State of California—Health and Human Services Agency
Department of Health Care Services

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NOTICE OF ADDITIONAL CHANGES TO THE TEXT OF PROPOSED REGULATIONS AND ADDITION OF DOCUMENTATION TO THE RULEMAKING FILE REGARDING

DHCS-14-026 – Narcotic Treatment Program (California Code of Regulations, Title 9)

Pursuant to Government Code Section 11346.8, notice is hereby given that the Department of Health Care Services (Department) is making additional changes to the text of the proposed subject regulations. A copy of the regulation text with the additional changes clearly indicated is attached.

Pursuant to Government Code Section 11347.1, notice is hereby given that the Department is adding supporting documentation to the rulemaking file for the proposed subject regulations.

The Department is making the additional changes and the added documentation available for review during a 15-day public comment period.

WRITTEN COMMENT PERIOD

Any interested person or his or her duly authorized representative may submit written comments to the Department. *Only the additional changes to the proposed regulation text and supporting documentation added to the rulemaking file, as described in this notice, are subject to comment.*

Please label any comments as pertaining to Narcotic Treatment Program, DHCS-14-026 and submit using any of the following methods:

Mail Delivery: Department of Health Care Services
Office of Regulations, MS 0015
P.O. Box 997413
Sacramento, CA 95899-7413

Hand Delivery: Department of Health Care Services
Office of Regulations
1501 Capitol Avenue, Suite 5084
Sacramento, CA 95814

FAX: (916) 440-5748

Email: regulations@dhcs.ca.gov

The Department will accept written comments from June 4, 2019 through June 19, 2019. Any written comments, regardless of the method of transmittal must be received by the Office of Regulations by 5:00 pm on June 19, 2019, for consideration and response by the Department in the Final Statement of Reasons.

Written comments should include the author's contact information so the Department can provide notification of any further changes to the regulation proposal.

METHOD OF INDICATING CHANGES

The additional changes to the text of the proposed regulations for Narcotic Treatment Program, DHCS-14-026, are shown by using double strikeout for deletions (~~double strikeout for deletions~~) and double underline for additions (double underline for additions.)

SUMMARY OF ADDITIONAL CHANGES

Upon further consideration and as a result of public comment the Department received during the 45-day comment period, the Department is proposing additional changes to the regulation text under California Code of Regulations, title 9, chapter 8: These changes and the explanations for these changes are further discussed below.

Section 10000
Subsection (a)(2): As a result of public comment, this subsection is amended to remove the language that specifies the routes of administration of buprenorphine. Specifying the routes of administration for this medication creates an unnecessary limitation, since other acceptable routes of administration can develop over time. Specifically, the language "intravenously or intramuscularly" and "sublingually to" are deleted. Additionally, the word "treat" is removed and replaced with "control" since buprenorphine can be prescribed for pain management. These amendments bring the definition into alignment with the medical definition of 'Buprenorphine' found in the Merriam-Webster's Dictionary http://www.merriamwebster.com/medical/buprenorphine. This definition is now 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)(5): Upon further consideration and as a result of public comment, this subsection 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): Upon further consideration, this subsection 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): The comma is changed to a semicolon for consistent punctuation throughout the regulations. Specifically for paragraph (B), the term "and" is removed since it is added in paragraph (C).

Subsection (a)(15)(C): Upon further consideration, this subsection is amended to read as follows: "Buprenorphine and buprenorphine products approved by the federal Food and Drug Administration for maintenance treatment or detoxification treatment of opioid addiction;". This amendment brings the definition into alignment with Health and Safety Code section 11839.2(c). Additionally, the word "and" is added due to the addition of paragraph (D).

Subsection (a)(15)(D): As a result of public comment and upon further consideration, this subsection is amended to add the following language: "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).

Subsections (a)(20) and (a)(34)(C): Upon further consideration, these subsections are amended to remove the language "opioid 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.

Section 10030

Subsection (a)(12): As a result of public comment and upon further consideration, the language "(physical or electronic)" is added 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): Upon further consideration, 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
Subsection (c)(3): The timeframe of "2018-2019" is replaced with "2020-2021" to better reflect the estimated time of completion for this regulation package.

Section 10056.5
Subsection (c): The timeframe of "2018-2019" is replaced with "2020-2021" to better reflect the estimated time of completion for this regulation package.

Section 10060
Upon further consideration, 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).)

Section 10160
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 (b): As a result of public comment and upon further consideration, 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): Upon further consideration, this subsection is added 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): As a result of public comment and upon further consideration, this subsection 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): Upon further consideration, the beginning of 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.

Subsections (b)(2), (c)(1) and (c)(5): Upon further consideration, the language "success or failure of treatment" and "treatment failure"; is amended to "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): To correct an inconsistency, this subsection is amended to remove the language "two years" and replace 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): As a result of public comment and upon further consideration, this subsection is 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."

