45-Day Public Comment Period
List of Commenters

Commenter #1 (submitted 9-25-18)
Brian Clear - MD

Commenter # 2 (submitted 10-1-18)
Rachel McLean, MPH - Chief, Office of Viral Hepatitis Prevention STD Control Branch, CDPH

Commenter #3 (submitted 10-2-18)
April Grant - Director, Policy & Government Relations, Alkermes, Inc.

Commenter #4 (submitted 10-2-18)
Elizabeth Stanley-Salazar, MPH - Stanley Salazar Consulting

Commenter #5 (submitted 10-2-18)
Jason Kletter, Ph.D. - President, BayMark Health Services

Commenter #6 (submitted 10-3-18)
Brad Shapiro, MD, FASAM - Member, CSAM Opioid Committee

Commenter #7 (submitted 10-3-18)
Hector Hernandez-Delgado - Staff Attorney, National Health Law Program

Section 10000(a)(2)

Comment #2A

Page 1, The definition of buprenorphine in § 1000. Definitions. 4, Title 9, California Code of Regulations as being "administered intravenously or intramuscularly to treat moderate to severe pain and sublingually to treat opioid dependence" seems limiting. I would imagine there will be different formulations and routes of administration over time, and would recommend that DHCS consider removing the routes of administration (intravenously, muscularly, sublingually) from this section. Or add something that can be inclusive later on, such as "**and by other routes**."

Response #2A

While the commenter referenced § 1000, the Department believes this comment is in reference to the proposed definition for buprenorphine under Section 10000(a)(2). As a result of public comment, this subsection was 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 as proposed "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.)

Comment #4A

(1) use chemical formula (as with Methadone in 10000 (17) and LAAM in 10000 (10). Buprenorphine is now available for SQ injection for opioid use disorder and route of administration may continue to change.

The commenter proposed deleting the following language "intravenously or intramuscularly to treat moderate to severe pain and sublingually to treat opioid dependence."

Response #4A

As a result of public comment, this subsection was amended. Please see response #2A.

Comment #6A

(1) use chemical formula (as with Methadone in 10000 (17) and LAAM in 10000 (10). Buprenorphine is now available for SQ injection for opioid use disorder and route of administration may continue to change.

The commenter proposed deleting the following language "intravenously or intramuscularly to treat moderate to severe pain and sublingually to treat opioid dependence."

Response #6A
As a result of public comment, this subsection was amended. Please see response #2A.

Section 10000(a)(5)

Comment #1A
10000(a)(5) Detoxification Treatment: the phrase "reduce or eliminate opioid *addiction*" is inaccurate as "opioid addiction" is defined in section 10000 (a) (23). Detoxification treatment is known to reduce or eliminate "physical dependence to opioids," as defined in 10000 (a) (24) but is known to offer no benefit for treatment of use disorders or "addiction," itself.

Response #1A
As a result of public comment, this subsection was 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).

Section 10000(a)(15)(C)

Comment #4B
Clarifies interface with federal guidelines governing OBOT and the NTP/OTP. Allows individualized medical treatment at one site without inappropriate restrictions to waivered MD. However, the federal guidelines state that programs/practitioners providing the option for OPT or OBOT within one program must develop clear policies and procedures for assigning patients to one or the other model and establish criteria for a specific pharmacotherapy. (Federal Standards Page 50) See added language to 10145.

The commenter proposed adding the following language:

> "Treatment with other pharmacotherapies may be provided in a manner consistent with the best medical practices for each medication and consistent with DATA 2000 federal guidelines."

Response #4B
This comment was considered, however, the regulations were not amended. This section defines medication in accordance with Health and Safety Code section 11839.2. However, expanding the definition of "medication" to include treatment with other pharmacotherapies provided in a manner consistent with the best medical practices for each medication and consistent with DATA 2000 federal guidelines, goes beyond the authority set forth in Health and Safety Code section 11839.2.

While not explicitly stated, the Department believes that this comment refers to the delivery of care and the availability of pharmacotherapies in an office-based opioid treatment (OBOT). OBOT refers to outpatient treatment services provided in a medical office setting by a clinician who has a waiver under the Drug Addiction Treatment Act of 2000 (DATA 2000) to prescribe buprenorphine for treatment of opioid use disorder. OBOTs allow clinicians to treat opioid addiction within their regular medical practice outside of a licensed NTP. (https://www.asam.org/docs/default-source/public-policy-statements/statement-on-regulation-of-obot.pdf?sfvrsn=df8540c2_2)

Implementing requirements for an OBOT were not within the scope of this proposal; therefore, requirements for a DATA 2000 waivered physician were not addressed.

Comment #6B
Clarifies interface with federal guidelines governing OBOT and the NTP/OTP. Allows individualized medical treatment at one site without inappropriate restrictions to waivered MD. However, the federal guidelines state that programs/practitioners providing the option for OPT or OBOT within one program must develop clear policies and procedures for assigning patients to one or the other model and establish criteria for a specific pharmacotherapy. (Federal Standards Page 50) See added language to 10145.

The commenter proposed deleting "opioid agonist" and "use in replacement narcotic therapy" from the definition of "Medication" to read as follows:

> "Medication" means any medications that have been approved for the treatment of opioid use disorder, including:…"

The commenter also proposed to add the following language:

> "Treatment with other pharmacotherapies may be provided in a manner consistent with the best medical practices for each medication and consistent with DATA 2000 federal guidelines.

Response #6B
This comment was considered, however, the regulations were not amended. The proposed deletions to the definition of "medication" were not implemented since these words are needed for clarity and consistency. The phrase "opioid agonist" clarifies

the type of medications being defined and the phrase “use in replacement narcotic therapy” is consistent with Health and Safety Code section 11839.2. Please also see response #4B.

Section 10000(a)(15)(D)

Comment #5A

The commenter proposed deleting “opioid agonist” and “replacement” from the definition of “Medication” to read as follows:

> “Medication” means any medications that have been approved for use in narcotic therapy, including:…”

The commenter also proposed adding the following language:

> “(D) 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.”

Response #5A

As a result of public comment, this subsection was amended to partially implement the commenter’s proposed changes. The proposed deletions to the definition of “medication” were not implemented since these words are needed for clarity. The phrase “opioid agonist” is necessary to clarify the type of medications being defined and the term “replacement” clarifies the type of narcotic therapy being referenced.

However, the definition was amended to add the commenter’s proposed language under paragraph (D), which brings the definition into alignment with Health and Safety Code section 11839.2(d).

Section 10000(a)(16)

Comment #2B

Page 3, The definition of a medication unit in line 16 to a private provider seems limiting; could a medication unit also be run by a public provider?

Response #2B

This comment was considered, however, the regulations were not amended. As discussed in the Initial Statement of Reasons (ISOR), the proposed amendments to this subsection bring the definition into alignment with 42 Code of Federal Regulations (CFR) section 8.2, which states that a “Medication unit means a facility established as part of, but geographically separate from, an opioid treatment program from which licensed private practitioners or community pharmacists dispense or administer an opioid agonist treatment medication or collect samples for drug testing or analysis.” The Department believes that the term “public provider,” as used by the commenter, refers to a federal, state, county or other local government agency. A public provider may

own/operate a medication unit. They are required to apply with Department and adhere to the same state and federal regulations as a privately owned NTP.

Section 10000(a)(19)

Comment #1B

10000(a)(19) and further instances throughout: The phrase “Narcotic Treatment Program” is a stigmatizing and medically inaccurate nomenclature for use of methadone or buprenorphine in a structured out-patient treatment environment. "Narcotic" as defined in 10000 (a) (18) and as commonly understood does not correctly describe methadone or buprenorphine treatment under appropriate medical supervision which does not produce "insensibility or stupor." Treatment access is harmed by incorrect use of this term with associated negative legal and medical connotation. I recommend replacement of “narcotic treatment program” with the more current and appropriate nomenclature “opioid treatment program,” throughout.

Response #1B

This comment was considered, however, the regulations were not amended. “Narcotic treatment program” is the term used throughout Division 10.5, Part 2, Chapter 10 of the California Health and Safety Code, which provides the Department’s legal authority to regulate these programs. Therefore, the term “narcotic treatment program” was used throughout the regulations to remain in alignment with statutory authority.

Comment #4C

Make consistent with change in CFR Title 42 Part 8. This reflects changes in OUD treatment, reduces stigma, and supports practitioner engagement in delivery of treatment options. Make reference consistent throughout regulations changing all 39 NTP references in addition to the definition.

The commenter proposed amendments to the beginning of the definition to read as follows:

“Opioid Treatment Program (formerly known as Narcotic Treatment Program) means…”

Response #4C

This comment was considered, however, the regulations were not amended. Please see response #1B.

Comment #6C

Make consistent with change in CFR Title 42 Part 8. This reflects changes in OUD treatment, reduces stigma, and supports practitioner engagement in delivery of treatment options. Make reference consistent throughout regulations changing all 39 NTP references in addition to the definition.

The commenter proposed amendments to the beginning of the definition to read as follows:
"Opioid Treatment Program (formerly known as Narcotic Treatment Program) means….".

The commenter also proposed to replace the phrase "replacement narcotic therapy" with "opioid agonist" or "opioid agonist treatment."

Response #6C
This comment was considered, however, the regulations were not amended. Please see response #1B regarding the use of the phrase "Narcotic Treatment Program." The phrase "replacement narcotic therapy" was not replaced since it is a defined term used throughout the regulations and is consistent with Health and Safety Code section 11839.2.

Section 10000(a)(20)

Comment #2C
Page 4, The definition of an office-based narcotic treatment network contains potentially stigmatizing language. According to SAMHSA, "The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), no longer uses the terms substance abuse and substance dependence, rather it refers to substance use disorders, which are defined as mild, moderate, or severe to indicate the level of severity, which is determined by the number of diagnostic criteria met by an individual." We would recommend replacing the phrase "opioid-abusing population" here and throughout the regulation with the phrase "**people with opioid use disorders**."

Response #2C
This comment was considered, however, the regulations were not amended as suggested. Instead, this subsection was amended to replace the language "opioid-abusing" 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.

Comment #4D
Assessment should be comprehensive.

The commenter proposed adding "and other non-opioid drugs" to the definition.

Response #4D

The Department believes this comment suggests that an office-based narcotic treatment network (OBNTN) provider be required to offer a more comprehensive assessment to patients receiving services to include non-opioid drugs. This comment was considered, however the regulations were not amended. The scope of this regulatory proposal is specific to narcotic treatment programs; accordingly, the patients will be receiving counseling by addiction counselors covering issues regarding illicit drug use. This definition is consistent with Section 10345(d)(4)(B), which requires a counselor to respond and document a patient's drug-screening specimen which is positive for illicit drugs or is negative for the replacement narcotic therapy medication dispensed by the program.

Comment #6D
Assessment should be comprehensive.

The commenter proposed adding "and other non-opioid drugs" to the definition.

Response #6D
This comment was considered, however the regulations were not amended. Please see response #4D.

Comment #4E
Abuse is no longer a term used in practice of addiction medicine / less stigmatizing language

The commenter proposed amending the definition to read
"…screening for diseases that occur disproportionately in the individuals suffering from opioid use disorder population…"

Response #4E
The Department believes the commenter intended to propose the following language, "…screening for diseases that occur disproportionately in the individuals suffering from opioid use disorder," This comment was considered, however, the regulations were not amended as suggested. Instead, the subsection was amended as discussed in response #2C.

Comment #6E
Abuse is no longer a term used in practice of addiction medicine / less stigmatizing language

The commenter proposed amending the definition to read
"…screening for diseases that occur disproportionately in the individuals suffering from opioid use disorder…"

Response #6E
This comment was considered, however, the regulations were not amended as suggested. Instead, the subsection was amended as discussed in response #2C.

Comment #4F
Allows access to services and flexibility in the design and delivery of services within a local community. Also pharmacies will hopefully serve as medication units, and they will generally not be willing to collect body substances for drug testing, so it will need to happen in the OBNTN.

The commenter proposed to add the following language:
"OBNTN may collect sample for drug testing or analysis."

Response #4F
This comment was considered, however, the regulations were not amended. The OBNTN is a means of increasing access to counseling services, evaluations and screening for diseases when a patient is unable to receive these services at the primary NTP. Collection or test of a patient body specimen for illicit drug use may be completed at the primary NTP or medication unit. The purpose of a medication unit is to dispense or administer an opioid agonist treatment medication and/or collect samples for drug testing or analysis, if the patient is unable to obtain these particular services at the primary NTP. Medication Units as defined in Section 10000(a)(16) are not limited to pharmacies and include licensed private practitioners, who in addition to administering and dispensing medications may also collect patient body specimens for testing or analysis for illicit drug use.

Comment #6F
Allows access to services in rural communities.

The commenter proposed adding the following language:
"OBNTN may collect sample for drug testing or analysis."

Response #6F
This comment was considered, however, the regulations were not amended. Please see response #4F.

Comment #6G
And flexibility in the design and delivery of services within a local community. Also pharmacies will hopefully serve as medication units, and they will generally not be willing to collect body substances for drug testing, so it will need to happen in the OBNTN

Response #6G
This comment was considered, however, the regulations were not amended. Please see response #4F.

Section 10000 (a)(23)

Comment #2D
Consider replacing the term "opioid addiction" with **"opioid use disorder**" here and throughout the regulation for the same reasons listed above – that SAMHSA and the DSM-V now use the term "substance use disorder."

Response #2D
This comment was considered, however, the regulations were not amended. Opioid addiction is referenced throughout the Federal Guidelines for Opioid Treatment Programs, is defined in Section 10000(a)(23) and is used throughout the regulations.

Comment #4G
Opioid Use Disorder is the correct medical lexicon, clarified in general use by the next two references

Response #4G
The Department believes the commenter was proposing to replace the word "addiction" with "use disorder." This comment was considered, however, the regulations were not amended. Please see response #2D.

Comment #6H
Opioid Use Disorder is the correct medical lexicon, clarified in general use by the next two references

The commenter proposed replacing the word "addiction" with "use disorder."

Response #6H
This comment was considered, however, the regulations were not amended. Please see response #2D.

Section 10000(a)(34)(C)

Comment #4H
Abuse is no longer a term used in practice of addiction medicine/ less stigmatizing wording

The commenter proposed the following language:

"Screening for diseases that occur disproportionately in individuals suffering from opioid use disorder population."

