary in order for the Department to contact the County Alcohol and Drug Program Administrator during the review period to ask questions or remediate deficiencies.

Section E, County Recommendation

This section instructs the County Alcohol and Drug Program Administrator to check the applicable box. The first box states that the county recommends the program’s initial licensure, renewal or relocation. The second box states that the county does not recommend initial program licensure, renewal or relocation. If the second box is checked the county must attach supporting documentation. Supporting documentation is necessary for the Department to determine if the denial of the program’s request is justified.

Section F, Declaration

This section is necessary and required pursuant to Sections 10030, 10040, 10045 and 10055 and to ensure that the authorized individual signing the County Certification form DHCS 5027 (04/16) is aware of and acknowledges the requirements and stipulations within this form.

The Declaration section instructs the representative to attest to the following:

> I declare that I am the County Alcohol and Drug Program Administrator responsible for issuing the county recommendation.

This section provides the following information:

- The “Print Name” section instructs the County Alcohol and Drug Program Administrator to print his/her name. This information is needed to confirm the identity of the individual signing the document.

- The “Title” section is pre-filled by the Department with the title “County Alcohol and Drug Program Administrator.” This information is necessary to specify the individual that is authorized to sign the form.

- The “Signature” section instructs the County Alcohol and Drug Program Administrator to provide an original signature. This information is necessary to ensure that the individual signing the application is authorized and aware of and acknowledges the requirements and stipulations within this form.

- The “Date” section instructs the applicant to enter the date the application is being signed. This field is standard information that is requested across all Department forms and assists the Department in determining when the form was completed.

Privacy Statement
A privacy statement is adopted in order to comply with Civil Code Section 1798.17. The privacy statement is included on each form that is incorporated by reference through this regulatory action. This privacy statement is necessary to inform the applicant that all information requested is mandatory and includes references to the bodies of law that authorize NTPs. The Department gives its due diligence by advising the applicant of the consequences of not providing the required information. This privacy statement also advises the applicant that information may be shared with additional entities, as required or permitted by law. Lastly, the applicant is given the Narcotic Treatment Programs Section’s telephone number for more information or to access records.

Organizational Responsibility Form DHCS 5031 (04/16)

The Department proposes to amend Section 10030 to incorporate the Organizational Responsibility form DHCS 5031 (04/16) by reference. This form is incorporated by reference because it would be too cumbersome to print it directly in the CCR. The NTP forms are made available on the Department’s internet website at http://www.dhcs.ca.gov/individuals/Pages/NTP-Applications-and-Forms-.aspx.

The adoption of this form is necessary for the Department to ensure that it has current and accurate information pertaining to the organizational responsibilities of the entity applying. The Organizational Responsibility form DHCS 5031 (04/16) shall be submitted with a written protocol, by the program sponsor, as part of an application package for licensure of an NTP.

The following standardized information is included in the header and footer portions of each form that is incorporated by reference throughout this regulatory action.

Header

- The name of the State, Agency, Department, and program. This information is necessary to identify the entity responsible for the form.

- The mailing address for the Department's Narcotic Treatment Program. This information is necessary for the applicant to submit the form and/or any additional required protocols or information to the correct address.

Footer

- The form number and revision date. This information is necessary for the applicant to identify the correct type and version of a form.

- The page number formatted to show the current page number and the total number of pages of the form. This information is necessary for the applicant to ensure that all pages are completed and included with submission.

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

The instructions that accompany this form are necessary to provide supporting guidance to the applicant on how to correctly fill out and submit the form. The instructions highlight the type of information that must be included in order for the form to be considered complete and accurate and to ensure the integrity of the form. The directive to read all of the instructions on the form is included as a reminder for the applicant. A cross reference to the location in the CCR that includes the requirements and standards for the Narcotic Treatment Programs is included for the applicant's convenience.

The instructions also provide additional information to support a clear understanding of the requirement of each field on the form and the submission of correct information including:

- Instructions to submit a copy of the county filing if operating the business under a fictitious name.

- Cross references to additional information including links to the California Secretary of State for information on legal entities, and the United States Postal Service for information on how to obtain the exact zip code for the physical address of a facility.

ORGANIZATIONAL RESPONSIBILITY FORM DHCS 5031 (04/16)

Section A, Type of Organization

- The "Tax Status" section instructs the applicant to check the applicable box indicating the tax status of the applicant's entity. This information is necessary to inform the Department of the applicant's legal business structure.

Section B, Organizational Information

The “Organizational Information” section instructs the applicant to supply pertinent information regarding the organization. This information is necessary during the application process for identification and verification purposes and includes the following:

- The “License Number” section instructs the applicant to enter their license number, or to enter N/A if not applicable. This information is necessary for the Department to identify the organization and to determine if the applicant is already licensed.

- The “Federal Tax ID Number” section instructs the applicant to enter the tax identification number assigned to the organization. This information is necessary for the Department to be able to verify the type of organization as filed with the Internal Revenue Service.

- The “Name of Organization” section instructs the applicant to enter the name of the entity. This information is necessary for the Department to identify the entity submitting the requested organizational information.

- The “Facility Street Address” section instructs the applicant to list the exact physical address of the NTP location including room, suite, unit number, city, county and zip code of the actual location where services are rendered. The physical street address is necessary in order for the Department to conduct site reviews and determine whether the applicant meets established requirements pursuant to Section 10030.

Section C, Individual Information

The “Individual Information” section instructs the applicant to supply pertinent information regarding individuals who are considered a partner, officer, director or 10 percent or greater shareholder of the organization. This information is necessary during the application process for identification and verification purposes.

This section specifically instructs the applicant to enter the name, title, address and telephone number of individuals who are considered a partner, officer, director or 10 percent or greater shareholder of the organization. If applicable, the applicant is instructed to provide the percentage of the organization owned by the partner, officer, director or 10 percent or greater shareholder if it is a for-profit organization. For a non-profit organization, the applicant is instructed to enter the dates that the term of the partner, officer, director or 10 percent or greater shareholder of the organization began and will expire. This information is necessary for the Department to identify the individual(s) who assume responsibility of the facility.

