


# Online SMA-162 Form

*denotes a required field

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| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION<br>CENTER FOR SUBSTANCE ABUSE TREATMENT<br><br>**Application for Certification to Use Opioid Drugs in a Treatment Program Under 42 CFR § 8.11** | Form Approved: OMB Number 0930-0206<br>Expiration Date: 01/31/2010<br>OMB Statement<br><br>Date of Submission: 3/3/2010 |

**Note:** This form is required by 42 CFR 8.11 pursuant to Sec. 303, Controlled Substances Act (21 USC § 823 and the Drug Abuse Prevention and Control Act of 1970 (42 USC § 275(a)). Failure to report may result in a recommendation for the suspension or revocation of the opioid treatment program registration.

* **1a. Name of Program** (*Name of primary dispensing location*):

* **b. Doing Business As**:

* **c. Program Setting**: ○ Outpatient ○ Hospital-based

* **d. DEA Registration Number:**

**2. Address of Primary Dispensing Location**

* Address 1:

* Address 2:

* City:

* State:

* Zip:

**3. Program Telephone Number** ( *e.g. 999-999-999*

**4. Program Fax Number** (*e.g. 999-999-9999*)

**5. Program E-Mail Address**

**7. Program Sponsor Telephone Number** (*e.g.*

**6. Name and Address of Program Sponsor**

* First Name:

* Last Name: (*Must be the name of an individual, not a company or organization*)

Degree:

☐ Same address as primary dispensing location

* Address 1:

* Address 2:

* City:

* State:

* Zip:

* **7. Program Sponsor Telephone Number** (*e.g. 999-999-9999*)

* **8. Program Sponsor Fax Number** (*e.g. 999-999-9999*)

* **9. Program Sponsor E-Mail Address**

*A confirmation email will be sent to this address. The Program Sponsor must respond to that email to electronically sign this SMA-162 and complete the submission process.*

**10. Name of Medical Director (and Address-***If different than Dispensing Location, above*)

☐ Check if Medical Director pending

* First Name: *(Enter "Pending" if not available)*

* Last Name:

Degree:

☐ Same address as primary dispensing location

* Address 1:

* Address 2:

* City:

**11. Medical Director Telephone Number** (*e.g. 999-999-9999*)

**12. Medical Director Fax Number** (*e.g. 999-999-9999*)

**13. Medical Director DEA Number**

**14. Medical Director E-Mail Address**

*The Medical Director's email address must be one to which only the Medical Director has access. It must not be the same as the program's email address or that of any other program personnel.*

Why?

* State:

* Zip:

***15. Purpose of Application**

☐ Provisional Certification ☐ Renewal/Re-certification ☐ New Sponsor ☐ New Medical Director ☐ Relocation ☐ Medication Unit

*** 16. Number of Patients in Treatment on Date of Submission:**

☐ Methadone ☐ Subutex/Suboxone (Buprenorphine)

☐ Levo-Alpha-Acetyl-Methadol (LAAM) ☐ Other (Medication Name):

*** 17a. Program Status:** ProgramStatus: --Select one--

*** b. Program Funding Sources** (*Check each appropriate agency and attach the address of each, if applicable.*)

☐ SAMHSA Grant ☐ Private Charities ☐ Department Of Veterans Affair
☐ Patient Payment ☐ State Government ☐ County Government
☐ Indian Health Service ☐ Private Health Insurance ☐ Other *(Specify):*

**18. Comments**

**19. Application**

Substance Abuse and Mental Health Services Administration
Division of Pharmacologic Therapies
Attention: OTP Certification Program
1 Choke Cherry Road
Suite 2-1073
Rockville, MD 20857
Fax: 240-276-2710

Dear Sir/Madam:

As the person responsible for the program (OTP), I submit this application for approval to use approved opioid drugs in a program for detoxification and/or maintenance treatment for

E. A medical director will be designated to assume responsibility for administering all medical services performed by the program. If a medical director is responsible for more than one program, the feasibility o such an arrangement will be documented and submitte to SAMHSA. Within three weeks of any replacement of medical director, I shall notify SAMHSA.

