FINAL STATEMENT OF REASONS

UPDATE OF INITIAL STATEMENT OF REASONS

As authorized by Government Code Section 11346.9(d), the Department of Health Care Services (Department) incorporates by reference the Initial Statement of Reasons (ISOR) prepared for this rulemaking.

The specific amendments to the ISOR are provided under the "AMENDMENTS TO INITIAL STATEMENT OF REASONS" section below.

SCHEDULE OF RULEMAKING PROCEEDING

The original proposed regulation text was made available for public comment for at least 45 days, from August 17, 2018 through October 3, 2018. Seven individuals submitted comments.

During the 45-day comment period, the Department did not receive a request for a public hearing. Therefore, a public hearing was not scheduled for this regulatory action.

Based on public comment and additional Department consideration, the Department proposed additional changes to the regulation text. These additional changes to the regulation text and additional supporting documentation included in the rulemaking file, were made available for public comment during a 15-day Public Availability, from June 4, 2019 through June 19, 2019. One individual submitted a comment.

The Department submitted the proposal to the Office of Administrative Law (OAL) for review on August 13, 2019 (OAL Matter Number: 2019-08-13-02). OAL disapproved the regulation package on September 25, 2019, after determining that Sections 10056 and 10056.5 failed to comply with the "clarity" standard of Government Code Section 11349.1.

To address this clarity issue, the Department proposed additional changes to the regulation text. These changes included reverting back to the original regulation text of Section 10056 with minor amendments and eliminating the proposed adoption of Section 10056.5.

The second set of additional changes to the regulation text and additional supporting documentation included in the rulemaking file were made available for public comment, during a second 15-day Public Availability, from January 15, 2020 through January 30, 2020. Five individuals submitted timely comments and one individual submitted a late comment.

SUMMARY AND RESPONSE TO PUBLIC COMMENTS

The Department received comments during the 45-day and 15-day comment periods. A summary of the comments and the Department's responses are set forth in Addendums I, II and III.

- ADDENDUM I – Summary and Responses to 45-day Public Comments
- ADDENDUM II – Summary and Responses to 15-day Public Comments
- ADDENDUM III – Summary and Responses to Second 15-day Public Comments

A "List of Commenters" is also included with each Addendum.

NON-SUBSTANTIVE CHANGES

Additional non-substantive changes were made to the proposal to reflect the recent Department re-organization that became effective on July 1, 2019. Amendments were made to remove/update outdated Department program names, as shown in Section 10057. Amendments were made to the Privacy Statement on all of the forms incorporated by reference listed below:

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)

Non-substantive changes were also made to correct grammar, punctuation and to eliminate redundancy. Specifically, the phrase "of this regulation" was deleted throughout the regulations when it followed a reference to a subsection, because this phrase is not necessary. These amendments discussed above were non-substantive as they do not materially alter any requirement, right, responsibility, condition, prescription or other regulatory element of the regulations.

AMENDMENTS TO INITIAL STATEMENT OF REASONS

Additional changes were made to the original proposed regulation text as discussed above. Therefore, the Department updated the ISOR to reflect these additional changes to the regulation text.

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 wait 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 recordkeeping.

Section 10000

Subsection (a)(2)
A definition for Buprenorphine is adopted to describe the medication approved in October 2002, by the Food and Drug Administration (FDA) for use in the treatment of opioid use disorders. Pursuant to Health and Safety Code Section 11839.2, buprenorphine is authorized as an allowable agonist treatment medication for use at a Narcotic Treatment Program (NTP). Buprenorphine is a semisynthetic narcotic analgesic that is derived from thebaine and is administered in the form of its hydrochloride $C_{29}H_{41}NO_4 \cdot HCl$ to control moderate to severe pain and treat opioid dependence. 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. This definition is also consistent with the definitions for other medications used in replacement narcotic therapy, which include the chemical structure but do not specify the routes of administration of the medications. (See definitions for Levoalphacetylmethadol and Methadone, subsections (a)(10) and (17), respectively.)

Subsection (a)(4)
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, specifically 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)(5)
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)(6)
The definition for detoxification treatment is amended to remove the existing language "reduce or eliminate opiate addiction" and replace it with "treat physical dependence." While detoxification treatment addresses the physical dependence to opioids, it does not eliminate the addiction to opioids. Therefore, the concept to "reduce or eliminate

opiate addiction" is replaced with "treat physical dependence," which is the purpose for detoxification treatment. The phrase "a comprehensive range of" was added for consistency with the definition of maintenance treatment under Section 10000(a)(13).