Section D, Declaration

This section is necessary and required pursuant to Sections 10030 and 10055 to ensure that the Program Sponsor signing the Organizational Responsibility form DHCS 5031 (04/16) is aware of and acknowledges the requirements and stipulations within this form.

The Declaration section instructs the applicant to attest to the following:

> 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.

This section provides the following information:

- The “Print Name” section instructs the Program Sponsor to print his/her name. This information is needed to confirm the identity of the individual signing the document and to ensure that the individual is authorized to sign.

- The “Title” section is pre-filled by the Department with the title Program Sponsor. This information is necessary to specify the individual that is authorized to sign the form.

- The “Signature” section instructs the Program Sponsor to provide an original signature. This information is necessary to ensure that the individual signing the application is authorized and aware of and acknowledges the requirements and stipulations within this form.

- The “Date” section instructs the Program Sponsor to enter the date the form is being signed. This field is standard information that is requested across all department applications and assists the Department in determining when the application was completed.

Privacy Statement

A privacy statement is adopted in order to comply with Civil Code Section 1798.17. The privacy statement is included on each form that is incorporated by reference through this regulatory action. This privacy statement is necessary to inform the applicant that all information requested is mandatory and includes references to the bodies of law that authorize NTPs. The Department gives its due diligence by advising the applicant of the consequences of not providing the required information. This privacy statement also advises the applicant that information may be shared with additional entities, as required or permitted by law. Lastly, the applicant is given the Narcotic Treatment Programs Section’s telephone number for more information or to access records

Patient Death Report, DHCS 5048 (04/16)

The Department proposes to amend Section 10195 to incorporate the Patient Death Report form DHCS 5048 (04/16) by reference. This form is incorporated by reference because it would be too cumbersome to print it directly in the CCR. NTP forms are available on the Department's internet website http://www.dhcs.ca.gov/individuals/Pages/NTP-Applications-and-Forms-.aspx.

The adoption of this form is required as part of a report to be submitted to the Narcotic Treatment Programs Unit by the Program Physician pursuant to CCR, Title 9 Section 10195. The Patient Death Report form DHCS 5048 (04/16) shall be submitted to inform the Department of patient deaths occurring at the program site and deaths caused by ingestion of medication provided by the program.

The following standardized information is included in the header and footer portions of each form that is incorporated by reference throughout this regulatory action.

Header

- The name of the State, Agency, Department, and program. This information is necessary to identify the entity responsible for the form.

- The mailing address for the Department's Narcotic Treatment Program. This information is necessary for the program to submit the form and/or any additional required protocols or information to the correct address.

Footer

- The form number and revision date. This information is necessary for the program to identify the correct type and version of a form.

- The page number formatted to show the current page number and the total number of pages of the form. This information is necessary for the program to ensure that all pages are completed and included with submission.

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

The instructions that accompany this form are necessary to provide supporting guidance to the program on how to correctly fill out and submit the form. The instructions highlight the type of information that must be included in order for the form to be considered complete and accurate and to ensure the integrity of the form. The directive to read all of the instructions on the form is included as a reminder for the program. A cross reference to the location in the CCR that includes the requirements and standards for the Narcotic Treatment Programs is included for the program's convenience.

The instructions also provide additional information to support a clear understanding of the requirement of each field on the form and the submission of correct information including:

- Cross references to additional information including links to the CMS National Plan and Provider Enumeration System for information on NPIs, the California Secretary of State for information on legal entities, and the United States Postal Service for information on how to obtain the exact zip code for the mailing address or physical address of a facility.

PATIENT DEATH REPORT FORM DHCS 5048 (04/16)

Section A, Regulation Authority

The "Regulation Authority" section notifies the program of the reporting requirements related to a patient's death, as specified under Title 9, CCR Section 10195, which requires the program to notify the Department within one (1) working day 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 90 calendar days for all other patient's death. This cross reference to Section 10195 is provided for the convenience of the program and so the program has easy access to this relevant information. The address, e-mail and fax where this form shall be submitted and a note that the facility should contact the Department to confirm receipt is also included to ensure that the program has the information necessary to submit this form accurately and timely and to confirm its receipt.

Section B, Program Information

The "Program Information" section instructs the program to supply pertinent information regarding the program. This information is necessary for identification and verification purposes and includes the following:

- The "License Number" section instructs the program to enter their license number of the program. This information is necessary for the Department to identify the program.

- The "National Provider Identifier (NPI)" section instructs the program to enter their assigned NPI. Section 162.410 of the CFR, Title 45, Part 162, requires all covered healthcare providers to obtain NPI numbers. Federal entities overseeing the operation of NTPs commonly utilize the NPI as a program identifier. The Department is required to utilize the NPI as a program identifier when electronically transmitting health information in connection with HIPAA standard transactions and also uses the NPI as a program identifier in communications with federal administrative entities.

- The "Name of Legal Entity" section instructs the program to provide the legal name of the entity. This information is necessary for the Department to identify the program that is filing this form.

- The “Name of Narcotic Treatment Program” section instructs the program to provide the name of the NTP if it is different from legal entity name. This information is necessary for the Department to correlate the legal name with the business name of the program filing this form.

- The “Facility Street Address” section instructs the program to list the physical address of the facility location including room, suite, unit number, city, county and zip code of the actual location where services are rendered by the program. The facility street address is necessary in order for the Department to conduct site reviews.

- The “Mailing Address” section instructs the program to list the mailing address if different from the facility street address of the program. The mailing address, including room, suite, unit number, city, county and zip code, is necessary in order for the Department to mail pertinent information to the program and to maintain current files.

- The “Telephone Number” section instructs the program to list the telephone number, including an extension if applicable. The telephone number is necessary to assist the Department during the investigation of the patient death process when clarification is needed.

- The “Fax Number” section instructs the program to list the fax number. This information is necessary to assist the Department during the investigation of the patient death process when clarification is needed.

