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

JENNIFER KENT
Director

EDMUND G. BROWN JR.
Governor

NOTICE OF PROPOSED RULEMAKING

SUBJECT: Narcotic Treatment Program, DHCS-14-026

NOTICE IS HEREBY GIVEN that the Department of Health Care Services (Department) proposes to adopt Sections 10021, 10036, 10037, 10056.5 and 10386; amend Sections 10000, 10010, 10020, 10025, 10030, 10035, 10040, 10045, 10055, 10056, 10057, 10060, 10095, 10125, 10130, 10145, 10160, 10165, 10190, 10195, 10240, 10260, 10270, 10280, 10315, 10320, 10330, 10345, 10355, 10360, 10365, 10370, 10375, 10380, 10385, 10410, and 10425; and repeal Sections 10015 and 10340 of Title 9 of the California Code of Regulations (CCR) after considering all public comments, objections, and recommendations.

WRITTEN COMMENT PERIOD

Any interested person or his or her duly authorized representative may submit written comments to the Department relevant to the regulatory action described in this notice.

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

Mail Delivery:	Department of Health Care Services Office of Regulations, MS 0015 P.O. Box 997413 Sacramento, CA 95899-7413
Hand Delivery:	Department of Health Care Services Office of Regulations 1501 Capitol Avenue, Suite 5084 Sacramento, CA 95814
FAX:	(916) 440-5748
Email:	regulations@dhcs.ca.gov

The written comment period closes at **5:00 pm on October 3, 2018,** any written comments, regardless of the method of transmittal must be received by the Office of Regulations by **5:00 pm** on this date for consideration.

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

A public hearing has not been scheduled for this rulemaking. However, the Department will conduct a hearing if a written request for a public hearing is received from any interested person or his or her duly authorized representative, no later than 15 days prior to the close of the written comment period, pursuant to Government Code Section 11346.8.

The Department shall consider all comments received regarding the proposal equally, whether submitted in writing or through oral testimony at a public hearing.

Authority and Reference
These regulations are being proposed under the following authorities:

Sections 20, 11750, 11755, 11835, 11839.3, 11839.6 and 11839.20, Health and Safety Code.

These proposed regulations implement, interpret, or make specific the following:

Sections 11217, 11839.2, 11839.3, 11839.4, 11839.5, 11839.6, 11839.7, 11839.9, 11839.10, 11839.12, 11839.16, 11839.19, 11839.20, 11839.22 and 11839.24, Health and Safety Code; and Chapter 5 (commencing with Section 11500), Part 1, Division 3, Title 2, Government Code.

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

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

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

security requirements for storage and dispensing of controlled substances as administered by the United States Drug Enforcement Administration (DEA).

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

Related Existing Laws and Regulations

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

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

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

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

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

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

Statement of Purpose/Problem to be Addressed

SB 973, effective January 1, 2015, allows an NTP to admit a patient to narcotic maintenance or narcotic detoxification treatment at the discretion of the medical director by removing the requirement that a patient waits seven days in-between treatment episodes, enables patients to qualify for self-administered take-home medication under specified circumstances, requires a medical director to determine whether or not to dilute self-administered take-home medication, and requires a unique patient identifier for record keeping. The purpose of this regulation package is to implement, interpret and make specific the NTP services defined in HSC, Division 10.5, Chapter 10 and to enact changes from SB 973 to remove barriers to access treatment and prevent unnecessary discomfort for patients in addiction recovery. Other changes are made to expand oversight of NTPs and improve the health and safety of NTP patients.

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

Currently, 28 out of 58 counties do not provide NTP services. This is a major hurdle to access for the people in need of services in many rural communities. Also, many of the counties with the highest rates of opioid overdose resulting in death do not have access to NTP services. One of the most prominent reasons this lack of access is occurring is the inability to set up a traditional NTP business model in a rural area where there is a relatively small number of patients. An evidence based solution to this problem, included in this regulation proposal, is to create Office-Based Narcotic Treatment Networks (OBNTNs) and to expand the availability of medication units. These OBNTNs

and medication units are affiliated and associated with a licensed NTP and provide specified limited services. These smaller, limited facilities will be more feasible for expansion into rural areas; will reduce travel time to NTP services for many existing patients; and will increase access to NTP services in underserved areas.

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

Anticipated Benefits of the Regulations

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

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

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

Stakeholder Involvement in Preparation of the Regulations

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

- Small, Medium and Large Narcotic Treatment Programs

- California Society of Addiction Medicine
- California Alcohol and Drug Program Executives
- California Opioid Maintenance Providers
- California Behavioral Health Directors' Association
- Patient Advisory and Advocacy Group

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

Each date and topic that was discussed is listed below:

- March 18, 2015: Draft of entire regulation package was reviewed
- June 17, 2015: Medication Units were discussed with an opportunity for feedback
- September 30, 2015: Allowed time for stakeholder feedback
- January 7, 2016: Overview of regulation package and opportunity to comment
- May 9, 2016: Overview of next steps and opportunity for feedback
- June 1, 2016: Draft of entire regulation package was sent to stakeholders for informal feedback
- June 9, 2016: Conference call with walkthrough of all topics in the regulation package and opportunity to provide feedback
- September 7, 2016: Overview of next steps and opportunity to provide feedback

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

Consistency and Compatibility with Existing State Regulations

The Department has conducted an evaluation of the related existing state regulations under Title 9, CCR, Division 4 and has determined that the regulations are consistent with and compatible with those regulations. An automated search of Title 9, Division 4 using the following keywords "Methadone, Narcotic treatment, Buprenorphine, Take-home medication, Opioid, and Unique identifier" was conducted via Westlaw and yielded no conflicting state regulations.