Response #4H
This comment was considered, however, the regulations were not amended as suggested. Instead, this subsection was 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.

Comment #6I
Abuse is no longer a term used in practice of addiction medicine/ less stigmatizing wording

The commenter proposed the following language:
"Screening for diseases that occur disproportionately in individuals suffering from opioid use disorder."

Response #6I
This comment was considered, however, the regulations were not amended as suggested. Please see response #4H.

Section 10020(b)(1)

Comment #5B
If eliminating this requirement, what mechanism will the department employ to prevent service area overlap?

Response #5B
This comment was considered, however, the regulations were not amended. The proposed language for subsection (b) specifies the requirements for a primary NTP to request Department approval to add a medication unit to its existing license. This process includes the completion of the Facility and Geographical Area form DHCS 5025 (04/16) to provide a description of the geographical surrounding areas to be served and the population of the areas to be served (subsections (b)(1)-(2) respectively.) The removal of the existing provision, as discussed in the ISOR, is to reduce barriers to establishing medication units thereby allowing greater access to services, which may result in service area overlap.

Section 10020(h)

Comment #7A
A major barrier to access to methadone and buprenorphine treatment in California is the fact that most NTPs in the state are located in urban areas. In 2016, 13% of all NTPs in the U.S. were located in California. However, the vast majority of these NTPs are concentrated in counties with populous urban areas, such as Alameda, Los Angeles, Sacramento, San Diego, and San

Francisco. In fact, in 28 of California's 58 counties there are no licensed NTPs. These 28 counties are located in the most rural and isolated areas of the state. This creates a major barrier for individuals with SUD who reside in rural areas of the state, which also bear the highest burden of the opioid epidemic. For example, in 2017, the counties of Modoc, Humboldt, and Lake had the highest opioid overdose rate of all California counties. However, there are currently no licensed NTPs in any of these counties, which means that residents of these counties who seeking to access SUD treatment would have to travel long distances to receive medication at an NTP.

Medication units and OBNTNs may help alleviate these concerns by allowing NTPs to operate satellite locations without the need to go through the whole licensing process. Under federal regulations, medication units may be established by an NTP as long as the NTP notifies SAMHSA of its intention to establish such a unit and provided the NTP (and its medical unit(s)) continue abiding by the requirements of 21 C.F.R. § 1300 et seq. The federal rule requires NTPs to comply with all state requirements in addition to the federal requirements; that is the federal rule does not preclude the state from enacting more stringent requirements for establishment of medication units by properly licensed NTPs.

By imposing requirements that are more stringent than the federal requirements for establishment of medication units and OBNTNs, current California regulations serve as a barrier for NTPs to expand to and operate in isolated areas of the state. Because there is no federal requirement that medication units or OBNTNs be licensed in the same way that primary NTPs are, we strongly support the proposal to eliminate this requirement from the state regulations. We believe this change will encourage NTP expansion into those areas where MAT is desperately needed, but where expansion is currently not viable due to licensing restrictions. In addition, we commend DHCS for its proposal to remove the strict requirement that medication units and OBNTNs be geographically isolated "to such an extent that regular patient travel to the [principal NTP] is impractical and would cause the patient great hardship." While we agree that the main purpose of medication units and OBNTNs is to provide an alternative for isolated areas, we believe limiting the requirements to compliance with the federal rule suffices and that all units that have received SAMHSA approval should be similarly approved by DHCS.

For that same reason, we recommend that the proposed provision limiting the combined licensed patient capacity of primary NTP and medication units to the general capacity of the NTP be removed. This limitation is not mandated by the federal rule and may negate the benefits of facilitating the establishment of medication units and OBNTNs in the first place. Limiting the number of patients is also not consistent with available evidence regarding MAT and would add another barrier on top of the already stringent federal requirements around provider administration and prescribing of methadone and buprenorphine.

Response #7A

The Department appreciates the comment of support regarding the removal of requirements that are potential barriers to access substance use disorder services and treatment.

The Department believes the other comment is in reference to Section 10020(h). The comment was considered, however, the regulations were not amended. Health and Safety Code section 11839.3(d) provides the Department with the sole responsibility and authority to establish the maximum (treatment) patient capacity of a license. The primary NTP license is inclusive of any medication unit and/or OBNTN, therefore, the patient capacity cannot exceed the patient capacity set forth on the NTP license. However, the Department has implemented flexibility in its assessment and determination of patient capacity by removing the 750 patient capacity limitation for an NTP and providing the NTPs the ability to request an increase to patient capacity at any time. See regulation text Sections 10145 and 10035, respectively.

Section 10020(m)

Comment #1C

10020 (m) Limiting on-site testing of samples to that for "illicit" drug use may reasonably be interpreted as precluding the ability to test for alcohol use on site, for instance by way of breath alcohol testing, which is a necessary component of safe medication administration for certain patients. I recommend eliminating the word "illicit."

Response #1C

This comment was considered, however, the regulations were not amended. The term “illicit” is a commonly used term throughout the Federal Guidelines for Opioid Treatment Programs and Health and Safety Code section 11839.20(c), which states, “The Legislature declares the ultimate goal of all narcotic treatment programs shall be to aid the patient in altering his or her lifestyle and eventually to eliminate the improper use of legal drugs and the use of illicit drugs.” The use of the term “illicit” within this section does not preclude testing for alcohol. While patient body specimens are collected for testing or analysis for illicit drug use, the medication unit is also responsible for evaluating a patient prior to dispensing or administering replacement narcotic therapy. For the health and safety of the patient, this evaluation may include testing for the use of alcohol or other substances.

Section 10030(a)(22)

Comment #4I

While the use of physician extenders is critical and widely supported to provide access to a myriad of health care services where physicians are not available, the roles and responsibilities of these practitioners must be defined within operations workflows and a description of how the agency will meet any “supervision” outlined in DHCS or Medical Board requirements.

The commenter proposed the following amendments to the regulation text:

", including a supervision plan in accordance with state regulations related to physician extenders under the medical director, if ~~appropriate~~;"

Response #4I
This comment was considered, however, the regulations were not amended. The roles and responsibilities of these practitioners are already specified in regulation under California Code of Regulations, title 9, section 10120. Furthermore, supervision requirements for these practitioners fall under the purview of their licensing entity (i.e. Medical Board of California or Board of Registered Nursing) and is outside of the Department's jurisdiction.

Comment #6J
While the use of physician extenders is critical and widely supported to provide access to a myriad of health care services where physicians are not available, the roles and responsibilities of these practitioners must be defined within operations workflows and a description of how the agency will meet any "supervision" outlined in DHCS or Medical and/or nursing Board requirements

The commenter proposed the following amendments to the regulation text:
", including a job description based on scope of practice and supervision plan in accordance with state regulations related to physician extenders under the medical director~~, if appropriate~~"

Response #6J
This comment was considered, however, the regulations were not amended. Please see response for #4I

Section 10040

Comment #4J
Reflects current county structures as well as small county administration. Make this correction throughout document

The commenter proposed adding the following language to the section title:
"Behavioral Health and/or."

Response #4J
This comment was considered, however, the regulations were not amended. The references in this section and throughout these regulations to the "county alcohol and drug program administrators" are consistent with Health and Safety Code section 11839.3(a)(6), which states, "the department shall evaluate recommendations made by county alcohol and drug program administrators regarding licensing activity in their respective counties."

Comment #6K
Reflects current county structures as well as small county administration. Make this correction throughout document

The commenter proposed adding the following language to the section title:
"Behavioral Health and/or."

Response #6K
This comment was considered, however, the regulations were not amended. Please see response #4J.

Section 10055(b)(2)

Comment #5C
we agreed to only require county certification upon initial licensure

The commenter proposed removing the following language in subsection (b)(2):
"(2) The County Alcohol and Drug Program Administrator submits to the Department the County Certification form DHCS 5027 (04/16) that includes:
() A certification of need for continued services of the narcotic treatment program; and
() A recommendation for renewal of the license. we agreed to only require county certification upon initial licensure."

Response #5C
This comment was considered, however the regulations were not amended. A county recommendation is required for NTP licensing actions including initial licensure, relocations, and annual license renewals. This is consistent with Health and Safety Code section 11839.3(a)(6) which states, "the department shall evaluate recommendations made by county alcohol and drug program administrators regarding licensing activity in their respective counties."

Section 10060

Comment #2E
Page 49, Regarding the department's evaluation of programs, we would recommend allowing for the reality that some people will continue to use drugs throughout their lifetime. Suggest editing as follows: "The department may study and evaluate all programs on an ongoing basis to determine the effectiveness of each program's effort to aid patients ~~in altering their life styles~~ to **reduce or eliminate their opioid use disorder** ~~and eventually eliminate their opioid addiction.~~"

Response #2E
This comment was considered, however, the regulations were not amended as suggested. Instead, the section was 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.

Section 10145(b)

Comment #4K
Clarifies the interface OTP and OBOT which is not the OBNTN model. This is spelled out in federal guidelines on page 50 and in other SAMHSA sources.

The commenter proposed adding the following language:

> “In the case of qualified waivered practitioner providing office based opioid treatment services under Drug Addiction Treatment Act of 2000 (DATA 2000) rules, the program shall develop clear policies and procedures for assigning patients to a specific model of care i.e. OTP (NTP) or OBOT and establish criteria for determining a specific pharmacotherapy.”

Response #4K
This comment was considered, however, the regulations were not amended. This section specifies the requirements for the licensed patient capacity of the NTP, medication unit, and/or OBNTN. Implementing requirements for an OBOT were not within the scope of this proposal; therefore, requirements for a DATA 2000 waivered physician were not addressed.

Comment #6L
Clarifies the interface OTP and OBOT which is not the OBNTN model. This is spelled out in federal guidelines on page 50 and in other SAMHSA sources.

The commenter proposed adding the following language:

> “In the case of qualified waivered practitioner providing office based opioid (OBOT) treatment services under Drug Addiction Treatment Act of 2000 (DATA 2000) rules, the program shall develop clear policies and procedures for assigning patients to a specific model of care i.e. OTP (NTP) or OBOT and establish criteria for determining a specific pharmacotherapy.”

Response #6L

This comment was considered, however, the regulations were not amended. Please see response #4K.

Section 10160(a)(1)

Comment #1D

10160 (a) (1) Phrasing here fails to consider current norms in electronic medical record-keeping which often require patient data to be stored on media physically located outside the facility. Recommend re-phrasing to "…a secure location that is immediately accessible from within the facility." or similar.

Response #1D

As a result of public comment, section 10160(b) 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.

Comment #4L

Many agencies have converted to EHR

The commenter proposed adding the following language:

"using a secure electronic health record and/or paper record."

Response #4L

As a result of public comment, the regulations were amended. Please see response #1D.

Comment #6M

Many agencies have converted to HER

The commenter proposed adding the following language:

"using a secure electronic health record and/or paper record."

Response #6M

While the commenter references "HER", the Department believes this comment is regarding "EHR" – electronic health records. As a result of public comment, the regulations were amended. Please see response #1D.

Section 10165(a)(2)

Comment #4M
Add number of days and establish an appropriate deadline. As stated there is no measure of accountability.

The commenter proposed amending subsection (a)(2) to (a)(1)(A) and adding the following language:
"within XX days of admission and or testing."

Response #4M
This comment was considered, however, the regulations were not amended. The commenter proposes that Section 10165 of the regulations should also specify the timeframe within which a physical examination should be completed. However, Section 10165 only establishes the documentation that must be maintained in a patient's record, which includes "physical examination data." The timeframe within which this physical examination should be completed is already specified in Section 10270 – Criteria for Patient Selection. Specifically, Section 10270(a) requires a physical evaluation to be completed before admitting an applicant into treatment.

Comment #6N
Establish and appropriate deadline. As stated there is no measure of accountability.

The commenter proposed amending subsection (a)(2) to (a)(1)(A) and adding the following language:
"within XX days of admission and or testing."

Response #6N
This comment was considered, however, the regulations were not amended. Please see response #4M.

Section 10165(a)(3)

Comment #4N
There is no medical or regulatory reason to differentiate between heroin and other opioids.

The commenter proposed amending subsection (a)(3) to (a)(2) and adding the following language:
"opioid physical dependence use of heroin or other opiates opioids."

Response #4N
The Department believes the commenter intended to propose the following language, "Evidence of current opioid physical dependence." This comment was considered, however, the regulations were not amended as suggested. Instead, the subsection

was amended to remove the language “heroin or other.” This is necessary for consistency throughout the regulations, which were 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.

Comment #6O
There is no medical or regulatory reason to differentiate between heroin and other opioids

The commenter proposed amending subsection (a)(3) to (a)(2) and amending the language as follows:
“physical opioid dependence ~~use of heroin or other opiates opioids~~”

Response #6O
This comment was considered, however there regulations were not amended as suggested. Instead this subsection was amended as discussed in response #4N.

Comment #6P
Consistent with medical criteria and other sections of these proposed regulations

Response #6P
This comment was considered, however, the regulations were not amended. The commenter’s request was unclear. This comment was associated with the word “opioids,” which is in strikeout. Therefore, the Department believes the word is proposed to be deleted by the commenter. However, this is in conflict with the Department’s proposed amendments to replace the word “opiate” with “opioid” which is the current terminology used within the substance use disorder community. Please see ISOR discussion for Section 10000(a)(22).

Section 10165(a)(6)

Comment #2F
Section 10165(a)(6) The phrase “arrest and conviction or any other signs of retrogression” is potentially stigmatizing, especially given that people of color in particular are more likely to be arrested without probable cause.

Response #2F
This comment was considered, however, the regulations were not amended. Replacement narcotic therapy in combination with counseling and behavioral therapies provides a whole-person approach to the treatment of specific substance use disorders. Research shows that a combination of replacement narcotic therapy and behavioral therapies is a successful method to treat

substance use disorders. The program being aware of arrests, convictions or any other signs of retrogression is necessary for the patient's assigned counselor to provide comprehensive services.

Comment #4O
Defines accountability. The commenter suggested adding the word "Known" at the beginning of this subsection.

Response #4O
As a result of public comment, this subsection was 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.