Section C, Patient Information

The “Patient Information” section instructs the program to supply pertinent information regarding the deceased patient. This information is necessary during the investigation process for identification and verification purposes and includes the following:

- The “Name” section instructs the program to provide the first and last name of the patient. This information is needed in order for the Department to identify the deceased patient and to ensure that the report is accurate and consistent with information in the patient’s records.

- The “Patient Record Number” section instructs the program to enter the record number assigned to the patient. This information is necessary so the Department’s death investigation and report are accurate and consistent with information in patient’s records.

- The “Gender” section instructs the program to enter the gender of the deceased patient. This information is reviewed as part of the investigation and is necessary so the Department’s report has accurate information that is consistent with information in the patient’s records.

- The “Dose level” section instructs the program to enter the medication dose level at the patient’s time of death. This information is reviewed as part of the investigation and is necessary so the Department’s report has accurate information that is consistent with information in the patient’s records.

- The “Take-home status” section instructs the program to enter the patient’s take-home status at the time of the patient’s death. This information is reviewed as part of the investigation and is necessary so the Department’s report has accurate information that is consistent with information in the patient’s records.

- The “Date of Patient Death” section instructs the program to enter the date of the patient’s death. This information is reviewed as part of the investigation and is necessary so the Department’s report has accurate information that is consistent with information in the patient’s records.

- The “Age of Patient at Death” section instructs the program to enter the age of the patient at death. This information is reviewed as part of the investigation and is necessary so the Department’s report has accurate information that is consistent with information in the patient’s records.

- The “Date Death Information was received by Program” section instructs the program to enter the date the program received the information that the patient had died. This information is reviewed as part of the investigation and is necessary so the Department’s report has accurate information that is consistent with information in the patient’s records.

- The “Cause of Death” section instructs the program to provide details on the circumstances surrounding the patient’s death. This information is reviewed as part of the investigation and is necessary so the Department’s report has accurate information that is consistent with information in patient’s records.

<u>Section D, Declaration</u>
This section is necessary and required pursuant to Section 10195 to ensure that the individual authorized to represent the program and sign the Patient Death Report form DHCS 5048 (04/16) is aware of and acknowledges the requirements and stipulations within this form.

The Declaration section instructs the representative to attest to the following:

> “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.”

This section provides the following information:

- The “Print Name” section instructs the authorized program representative to print his/her name. This information is needed to confirm the identity of the individual signing the document.

- The “Title” section instructs the authorized program representative to enter his or her title. This information is necessary for the Department to ensure that the individual signing is an authorized individual.

- The “Signature” section instructs the authorized program representative to provide an original signature. This information is necessary to ensure that the individual signing the application is authorized and aware of and acknowledges the requirements and stipulations within this form.

- The “Date” section instructs the authorized program representative to enter the date the form is being signed. This field is standard information that is requested across all Department applications and assists the Department in determining when the form was completed.

Privacy Statement
A privacy statement is adopted in order to comply with Civil Code Section 1798.17. The privacy statement is included on each form that is incorporated by reference through this regulatory action. This privacy statement is necessary to inform the applicant that all information requested is mandatory and includes references to the bodies of law that authorize NTPs. The Department gives its due diligence by advising the applicant of the consequences of not providing the required information. This privacy statement also advises the applicant that information may be shared with additional entities, as required or permitted by law. Lastly, the applicant is given the Narcotic Treatment Programs Section’s telephone number for more information or to access records.

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

The Department proposes to amend Section 10020 to incorporate the Affiliated and Associated Acknowledgment form DHCS 5134 (04/16) by reference. This form is incorporated by reference because it would be too cumbersome to print it directly in the CCR. The NTP forms are made available on the Department’s internet website at http://www.dhcs.ca.gov/individuals/Pages/NTP-Applications-and-Forms-.aspx.

The adoption of this form is necessary for the Department to ensure that an agreement exists between the primary NTP and the Office-Based Narcotic Treatment Network (OBNTN) or the Medication Unit (MU). This form will also be used to account for services being provided by the OBNTN or MU. In addition to the supplemental protocol and Initial Application Coversheet form DHCS 5014 (04/16), the primary NTP must submit the Affiliated and Associated Acknowledgment form DHCS 5134 (04/16), as part of a request to add an OBNTN or MU to the primary NTP.

The following standardized information is included in the header and footer portions of each form that is incorporated by reference throughout this regulatory action.

Header

- The name of the State, Agency, Department, and program. This information is necessary to identify the entity responsible for the form.

- The mailing address for the Department's Narcotic Treatment Program. This information is necessary for the applicant to submit the form and/or any additional required protocols or information to the correct address.

Footer

- The form number and revision date. This information is necessary for the applicant to identify the correct type and version of a form.

- The page number formatted to show the current page number and the total number of pages of the form. This information is necessary for the applicant to ensure that all pages are completed and included with submission.

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

The instructions that accompany this form are necessary to provide supporting guidance to the applicant on how to correctly fill out and submit the form. The instructions highlight the type of information that must be included in order for the form to be considered complete and accurate and to ensure the integrity of the form. The directive to read all of the instructions on the form is included as a reminder for the applicant. A cross reference to the location in the CCR that includes the requirements and standards for the Narcotic Treatment Programs is included for the applicant's convenience.

The instructions also provide additional information to support a clear understanding of the requirement of each field on the form and the submission of correct information including:

- Instructions to submit a copy of the county filing if operating the business under a fictitious name.

- Cross references to additional information including links to the CMS National Plan and Provider Enumeration System for information on NPIs, the California Secretary of State for information on legal entities, and the United States Postal Service for information on how to obtain the exact zip code for the mailing address or physical address of a facility.

AFFILIATED AND ASSOCIATED ACKNOWLEDGMENT FORM DHCS 5134 (04/16)

Section A, Narcotic Treatment Program (NTP) Information

The "Narcotic Treatment Program (NTP) Information" section instructs the applicant to supply pertinent information regarding the NTP. This information is necessary during the application process for identification and verification purposes and includes the following:

- The "License Number" section instructs the applicant to enter their license number. This information is necessary for the Department to identify the NTP.

