NARCOTIC TREATMENT PROGRAMS (NTP) REGULATIONS

Frequently Asked Questions

Revised July 2021

For additional information regarding the updates to Title 9 CCR Division 4, Chapter 4, Subchapter 1 (Narcotic Treatment Programs):

- Visit our NTP page
- Contact DHCSNTP@dhcs.ca.gov

1. Are NTPs required to complete a confirmatory test for a positive test screen result for fentanyl? (New Updated 7/28/2021)

DHCS strongly recommends conducting a confirmation test to confirm if a fentanyl screen test result yields a false-positive result. Confirmation tests allow for specific drug identification and allows for quantification and identification of drugs and their metabolites. Knowledge of these potential impediments and adopting the practice that immunoassay positive results are considered presumptive until confirmed by a confirmatory test will ensure the best course of action for patient care.

Screening tests have been reported to yield false positive results when testing for the presence of fentanyl. Although screening tests are a quick testing method for determining the presence of fentanyl, they are subject to cross-reactivity with structurally related and unrelated compounds, potentially producing false-positive results. When common medications (e.g., quinolone antibiotics, rifampin) cross-react with frequently used substances, false-positive results on opiate screening testing can lead to invalid conclusions. Fentanyl false-positive results may cause repercussions in treatment such as revocation of take-home privileges in accordance with CCR, Title 9, Chapter 4, § 10390, patients discouraged from continuing treatment, loss of patient trust and rebuilding of relationships.

2. Can a patient refuse HCV testing upon admission?

The regulation requires laboratory tests for determination of HCV. The program is required to offer testing and document a reason for patient refusal in the medical record. The following circumstances may be considered by the Medical Director when determining if a patient may opt out of HCV testing:

- If the patient was recently treated for hepatitis C infection, cured, and absent of ongoing risk factors (ie are using pills and not injecting)
- If the patient is in crisis and it is not prepared to receive an HCV diagnosis; in this case, the patient should be offered testing after they are stable
- If the patient's veins are severely damaged to the extent that a blood specimen cannot be obtained

3. When did the new regulatory changes go into effect?

The changes to Title 9 CCR Division 4, Chapter 4, Subchapter 1 went into effect on July 1, 2020.

4. Where can I learn more detailed information about the changes to regulations?

You can see the updated regulations and documentation of the rulemaking process including drafts of the regulation text, the Statement of Reasons, and updated NTP forms at DHCS-14-026 - Narcotic Treatment Programs.

5. How did SB 973 (2014) change Title 9?

The following changes were made:

- Electronic or physical patient identification systems may be used
- Retired or medically disabled patients are eligible for take-home medications, up to 30 days
- Allows for NTPs to close on Sundays and holidays and provide take-homes to eligible patients, without an exception request
- Changes in body specimen testing
- Allows medical director to determine whether or not to dilute take-homes

6. What substantive changes were made to the regulations?

Among other amendments, the updated regulations:

- Streamline the capacity change process, including how fees are calculated and collected1, and eliminate barriers to access that the previous capacity change process caused;

See numbers 4-7 for more information about the new fee structure.

- Add provisions for the establishment of Office Based Narcotics Treatment Networks (OBNTN) and to expand the availability of mobile units—both of which address barriers to accessing SUD treatment services in rural areas.
- Further specify the requirements for NTPs treating patients with buprenorphine and buprenorphine products;
- Eliminate an unnecessary 7-day wait time requirement between treatment episodes;
- Add retirement and disability to the list of qualifying factors for take-home medication privileges;
- Revise patient selection requirements; and
- Leave the decision to dilute medication to the medical director.

7. In what circumstances do programs need to pay an application fee?

Programs must pay the application fee upon submitting their application for NTP licensure. They must also pay an application fee when applying for licensure of a new mobile unit or OBNTN. Application fees are nonrefundable, because the Department will incur costs associated with reviewing the application, even if the program does not ultimately become licensed.

8. What is the annual license fee?

The annual license fee includes the base annual license fee plus a patient slot fee, based on the NTP's treatment capacity.

9. When is the annual license fee due?

Application for license renewal is due no later than March 31. Annual fees are due quarterly on September 30, December 31, March 31 and May 31. The Department by September 30 of the same year must receive total annual license fees paid in full.

10. What is an Office Based Narcotics Treatment Network (OBNTN)?

An Office Based Narcotics Treatment Network (OBNTN) is a facility licensed to provide crucial services for those with SUD, including mental health evaluations, mental health counseling, counseling by addiction counselors, screening for diseases that disproportionately affect people with SUD. OBNTNs are affiliated and associated with a primary licensed NTP, but geographically separate from NTP and may or not be in the same county as the primary NTP.

11. What is the difference between OBNTN and Office-Based Opioid Treatment (OBOT)?

OBOT refers to outpatient treatment services provided in a medical office setting by a clinician with a waiver under the Drug Addiction Treatment Act of 2000 to prescribe buprenorphine for treatment of an OUD. OBOTs allow clinicians to treat OUD within their regular medical practice outside of a licensed NTP. Unlike OBNTNs, OBOTS are not affiliated with a licensed primary NTP.

12. When is a county certification DHCS 5027 required?

A county certification is required for initial licensure, license renewal and relocation. A county certification is no longer required for a capacity change, but the NTP must notify the county of the capacity change in writing.

13. Which protocol amendments require prior approval from the Department?

The following protocol amendments require prior approval:

- Relocation within county
- Capacity changes
- Addition or termination of services provided by the NTP
- Change in program sponsor
- Change in partner, officer, director, 10 % or greater owner
- Change in physical structure or floor plans, expansion, and any changes to the dispensing stations

14. Does a relocation outside of the county require a completely new application?

Yes, along with the relocation fee, a protocol amendment and an Initial Application Coversheet (form DHCS 5014) must be completed and submitted to DHCS at least 120 days prior to the proposed relocation date. A new license number will be issued as it is in a different county. You must show that there is a demonstrated need in the relocation area and a recommendation from the County Alcohol and Drug Program Administrator must be obtained. A site inspection will be conducted by DHCS. Both DEA and SAMHSA's approval is required.