Comment #6Q
Defines accountability. The commenter suggested adding the word "Known" at the beginning of this subsection.

Response #6Q
As a result of public comment, this subsection was amended. Please see response #4O.

Section 10165(c)(1)

Comment #1E
10165 (c)(1 and 5) In (1) replace "failure" with "episodes." A period of time in treatment followed by relapse then return to treatment is not accurately described as a failure; rather it is a commonly observed and expected characteristic of the course of treatment for most patients.

Response #1E
As a result of public comment, this subsection was amended to replace "treatment failure" 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."

Section 10165(c)(3)

Comment #4P
Unnecessary. There is no medical rationale supporting treatment of less than 2 years duration. Documentation would occur under continuation of treatment MD notations.

The commenter proposed deleting the following language

"For any patient who is to be continued on maintenance treatment beyond two years,"

Response #4P

This comment was considered, however, the regulations were not amended as suggested. Instead, this subsection was 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 correct an inconsistency and to align with proposed 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. Please see ISOR discussion for Section 10410(a).

Comment #6R

Unnecessary. There is no medical rationale supporting treatment of less than 2 years duration. Documentation would occur under continuation of treatment MD notations.

The commenter proposed deleting subsection (c)(3).

Response #6R

This comment was considered, however, these regulations were not amended as suggested. Please see response #4P.

Section 10165(c)(5)

Comment #1F

10165 (c) (1 and 5) In (5) replace "success or failure of treatment," with "treatment outcome" for same reason.

Response #1F

This comment was related to Comment #1E. As a result of public comment, the regulations were amended. Please see response #1E.

Section 10190(a)

Comment #4Q

Recognize the use of physician extenders throughout program operation where appropriate and guided by Program Protocols and Job Responsibilities. This begins to address workforce crisis.

The commenter proposed adding the phrase "physician extender" to the regulation text.

Response #4Q
This comment was considered, however, the regulations were not amended. This section does not preclude the medical director from delegating these duties to a physician extender in accordance with Section 10030(a)(22) and Section 10120. Please also see response #4I.

Comment #6S
Recognize the use of physician extenders throughout program operation where appropriate and guided by Program Protocols and Job Responsibilities. This begins to address workforce crisis.

The commenter proposed adding the phrase "physician extender" to the regulation text.

Response #6S
This comment was considered, however, the regulations were not amended. Please see response #4Q.

Section 10190(a)

Comment #2G
Page 59 Regarding procedures in the event of a patient's incarceration, include treatment not only for withdrawal symptoms but also for opioid use disorder. "If the program is aware that a patient has been incarcerated, the program physician or program director shall attempt to cooperate with the jail's medical officer in order to ensure the necessary treatment for opioid withdrawal symptoms **or opioid use disorder, where treatment is available,** whenever it is possible to do so." Treatment for people with opioid use disorder is critical during incarceration and has been shown to reduce the high likelihood of overdose death upon release from an even brief period of incarceration. It is also critically important for pregnant women during the period of incarceration and upon release.

Response #2G
As a result of public comment, this subsection was amended to partially implement the commenter's proposed language. Specifically, the language "or opioid addiction, where treatment is available" was added 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 "opioid addiction" was implemented instead of "opioid use

disorder" since it is a defined term used throughout the regulations. The phrase "whenever it is possible to do so" is removed since it is redundant to the phrase "where treatment is available."

Section 10195

Comment #4R

Details of cause of death are not always known. Form 5048 should be updated to reflect this fact.

The commenter proposed adding the following language to the first sentence of this section:

"and information known"

Additionally, the commenter proposed adding the following language for subsection (a)(2):

"Patient Death Report should be updated with more complete information regarding cause of death within 30 days if it becomes available."

Response #4R

This comment was considered, however, the regulations and Patient Death Report form DHCS 5048 were not amended. As currently proposed, Patient Death Report form DHCS 5048, already reflects that the details of the cause of death are not always known. If there is an "unknown cause of death" it should be specified on the Patient Death Report Form DHCS 5048, in the Section C, titled "Cause of Death (describe the cause of death and all relevant details ***known*** about the death of the patient)" (emphasis added.)

The proposed requirement that the program update the Patient Death Report form DHCS 5048 within 30 days with additional information regarding the cause of death is not necessary. The regulation does not preclude the Department from requesting updated information in the event additional details are needed.

Comment #6T

Details of cause of death are not always known. Form 5048 should be updated to reflect this fact

The commenter proposed adding the following language to the first sentence of this section:

"and information known"

Additionally, the commenter proposed adding the following language for subsection (a)(2):

"Patient Death Report should be updated with more complete information regarding cause of death within 30 days if it becomes available."

Response #6T
This comment was considered, however, the regulations were not amended. Please see response #4R.

Section 10240(b)

Comment #4S
ID will use unique identifier when issued.

Response #4S
This comment was considered, however, the commenter's request was unclear. This comment was associated with subsection (b) and the Department believes the commenter intended to propose the deletion of this subsection. As a result of public comments, this subsection was amended to require the assignment of a unique identifier to a patient as part of a program's patient identification system. The use of a unique identifier to identify a patient is required for all types of patient identification systems, whether or not 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) and for consistency with Section 10160(a).

Comment #6U
ID will use unique identifier when issued**.** The commenter proposed to delete subsection (b).

Response #6U
As a result of public comment, this subsection was amended. Please see response #4S.

Section 10240(f)(4)

Comment #4T
Many programs utilize secure electronic systems

The commenter proposed adding the following language:

(4) Programs may use electronic identification cards, while patient is at the program in place of hard copy cards. The electronic identification should be accessible at the front desk, dispensary, and on management and/or counselor computers.

Response #4T
As a result of public comment, Section 10240 was amended to specify the requirements for a "Patient Identification System." Accordingly, the title of this section was 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 were 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. The additional amendments to this section are discussed below.

Subsection (a) was amended to require a program to establish and maintain a patient identification system. This was 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, was 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) was amended as discussed in Response #4S.

Existing subsection (c) was re-designated to subsection (d)(1). New language was proposed to be added under subsection (c) to specify the information that shall be maintained in a program's patient identification system. This was necessary to provide programs guidance as to the required information to 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.

Newly proposed subsection (d) was 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, were necessary to organize requirements related to the use of patient identification cards under one subsection for clarity.

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

Existing subsection (c)(7), was re-designated as subsection (d)(1)(G) and was amended to clarify that the provisions pertain to "patient" identification cards for consistency throughout this section.

Existing subsection (d) was re-designated to subsection (d)(2) and was amended to clarify that the provisions pertain to "patient" identification cards for consistency throughout this section.

Existing subsection (e) was re-designated to subsection (d)(3) and was amended to clarify that the provisions pertain to "patient" identification cards for consistency throughout this section.

Existing subsection (f) was re-designated to a new 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 was 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) was 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 was amended to clarify the type of information that should be specified in the program's protocol regarding the assignment of patient identification cards. This was 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 was necessary to provide clear guidance to programs regarding protocol requirements and to safely secure identifying information.

Comment #6V

Many programs utilize secure electronic systems

The commenter proposed adding the following language:

> "(4) Programs may use electronic identification cards, while patient is at the program in place of hard copy cards. The electronic identification should be accessible at the front desk, dispensary, and on management and/or counselor computers . The procedure for use of electronic record will provide a contingency plan for outages."

Response #6V
As a result of public comment, the regulations were amended. Please see response #4T.

Section 10260(a)

Response #5D
The commenter suggested adding the following language at the end of subsection (a): "…/medication-assisted treatment."

Response #5D
This comment was considered, however, the regulations were not amended. The term "replacement narcotic therapy" as defined under Section 10000(a)(32) means "…medication assisted treatment…" Therefore, adding the phrase "medication-assisted treatment" at the end of this subsection is not necessary since it is redundant to the definition.

Section 10260(c)(6)

Comment #4U
Make consistent with section 10380.

The commenter proposed adding the following language at the end of subsection(c)(6):
"…unless program is closed on Sundays and complies with section 10380."

Response #4U
This comment was considered, however, the regulations were not amended. Section 10380 clearly specifies the take home medication procedures for holidays or Sunday closure. Therefore, methadone is made available to patients seven days a week.

Comment #6W
Made consistent with Section 10380.

The commenter proposed adding the following language at the end of (c)(6):
"…unless program is closed on Sundays and complies with section 10380."

Response #6W
This comment was considered, however, the regulations were not amended. Please see response #4U.

Section 10270(a)

Comment #4V

Complete fully documented is language used in CFR Clarification is needed here in the role of Physician Extender – can PE complete entire requirement in section 10270 for the admission of a Buprenorphine patient admission

The commenter proposed amending the language to read as follows:

> "…conduct a complete fully documented physical medical evaluation or document his or her review and concurrence of a evaluation conducted by the physician extender within 14 days of admission."

Response #4V

This comment was considered, however, the regulations were not amended. The commenter's proposed changes were redundant to the existing requirements regarding medical evaluations. For the health and safety of the patient, a medical evaluation is required to be completed prior to admission to treatment. As specified, a medical evaluation includes a physical exam and must be fully documented according to Section 10270. Additional documentation requirements are specified under Section 10165(a)(2), which requires documentation of a patient's physical examination data in the patient's file. Lastly, the existing language clearly states that the medical evaluation requirements outlined in Section 10270 may be conducted by a physician extender. Section 10270 establishes criteria for all patient admission to treatment and applies to all forms of replacement narcotic therapy.

Comment #6X

Complete fully documented is language used in CFR Clarification is needed here in the role of
Physician Extender – can PE complete entire requirement in section 10270 for the admission of a Buprenorphine patient admission

The commenter proposed amending the language to read as follows:

> "…conduct a complete fully documented physical evaluation or document his or her review and concurrence of a evaluation conducted by the physician extender within 14 days of admission."

Response #6X

This comment was considered, however, the regulations were not amended. Please see response #4V.

Section 10270(a)(2)

Comment #1G

10270 (a) (2) Universal syphilis screening is not indicated in this population and is very low- yield, recommend removal of this requirement. Notably the USPSTF recommends against syphilis screening for adults who are not at increased risk as defined in the following excerpt from clinical considerations: "Populations at increased risk for syphilis infection (as determined by incident rates) include men who have sex with men and engage in high-risk sexual behavior, commercial sex workers, persons who exchange sex for drugs, and those in adult correctional facilities. There is no evidence to support an optimal screening frequency in this population. Clinicians should consider the characteristics of the communities they serve in determining appropriate screening strategies. Prevalence of syphilis infection varies widely among communities and patient populations. For example, the prevalence of syphilis infection differs by region (the prevalence of infection is higher in the southern U.S. and in some metropolitan areas than it is in the U.S. as a whole) and by ethnicity (the prevalence of syphilis infection is higher in Hispanic and African American populations than it is in the white population)." Most patients enrolled in OTPs do not fit this profile, and unindicated screening is a wasteful and harmful practice. Mandating that the test be offered but that a patient opt-out be permitted would be reasonable.

Response #1G
This comment was considered, however, the regulations were not amended. An opt-out provision for syphilis screening was not included since it would defeat one of the main purposes of the initial medical evaluation, which is 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." Screening should be conducted for common co-occurring conditions even if the patient has no personal history of them, including screening for Hepatitis C, the human immunodeficiency virus, sexually transmitted infections (STIs), cardio-pulmonary disease, and sleep apnea. (Federal Guidelines for Opioid Treatment Programs, March 2015, Page 29.) Syphilis is considered a STI/STD – sexually transmitted disease (https://www.cdc.gov/std/syphilis/stdfact-syphilis.htm.) A study has concluded that there is a prevalence of syphilis infection within the substance use disorder population. (https://bmcinfectdis.biomedcentral.com/articles/10.1186/1471-2334-5-33).

Comment #1H
10270 (a)(2) Agree with addition of mandated HIV and Hep C testing if patient opt-out is included as a permissible justification for medical provider waiver of this test requirement.

Response #1H
As a result of public comment, this subsection was amended to partially implement the commenter's proposed changes. Specifically, regarding HIV testing, the following language was added to subsection (a)(2), "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.

However, an opt-out provision for Hepatitis C screening was not included since it would defeat one of the main purposes of the initial medical evaluation, which is 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." The Federal Guidelines for Opioid Treatment Programs and the SAMHSA Guidelines for the Accreditation of Opioid Treatment Programs include HIV and Hepatitis C screening as part of the initial medical evaluation, prior to patient admission to treatment. Providing an opt-out provision for Hepatitis C screening would be counter to both the Federal Guidelines for Opioid Treatment Programs and the SAMHSA Guidelines for the Accreditation of Opioid Treatment Programs.

Comment #4W
HIV and HCV should be opt-out testing (see next comment). The inclusion of TB and syphilis is historic and may have public health benefits but is not related to treatment of OUD.

The commenter proposed amending the language to read as follows:

> (2) Laboratory tests for determination of narcotic drug use, HIV and infectious diseases including tuberculosis, and syphilis if determined appropriate by the medical director.

Response #4W
This comment was considered, however, this subsection was not amended as suggested. Instead, the subsection was amended as discussed in response #1H for HIV screening (testing). Regarding tuberculosis and syphilis screening, the Guidelines for the Accreditation of Opioid Treatment Programs still includes both as part of the initial medical evaluation. Therefore, screening for tuberculosis and syphilis will remain. Please also see response #1G for additional discussion regarding syphilis screening. Lastly, adding the phrase "if determined appropriate by the medical director" is not necessary as the medical director may act as necessary and appropriate within the scope of his/her license.

Comment #6Y
See section below. HIV and HCV should be opt-out testing. The inclusion of TB and syphilis is historic and may have public health benefits, but is not clearly related to treatment of OUD. The commenter proposed deleting HIV and HCV as required tests.

Response #6Y
This comment was considered, however, this subsection was not amended as suggested. Please see response #4W.

Comment #4X
Patient may opt out of testing. Requiring additional testing and counseling as a pre-condition for services creates barriers to testing. See CDC recommendations: "Prevention counseling—defined as an interactive process of assessing risk of infection, recognizing specific behaviors that increase this risk, and developing a plan to reduce risk—should not be required with HIV diagnostic testing or as part of HIV screening programs in health-care settings."