- The "National Provider Identifier (NPI)" section instructs the applicant to enter their assigned NPI. Section 162.410 of the CFR, Title 45, Part 162, requires all covered healthcare providers to obtain NPI numbers. Federal entities overseeing the operation of NTPs commonly utilize the NPI as a program identifier. The Department is required to utilize the NPI as a program identifier when electronically transmitting health information in connection with HIPAA standard transactions and also uses the NPI as a program identifier in communications with federal administrative entities.

- The "Name of Legal Entity" section instructs the applicant to provide the legal name of the entity. This information is necessary for the Department to identify the NTP that is filing this form.

- The "Name of NTP" section instructs the applicant to provide the name of the NTP if it is different from the name of the legal entity. This information is necessary for the Department to correlate the legal name with the business name of the program filing this form.

- The "Facility Street Address" section instructs the applicant to list the physical address of the facility location including room, suite, unit number, city, county and zip code of the actual location where services are rendered by the NTP. The physical street address is necessary in order for the Department to conduct site reviews and determine whether the applicant meets established requirements pursuant to Sections 10020 and 10021.

- The "Mailing Address" section instructs the applicant to list the mailing address of the NTP, including room, suite, unit number, city, county and zip code. The mailing address of the NTP is necessary in order for the Department to mail pertinent information to the NTP and to maintain current files.

- The "Telephone Number" section instructs the applicant to enter the telephone number and if applicable, the extension number of the NTP's contact person. This information is necessary to assist the Department during the application review process when clarification is needed and to maintain current files.

- The “Fax Number” section instructs the applicant to list the fax number for the NTP facility. This will assist the Department in being able to contact the applicant for clarification or remediation’s that can be done via fax and to maintain current files.

Section B, Office-Based Narcotic Treatment Network (OBNTN) / Medication Unit (MU) Information

The “Office-Based Narcotic Treatment Network (OBNTN) / Medication Unit (MU) Information” section instructs the applicant to supply pertinent information regarding the OBNTN or MU. This information is necessary during the application process for identification and verification purposes and includes the following:

- The “Name of Provider” section instructs the applicant to enter the name of the provider that will be affiliated and associated with the primary NTP. This information is necessary to confirm whom the provider agreement is between.

- The “Professional License or Certification Number” section instructs the applicant to list the professional license or certification number of the provider if applicable. This information is necessary to verify that the staff person holds the appropriate certification/license that is required for that person’s job functions.

- The “NPI” section instructs the applicant to enter the assigned NPI of the OBNTN or MU. NPI numbers are required for all healthcare providers pursuant Section 162.410 of the CFR, Title 45, Part 162. This information is necessary because an NPI must be used in place of other provider or organization identifiers for the electronic transmission of health information in connection with HIPAA standard transactions.

- The “Facility Street Address” section instructs the applicant to list the exact physical address of the OBNTN or MU location including room, suite, unit number, city, county, zip code, of the actual location where services are rendered. The physical street address is necessary in order for the Department to conduct a site visit to determine whether the applicant meets established requirements pursuant to Sections 10020 and 10021.

- The “Telephone Number” section instructs the applicant to enter the telephone number and if applicable, the extension number of the OBNTN or MU’s contact person. This information is necessary in order for the Department to contact the applicant by phone with any questions and to maintain current files.

- The “Fax Number” section instructs the applicant to provide the fax number for the OBNTN or MU. This information is necessary for the Department to contact the applicant for clarification or remediation that can be done via fax and to maintain current files.

- The “Describe Services” section instructs the applicant to provide a description of the services that the provider affiliated and associated with the primary NTP will offer. The applicant is further instructed to attach additional pages to the form if necessary. This information is necessary to inform the Department of the type of treatment services the affiliated and associated provider will provide.

Section C, Acknowledgment of Agreement

The “Acknowledgment of Agreement” section is adopted to notify the applicant that this section must be read and agreed to by both the primary NTP and the OBNTN or MU. This is necessary because the provider must understand that it operates under the authority of the primary NTP license; the provider is not issued a separate license from the Department. The provider is required to adhere to the protocol of the primary NTP and the supplemental written protocol as approved by the Department. Since the provider is not issued a separate license it is necessary to include an explicit prohibition against providing services in the event that the primary NTP license is suspended or revoked. The requirement of notice is necessary to ensure that the Department receives notification of a provider’s intention to discontinue services at least 30 days prior to cessation of services. The effective date of the Affiliated and Associated Acknowledgment form DHCS 5134 (04/16) is the date the Department approves the supplemental written protocol. This is necessary as provider services cannot be rendered unless and until the Department approves the supplemental written protocol. The agreement remains in effect until a license is revoked or expires, or the provider gives notice of discontinued services.

Section D, Declaration

This information is necessary to ensure that the authorized individuals signing this form are aware of and acknowledge the requirements and stipulations within this form.

The Declaration section instructs the applicant to attest to the following:

> 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.

There is an additional line reading, “I declare I have the authority to legally bind the NTP.” This line delineates the portion of Section D to be completed by the NTP’s Program Sponsor.

This section provides the following information:

- The “Print Name” section instructs the Program Sponsor to print their name. This information is needed to confirm the identity of the individual signing the document and to ensure that the individual is authorized to sign on behalf of the NTP pursuant to Section 10000(a)(29).

- The “Title” section is pre-filled by the Department with the title Program Sponsor. This information is necessary to specify the individual that is authorized to sign the form.

- The “Signature” section instructs the Program Sponsor to provide an original signature. This information is necessary to ensure that the individual signing the application is authorized and aware of and acknowledges the requirements and stipulations within this form.

- The “Date” section instructs the Program Sponsor to enter the date that the form is being signed. This field is standard information that is requested across all Department applications and assists the Department in determining when the form was completed.

There is an additional line reading, “I declare I have the authority to legally bind the Provider.” This line delineates the portion of Section D to be completed by the Provider’s Legal Representative.

- The “Print Name” section instructs the OBNTN or MU’s legal representative to print their name. This information is needed to confirm the identity of the individual signing and to ensure the individual is authorized to sign on behalf of the Provider.

- The “Title” section is pre-filled by the Department with the title Legal Representative. This information is necessary to specify the individual that is authorized to sign the form.