Forms

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

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

These forms are incorporated by reference because it would be too cumbersome to publish the forms directly in the CCR.

DISCLOSURES REGARDING THE PROPOSED ACTION
The Department has made the following initial determinations:

Fiscal Impact Statement

A. Costs to any Local Agency or School District that is required to be reimbursed Under Part 7 (commencing with Section 17500), Division 4 of the Government Code: Costs and/or savings are indeterminate.

   Costs to any Local Agency or School District that is not reimbursable by the State: Costs and/or savings are indeterminate.

B. Costs or Savings to any State Agency: Overall state costs and/or savings are indeterminate.

C. Costs or Savings in Federal Funding to the State: None.

D. Other Nondiscretionary Costs or Savings Including Revenue Changes Imposed on State or Local Agencies: Costs and/or savings are indeterminate.

All cost impacts, known to the Department at the time the notice of proposed action was submitted to the Office of Administrative Law, that a representative private person or business would necessarily incur in reasonable compliance with the proposed action:

The agency is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Mandates on Local Agencies or School Districts

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

Significant Statewide Adverse Economic Impact Affecting Businesses

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

Results of the Economic Impact Assessment (Analysis)

In accordance with Government Code Section 11346.3(b)(1), the Department has determined that the proposed regulations would not significantly affect the following:

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

Impact on Jobs and Businesses

The Department has made the determination that the impact on jobs and businesses would only affect those providers operating NTPs who choose to open medication units and OBNTNs. It is estimated that from 2017-2022 that a total of 14 medication units and/or OBNTNs may open, based on the number of counties that currently do not provide NTP services. A new application fee will be required for these facility types. The fee is consistent with statutory requirements and is developed based on the costs incurred by the Department. There is no anticipated impact to businesses related to this fee or the application process as it is consistent with the existing process to open a primary NTP.

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

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

Benefits of the Proposed Regulation

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

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

Effect on Small Businesses

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

Housing Costs Determination

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

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code Section 11346.5(a)(13), the Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Existing regulations found in Title 9, CCR, Division 4, Chapter 4, Subchapter 1 commencing with Section 10000 are the primary regulations for NTPs. These regulatory

provisions address numerous topics including program licensure, evaluation and administration, medication security and patient treatment. Many of these provisions will be updated and amended through this regulatory proposal. Using this regulatory proposal to adopt and amend requirements regarding NTPs is the most effective and convenient way to provide (current/updated) information directly to those impacted including the providers, patients and county departments.

ASSISTIVE SERVICES

For individuals with disabilities, the Department can provide assistive services such as the conversion of written materials into Braille, large print, audiocassette and computer disk. For public hearings, assistive services can include sign-language interpretation, real-time captioning, note takers, reading or writing assistance. To request these assistive services, please call (916) 440-7695 (or California Relay at 711 or 1-800-735-2929), email – regulations@dhcs.ca.gov, or write to the Office of Regulations at the address noted above. Note: The range of assistive services available may be limited if requests are received less than ten business days prior to a public hearing.

The Department shall provide, upon request from a person with a visual disability or other disability for which effective communication is required under state or federal law, a narrative description of the additions to, and deletions from, the California Code of Regulations or other publication in a manner that allows for accurate translation by reading software used by the visually impaired. Providing this description may require extending the period of public comment for the proposed action pursuant to Government Code Section 11346.6.

CONTACT PERSONS

Inquiries regarding the proposed regulations described in this notice may be directed to Michael Freeman, Narcotic Treatment Programs at (916) 345-7590.

All other inquiries concerning the action described in this notice may be directed to Kenneisha Moore of the Office of Regulations, at (916) 345-8342, or to the designated backup contact person, Jasmin Delacruz, at (916) 440-7695.

AVAILABILITY OF TEXT OF REGULATIONS AND STATEMENT OF REASONS

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, at the address noted above, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file). In addition, a copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

The full text of any regulation which is changed or modified from the express terms of this proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

Materials regarding the regulatory action described in this notice (including this public notice, the regulation text, and the initial statement of reasons) are posted to the Department's Internet site at: http://www.dhcs.ca.gov/formsandpubs/laws/Pages/ProposedRegulations.aspx.

In order to request a copy of this public notice, the regulation text, and the initial statement of reasons be mailed to you, please call (916) 440-7695 (or California Relay at 711 or 1-800-735-2929), email regulations@dhcs.ca.gov, or write to the Office of Regulations at the address noted above.