The commenter proposed adding the following language at the end of subsection (a)(2):

> "Prior to ordering a test that identifies infection of a patient with HIV, a medical care provider shall inform the patient that the test is planned, provide information about the test, inform the patient that three are numerous treatment options available for a patient who tests positive for HIV and that a person who tests negative for HIV should continue to be routinely tested, and advise the patient that he or she has the right to decline the test. If a patient declines the test, the medical care provider shall note that fact in the patient's medical file."

Response #4X
This comment was considered, however, this subsection was not amended as suggested. Instead, the subsection was amended as discussed in response #1H.

Comment #6Z
The appropriate mandate here is opt-out testing: a requirement that testing be available and provided to all patients as a default and that patients are informed and have the absolute right to decline HIV and HCV testing. Most patients will accept, but some are not psychologically ready on day one (or ever) at a new clinic to participate in testing.

The commenter proposes to add the following language to subsection (a)(2):

> "All patients should receive opt-out testing for HIV and HCV (a test will be performed unless the patient declines). Provision of HIV testing must be consistent with Health and Safety Code 120990."

Response #6Z
This comment was considered, however, this subsection was not amended as suggested. Instead, the subsection was amended as discussed in response #1H.

Comment #6AA

The language here is not correct as it indicates “opt into testing” rather than opt out. The following needs to be done prior to ordering an HIV test (HSC 120990): “Prior to ordering a test that identifies infection of a patient with HIV, a medical care provider shall inform the patient that the test is planned, provide information about the test, inform the patient that there are numerous treatment options available for a patient who tests positive for HIV and that a person who tests negative for HIV should continue to be routinely tested, and advise the patient that he or she has the right to decline the test. If a patient declines the test, the medical care provider shall note that fact in the patient’s medical file.” Requiring additional counseling as a pre-condition for testing creates barriers to testing. See CDC recommendations: “Prevention counseling—defined as an interactive process of assessing risk of infection, recognizing specific behaviors that increase this risk, and developing a plan to reduce risk—should not be required with HIV diagnostic testing or as part of HIV screening programs in health-care settings.”

Response #6AA
This comment was considered, however, this subsection was not amended as suggested. Instead, the subsection was amended as discussed in response #1H.

Comment #2H
Page 65, Thank you for including HIV and hepatitis C testing! We would recommend spelling this out and clarifying the best practices for hepatitis C testing as follows: “(2) Laboratory tests for determination of narcotic drug use, HIV, **hepatitis C virus (HCV)”**

Response #2H
The Department appreciates your comment of support. As a result of public comment, this subsection was amended to spell out the acronyms for HIV and HCV by adding the words “(human immunodeficiency virus)” and “(hepatitis C virus)” respectively, for clarity.

Section 10270(a)(3)(C)

Comment #1I
10270 (a) (3) (C) a breast exam is not only unnecessary and unhelpful but extremely inappropriate on program admission and should not be universally required by law.

Response #1I
As a result of public comment, this subsection was amended to remove the requirement for a breast exam at the initial medical evaluation. A breast exam is not medically indicated, and therefore is unnecessary for patient 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).

Comment #4Y
Eliminate requirement for thyroid and breast exam. Thyroid exam is not necessary for admission to OTP and can be at medical provider discretion. Breast exam is highly sensitive and unnecessary at admission to OTP. Female patients should never be required to have a breast exam in order to receive treatment—it is not medically indicated. It also necessitates the presence of a nurse or other person in the room in some settings which represents an unreasonable burden. Further, it can be re-traumatizing for patients who have experience sexual abuse.

Response #4Y
As a result of public comment, this subsection was amended to partially implement the commenter's proposed changes. The requirement to perform a breast exam at the initial medical evaluation was removed. Please see response #1I for additional discussion regarding breast exams. However, the thyroid exam will remain a requirement as part of the initial medical evaluation. Research shows that abnormalities in thyroid function is associated with methadone treatment.
https://www.ncbi.nlm.nih.gov/pubmed/3141082

Comment #6AB
Eliminate requirement for thyroid and breast exam. Thyroid exam is not necessary for admission to OTP and can be at medical provider discretion. Breast exam is highly sensitive and unnecessary at admission to OTP. Female patients should never be required to have a breast exam in order to receive treatment—it is not medically indicated. It also necessitates the presence of a nurse or other person in the room in some settings which represents an unreasonable burden. Further, it can be re-traumatizing for patients who have experience sexual abuse.

Response #6AB
As a result of public comment, this subsection was amended to partially implement the commenter's proposed changes. Please see response #4Y.

Section 10270(d)

Comment #5E
The commenter proposes to add the word "methadone" in subsection (d) to read as follows:

Maintenance Treatment.
The program shall determine which applicants with an addiction to ~~opiates~~ opioids are accepted as patients for methadone maintenance treatment subject to the following minimum criteria which shall be entered in the patient records:

Response #5E
This comment was considered, however, the regulations were not amended. Adding the term "methadone" would be too limiting for this provision, which can also apply to other medications used for replacement narcotic therapy.

Section 10270(d)(1)

Comment #5F
The commenter proposed adding the following language to subsection (d)(1)
"Patients administered buprenorphine shall not be required to adhere to demonstrate a one year history. They must only meet the diagnostic criteria for opioid use disorder as defined by the most recent version of the Diagnostic and Statistical Manual of Mental Disorders (DSM)."

Response #5F
This comment was considered, however, the regulations were not amended. Buprenorphine patients are subject to the same patient admission criteria as any other patients receiving replacement narcotic therapy in the NTP setting. Section 10270 establishes criteria for all patient admission to treatment and applies to all forms of replacement narcotic therapy.

Section 10270(d)(2)

Comment #1J
10270 (d) (2) An allowance for use of non-methadone treatment specifically for minors who are determined to be unable to engage in or otherwise inappropriate for office-based treatment of addiction would be beneficial to serve the needs of this population. Homeless minors specifically are a highly vulnerable population that is likely to have no other viable treatment environment available when every-day observed treatment is needed. Recommend rephrasing to "a minimum age of 18 years for methadone treatment."

Response #1J
This comment was considered, however, the regulations were not amended. Buprenorphine patients are subject to the same patient admission criteria as any other patients receiving replacement narcotic therapy in the NTP setting. Section 10270 establishes criteria for all patient admission to treatment and applies to all forms of replacement narcotic therapy.

Section 10270(d)(3)

Comment #2I

Page 68, We recommend specifying that linkage to care is needed for HIV, HCV, TB, and syphilis if diagnosed through testing. "Certification by a physician of fitness for replacement narcotic therapy based on physical examination, medical history, and indicated laboratory findings. Plans for correction of existing medical problems, **including linkages to care and treatment, where needed, for patients who test positive for HIV, HCV, tuberculosis or syphilis,** should be indicated.

Response #2I

As a result of public comment, this subsection was amended to add the language "including linkages to care and treatment, where needed, for patients who test positive for HIV, HCV, tuberculosis or syphilis." This was necessary 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 10270(d)(4)

Comment #4Z

Following the federal guidelines which say, "that the person is currently addicted to an opioid drug." Physical dependence is one of 11 criteria for opioid use disorder. Some patients without signs of physical dependence will still need treatment and will not meet 4 (A) or 4 (B)

The commenter proposed the following language:

"Evidence that the person is currently addicted to an opioid drug"

Response #4Z

This comment was considered, however, the regulations were not amended. This provision is specific to the requirements for maintenance treatment, which involves replacement narcotic therapy. The replacement narcotic therapy is used to address opioid addiction. While the commenter states that "physical dependence is one of 11 criteria for opioid use disorder," the intent of this provision is to ensure the patient is a candidate for maintenance treatment.

Comment #6AC
following the federal guidelines which say, "that the person is currently addicted to an opioid drug." Physical dependence is one of 11 criteria for opioid use disorder. Some patients without signs of physical dependence will still need treatment and will not meet 4 (A) or 4 (B)

The commenter proposed amending this subsection to read as follows:
"(4) Evidence that the person is currently addicted to an opioid drug"

Response #6AC
While the comment was labeled Section 10270c.(4), the Department believes this comment was in reference to Section 10270(d)(4). Please see response #4Z.

Section 10270(e)

Comment #4AA
If the patient needed opioid agonist treatment initiation during the pregnancy, the default should be continuation of that treatment in the post-partum period (very high risk of relapse).

The commenter proposed amending the language to read as follows:
"d. Pregnant patients admitted pursuant to subsection (d)(~~6~~5) immediately above shall be reevaluated by the program physician for the continuation of treatment in the post-partum period not later than 60 days following termination of the pregnancy in order to determine the appropriate level of~~whether continued~~ maintenance treatment ~~is~~ appropriate."

Response #4AA
While the comment was labeled Section 10270(d), the Department believes this comment was in reference to Section 10270(e). This comment was considered, however, the regulations were not amended. The existing provision provides the physician the flexibility to re-evaluate the patient after pregnancy, in order to determine if continued maintenance treatment is appropriate.

Comment #6AD
60 days is too long a period Postpartum is a high risk time for relapse and tx plan should reflect this fact.

Response #6AD
While the comment was labeled Section 10270d., the Department believes this comment was in reference to Section 10270(e). This comment was considered, however, the regulations were not amended. The regulations provide the physician flexibility to re-

evaluate the patient at anytime within 60 days following termination of the pregnancy. Accordingly, a physician may re-evaluate a patient immediately following childbirth.

Comment #6AE
This is not a question about the length of time. If the patient needed opioid agonist treatment initiation during the pregnancy, the default should be continuation of that treatment in the post-partum period (very high risk of relapse).

Response #6AE
This comment was considered, however, the regulations were not amended. Please see response #4AA.

Comment #7B
Criteria for Patient Selection (Section 10270)
We also strongly support the much needed changes proposed to Section 10270 that would remove certain patient selection criteria requirements that are incompatible with evidence-based practices regarding MAT and that go beyond the limitations imposed by federal law. In particular, the current provision limiting patient eligibility for NTP treatment to patients that have a confirmed history of two or more unsuccessful attempts in withdrawal treatment with subsequent relapse to illicit opiate use is not consistent with best practices in the field. While it is our understanding that DHCS is currently not enforcing this provision, it is imperative that the language is removed from the regulation given the detrimental consequences that it may cause.

SUD and OUD are chronic disorders, just as diabetes and heart disease are. In the same way that postponing treatment for a heart condition would exponentially increase the risk of death, denying immediate access to MAT to individuals with SUD and OUD increases the risks of overdose and other harms associated with drug use. Commencing treatment at once is also highly cost-effective. A recent study analyzed the impact of Section 10270(d)(2) vis-à-vis immediate treatment initiation and found that "[t]he value of publicly funded treatment of opioid use disorder in California is maximized when [MAT] is delivered to all patients *initially* presenting for treatment" (emphasis added). For the same reasons, we commend the proposal to remove the requirement for NTP acceptance that "at least seven days have elapsed since termination of the immediately preceding episode of detoxification treatment." This requirement is not contained in federal law, is not consistent with evidence-based practices, and only serves as a barrier to immediately accessing life-saving treatment.

Finally, we strongly support the proposed changes that would 1) reduce the timeframe of documented OUD from two years to one year for purposes of admission to an NTP; 2) expand the timeframe for getting an exception to the one-year requirement for individuals who were recently released from a penal or chronic care institution (from one month to six 5 months after discharge) and for individuals who recently voluntarily detoxified from maintenance treatment (from six months to two years after discharge);

and 3) waive the one-year OUD requirement for individuals who are pregnant and currently have an OUD. Individuals who have been recently released from penal or chronic care institutions are at heightened risk of misusing drugs and developing (or sustaining) an OUD. Similarly, pregnant women with OUD are at risk of pregnancy-related complications, including the harms associated with neonatal abstinence syndrome. Thus, expanding the timeframe to receive an exception from the requirement to document their condition or, in the case of pregnant individuals, waiving this requirement altogether, would provide immediate access to MAT at NTPs for highly vulnerable individuals. These changes would also bring the California rules in line with federal law.

Response #7B
The Department appreciates your comment of support.

Section 10280(a)(1)

Comment #1K
10280 (a) (1) Per consistent and correct use of terminology defined in this document and as used medically, medications used appropriately for treatment are not "addicting," but rather cause physiologic dependence. Propose rephrasing to "The nature of medications used in replacement narcotic [opioid] therapy and expected development of dependence."

Response #1K
This comment was considered, however, the regulations were not amended. This change is not necessary as the intent of this provision is to advise patients that replacement narcotic therapy may be habit forming.

Comment #4AB
Inaccurate and inappropriate use of addicting. The medications cause physical dependence when used in the treatment setting.

The commenter proposed the following amendments:
"The physical dependence caused by the ~~addicting nature of~~ medications used in replacement narcotic therapy."

Response #4AB
This comment was considered, however, the regulations were not amended. Please see response #1K.

Comment #6AF
Inaccurate and inappropriate use of "addicting". The medications cause physical dependence when used in the treatment setting.

The commenter proposed the following amendments:

"The physical dependence caused by the ~~addicting nature of~~ medications used in replacement narcotic therapy."

Response #6AF

This comment was considered, however, the regulations were not amended. Please see response #1K.

Section 10280(a)(2)

Comment #1L

10280 (a) (2) Recommend rephrasing "hazards and risks" to "risks and benefits." "Hazards and risks" is redundant, whereas risk vs benefit counseling is a commonly understood and necessary component of any medical treatment planning.

Response #1L

This comment was considered, however, the regulations were not amended. It is important that the patient is informed regarding what to expect when undergoing replacement narcotic therapy. However, this proposed change is not necessary since the program is not limited to providing patients information on the hazards and risks involved with replacement narcotic therapy. As specified in Section 10280(a), "Programs shall advise patients of the nature and purpose of treatment which shall include but shall not be limited to the following…" As written, the existing provision does not preclude the program from discussing other information during the patient's orientation, including the benefits of treatment.

Section 10280(a)(3)

Comment #4AC

Patient rights

The commenter proposed adding the following language:

"and the circumstances under which medications could be withdrawn."

Response #4AC

This comment was considered, however, the regulations were not amended. This proposed amendment is not necessary since Section 10280(a)(10) already requires that information be provided to the patient regarding the procedures for the withdrawal from medications used in replacement narcotic therapy.

Comment #6AG

Section 10280(a)(iii) Patient rights

The commenter proposed adding the following language:

"and the circumstances under which medications could be withdrawn."