- The “Signature” section instructs the OBNTN or MU’s legal representative to provide an original signature. This information is necessary to ensure that the provider’s legal representative is aware of and acknowledges the requirements and stipulations within this form.

- The “Date” section instructs the applicant to enter the date the application is signed by the legal representative for the provider. This field is standard information that is requested across all Department applications and assists the Department in determining when the application was completed.

Privacy Statement

A privacy statement is adopted in order to comply with Civil Code Section 1798.17. The privacy statement is included on each form that is incorporated by reference through this regulatory action. This privacy statement is necessary to inform the applicant that all information requested is mandatory and includes references to the bodies of law that authorize NTPs. The Department gives its due diligence by advising the applicant of the consequences of not providing the required information. This privacy statement also advises the applicant that information may be shared with additional entities, as

required or permitted by law. Lastly, the applicant is given the Narcotic Treatment Programs Section's telephone number for more information or to access records.

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

The Department proposes to amend Section 10035 to incorporate the Application for Protocol Amendment form DHCS 5135 (04/16) by reference. This form is incorporated by reference because it would be too cumbersome to print it directly in the CCR. The NTP forms are made available on the Department's internet website at http://www.dhcs.ca.gov/individuals/Pages/NTP-Applications-and-Forms-.aspx.

The adoption of this form is necessary to set forth the requirements for protocol amendments and changes. This form specifies what changes require prior approval from the Department and how to submit this information. The Department shall receive the Application for Protocol Amendment form DHCS 5135 (04/16), from the Program Sponsor, anytime there's a change in the original protocol or written supplemental protocol.

The following standardized information is included in the header and footer portions of each form that is incorporated by reference throughout this regulatory action.

Header

- The name of the State Agency, Department, and program. This information is necessary to identify the entity responsible for the form.

- The mailing address for the Department's Narcotic Treatment Program. This information is necessary for the applicant to submit the form and/or any additional required protocols or information to the correct address.

Footer

- The form number and revision date. This information is necessary for the applicant to identify the correct type and version of a form.

- The page number formatted to show the current page number and the total number of pages of the form. This information is necessary for the applicant to ensure that all pages are completed and included with submission.

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

The instructions that accompany this form are necessary to provide supporting guidance to the applicant on how to correctly fill out and submit the form. The instructions highlight the type of information that must be included in order for the form to be considered complete and accurate and to ensure the integrity of the form. The directive to read all of the instructions on the form is included as a reminder for the applicant. A cross reference to the location in the CCR that includes the requirements

and standards for the Narcotic Treatment Programs is included for the applicant's convenience.

The instructions also provide additional information to support a clear understanding of the requirement of each field on the form and the submission of correct information including:

- A cross reference to Section 10085 of the CCR that includes related regulatory provisions.
- Cross references to additional information including links to the CMS National Plan and Provider Enumeration System for information on NPIs, the California Secretary of State for information on legal entities, and the United States Postal Service for information on how to obtain the exact zip code for the mailing address or physical address of a facility.
- Instructions to submit a copy of the county filing if operating the business under a fictitious name.
- Instructions that additional documentation and forms may be required if there's a change in an NTP's program sponsor, change of individual or change in hours of operation.

APPLICATION FOR PROTOCOL AMENDMENT FORM DHCS 5135 (04/16)

Section A, Facility Type

- The "Facility Type" section instructs the applicant to check the appropriate box for the following facility types; "Narcotic Treatment Program," "Medication Unit," or "Office-Based Narcotic Treatment Network." This adoption is necessary for compliance with Sections 10030, 10020, and 10021. This information is necessary for the Department to identify the type of facility or provider the protocol amendment is being requested for and to verify against existing Department records.

Section B, Type of Amendment

- The "Type of Amendment" section instructs the applicant to check the appropriate box(es) and complete the corresponding sections for the protocol amendment(s) or changes they are applying for. This section is necessary so the Department knows the specific area of the protocol being amended/changed and if additional documentation or a site visit is necessary.

Section C, Existing Licensee Information

The "Existing Licensee Information" section instructs the applicant to supply pertinent information regarding the applicant. This information is necessary during the application process for identification and verification purposes and includes the following:

- The "License Number" section instructs the applicant to enter their license number. This information is necessary to verify that the applicant is already a licensed NTP.

- The “National Provider Identifier (NPI)” section instructs the applicant to enter their assigned NPI. Section 162.410 of the CFR, Title 45, Part 162, requires all covered healthcare providers to obtain NPI numbers. Federal entities overseeing the operation of NTPs commonly utilize the NPI as a program identifier. The Department is required to utilize the NPI as a program identifier when electronically transmitting health information in connection with HIPAA standard transactions and also uses the NPI as a program identifier in communications with federal administrative entities.

- The “Name of Legal Entity” section instructs the applicant to provide the legal name of the entity. This information is necessary for the Department to identify who is applying for licensure.

- The “Name NTP, MU or OBNTN” section instructs the applicant to provide the name of the provider, if it is different from the name of the legal entity. This information is necessary for the Department to correlate the legal name with the business name of the provider.

- The “Tax Status” section instructs the applicant to check the applicable box indicating the tax status of the applicant’s entity. This information is necessary to inform the Department of the applicant’s legal business structure.

- The “Facility Street Address” section instructs the applicant to list the exact physical address of the NTP location including room, suite, unit number, city, county and zip code of the actual location where services are rendered. The physical street address is necessary in order for the Department to conduct site reviews and determine whether the applicant meets established requirements pursuant to Section 10030.

- The “Mailing Address” section instructs the applicant to list the mailing address if different from the facility street address of the NTP. The mailing address, including room, suite, unit number, city, county and zip code, is necessary in order for the Department to mail pertinent information to the applicant and to maintain current files.

- The “Telephone Number” section instructs the applicant to enter the telephone number and if applicable, the extension number of the applicant. This information is necessary in order for the Department to contact the applicant by phone and to maintain current files.

- The “Fax Number” section instructs the applicant to provide the fax number. This information is necessary in order for the Department to contact or communicate with the individual via fax and to maintain current files.

