



## DHCS Frequently Asked Questions:

### Narcotic Treatment Programs

#### Medication Unit Application

All sections (§) cited are from Title 9, California Code of Regulations (CCR), Division 4, Chapter 4, Subchapter 1 commencing with Section 1000, which outline the requirements and standards for Medication Units (MU) licensed under an affiliated Narcotic Treatment Program (NTP). Read all sections carefully.

#### 1. What forms are required for an initial MU application?

- Initial Application Coversheet Form (DHCS 5014)
- Staff Information Form (DHCS 5026)
- Organizational Responsibility Form (DHCS 5031)
- Affiliated and Associated Acknowledgment Form (DHCS 5134)
- Facility and Geographical Area Form (DHCS 5025)

In addition, ensure to attach any additional information when necessary and pertinent to each form. All fields must be complete on the DHCS forms.

#### 2. How should all documentation be presented and formatted when submitted to DHCS?

Each page of the protocol, including any index, must be numbered beginning with page one. Do not break the numerical order when changing headings. The sample patient maintenance, patient detoxification and employee file do not need numbered pages but should be identified as attachments to your protocol. Failure to number pages properly could delay processing your application.

Copies of all forms developed and to be used by the proposed program must be submitted as required by §10030(a)(36). If you are contracting with an electronic service to utilize electronic health records (EHR), provide sample pages produced by the electronic system e.g.: intake documents, dosing sheet, treatment plan.

### **3. What treatment services may be offered at an MU?**

Treatment services at an MU are limited to the administering and dispensing of medications and/or the collection of patient body specimens for testing or analysis of samples for illicit drug use. The primary NTP is responsible for ensuring that patients have access to all other treatment services not provided at the MU.

### **4. What are the business legal documents that need to be submitted in addition to the protocol for initial application?**

Required business legal documents by entity type:

*Sole Proprietorship:* Business License and Fictitious Business Name Statement

*Corporation:* Articles of incorporation; by-laws; business license; name, address, and telephone number of each officer, director, or 10 percent or greater shareholder; and Fictitious Business Name Statement (if applicable).

*Partnership:* Partnership agreement; name, address, and phone number for each partner; business license, and Fictitious Business Name Statement (if applicable).

*Limited Liability Company:* Articles of organization; by-laws; business license; name, address, and telephone number for each officer, director, or 10 percent or greater shareholder; and Fictitious Business Name Statement (if applicable).

*Other:* Legal documents that verify the type of legal entity response for the program.

### **5. What documents are required to be submitted as a complete protocol for DHCS to begin review of the MU initial application?**

Please submit the protocol and appropriate documents in the order outlined below:

#### **I. APPLICATION**

1. Application §10020
2. Application Fee §10056, Mail to:

Department of Health Care Services  
Counselor & Medication Assisted Treatment Section, MS 2603  
P.O. Box 997413, Sacramento, California 95899-7413

## **II. REQUIRED FORMS**

1. DHCS 5014 NTP Application, §10020 (b)
2. DHCS 5025 Facility and Geographical Area, §10020 (b)(1-2)(4-9)
3. DHCS 5026, Staff Information, §10020 (b)(3)
4. DHCS 5134, Affiliated and Associated Acknowledgement, §10020 (c)
5. DHCS 5031 Organizational Responsibility Form
6. Fictitious Business Name Statement, if appropriate
7. Copy of Substance Abuse and Mental Health Services Administration SMA-162 Form

## **III. PROGRAM ADMINISTRATION**

1. First Year Budget, §10030 (a)(17)
2. Plan of Operation, §10030 (a)(1)
3. Program Goals, §10030 (a)(7)
4. Research Goals, §10030 (a)(8)
5. Letters of Community Support (a)(11)
6. Patient identification system §10030 (a)(12-13)
7. Plan for Evaluation, §10030 (a)(9), §10065, §10070
8. Program Forms, §10030(a)(36)
9. Operational Procedures, §10030 (a)(30) and §10175
10. Procedure in the event of Emergency or Disaster, §10030 (a)(32), §10170 (b)(8), §10180
11. 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, §10030 (a)(31), §10185, § 10190
12. Report of Patient Death, §10195

13. Fingerprint Clearance-LIVESCAN, §10095, Health & Safety Code (HSC) 11839.8

14. Program Rules and Instructions, §10030 (a)(26), §10170

- a. Place patient rules under patient file content, sample patient file.
- b. If using a patient handbook, place a copy of patient rules in handbook.