Response #6AG

While the commenter referenced Section 10280(a)(iii), the Department believes this comment was in reference to Section 10280(a)(3). Please see response #4AC.

Section 10280(a)(7)

Comment #1M

10280 (a) (7) The purpose of this item is unclear to me. Treatment in an ambulatory setting should never be changed without knowledge of the patient. Recommend removal of item 7.

Response #1M

This comment was considered, however, the regulations were not amended. There are legitimate treatment conditions, where a patient's dosage levels are adjusted without the patient's knowledge. As specified in Section 10355(h), a patient's dose or medications are determined by the medical director or the program physician. After consultation with the medical director or program physician, patients may request a blind taper and accordingly would not be notified of a change in their dosage levels.

Section 10280(a)(10)

Comment #4AD

The patient does not have this right in cases of immediate danger to staff or other patients.

The commenter proposed adding the following language:

"…unless in the event of danger to staff or other patients."

Response #4AD

This comment was considered, however, the regulations were not amended. The patient does have the right to humane detoxification. The Federal Guidelines for Opioid Treatment Programs (Page 26-27) state that "The underlying goal is for involuntary medically supervised withdrawal to reflect a humane partnership between the patient and the treatment program….When a patient is administratively discharged from an OTP, the program must employ the same principles as those used for voluntary medically supervised withdrawal from medication. The goal is to follow a withdrawal schedule that is based on sound clinical judgment and close patient monitoring."

Comment #6AH
The patient does not have this right in cases of immediate danger to staff or other patients.

The commenter proposed adding the following language:
"…unless in the event of danger to staff or other patients."

Response #6AH
This comment was considered, however, the regulations were not amended. Please see response #4AD.

Section 10280(a)(13)

Comment #4AE
Allows alignment of the NTP OBNTN and MU with other health care providers within a Whole Person Care paradigm.

The commenter proposed adding the following subsection/language:
"(13) Request for consent to coordinate care with primary care and/or other specialty providers, if other than NTP provider."

Response #4AE
This comment was considered, however, the regulations were not amended. The NTP is required to have procedures in the protocol for coordination of care in the event of patient hospitalization or incarceration as specified under Section 10030(a)(31).

Comment #6AI
Allows alignment of the NTP, OBNTN and MU with other health care providers within a Whole Person Care paradigm

The commenter proposed adding the following subsection/language:
"xiii. Request for consent to coordinate care with primary care and/or other specialty providers, if other than NTP provider."

Response #6AI
While the commenter referenced Section 10280a.xiii., the Department believes this comment was in reference to Section 10280(a)(13). This comment was considered, however, the regulations were not amended. Please see response #4AE.

Section 10310

Comment #7C

Procedures for Collection of Patient Body Specimens (Section 10310)
Testing NTP patients to determine if they are taking NTP medication as prescribed and to determine if they are using illicit drugs can be a useful clinical tool for improving care. However, it can also be a barrier to treatment for uninsured and underinsured individuals. According to the American Society of Addiction Medicine (ASAM), "drug testing frequency [should be] determined by stage of treatment as well as other patient factors and should be individualized." ASAM also notes that "providers should always consider cost to patients and insurers when utilizing drug testing." We therefore recommend that drug testing requirements be limited to those required by federal law, with more frequent testing imposed on an individualized basis by the patient's treating provider only where such testing is medically necessary for a particular patient.

Federal law requires that NTPs conduct drug testing eight times per year for patients receiving maintenance treatment. This standard is followed by 31 other states. There is no evidence that mandating more frequent testing provides benefits that exceed the increased cost to the patient and insurer. We therefore recommend that Section 10310 be amended as follows:

> *(a) Each program shall set forth in its protocol a plan for collection of patient body specimens for testing or analysis of samples for **prescribed and** illicit drug use that describes the procedures to be used for:*
>
> *(e) A test or analysis for illicit drug use shall be performed at least monthly **eight times per year** for every patient in maintenance treatment.*

Response #7C
This section was not proposed for amendment and is outside the scope of this regulatory proposal. Therefore, the regulations were not amended based on this comment.

Section 10315(a)

Comment #4AF
There is no reason to test for methadone metabolite in patients whose OTP medication is buprenorphine. Since OTPs may use a different testing panel for buprenorphine maintained patients, requiring methadone metabolite will be pointless and wasteful.

The commenter proposed adding the following language:
"…using an appropriate screening panel based on prescribed treatment medication."

Response #4AF

This comment was considered, however, the regulations were not amended. Testing for methadone and its metabolites allows the program to know if a patient, who is on buprenorphine for maintenance treatment of their opioid addiction, is also consuming methadone.

Comment #6AJ
There is no reason to test for methadone metabolite in patients whose OTP medication is buprenorphine. Since OTPs may use a different testing panel for buprenorphine maintained patients, requiring methadone metabolite will be pointless and wasteful.

The commenter proposed adding the following language:
"…using an appropriate screening panel based on prescribed treatment medication."

Response #6AJ
This comment was considered, however, the regulations were not amended. Please see response #4AF.

Section 10315(a)(5)

Comment #1N
10315 (a)(5) Propose removal of barbiturates from substances required to be tested. Barbiturates are no longer a common substance of misuse, and this test is extremely low- yield, positive in less than 0.5% of our random drug screens.

Response #1N
This comment was considered, however, the regulations were not amended. The Federal Guidelines for Opioid Treatment Programs (Page 44) recommend including barbiturates in the drug screening and testing panels. Therefore, the requirement to test for barbiturates will remain.

Section 10315(c)

Comment #1O
10315 (c) This is vague and does not define a standard for determining commonality. Recommend rephrasing to "Programs shall additionally have samples collected from each patient body specimen tested or analyzed for other substances as necessary for treatment safety and diversion control. Necessity is determined by the medical director."

Response #1O
This comment was considered, however, the regulations were not amended. The existing language already provides that programs may test for evidence of other drugs based on local drug use patterns and trends. As defined, the medical director is

responsible for the medical services provided by the program; therefore, it is understood that medical necessity for any additional testing would be determined by the medical director.

Section 10340

Comment #7D

The proposed changes would remove current Section 10340, which requires NTPs that are not physically located in a hospital to enter into an agreement with a hospital official to provide general medical care for both inpatients and outpatients who may require such care. We see no reason why this requirement should be eliminated. Section 10340 is the only provision in the rules regarding licensing of NTPs that makes NTPs responsible for coordination of care. California's health care system is becoming increasingly fragmented and it is imperative that the different systems of care maintain communication and coordination at all times. In the Medi-Cal program, for example, there are separate entities responsible for provision of physical health care, mental health care, and SUD care, which creates confusion among beneficiaries and may serve as a barrier for unexperienced individuals to navigate the system. As such, DHCS rules should move towards increased coordination between all systems of care. We recommend that Section 10340 be maintained or, as an alternative, that other obligations for NTPs to enter into agreements with primary care physicians or similarly-situated providers be enacted.

Response #7D

This comment was considered, however, the regulations were not amended. The NTP is required to have procedures in the protocol for coordination of care in the event of patient hospitalization or incarceration according to Section 10030(a)(31). Furthermore, this section was 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 10340(b)

Comment #5G

Can these regulations allow NTP's to provide primary medical care? If not, why not?

Response #5G

This comment was considered, however, the regulations were not amended. Programs are not required, but may provide primary medical care. According to the Federal Guidelines for Opioid Treatment Programs (Page 43), "It is highly recommended, but not required, that OTPs provide basic primary care onsite. OTP physicians can prescribe medication as appropriate for co-occurring medical and psychiatric disorders. Program staff should provide care coordination, making referrals for medical and psychiatric

treatment when indicated. The staff members responsible for establishing linkages with other healthcare organizations and practitioners should be knowledgeable about pharmacotherapy treatment (e.g., drug interactions, acute withdrawal, and overdose), actively seek patient consent to talk with other providers, and check their state's PDMP." The amendments to Section 10270(d)(3), which specifies that "plans for correction of existing medical problems should be indicated, including linkages to care and treatment, where needed…" align with these federal guidelines.

Additionally, pursuant to Welfare and Institutions Code section 14124.22, NTPs enrolled as Medi-Cal providers "may provide medically necessary medical treatment of concurrent health conditions within the scope of the provider's practice, to Medi-Cal beneficiaries who are not enrolled in managed care plans."

Section 10345

Comment #5H

Can this section be amended to allow for case management services?

Response #5H

This comment was considered, however, the regulations were not amended. Section 10345 specifies the requirements for Counseling Services in Maintenance Treatment. These regulations are specific to oversight of licensed NTPs. The addition of reimbursable services, such as case management, is not within the scope of this package.

Section 10345(b)(3)(C)

Comment #1P

10345 (b)(3)(C) There seems to be no reason why the medical director should be the only provider able to satisfy this requirement. Any program physician or NP/PA provider qualified to provide such service should be able to do so. Recommend changing "the medical director," to "a program medical provider."

Response #1P

This comment was considered, however, the regulations were not amended. The proposed amendments were not necessary since a medical director may delegate duties as prescribed in the program protocol to another licensed program physician, as specified in Section 10110(c). Similarly, program physicians may delegate duties, as prescribed in the program protocol, to other appropriately licensed personnel who are members of the program staff, as specified under Section 10115.

Comment #4AG

Utilize physician extenders throughout regulations where appropriate.

The commenter proposed adding the following language:
"and/or physician extender"

Response #4AG
This comment was considered, however the regulations were not amended. Please see response #1P.

Comment #6AK
Utilize physician extenders throughout regulations where appropriate

The commenter proposed adding the following language:
"and/or physician extender"

Response #6AK
The commenter references Section 10345(b)(iii)3., however, the Department believes this comment is in reference to Section 10345(b)(3)(C). This comment was considered, however the regulations were not amended. Please see response #1P.

Section 10355(b)(2)

Comment #1Q
10355 (b) (2) Recommend changing "opioid abstinence symptoms," to "opioid withdrawal symptoms," for consistency with accepted medical terminology. (Also applies to 10355 (d) (2))

Response #1Q
This comment was considered, however, the regulations were not amended. The phrase "opioid abstinence" is consistent with terminology used in the Federal Guidelines for Opioid Treatment Programs (page 51.)

Section 10355(c)(1)(B)

Comment #4AH
The system has grown to a point where there will be increasing transfers between settings and levels of care and guidelines related to dosing when transfers occur are needed.

The commenter proposed adding the following language:

"Transfers: if the patient is transferring from another program or last dose at an outside facility such as a hospital, this transfer information shall be documented and the medical director will adjust maximum doses based on best practice and secure any exceptions needed from the Department."

Response #4AH
This comment was considered, however, the regulations were not amended. The regulations already provide guidance regarding dosing when transfers occur. Specifically, Section 10030(a)(31) requires the NTP to have in the program protocol, "Procedures, which provide for cooperation with local jails for either detoxification or maintenance treatment while in custody, in the event of patient hospitalization or incarceration." Furthermore Section 10375(c) specifies "In the case of a patient who transfers to the program from another program without a break in treatment, the new medical director or program physician may consider the time the patient has spent at the former program when considering the patient's eligibility for take-home medication privileges, as well as for advancement to a new step level. In no case shall any patient be placed, upon admission, at a step level higher than that which was occupied in the former program immediately before transferring to the new program."

Comment #6AL
The access points in the system of care has grown to a point where there will be increasing transfers between settings and levels of care and guidelines related to dosing when transfers occur are needed

The commenter proposed the following language:
"Transfers: if the patient is transferring from another program or has received his/her last dose at an outside facility such as a hospital, the medication information shall be documented and the medical director will adjust maximum doses based on best practice and secure any exceptions needed from the Department."

Response #6AL
This comment was considered, however the regulations were not amended. Please see response #4AH.

Section 10355(d)(1)

Comment #1R
10355 (d)(1) This restriction does not permit clinical discretion to address the common situation in which a recent methadone dose is confirmed and tolerance to that dose is known, but because of the treatment environment in which that medication was received (not another opioid treatment program) or because of a brief interruption in treatment, it cannot be continued by law and must instead by re-titrated from 30. This causes harm to the patient by way of causing unnecessary withdrawal likely to result in relapse to illicit use and potential harms thereof. I recommend adding an exception to this requirement in the form of an "OR

(d) (1) (c)" item with the following language borrowed from the LAAM maintenance items: "the patient's tolerance for the medication is known by the medical director or program physician and he/she documents in the patients record the basis for this determination."

Response #1R
This comment was considered, however, the regulations were not amended. Section 10355(d)(2), states "The total dose of methadone for the first day shall not exceed 40 milligrams **unless** the medical director or program physician determines that 40 milligrams is not sufficient to suppress the patient's opioid abstinence symptoms, and documents in the patient's record the basis for his/her determination." This language allows the medical director or program physician to determine the dose according to his/her clinical judgement that is in the best interest of the patient's health and safety.

Section 10355(d)(3)

Comment #4AI
Unnecessary Medical Director is responsible for all dosing and securing any needed exceptions.

The commenter proposed deleting the following language:
"~~A daily dose above 100 milligrams shall be justified by the medical director or~~ program physician in the patient's ~~record~~."

Response #4AI
This comment was considered, however, the regulations were not amended. While it is stated elsewhere in these regulations that the medical director or program physician is responsible for medication dosing, this provision simply emphasizes the requirement for justification in a patient's record for a daily dose of methadone above 100 milligrams.

Comment #5I
The commenter proposes deleting the following language:
"~~A daily dose above 100 milligrams shall be justified by the medical director or program physician in the patient's record~~."

Response #5I
This comment was considered, however, the regulations were not amended. Please see response #4AI.

Comment #6AM
Unnecessary Medical Director is responsible for all dosing levels and securing any needed exceptions

The commenter proposed deleting the following language:

" ~~A daily dose above 100 milligrams shall be justified by the medical director or program physician in the patient's record~~."

Response #6AM

This comment was considered, however, the regulations were not amended. Please see response #4AI.

Section 10355(f)(2)

Comment #5J

The commenter proposed the following language:

"~~(2)~~ Dosing decisions shall be made by the medical director~~,~~ ~~or~~ a program physician, or advanced practice nurse (nurse practitioner or physician's assistant)…"

Response #5J

This comment was considered, however, the regulations were not amended. Section 10110 specifies that the medical director is not permitted to delegate responsibility for initiating, altering and terminating replacement narcotic therapy medications and dosage amounts to physician extenders. Furthermore, 42 CFR §8.12(h)(4) specifically states dosing decisions shall be made by a program physician.