15. What elements shall the patient identification system contain?

The following shall be included in the patient identification system:

- The patient's name;
- The patient's unique identifier;
- The patient's physical description;
- The patient's signature;
- A full-face photograph of the patient; and
- Positive identification of the patient and a correct recording of attendance and/or medication.

The protocol shall set forth a process for positive identification and a correct recording of attendance and/or medication. Each protocol shall specify the method in place to safeguard physical or electronic patient records.

16. Can programs employ the use of patient identification (ID) cards in the patient identification system?

Yes, this system may employ the use of patient ID cards. The protocol shall include a description of the issuance and tracking of patient ID cards and include recovery of the ID cards when a patient ID card has expired or when the patient has either completed or terminated treatment.

17. Who is authorized to coordinate care with a jail for a patient?

The new regulations allow the program director and program physicians to cooperate with the jail's medical officer and ensure the necessary treatment is available

18. Are breast exams required?

The physical exam no longer requires a breast exam.

19. What are the patient admission requirements for maintenance treatment for patients under 18?

The following requirements for patients under 18 align with federal regulations:

- A documented history of two unsuccessful attempts at short-term detox or drug-free treatment within a 12-month period.
- Must have the written consent of their parent(s) or legal guardian prior to admission into maintenance treatment.

20. What patient laboratory tests are required for treatment admission?

The hepatitis C virus, tuberculosis and syphilis laboratory tests are required laboratory tests for patient admission. The Human Immunodeficiency Virus (HIV) laboratory test is optional in accordance with HSC Division 105, Part 4, Chapter 7 and this test should be offered during patient selection. Programs must provide patients information on the HIV test, HIV treatment options, and the patient's right to decline the HIV test. Linkages to care and treatment should be included in the patient's record for patients who test positive for HIV, HCV, tuberculosis, or syphilis.

21. How was the 2 + 2 amended (2 years of addiction to opiates and 2 unsuccessful attempts in withdrawal treatment)?

Previously the 2 + 2 required a patient to have a documented history of at least two years of addiction to opiates and a confirmed history of two or more unsuccessful attempts in withdrawal treatment with subsequent relapse to illicit opiate use.

The 2 + 2 was amended and reduced the timeframe from a two year history of addiction to opioids to a one year history of addiction to opioids to align with the federal requirements for maintenance treatment admission provided in 42 CFR Section 8.12(e)(1). Also, the regulations remove the need for a confirmed history of unsuccessful attempts in treatment.

22. How long after discharge can a patient return to treatment without documentation of current physical dependence?

The patient who voluntarily detoxified from maintenance treatment may return to treatment within 2 years after discharge without documentation of current physical dependence. Also, physicians conducting the intake process at a NTP are assured that a patient had a previous dependence issue without the physical signs being present because the patient was previously in maintenance treatment.

Additionally, the timeframe for an applicant from a penal institution or chronic care institution to be admitted into maintenance treatment is within 6 months of release without documented evidence of physical dependence.

23. How did NTP 14-026 change the official state holidays?

Regulations package 14-026 added Cesar Chavez Day, March 31st and removed California Admission Day, September 9th. The official state holidays listed in Government Code Section 6700 include Cesar Chavez Day. While California Admission Day is a legally observed holiday, it is removed from the list of holidays because most public offices do not close for business on this day, including DHCS.

24. What new substances have been added to be analyzed in samples collected from patient body specimens?

Benzodiazepines were added to the required testing panel as benzodiazepines are now commonly misused. Testing for the use of benzodiazepines is anticipated to improve the health and safety of NTP patients. In addition, buprenorphine was added to ensure that the patients receiving buprenorphine as part of their narcotic replacement therapy are taking the medication as ordered. Additionally, the word Opiates was changed to Opioids, which added synthetic opioids like oxycodone and fentanyl to the testing panel.

25. How many patients are allowed in a group counseling session?

Each counseling session allows between two (2) to twelve (12) patients in each group. This change aligns with Title 22 Drug Medi-Cal regulations and conforms to the State Plan Amendment CA-15-012.

26. Who is additionally authorized to provide care for pregnant patients?

A physician assistant, nurse practitioner, licensed midwife or certified nurse midwife were added as authorized individuals to care for pregnant patients.

27. Do time in treatment requirements apply to patients' receiving buprenorphine?

No, the time in treatment requirements do not apply to patients receiving buprenorphine pursuant to the final rule by SAMHSA and the Department of Health and Human Services found in the link here: https://www.federalregister.gov/documents/2012/12/06/2012-29417/opioid-drugs-in-maintenance-and-detoxification-treatment-of-opiate-addiction-proposed-modification

28. Is a split dose considered a take-home medication?

Yes, a split dose shall be considered a one-day take-home supply. The provision is necessary because any medication that is removed from the facility has the same diversion potential. Only patients determined responsible in handling narcotic medications, and when it is determined medically necessary, are eligible for split dosing. The medical necessity for split doses, the dosage amounts, and the ingestion times of the doses must be documented in the patient's record.

29. How often shall a medical director or program physician evaluate a patient's maintenance treatment?

The patient's maintenance record shall be evaluated after one year of continuous treatment to ensure that patients are reaching their treatment plan goals and receiving adequate care and support to maximize their recovery.

30. How are forms submitted to the Department?

Submit all forms and supporting documents to: Department of Health Care Services

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