- The “Name of Program Sponsor” section instructs the applicant to enter the name of the program sponsor. This information is necessary in order for the Department to confirm the identity of the person or organization responsible for the operation of the NTP and who assumes responsibility for all its employees.

- The “Name of Program Director” section instructs the applicant to enter the name of the program director. This information is necessary in order for the Department to confirm the name of the person who has primary administrative responsibly for operation of the NTP.

- The “Name of Medical Director” section instructs the applicant to enter the name of the medical director. This information is necessary in order for the Department to confirm the identity of the physician licensed to practice medicine in California, and who is responsible for medical services provided by the NTP.

Section D, Relocation

The “Relocation” section instructs the applicant to complete Section D if the applicant is applying for a program relocation. This information is necessary during the application process to ensure that additional required documentation is received, to coordinate a site visit, and to verify county recommendation, and includes the following:

- The “Written Statement Explaining Relocation” section instructs the applicant to check the box to indicate a written statement explaining the proposed program relocation is attached to the form. This information is necessary to inform the Department of the date of the proposed relocation, the determined economic and fiscal impact of the relocation and if the relocation affects the original plan of operation.

- The “Facility and Geographical Area form DHCS 5025 (04/16)” section instructs the applicant to complete the Facility and Geographical Area form DHCS 5025 (04/16) for the new program location and attach to this form. The submission of this form is necessary for the Department to ensure the new facility provides appropriate physical treatment space and availability for patient services. The Department also uses the form, if applicable, to assess the distance of the medication unit from the primary NTP to ensure that patients have access to the services provided at the primary NTP.

- The “County Certification form DHCS 5027 (04/16)” section instructs the applicant to complete the County Certification form DHCS 5027 (04/16) for the new program location and attach to this form. The submission of this form is necessary to ensure that the requirement of county certification obtained from the County Alcohol and Drug Program Administrator for the new location is satisfied.

- The “Letters of Community Support” section instructs the applicant to obtain written verification of support from the community for the new NTP location and attach to the form. The submission of this information is necessary for the

Department to determine and evaluate the community's support, justification and recommendation for NTP services in the area.

Section E, Change in Licensed Patient Capacity

The "Change in Licensed Patient Capacity" section instructs the applicant to complete Section E if the applicant is applying for a change in licensed patient capacity. This information is necessary during the application process for verification purposes and to ensure that additional required documentation is received, and includes the following:

- The "Written Statement Explaining Change in Licensed Patient Capacity" section instructs the applicant to check the box to indicate a written statement explaining the proposed change in licensed capacity is attached to the form. This information is necessary to inform the Department of the date of proposed change in licensed patient capacity, the determined economic and fiscal impact of the change in licensed capacity and if the proposed change affects the original plan of operation.

- The "Current Licensed Patient Capacity" section instructs the applicant to enter the Department approved maximum licensed patient capacity for maintenance and detoxification treatment. This information is necessary pursuant to Section 10145, to ensure that the primary NTP has not reached the maximum licensed patient capacity. This information is necessary to maintain current files.

- The "Amount of Licensed Patient Capacity Increase or Decrease" section instructs the applicant to enter the amount of capacity increase or decrease the applicant is requesting for maintenance and detoxification treatment. This information is necessary pursuant to Section 10145, to ensure that the primary NTP has not reached the maximum licensed patient capacity. This information is necessary to maintain current files.

- The "Requested Licensed Patient Capacity" section instructs the applicant to enter the total requested licensed patient capacity for maintenance and detoxification treatment. This information is necessary pursuant to Section 10145, to ensure that the primary NTP has not reached the maximum licensed patient capacity. This information also is necessary pursuant to HSC Section 11839.3(d), which specifies that the Department shall not increase the capacity of a program unless it determines that the licensee is operating in full compliance with applicable laws and regulations. This information is necessary to maintain current files.

- The "Number of Deaths Reported…" section instructs the applicant to enter the number of patient deaths reported in the last 90 days as required by Section 10195. This information is necessary for the Department to verify compliance against existing Department records.

- The “Current Program Census” section instructs the applicant to enter the total number of patients currently receiving maintenance or detoxification treatment at the NTP. This information is necessary to assist the Department in assessing the need for and determination for an increase or decrease in capacity.

- The “Proposed Counselor to Patient Ratio” instructs the applicant to enter the number of counselors per patient with the additional capacity. This information is necessary for the Department to determine how the increase or decrease in program capacity will affect counselor caseloads. Pursuant to HSC Section 11839.20(b) each NTP shall have a strong rehabilitative environment, including, but not limited to, individual and group therapy, counseling, vocational guidance and job and educational counseling.

- The “Updated Facility Map” section instructs the applicant to check the “Yes” box to confirm an updated map of the NTP location is attached to the form. This information is necessary for the Department to verify the flow of patients entering and exiting the facility and to ensure patient confidentiality.

Section F, Addition, Reduction or Termination of Services

The “Addition, Reduction or Termination of Services” instructs the applicant to complete Section F if the applicant is applying for an addition, reduction or termination of services. This information is necessary during the application process for verification purposes and to ensure that additional required documentation is received, and includes the following:

- The “Written Statement Explaining Addition, Reduction or Termination of Services” section instructs the applicant to check the box to indicate a written statement explaining the change in services is attached to this form. This information is necessary to inform the Department of the proposed date for the change of services, the determined economic and fiscal impact of the change of services and if the change affects the original plan of operation.

Section G, Change in Program Sponsor

The “Change in Program Sponsor” section instructs the applicant to complete Section G if the applicant is applying for a change in the person or organization responsible for the operation of the NTP and who assumes responsibility for all of its employees.

- The “Name of Current Program Sponsor” section instructs the applicant to enter the name of the current program sponsor. This information is necessary in order for the Department to confirm the identity of the person or organization currently responsible for the operation of the NTP and who assumes responsibility for all its employees.

- The “Name of New Program Sponsor” section instructs the applicant to enter the name of the new program sponsor. This information is necessary in order for the

Department to confirm the identity of the person or organization responsible for the operation of the NTP and who assumes responsibility for all its employees.