Section 10355(g)

Comment #1S

10355 (g) This item creates a unique and harmful requirement for California opioid treatment programs that hinders patient care. The problematic phrasing is "AFTER a patient has missed 3 or more consecutive days… the medical director or program physician shall provide a new medication order BEFORE continuation of treatment." Most programs function with part-time physician coverage, often augmented by additional part-time or full time NP or PA coverage. Patients returning following 3-day absences are common and result in a very high call-volume to covering physicians which results in delayed responses to these non-emergency calls often due to overlapping clinical responsibilities. This results in patient wait-times to receive needed medication and also discourages timely return to care once a patient has missed 3 days. Some programs are forced to adopt policies by which returning patients cannot resume their treatment outside of designated hours with on-site physician coverage, a practice of great detriment to patients which causes unnecessary withdrawal and cravings as are known to be associated with relief-seeking in the form of costly unnecessary ER visits or criminality. As done broadly outside of California, treatment reinstatements can be achieved safely through written nursing protocols or patient-specific PRN orders written in advance. It is rare to deviate from routine dose adjustments for absences, and nurses are qualified and can be utilized to identify exceptional

situations that require urgent physician review, whereas legally mandating this physician review in all situations is highly inefficient. To correct this, I recommend simply changing the words “after,” to “when,” and “before” to “for.” This permits a protocol-based initial adjustment that requires timely rather than immediate physician review and approval, as do all orders.

Response #1S
As a result of public comment, this subsection was amended to partially implement the commenter’s proposed changes. Specifically, the word “After” was replaced with “When” for clarity. However, the medication order must still be provided prior to the continuation of treatment. This section was 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

Comment #6AN
I agree with this in practice 100% but it does not belong in the regulations as there is nothing here other than the requirement to document reasons for not providing split dosing that is new . We currently already have to obtain exceptions. The issue here is one of clinical practice, not regulatory standard. What should be in the regulatory standards is an exception to time in treatment requirements for split dosing for pregnant patients, so that there would not be a need to obtain an exception in patients in whom the Medical Director has determined that a clinical need exists. This would require federal changes as well.

Response #6AN
This comment was considered, however, the regulations were not amended. The commenter’s request was unclear. The Department believes this comment is part of a discussion between two parties regarding the regulations. While related to the topic of additional requirements for pregnant patients, the comment was not specifically directed to the language proposed by the Department.

Comment #6AO
Research supports recognition that NTP is treating both mother and fetus which allows MD to respond accordingly

Response #6AO
This comment was considered, however, the regulations were not amended. The commenter's request was unclear. The Department believes this comment is part of a discussion between two parties regarding the regulations. While related to the topic of additional requirements for pregnant patients, the comment was not specifically directed to the language proposed by the Department.

Section 10360(a)(1)

Comment #6AP
This is not a reasonable requirement. Most OTP medical providers are not trained in obstetrics, nor do they have the clinical tools and resources to do this. If a patient does not enter prenatal care despite repeated efforts by the OTP, the Medical Director should make the best efforts to support the patient that he/she can. Requiring the Medical Director to assume full medical responsibility for prenatal care leads to large numbers of clinics not accepting pregnant.

Response #6AP
While the commenter referenced Section 10360a.i., the Department believes this comment was in reference to Section 10360(a)(1). This comment was considered, however, the regulations were not amended. While not explicitly stated, the Department believes the commenter was proposing to delete Section 10360(a)(1). The commenter states that it is not reasonable to require a medical director to accept medical responsibility for the patient's prenatal care as specified in Section 10360(a)(1). However, the existing provision under Section 10360(a)(2) provides the medical director with another option, which is to verify that the pregnant patient is under the care of another health care professional licensed by the State of California and trained in obstetrics and/or gynecology. This is consistent with 42 CFR §8.12(f)(3), which specifies that "OTPs must maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal care and other gender specific services or pregnant patients must be provided either by the OTP or by referral to appropriate healthcare providers." Please see response #4AJ for additional discussion regarding Section 10360(a)(2).

Section 10360(a)(2)

Comment #4AJ
Reflects current options available to women for obstetric services.

The commenter proposed amending the language to read:

> "(2) Request a voluntary patient consent for coordination of care and verification that the patient is under the care of a qualified physician, Nurse Practitioner, Physician Assistant and/or California Nurse Midwife trained in obstetrics;"

Response #4AJ
As a result of public comment, this subsection was amended to partially implement the commenter's proposed language. Specifically, the regulations were updated to allow a pregnant patient to be under the care of a physician assistant, nurse practitioner, licensed midwife or certified nurse midwife, who is licensed to practice in California. This amendment acknowledges 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. The program physician may, in his/her own clinical judgement, request patient consent to coordinate care with the health care provider responsible for the patient's prenatal care.

Comment #6AQ
Patient consent is voluntary.

The commenter proposed amending the language to read:

> **"**Attempt to Secure a Patient Consent for care coordination and verification that the patient is under the care of a qualified physician, Nurse Practitioner, Physician Assistant and/or California Nurse Midwife trained in obstetrics ~~and/or gynecology~~;"

Response #6AQ
While the commenter referenced Section 10360a.ii., the Department believes this comment was in reference to Section 10360(a)(2). As a result of public comment, this subsection was amended to partially implement the commenter's proposed language, as discussed in response #4AJ.

Comment #6AR
Being trained in only gynecology will not suffice here.

Response #6AR
While the commenter referenced Section 10360a.ii., the Department believes this comment was in reference to Section 10360(a)(2). This comment was considered, however, the regulations were not amended based on this comment. The commenter's request was unclear. The Department believes this comment is part of a discussion between two parties regarding the regulations. Please see response #4AJ for discussion regarding amendments to Section 10360(a)(2).

Comment #6AS
Accountability requires Consent. Include physician extenders

Response #6AS
While the commenter referenced Section 10360a.ii., the Department believes this comment was in reference to Section 10360(a)(2). The comment was considered, however, the regulations were not amended based on this comment. The Department believes this comment is part of a discussion between two parties regarding the regulations. Please see response #4AJ for discussion regarding amendments to Section 10360(a)(2) related to including physician extenders.

Section 10360(b)

Comment #4AK
LAAM is no longer medication of choice in pregnancy and other medications are available.

The commenter proposed amending the language to read:

> "(b) The medical director shall document a medical order and his or her rationale for determining the appropriate medication and dosing for the patient prior to:
> (1) Placing a pregnant applicant on ~~LAAM~~ medication regime ~~therapy~~; or
> (2) Continuing ~~LAAM~~ therapy after confirmation of patient's pregnancy."

Response #4AK
This comment was considered, however, the regulations were not amended. While LAAM may no longer be the medication of choice for pregnant patients, LAAM is still authorized as a medication for use in narcotic replacement therapy by licensed narcotic treatment programs as specified in Health in Safety Code Section 11839.2(b). Further, Section 10360(b)(1) and (2) do not preclude the use of other medications for replacement narcotic therapy as determined by the medical director.

Comment #6AU
LAAM is no longer medication of choice in pregnancy and other medications are available.

Response #6AU
This comment was considered, however, the regulations were not amended. The commenter's request was unclear. The Department believes this comment is part of a discussion between two parties regarding the regulations. While related to the topic of additional requirements for pregnant patients, the comment was not specifically directed to the language proposed by the Department. Please see response #4AK for additional discussion regarding LAAM.

Comment #4AL

Research supports recognition that NTP is treating both mother and fetus.

The commenter proposed adding the following language:

"(3) For all pregnant patients, the Medical Director should strongly consider split dosing of medication unless there is a contraindication and obtain any exceptions required."

Response #4AL
This comment was considered, however, the regulations were not amended. The commenter's proposed language is not necessary since Section 10386 specifies the requirements for split doses. Section 10386(a) provides that the medical director or program physician may determine that a split dose is medically necessary. The split dosing requirements under Section 10386 apply to all patients including pregnant patients. Please see ISOR discussion for Section 10386.

Comment #6AV
For the health of the fetus split dosing is the method of choice unless there are overriding safety considerations that must be documented

Response #6AV
This comment was considered, however, the regulations were not amended. The commenter's request was unclear. The Department believes this comment is part of a discussion between two parties regarding the regulations. While related to the topic of additional requirements for pregnant patients, the comment was not specifically directed to the language proposed by the Department. Please see response #4AL for additional discussion regarding split doses.

Comment #6AW
LAAM is not utilized.

Response #6AW
While the commenter referenced Section 10360a.iii., the Department believes this comment was in reference to Section 10360(b)(2). The comment was considered, however, the regulations were not amended. Please see response #4AK for additional discussion regarding LAAM.

Comment #6AT

This entire section (10360 b) is about LAAM and should be replaced entirely with the brief statement: “For all pregnant patients, the Medical Director should strongly consider split dosing of medication unless there is a contraindication and obtain any exceptions required.”

Response #6AT
This comment was considered, however, the regulations were not amended. Please see response #4AK for additional discussion regarding LAAM and response #4L for additional discussion regarding split doses for pregnant patients.

Section 10360(d)

Comment #2J
Page 84, instruction on prenatal topics should include “**evidence-based practices for managing neonatal abstinence syndrome.”**

Response #2J
As a result of public comment, this subsection was amended to include the prenatal topic “evidence-based practices for managing neonatal abstinence syndrome.” This was necessary to align with the Federal Guidelines for Opioid Treatment Programs (Page 32) and to ensure that the program staff are knowledgeable in current practices regarding neonatal abstinence syndrome.

Section 10360(d)

Comment #6AX
Primary source of complex medical information in pregnancy should not be delegated to lower levels of scope of practice given the risk to mother and fetus

The commenter proposed amending the language to read:

> c. The medical director, physician or physician extender ~~licensed health~~ ~~personnel~~ designated by the medical director shall document completion of instruction on each of the following prenatal topic:

Response #6AX
While the commenter referenced Section 10360c., the Department believes this comment was in reference to Section 10360(d). This comment was considered, however the regulations were not amended. Section 10110 outlines the responsibilities and duties of the medical director, including delegation. Specifically, the medical director may delegate duties as appropriate within his/her clinical judgement.

Comment #6AY
Section 10360c. - I do not agree with this statement. I do not know what it means to say "lower levels of scope of practice." Patient education is well within the scope of practice of NP/PAs.

Response #6AY
While the commenter referenced Section 10360c., the Department believes this comment was in reference to Section 10360(d). This comment was considered, however the regulations were not amended. The commenter's request was unclear. The Department believes this comment is part of a discussion between two parties regarding the regulations. While related to the topic of additional requirements for pregnant patients, the comment was not specifically directed to the language proposed by the Department. Please see additional discussion in response #6AX.

Section 10360(g)

Comment #6AZ
This is excessive and burdensome and beyond the scope of the OTP.

The commenter proposed amending the language to read:

> ~~f~~. Within fourteen (14) calendar days from the date of the birth and/or termination of the pregnancy, the primary counselor shall update the patient's treatment plan in accordance with Section 10305. ~~The nature of pediatric care and child immunization shall be reflected in subsequent updated treatment plans until the child is at least three (3) years of age.~~

Response #6AZ
The Department believes this comment was in reference to Section 10360(g). This comment was considered, however, the regulations were not amended. The intent of this provision is to document in the patient's future treatment plans the nature of pediatric care and immunizations provided to the patient's child. This is necessary as part of the patient's comprehensive behavioral therapy, which takes into consideration the patient's ability to care for and ensure the health and safety of her child. This requirement aligns with the Federal Guidelines for Opioid Treatment Programs (Page 31-32), which states that the program shall "…ensure appropriate follow-up and primary care for the new mother and well-baby care for the infant."

Section 10360(a), (c)(2), (f) & (g)

Comment #7E
While we agree with and support most of the proposed changes aimed at increasing access to MAT at NTPs for pregnant individuals, we would also like to see changes to some of the language in the rule that is either inconsistent with state law and/or is outdated or may create confusion. For example, it is important to clarify that, in California, Medi-Cal beneficiaries are entitled to

receive midwife services in addition to being entitled to receive care from an obstetrician or gynecologist. Thus, we recommend that Section 10360 be amended as follows:

"(a) Within fourteen (14) calendar days from the date of the primary counselor's knowledge that the patient may be pregnant, as documented in the patient's record, the medical director shall review, sign, and date a confirmation of pregnancy. Also within this time frame, the medical director shall document his or her: …
*(2) Verification that the patient is under the care of a physician licensed by the State of California and trained in obstetrics and/or gynecology.***, or under the care of a midwife."**

(This comment was included under Section 10310 of the commenter's letter, but actually proposed an amendment to Section 10360)
Federal law does not require more frequent drug testing for pregnant women, nor does ASAM suggest it as a best practice. No evidence is presented that more frequent drug testing (particularly weekly testing) improves patient outcomes. We therefore recommend that Section 10360 be amended as follows:

"(c)(2) Collection of patient body specimens at least once each calendar ~~week~~ ***month*** *in accordance with collection procedures specified in Section 10310."*

We further propose that, to account for patients who have had an abortion, Section 10360(f)-(g) be amended as follows:

"(f) Within fourteen (14) calendar days after the date of birth and/or termination of the pregnancy, the medical director shall document in the patient's record the following information:
(1) The hospital's or attending physician's summary of the delivery and treatment outcome for the patient and ~~offspring~~ ***if relevant, children.***
(g) Within fourteen (14) calendar days from the date of the birth and/or termination of the pregnancy, the primary counselor shall update the patient's treatment plan in accordance with Section 10305. ***If relevant,*** *~~T~~the nature of pediatric care and child immunization shall be reflected in subsequent updated treatment plans until the child is at least three (3) years of age*."

Response #7E
As a result of public comment, Section 10360(a)(2) was amended as discussed in response #4AJ.

The comment regarding Section 10360(c)(2) was considered, however, the regulations were not amended. The federal law under 42 CFR §8.12(f)(6) establishes the minimum required testing. The Department determined that weekly testing is appropriate for the health and safety of a pregnant patient on maintenance treatment.