#### **IV. PERSONNEL POLICIES AND STAFFING**

1. Personnel Policies, §10130
2. Procedure to assure that appropriate staff time will be provided to the program in the event of short-term emergency, vacation, or sickness for all staff, §10130 (a)(4-5), (b)
3. Medical Director provision for leave and/or replacement e.g.: death, extended illness, sick, §10130 (a)(4-5)
4. Plan for delegation of Medical Director's Duties, §10030(a)(22), §10110
5. Program Director Responsibilities, §10105, §10140, §10155
6. Medical Director Responsibilities, §10110
7. Program Physician Responsibilities, §10115
8. Physician Extender Responsibilities, §10120
9. Duties and responsibilities of each staff member and the relationship between the staffing pattern and the treatment goals, §10030 (a)(19)
10. Each Staff Members Profile, §10030 (a)(20) and §10130
11. Personnel File, §10030 (a)(36) and §10130: submit a sample file
  - a. Employee Code of Conduct
12. Duty Statements for all positions, §10030 (a)(19)(21), §10105, §10110, §10115, §10120

#### **V. PATIENT RECORDS**

1. Patient Records, §10155, §10160
2. Patient Record Content, §10165, submit sample for Maintenance and Detoxification

3. Schedule of Patient fees, §10030 (a)(18)

## **VI. HANDLING AND SECURITY OF MEDICATION**

1. Medication Record Keeping, §10255
2. Administration or Dispensing of Medication, §10260
3. Security of Medication Stock, §10265

## **VII. PATIENT TREATMENT**

1. Patient Attendance – Courtesy Dosing, §10295
2. Patient Absence, §10300, H&S 11839.3(b)

## **VIII. TAKE-HOME PRIVILEGES**

1. Procedures for quantity, safeguarding, packaging, §10365
2. Criteria, §10370
3. Step level criteria, §10365, §10370, §10375
4. State Holidays or Sunday Closure, §10380
5. Restricting patient's take-homes, §10390
6. Restoring restricted take-homes, §10400
7. Exception to take-home medication, §10385(a)(1-2)(b)(c)(d)

## **IX. BODY SPECIMEN COLLECTION AND STORAGE**

1. Body specimen collection and storage, §10030 (a)(33), §10310, §10360
2. Prevention of tampering, §10310
3. Substance to be tested, §10315
4. Reliability of tests, §10325
5. Test or analysis records, §10330
6. Failure of patients to provide a body specimen, §10335
7. Use of approved licensed laboratories for testing of analyzing samples, §10320
  - a. Submit copy of contract.

## **X. DOSAGE LEVELS**

1. Dosage levels, §10350
2. Detoxification, §10030 (a)(29), §10355

## **XI. TREATMENT TERMINATION PROCEDURES**

1. Treatment termination, §10300 (a)(34), §10410
2. Voluntary, §10030 (a)(34), §10415
3. Involuntary, §10030 (a)(34), §10415
4. Fair Hearing, §10030 (a)(35), § 10420
5. Fair Hearing, Drug Medi-Cal Patients, Title 22, §51341.1 (p)

### **6. Are there specific requirements regarding any other entities that oversee MUs and what would they be?**

The Department of Health Care Services (DHCS) oversees NTPs, MUs and Office-Based Narcotic Treatment Networks (OBNTN) in conjunction with the Substance Abuse and Mental Health Services Administration (SAMSHA), Center for Substance Abuse Treatment (CSAT) and the Federal Drug Enforcement Agency (DEA).

Approval must also be received from the U.S. Drug Enforcement Administration and the Substance Abuse and Mental Health Service Administration before obtaining NTP licensure from DHCS and program operations can commence.

#### **Substance Abuse and Mental Health Services Administration (SAMHSA)**

- SAMHSA determines whether an NTP is qualified to carry out treatment for substance use disorders under [Certification of Opioid Treatment Programs, 42 Code of Federal Regulations \(CFR\) 8](#) and [42 CFR Part 2](#).
- For provisional certification of a new NTP form SMA-162 and supporting documents must be submitted. Click [here](#) to start the process.
- To speak to a Compliance Officer, please call (240) 276-2700 or email [DPT@samhsa.hhs.gov](mailto:DPT@samhsa.hhs.gov).

#### **Drug Enforcement Administration (DEA)**

- Federal registration by DEA is required in accordance with [Title 21, Code of Federal Regulations \(CFR\) Chapter 2](#).
- New NTP programs need to be registered with the DEA, form 363 and supporting documents must be submitted. Click [here](#) to start the process.

- To speak with the Diversion Field Office, please call (800) 882-9539 or email [DEA.Registration.Help@usdoj.gov](mailto:DEA.Registration.Help@usdoj.gov).

### **SAMHSA NTP Accrediting Bodies**

- Federal regulations require programs to become accredited by an approved accrediting body. Form SM-163 and supporting documents must be submitted. Click [here](#) to start the process.
- SAMHSA approved the following accreditation bodies to conduct accreditation surveys for Opioid Treatment Programs
  - Commission on Accreditation of Rehabilitation Facilities (CARF)
  - Council on Accreditation (COA)
  - The Joint Commission (JCAHO)

### **7. When must an MU begin operations?**

MUs affiliated with the licensed NTP must be operational within six (6) months after the date of licensure in accordance with §10050 (a). Programs which fail to meet this time limit may reapply for an MU by submitting to the Department a letter of explanation or a new protocol. Each program shall notify the Department in advance of the date the program plans to begin its operations. Each program shall also notify the Department of the date such operations actually commence.