Subsection (a)(13)
The definition for maintenance treatment is amended to remove the existing language "reduce or eliminate chronic opiate" and replace it with "treat opioid." Opioid addiction is a condition that may always be present, with the possibility of an individual relapsing at any time. There is no assurance that an opioid addiction is ever eliminated. The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), Section II, Page 483, states, "The essential feature of a substance use disorder is a cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite the significant substance-related problems… An important characteristic of substance use disorders is an underlying change in brain circuits... The behavioral effects of these brain changes may be exhibited in the *repeated relapses (emphasis added)* and intense drug craving when the individuals are exposed to drug-related stimuli." Furthermore, addiction is a chronic brain disease, according to the U.S. National Library of Medicine National Institutes of Health, (https://medlineplus.gov/opioidabuseandaddiction.html and https://medlineplus.gov/magazine/issues/spring07/articles/spring07pg14-17.html). Since opioid addiction is considered a long-term, on-going condition, the concept to "reduce or eliminate" opioid addiction is replaced with "treat" opioid addiction, which is the purpose of maintenance treatment.

Subsection (a)(15)(A) and (B)
Semicolons are added for consistent punctuation throughout the regulations. Specifically for paragraph (A), the term "and" is removed since it is added in paragraph (C).

Subsection (a)(15)(C)
The definition of medication is amended to include Buprenorphine and Buprenorphine products approved by the federal Food and Drug Administration for maintenance treatment or detoxification treatment of opioid addiction. This is necessary to be consistent with the description of the medications found in Health and Safety Code Section 11839.2(c), and to include all controlled substances approved by the FDA for use in replacement narcotic therapy. Additionally, the word "and" is added due to the addition of paragraph (D).

Subsection (a)(15)(D)
The definition of "medication" is amended to include: "Any other medication approved by the federal Food and Drug Administration for the purpose of narcotic replacement treatment or medication-assisted treatment of substance use disorders." This amendment brings the definition into alignment with Health and Safety Code Section 11839.2(d).

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 Health and Safety Code 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 Health and Safety Code Section 11839.6(a)(2). The treatment services to be provided to the substance use disorder population at an OBNTN mirror the services for this population that are 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 Code of Federal Regulations (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)(34)(C)
This subsection is amended to remove the language “opiate abusing” and replace it with “substance use disorder” to align with the language utilized in The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), Section II, Page 483 and it is consistent with the use of this phrase in Section 10000(a)(20).

Section 10030

Subsection (a)(12)
This subsection is amended to add the language “(physical or electronic)” for clarity. This is necessary to clearly specify for programs that they may use either a physical or electronic identification system. For example, a physical identification system may include the use of photo identification cards; whereas an electronic identification system is an electronic health record that has a digital photo of the patient stored in the system. Currently, programs use both physical and electronic systems to identify patients.

Subsection (a)(13)
This subsection is amended to remove the word “cards” and replace it with “system” for clarity. As discussed above, programs may utilize an identification system that relies on an identification card or other means to identify a patient. Regardless of the system used, programs shall provide information in their protocol on the control and security of their overall patient identification system. This information should include but not be limited to the control and security of patient identification cards. The term “patient” is also added to clarify who is being identified by the system. These amendments are consistent with the proposed amendments in Sections 10030(a)(12) and 10240 that also clarify that programs may utilize either a physical or electronic patient identification system.

Section 10056

The Department made minor amendments and modifications to the existing language of Section 10056, as specified below. These amendments are necessary to ensure consistency of the language throughout the regulatory proposal. The amendments and modifications create a more seamless transition into the existing language and are necessary to ensure consistency with other proposed changes throughout the regulations, which are discussed herein.

Subsection (a)(1)
This subsection is amended to remove the language "licensure of components such as medication units" and replace with language that allows for the addition of a medication unit or an OBNTN to the primary NTP's existing license. This amendment is necessary since the Department does not issue a separate license for medication units and OBNTNs. This amendment is also consistent with Sections 10020 and 10021 that specify the requirements to lawfully operate a medication unit or OBNTN, respectively. Cross-references to these two sections are included for clarity.

Subsection (a)(2)(B)
This subsection is amended to change the phrase "authorized patient capacity" to "licensed patient capacity." This amendment is necessary for consistency throughout the regulations, including Section 10045 (titled) "Licensed Patient Capacity."