The comments regarding Section 10360(f) and (g) were considered, however, the regulations were not amended. The existing language for both Section 10360(f) and (g), which reads: "Within fourteen (14) days from the *date of the birth and/or termination of the pregnancy"* (emphasis added) already reflects the different ways in which the pregnancy may end.

Section 10370(a)

Comment #4AM
As opposed to OBOT

The commenter proposed adding the following language:
",for patients enrolled in NTP,"

Response #4AM
This comment was considered, however, the regulations were not amended. Implementing requirements for an OBOT were not within the scope of this proposal. The scope of this regulatory proposal is specific to narcotic treatment programs, therefore, this clarification is not necessary.

Comment #6AAA
Need to distinguish protocols for NTP from prescribing under OBOT (DATA 2000)

Response #6AAA
While the commenter referenced Section 10370a., the Department believes this comment was in reference to Section 10370(a). This comment was considered, however, the regulations were not amended. Implementing requirements for an OBOT were not within the scope of this proposal; therefore, requirements for a DATA 2000 waivered physician were not addressed. The scope of this regulatory proposal is specific to narcotic treatment programs, therefore, this distinction is not necessary.

Comment #6AAB
Medications are not prescribed in the OTP setting, and this is adding confusion to the regs.

Response #6AAB
While the commenter referenced Section 10370a., the Department believes this comment was in reference to Section 10370(a). This comment was considered, however, the regulations were not amended. The commenter's request was unclear. The

Department believes this is one commenter's feedback regarding another commenter's proposed language and part of an ongoing discussion between these two parties regarding the regulations.

Section 10370(a)(1)

Comment #2K

Page 88 consider removing "absence of use of illicit drugs and abuse of other substances, including alcohol" from the criteria for take-home medication. Polysubstance use is common and opioid narcotic replacement therapy has not therapeutic effect on substance use disorder for cocaine, methamphetamine, and other non-opioid substances. Research has shown that people with substance use disorders can be adherent to treatment protocols while continuing to use other substances. Similarly, consider adding language to ensure that people who continue to use other substances, such as cocaine, not be penalized by having their treatment terminated. The benefits of treatment, including reductions in opioid-related overdose deaths and HIV and hepatitis C infections, greatly outweigh the harms, if any, of people continuing the polysubstance use that predated their engagement with treatment. This is critically important given the lack of biomedical interventions to treat substance use disorders among people who use cocaine, methamphetamine, and other stimulants.

Response #2K

This comment was considered, however, the regulations were not amended. Pursuant to Health and Safety Code section 11839.3 (a)(1), the Department has the authority to establish the criteria for take-home doses of controlled substances. For the health and safety of NTP patients, the Department determined patients using illicit drugs or other substances shall not be candidates for take-home doses.

Section 10370(b)(1)

Comment #6AAC

Remove this condition. Patients who work or take care of children, etc. often need take home doses at times that they are NOT working in order to manage the other parts of their life. This condition does not support patients in their recovery and is unnecessary.

The commenter proposed deleting the following language:

"and if the patient's daily attendance at the program would be incompatible with such activity;"

Response #6AAC

While the commenter referenced Section 10370b., the Department believes this comment was in reference to Section 10370(b)(1). This comment was considered, however, the regulations were not amended. This provision aligns with Health and

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.” As written, the provision allows take-home medication privileges, for patients who are gainfully employed or have homemaking responsibilities, under certain conditions.

Comment #5K
What is the rationale for this incompatibility requirement? If a patient is doing well in treatment, complying with program rules, participating in counseling, and has a job, they should benefit from the rewards for progress available under federal regulations.

Response #5K
This comment was considered, however, the regulations were not amended. This provision aligns with Health and 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.” As written, the provision allows take-home medication privileges, for patients who are adhering to program requirements, under certain conditions.

Section 10370(b)(3)

Comment #6AAD
Are these intended to apply to buprenorphine? It appears that they don’t as written.

Response #6AAD
This comment was considered, however, the regulations were not amended. The take-home requirements specified under subsection (b) are specific to methadone patients and do not apply to buprenorphine patients.

Section 10370(d)

Comment #5L
We need an affirmative statement confirming that buprenorphine take-homes are not subject to the same rules as methadone.

The commenter proposes the following language:
"(d) Take-home doses of buprenorphine are not limited to the requirements imposed on methadone and may be dispensed immediately upon program enrollment, without approval from the Department, pursuant to federal regulations."

Response #5L
This comment was considered, however, the regulations were not amended. The language proposed by the commenter is unnecessary, as the take-home requirements specified under subsection (b) are specific to methadone patients and do not apply to buprenorphine patients. Pursuant to Health and Safety Code section 11839.3 (a)(1), the Department has the authority to establish the criteria for take-home doses of controlled substances. For the health and safety of the patient, the Department established, under subsection (a), the take-home requirements for methadone, buprenorphine, and buprenorphine products.

Section 10370(c) and 10375(a)(1)

Comment #7F
Traveling daily to an NTP can impose serious financial and other burdens on the patient. We therefore recommend that "take home doses" of methadone be limited only to the extent required by federal law. In no circumstance should such dosing be limited by such arbitrary factors as whether the patient is currently employed. Further, these requirements should apply only to methadone, and not to buprenorphine, which is explicitly exempted from such requirements under federal law.

We therefore support the draft's removal of Section 10370(c), and further recommend that Section 10370 be amended as follows:

(a) ~~Self-administered take-home medication~~ **Methadone** shall only be provided to a patient **as a take-home medication** if the medical director or program physician has determined, in his or her clinical judgment, that the patient is responsible in handling narcotic medications, and has documented his or her rationale in the patient's record. The rationale shall be based on consideration of the following criteria:

(b) The medical director or program physician may place a patient on one of the six take-home medication schedules, as specified in Section 10375, only when at least the additional following criteria have been met~~: (1) Documentation in the patient's record that the patient is participating in gainful vocational, educational, or responsible homemaking (i.e., primary care giver, retiree with household responsibilities, or volunteer helping others) activity and the patient's daily attendance at the program would be incompatible with such activity;~~

Federal law limits take home-dosing of methadone to a single dose each week during the first 90 days of treatment, two doses per week in the second 90 days of treatment, three doses per week in the third 90 days of treatment, a 6-day supply "in the remaining

months of the first year," a 2-week supply after 1 year of continuous treatment, and a 1-month supply after 2 years of continuous treatment. California regulations should not be more restrictive than those requirements. We therefore recommend that Section 10375 be amended as follows:

(a) A **methadone** patient shall not be placed on a take-home medication schedule or granted a step level increase until he or she has been determined responsible in handling narcotic medications as specified in Section 10370(a). Each program shall adhere to the following schedules with respect to providing a patient with take-home medication privileges permitted under Section 10370(b):

(1) Step 1 Level – During the first 90 days of continuous maintenance treatment, the medical director or program physician may grant the patient not more than one-day take-home supply of medication.

We support other changes to paragraph (a) in the NPR.

Response #7F
This comment regarding Section 10370(a) was considered, however, the regulations were not amended. Pursuant to Health and Safety Code section 11839.3 (a)(1) the Department has the authority to establish the criteria for take-home doses of controlled substances. For the health and safety of the patient, the Department established, under subsection (a), the take-home requirements for methadone, buprenorphine, and buprenorphine products.

The comment regarding the deletion of Section 10370(b)(1) was considered, however, the regulations were not amended. This provision aligns with Health and 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."

As a result of public comment, Section 10375(a)(1) was amended to specify that within the first 90 days of continuous maintenance treatment, the medical director or program physician may grant a patient a single dose of take-home supply of medication per week. This amendment aligns with the time in treatment requirements for take-home medication, as specified in 42 CFR §8.12(i)(3)(i).

Section 10386(f)

Comment #6AAE
Does the State have the authority to "calculate" this differently? From a clinical and diversion prevention perspective, a patient who is coming to the clinic to dose every day and taking a split dose portion home daily is subject to more monitoring and tighter control than a patient receiving 2 THs/week. Could the "calculation" for split dosing be based on the number of days of clinic attended per week instead? We are looking for increased flexibility to meet the needs of pregnant patients (and very rapid metabolizers) without going through the exception process.

Response #6AAE
This comment was considered, however, the regulations were not amended. Section 10386 specifies requirements for split doses. The medical director or program physician is responsible for evaluating a patient to determine if a split dose is medically necessary for a patient. The determination of a split dose is not based on a standard calculation. Patients who receive split doses as take-home medication will receive two bottles of medication per day. However, the two bottles are considered a single take-home dose under the take-home schedule in Section 10375.

Section 10410(d)

Comment #1T
10410 (d) Recommend removing the word "scheduled," and also eliminating the phrase "indicating an average period for a maintenance treatment episode before such scheduled termination." Scheduled termination of treatment is directly contrary to standard of care medicine for opioid use disorder and known to be harmful. Voluntary termination procedures on patient request are certainly warranted and such protocols should be required, but requiring programs to state an "average period of maintenance treatment," is harmful by implying that protocol should routinely include scheduled termination of treatment.

Response #1T
This comment was considered, however, the regulations were not amended. The use of the term "scheduled" is necessary to clearly specify that the NTPs must have a planned process in place for when patients voluntarily conclude maintenance treatment. The requirement to indicate "an average period for a maintenance treatment episode before such scheduled termination" is necessary to provide an estimated framework regarding the end of maintenance treatment. However, the medical director or program physician is responsible for evaluating a patient to determine if ongoing treatment is medically necessary.

Comment #5M
Why would we schedule termination from treatment when we know that mortality increases eight fold when people leave treatment. We would never schedule termination from treatment for a diabetic taking insulin.

The commenter also proposed the deletion of subsection (d.)

Response #5M
This comment was considered, however, the regulations were not amended. The requirement specified under subsection (d) is necessary to ensure the health and safety of patients that choose to end maintenance treatment at an NTP. The NTP must have procedures and planned processes in place to support a patient at the conclusion of maintenance treatment. These procedures shall include providing counseling and other patient support and resources to ensure a patient's smooth transition when ending maintenance treatment services. Please also see response #1T.

Comment #6AAF
There is no medical indication for scheduled termination of maintenance treatment. It is always an individualized decision made in conjunction with the patient.

Response #6AAF
This comment was considered, however, the regulations were not amended. Please see responses #1T and #5M.

COVER LETTERS and ADDITIONAL COMMENTS

Comment #3A
Alkermes is a biopharmaceutical company with a steadfast commitment to developing innovative medicines to address unmet needs and challenges of people living with debilitating diseases, including opioid dependence. As a company we support sound public policy that brings attention to these diseases and enables people to access the information they need to advocate for themselves and for those for whom they care.

Alkermes manufactures and markets VIVITROL® (naltrexone for extended-release injectable suspension), a non-narcotic, once-monthly medication approved by FDA for the treatment of alcohol dependence in patients who are able to abstain from alcohol and for the prevention of relapse to opioid dependence, following opioid detoxification. Treatment with VIVITROL should be part of a comprehensive management program that includes psychosocial support.

The Substance Abuse and Mental Health Services Administration (SAMHSA) defines medication-assisted treatment (MAT) as "the use of FDA-approved medications, in combination with counseling and behavioral therapies, to provide a 'whole-patient'

approach to the treatment of substance use disorders."[1] VIVITROL is among the list of FDA-approved medications available to assist in the treatment of opioid dependence, specifically indicated to prevent relapse post detoxification.

We would like to respond to request for comments to Narcotic Treatment Program, DHCS-14-026. Specifically, the proposed regulation package completely ignores the passage of Assembly Bill (AB) 395 (Bocanegra, Chapter 223, Statutes of 2017) which amended Sections 11220, 11839.1, 11839.2, 11839.3, 11839.5, and 11839.6 of the Health and Safety Code, and to amend Section 14021.6 of the Welfare and Institutions Code, relating to substance use treatment providers.

AB 395 made several changes to the Health and Safety Code to expand the treatment options available to providers treating substance use disorders to include additional FDA-approved treatment medications. Specifically it modified the specific controlled substances authorized for use in narcotic replacement therapy to include medication-assisted treatment and refer to medications, rather than controlled substances.

"SEC. 2. Section 11839.2 of the Health and Safety Code is line 14 amended to read:
11839.2. The following controlled substances *medications* are authorized for use in narcotic replacement therapy *medication-assisted treatment* by licensed narcotic treatment programs:
(a) Methadone.
(b) Levoalphacetylmethadol (LAAM) as specified in paragraph (10) of subdivision (c) of Section 11055.
(c) Buprenorphine products or combination of products approved by the federal Food and Drug Administration for maintenance or detoxification of opioid dependence.
(d) Any other federally approved, controlled substances approved medications used for the purpose of narcotic replacement treatment *and medication-assisted treatment."*

The proposed purpose of these regulations is to expand and streamline access to treatment. According to the state 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

[1] Substance Abuse and Mental Health Services Administration. (2018). *Medication-Assisted Treatment (MAT)* (website). Available at: https://www.samhsa.gov/medication-assisted-treatment.

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 rural settings. (Page 5, Proposed Rule) Currently, long acting injectable naltrexone, VIVITROL, is an allowable service in both NTPs and OBNTNs, even without AB 395 which broadened the scope of NTPs.

Additionally, we would respectfully submit that – as of the date of this submission – the Governor has signed into law AB 349 (McCarty) to provide the Department even greater flexibility in advancing the rate setting process for Drug Medi-Cal Treatment. Although this new measure takes effect on January 1, 2019, its enactment by Governor indicates that the new law is representative of the Administration's outlook on Drug Medi-Cal Rate setting.

The new law amends existing state law that provides for the Drug Medi-Cal, under which each county enters into contracts with the State Department of Health Care Services to provide various drug treatment services to Medi-Cal recipients, or the department directly arranges to provide these services if a county elects not to do so, to authorize the department to implement, interpret, or make specific those provisions until the time that necessary regulations are adopted. The new law expressly authorizes the Department to annually establish and update the statewide maximum allowable reimbursement rates by means of bulletins or similar instructions. This affords the Department ample flexibility and discretion to fulfill the Administration's (and the Legislature's) earlier intent to expand available therapies at Narcotic Treatment Programs by also setting rates for ancillary services necessary for the implementation of full availability of all Medication Assisted Treatment at NTPs around the state.