### **8. Does an MU have a separate license and capacity?**

Approved MUs are reflected on the license of the primary NTP and share the total licensed patient capacity on the NTP license. This licensed patient capacity is inclusive of the patient capacity to be served at the MU. See Figure 1 below for an example of an MU license.

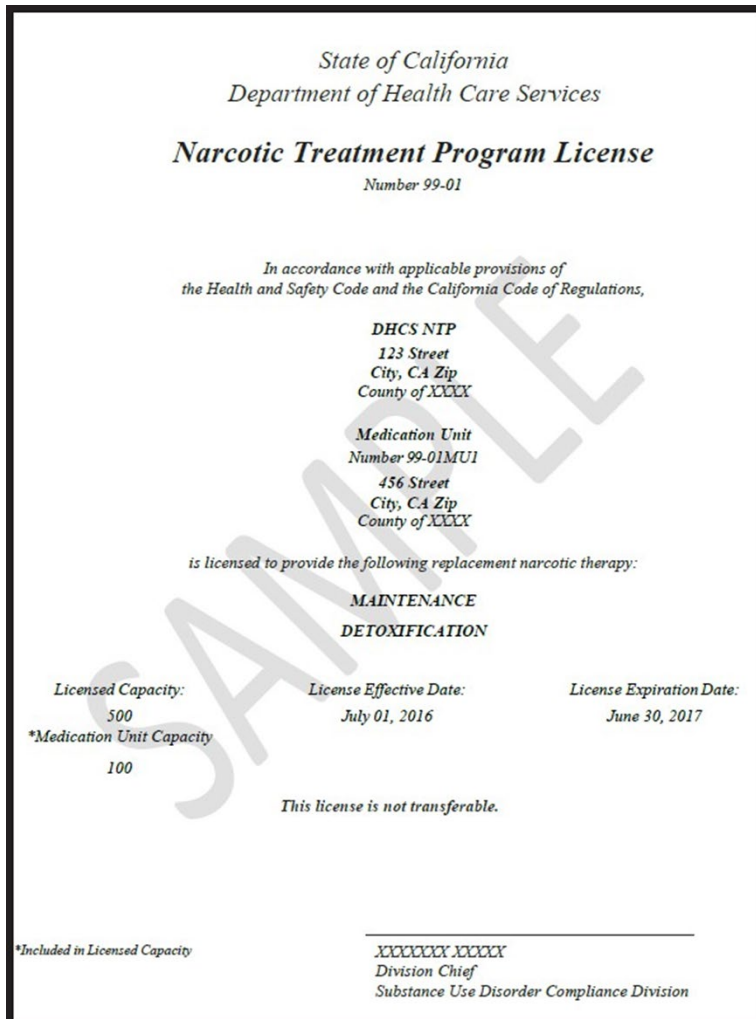


Figure 1 – Sample NTP & MU License

**9. Must an MU complete a fire clearance?**

Yes, an MU must obtain a fire clearance in accordance with § 10040 (b)(2).

**10. How long does it take for an approval of an MU application to occur?**

Approval of MU Application Timelines § 10020 (d):

The Department shall notify the primary NTP, in writing, within 60 days of receipt of the Initial Application Coversheet form DHCS 5014 (04/16), supplemental written protocol, and the Affiliated and Associated Acknowledgement form DHCS 5134 (04/16), whether the documents are:

- (1) Complete, including all required documents specified in subsections (b) and (c), and accepted for review; or



(2) Incomplete, and the Department shall specify the missing or incomplete information or documentation. The primary NTP shall have 60 days from the date of the notification to provide the missing information or documentation. The Department shall terminate review of the application if the primary NTP does not provide the required information or documentation within 60 days. Upon termination of review, the incomplete application shall be returned to the primary NTP. A primary Page 5 of 61 NTP may reapply by submitting a new application to the Department. Termination of review of the application shall not constitute a licensing action.

(e) The proposed medication unit shall be subject to a site inspection by the Department prior to approval of the supplemental written protocol.

(f) The Department shall either approve or deny, in writing, a complete application for approval of a medication unit within 60 days after the application is accepted for review.

### **11. Is there an application fee to apply for an MU?**

Yes, there is a fee for processing a MU application (California Health and Safety Code, Section 11839(a)(3)). Public Programs are exempt from this fee. The fee must be received by the Department to begin review and processing of the application. For the current fiscal year fees please see: [NTP Licensure Fees](#)

### **12. Where can I send my completed MU application and initial application fee?**

You may mail your complete application and fee to:

Department of Health Care Services  
Counselor & Medication Assisted Treatment Section, MS 2603 PO Box 997413  
Sacramento, CA 95899-7413

Or you may submit your application electronically to [DHCSNTP@dhcs.ca.gov](mailto:DHCSNTP@dhcs.ca.gov).

### **13. Who do I contact if I have questions on submitting an MU application?**

You may receive technical assistance by contacting a CMAT analyst at (916) 322-6682 or by email [DHCSNTP@dhcs.ca.gov](mailto:DHCSNTP@dhcs.ca.gov).