- The “Business Address of New Program Sponsor” section instructs the applicant to enter the business address of the new Program Sponsor. This information is necessary in order for the Department to mail pertinent information to the person or organization responsible for the operation of the NTP and to maintain current files.

- The “Telephone Number of New Program Sponsor” section instructs the applicant to enter the telephone number of the new Program Sponsor and if applicable, the extension number. This information is necessary for the Department to contact the new Program Sponsor during the application review process and to maintain current files.

- The “Email Address of New Program Sponsor” section instructs the applicant to enter the email address of the new Program Sponsor. This information is necessary for the Department to contact the new Program Sponsor during the application review process when clarification is needed and to maintain current files.

- The “Written Statement Explaining Change in Program Sponsor” section instructs the applicant to check the box to indicate that a written statement explaining the request for a change in Program Sponsor is attached to the form. This information is necessary to inform the Department of the date of change in program sponsor, the determined economic and fiscal impact of the proposed change in program sponsor and if the relocation change in program sponsor affects the original plan of operation.

- Instructions for “New Program Sponsor Resume” section instructs the applicant to check the box to indicate that the new Program Sponsor’s resume is attached to the form. This supplemental documentation is necessary for the Department to evaluate the new Program Sponsor’s qualifications and to ensure organizational stability and responsibility as it relates to the continuity of program operations.

<u>Section H, Change in Individual Pursuant to CCR, Title 9 § 10035(a)(5)</u>
The “Change in Individual Pursuant to CCR, Title 9 § 10035(a)(5)” section instructs the applicant to complete Section H if the applicant is applying for 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.

- The “Name of Individual” section instructs the applicant to 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. This information is necessary for the

Department to identify the individual the change is requested for and to ensure Department records are maintained and current.

- The “Telephone Number” section instructs the applicant to enter the telephone number 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. This information is necessary for the Department to contact the individual the change is requested for during the application review process when clarification is needed and to maintain current files.

- The “Email Address” section instructs the applicant to 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. This information is necessary for the Department to contact the individual the change is requested for during the application review process when clarification is needed and to maintain current files.

- The “Individual Live Scan Fingerprinting Date” section instructs the applicant to 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. This information is necessary for the Department’s determination that the program is currently in compliance with applicable State and federal laws and regulations. This information is necessary pursuant to HSC Section 11839.9(b).

- The “Written Statement Explaining Change in Individual” section instructs the applicant to check the box to indicate that a written statement explaining the request for a change in individual pursuant to CCR, Title 9 Section 10035(a)(5) is attached to the form. This information is necessary to inform the Department of the date of proposed change in individual, the determined economic and fiscal impact of the change in individual and if the change in individual sponsor affects the original plan of operation.

- The “Organizational Responsibility form DHCS 5031 (04/16)” section instructs the applicant to check the box if the applicant has completed and attached the Organizational Responsibility form DHCS 5031 (04/16). This form is necessary for the Department to ensure that it has current and accurate information pertaining to the organizational responsibilities of the entity. This information is necessary to maintain current files.

- The “Written Statement Explaining Change in Individual” section instructs the applicant to check the box to indicate that a written statement explaining the request 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 is attached to the form. This information is necessary to inform the Department of the date of proposed change in individual, the determined economic and fiscal impact of the change in individual and if the change in individual sponsor affects the original plan of operation.

- The “Staff Information form DHCS 5026 (04/16)” section instructs the applicant to check the box if the applicant has completed and attached the Staff Information form DHCS 5026 (04/16). This form is required for the Department to ensure staff members hold appropriate licenses and/or certifications required for duties they will perform and to ensure the health and welfare of program participants.

- The “Written Documentation of Medical Licensure” section instructs the applicant to check the box to indicate the applicant has attached written documentation of medical licensure. The applicant is instructed to complete this requirement only if the application for protocol amendment is 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. This information is necessary to ensure the staff member holds the appropriate license required for duties they will perform and to ensure the health and welfare of program participants.

- The “Procedure for Replacement” section instructs the applicant to check the box to indicate the applicant has attached a written statement describing the procedure to assure that the NTP has a procedure for replacement in the event of a death, retirement or prolonged sickness. This information is necessary to ensure that an unforeseen circumstance does not interrupt the treatment services of NTP patients and to ensure the health and welfare of NTP patients.

- The “Procedure to Assure Appropriate Staff Time” section instructs the applicant to check the box to indicate the applicant has attached 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-term emergency, vacation, or sickness. This information is necessary to ensure that an unforeseen circumstance does not interrupt the treatment services of NTP patients and to ensure the health and welfare of NTP patients.

- The “Resume” section instructs the applicant to check the box and to attach a resume only if the change request is for the 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. This information is necessary in order for the Department to confirm the identity of the 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. This document is required for the Department to ensure staff members hold appropriate licenses and/or certifications required for duties they will perform and to ensure the health and welfare of program participants.

Section I, Change in Physical Structure

The "Change in Physical Structure" section instructs the applicant to complete Section I if the applicant is applying for a change in physical structure. This information is necessary during the application process to coordinate a site visit and ensure that additional required documentation is received, which includes the following:

- The "Written Statement Explaining Change in Physical Structure" section instructs the applicant to check the box to indicate a written statement explaining the change in physical structure is attached to the form. This information is necessary to inform the Department of the date of a proposed change in physical structure, the determined economic and fiscal impact of the change in physical structure and if the change in physical structure affects the original plan of operation.

- Instructions for "Facility and Geographical Area form DHCS 5025 (04/16)" section instructs the applicant to check the box to indicate the Facility and Geographical form DHCS 5025 (04/16) is attached to the form. The information is necessary for the Department to assess and ensure the change in physical structure allows for appropriate physical treatment space and availability of patient services.

- The "Updated Facility Map" section instructs the applicant to check the box to confirm that an updated map of the NTP location is attached to the form. This information is necessary for the Department to verify the flow of patients entering and exiting the facility and to ensure patient confidentiality.