F. Attached is the address of each medication unit or ot facility under control of the OTP. Any new dispensing s for this program, including medication units shall be approved by SAMHSA and the State authority prior to i use. SAMHSA and the State authority shall be notified within three weeks of the deletion of any facility used to dispense opioid treatment drugs.

G. A patient records system will be established and

narcotic addicts in accordance with 42 CFR Part 8, Certification of Opioid Treatment Programs. A copy of this application has been sent to the State Authority within which State the program is located. I understand that SAMHSA and State approvals are necessary to obtain a registration from the Drug Enforcement Administration (DEA).

A. I have a copy of, or access to 42 CFR Part 8, Certification of Opioid Treatment Programs, including 42 CFR §8.12, the Federal Opioid Treatment Standards. I have read, understand and will comply with these standards which govern the treatment of narcotic addiction with approved opioid drugs.

B. Attached is a description of the current accreditation status of the OTP. This description includes the name and address of the accreditation body and the date of the last accreditation action.

C. Attached is a description of the organizational structure of the OTP which includes the name and complete address of any central administration or larger organizational structure to which this program is responsible. The description shall specify how the program will provide adequate medical, counseling, vocational, educational, and assessment services, at the primary facility, unless the program sponsor has entered into a formal documented agreement with another entity to provide these services to patients enrolled in the OTP. In addition, the attachment includes the names of the persons responsible for the OTP.

D. Attached are the names, addresses, and a description of each hospital, institution, clinical laboratory, or other facility used by this program to provide the necessary medical and rehabilitative services.

maintained to document and monitor patient care in th program. It shall be maintained so as to comply with th Federal and State reporting requirements relevant to narcotic treatment. A drug dispensing record will be maintained to show dates, quantity, and batch or code marks of the drug administered or dispensed, traceable specific patients. This drug dispensing record must be retained for a period of three years from the date of dispensing.

H. I have a copy of, or access to 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records. I have read and understand the requirements maintain the confidentiality of alcohol and drug abuse treatment patient records. I agree to protect the identit all patients in accordance with the regulations.

I. I shall comply with the security standards for the distribution of controlled substances, as required by 21 CFR §1301, Registration of Manufacturers, Distributors and Dispensers of Controlled Substances.

J. I agree to comply with the conditions of certification forth under 42 CFR §8.11(f). In addition, I shall allow, i accordance with Federal controlled substance laws and Federal confidentiality laws, inspections and surveys by duly authorized employees of SAMHSA, by accreditatio bodies, the DEA, and by authorized employees of any relevant State or Federal governmental authority. I agr that OTPs must operate in accordance with Federal opi treatment standards and accreditation elements.

K. I agree to adhere to all rules, directives, and procedu set forth in 42 CFR Part 8, and any regulation regardin the use of an opioid drug for the treatment of narcotic addiction which may be promulgated in the future. I sh inform other individuals who work in this treatment program of the provisions of this regulation, and monit their activities to assure compliance with the provisions

L. I understand that failure to abide by the rules directi and procedures described above may cause a suspensio or revocation of approval of my registration by the Dru Enforcement Administration.

M. I, as program sponsor, certify that the information submitted in this application is truthful and accurate.

I certify that the information being submitted is true and correct to the best of my knowledge. I certify that will notify SAMHSA at the address below if any of the information submitted changes. Note: Any false, fictitious, or fraudulent statements or information presented in this submission or misrepresentations relat thereto may violate Federal laws and could subject you to prosecution, and/or monetary penalties, and or denial, revocation or suspension of DEA registration (see 18 U.S.C. Section 1001; 31 U.S.C. Sections 3801-3812; 21 U.S.C. Section 824.)

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average between 6 minutes and 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comm regarding this burden estimate or any other aspect of this collection of information, including suggestions f reducing this burden to SAMHSA Reports Clearance Officer; Paperwork Reduction Project (0930-0206); 1 Choke Cherry Road, Room 2-1075, Rockville, MD 20857. An agency may not conduct or sponsor, and a per is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0930-0206.

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FORM SMA-162 (revised 2007)

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Department of Health and Human Services
Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment
Division of Pharmacologic Therapies
1 Choke Cherry Road • Room 2-1075 • Rockville, MD 20857 • 240-276-2700 • otp@samhsa.hhs.gov