Subsection (a)(3)
This subsection is amended to add a cross-reference to Section 10037. This amendment is necessary to clarify that a county shall pay a relocation fee when relocating within a county or relocating outside of the current county indicated on its license, as specified in Sections 10035 and 10037, respectively. Accordingly, the word "section" is amended to "Sections" for correct grammar.

Subsection (d)
This subsection is amended to change the date by which the Department calculates the annual license fee for the future fiscal year from April 30 to March 1st. This amendment is necessary to coincide with the revised submission date for an annual license renewal, which is now March 31st, as specified in Section 10055. Accordingly, the March 1st date is necessary to give programs adequate notice of the upcoming annual license fee, prior to submission of their annual license renewal.

This subsection is also amended to specify that if all conditions in Section 10055 are met, the program license shall be renewed effective July 1st. A cross-reference to subsection (h) regarding the payment of the license fee is also included. These amendments are necessary to clarify the license renewal process as it relates to the payment of the annual license fee.

Subsection (e)
This subsection is amended to change the date by which the Department provides written notice to programs of the license fees for the future fiscal year from April 30 to March 1st. This amendment is necessary to coincide with the revised submission date for an annual license renewal, which is now March 31st, as specified in Section 10055. Accordingly, the March 1 date is necessary to give programs adequate notice of the upcoming annual license fee, prior to submission of their annual license renewal.

Subsection (h)(1) and (2)
These subsections are amended to replace the phrase “he/she” with “the licensee.” This amendment is necessary for consistency throughout the regulations, which already references “the licensee” and eliminates the unnecessary use of gender-based pronouns.

Subsection (h)(3)(A)
This subsection is amended to replace the phrase “that he/she has failed” with “of the failure.” This amendment is necessary for consistency throughout the regulations and eliminates the unnecessary use of gender-based pronouns.

Subsection (h)(3)(D)
This subsection is amended to replace the phrase “his/her” with “the.” This amendment is necessary for consistency throughout the regulations and eliminates the unnecessary use of gender-based pronouns.

Subsection (h)(3)(F)
This subsection is amended to replace the phrase “that he/she may” with “of the right to.” This amendment is necessary for consistency throughout the regulations and eliminates the unnecessary use of gender-based pronouns.

Subsection (h)(4)
This subsection is amended to replace the phrase “his/her” with “the.” This amendment is necessary for consistency throughout the regulations and eliminates the unnecessary use of gender-based pronouns.

Subsection (i)
This newly proposed subsection is added to specify 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

Health and Safety Code Section 11839.7(a)(2) and have been previously invoiced through that date.

Section 10057

Subsection (b)(1)
This subsection is amended to remove the references to "Deputy Director('s)" and replaces them with "Division Chief('s)" to align with changes made to the organizational structure when the former ADP merged into the Department.

Subsection (d)(2)
This subsection is amended to add "Deputy" and "Behavioral Health" 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 Health and Safety Code Section 11750. A semicolon is added under subsection (d)(2)(A)1. for punctuation.

Section 10060

This section is amended to remove the words "eventually to eliminate" and replace it with "treating." Since opioid addiction is considered a condition that may always be present with the possibility of an individual relapsing at any time, there is no assurance that an opioid addiction is ever eliminated. Therefore, the concept of "eliminating opioid addiction" is replaced with "treating opioid addiction," which is the main purpose for these substance use disorder programs. (See additional discussion under Section 10000(a)(13).) Additionally, the term "opiate" is replaced with "opioid" for reasons as discussed in Section 10000(a)(22).

Section 10160

Subsections (a) – (d)
Subsections under this section are re-designated to clarify that each of these provisions is a distinct and separate requirement. The re-designations are as follows:

- Subsection (a)(1) is re-designated to the new subsection (b).
- Subsection (b) is re-designated to the new subsection (c).
- Subsection (c) is re-designated to the new subsection (d).

Subsection (a)
This subsection is amended to remove the phrase "consecutive numbers" and replaces it with "a unique identifier." In accordance with Health and Safety Code 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.

Subsection (b)
This subsection is amended to add the language “or in a secure electronic medical record database.” This is necessary as patient data may be stored electronically and this method of record keeping is widely utilized by programs.

Subsection (e)
This subsection is adopted to add the following language: “Each program shall specify in its protocol, the methods in place to safeguard physical and/or electronic patient records.” This subsection is necessary to include a protocol requirement regarding the security of patient records. A program must specify in its protocol the methods in place to maintain patient records in a secure manner. This is necessary to protect patients’ personal health information.