Section 10240
Upon further consideration, 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 inform the patient of the availability of an identification card 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 Welfare and Institutions Code section 11839.3(a)(1).

Subsection (c): Existing subsection (c) has been re-designated to subsection (d)(1). New language is added under subsection (c) 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 subsection is added to clarify that patient identification cards can still be used as part of a program’s patient identification system. Subsection (d)(1) was formerly subsection (c) and is amended for clarity and consistency. Accordingly, existing subsection (c)(1)-(7) is re-designated as (d)(1)(A)-(G), respectively. Subsections (d)(1)(G), (d)(2) and (d)(3) are all amended to clarify that the provisions pertain to a “patient” identification card for consistency throughout this section.

Existing subsections (d) and (e): These existing subsections are re-designated to (d)(2) and (d)(3), respectively. This is necessary to organize requirements related to the use of patient identification cards under one subsection for clarity.

Existing subsection (f): This subsection 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.

Subsection (e)(1): The language of this provision 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.

Subsection (e)(2): This subsection is added as a lead in to specify that these additional protocol requirements only apply when a program employs the use of patient identification cards.

Subsection (e)(2)(A): This subsection is re-designated from 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 patient identification cards. This is necessary to provide clear guidance to programs regarding protocol requirements and to safely secure identifying information.

Subsection (e)(2)(B): This subsection is re-designated from 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 10270
Subsection (a)(2): As a result of public comment and upon further review, this subsection is amended to spell out the acronyms for HIV and HCV by adding the words "(human immunodeficiency virus)" and "(hepatitis C virus)" for clarity. This subsection is also amended to include the following language, "An optional laboratory test for the determination of HIV (human immunodeficiency virus) 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.

Subsection (a)(3)(C): As a result of public comment and upon further consideration, the word "and" is added 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): Upon further consideration, the word "failures" is removed and replaced with "outcomes,"; as the Federal Guidelines for Opioid Treatment Programs, Pages 15, 16, and 46, utilizes the language "treatment outcome."

Subsection (d)(2): Upon further consideration the existing language under subsection (d)(2) is deleted and 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 a 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 Code of Federal Regulations, 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): As a result of public comment and upon further consideration, the language "including linkages to care and treatment, where needed, for patients who test positive for HIV, HCV, tuberculosis or syphilis" is added 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 10355

Subsection (g): As a result of public comment and upon further consideration, the word "After" is replaced with "When" for clarity. This section 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): As a result of public comment and upon further consideration, this section is amended to allow 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): Upon further consideration, this subsection is added 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): Upon further consideration, 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): As a result of public comment and upon further consideration, the proposed language "During the first 90 days of continuous maintenance treatment, take-home medication is not permitted, except as provided in Section 10380" is removed. It is replaced with the following language, "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 a week for observed ingestion." This is necessary to align with the time in treatment requirements for take-home medication as specified in 42 Code of Federal Regulations section 8.12(i)(3)(i) and for consistency with the remainder of subsection (a)(2)-(6).

Subsection (a)(2)-(3): These subsections are amended to include the clarifying phrase "per week", which is consistent with the language in 42 Code of Federal Regulations section 8.12(i)(3)(ii) and (iii), respectively.

DOCUMENTATION ADDED TO THE RULEMAKING FILE

1. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), Section II, page 483.
2. 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.
3. Federal Guidelines for Opioid Treatment Programs, March 2015, pages 15, 16, 29, 32 and 46.
4. The Canadian Women's Health Network (CWHN) - http://www.cwhn.ca/en/node/42905.

CONTACT PERSONS

Inquiries regarding the proposed changes to the regulations and/or documentation added to the rulemaking file described in this notice may be directed to Crystal Sanchez, Substance Use Disorder Compliance Division at (916) 345-7482.

All other inquiries concerning the regulatory action described in this notice may be directed to Kenneisha Moore of the Office of Regulations, at (916) 345-8403, or to the designated backup contact person, Jasmin Delacruz, at (916) 440-7695.

ASSISTIVE SERVICES

The Department can also provide assistive services such as the conversion of written materials into Braille, large print, audiocassette, or computer disk. To request these assistive services, please call (916) 440-7695 (or California Relay at 711 or 1-800-735-2929), email – regulations@dhcs.ca.gov, or write to the Office of Regulations at the address noted above.

AVAILABILITY OF MATERIAL REGARDING THE REGULATORY ACTION

Materials regarding the regulatory action described in this notice (including this public notice and the additional changes to the text of the proposed regulations) are posted to the Department's Internet site at:
https://www.dhcs.ca.gov/formsandpubs/laws/regs/Pages/14-026.aspx.