Section J, Declaration

This information is necessary to ensure that the authorized individual signing the application is aware of and acknowledges the requirements and stipulations within this application.

The Declaration section instructs the applicant to attest to the following:

> 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.

The section provides the following information:

- The "Print Name" section instructs the applicant to print the name of the Program Sponsor who will sign the Declaration section. This information is needed to

confirm the identity of the individual signing and to ensure that the individual is authorized to sign on behalf of the NTP, MU, or OBNTN.

- The “Title” section is pre-filled by the Department with the title “Program Sponsor.” This information is necessary to specify the individual that is authorized to sign the form.

- The “Signature” section instructs the applicant to provide an original signature of the Program Sponsor. This information is necessary to ensure that the authorized individual signing the application is aware of and acknowledges the requirements and stipulations within this application.

- The “Date” section instructs the applicant to enter the date the application is signed by the Program Sponsor. This field is standard information that is requested across all Department applications and assists the Department in determining when the application was completed.

Privacy Statement

A privacy statement is adopted in order to comply with Civil Code Section 1798.17. The privacy statement is included on each form that is incorporated by reference through this regulatory action. This privacy statement is necessary to inform the applicant that all information requested is mandatory and includes references to the bodies of law that authorize NTPs. The Department gives its due diligence by advising the applicant of the consequences of not providing the required information. This privacy statement also advises the applicant that information may be shared with additional entities, as required or permitted by law. Lastly, the applicant is given the Narcotic Treatment Programs Section’s telephone number for more information or to access records.

LIST OF DOCUMENTS RELIED UPON

1. http://www.merriam-webster.com/medical/buprenorphine
2. http://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine
3. American Society of Addiction Medicine, National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use, May 27, 2015, page 33
4. http://www.samhsa.gov/medication-assisted-treatment/treatment#medications-used-in-mat
5. http://www.samhsa.gov/medication-assisted-treatment/treatment/common-comorbidities
6. http://www.dhcs.ca.gov/formsandpubs/laws/Documents/15-012_Approved_Package.pdf
7. http://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/dear_colleague_letters/2012-colleague-letter-final-rule-42-cfr-part-8.pdf
8. http://store.samhsa.gov/shin/content//PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf

STATEMENTS OF DETERMINATION
(a) ALTERNATIVES CONSIDERED

The Department has determined that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which this regulatory action is proposed, would be as effective and less burdensome to affected private persons than the regulatory action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Existing regulations found in Title 9, CCR, Division 4, Chapter 4, Subchapter 1 commencing with Section 10000 are the primary regulations for NTPs. These regulatory provisions address numerous topics including program licensure, evaluation and administration, medication security and patient treatment. Many of these provisions will be updated and amended through this regulatory proposal. Using this regulatory proposal to adopt and amend requirements regarding NTPs is the most effective and convenient way to provide (current/updated) information directly to those impacted including the providers, patients and county departments.

(b) LOCAL MANDATE DETERMINATION

The Department has determined that the proposed regulations would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

(c) ECONOMIC IMPACT ANALYSIS/ASSESSMENT

The Department has made an initial determination that the proposed regulations would not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

The Department has determined that the proposed regulations would not significantly affect the following:

1. The creation or elimination of jobs within the State of California.
2. The creation of new businesses or the elimination of existing businesses within the State of California.
3. The expansion of businesses currently doing business within the State of California.

Impact on Jobs and Businesses
The Department has made the determination that the impact on jobs and businesses would only affect those providers operating NTPs who choose to open medication units and OBNTNs. It is estimated that from 2017-2022 that a total of 14 medication units

and/or OBNTNs may open, based on the number of counties that currently do not provide NTP services. A new application fee will be required for these facility types. The fee is consistent with statutory requirements and is developed based on the costs incurred by the Department. There is no anticipated impact to businesses related to this fee or the application process as it is consistent with the existing process to open a primary NTP.

The opening of an OBNTN or a medication unit will involve costs to the provider related to infrastructure. These costs will heavily depend on the region and include costs associated with meeting the requirements for physically securing the medications to meet the DEA storage requirements in addition to staffing costs. There will likely also be costs associated with adapting information systems to maintain the records of the patients being seen by these facilities.

If a provider opens an OBNTN or medication unit, new health care jobs will be created because it is estimated that each medication unit will require at least one licensed physician, physician extender or medical personnel authorized to dispense schedule II narcotics, as well as an administrative professional costing altogether approximately $75,000 per year. Depending on the services offered, each OBNTN is estimated to require approximately two registered or certified counselors or licensed professionals acting as counselors, one administrative professional and a part-time physician or physician extender costing altogether approximately $120,000 per year.

Benefits of the Proposed Regulation

The Department has determined that the regulations will not specifically affect worker safety yet will have an impact on the public health, welfare and safety of Californians. The opioid epidemic affecting the nation is resulting in a tremendous strain on families and their communities due to a lack of access to treatment in rural settings for individuals needing treatment. The effect is seen in rising overdose rates resulting in a heavy impact on emergency services and in death for many individuals. The current reality of these effects are taking a tremendous toll on the public health, welfare and safety of Californians. For those seeking services, they are often faced with access barriers due to services not being available in their communities and not having the ability to travel the distances required to get to services while still maintaining employment.

The regulations will benefit NTP providers through the provision of clear and comprehensive requirements for participation while adding new cost-effective opportunities for the provision of services. This in turn will benefit those in need of access to these services. This regulatory proposal ensures the proper and efficient administration of NTP services, in accordance with federal and state laws. The proposed amendments improve the integrity of the licensure requirements through clarity to the application process and a fee structure that is aligned correctly with statute yet will not have a notable change in the amounts due by NTP providers, or in their overall operations.

(d) EFFECT ON SMALL BUSINESSES

The Department has determined that the proposed regulations would only affect small businesses that choose to provide NTP services. While compliance with the proposed regulations is mandatory for all licensed NTP providers, the new provisions allowing for an OBNTN and/or medication unit are voluntary and not required for providers to participate in these service opportunities.

(e) HOUSING COSTS DETERMINATION

The Department has made the determination that the proposed regulations would have no impact on housing costs.