Section 10165

Subsection (a)(3)
This subsection is amended to replace the term “opiates” with “opioids” for reasons as discussed in Section 10000(a)(22). Additionally, subsection (a)(3) is amended to remove the language “heroin or other.” This is necessary for consistency throughout the regulations, which are updated to simply utilize the term “opioid,” as it is the term currently used by the substance use disorder community. This amendment also eliminates redundancy since as defined under Section 10000(a)(22) the term “opioid” includes heroin.

Subsection (a)(6)
This subsection is amended to read, “Known arrests, convictions.” This is necessary for clarity since the program can only document these types of incidents if they are made aware and notified of these incidents by patients, law officials, or other sources.

The word “subsection” is added in subsections (b) and (c) in order to use consistent terminology for references throughout the regulation text.

Subsections (b) – (c)
Subsections (b)(2), (c)(1) and (c)(5) are amended to remove the language "success or failure of treatment” and “treatment failure”; and replace it with "treatment outcomes.” This is consistent with the Federal Guidelines for Opioid Treatment Programs, March 2015, pages 15, 16, and 46, which utilizes the language “treatment outcome.”

Subsection (c)(3)
This subsection is amended to correct an inconsistency by removing the language "two years” and replacing it with "one year” to require documentation justifying maintenance treatment beyond one year. This amendment is necessary to align with (initial) changes made in Section 10410(a), which requires the medical director or program physician to evaluate a patient’s maintenance treatment after one continuous year of treatment.

Section 10190

Subsection (a) – (b)
Subsections (a) and (b)(1) are amended to 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.

Subsection (a) is also amended to add the language “or opioid addiction, where treatment is available” to specify that coordination of necessary treatment should include any treatment for opioid addiction and not just detoxification treatment. The coordination of care with local jails is critical for a patient with opioid addiction to reduce the likelihood of relapse upon release. This amendment is also consistent with Section 10030(a)(31), which requires a program to develop procedures, which provide for the cooperation with local jails for either detoxification or maintenance treatment. The phrase “whenever it is possible to do so” is removed since it is redundant to the phrase “where treatment is available.” Additionally, the term “opiate” is replaced with “opioid” for reasons as discussed in Section 10000(a)(22).

Section 10240

This section is amended to specify the requirements for a “Patient Identification System.” Accordingly, the title of this section is amended to remove the term “card” and replace it with “system.” This is consistent with Section 10030(a)(12), which refers to an overall “patient identification system.” The amendments to this section are necessary to clarify the flexibility that programs have regarding the type of patient identification system they may implement. Programs have been able to utilize an identification system that relies on photo identification cards or an electronic identification system. These amendments make it clear that programs have the ability to utilize newer technology such as electronic health records, digital photos, fingerprint scans or key card access to identify a patient.

Subsection (a)
This subsection is amended to require a program to “establish and maintain a patient identification system.” This is necessary to clarify that a program shall have a system in place to accurately identify patients that are admitted into treatment. The current language, which requires the program to “make known to each patient the availability of a completed identification card which shall be supplied by the program,” is deleted since it did not clearly specify the requirement for a program to implement a patient identification system. A patient identification system is necessary for a program to track patient attendance to treatment and patient medication.

Subsection (b)
This subsection is amended to clarify its application to the overall patient identification system. This is necessary since the assignment of a unique identifier to a patient is required of all patient identification systems, regardless if the identification system utilizes identification cards. The language “be numbered consecutively” is replaced with

"assign unique identifiers to patients." This is necessary to comply with Health and Safety Code Section 11839.3(a)(1).

Subsection (c)
This newly proposed subsection is added to specify the information that shall be maintained in a program's patient identification system. This is necessary to provide programs guidance as to the required information that shall be collected in its system to identify the patient. The information required is the same as the identifying information currently required to be on a patient identification card. This information, as specified in newly proposed subsection (c)(1)-(5), includes the patient's name, unique identifier, physical description, signature and a full-face photograph of the patient. This personal information is requested since they are commonly used for identification purposes.

Subsection (d)
This newly proposed subsection is added to clarify that patient identification cards can still be used as part of a program's patient identification system. The re-designation of paragraphs under newly proposed subsection (d), as described below, are necessary to organize requirements related to the use of patient identification cards under one subsection for clarity.

Existing subsection (c) is re-designated to subsection (d)(1) and is amended for clarity and consistency. Accordingly, existing subsection (c)(1)-(7) is re-designated as (d)(1)(A)-(G), respectively.