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 in the NTP. These forms include criteria related to an applicant's/providers: 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 in the 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.

We would respectfully submit that this would be an appropriate time to ensure that all FDA approved medication assisted treatments and services are included on newly developed forms and applications. Also, we believe that all provider bulletins and

guidelines need to incorporate the changes made by AB 395 so that there is no provider confusion about their ability to prescribe appropriate medications.

In short, this regulatory rulemaking process should incorporate the most recent changes existing health codes to accomplish its goal of expanding treatment infrastructure and treatment options.

Response #3A
The Department appreciates your valuable input regarding this regulatory proposal. As described in the ISOR, the purpose of this proposal, in part, was to implement changes from Senate Bill (SB) 973 to remove barriers to access treatment. (Please see the Statement of Purpose/Problem to be Addressed in the ISOR.) However, implementing changes from Assembly Bill (AB) 349, was not within the scope of this regulatory proposal. AB 349 impacts the Drug Medi-Cal ratesetting process, whereas the scope of this regulatory proposal is specific to the Department's oversight of licensed NTPs.

Additionally, as a result of public comment, the definition for "medication" under Section 10000(a)(15) was 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. Please see response #5A.

Comment #4AN
There is a consensus that Narcotic Treatment Programs (NTP) should be renamed Opioid Treatment Programs (OTP) in alignment with the Code of Federal Regulations, Part 8. All references to opioid addiction, addiction, and opioid dependences should be changed to reflect current medically accurate terminology i.e. Opioid Use Disorder. These actions will not only reflect the evolving understanding of science in opioid use disorder and its treatment, but also, will reduce stigma and encourage access to new practitioners.

Response #4AN
This comment was considered, however, the regulations were not amended. Please see response #1B.

Comment #4AO
The intent and the structure of the Office Based Narcotic Treatment Network (OBNTN) was not clearly understood. The common understanding of the group is that the OBNTN is an attempt to define the "spokes" of the Hub and Spoke Model. However, many practitioners including those in current NTPs are waivered under the Drug Addiction Treatment Act of 2000 to provide office-based services (OBOT). The Federal Guidelines clarify this interface and language is recommended in the attached comments to clarify

the interface here in California. Several questions arose related to 42 CFR Patient Confidentiality in federally funded SUD services which need clarification.

Using the Federal Guidelines as standard, language the following was added in comments: "*In the case of qualified waivered practitioner providing office based opioid treatment under the Drug Addiction Act of 2000 (DATA 2000) rules, the program should develop clear policies and procedures for assigning patient to a specific model of care i.e. NTP or OBOT and establish criteria for determining specific pharmacotherapy."*

Response #4AO
This comment was considered, however, the regulations were not amended. The "Hub and Spoke" system is an initiative funded through a two-year federal grant called the State Targeted Response (STR) to the Opioid Crisis Grant Program. This system utilizes NTPs as "hubs" that provide specialized expertise in opioid treatment and regional physicians as "spokes" to prescribe buprenorphine. However, implementing requirements for this "Hub and Spoke" system are not within the scope of this proposal. Furthermore, the creation of an OBNTN is not intended to represent the "spoke" within the "Hub and Spoke" system. For additional discussion regarding the purpose and intent of an OBNTN, please see response #6AAH and for additional discussion regarding DATA 2000 and OBOTs please see response #4B.

Comment #4AP
The Proposed Regulations do not address science and best medical practices related to pregnancy and the withdrawal from methadone for the fetus or infant. The Federal Guidelines Opioid Treatment Programs published in 2015 begin to discuss the issues but are *constrained* by outdated federal regulations. We strongly recommend legislative efforts both at the state and federal levels to address the needed services recognizing the increase metabolic clearances of methadone in pregnancy as well as the fetal requirements for stability of methadone exposure, pregnant and post part- partum nursing mothers. Medical Director and practitioner outreach and education is critical related to the important of split dosing i.e. a take home part of the daily dose.

Response #4AP
The Department appreciates your valuable input regarding these specific topics related to pregnancy and methadone treatment. This comment was considered, however, the regulations were not amended based on this comment. Please note that seeking federal and state legislative changes are outside the scope of this proposal.

Comment #4AQ

The group recommends strengthening outreach and education that supports care coordination between NTPs and Primary Care using the DMC-ODS coordination paradigm. Limited comments were provided that strengthen language related to orientation of the patient and securing consents for care coordination (bidirectional release of information).

Response #4AQ
This comment was considered, however, the regulations were not amended. Section 10280 requires programs to advise patients on specific topics during patient orientation. However, programs are not precluded from discussing other topics, including care coordination. Furthermore, the program physician may, in his/her own clinical judgement, request patient consent to coordinate care with the health care provider responsible for the patient's primary care.

Comment #4AR
The use of physician extenders (outdated term) is reflected in the Staffing Section and some operation areas of the proposed regulations but not others. There is an opportunity to review the role and responsibilities of licensed health practitioners such as nurse practitioners and physician assistants throughout the document and align with their scope of practice.

Response #4AR
This comment was considered, however, the regulations were not amended. Section 10120 already describes the term "physician extenders," including the roles and responsibilities of these practitioners. Additionally, the program physician may delegate duties, as prescribed in the program protocol, to other appropriately licensed personnel who are members of the program staff, as specified under Section 10115.

Comment #4AS
Given the intent of SB 973 to reduce stigma and increase access, State Guidelines for Medication Assisted Treatment for Opioid Use Disorder that describe and advise on best practices in pharmacotherapy, the multiple settings, methods of delivery and billing are needed. The State Opioid Response Grant 2.0 is recognized as an opportunity to expand outreach and education and service points throughout the state. Updating the NTP regulations is a first step to our response to the opioid epidemic.

Response #4AS
This comment was considered, however, the regulations were not amended. The commenter did not specify a requested change. The Department appreciates your comment of support.

Comment #6AAG
(1) Changes to outdated or stigmatizing language:

a. Narcotic Treatment Programs (NTP) should be renamed Opioid Treatment Programs (OTP) in alignment with the code of Federal Regulations, Part 8.
b. All references to opioid addiction, addiction, and opioid dependence should be changed to reflect current medically accurate terminology (usually Opioid Use Disorder)
c. The term “Physician Extenders” should be eliminated. It is both outdated, pejorative, and inaccurate as a reference to Nurse Practitioners and Physician Assistants.
d. References to a baby as addicted or having addiction should be removed (newborn babies may have a physical dependence on opioids and exhibit withdrawal signs, but this is not addiction).

Response #6AAG

a. This comment was considered, however, the regulations were not amended. Please see response #1B.
b. This comment was considered, however, the regulations were not amended. Please see response #2D.
c. This comment was considered, however, the regulations were not amended. Please see response #4AR.
d. This comment was considered, however, the regulations were not amended. California Code of Regulations, title 9, chapter 4 does not use the term “baby”, “newborn”, or “fetus” in reference to addicted or having addiction.

Comment #6AAH

The role of the Office Based Narcotic Treatment Network (OBNTN) is not clearly delineated. The services mentioned for OBNTNs include general medical services, social services and NTP type services without clarifying different rules and standards for these different kinds of services.

Response #6AAH

This comment was considered, however, the regulations were not amended. The term “Office-Based Narcotic Treatment Network” (OBNTN) is defined in Section 10000(a)(20), which also specifies the services provided at the OBNTN. Additional information on how to lawfully operate an OBNTN is described in Section 10021. As discussed in the ISOR, the role of the OBNTN is to increase access to NTP services in underserved areas. (Please see page 3 of the ISOR.) Since the OBNTN falls under the license of its primary NTP, the same rules and standards apply for services provided at either location.

Comment #6AAI

The decision to place urine drug screening in medication units rather than OBNTNs is problematic. Community pharmacies will hopefully serve as medication units (they already are in the SFDPH pilot in San Francisco) particularly in rural areas, and they will generally not be willing to collect body substances for drug testing, so it will need to happen in the OBNTN. OBNTNs will often be medical offices in which urine collections will be a usual and customary part of clinical practice.

Response #6AAI
This comment was considered, however, the regulations were not amended. As defined in Section 10000(a)(16), medication units dispense or administer an opioid agonist treatment medication *or* (emphasis added) collect samples for drug testing or analysis. Therefore, a community pharmacy approved as a medication unit is not required to collect samples for drug screening. The purpose of a medication unit and an OBNTN is to expand access to specific NTP services in rural areas under the license of the its primary NTP. However, services that are not provided at the medication unit or OBNTN shall be provided at the primary NTP.

Comment #6AAJ
Pregnancy related recommendations:

a. Split dosing in pregnancy is a standard of care in most cases, and the requirement to obtain an exception when patients do not have sufficient time in treatment is a barrier to appropriate care. We recognize that this is a federal issue, and we recommend that DHCS and CSAT continue their collaborative approach to exception management and develop a blanket exception for pregnant patients or make changes to both federal and state regulations.
b. CSAM believes that pregnant patients deserve and need closer medical management from OTP medical providers with knowledge and skills in their care. We have different opinions on how that should impact the regulations and therefore do not present a recommended regulatory change here.

Response #6AAJ
The commenter did not specify a requested change. However, the Department appreciates the valuable input regarding these pregnancy related topics.

Comment #6AAK
HIV and HCV testing: The current proposed language must be changed. HIV testing in particular cannot be mandated. HIV and HCV should be included as opt-out testing. I include here some relevant sections of the HSC and CDC guidance.

a. The following needs to be done prior to ordering an HIV test (HSC 120990): “Prior to ordering a test that identifies infection of a patient with HIV, a medical care provider shall inform the patient that the test is planned, provide information about the test, inform the patient that there are numerous treatment options available for a patient who tests positive for HIV and that a person who tests negative for HIV should continue to be routinely tested, and advise the patient that he or she has the right to decline the test. If a patient declines the test, the medical care provider shall note that fact in the patient’s medical file.”
b. Requiring additional counseling as a pre-condition for testing creates barriers to testing. See CDC recommendations: “Prevention counseling—defined as an interactive process of assessing risk of infection, recognizing specific behaviors that

increase this risk, and developing a plan to reduce risk—should not be required with HIV diagnostic testing or as part of HIV screening programs in health-care settings."

Response #6AAK
As a result of public comment, this subsection was amended to partially implement the commenter's proposed changes. Please see response #1H.

Comment #6AAL
"Physician Extenders": As noted above, the language should be changed. More fundamentally, unnecessary restrictions on the role of NPs and PAs in the OTP setting should be eliminated to support needed increases in OTP workforce and because there is no reason for them. The Opioid Committee did not agree on the extent to which physicians should be required to be the medical providers interacting with pregnant patients, with some members recommending that certain kinds of medical education for pregnant patients come from the physician only, while others believe that with appropriate physician oversight and training, these roles can be managed by NPs and PAs.

Response #6AAL
This comment was considered, however, the regulations were not amended. Physician extenders are authorized to provide services at an NTP in accordance with their scope of practice. Please also see response #4AR.

Comment #6AAM
As a broader point, we encourage DHCS to be thoughtful about the need for each additional regulation that restricts OTP treatment beyond the federal regulations. Medical practice is guided by a number of regulatory agencies and boards and tends to function best when it can evolve with new research findings and the development of new kinds of treatments and medications. We appreciate regulations that insure patient safety, eliminate fraud, and reduce incentives for "shortcuts" that result in less than optimal clinical care.

Response #6AAM
The Department appreciates your valuable input.

Comment #7 – Intro
The National Health Law Program (NHeLP) would like to thank you for the opportunity to provide comments and feedback on Notice of Proposed Rulemaking 14-026 on Licensing of Narcotic Treatment Programs (NTPs) in California. NHeLP protects and

advances the health rights of low-income and underserved individuals. Below you will find overarching comments related to the proposed changes as well as comments specific to certain sections of the proposed rule.

We commend DHCS for undertaking necessary changes to the state regulations regarding licensing requirements for NTPs. Many of the proposed changes would bring California law in line with federal regulations pertaining to opioid treatment programs (OTPs). The changes are also necessary to ensure that DHCS regulations reflect California law, in particular SB 973 (2014), which authorizes NTPs to admit a patient at the discretion of the medical director; authorizes take-home doses to be provided to NTP patients who are adhering to the requirements of the program; and requires NTPs' medical directors to determine whether or not to dilute take-home doses.

Most importantly, the proposed changes to the regulations would remove current barriers to access to medication-assisted treatment (MAT) for individuals with substance use disorders (SUDs) and opioid use disorders (OUDs) at a time when California and the rest of the nation face an unprecedented opioid overdose epidemic.

MAT with the medications buprenorphine and methadone is considered the goal standard of treatment for individuals with OUD. The American Society of Addiction Medicine (ASAM), the Centers for Disease Control and Prevention (CDC), the National Council for Behavioral Health (NCBH), the National Institute on Drug Abuse (NIDA), the World Health Organization (WHO), and patient advocacy groups all support increased access to MAT. There is overwhelming evidence demonstrating that MAT is highly effective in reducing overdose deaths, reducing the risk of relapse, reducing engagement in risky activities, and reducing costs associated with health care, criminal justice, and education.

Despite the effectiveness of MAT in reducing the harms associated with SUD and OUD, only about 11 percent of individuals in need of treatment are currently receiving it. There are many reasons for this alarmingly low intake, but legal barriers at the federal and state level are important contributors. For example, pursuant to federal law, methadone for maintenance treatment may only be dispensed from federally-licensed NTPs and must be provided concurrently with behavioral therapy. Because methadone for MAT (methadone maintenance treatment) is taken on a daily basis, patients must travel every day to the nearest NTP to receive this life-saving medication. Similarly, buprenorphine may only be prescribed by providers (physicians, physician assistants, or nurse practitioners) who have been waivered by the federal government to do so and even these waivered providers must abide by specific limits on the number of patients they may treat with buprenorphine at any given time.

Given these federal constraints, it is important that states avoid creating further barriers for individuals with SUD to access treatment. Unfortunately, current California rules around licensing of NTPs do precisely this by imposing limitations that go beyond those found in federal law and regulations. Thus, we strongly support the proposed changes included in this NPR that

would bring these barriers in line with federal requirements and in so doing will increase the availability of MAT for Californians at risk of overdose.

Response #7 – Intro
The Department appreciates your comments of support.