Existing subsection (c)(2) is re-designated to subsection (d)(1)(B) and is amended to remove the phrase "record number" and replace it with "unique identifier." Pursuant to Health and Safety Code 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.

Existing subsection (c)(7) is re-designated to subsection (d)(1)(G) and is amended to clarify that the provision pertains to a "patient" identification card for consistency throughout this section.

Existing subsection (d) is re-designated to subsection (d)(2) and is amended to clarify that the provision pertains to a "patient" identification card for consistency throughout this section.

Subsection (e)
Existing subsection (e) is re-designated to subsection (d)(3) and is amended to clarify that the provision pertains to a "patient" identification card for consistency throughout this section.

Subsection (f)
Existing subsection (f) is re-designated to subsection (e) due to the re-organization of the previous provisions. Subsection (e) also includes grammatical amendments for clarity; however, the original intent of the provision remains the same.

The language of newly proposed subsection (e)(1) was originally located under existing subsection (f)(3). This provision is re-located since this protocol requirement applies to all patient identification systems, regardless if the identification system utilizes identification cards. However, the original intent of the provision remains the same.

The language of newly proposed subsection (e)(2) is included as a lead in to specify that these additional protocol requirements only apply when a program employs the use of patient identification cards.

The language of newly proposed subsection (e)(2)(A) was originally part of subsection (f)(1) and is amended to clarify the type of information that should be specified in the program's protocol regarding the assignment of a patient identification card. This is necessary to provide clear guidance to programs regarding protocol requirements and to safely secure identifying information.

The language of newly proposed subsection (e)(2)(B) was originally part of subsection (f)(2) and is amended to clarify the type of information that should be specified in the program's protocol regarding the return of a patient identification card. This is necessary to provide clear guidance to programs regarding protocol requirements and to safely secure identifying information.

Section 10260

The title of this section was amended to read "Administering or Dispensing of Medications" for grammatical purposes and for consistency with the provisions of this section.

Section 10270

Subsection (a)(2)
This subsection is amended to include the following language, "An optional laboratory test for the determination of human immunodeficiency virus (HIV) in accordance with Division 105, Part 4, Chapter 7 of the Health and Safety Code; and". This language is necessary to clearly specify that HIV testing is not required. Additionally, the cross-reference is necessary to direct programs providing HIV testing to the requirements specified under the Health and Safety Code, which include providing information on the HIV test, HIV treatment options, and the patient's right to decline the HIV test.

This subsection is also amended to add "hepatitis C virus (HCV)" as a required test to be conducted as part of the patient selection process for clarity. 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.

Subsection (a)(3)(C)
This subsection is amended to add the word “and” for proper grammar and the language “, and breasts” is removed as a breast exam is not medically indicated and therefore not necessary for admission to treatment. Additionally, breast exams may require the presence of a nurse or other person in the room in some settings, which can be burdensome to some programs.

Breast exams are a highly sensitive exam and most patients refuse the exam. Many women who are treated for a substance use disorder are also victims of past sexual abuse. A breast exam could potentially be a trigger that re-traumatizes patients who have experienced past sexual abuse; and this requirement could pose a major obstacle to treatment for these individuals. The Canadian Women’s Health Network - (http://www.cwhn.ca/en/node/42905).

Subsection (d)(1)
This subsection is amended to reduce 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). This subsection also removes the word "failures” and replaces it with "outcomes,”; as the Federal Guidelines for Opioid Treatment Programs, Pages 15, 16, and 46, utilizes the language “treatment outcome.”

Subsection (d)(2)
Existing subsection (d)(2) is amended to remove 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).

The existing language under subsection (d)(2) is replaced with language to implement the patient admission requirements for patients under the age of 18. Specifically, the following language is added, “For patients under the age of 18 years, a documented history of two unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period. The methods to confirm this history and the types of documentation to be maintained in the patient's record shall be stated in the protocol. Patients under the age of 18 years shall also have the written consent of their parent(s) or guardian prior to the admission into maintenance treatment.” These criteria are necessary to align with patient admission criteria, as specified under 42 CFR, section 8.12(e). The requirement for programs to specify in their protocol how a patient’s history is confirmed and documented is necessary to establish a consistent patient admission process and to enable the Department to evaluate compliance with this process.

Subsection (d)(3)
This subsection is amended to add the following: ", including linkages to care and treatment, where needed, for patients who test positive for HIV, HCV, tuberculosis or syphilis" to clarify the type of information to be included in the patient's record for maintenance treatment. This coordination with physical health is pertinent for whole person care. It is important for the physician to "identify co-occurring medical and psychiatric conditions that may make medication-assisted treatment unsafe, limit its effectiveness, influence the selection of pharmacotherapy, or require prompt medical attention." (Federal Guidelines for Opioid Treatment Programs, March 2015, Page 29.) These four conditions (HIV, HCV, tuberculosis and syphilis) are specified for consistency with the required screening under Section 10270(a)(2). Therefore, if a patient tests positive for any of these conditions, the referrals and information relevant to the treatment of these conditions should be documented in the patient's file.

Section 10320
The words "State" and "Health Services" are removed and replaced with "California" and "Public Health," respectively, for reasons as discussed in Section 10000(a)(9) of the Initial Statement of Reasons. 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 10355

Subsection (g)
This subsection is amended to replace the word "After" with "When" for clarity. This subsection is also amended to add the following language, "The new medication order shall be provided by the medical director or program physician, either in person, by verbal order, or through other electronic means; and shall be documented and justified in the patient's record." This is necessary to clearly specify that a new medication order for the continuation of treatment may be provided in one of three ways, which is consistent with how the medical director or program physician may authorize changes to a patient's medication dosage schedule (see existing language under subsection (h).) This provision also requires documentation and justification, for allowing the patient to continue treatment, in the patient's record. This is necessary since it is the medical director and/or the program physician's responsibility to manage and document the patient's care. This amendment will benefit programs by allowing flexibility as it relates to obtaining a new medication order and benefits patients by allowing a more timely return to treatment.

Section 10360

Subsection (a)(2)
This subsection is amended to add the language: ", physician assistant, or nurse practitioner" and "; or a licensed midwife or certified nurse midwife licensed by the State

of California." This amendment allows a pregnant patient to be under the care of a physician assistant, nurse practitioner, licensed midwife or certified nurse midwife, as long as the provider is licensed to practice in California. These amendments acknowledge that patients may choose to be under the care of other health care providers, who are trained in obstetrics and/or gynecology, other than a physician.

Subsection (d)(10)
This subsection is adopted to include the prenatal topic "evidence-based practices for managing neonatal abstinence syndrome." This is necessary to align with the Federal Guidelines for Opioid Treatment Programs, March 2015, Page 32, and to ensure that the program staff are knowledgeable in current practices regarding neonatal abstinence syndrome.

Section 10370

Subsection (a)
This subsection is amended to remove the phrase "self administered take-home medication" and replace 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. Additionally, this subsection is amended to include the language: "is adhering to program requirements," as a patient criterion to be eligible for take-home medication. This is necessary to align with Health & Safety Code Section 11839.3(b), which states, "It is the intent of the Legislature in enacting this section, in order to protect the general public and local communities, that take-home doses shall only be provided when the patient is clearly adhering to the requirements of the program, and if daily attendance at a clinic would be incompatible with gainful employment, education, responsible homemaking, retirement or medical disability, or if the program is closed on Sundays or holidays and providing a take-home dose is not contrary to federal laws and regulations governing narcotic treatment programs."

Section 10375

Subsection (a)(1)
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 "Day 1 through 90 of continuous maintenance treatment, the medical director or program physician may grant the patient a single dose of take-home supply of medication per week. The patient shall attend the program at least six times per week for observed ingestion." This is necessary to align with the time in treatment requirements for take-home medication as specified in 42 CFR section 8.12(i)(3)(i) and for consistency with the remainder of subsection (a)(2)-(6).

Subsections (a)(2) – (6)
These subsections are amended to include the clarifying phrase “per week” or “per month” as appropriate. This is necessary for consistency with the language in 42 CFR section 8.12(i)(3) and throughout the provisions of this section.

LIST OF DOCUMENTS RELIED UPON (continued from the ISOR)

9. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), Section II, page 483.
10. U.S. National Library of Medicine National Institutes of Health https://medlineplus.gov/opioidabuseandaddiction.html and https://medlineplus.gov/magazine/issues/spring07/articles/spring07pg14-17.html.
11. The Canadian Women’s Health Network (CWHN) - http://www.cwhn.ca/en/node/42905.
12. Office of Administrative Law Decision of Disapproval of Regulatory Action, OAL Matter Number: 2019-0813-02

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.

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 the action was taken, would be as effective and less burdensome to affected private persons 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, California Code of Regulations (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.